

**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 IPR2024-00277
Patent No. 11,241,271

**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, 6-12, and 16 (the “Challenged Claims”) of U.S. Patent No. 11,241,271 (“the ’271 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

'271 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 '271 patent.

II. SUMMARY OF MY OPINIONS

19. In summary, it is my opinion that each of the Challenged Claims of the '271 patent is valid and patentable. Petitioners and their experts, Dr. DelGaudio and Dr. Martin, have failed to show that the Challenged Claims of the '271 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 '271 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.

25. It is my understanding that a method claim requires an ordering of steps when the claim language, as a matter of logic or grammar, requires that the steps be performed in the order written, or the specification directly or implicitly requires an order of steps.

B. Legal Standard for Obviousness

26. 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 '271 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 '271 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.

27. 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.

28. 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

29. I have reviewed the '271 patent, including the Challenged Claims and the prosecution history of the '271 patent. (Ex-1001 and Ex-1003.)

30. 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. DelGaudio (Ex-1002), the attached Declaration of Dr. Martin (Ex-1004), the transcript of the deposition of Dr. Martin (Ex-2003 and Ex-2004), certain exhibits to the deposition of Dr. Martin (Ex-2005 and Ex-2006), the transcript of the deposition of Dr. DelGaudio (Ex-2007), as well as the Exhibits to Petitioners' Petition.

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

32. 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.

33. 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

34. 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 '271 patent at the time of the invention of the Challenged Claims.

35. 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.

36. 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 '271 patent.

37. 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.)

38. 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 '271 patent would have had more experience than just clinically using medical devices or simply conducting tests with medical devices.

39. The claims of the '271 patent require, among other things, a "nasal airway treatment device" having a "treatment element" comprising "two rows of bipolar electrode pairs." (Ex-1001 at claim 1.) Challenged Claims 4 and 8-10 additionally recite: (i) applying radiofrequency energy "in the form of a 460 kHz sinusoid wave"; (ii) "wherein the radiofrequency energy is produced by a radiofrequency energy source configured to run between 1 Watt and 100 Watts"; (iii) "wherein applying the radiofrequency energy comprises heating the target tissue to a temperature between 50 degrees Celsius to 70 degrees Celsius"; and (iv) "wherein the amount of time the radiofrequency energy is applied to the target tissue is between fifteen seconds and one minute." (*Id.* at claims 4, 8-10.) Claim 5 of the '271 patent, which was not challenged, recites "a thermocouple positioned between the two rows of bipolar electrode pairs on the treatment element." (*Id.* at claim 5.)

40. Each of the above limitations represents a technical requirement associated with the features of the claimed invention, and a person who merely

tests or uses such devices is not qualified to speak to such technical requirements. For instance, someone who has merely used or tested medical devices is not qualified to speak to the technical issues associated with implementing a “nasal airway treatment devices” having a “treatment element” comprising “two rows of bipolar electrode pairs.” A person who has never designed or developed such a medical device would not have the requisite background on how to implement such a device.

41. 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.

42. I met both parties’ definitions of a POSITA as of the time of the invention of the Challenged Claims of the ’271 patent. My opinions herein are the same regardless of which definition the Board applies.

VI. OVERVIEW OF THE ’271 PATENT AND THE CHALLENGED CLAIMS

43. The ’271 patent, entitled “Methods and Devices to Treat Nasal Airways,” issued on February 8, 2022, from U.S. Patent Application No. 16/514,316 (filed on July 17, 2019). (Ex-1001 at [21], [22], [45], [54].) The ’271

patent claims priority to a provisional patent application (Application No. 61/496,930) which was filed on June 14, 2011. (*Id.* at [60].)

44. The '271 patent and the Challenged Claims are generally directed toward methods “for treating a nasal airway to reduce mucus production.” (*Id.* at claim 1.) The '271 patent describes “treating a nasal airway by modifying a property of a nasal tissue of or near a nasal valve of the airway, without using a surgical incision or an implant...” (*Id.* at Abstract.) The '271 patent discloses a method for decreasing nasal congestion, including reducing mucus production, and increasing nasal air flow. (*Id.* at 10:56-67, 48:1-7.) The method of the '271 patent includes treating a patient’s nasal airway using a treatment device to deliver energy to tissues within the nose to modify a property of that tissue without using a surgical incision. (*Id.* at 8:1-13.)

45. The method of the '271 patent uses a treatment probe having multiple pairs of bipolar electrodes on the outside surface that directly contact the nasal mucosa and apply radiofrequency (“RF”) energy to target tissue underlying the nasal mucosa. (*See, e.g., id.* at 7:51-67, 20:18-38, 23:40-24:1, 26:63-27:4, 33:27-62, 42:60-66, 39:52-56.) The '271 patent describes a pair of bipolar electrodes as comprising electrodes of opposite polarities. (*Id.* at 22:28-30; *see also id.* at FIGS. 8F-G.) As shown below, the '271 patent discloses a claimed embodiment where

the bipolar electrodes are arranged in two rows, with each row having multiple bipolar electrode pairs:

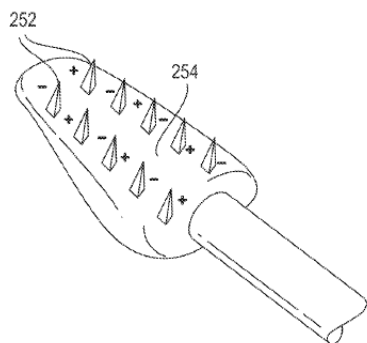


FIG. 8F

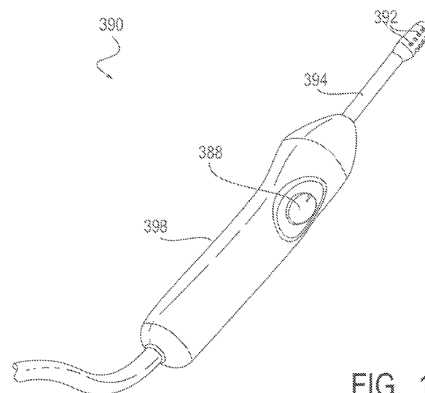


FIG. 18

(*Id.* at FIGS. 8F and 18; *see also id.* at Abstract, 8:21-25.)

46. The '271 patent also discloses an embodiment where the bipolar electrode pairs are arranged in a single row:

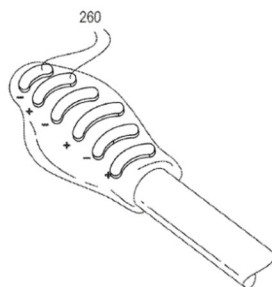


FIG. 8G

(*Id.* at FIG. 8G; *see also id.* at 23:54-59.)

47. The '271 patent further teaches 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 6:28-36, 7:43-50, 8:26-34, 15:56-60, 30:24-30, 33:27-48, 43:45-57, 44:50-45:5.) The '271 patent describes that “[o]ne mechanism of action that may be involved” in its method “may be to reduce mucus

production and/or accumulation in and/or around any treated areas.” (*Id.* at 48:1-7.)

48. Independent Challenged Claim 1, the only independent claim of the ’271 patent, is reproduced below:

1. A method for treating a nasal airway to reduce mucus production, the method comprising:

1[a] contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises two rows of bipolar electrode pairs;

1[b] applying radiofrequency energy with the bipolar electrode pairs through the nasal mucosa to a target tissue underlying the nasal mucosa for an amount of time to heat the target tissue; and

1[c] removing the treatment element from the nasal airway,

1[d] wherein heating the target tissue with the applied radiofrequency energy modifies at least one property of the target tissue, and

1[e] wherein the modified at least one property of the target tissue causes a reduction in mucus production in the nasal airway.

(*Id.* at claim 1.)

VII. OVERVIEW OF THE ASSERTED PRIOR ART

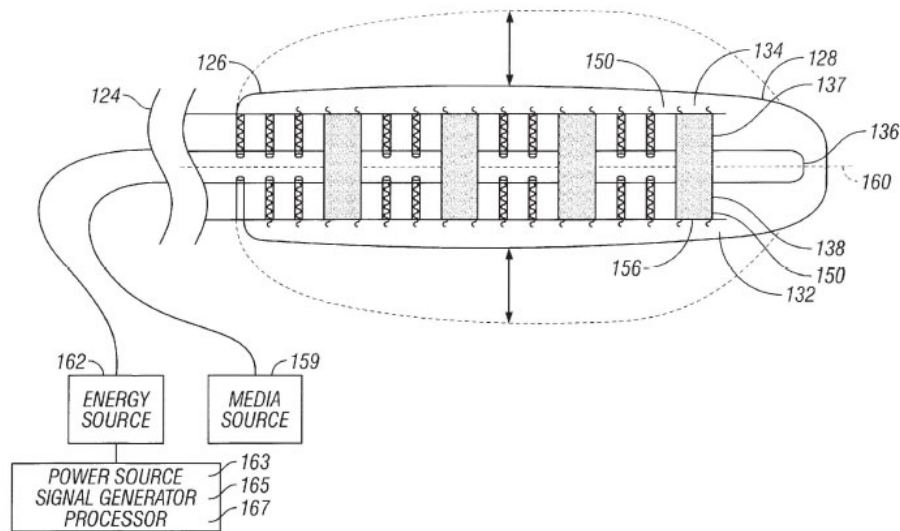
A. U.S. Patent No. 6,517,535 (“Edwards-535”)

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.)

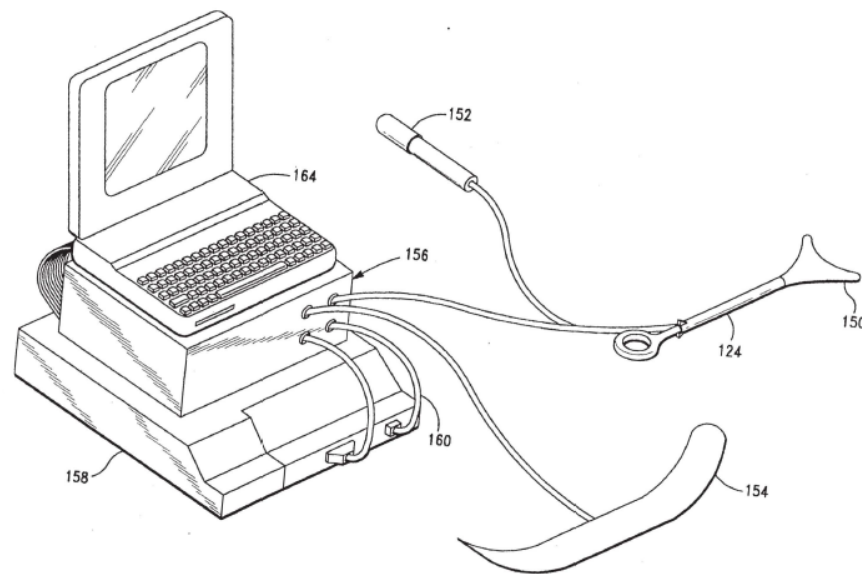


FIG. - 12

(*Id.* at FIG. 12.)

C. Kong

54. I have reviewed Kong. Kong is a clinical study that discusses "[s]urgical methods" using "radiofrequency ablation treatment [for] perennial

allergic rhinitis.” (Ex-1040- Kong at 214.) The study describes a surgical technique involving delivering RF energy via an electrode inserted into “1-2 holes made in each part” of the inferior turbinate, which was divided into two or three parts. (*Id.*) The holes were “approximately 1.5-2.0 cm” deep “under the mucosa.” (*Id.*) Kong states that “blood loss” from the surgery was “approximately 5-10 ml” and that in 5 out of the 35 patients, “scabs were formed at the hole site.” (*Id.*)

D. Liang

55. I have reviewed Liang. Liang is a clinical study describing using a radiofrequency device “to perform thermal coagulation treatment on the bilateral nasal ridge and the corresponding nasal septum mucosa.” (Ex-1056-Liang at 341.) The study states that an “SHP-I radiofrequency treatment device for facial organs (manufactured by Guangzhou Medical Device Factory)” was used to “perform thermal coagulation treatment,” but provides no details on the device or the settings used in the study. (*Id.*) The study explains that radiofrequency treatment can cause “degeneration and atrophy of the sensitive mucosa on the nasal ridge and corresponding nasal septum.” (*Id.* at 341-42.) The study also states that “the patients might experience symptoms such as ... a small amount of bloody secretions” following treatment and that some patients “developed nasal adhesion.” (*Id.* at 341.) Liang recognizes that the described procedure can damage the sensitive mucosa surface. (*Id.* at 341-42.)

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 '271 patent. To the extent an express claim construction of a claim term 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.

57. It is my opinion that, as a matter of grammar and logic, the claimed method steps of Challenged Claim 1 must be performed in the order written.

58. The first method step of Challenged Claim 1 is “contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway,” and the second method step is “applying radiofrequency energy with the bipolar electrode pairs through the nasal mucosa to a target tissue underlying the nasal mucosa for an amount of time to heat the target tissue.” (Ex-1001 at claim 1.) In the second step, the “nasal mucosa” to which RF energy is applied is the same “nasal mucosa” that was contacted with the treatment element in the first step. (*Id.*)

59. Additionally, the third method step of Challenged Claim 1 is “removing the treatment element from the nasal airway.” (*Id.*) In the third step,

the “treatment” element that is removed from the nasal airway is the same “treatment element” that was inserted into the nasal airway in the first step. (*Id.*)

60. It makes logical sense to perform the claimed methods steps in order because each step depends on the completion of the previous step. RF energy cannot be applied to the target tissue until the treatment element contacts the nasal mucosa, so the “contacting ... nasal mucosa” step must be completed before the “applying radiofrequency energy” step. Similarly, RF energy cannot be applied to the target tissue if the treatment element is not inside the nasal airway, so the “applying radiofrequency energy” step must be completed before the “removing the treatment element from the nasal airway” step.

61. As discussed further below, Petitioners’ asserted prior art combinations fail to render the Challenged Claims obvious because the asserted combinations do not teach performing the claimed method steps in their written order. To be clear, however, Petitioners fail to show that any of the Challenged Claims are obvious regardless of whether the claimed method steps are construed to require a specific order.

IX. PETITIONERS HAVE FAILED TO MEET THEIR BURDEN OF PROVING THAT THE CHALLENGED CLAIMS OF THE '271 PATENT ARE UNPATENTABLE AS OBVIOUS

A. Ground 1: Petitioners Have Failed To Show That Edwards-535 In View Of Kong And Stern Renders Challenged Claims 1-3, 6-12, And 16 Obvious.

1. Petitioners Have Failed To Show That Edwards-535 In View Of Kong And Stern Teaches Limitation 1[a]: “contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises two rows of bipolar electrode pairs.”

(a) Petitioners Have Failed To Show That Edwards-535 In View Of Kong And Stern Teaches “bipolar electrode pairs.”

62. Challenged Claim 1 of the '271 patent recites, among other things, “contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises ... bipolar electrode pairs” and “applying radiofrequency energy with the bipolar electrode pairs.” (Ex-1001 at claim 1.)

63. Petitioners assert that Stern’s Figure 15 teaches “bipolar electrode pairs” and that a POSITA would have been motivated to implement Stern’s Figure 15 in Edwards-535’s device. (Petition at 39-40; Ex-1004-Martin, ¶¶ 70-72; Ex-2003 at 232:13-18.) Petitioners argue that “Stern’s teachings would have been applied to Edwards-’535 in the same way they are used in Stern.” (Ex-1004-Martin, ¶ 88; Petition at 45.)

64. I disagree with Petitioners that Stern teaches the claimed “bipolar electrode pairs.” Rather, Stern teaches a device comprising at most a single pair of bipolar electrodes.

65. Consistent with the '271 patent's description, a POSITA would have understood a “pair” of bipolar electrodes to be two electrodes located near each other that have opposite polarities. (Ex-1001 at 22:28-30, FIGS. 8F-G.)

66. 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.)

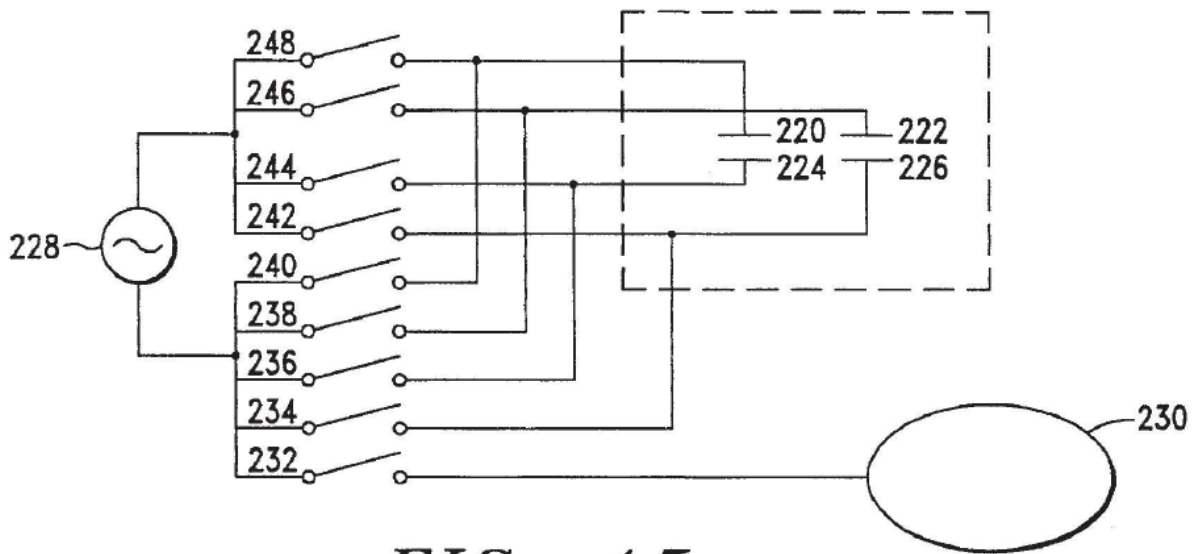


FIG. - 15

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

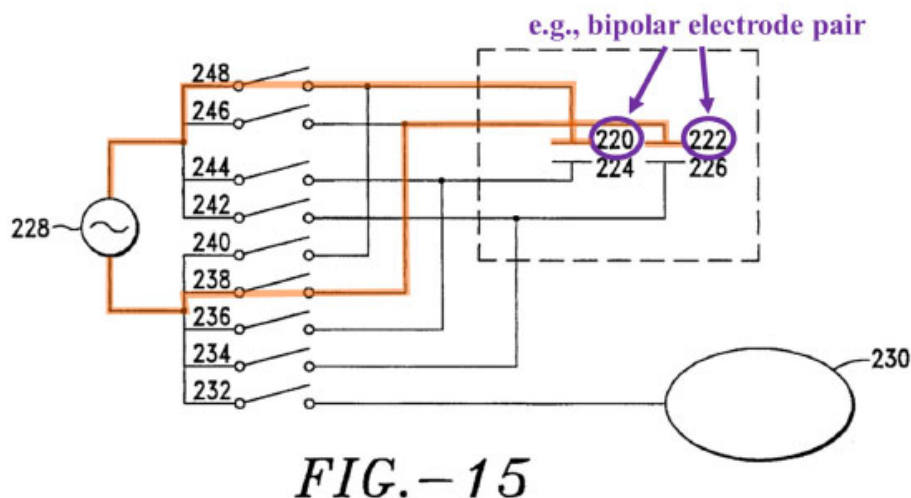
67. Stern describes its electrodes as “an array of separate electrodes.” (Ex-1033-Stern at 2:26-29, 2:39-40, 2:59-60.) Depending on which switches are closed, any of electrodes 220, 222, 224, and 226 in Figure 15 can be a monopolar electrode. (*Id.* at FIG. 15, 12:46-55.) Similarly, depending on which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

68. 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.)

69. To form multiple pairs of bipolar 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.

70. Petitioners likewise fail to identify where Stern teaches closing three or more switches at the same time. At most, Petitioners identify one example where Stern's Figure 15 device is configured to have a single pair of electrodes (*i.e.*, electrodes 220 and 222) by closing switches 248 and 238. (Petition at 39-40 (citing Ex-1033-Stern at 12:65-13:2); Ex-1004-Martin, ¶ 71 (same).) The deficiency in Petitioners' analysis is illustrated in Petitioners' own annotations to Stern's Figure 15 (reproduced below), which show Stern's device configured to have a single pair of electrodes:



(Petition at 40 (annotations in original).)

71. I understand that Petitioners also cite to Stern's Figure 19, but Figure 19 also fails to teach multiple pairs of bipolar electrodes. Stern's description of

Figure 19 states that “a plurality of electrodes 322 are formed on the surface of the bladder 320.” (Ex-1033-Stern at FIG. 19, 14:8-42.) Stern’s Figure 19 does not illustrate, and the related description of Figure 19 does not mention anything about, “bipolar” electrodes or electrode “pairs.” (*Id.*) Figure 19 simply discloses a physical arrangement of electrodes on the surface of a bladder. (*Id.*) Stern’s Figure 19 and its associated description fail to teach the claimed “bipolar electrode pairs.”

(b) Petitioners Have Failed To Show That Edwards-535 In View Of Kong And Stern Teaches “wherein the treatment element comprises two rows of bipolar electrode pairs.”

72. Challenged Claim 1 of the ’271 patent recites, among other things, “contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises two rows of bipolar electrode pairs.” (Ex-1001 at claim 1.)

73. Petitioners assert that Stern’s Figures 15 and 19 teach the claimed “two rows of bipolar electrode pairs” and that a POSITA would have been motivated to implement Stern’s electrode arrangement on Edwards-535’s expandable member 132. (Petition at 38-41, 47-49; Ex-1002-DelGaudio, ¶¶ 92-94; Ex-1004-Martin, ¶¶ 70-74, 94-97.) Petitioners provide the following annotated drawings in support of their argument:

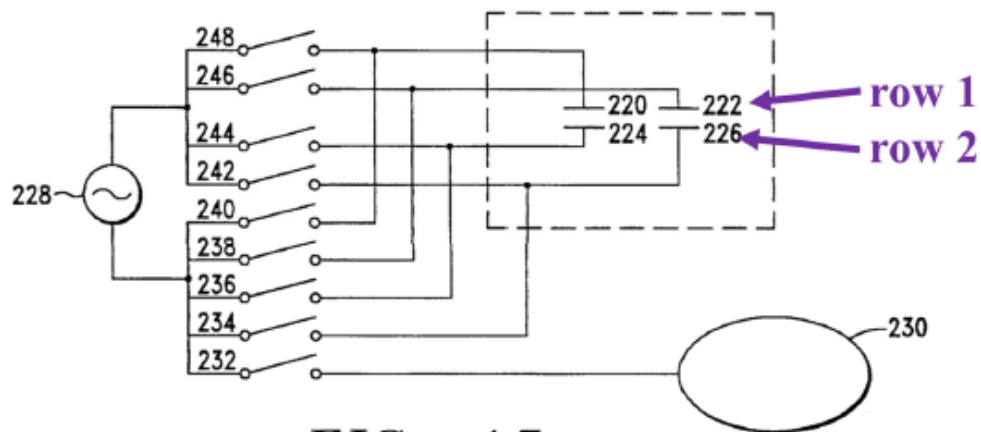


FIG. -15

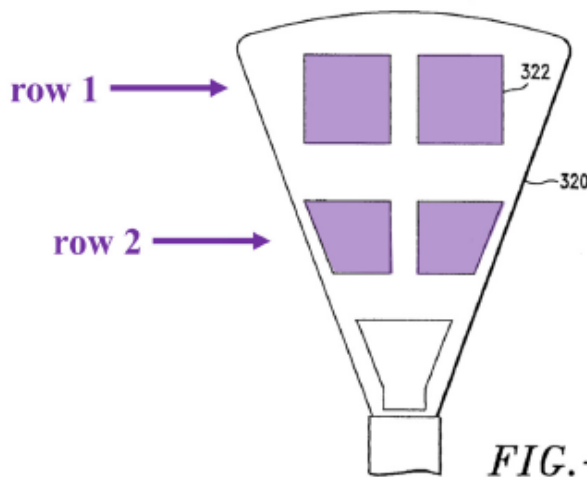


FIG. -19

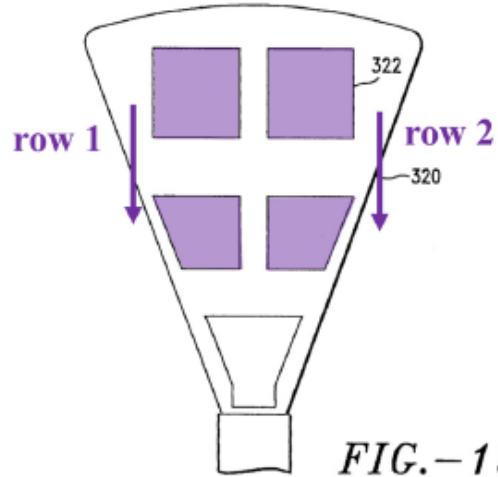


FIG. -19

(Petition at 41 (annotations in original); Ex-1004-Martin, ¶ 73 (same).)

74. I disagree with Petitioners that Stern teaches “two rows of bipolar electrode pairs.” Even if Stern teaches a treatment element comprising “bipolar electrode pairs” (it does not), Stern teaches two rows of a single pair each—not two rows of pairs.

75. The claim term “bipolar electrode pairs” is written in the plural, and thus requires multiple pairs. A row of only two electrodes is not a row of bipolar

electrode pairs because a row of only two electrodes has at most a single pair (not multiple pairs). A row of bipolar electrode pairs requires at least three electrodes in the row.

76. As shown in Petitioners’ annotated drawings reproduced above, each of Petitioners’ alleged “rows” has only two electrodes. (Petition at 41; Ex-1004-Martin, ¶ 73; Ex-2007 at 240:17-241:22, 242:4-20.) However, as I mentioned earlier, a row of only two electrodes is not a row of “bipolar electrode pairs.” Thus, Stern at most teaches two rows of a single pair each—not two rows of bipolar pairs.

77. My opinion is consistent with the ’271 patent’s teachings. For example, as illustrated below, FIG. 8F depicts a treatment element with two rows of five electrodes each, FIG. 8G depicts a treatment element with a single row of six electrodes, and FIG. 18 depicts a treatment element with two rows of four electrodes each:

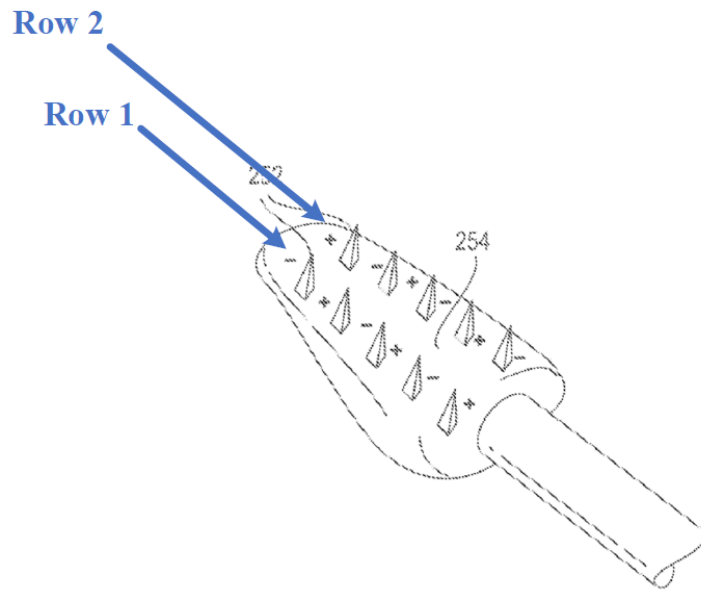


FIG. 8F

(Ex-1001 at FIG. 8F (annotated).)

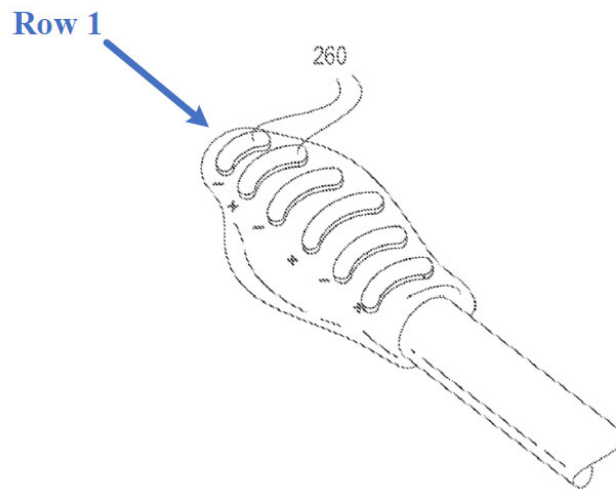


FIG. 8G

(*Id.* at FIG. 8G (annotated).)

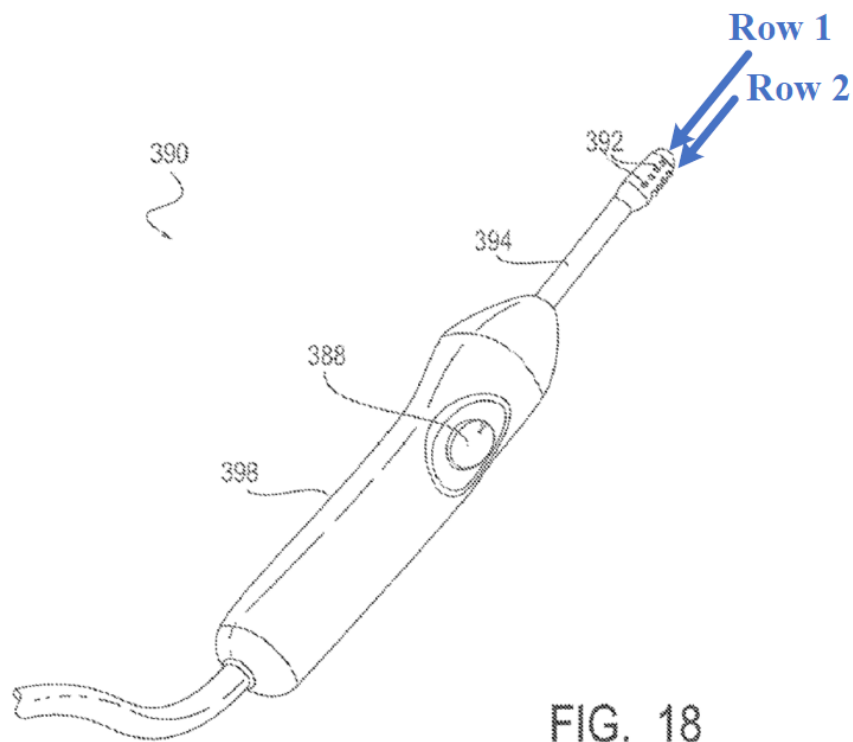


FIG. 18

(*Id.* at FIG. 18 (annotated).)

78. I understand that Petitioners' expert, Dr. Martin, testified at his deposition that "placing electrode pairs at random" does not meet the claimed "two rows of bipolar electrode pairs." (Ex-2003 at 270:15-19.) I agree with Dr. Martin. An interpretation of Challenged Claim 1 that encompasses random arrangements is incorrect. However, Petitioners' interpretation of the claims does just that. Petitioners simply draw an imaginary line between two electrodes and label the imaginary line a row. (Petition at 41.) But an imaginary line can always be drawn between two objects, even if the objects are arranged at random.

79. In view of the plain language of the claims and the '271 patent's specification, a POSITA would not have understood the claimed "two rows of bipolar electrode pairs" to be simply "two rows of bipolar electrodes." "Two rows of electrodes" has different requirements than "two rows of electrode pairs." "Two rows of electrodes" requires each row to have multiple "electrodes" (*i.e.*, at least two electrodes per row). "Two rows of electrode pairs," on the other hand, requires each row to have multiple "pairs" of electrodes (*i.e.*, at least three electrodes per row).

2. Petitioners Have Failed To Show That Edwards-535 In View Of Kong And Stern Teaches Limitation 1[b]: "applying radiofrequency energy with the bipolar electrode pairs through the nasal mucosa to a target tissue underlying the nasal mucosa for an amount of time to heat the target tissue."

80. Challenged Claim 1 recites the step of "applying radiofrequency energy with the bipolar electrode pairs." (Ex-1001 at claim 1.) The claim requires applying radiofrequency energy with pairs of bipolar electrodes, not just one pair. (*Id.*)

81. As discussed earlier, the method steps of Challenged Claim 1 must be performed in their written order, so the step of "applying radiofrequency energy with the bipolar electrode pairs" must be performed after the step of contacting the treatment element directly with nasal mucosa and before the step of removing the treatment element from the nasal airway. (Ex-1001 at claim 1.)

82. Regardless of whether Stern teaches “bipolar electrode pairs” (it does not), Petitioners have failed to show that Edwards-535 in view of Kong and Stern teaches the step of “applying radiofrequency energy with the bipolar electrode pairs.” (Petition at 49-51; Ex-1002-DelGaudio, ¶¶ 95-96.)

83. As discussed previously, Stern teaches 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.) Nothing in Stern teaches applying energy with multiple electrode pairs before removing the treatment device from the nasal airway. Further, applying energy with multiple bipolar electrode pairs would be contrary to 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.)

3. Petitioners Have Failed To Show That A POSITA Would Have Been Motivated To Combine Edwards-535 With Stern.

84. Petitioners argue that a POSITA would have been motivated to combine Edwards-535 with Stern’s electrode arrangement. (Petition at 38-41, 47-49; Ex-1002-DelGaudio, ¶¶ 92-94; Ex-1004-Martin, ¶¶ 70-74, 94-97.) According to Petitioners, a POSITA would have combined Edwards-535 with Stern’s electrode arrangement because: (i) Edwards-535 “instructs a POSITA to look to Baker for how to dispose electrodes on the surface of a membrane” and “Baker,

like Stern, also discloses electrodes in rows”; and (ii) arranging electrodes in rows “facilitates simple spatial resolution of the applied energy” for targeting particular portions of tissue. (Petition at 47-48; Ex-1004-Martin, ¶¶ 94-95.) Petitioners also argue that the proposed combination “would have involved an obvious duplication of parts.” (Petition at 48; Ex-1004-Martin, ¶ 95.) I disagree with Petitioners’ arguments.

85. First, Edwards-535 does not “instruct[] a POSITA to look to Baker for how to dispose electrodes on the surface of a membrane.” Edwards-535 states only the following with respect to U.S. Patent App. Ser. No. 08/319,373 (“Baker Application”): “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.” (Ex-1010-Edwards-535 at 8:28-31.) This passage does not disclose anything about electrodes or electrode arrangements. (*Id.*)

86. Edwards-535’s incorporation by reference passage has nothing to do with the Baker Application’s electrodes or electrode arrangement. Edwards-535 discloses that the expandable member may be “an expandable porous membrane” that is “permeable to [an] electrolytic medium used to expand the member.” (Ex-1010-Edwards-535 at 7:66-8:7.) Other than Edwards-535’s incorporation by reference passage, this is the only time Edwards-535 discloses a “membrane.”

(*Id.*) The Baker Patent similarly describes “an expandable member made of a material with a porous exterior surface,” wherein an electrolytic solution is released through the porous exterior surface. (Ex-1011-Baker at Abstract; *see also id.* at 3:11-17, 3:33-37, claim 1, claim 17.) In view of the above, Edwards-535’s incorporation by reference passage incorporates the Baker Application’s description of a “porous exterior surface” for releasing an electrolytic solution, not the Baker Application’s electrode arrangement.

87. I note that Edwards-535’s incorporation by reference passage does not incorporate the Baker Application in its entirety. (Ex-1010-Edwards-535 at 8:28-31.) Edwards-535 cites the Baker Application just for one limited example (*i.e.*, “An example of a suitable surface for disposition on the membrane”). (Ex-1010-Edwards-535 at 8:28-31.) The Baker Application’s other teachings (*e.g.*, the Baker Application’s electrode arrangement) are not incorporated by reference in Edwards-535. (*Id.*)

88. Second, I disagree with Petitioners’ assertion that arranging electrodes in rows “facilitates simple spatial resolution of the applied energy.” There are numerous (if not infinite) “ordered arrangements” for bipolar electrodes, of which Stern’s electrode arrangement is merely one possibility. In bipolar operation, energy flows from a positive electrode to a negative electrode. The application of this energy can be controlled in many ways, such as varying the position or

orientation of the device, varying which electrodes are activated (*e.g.*, electrodes that are closer together or further away, electrodes that have different orientations with respect to each other, etc.), varying the power, placing an insulating material near the electrodes, and the like. Using only two electrodes, or arranging the electrodes in a single row, provides the simplest way to control the applied energy. Other electrode arrangements do not simplify anything. Instead, they add complexity.

89. Third, I disagree with Petitioners' argument that the proposed combination would have been a mere "duplication of parts." Edwards-535 and Stern have completely different "parts." Edwards-535 discloses a single row of four ring electrodes, each of which wraps around the circumference of the device. (Ex-1010-Edwards-535 at FIG. 6, 8:18-24.) Stern, on the other hand, discloses five surface electrodes positioned on just one side of the device. (Ex-1033-Stern at FIG. 19, 14:14-42.) Duplicating Edwards-535's electrodes would have resulted in a single row of eight ring electrodes—not two rows of electrodes, or anything remotely resembling Stern's electrode arrangement.

4. Petitioners Have Failed To Show That Edwards-535 In View Of Kong And Stern Renders Dependent Challenged Claims 2-3, 6-12, And 16 Obvious.

90. Petitioners have failed to show that Edwards-535 in view of Kong and Stern renders dependent Challenged Claims 2-3, 6-12, and 16 obvious in view of their dependency on Challenged Claim 1.

91. Petitioners have also failed to show that Edwards-535 in view of Kong and Stern renders dependent Challenged Claims 11 and 16 obvious for the reasons discussed below.

5. Petitioners Have Failed To Show That Edwards-535 In View Of Kong And Stern Renders Obvious Challenged Claim 11: “The method of claim 1, further comprising, before removing the treatment element from the nasal airway: repositioning the treatment element to contact a different portion of nasal mucosa; and applying radiofrequency energy with the bipolar electrode pairs through the different portion of nasal mucosa to a different portion of target tissue for the amount of time to heat the different portion of target tissue.”

92. Challenged Claim 11 recites, among other things, “before removing the treatment element from the nasal airway: repositioning the treatment element to contact a different portion of nasal mucosa; and applying radiofrequency energy with the bipolar electrode pairs through the different portion of nasal mucosa to a different portion of target tissue.” (Ex-1001 at claim 11.)

93. Petitioners argue that Edwards-535 in view of Kong discloses repositioning the treatment element to contact a different portion of nasal mucosa

before removing the treatment element from the nasal airway and applying radiofrequency energy with the bipolar electrode pairs through the different portion of nasal mucosa. (Petition at 65-68; Ex-1002-DelGaudio, ¶¶ 132-139.)

94. I disagree with Petitioners that Edwards-535 in view of Kong discloses Challenged Claim 11. Neither Edwards-535 nor Kong, alone or in combination, discloses before removing the treatment element from the nasal airway repositioning the treatment element to contact a different portion of nasal mucosa and applying radiofrequency energy with bipolar electrode pairs through the different portion of nasal mucosa.

95. First, neither Edwards-535 nor Kong discloses “bipolar electrode pairs.” Thus, Edwards-535 in view of Kong cannot disclose “applying radiofrequency energy with [] bipolar electrode pairs.”

96. Second, neither Edwards-535 nor Kong discloses applying radiofrequency energy to a different portion of nasal mucosa before removing the treatment element from the nasal airway.

97. Edwards-535 discloses that “energy is delivered to a selected section [singular] of one of the nasal concha. For example, energy may be selectively delivered to the anterior or posterior sections of the inferior nasal concha.” (Ex-1010-Edwards-535 at FIGS 3B, 3D, 3:7-17, 6:38-55.) Nothing in Edwards-535

discloses applying energy to multiple portions or sections of the nasal concha before removing the device from the nasal airway. (*Id.*)

98. Similarly, nothing in Kong discloses applying energy to multiple portions of nasal mucosa before removing the device from the nasal airway. Rather, Kong discloses applying energy to a single portion of nasal mucosa before removing the device from the nasal airway. Specifically, Kong discloses inserting an RF electrode into the inferior turbinate, pressing and holding a “cutting pedal” for ten seconds while “the RF electrode remained stationary,” deactivating the RF electrode, and then slowly removing the RF electrode. (Ex-1040-Kong at 214.) While Kong discloses making holes in various parts of the inferior turbinate, making holes in the nasal mucosa is not what is claimed.

99. Third, even if Edwards-535 in view of Kong disclosed “bipolar electrode pairs” and applying radiofrequency energy to a different portion of nasal mucosa before removing the treatment element from the nasal airway (it does not), Petitioners have not shown that Edwards-535 in view of Kong discloses applying radiofrequency energy to a different portion of nasal mucosa with “bipolar electrode pairs [plural].” (Petition at 67-68; Ex-1002-DelGaudio, ¶¶ 137-138.) Rather, Petitioners merely assert that Edwards-535 in view of Kong discloses “apply[ing] RF energy” to different locations of the turbinate. (Petition at 67-68; Ex-1002-DelGaudio, ¶¶ 137-138.)

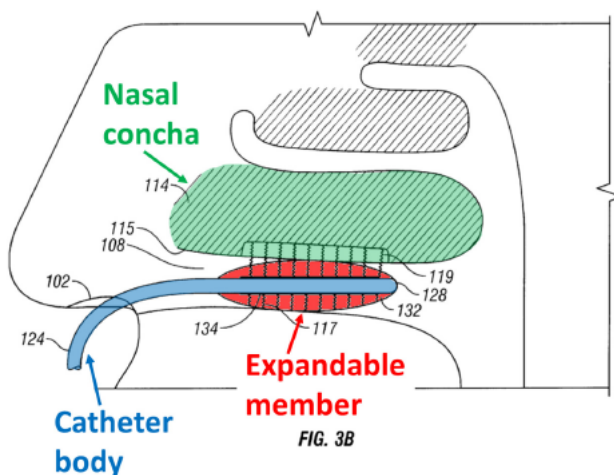
100. Fourth, Petitioners’ argument that it would have been obvious to move Edwards-535’s to different locations before removing the device and to apply RF energy at each of these locations is unsupported. Petitioners fail to provide any reason why it allegedly would have been obvious to move Edwards-535’s to different locations before removing the device and to apply RF energy at each of these locations. (Petition at 67-68; Ex-1002-DelGaudio, ¶ 136.) As discussed above, nothing in Edwards-535 or Kong supports Petitioners’ unsupported argument.

6. Petitioners Have Failed To Show That Edwards-535 In View Of Kong And Stern Renders Obvious Challenged Claim 16: “The method of claim 1, further comprising bending a shaft of the nasal airway treatment device before contacting the treatment element with the nasal mucosa.”

101. Challenged Claim 16 recites, among other things, “bending a shaft of the nasal airway treatment device before contacting the treatment element with the nasal mucosa.” (Ex-1001 at claim 16.)

102. Petitioners assert that Edwards-535 discloses or renders obvious this limitation. (Petition at 69-71; Ex-1002-DelGaudio, ¶¶ 143-148.) Specifically, Petitioners assert that Edwards-535’s Figure 3B “depicts an apparatus 124 (i.e., treatment device) with a bent catheter body (i.e., shaft) inserted into a patient’s nostril.” (Petition at 69; Ex-1002-DelGaudio, ¶ 144.) Petitioners also assert that, “to the extent PO argues that claim 16 requires ... a particular mechanism for

forming the bend shown in Figure 3B, a POSITA would have found it obvious to implement Edwards-'535 teachings using any number of well-known mechanisms for forming bends in catheter shafts.” (Petition at 70; Ex-1002-DelGaudio, ¶¶ 145-146.) Petitioners provide the following annotated version of Edwards-535’s Figure 3B:



(Petition at 70 (annotations in original).)

103. I disagree with Petitioners that Figure 3B of Edwards-535 discloses Challenged Claim 16. As shown above, Figure 3B depicts the treatment element (*i.e.*, the expandable member) already in contact with the nasal mucosa (*i.e.*, the nasal concha). (Ex-1010-Edwards-535 at FIG. 3B.) However, Challenged Claim 16 requires bending the shaft of the nasal airway treatment device “before contacting the treatment element with the nasal mucosa.” (Ex-1001 at claim 16.)

104. I also disagree with Petitioners that Edwards-535, alone, renders Challenged Claim 16 obvious. Challenged Claim 16 does not recite how the shaft

of the nasal airway treatment device is bent. (Ex-1001 at claim 16.) Rather, Challenged Claim 16 recites when the shaft is bent (*i.e.*, “before contacting the treatment element with the nasal mucosa”). (*Id.*) While Petitioners argue that there were a “number of well-known mechanisms for forming bends in catheter shafts,” Petitioners do not explain what these unidentified techniques were or whether any of them involved bending a catheter shaft before contacting a nasal mucosa. (Petition at 70-71.) Petitioners also do not provide any reason why a POSITA would have been motivated to use any of these unidentified techniques with Edwards-535’s device. (*Id.*)

B. Ground 2: Petitioners Have Failed To Show That Edwards-535 In View Of Kong, Stern, And Edwards-886 Renders Dependent Challenged Claim 4 Obvious.

105. Petitioners have failed to show that Edwards-535 in view of Kong, Stern, and Edwards-886 renders dependent Challenged Claim 4 obvious in view of its dependency on Challenged Claim 1.

C. Ground 3: Petitioners Have Failed To Show That Edwards-535 In View Of Liang And Stern Renders Challenged Claims 1-3, 6-12, And 16 Obvious.

1. Petitioners Have Failed To Show That Edwards-535 In View Of Liang And Stern Renders Challenged Claim 1 Obvious.

106. Petitioners’ Ground III analysis of the limitations “wherein the treatment element comprises two rows of bipolar electrode pairs” and “applying

radiofrequency energy with the bipolar electrode pairs” relies on Petitioners’ Ground I analysis. (Petition at 79-81; Ex-1002-DelGaudio, ¶¶ 164-169.) For the same reasons discussed above in Ground I, Petitioners have failed to show that Edwards-535 in view of Liang and Stern teaches the claimed “wherein the treatment element comprises two rows of bipolar electrode pairs” and “applying radiofrequency energy with the bipolar electrode pairs” in Ground III.

107. Petitioners’ Ground III analysis for the motivation to combine Edwards-535 with Stern’s electrode arrangement also relies on Petitioners’ Ground I analysis. (Petition at 79-80; Ex-1002-DelGaudio, ¶ 166.) To the extent Petitioners’ Ground III analysis adds anything to Petitioners’ Ground I analysis, Petitioners merely assert that using two rows of bipolar electrode pairs would have been “useful” to avoid perforating the nasal septum. (*Id.*)

108. However, as it relates to avoiding nasal septum perforation, Stern’s electrode arrangement is not in and of itself superior to any other electrode arrangement, including the single row arrangement already disclosed in Edwards-535. Regardless of the electrode configuration, approaches that may be taken to reduce the risk of perforating the nasal septum include, for example, placing a piece of insulative material over the nasal septum, controlling the intensity of the applied energy, and/or controlling the amount of time the energy is applied.

109. Indeed, Edwards-535 already discloses “an insulator” designed to ensure that ablative energy is delivered only to the selected portion of the nasal concha while insulating other nasal tissues from the ablative energy. (Ex-1010-Edwards-535 at FIG. 3D, 3:7-17, 3:56-57, 4:3-5, 6:46-58, 8:34-46.) A POSITA would have had no reason to look beyond Edwards-535’s teachings to address any potential issue of nasal septum perforation.

110. Accordingly, and for the same reasons discussed above in Ground I, Petitioners have not shown in Ground III that a POSITA would have been motivated to combine Edwards-535 with Stern’s electrode arrangement.

2. Petitioners Have Failed To Show That Edwards-535 In View Of Liang And Stern Renders Dependent Challenged Claims 2-3, 6-12, And 16 Obvious.

111. Petitioners have failed to show that Edwards-535 in view of Liang and Stern renders dependent Challenged Claims 2-3, 6-12, and 16 obvious in view of their dependency on Challenged Claim 1.

112. Petitioners have failed to show that Edwards-535 in view of Liang and Stern renders dependent Challenged Claims 11 and 16 obvious for the reasons discussed below.

3. Petitioners Have Failed To Show That Edwards-535 In View Of Liang And Stern Renders Obvious Challenged Claim 11: “The method of claim 1, further comprising, before removing the treatment element from the nasal airway: repositioning the treatment element to contact a different portion of nasal mucosa; and applying radiofrequency energy with the bipolar electrode pairs through the different portion of nasal mucosa to a different portion of target tissue for the amount of time to heat the different portion of target tissue.”

113. Challenged Claim 11 recites, among other things, “before removing the treatment element from the nasal airway: repositioning the treatment element to contact a different portion of nasal mucosa; and applying radiofrequency energy with the bipolar electrode pairs through the different portion of nasal mucosa to a different portion of target tissue.” (Ex-1001 at claim 11.)

114. Petitioners argue that Edwards-535 in view of Liang discloses repositioning the treatment element to contact a different portion of nasal mucosa before removing the treatment element from the nasal airway and applying radiofrequency energy with the bipolar electrode pairs through the different portion of nasal mucosa. (Petition at 87-89; Ex-1002-DelGaudio, ¶¶ 186-187.)

115. I disagree with Petitioners that Edwards-535 in view of Liang discloses Challenged Claim 11. Neither Edwards-535 nor Liang, alone or in combination, discloses before removing the treatment element from the nasal airway repositioning the treatment element to contact a different portion of nasal

mucosa and applying radiofrequency energy with bipolar electrode pairs through the different portion of nasal mucosa.

116. First, neither Edwards-535 nor Liang discloses “bipolar electrode pairs.” In fact, Liang discloses a monopolar device. (Ex-1056-Liang at 341 (disclosing that a reference electrode, which is used in monopolar devices, is “connected to the lower part of the patient’s chin”).) Thus, Edwards-535 in view of Liang does not disclose “applying radiofrequency energy with [] bipolar electrode pairs.”

117. Second, neither Edwards-535 nor Liang discloses applying radiofrequency energy to a different portion of nasal mucosa before removing the treatment element from the nasal airway.

118. As discussed above in Ground I, Edwards-535 does not disclose applying energy to multiple portions or sections of the nasal concha before removing the device from the nasal airway.

119. Liang also does not disclose applying energy to multiple portions of nasal mucosa before removing the device from the nasal airway. Liang at most discloses that “the emitter was used to perform thermal coagulation treatment on the bilateral nasal ridge and the corresponding nasal septum mucosa.” (Ex-1056-Liang at 341.) Liang does not specify whether the treatment device was removed from the nasal airway between treatments. (*Id.*)

120. Third, even if Edwards-535 in view of Liang disclosed “bipolar electrode pairs” and applying radiofrequency energy to a different portion of nasal mucosa before removing the treatment element from the nasal airway (it does not), Petitioners have not shown that Edwards-535 in view of Liang discloses applying radiofrequency energy to a different portion of nasal mucosa with “bipolar electrode pairs [plural].” (Petition at 87-89; Ex-1002-DelGaudio, ¶¶ 186-187.) Rather, Petitioners merely assert that Edwards-535 in view of Liang discloses “apply[ing] RF energy” to different locations of the turbinate. (Petition at 87-88; Ex-1002-DelGaudio, ¶¶ 186-187.)

121. Fourth, Petitioners’ argument that it would have been obvious to move Edwards-535’s to different locations before removing the device and to apply RF energy at each of these locations is unsupported. Petitioners fail to provide any reason why it allegedly would have been obvious to move Edwards-535’s to different locations before removing the device and to apply RF energy at each of these locations. (Petition at 87-89; Ex-1002-DelGaudio, ¶¶ 186-187.) As discussed above, nothing in Edwards-535 or Liang supports Petitioners’ unsupported argument.

4. Petitioners Have Failed To Show That Edwards-535 In View Of Liang And Stern Renders Obvious Challenged Claim 16: “The method of claim 1, further comprising bending a shaft of the nasal airway treatment device before contacting the treatment element with the nasal mucosa.”

122. Petitioners’ Ground III analysis of Challenged Claims 16 relies on Petitioners’ Ground I analysis of Challenged Claim 16. (Petition at 90.) For the same reasons discussed above in Ground I, Petitioners have not shown that Edwards-535 in view of Liang and Stern renders Challenged Claim 16 obvious in Ground III.

D. Ground 4: Petitioners Have Failed To Show That Edwards-535 In View Of Liang, Stern, And Edwards-886 Renders Dependent Challenged Claim 4 Obvious.

123. Petitioners have failed to show that Edwards-535 in view of Liang, Stern, and Edwards-886 renders dependent Challenged Claim 4 obvious in view of its dependency on Challenged Claim 1.

X. CONCLUSIONS

- The Challenged Claims of the ’271 patent are not obvious in light of the disclosures of the asserted prior art references.
- The Challenged Claims of the ’271 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