

**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 IPR2024-00278
Patent No. 11,033,318

**DECLARATION OF DR. MAROM BIKSON IN SUPPORT OF PATENT
OWNER'S RESPONSE**

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I, Dr. Marom Bikson, declare as follows:

I. INTRODUCTION

1. My name is Dr. Marom Bikson. I have been retained by counsel for Patent Owner Aerin Medical, Inc. (“Patent Owner” or “Aerin”) to provide my independent analysis regarding the validity of claims 1, 4-6, 9-10, 12-13, and 15-17 (the “Challenged Claims”) of U.S. Patent No. 11,033,318 (“the ’318 patent”).

A. My Background, Qualifications, Publications, and Testimony

2. My background, qualifications, and educational and employment history are set forth in my curriculum vitae, which I understand has been submitted in this proceeding as **Exhibit 2002**.

3. I earned my Bachelor of Science in Biomedical Engineering, with a concentration in Electrical Engineering, from Johns Hopkins University in 1995. I earned my Ph.D. in Biomedical Engineering from Case Western Reserve University in 2000. My Ph.D. thesis covered the impacts of electrical stimulation on humans. Subsequently, I spent three years conducting neurophysiology research as a postdoctoral fellow at the University of Birmingham.

4. My Biomedical Engineering coursework included advance physiology and neurology classes, during which I studied all parts of the human head, including, without limitation, the nose, nasal cavity, and throat.

5. In addition, I have extensive experience in human head imaging, which includes imaging of the nasal cavity.

6. I have significant experience in the design and development of medical devices that deliver energy to tissue. For example, in 2009, I founded Soterix Medical Inc. (“SMI”), for which I currently serve as a board member and technical advisor. Soterix Medical designs, builds, distributes, and validates technology to stimulate the body as well as devices to measure the effects of that stimulation on the body. Soterix Medical technology is used in hundreds of medical centers around the world.

7. Some of my additional design and development experience includes: (i) co-developing foundational guidance on electrical energy application and related technology, electrodes, waveform, and safety features; (ii) co-developing advanced models of tissue heating by electrical stimulation; (iii) co-developing approaches to control tissue heating by electrical stimulation; (iv) analyzing electrical stimulation technology, including as used in and around the nose; (v) developing fundamental guidance and analysis related to electrical stimulation technology, such as electrodes; (vi) developing state-of-the-art approaches to design medical devices, such as electrical energy application devices, based on detailed scans of the human head; (vii) co-developing approaches to balance

efficacy and safety in electrical stimulation; and (viii) co-developing an approach to optimize energy delivery to targeted brain regions while avoiding other regions.

8. I am a tenured Professor at the City University of New York in the Department of Biomedical Engineering. I began as an Associate Professor in 2003. I serve as the University's (Shames) Professor of Biomedical Engineering, a position I have held since 2014. I currently teach graduate and undergraduate level biomedical engineering courses, including on biomedical instrumentation.

9. I have been involved in biomedical research since 1995. I have been teaching graduate level courses in biomedical engineering since 2003. In addition to teaching and research, I am an elected member of the American Institute for Medical and Biological Engineering.

10. From 2003-2007, in addition to serving as the Harold Shames Assistant Professor of Biomedical Engineering at the City College of the City University of New York, I also served as an Assistant Professor for Programs in Engineering and Biology – Neuroscience at The Graduate School of the University Center of the City University of New York.

11. From 2008-2014, in addition to serving as an Associate Professor of Biomedical Engineering at The City College of the City University of New York, I also served as a Professor for Programs in Engineering and Biology –

Neuroscience at The Graduate School of the University Center of the City University of New York.

12. I serve on the leadership of numerous key scientific organizations in the field of body stimulation. This includes as a member of the scientific program committee of the North American Neuromodulation Society, and the scientific program committee of the International Brain Stimulation Conference. I am the founding chairman of the NYC Neuromodulation meeting and have co-chaired each occurrence of this meeting.

13. I have authored or co-authored nearly 500 articles, texts, and chapters in the fields of electrical and biomedical engineering. For example, I have published an authoritative document (DOI: 10.1016/j.brs.2011.10.001) that explains how waveform parameters (pulse shape, frequency) and electrode design govern the resulting electrical current flow through the body and hence all physiological effects. I am a co-author and among the leaders on the technology section, specifically device design, of what is considered the definite guidance paper on stimulation (DOI: 10.1016/j.clinph.2020.10.003). I co-authored among the most studied and impactful papers on the design of electrical stimulation parameters (<https://doi.org/10.1016/j.jneumeth.2004.10.020>) which has been cited over 2490 times in scientific publications. I am the deputy editor responsible for technology at Brain Stimulation, among the most highly regarded journals in the

field, where my responsibility includes oversight of the review of stimulation devices. I have lectured broadly on the principles of application of energy to the body, including providing the keynote or plenary lecture at major national and international meetings.

14. I have received numerous grants in the fields of electrical and biomedical engineering. I am currently in receipt of, or was involved in work associated with: a \$44.5K grant for developing new protocols for read-write Neuromodulation from General Patent Corporation; a \$1.7m grant from the National Institute of Health (“NIH”) for developing a new mechanism of brain stimulation via the coupled vascular hypothesis for transcranial direct current stimulation (“tDCS”); a \$2.2m grant from the NIH for developing automatic modeling software regarding tDCS; a \$955K grant from New York University and the City College of New York for advancing technology for home Neuromodulation in multiple sclerosis; a \$174K grant from the U.S. Department of Education for designing a device to assist visually impaired children; a \$485K grant from the NIH for enhancing drug delivery to brain tumors; a \$1.7m grant from the NIH for evaluating the effects of tDCS on neuronal plasticity in brain slices; a \$4m grant from the NIH for evaluating neural oscillatory patterns underlying auditory cognitive impairments in schizophrenia; a \$384K grant from Boston Scientific for researching high frequency spinal cord stimulation; a \$3.7m

grant from the New York State Department of Health for developing translational models for electrotherapy of spinal cord injuries; and a \$3m grant from the NIH to Soterix Medical for supporting a clinical trial on tDCS for rehabilitation.

15. I am the previous recipient of at least an additional 52 other grants or awards, totaling millions of dollars in direct costs awarded.

16. I am a co-inventor of numerous U.S. patents that are related to electrical stimulation, for example: U.S. Patents 8,818,515 (titled, Voltage limited neurostimulation), 8,965,514 (titled, Transcranial stimulation), 9,440,063 (titled, Methods for reducing discomfort during electrostimulation, and compositions and apparatus therefor), 8,718,778 (titled, Apparatus and method for neurocranial electrostimulation), 9,339,642 (titled, System and method for conducting multielectrode electrical stimulation), 9,956,395 (titled, Electrode assembly), and 10,143,832 (titled, Electrode assemblies for delivering therapeutic electrostimulation).

B. Compensation

17. My compensation in this case is my standard rate of \$600 per hour without regard to the outcome of this proceeding.

18. I am not, and never have been, an employee of Aerin. I am not receiving compensation for this declaration beyond my normal hourly fees based on my time actually spent analyzing and documenting my opinions herein on the

'318 patent. My compensation is not related to the outcome of this proceeding, and I will not receive any additional compensation based on the outcome of any IPR or other proceeding involving the '318 patent.

II. SUMMARY OF MY OPINIONS

19. In summary, it is my opinion that each of the Challenged Claims of the '318 patent is valid and patentable. Petitioners and their expert, Dr. Martin, have failed to show that the Challenged Claims of the '318 patent are rendered obvious by the prior art under 35 U.S.C. § 103.

III. LEGAL PRINCIPLES

20. I will not offer opinions of the law, as I am not an attorney. However, patent counsel has informed me of several patent law principles, upon which I have relied to arrive at my conclusions.

A. Legal Standard for Claim Construction

21. It is my understanding that the purpose of the claim construction process is to determine the meaning of the terms in the Challenged Claims of the '318 patent to a person of ordinary skill in the art ("POSITA") as of the time that the claimed invention was filed. I also understand that the words of the claims, the specification, and the prosecution history are to be primarily considered in order to construe the claims. These three sources are commonly referred to as "intrinsic evidence," while everything else is referred to as "extrinsic evidence."

22. It is my understanding that in an *Inter Partes* Review the words of a claim are generally given their ordinary and customary meaning to a POSITA as of the time that the patent application containing the claimed invention was filed.

23. It is my further understanding that the same words and phrases within a claim or claims are presumed to have the same meaning. It is also my understanding that different words and phrases within a claim or claims are presumed to have different meanings. Similarly, all words in a claim have meaning, and a word or phrase in a claim should not be interpreted so as to render other words or phrases in the claim superfluous.

24. It is also my understanding that a POSITA is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification and the prosecution history.

B. Legal Standard for Obviousness

25. I understand that a patent claim may be unpatentable if the invention recited in the claim would have been obvious to one of ordinary skill in the art at the time the invention was made. In considering whether the Challenged Claims of the '318 patent are obvious, I have been asked to consider (a) the level of ordinary skill in the art at the time of the claimed invention, (b) the scope and content of the prior art, and (c) any differences between the prior art and the Challenged Claims

of the '318 patent. I further understand that the patent owner may show “secondary factors” related to non-obviousness, including commercial success, long-felt but unresolved need, failure of others, copying, praise by others, and unexpected results.

26. I understand that a patent claim composed of several elements is not necessarily proved obvious merely by demonstrating that each of its elements was independently known in the prior art. I also understand that obviousness should not be analyzed using the benefit of hindsight. Instead, it must be analyzed from the standpoint of what was known and understood by a POSITA at the time of the claimed invention. I further understand that a party seeking to invalidate a patent claim as obvious must demonstrate that a skilled artisan would have had reason to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so. I also understand that the party must persuasively explain how the references would be combined to arrive at the claimed invention. I understand that a proposed modification or combination is inappropriate for an obviousness inquiry when the modification or combination would change a prior art reference’s basic principle of operation or would render the prior art reference inoperable for its intended purpose.

27. I understand that a reference qualifies as prior art for an obviousness determination only when it is analogous to the claimed invention. I understand that prior art is analogous if it is from the same field of endeavor or if it is reasonably pertinent to the particular problem the inventor is trying to solve.

IV. THE BASES FOR MY OPINIONS

28. I have reviewed the '318 patent, including the Challenged Claims and the prosecution history of the '318 patent. (Ex-1001 and Ex-1003.)

29. I have also reviewed the Petition for *Inter Partes* Review filed by Petitioners Neurent Medical Inc. and Neurent Medical Ltd. ("Petitioners" or "Neurent"), the attached Declaration of Dr. Martin (Ex-1002), the transcript of the deposition of Dr. Martin (Ex-2003 and Ex-2004), certain exhibits to the deposition of Dr. Martin (Ex-2005, Ex-2006, and Ex-2007), as well as the Exhibits to Petitioners' Petition.

30. I have also reviewed the Board's Institution Decision.

31. In forming my opinions, I have considered the materials listed above and any other documents cited in this declaration. I have also relied on my own education, knowledge, and experience in the relevant art.

32. I have also considered the understanding of a person of ordinary skill in the art around the time of the invention of the Challenged Claims.

V. PERSON OF ORDINARY SKILL IN THE ART

33. I am informed that prior art and any opinions related to the prior art are to be analyzed from the perspective of a POSITA who would be involved in the same field as the '318 patent at the time of the invention of the Challenged Claims.

34. I understand that Petitioners have applied a priority date of June 14, 2011. (Petition at 5.) I have likewise applied a priority date of June 14, 2011, to my analysis.

35. All the opinions that I express in this declaration have been made from the standpoint of a POSITA at the time of the invention of the Challenged Claims of the '318 patent.

36. I understand that Petitioners' definition of a POSITA is: "(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." (Petition at 20-21.)

37. I disagree with part (2) of Petitioners' definition. Part (2) of Petitioners' definition encompasses within the definition of a POSITA persons who only have experience with the clinical use or testing of medical devices. But a POSITA in the field of the '318 patent would have had more experience than just clinically using medical devices or simply conducting tests with medical devices.

38. The claims of the '318 patent require, among other things, a “device for delivering energy to a nasal airway to improve nasal airflow” having: “an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element; multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes, wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels; and multiple sensors on the tissue treatment surface, wherein the multiple sensors are selected from the group consisting of impedance sensors, electrodes and thermocouples.” (Ex-1001 at claim 1.)

39. A person who merely tests or uses such devices is not qualified to speak to the technical requirements associated with the features of the claimed device. For instance, someone who has merely used or tested medical devices is not qualified to speak to the technical issues associated with implementing an “an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element” in combination with “multiple radiofrequency output channels” and “multiple sensors on the tissue treatment surface.” A person who has never designed or developed such a medical device would not have the requisite background on how to implement “an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment

surface of the treatment element” in combination with “multiple radiofrequency output channels” and “multiple sensors on the tissue treatment surface.”

40. The correct definition of a POSITA is someone who has: (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 design and development of medical devices, including medical devices that deliver energy to tissue.

41. I met both parties’ definitions of a POSITA as of the time of the invention of the Challenged Claims of the ’318 patent. My opinions herein are the same regardless of which definition the Board applies.

VI. OVERVIEW OF THE ’318 PATENT AND THE CHALLENGED CLAIMS

42. The ’318 patent, entitled “Methods and Devices to Treat Nasal Airways,” issued on June 15, 2021, from U.S. Patent Application No. 16/412,982 (filed on May 15, 2019). (Ex-1001 at [21], [22], [45], [54].) The ’318 patent claims priority to a provisional patent application (Application No. 61/496,930) which was filed on June 14, 2011. (*Id.* at [60].)

43. The ’318 patent and the Challenged Claims are generally directed toward a medical device “for delivering energy to a nasal airway to improve nasal airflow.” (*Id.* at claim 1; *see also id.* at 1:31-37.) Figure 3, reproduced below, provides an exemplary illustration of the medical device:

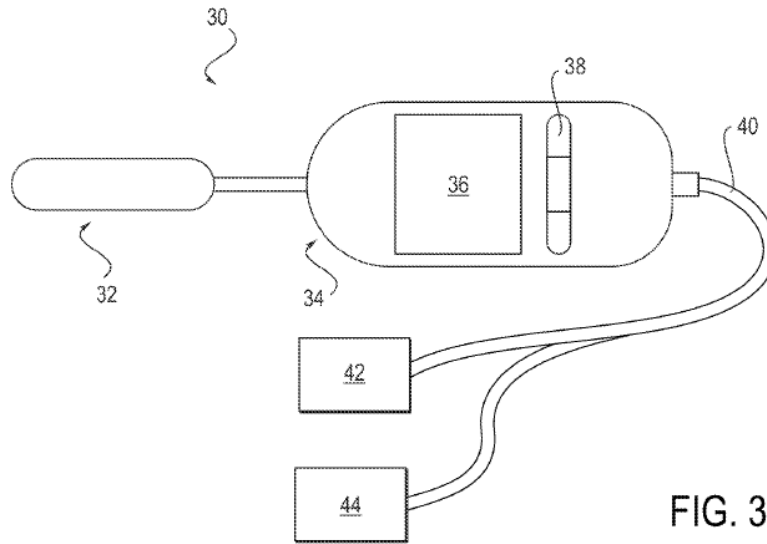


FIG. 3

(*Id.* at FIG. 3.)

44. As shown above, the medical device 30 of the '318 patent includes a handle 34, a shaft, and a treatment element 32 that can be inserted into a nostril. (*Id.* at FIG. 3, 4:34-44, 8:66-67, 15:64-16:5.) The '318 patent discloses that the treatment element is configured to expand from a collapsed configuration for insertion into the nasal passageway to an expanded configuration for contacting a surface of the nasal passageway. (*Id.* at FIGS. 4A-4C, 9:1-6, 18:3-17, 18:21-32.)

45. The device of the '318 patent also comprises an array of multiple pairs of bipolar electrodes disposed on a treatment surface of the treatment element. (*Id.* at FIG. 8F, FIG. 8G, FIG. 18, 5:1-13, 24:21-49.) The '318 patent describes a pair of bipolar electrodes as comprising electrodes of opposite polarities. (*Id.* at 23:7-11, 49:7-9, 49:18-24, 49:35-37, 49:46-54.) Two exemplary arrays of bipolar electrode pairs described in the '318 patent are shown below:

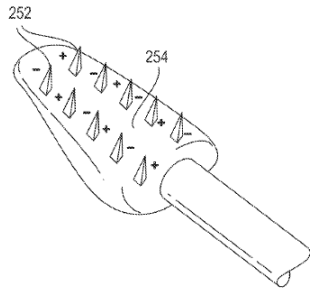


FIG. 8F

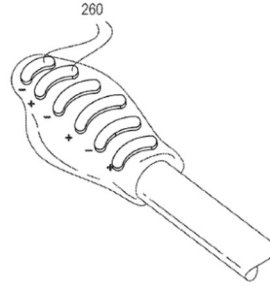


FIG. 8G

(*Id.* at FIGS. 8F-G.)

46. Further, the '318 patent discloses that a radiofrequency ("RF") output channel may be assigned to each electrode pair. (*Id.* at 49:5-14, 49:18-26, 49:33-38, 49:61-66; *see also id.* at 24:45-49, 48:63-65.) The '318 patent discloses that the RF output channels can be separately controllable, allowing different regions of the treatment element to be activated separately and avoiding the situation where, due to varying degrees of contact with the target tissue, treatment energy is "diverted to pairs of electrodes that experience a relatively lower magnitude of impedance due to a relatively lower degree of tissue contact." (*Id.* at 24:45-64, 48:42-49:4; *see also id.* at 49:65-50:2, 50:9-15.)

47. The device of the '318 patent may also have sensors on the treatment element for measuring a temperature or impedance near the tissue to be treated and adjusting the level of energy to be delivered with a control system. (*Id.* at 5:18-30, 8:20-25, 16:27-40.) According to the '318 patent, "[r]emodeling or changing the structure of the nasal valve can improve nasal airflow in people with inadequate nasal airflow resulting from causes other than nasal valve dysfunction, such as

deviated septum, enlarged turbinates, mucosal swelling, and/or mucous production.” (*Id.* at 11:29-34.)

48. Independent Challenged Claim 1, the only independent claim of the ’318 patent, is reproduced below:

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

1[a] a handle;

1[b] a shaft extending from one end of the handle;

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

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

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

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

(*Id.* at claim 1.)

VII. OVERVIEW OF THE ASSERTED PRIOR ART

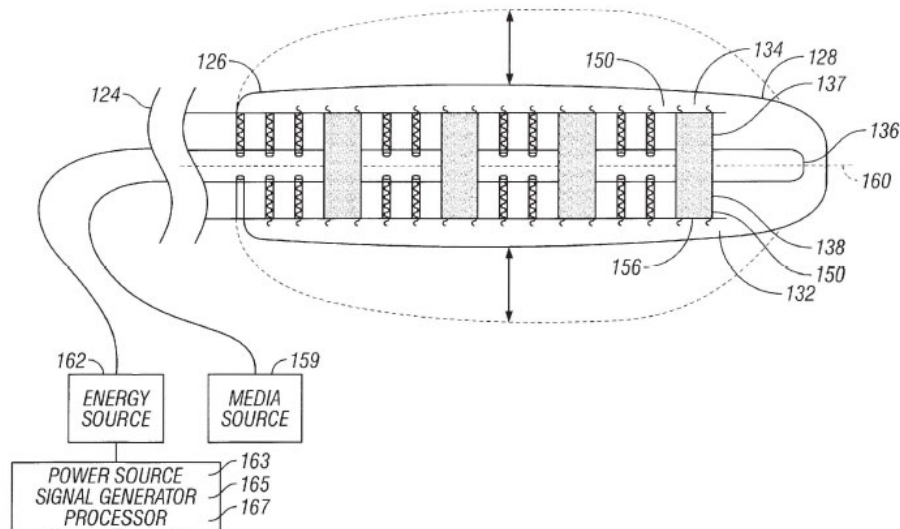
A. U.S. Patent No. 6,517,535 (“Edwards-535”)

49. I have reviewed Edwards-535. Edwards-535 is generally directed towards “a method and apparatus for treating airway obstructions,” such as those caused by “[s]leep apnea syndrome,” by “reducing the volume of the turbinates in order [to] reduce nasal airway obstructions.” (Ex-1010-Edwards-535 at 1:22-26, 1:30-33.) Edwards-535’s “invention provides a method for reducing the size of a nasal concha without the formation of a wound on the surface of the nasal concha.” (*Id.* at 4:63-66, 6:26-27.) To that end, Edwards-535 teaches cooling the surface of the nasal concha being ablated such that ablation can be performed to remove an internal section of a nasal concha without damaging the surface of the nasal concha. (*Id.* at 4:60-63, 6:12-16.) Thus, Edwards-535’s method can be performed bloodlessly and eliminates the need for surgical cutting. (*Id.* at 4:58-60, 4:55-57.)

50. Edwards-535 further teaches an apparatus 124 comprising an expandable member 132 that conforms to the surface of the nasal concha and an energy delivery device 134 for delivering ablative energy. (*Id.* at 7:28-39.) To expand the expandable member 132, a medium 138 is delivered through apertures 137 from a lumen 136 coupled with a catheter body 126. (*Id.* at 7:40-47.) The expandable member 132 is preferably formed of a material that is permeable to the medium used to expand the member, thus allowing the medium to pass through the

expandable member 132 to the surface of the nasal concha being ablated. (*Id.* at 7:66-8:5.) In one embodiment, the expandable member 132 is an expandable porous membrane. (*Id.* at 8:5-7.)

51. Edwards-535 teaches that the energy delivery device 134 may include one or more ring electrodes 156 disposed on the surface of the expandable member 132. (*Id.* at 8:18-20.) The plurality of ring electrodes 156 are disposed in parallel with their axes aligned with a long axis 160 of the catheter body 126. (*Id.* at 8:21-23.)



(*Id.* at FIG. 6.)

B. U.S. Patent No. 5,562,720 (“Stern”)

52. I have reviewed Stern. Stern is generally directed to a device for the “selective destruction of the endometrium,” the thin layer of tissue lining the uterus. (Ex-1033-Stern at 1:17-22, 6:56-59.) Stern explains that its “goal” is

“destruction of the endometrial cells.” (*Id.* at 6:60-62.) Stern describes destroying the endometrium using ablative radiofrequency energy while maintaining the average temperature of the myometrium, the tissue beneath the endometrium surrounding the uterine cavity. (*Id.* at 2:11-18, 6:66-7:6, 7:29-33.)

53. As illustrated below, Stern’s apparatus includes a “conventional” RF generator 158, a separate power source controller 156, a portable computer 164, an application device 124 with an electrode balloon 150, and an electrode belt 154 that provides a reference electrode for connection to the power source controller 156. (*Id.* at FIG. 12, 10:36-55.) An example schematic representation of the power source controller 156 is shown in FIG. 5. (*Id.* at 8:66-9:2.)

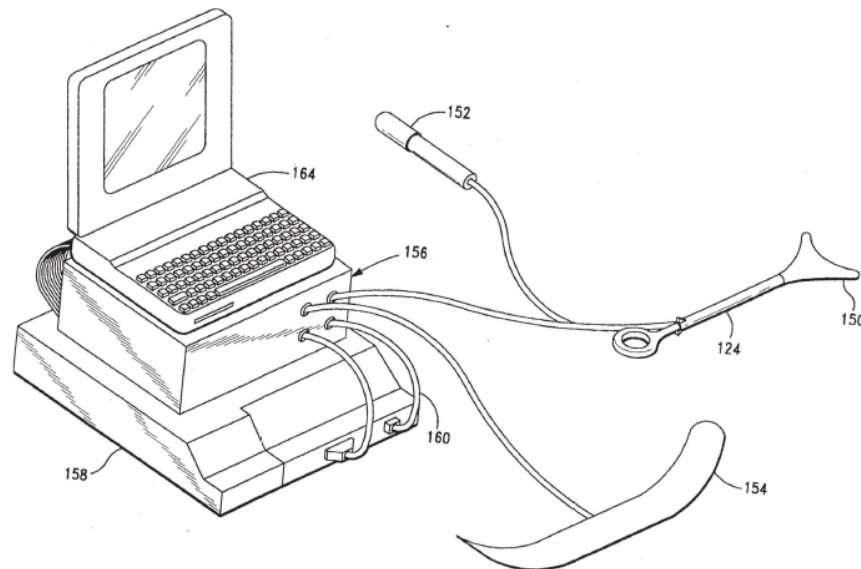


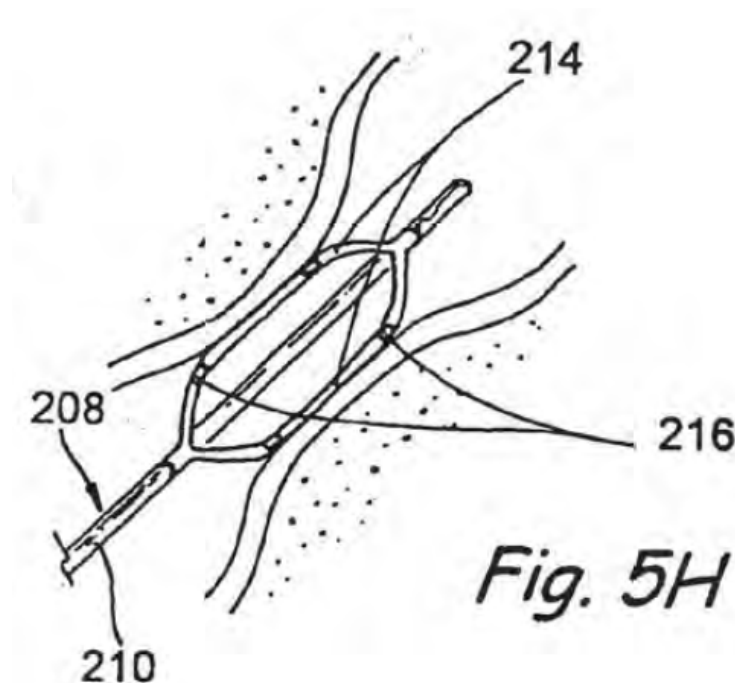
FIG. - 12

(*Id.* at FIG. 12.)

C. U.S. Patent App. Pub. No. 2005/0240147 (“Makower”)

54. I have reviewed Makower. Makower is generally directed to “minimally invasive, catheter based devices, systems and methods for treating sinusitis and other ear, nose & throat disorders.” (Ex-1021-Makower at [0001], [0042].) Makower discloses numerous device embodiments. (*Id.* at [0161]; *see also id.* at [0049]-[0128].)

55. Makower’s Figure 5H embodiment (reproduced below) comprises an electrosurgical device 208 comprising a catheter 210 with arched strut members 214 attached thereto. (*Id.* at [0187].) Electrodes 216 are located on the strut members 214. (*Id.*) In operation, the device 208 is advanced into the nostril and then current is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated. (*Id.*)



(*Id.* at FIG. 5H.)

VIII. CLAIM CONSTRUCTION

56. For the purposes of this declaration, I will give the claim terms their plain and ordinary meaning as understood by a POSITA as of the priority date of the '318 patent. To the extent an express claim construction is proposed in this proceeding or in another proceeding involving the '318 patent, I reserve the right to respond to such a construction and/or propose an express construction.

IX. PETITIONERS HAVE FAILED TO MEET THEIR BURDEN OF PROVING THAT THE CHALLENGED CLAIMS OF THE '318 PATENT ARE UNPATENTABLE AS OBVIOUS

A. Ground 1: Petitioners Have Failed To Show That Edwards-535 In View Of Stern Renders Challenged Claims 1, 4-5, 9-10, 12-13, And 15-17 Obvious.

1. **Petitioners Have Failed To Show That Edwards-535 In View Of Stern Teaches Limitation 1[d]: “an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element.”**

57. Challenged Claim 1 of the '318 patent recites, among other things, a device comprising “multiple pairs of bipolar radiofrequency electrodes.” (Ex-1001 at claim 1.)¹

58. Petitioners and their expert, Dr. Martin, assert that Stern’s Figure 15 teaches “multiple pairs of bipolar radiofrequency electrodes” and that a POSITA

¹ Challenged Claims 5, 13, 15, and 17 also recite “multiple pairs of bipolar radiofrequency electrodes.” (*Id.* at claims 5, 13, 15, 17.)

would have been motivated to implement Stern's Figure 15 in Edwards-535's device. (Petition at 34-41; Ex-1002-Martin, ¶¶ 101, 124; Ex-2003 at 228:20-229:3.) Petitioners and Dr. Martin also assert that "Stern's teachings would have been applied to Edwards-'535 in the same way they are used in Stern." (Petition at 40; Ex-1002-Martin, ¶¶ 116, 143.)

59. I disagree with Petitioners and Dr. Martin that Stern teaches "multiple pairs of bipolar radiofrequency electrodes." Rather, Stern teaches a device configured to have at most a single pair of bipolar radiofrequency electrodes.

60. Consistent with the '318 patent's description, a POSITA would have understood a "pair" of bipolar radiofrequency electrodes to be two electrodes located near each other that have opposite polarities. (Ex-1001 at 23:7-11, 49:7-9, 49:18-24, 49:35-37, 49:46-54.)

61. Stern's Figure 15, which is reproduced below, discloses a voltage source 228, four electrodes 220, 222, 224, and 226, a grounding pad 230, and nine switches 232, 234, 236, 238, 240, 242, 244, 246, and 248. (Ex-1033-Stern at FIG. 15; *id.* at 12:46-13:2.)

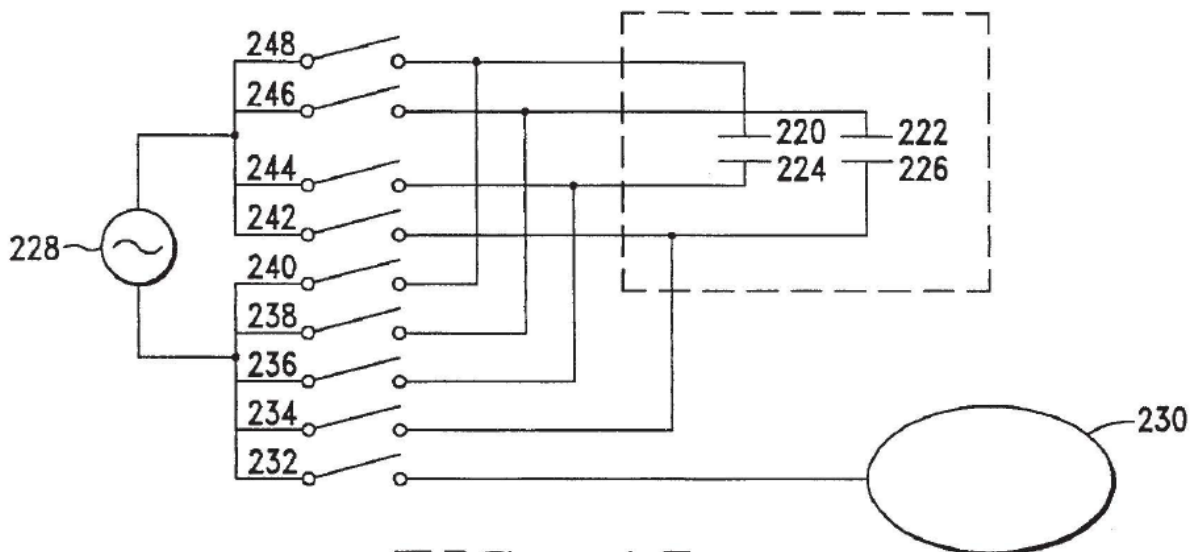


FIG. - 15

(Ex-1033-Stern at FIG. 15.)

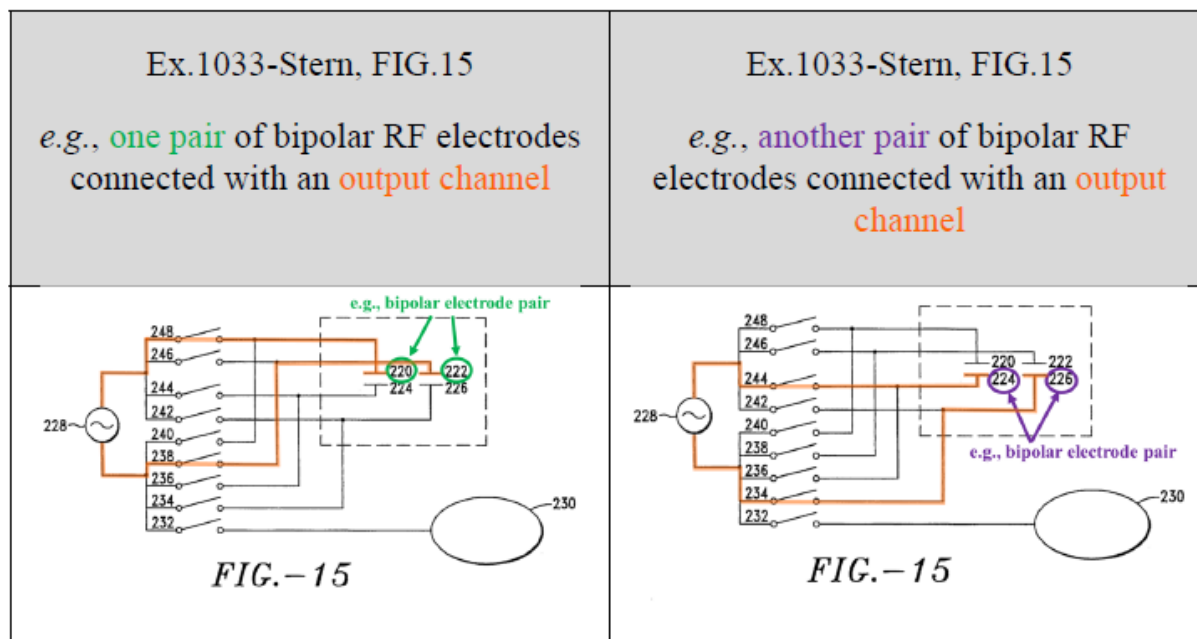
62. Stern describes its electrodes as “an array of separate electrodes.” (Ex-1033-Stern at 2:26-29, 2:39-40, 2:59-60.) Depending on which switches are closed, any of electrodes 220, 222, 224, and 226 in Figure 15 can be a monopolar electrode. (*Id.* at FIG. 15, 12:46-55.) Similarly, depending on which switches are closed, any of electrodes 220, 222, 224, and 226 can be a positive electrode or a negative electrode. (*Id.* at FIG. 15, 12:55-13:2.)

63. None of the electrodes in Stern’s Figure 15 have opposite polarities when all the switches are open, and thus there are no bipolar electrode “pairs” in Figure 15 when all the switches are open. (Ex-1033-Stern at FIG. 15, 12:37-13:2.) Rather, a bipolar electrode “pair” is formed in Stern’s Figure 15 only when certain switches are closed. (Ex-1033-Stern at FIG. 15, 12:37-13:2.)

64. To form “multiple pairs of bipolar radiofrequency electrodes” in Stern’s Figure 15, three or more of Figure 15’s switches must be closed at the same time. However, Stern does not teach this. Instead, Stern teaches that its device is configured to have at most a single pair of bipolar electrodes. Specifically, Stern teaches at most closing one of switches 242, 244, 246, and 248 and one of switches 234, 236, 238, and 240 to form a single pair of bipolar electrodes. (Ex-1033-Stern at 12:55-13:2.) This teaching is consistent with Stern’s teaching that its electrodes “are independently and sequentially energized.” (*Id.* at 2:31-33, 2:49-53, 10:48-52, 17:54-55.) To energize Stern’s electrodes “independently and sequentially,” at most two of Stern’s switches would be closed at a time.

65. Petitioners and Dr. Martin likewise fail to identify where Stern teaches closing three or more switches at the same time. At most, Petitioners and Dr. Martin identify two examples where Stern’s Figure 15 device can be configured in different ways to have a single pair of electrodes. In one example, Stern’s Figure 15 device is configured to have a single pair of electrodes (*i.e.*, electrodes 220 and 220) by closing switches 248 and 238. (Petition at 35-36 (citing Ex-1033-Stern at 12:65-13:2); Ex-1002-Martin, ¶ 101 (same).) In a second example, Stern’s Figure 15 device is again configured to have a single pair of electrodes (*i.e.*, electrodes 224 and 226) by instead closing switches 244 and 234. (Petition at 42; Ex-1002-Martin, ¶ 124.) The deficiency in Petitioners’ and Dr.

Martin's analysis is illustrated in Petitioners' own annotations to Stern's Figure 15 (reproduced below), which show two different ways to configure Stern's device to have a single pair of electrodes:



(Petition at 43 (annotations in original).)

2. Petitioners Have Failed To Show That Edwards-535 In View Of Stern Teaches Limitation 1[e]: “multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes, wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels.”

66. Challenged Claim 1 of the '318 patent recites, among other things, a device comprising “multiple radiofrequency output channels.” (Ex-1001 at claim 1.)²

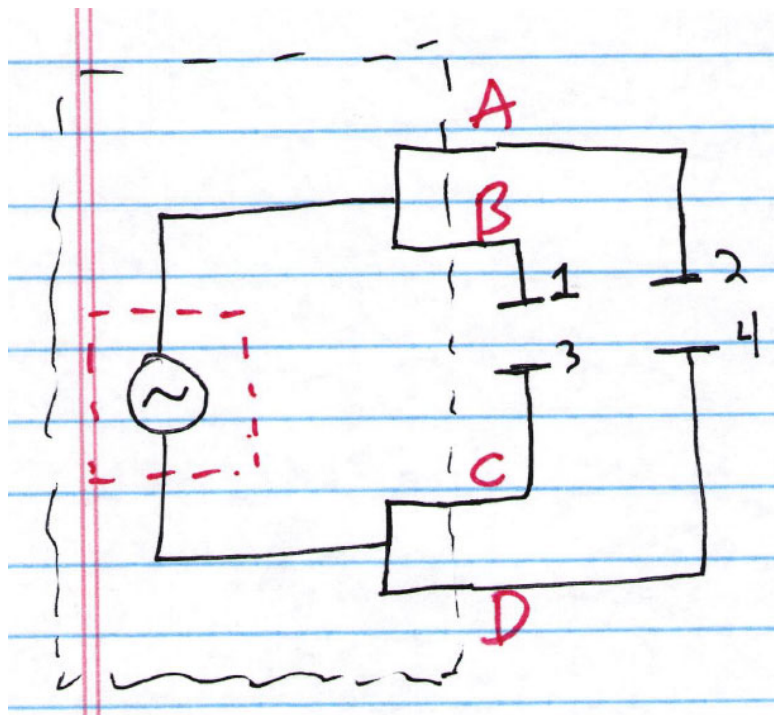
67. Petitioners and Dr. Martin assert that Stern’s Figure 15 teaches “multiple radiofrequency output channels” and that a POSITA would have been motivated to implement Stern’s Figure 15 in Edwards-535’s device. (Petition at 41-44; Ex-1002-Martin, ¶¶ 124-148; Ex-2003 at 228:20-229:3.) Petitioners and Dr. Martin also assert that “Stern’s teachings would have been applied to Edwards-535 in the same way they are used in Stern.” (Petition at 40; Ex-1002-Martin, ¶¶ 116, 143.)

68. I disagree with Petitioners and Dr. Martin that Stern teaches “multiple radiofrequency output channels.” Rather, Stern teaches at most a single radiofrequency output channel.

² Challenged Claims 9, 13, 16, and 17 also recite “multiple radiofrequency output channels.” (*Id.* at claims 9, 13, 16, 17.)

69. I understand that Dr. Martin testified at his deposition that the term “radiofrequency output channel” means “an output from a radiofrequency generator.” (Ex-2004 at 318:12-19; *id.* at 318:20-319:9, 319:17-320:2, 327:3-4, 329:21-22.) I agree with Dr. Martin.

70. The number of radiofrequency output channels depends on the number of outputs from the radiofrequency generator. For example, if the red dashed box in the demonstrative circuit reproduced below designates the radiofrequency generator, then the circuit below has only one radiofrequency output channel:



(Ex-2007.)

71. I note that a radiofrequency generator with a single radiofrequency output channel will have two terminals or connection points—one for the output from the generator (*i.e.*, the active signal) and one for the input back to the generator (*i.e.*, the return signal).

72. I understand that Dr. Martin agrees that the demonstrative circuit reproduced above has only one radiofrequency output channel if the red dashed box designates the radiofrequency generator. (Ex-2004 at 430:2-431:5, 432:16-433:4.)

73. In Stern's Figure 15, voltage source 228 represents the radiofrequency generator. As shown below, voltage source 228 is represented in Figure 15 as a circle with a sinusoid wave inside of it:

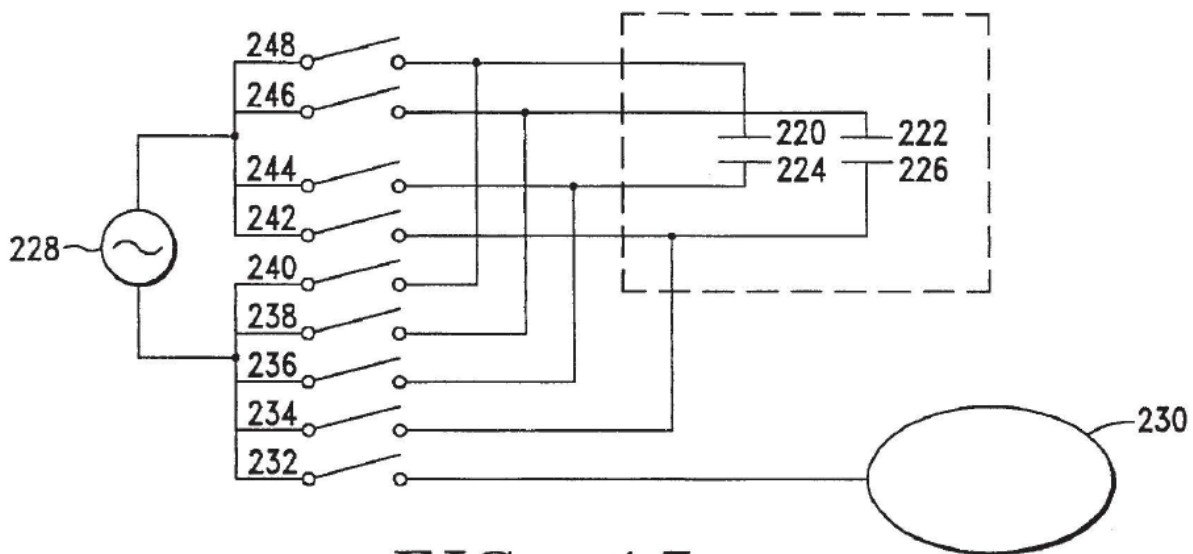


FIG. - 15

(Ex-1033-Stern at FIG. 15.)

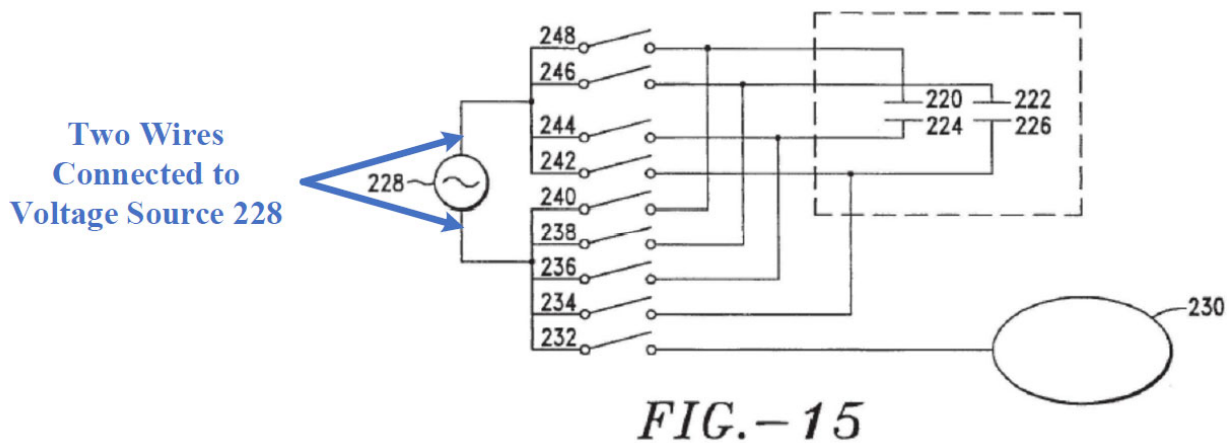
74. Prior to the invention of the '318 patent, it was standard in circuit diagrams to use a circle to represent a signal generator, such as a radiofrequency generator. A circle with a sinusoid wave inside of it, such as the one used for voltage source 228, was used to represent a sinusoidal waveform (*e.g.*, radiofrequency) generator that provided energy in the form of a sinusoid wave.

75. Further, Stern describes its radiofrequency generator as “a conventional electrosurgical power supply.” (Ex-1033-Stern at 2:50-51, 10:44, 10:54-55.) Prior to the invention of the '318 patent, it was common to use the phrases “voltage source” and “radiofrequency generator” interchangeably when referring to a conventional electrosurgical power supply. Indeed, Stern itself uses the terms “power source,” “power supply,” “voltage source,” “RF generator,” and “radiofrequency power means” synonymously and interchangeably. (*See, e.g.*, Ex-1033-Stern at Abstract, 2:49-53, 3:15-20, 8:56-57, 10:43-46, 10:53-55, 12:46-49, claim 1.)

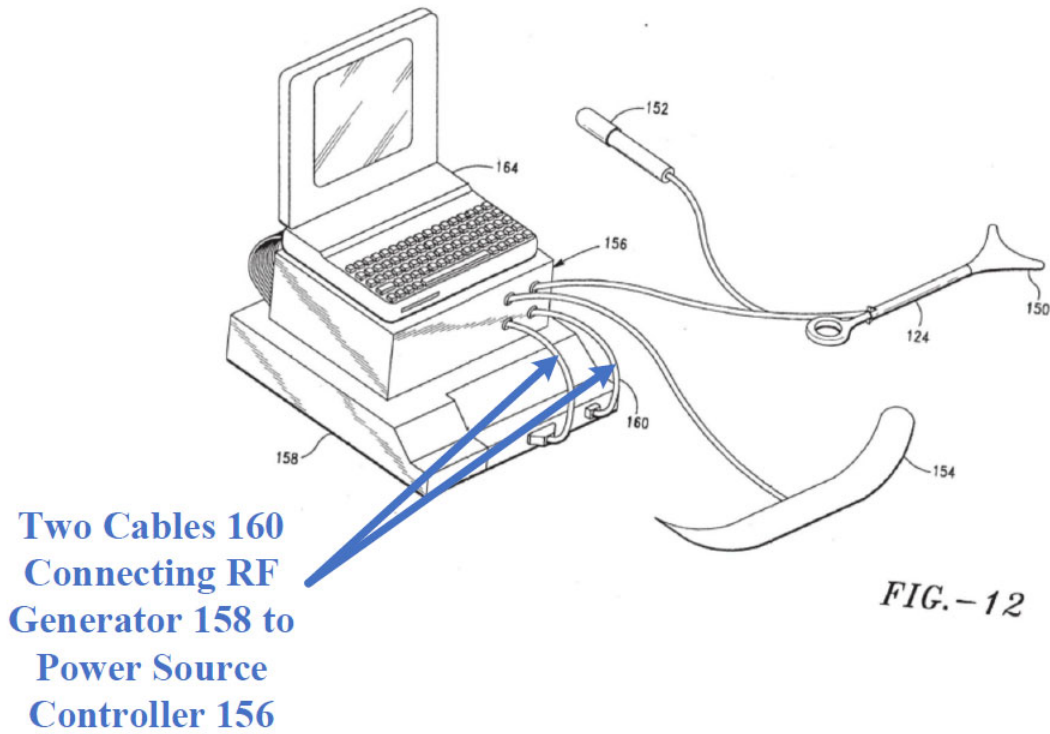
76. Moreover, as discussed in detail below in my analysis of Challenged Claim 9, Stern teaches that its radiofrequency generator has a single “output” which is provided to a separate power source controller via two wires/cables, and that Stern’s switches are in the separate power source controller. (Ex-1033-Stern at FIG. 5, FIG. 12, 2:49-53, 3:12-21, 8:66-67, 9:14-17, 10:42-46, 10:53-55, 11:49-51, 12:21-24, 12:38-61, claim 1.) Consistent with Stern’s description of the

radiofrequency generator, Stern's voltage source 228 has a single output and is connected to the rest of the circuit via two wires. (*Id.* at FIG. 15.) A POSITA would have understood that Stern's voltage source 228 represents the radiofrequency generator and the switches in Figure 15 are in the separate power source controller. (*Id.*)

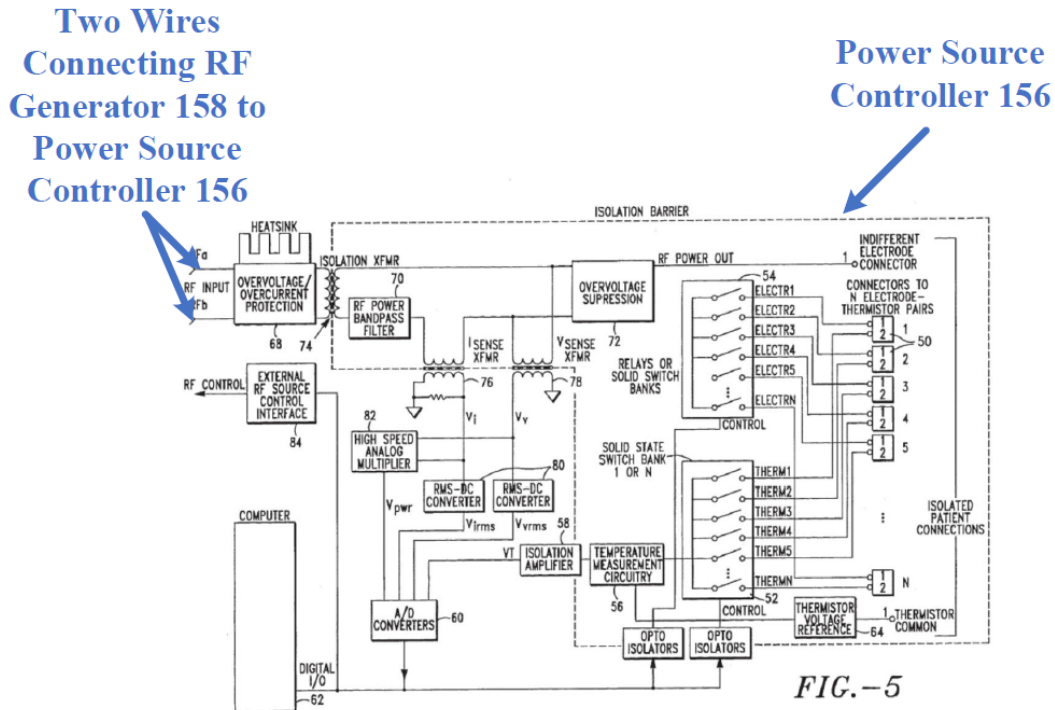
77. The consistency between Stern's Figures 5, 12, and 15 further confirms that Stern's voltage source 228 represents the radiofrequency generator. (Ex-1033-Stern at FIGS. 5, 12, 15.) Figure 15 depicts voltage source 228 with two wires connected to it. (*Id.*) Figure 12 similarly depicts a radiofrequency generator 158 with two cables 160 connected to it. (*Id.*) Likewise, Figure 5 shows that the power source controller is connected to the radiofrequency generator with two wires. (*Id.*) The consistency between Stern's figures is illustrated below:



(*Id.* at FIG. 15 (annotated).)



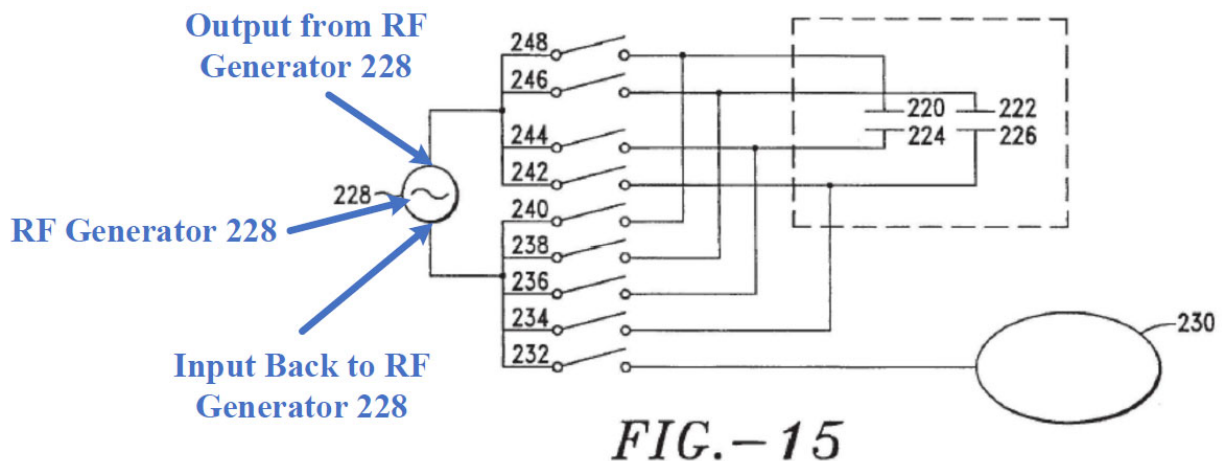
(Id. at FIG. 12 (annotated).)



(Id. at FIG. 5 (annotated).)

78. For all the above reasons, Stern's voltage source 228 represents the radiofrequency generator.

79. Importantly, Stern's voltage source 228 (*i.e.*, the radiofrequency generator) has only one radiofrequency output channel. As shown in annotated Figure 15 below, voltage source 228 has only a single output and a single input. Thus, Stern teaches at most a single radiofrequency output channel.



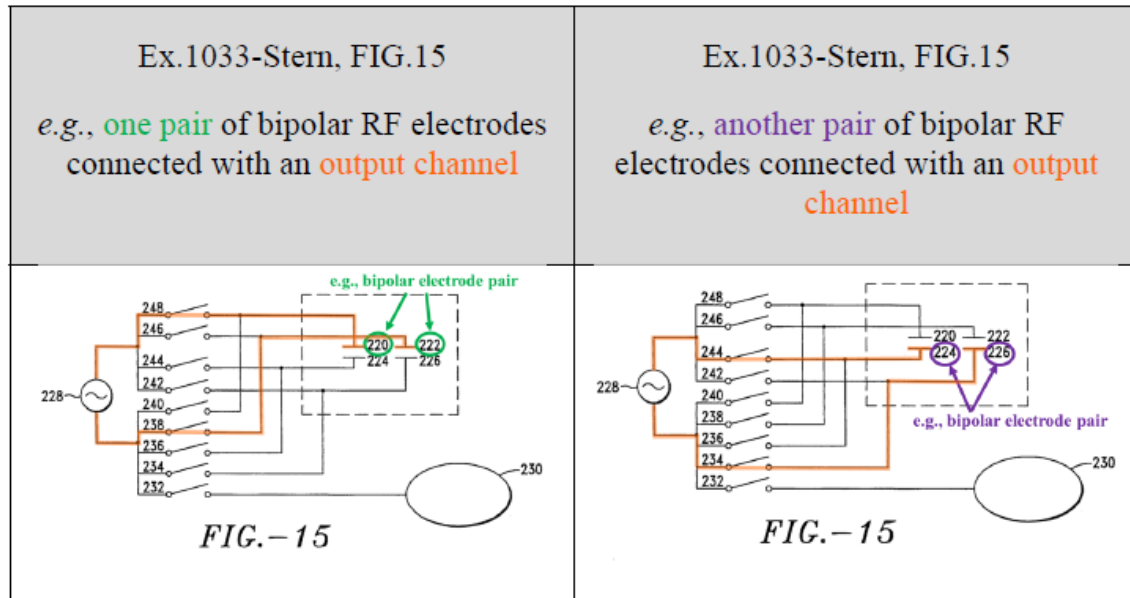
(Ex-1033-Stern at FIG. 15 (annotated); *see also id.* at 2:49-53, 3:12-21, 10:53-55, claim 1 (disclosing that the RF generator has “an output [singular]”).)

80. Further, the '318 patent teaches that one of the benefits of the claimed multiple radiofrequency output channels is that they are separately controllable, which prevents the situation where, due to varying degrees of contact with the target tissue, treatment energy is “diverted to pairs of electrodes that experience a relatively lower magnitude of impedance due to a relatively lower degree of tissue contact.” (Ex-1001 at 24:45-64, 48:42-49:4; *see also id.* at 49:65-50:2, 50:9-15.)

However, Stern's Figure 15 does not offer the same "separate control" described in the '318 patent. If, for example, switches 248, 246, 236, and 234 were closed at the same time—which, to be clear, is not taught in Stern—then current would be diverted to whichever electrodes experience less impedance. The '318 patent discloses that this was a problem faced by single channel designs. (Ex-1001 at 48:50-59.)

81. Regardless of whether Stern teaches "multiple pairs of bipolar radiofrequency electrodes" and "multiple radiofrequency output channels" (it does not), Petitioners and Dr. Martin have failed to show that Stern teaches "wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels," as recited in Challenged Claim 1. (Ex-1001 at claim 1.)

82. In Petitioners' and Dr. Martin's annotated versions of Stern's Figure 15, reproduced below, both alleged pairs of bipolar radiofrequency electrodes are connected to the same output of Stern's voltage source 228:



(Petition at 43 (annotations in original); Ex-1002-Martin, ¶ 124 (same).)

83. Petitioners and Dr. Martin do not show any alleged electrode pair connected to a different output of Stern's voltage source 228. (*Id.*) This is unsurprising, as Stern's voltage source 228 (*i.e.*, the radiofrequency generator) has only a single output. (Ex-1033-Stern at FIG. 15, 2:49-53, 3:12-21, 10:53-55, claim 1.)

3. Petitioners Have Failed To Show That Edwards-535 In View Of Stern Renders Dependent Challenged Claims 4-5, 9-10, 12-13, And 15-17 Obvious.

84. Petitioners have failed to show that Edwards-535 in view of Stern renders dependent Challenged Claims 4-5, 9-10, 12-13, and 15-17 obvious in view of their dependency on Challenged Claim 1.

85. Petitioners have also failed to show that Edwards-535 in view of Stern renders dependent Challenged Claims 5, 9, 15, and 17 obvious for the reasons discussed below.

4. Petitioners Have Failed To Show That Edwards-535 In View Of Stern Teaches Challenged Claim 5: “The device of claim 4, wherein at least one pair of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments.”

86. Challenged Claim 5 recites: “wherein at least one pair of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments.” (Ex-1001 at claim 5.)

87. Petitioners and Dr. Martin assert that Stern teaches a plurality of surface segments 42 (*i.e.*, the alleged “multiple segments”). (Petition at 51-52; Ex-1002-Martin, ¶ 167.) Petitioners and Dr. Martin also assert that “Stern teaches that the segments include at least one pair of the multiple pairs of bipolar RF electrodes...” (Petition at 52; Ex-1002-Martin, ¶ 170.)

88. I disagree with Petitioners and Dr. Martin that Stern teaches that each of its surface segments 42 includes a pair of electrodes. Rather, Stern teaches that each of its surface segments 42 has one electrode and one thermistor—not two electrodes. (Ex-1033-Stern at 8:49-59; *see also id.* at FIGS. 4a-4b, 5-7, 8a, 8:66-9:6, 11:8-16, 11:21-24, 11:30-32.)

5. Petitioners Have Failed To Show That Edwards-535 In View Of Stern Teaches Element 9[a]: “a radiofrequency generator configured to receive sensed signals from the multiple sensors and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels in the form of a 460 KHz sinusoid wave.”

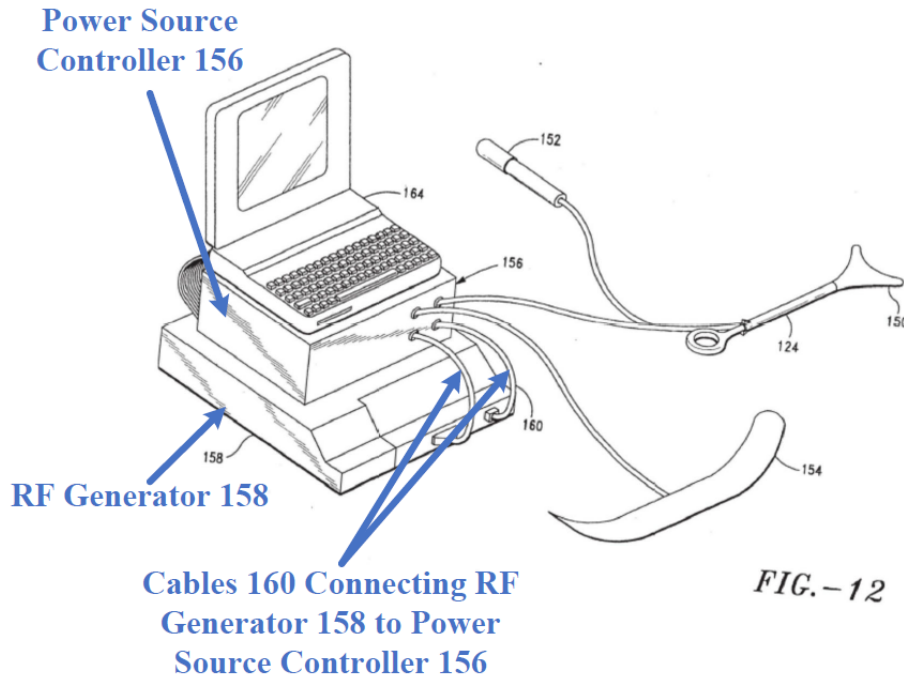
89. Challenged Claim 9 recites, among other things, “a radiofrequency generator configured to ... deliver radiofrequency energy separately to each of the multiple radiofrequency output channels.” (Ex-1001 at claim 9.)

90. Petitioners and Dr. Martin assert that Edwards-535 in combination with Stern “discloses a radiofrequency generator (*e.g.*, signal generator 165 in Edwards-’535 and/or RF generator 158 in Stern).” (Petition at 53; Ex-1002-Martin, ¶ 175.) Petitioners and Dr. Martin also assert that, “[a]s described in limitation 1[d]-[e], Edwards-’535 in view of Stern teaches the delivery of radiofrequency energy separately to each of the multiple radiofrequency output channels.” (Petition at 54; Ex-1002-Martin, ¶ 177.)

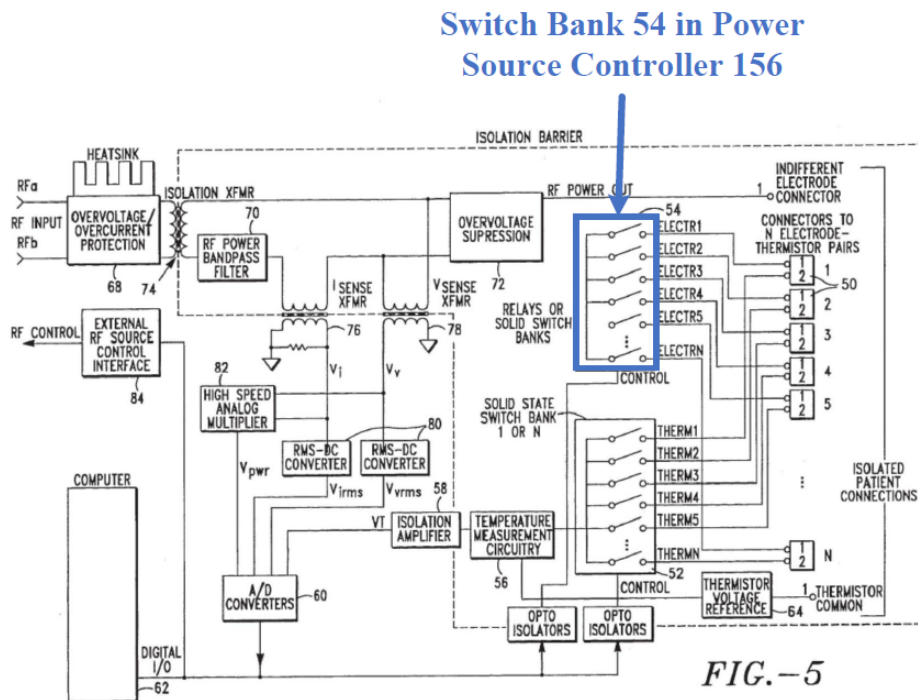
91. Petitioners and Dr. Martin fail to address what is claimed. Challenged Claim 9 expressly recites that the “radiofrequency generator” is configured to deliver radiofrequency energy separately to each of the multiple radiofrequency output channels. (Ex-1001 at claim 9.) However, Petitioners and Dr. Martin fail to explain in their Challenged Claim 9 analysis how Edwards-535 in view of Stern teaches a “radiofrequency generator” configured to deliver radiofrequency energy separately to each of the alleged multiple radiofrequency output channels, as

claimed. (Petition at 54; Ex-1002-Martin, ¶ 177.) Similarly, at no point in their analysis of limitations 1[d] and 1[e] do Petitioners or Dr. Martin demonstrate that Edwards-535 in view of Stern teaches a “radiofrequency generator” configured to deliver radiofrequency energy separately to each of the alleged multiple radiofrequency output channels. (*See generally* Petition at 32-45; Ex-1002-Martin, ¶¶ 93-148.)

92. In any case, Stern fails to teach that its RF generator 158 is configured to “deliver radiofrequency energy separately.” Stern teaches an “RF generator 158” in the form of “a conventional electrosurgical power supply.” (Ex-1033-Stern at FIG. 12, 10:44, 10:54-55; *id.* at 2:50-51.) The RF generator 158 has a single “output,” which is provided to a separate power source controller 156 via electrosurgical interface cables 160. (*Id.* at FIG. 12, 10:42-46; *id.* at 2:49-53, 3:12-21, 9:14-17, 10:53-55, claim 1.) Switches in the power source controller 156 control which electrodes in the application device 124 receive radiofrequency energy. (*Id.* at 3:12-21, 8:66-67, 11:49-51, 12:21-24, 12:38-61, claim 1, FIG. 5, FIG. 12, FIG. 15.)



(*Id.* at FIG. 12 (annotated).)



(*Id.* at FIG. 5 (annotated); see also *id.* at 8:66-67 (“FIG. 5 is a schematic representation of the power source controller”).)

93. Because Stern's RF generator 158 is configured to deliver only a single radiofrequency "output" to the power source controller 156, Stern's RF generator 158 is not configured to "deliver radiofrequency energy separately."

94. Further, Stern describes its radiofrequency generator as "a conventional electrosurgical power supply." (Ex-1033-Stern at 2:50-51, 10:44, 10:54-55.) Prior to the invention of the '318 patent, a conventional electrosurgical power supply typically had a single radiofrequency output.

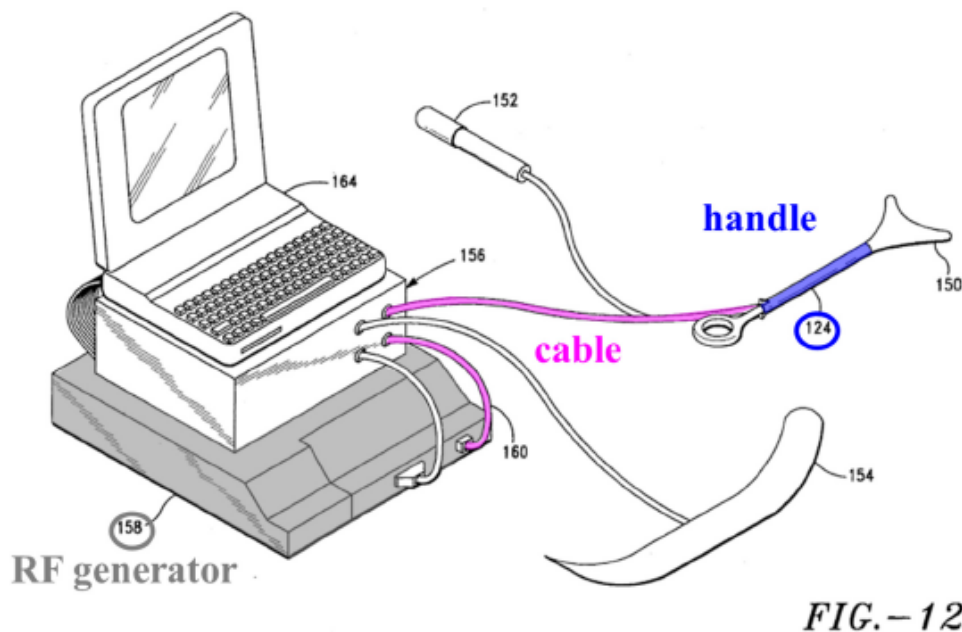
95. I also note that Stern's Figures 5 and 12 are consistent with Stern's Figure 15. (*Id.* at FIGS. 5, 12, 15.) Figure 15 depicts a radiofrequency generator 228 with two wires connected to it. (*Id.*) Figure 12 similarly depicts a radiofrequency generator 158 with two cables 160 connected to it. (*Id.*) Likewise, Figure 5 shows that the power source controller is connected to the radiofrequency generator with two wires. (*Id.*)

96. Edwards-535 does not teach "multiple radiofrequency output channels," and thus Edwards-535 cannot teach the claimed "radiofrequency generator." While Edwards-535 discloses a signal generator 165, Edwards-535 provides no details regarding how the signal generator 165 is configured beyond the fact that it can generate pulses, sine waves, and square waves. (Ex-1010-Edwards-535 at 8:54-60.) Thus, Edwards-535 also does not teach a radiofrequency generator that is configured to "deliver radiofrequency energy separately."

6. Petitioners Have Failed To Show That Edwards-535 In View Of Stern Teaches Element 9[b]: “a cable coupled to the handle for plugging the handle into the radiofrequency generator.”

97. Challenged Claim 9 also recites, among other things, “a cable coupled to the handle for plugging the handle into the radiofrequency generator.” (Ex-1001 at claim 9.)

98. Petitioners and Dr. Martin assert that Stern’s RF generator 158 is the claimed “radiofrequency generator.” (Petition at 53; Ex-1002-Martin, ¶ 175.) Petitioners and Dr. Martin also assert that Stern teaches a cable 160 coupled to the handle of application device 124 for plugging the handle into RF generator 158. (Petition at 58; Ex-1002-Martin, ¶¶ 187-188.) In support of their argument, Petitioners and Dr. Martin provide the following annotated figure:



(Petition at 58 (annotations in original).)

99. I disagree with Petitioners and Dr. Martin that Stern teaches a cable coupled to the handle of application device 124 for plugging the handle into the RF generator 158. As depicted in Petitioners' and Dr. Martin's annotated diagram above, Stern's RF generator 158 is connected to a separate power source controller 156 via electrosurgical interface cables 160. (Ex-1033-Stern at FIG. 12, 10:36-49.) The handle of application device 124 is plugged into power source controller 156 via a different cable. (*Id.*) Thus, the cable coupled to Stern's handle 124 is plugged into Stern's power source controller 156—not into Stern's RF generator 158 (*i.e.*, the alleged radiofrequency generator).

7. Petitioners Have Failed To Show That Edwards-535 In View Of Stern Renders Obvious Challenged Claim 15: “The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes.”

100. Challenged Claim 15 recites: “wherein the multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes.” (Ex-1001 at claim 15.)

101. Petitioners and Dr. Martin assert that Stern's Figure 19 discloses electrodes 322 arranged in two rows, and that, “as discussed above for limitations 1[d] and 1[e], such an electrode arrangement would have been obvious to incorporate in Edwards-'535.” (Petition at 66-67; Ex-1002-Martin, ¶¶ 214-216.) However, Petitioners and Dr. Martin do not assert or demonstrate in their

limitation 1[d] or 1[e] analyses that it would have been obvious to incorporate Stern's electrode arrangement of Figure 19 in Edwards-535's device. (*See generally* Petition at 32-45; Ex-1002-Martin, ¶¶ 93-148.)

102. Petitioners and Dr. Martin also argue that "there are only a finite number of ways to configure an array of bipolar electrodes." (Petition at 67; Ex-1002-Martin, ¶ 216.) I disagree. There are a significant (if not infinite) number of ways to configure an array of bipolar electrodes. An "array" of bipolar electrodes simply requires some sort of ordering. No particular ordering is required. Petitioners and Dr. Martin fail to explain why, out of the multitude of possible electrode arrangements, a POSITA would have specifically picked out Stern's Figure 19 electrode arrangement for use in Edwards-535's device. (Petition at 67; Ex-1002-Martin, ¶ 216.)

8. Petitioners Have Failed To Show That Edwards-535 In View Of Stern Teaches Challenged Claim 17: "The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes are connected to one another and to the multiple radiofrequency output channels in a multiplexed configuration."

103. Challenged Claim 17 recites, among other things, "wherein the multiple pairs of bipolar radiofrequency electrodes are connected to one another." (Ex-1001 at claim 17.)

104. Petitioners and Dr. Martin assert that Stern teaches that electrodes 220 and 222 can be connected to one another as a bipolar electrode pair. (Petition at

69-71; Ex-1002-Martin, ¶¶ 227, 229.) However, Challenged Claim 17 expressly recites that “the multiple pairs of bipolar radiofrequency electrodes are connected to one another.” (Ex-1001 at claim 17.) Petitioners and Dr. Martin do not show that Edwards-535 in view of Stern teaches what is claimed. (Petition at 69-71; Ex-1002-Martin, ¶¶ 227, 229.)

B. Ground 2: Petitioners Have Failed To Show That Edwards-535 In View Of Stern And Patel Renders Dependent Challenged Claim 6 Obvious.

105. Petitioners have failed to show that Edwards-535 in view of Stern and Patel renders dependent Challenged Claim 6 obvious in view of its dependency on Challenged Claim 1.

106. Petitioners have also failed to show that Edwards-535 in view of Stern and Patel renders Challenged Claim 6 obvious because Petitioners have failed to show that the proposed combination teaches the additional limitations of Challenged Claim 6.

107. Challenged Claim 6 recites: “The device of claim 4, wherein the multiple segments comprise a shape-memory alloy material configured to expand to a desired size and shape.” (Ex-1001 at claim 6.)

108. Challenged Claim 4 recites: “The device of claim 1, wherein the treatment element comprises multiple segments that are expandable from the first configuration to the second configuration.” (*Id.* at claim 4.)

109. Petitioners and Dr. Martin assert that Patel discloses electrodes made of nitinol, “a known shape memory alloy,” and that Patel’s electrodes “allow folding or furling of the balloon during insertion.” (Petition at 72-73; Ex-1002-Martin, ¶¶ 236-237.) Petitioners and Dr. Martin propose implementing Patel’s nitinol electrodes on Edwards-535’s expandable member 132. (Petition at 73; Ex-1002-Martin, ¶ 239.)

110. The claims of the ’318 patent recite that electrodes are different than the claimed “multiple segments.” (Ex-1001 at claims 1 and 4-5; *see also id.* at 18:3-20.) Specifically, the claims recite a device with a “treatment element” comprising “multiple segments that are expandable from [a] first configuration to [a] second configuration.” (*Id.* at claims 1 and 4.) “Bipolar radiofrequency electrodes,” which are separately claimed, are “disposed along [a] treatment surface of the treatment element.” (*Id.* at claim 1; *see also id.* at claim 5 (“at least one pair ... of bipolar radiofrequency electrodes is coupled with each of the multiple segments.”).)

111. At best, Petitioners’ and Dr. Martin’s proposed combination shows that the electrodes disposed on the surface of Edwards-535’s expandable member 132 comprise a shape-memory alloy material. Petitioners and Dr. Martin have not shown that the “multiple segments” of Edwards-535’s expandable member 132 comprise a shape-memory alloy material, as claimed.

112. Even if Patel’s electrodes could be considered the claimed “multiple segments,” Petitioners and Dr. Martin have not shown that Patel’s electrodes are “configured to expand to a desired size and shape,” as claimed. (Ex-1001 at claim 6.) For example, Petitioners and Dr. Martin do not assert that Patel’s electrodes are configured to expand to a desired size and shape. (Petition at 72-74; Ex-1002-Martin, ¶¶ 236-237.) At best, Petitioners and Dr. Martin assert that Patel’s electrodes “allow folding or furling of the balloon during insertion.” (*Id.*) However, folding and furling are the opposite of expanding, and whether Patel’s balloon can fold, furl, or expand has no bearing on whether Patel’s electrodes are configured to expand.

C. Ground 3: Petitioners Have Failed To Show That Edwards-535 In View Of Stern And Edwards-886 Renders Dependent Challenged Claims 9-10 Obvious.

113. Petitioners have failed to show that Edwards-535 in view of Stern and Edwards-886 renders dependent Challenged Claims 9-10 obvious in view of their dependency on Challenged Claim 1.

114. Further, Petitioners’ and Dr. Martin’s Ground III analysis of Challenged Claim 9 relies on their Ground I analysis of Challenged Claim 9, except as to the claimed “460 KHz sinusoid wave.” (Petition at 74-75; Ex-1002-Martin, ¶¶ 242-243, 247-248.) For the same reasons discussed above in Ground I,

Petitioners and Dr. Martin have failed to show that Edwards-535 in view of Stern and Edwards-886 renders Challenged Claim 9 obvious in Ground III.

D. Ground 4: Petitioners Have Failed To Show That Makower In View Of Stern Renders Challenged Claims 1, 4-6, 12-13, And 15-17 Obvious.

1. Petitioners Have Failed To Show That Makower In View Of Stern Renders Challenged Claim 1 Obvious.

115. Petitioners' and Dr. Martin's Ground IV analysis of the claimed "multiple pairs of bipolar radiofrequency electrodes" and the claimed "multiple radiofrequency output channels" relies on Stern's Figure 15 and their Ground I analysis. (Petition at 82-88; Ex-1002-Martin, ¶¶ 272-276, 289; Ex-2003 at 229:10-16.) For the same reasons discussed above in Ground I, Petitioners and Dr. Martin have failed to show that Makower in view of Stern teaches at least the claimed "an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element"; and "multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes, wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels."

2. Petitioners Have Failed To Show That Makower In View Of Stern Renders Dependent Challenged Claims 4-6, 12-13, And 15-17 Obvious.

116. Petitioners have failed to show that Makower in view of Stern renders dependent Challenged Claims 4-6, 12-13, and 15-17 obvious in view of their dependency on Challenged Claim 1.

117. Petitioners have failed to show that Makower in view of Stern renders dependent Challenged Claims 6 and 17 obvious for the reasons discussed below.

3. Petitioners Have Failed To Show That Makower In View Of Stern Teaches Or Suggests Challenged Claim 6: “The device of claim 4, wherein the multiple segments comprise a shape-memory alloy material configured to expand to a desired size and shape.”

118. Challenged Claim 6 recites: “wherein the multiple segments comprise a shape-memory alloy material configured to expand to a desired size and shape.” (Ex-1001 at claim 6.)

119. Petitioners and Dr. Martin assert that Makower’s strut members 214 are the claimed “multiple segments,” and that Makower teaches or suggests that strut members 214 are made of a shape-memory alloy material (*i.e.*, nitinol). (Petition at 90, 92; Ex-1002-Martin, ¶¶ 317-319.) Petitioners and Dr. Martin do not propose modifying Makower’s strut members 214 to be made of nitinol. (*Id.*)

120. I disagree with Petitioners and Dr. Martin that Makower teaches or suggests that its strut members 214 are made of nitinol.

121. Makower does not teach that its strut members 214 are made of nitinol. (Ex-1021-Makower at FIG. 5H, [0187], [0194].) Makower has no teachings regarding what strut members 214 are made of. (*Id.*)

122. Makower also does not suggest that its strut members 214 are made of nitinol. With respect to nitinol, Makower teaches at most the “use of elements to predictably deflect various sections of the catheter (e.g., tension straps or wires, shape memory alloys such as nitinol, etc.).” (Ex-1021-Makower at [0194].) This is the only time the word “nitinol” appears in Makower. (*Id.*) Importantly, Makower does not teach that its strut members 214 deflect the catheter. (*Id.* at FIG. 5H, [0187].) Thus, Makower’s only description of “nitinol” is unrelated to the strut members 214.

123. While Petitioners and Dr. Martin assert that Makower’s “strut members 214 deflect when expanded” (Petition at 92; Ex-1002-Martin, ¶ 319), this is again unrelated to Makower’s teaching that nitinol can be used to deflect various sections of the catheter. As noted above, Makower does not teach that its strut members 214 deflect the catheter. (Ex-1021-Makower at FIG. 5H, [0187].) Makower also expressly teaches that its strut members 214 are different than the catheter 210. (*Id.*) Specifically, Makower teaches that strut members 214 are attached to the flexible catheter 210 and that “sensing elements may also be attached to the catheter and/or strut members to monitor various parameters of the

catheter and/or surrounding tissue (e.g., temperature, etc.).” (*Id.*) Petitioners and Dr. Martin have failed to show that Makower teaches or suggests that its strut members 214 are made of nitinol.

4. Petitioners Have Failed To Show That Makower In View Of Stern Teaches Challenged Claim 17: “The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes are connected to one another and to the multiple radiofrequency output channels in a multiplexed configuration.”

124. Petitioners’ and Dr. Martin’s Ground IV analysis of Challenged Claim 17 relies on their Ground I analysis of Challenged Claim 17. (Petition at 95; Ex-1002-Martin, ¶ 331.) For the same reasons discussed above in Ground I, Petitioners and Dr. Martin have failed to show that Makower in view of Stern renders Challenged Claim 17 obvious in Ground IV.

E. Ground 5: Petitioners Have Failed To Show That Makower In View Of Stern And Edwards-886 Renders Dependent Challenged Claims 9-10 Obvious.

125. Petitioners have failed to show that Makower in view of Stern and Edwards-886 renders dependent Challenged Claims 9-10 obvious in view of their dependency on Challenged Claim 1.

126. Petitioners have also failed to show that Makower in view of Stern and Edwards-886 renders Challenged Claim 9 obvious for the additional reasons discussed below.

1. Petitioners Have Failed To Show That Makower In View Of Stern And Edwards-886 Teaches Element 9[a]: “a radiofrequency generator configured to receive sensed signals from the multiple sensors and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels in the form of a 460 KHz sinusoid wave.”

127. Challenged Claim 9 recites, among other things, “a radiofrequency generator configured to ... deliver radiofrequency energy separately to each of the multiple radiofrequency output channels.” (Ex-1001 at claim 9.)

128. For the same reasons discussed above in Ground I, Petitioners and Dr. Martin have failed to show that Makower in view of Stern and Edwards-886 teaches the claimed “radiofrequency generator configured to ... deliver radiofrequency energy separately to each of the multiple radiofrequency output channels.” (Petition at 95-97; Ex-1002-Martin, ¶ 334.)

129. Makower adds nothing to Petitioners’ and Dr. Martin’s Challenged Claim 9 “analysis,” as Makower mentions “a radio frequency generator” one time and provides no details about the “radio frequency generator.” (Ex-1021-Makower at [0040].)

2. Petitioners Have Failed To Show That Makower In View Of Stern And Edwards-886 Teaches Element 9[b]: “a cable coupled to the handle for plugging the handle into the radiofrequency generator.”

130. Challenged Claim 9 also recites “a cable coupled to the handle for plugging the handle into the radiofrequency generator.” (Ex-1001 at claim 9.)

131. Based on their Ground I analysis of Challenged Claim 9, Petitioners and Dr. Martin assert that Stern discloses this limitation. (Petition at 97; Ex-1002-Martin, ¶ 339.) For the same reasons discussed above in Ground I, Stern fails to disclose “a cable coupled to the handle for plugging the handle into the radiofrequency generator.”

X. CONCLUSIONS

- The Challenged Claims of the '318 patent are not obvious in light of the disclosures of the asserted prior art references.
- The Challenged Claims of the '318 patent are not unpatentable and were properly issued by the Patent and Trademark Office.

I have prepared this Declaration based upon my review of the materials referenced, and my own personal knowledge, education, skill and experience. I declare, under penalty of perjury under the laws of the United States of America, that the foregoing is true and correct.

Dated: October 25, 2024

A handwritten signature in dark ink, appearing to read "Marom Bikson", written over a horizontal line.

Dr. Marom Bikson