

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.

Petitioners,

v.

AERIN MEDICAL INC.,
Patent Owner.

Case No. IPR2024-00277

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

REPLY DECLARATION OF DR. JOHN DELGAUDIO

NEURENT 1083
NEURENT v. AERIN
IPR2024-00277

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I, John DelGaudio, declare as follows:

I. INTRODUCTION

1. I submitted a prior Declaration in this matter, which I understand was filed as Exhibit 1002 on January 18, 2024. My background and qualifications remain as stated in paragraphs 1-11 and Appendix A of my first Declaration (Ex. 1002). My understanding of the relevant legal principles stated in paragraphs 13-22 of my first Declaration, which I applied in my first Declaration and continue to apply here.

2. Since preparing my first Declaration, I have reviewed Patent Owner's Preliminary Response ("POPR"), the Board's Institution Decision ("ID"), the Patent Owner's Response ("POR"), and the Bikson Declaration (Ex. 2001). I have also reviewed and considered the documents cited by Dr. Bikson in his declaration, and the transcript of Dr. Bikson's deposition held on January 7, 2025 ("Bikson Deposition") (Ex.1084).

3. I confirm that the opinions in my first Declaration (Ex. 1002) remain my opinions and none of Dr. Bikson's opinions have persuaded me otherwise.

II. MY QUALIFICATIONS AS A PERSON OF ORDINARY SKILL IN THE ART

4. My previous declaration includes my understanding that when considering the claims of the '271 patent and the prior art, I must do so based on

the perspective of one of ordinary skill in the art at the relevant effective filing date. Ex.1002, ¶27. I also included my understanding of the factors that are considered in determining the person of ordinary skill in the art. Ex.1002, ¶28.

5. As a practicing otolaryngologist of over thirty years, I have decades of experience carrying out clinical procedures in the nose that are closely related to the claimed method of the '271 patent. As Dr. Bikson agrees, physicians like myself—and not engineers like Dr. Bikson—would be the ones to perform the method steps in the '271 patent claims. Ex.1084-Bikson-Tr., 82:13-84:5. To carry out those procedures, I have used dozens if not hundreds of medical devices that are inserted into the nose, including energy delivery devices like those described in the '271 patent.

6. However, Dr. Bikson proposes the following definition of a person of ordinary skill in the art which, unlike my definition, requires a person of ordinary skill in the art to have three years of design and development experience irrespective of any clinical use or testing experience.

My Definition of a POSITA (Ex.1002, ¶29)	Dr. Bikson's Definition of a POSITA (Ex.2001-Bikson-Decl., ¶41)
(1) a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline and	(1) a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline and

(2) at least three years of experience in the clinical use, design, development, and/or testing of medical devices, including medical devices that deliver energy to tissue. A higher level of education may compensate for less work experience, and vice versa	(2) at least three years of experience in the ~~clinical use~~, design <u>and</u>[[,]] development, ~~and/or testing~~ of medical devices, including medical devices that deliver energy to tissue.
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7. I disagree that three years of development and design experience is necessary to qualify as a person of ordinary skill in the art, as Dr. Bikson’s definition requires. Nevertheless, I qualify as a person of ordinary skill in the art under both definitions.

A. I am a person of ordinary skill in the art under both my and Dr. Bikson’s definitions

8. I am a person of ordinary skill in the art under my definition because I have at least three years of experience using and testing medical devices. Dr. Bikson does not appear to disagree with me that I qualify as a person of ordinary skill in the art under my definition. I am also a person of ordinary skill in the art under Dr. Bikson’s definition because I have at least three years of experience in the design and development of medical devices.

9. I have extensive experience developing and designing medical devices throughout my decades-long career. For example, I routinely consult with and

deliver feedback to device manufacturers to improve the features and performance of their devices. As one illustrative example, I helped to develop and improve an image-guided computer navigation system used for tracking the tip of an instrument inside a patient during sinus surgery. This system uses images of the patient's nasal cavity and other parts of the head. I understand that Dr. Bikson believes imaging of the nasal cavity is relevant to his qualifications as a person of ordinary skill in the art. Ex.2001-Bikson-Decl., ¶5. As part of my contributions, I travelled to the device manufacturer's headquarters and met with their engineers. Within their facilities, I ran tests of the tool and provided feedback to the engineers, and together we worked to identify and resolve the technical issues that we were facing. Through this process, we determined that the system's calibration was tailored for neurosurgical procedures, resulting in less accurate performance when the system was applied to otolaryngology. Once the issue was identified, I worked in collaboration with the manufacturer to modify the software and resolve the issue.

10. In addition to my experience collaborating with device manufacturers, I have also worked with teams to develop and design our own medical devices. As an illustrative example, I was a member of a team that developed a disposable microdebrider with the goal of designing a device that was cheaper than other

products on the market at the time. A microdebrider is a medical device with a powered blade and suction, which delivers mechanical energy using a blade to a patient to cut and remove tissue. As a member of the development and design team, I was involved throughout the product development process, including designing the blades, improving the handpiece ergonomics, selecting the material parameters, and testing the device on cadavers. Through these examples and other similar experiences throughout my career, I have acquired at least three years of experience in the design and development of medical devices, including medical devices that deliver energy to tissue.

11. In my deposition, I was asked about whether I had experience designing specific examples of energy-delivery devices, such as RF, microwave, and ultrasound. Ex. 2007 at 94:12-16, 95:1-16, 99:5-15. I understand that the Patent Owner relies on my responses to suggest that I have no experience at all in the design or development of medical devices. POR, 54. As I explained above, this is not the case. Through my collaboration with vendors and my experience implementing medical devices, including those that deliver energy to tissue, I qualify as a person of ordinary skill in the art even under Dr. Bikson's definition.

12. The fact that I am a person of ordinary skill in the art is not inconsistent with the fact that, in the course of preparing my first Declaration, I had

a discussion with Dr. Martin, an engineer with experience designing the underlying circuitry used to implement energy-delivery devices. Ex.1002, ¶¶94, 124, 127, 130, 151, 166, 183, 185, 193. Based on my own knowledge and experience, I was qualified to and did offer opinions on the teachings of Stern regarding configurations of bipolar electrodes and their applicability to the challenged claims. However, Stern goes further than the '271 patent in disclosing implementation details about the circuitry used to operate the bipolar electrodes, the physics of delivering energy to tissue, among other things. For these aspects of Stern that go beyond what the '271 patent itself teaches into how the energy-delivery devices work, my discussion with Dr. Martin helped support and confirm my understanding of the prior art teachings. It also helped support and confirm my opinion that a person of ordinary skill in the art would have been motivated to combine Edwards-'535 and Stern with a reasonable expectation of success. My discussion with Dr. Martin does not undermine my own qualifications and ability to opine on the patentability of the challenged claims.

B. Dr. Bikson's definition of a person of ordinary skill in the art is incorrect

13. Setting aside that I am a person of ordinary skill in the art under Dr. Bikson's definition, I disagree that a person of ordinary skill in the art must have

experience developing and designing medical devices (irrespective of experience using or testing those devices). The '271 patent describes a method of carrying out a clinical procedure using an energy delivery device within the nose. The patent's description of the device itself is limited to external, user-facing features that are well-understood by clinicians who use the device, such as the device's external configuration of electrodes that contact the nasal mucosa. To the extent a clinician may lack in-depth knowledge of the implementation details of the devices (e.g., the circuitry for operating the electrodes and the physics of how the energy from the electrodes interacts with tissue), those details are neither described nor claimed in the '271 patent.

14. Dr. Bikson appears to opine that a clinician who merely uses a medical device lacks any relevant knowledge of how the device works. Ex.2001-Bikson-Decl., ¶40. I disagree. An important part of a clinician's role is to understand the devices and instruments they use to treat patients. Before clinicians use devices on patients, they must be thoroughly trained and prepared to use the devices safely and effectively, and this process goes far beyond rote memorization of the instruction manual. For example, the process for learning to use a new device can include formal and informal training, discussions and meetings with the device manufacturer, reading instructions for use, practicing on cadavers, and

analyzing clinical data. Depending on the complexity of the device, the process can take hours, days, weeks, or more, and in any event no less than the time necessary to be fully in command of the device's capabilities when treating patients. The consequences of failing to meet this standard include, above all, the risk of endangering patients, but also reputational risk, risk of medical malpractice, loss of board certification, and potential criminal liability. I have reviewed Dr. Bikson's testimony and note that he agreed documents like Instructions for Use are intended to be used by clinicians who are using a device, and that such Instructions for Use can include technical information about a given product, including whether it is delivering bipolar energy and the location of electrodes. Ex.1084-Bikson-Tr., 91:6-94:8; Ex.1085-Bikson-Tr.-Ex.-A.

15. Clinicians gain experience in how medical devices work not only by using the devices according to their approved indications, but also by performing "off-label" procedures using the medical devices. Off-label usage is a routine part of many physicians' practices. When performing off-label procedures, a clinician gains an even deeper understanding of the device to evaluate the safety and effectiveness of treating new indications with the device. For example, off-label use of bipolar energy delivery devices is more common than for monopolar energy delivery devices due to a clinician's understanding that monopolar energy delivery

causes tissue to reach higher temperatures and undergoes greater dispersion (resulting in less control) than bipolar energy delivery.

16. None of Dr. Bikson's opinions raise any issue that would fall outside of the expertise of a person of ordinary skill in the art as I have defined it.

17. Accordingly, a person of ordinary skill in the art in the field of the '271 patent would have included a clinician with three years of experience in the clinical use of medical devices. Such a person would have acquired sufficient knowledge and skills related not only to the claimed method of treatment, but also to a treatment device with two rows of bipolar electrode pairs, as described and claimed in the '271 patent.

III. IT IS MY OPINION THAT CLAIM 1 IS OBVIOUS

A. Dr. Bikson's opinion that the claim limitations must be performed in the recited order does not change my opinion that the claims are obvious

18. Dr. Bikson opines that "the claimed method steps of Challenged Claim 1 must be performed in the order written." Ex.2001-Bikson-Decl., ¶¶57-61. I also understand that the Patent Owner has proposed construing claim 1 to require the claimed steps to be carried out in order. POR, 15-17. In my first Declaration, I explained that the prior art references disclose the claimed steps in the specific order in which they are claimed.

- First, the treatment element of Edwards-'535 in view of Kong (or Liang) and Stern contacts the mucosa, as recited by limitation 1[a] (Ex.1002, ¶¶83, 164);
- next, radiofrequency energy is applied, as recited by limitation 1[b] (Ex.1002, ¶¶95, 167); and
- finally, the treatment element is removed from the nasal airway, as recited by limitation 1[c] (Ex.1002, ¶¶100, 170).

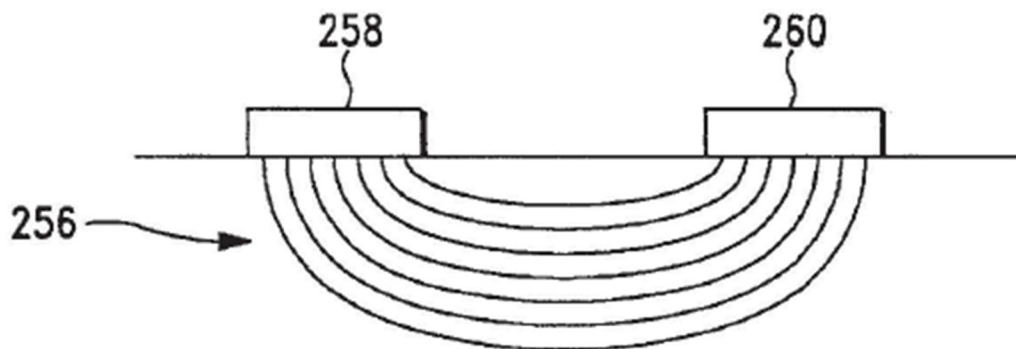
19. Accordingly, if the Board adopts the Patent Owner's construction requiring the steps of claim 1 to be carried out in order, that would not change my opinion that the claims are unpatentable.

B. Stern teaches “bipolar electrode pairs” (limitation 1[a])

20. I have reviewed Dr. Bikson's declaration and deposition transcript. Based on this review, I understand it is his opinion that limitation 1[a] requires bipolar electrode pairs that are active, i.e., delivering energy, “at the same time.” Bikson Tr., 99:21-100:6; Ex.2001-Bikson-Decl., ¶¶62-71. I disagree with his interpretation, but even if his interpretation was correct, that would not change my opinion that Stern discloses “bipolar electrode pairs.” Ex.1002, ¶92.

1. **“Bipolar electrode pairs” do not need to be active “at the same time”**

21. Claim 1 recites a “treatment element [that] comprises two rows of bipolar electrode pairs.” The concept of a bipolar electrode pair was well understood by the claimed priority date of the '271 patent. For example, as shown in Figure 17 of Stern, reproduced below, a bipolar electrode pair has two electrodes. When bipolar energy is applied, the “electric field lines proceed between the two electrodes.” Ex.1033-Stern, 13:11-14.



Ex.1033-Stern, Figure 17. A person of ordinary skill in the art would have further understood the “s” in “bipolar electrode pairs” to simply mean that there are multiple pairs of electrodes like those shown in Figure 17.

22. By contrast, a person of ordinary skill in the art would not have interpreted the term “bipolar electrode pairs” to add a further requirement that the multiple pairs are active or delivering energy “at the same time,” as Dr. Bikson

opines. Medical devices with bipolar electrode pairs were in widespread clinical use before the claimed priority date of the '271 patent. In my experience using such devices, the terminology used to describe the bipolar electrode pairs does not depend on whether the pairs are active or not. For example, when the device is turned off, a clinician would not cease to refer to the electrodes on the device as a “bipolar electrode pair.” Likewise, when there are two devices with bipolar electrode pairs, a clinician would not refer to them as “bipolar electrode pairs” (plural) when they are active at the same time and a “bipolar electrode pair” (singular) when only one pair is active – they would always be “bipolar electrode pairs.”

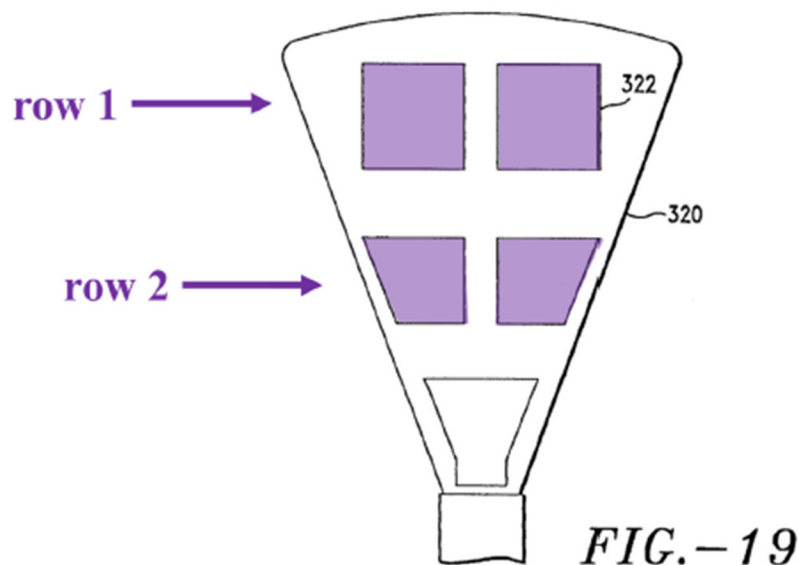
23. The understanding that “bipolar electrode pairs” encompasses pairs that are active, inactive, or combinations of active and inactive pairs is consistent with the '271 patent, which describes bipolar electrode pairs that are activated “separately” and “individually.” Ex.1001-USP'271, 23:64-24:1 (“each pair of electrodes (bipolar) or each electrode (monopolar) may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately”), 24:1-3 (“For example, the needles or needle pairs of Figure 8F may be individually controlled to produce an optimal treatment effect.”). Because the bipolar electrode pairs are activated separately and individually, there will be configurations where some pairs are active and others are not, including

arrangements only one pair is active at a time. Consistent with the understanding of a person of ordinary skill in the art, the '271 patent does not use different terminology for the case where only one bipolar pair is active at a time – the device is still described as having “pairs” (plural).

2. Stern teaches “bipolar electrode pairs” that are active “at the same time”

24. Although I disagree that “bipolar electrode pairs” require pairs that are active “at the same time” for the reasons explained above, Stern teaches bipolar electrode pairs that are active at the same time. For this reason, it my opinion that Stern discloses “bipolar electrode pairs” even under the Dr. Bikson’s interpretation.

25. As I explained in my first Declaration, Stern discloses bipolar electrode pairs that can be arranged in two rows. Ex.1002, ¶92. An exemplary arrangement of the two rows of bipolar pairs is shown in Figure 19, reproduced below using the same annotations from my first Declaration.



Ex.1033-Stern, Figure 19. As I further explained in my first Declaration, Stern teaches that “bipolar RF energy” can be selectively delivered to “chosen pairs” (plural) in the array shown above. Ex.1002, ¶92 (citing Ex.1033-Stern, 2:36-40, 13:1-44). Within the passages that I cited in my first Declaration, Stern further states that “any combination of pairs of electrodes [shown in Figure 15] may be utilized together.” Ex.1033-Stern, 13:39-42. A “combination” of pairs that is “utilized together” would be readily understood to disclose pairs that are active at the same time.

26. I further note that Stern uses the term “pairs” nine separate times to refer to its arrangement of bipolar electrode pairs. Ex.1033-Stern, 2:36-40, 3:38-40, 12:20-22, 12:22-24, 12:29-33, 13:27-31, 13:31-38, 13:39-42, 20:6-9. It would

be illogical for a person of ordinary skill in the art to adopt Dr. Bikson's restrictive meaning of "pairs" in claim 1, but then to find that Stern's express disclosure of "pairs" does not satisfy that meaning. That is, the only support Dr. Bikson offers for his interpretation is the pluralization of the term "pairs," *see* Ex.2001-Bikson-Decl., ¶69, and Stern uses the same plural term, so consistency dictates that a person of ordinary skill in the art would have understood them to refer to the same thing. For this separate reason, a person of ordinary skill in the art would have understood Stern to satisfy the Dr. Bikson's interpretation of "bipolar electrode pairs."

C. Stern teaches "two rows of bipolar electrode pairs" (limitation 1[A])

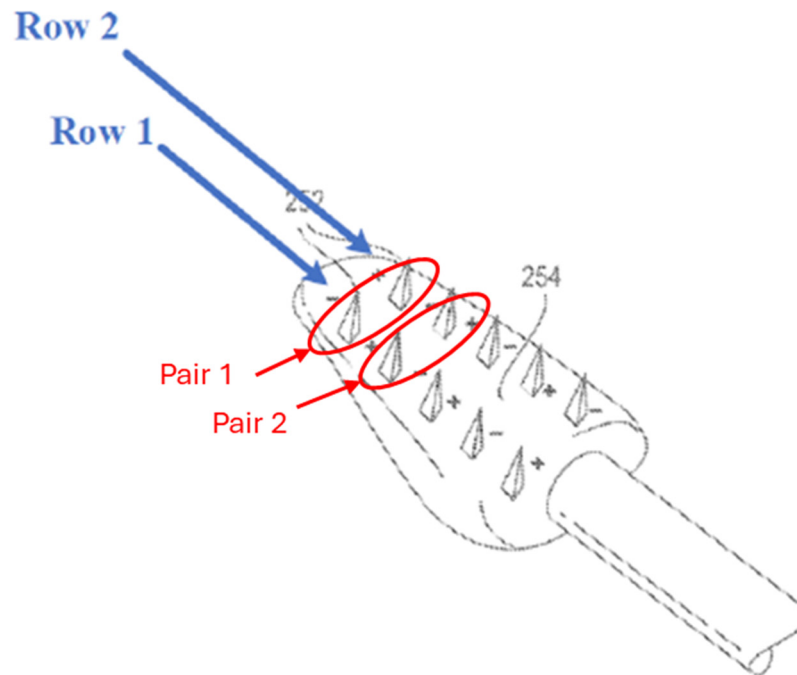
27. I have reviewed Dr. Bikson's declaration and deposition transcript. Based on this review, I understand it is his opinion that limitation 1[A] requires two rows of bipolar electrode pairs to have multiple pairs in each row. Ex.1084-Bikson-Tr., 139:4-140:6; Ex.1086-Bikson-Tr.-Ex.-B; Ex.2001-Bikson-Decl., ¶¶72-79. I again disagree with his interpretation, but even if this interpretation was correct, that would not change my opinion that Stern discloses "two rows of bipolar electrode pairs." Ex.1002, ¶92.

28. As an initial matter, I understand that the Patent Owner states that I “relied entirely on Dr. Martin for this limitation.” POR, 55. That is plainly not the case, as my first Declaration includes extensive independent analysis for this limitation. *See* Ex.1002, ¶¶92-93. As I explained above, I reviewed Dr. Martin’s declaration and spoke with him simply to confirm various implementation details in Stern that go beyond the level of detail the ’271 patent. This limited reliance on Dr. Martin does not diminish my own analysis for this limitation – on the contrary, it bolsters my analysis.

1. “Two rows of bipolar electrode pairs” does not mean the device needs to have multiple pairs in each row

29. Dr. Bikson interprets the plural term “pairs” in the phrase “two rows of bipolar electrode pairs” to require multiple pairs in each row. Ex.2001-Bikson-Decl., ¶¶74-76. However, Dr. Bikson does not appear to consider the alternative interpretation that “pairs” can simply refer to multiple pairs in the two rows, collectively. As I explained in my first Declaration, Stern discloses multiple bipolar electrode pairs in two rows, e.g., Stern’s Figure 19 configured as a two-by-two array with two rows and one pair in each row (for a total of two pairs). Ex.1002, ¶92.

30. My previous declaration includes my understanding that the terms of a claim are to be interpreted in the context of the entire patent, including the patent's specification and its figures. *See* Ex.1002, ¶63. Here, the term “row” appears only twice in the '271 patent, in both instances describing “row[s]” of electrodes where “radio frequency energy travels from one row of electrodes to the other row of electrodes.” Ex.1001-USP271, 8:21-25, Abstract. This description of two rows where pairs are formed between the rows is consistent with Figure 8F, which shows two rows of electrodes (blue) where bipolar pairs (red) are formed between the two rows. Ex.1001-USP271, 23:56-59 (“As opposed to FIG. 8F, where the pairs of electrodes are arranged side-by-side, the embodiment of FIG. 8G arranges the pairs of electrodes along the length of the treatment element.”). As such, the patent does not require that the multiple pairs be arranged within the same row.



Ex.1001-USP'271, Figure 8F (blue annotations are Dr. Bikson's, *see* Ex.2001-Bikson-Decl., ¶77, red annotations are my own).

31. In the above arrangements, where bipolar pairs are formed between two rows of electrodes, there are no pairs within a single row because each row only contains one electrode from each pair—i.e., only half of each pair lies within a given row. Dr. Bikson's interpretation, which requires multiple bipolar pairs within each row, would not cover such arrangements where the pairs do not lie within rows, but between them. Conversely, an interpretation that simply requires multiple pairs in the two rows collectively does cover these arrangements – there

are multiple pairs (e.g., Pair 1 and Pair 2, red) and they are arranged in two rows (e.g., Row 1 and Row 2, blue).

32. At his deposition, Dr. Martin was asked a series of questions about a “single row of bipolar electrode pairs.” Ex.2003-Martin-Tr., 285:10-11 (“So please draw for me a single row of bipolar electrode pairs”), 285:18-19, 285:21-22, 287:3-5 (“So you agree that row 1 of what you drew depicts a single row of bipolar electrode pairs; correct?”), 287:8-10, 287:13-15. Based on my reading of the transcript, Dr. Bikson misrepresents Dr. Martin’s responses to suggest that Dr. Martin agrees that “two rows of bipolar electrode pairs” requires multiple pairs in each row. Ex.2001-Bikson-Decl., ¶78. However, the phrase that Dr. Martin was asked about – “single row of bipolar electrode pairs” – is not claimed and presents different issues than the phrase “two rows of bipolar electrode pairs” in terms of what the plural term “pairs” can modify. Namely, when there is only a single row, any pairs necessarily fall within that row, so to have multiple “pairs” requires multiple pairs in a row. But when there are two rows, as claimed, the pairs no longer need to be within a row. For example, in the patent embodiments described above, the pairs are arranged between the two rows, not within them. Accordingly, because Dr. Martin was responding to questions about a “single row” rather than

“two rows,” I disagree with Dr. Bikson’s opinion that the testimony he cites supports his interpretation of “two rows of bipolar electrode pairs.”

33. Dr. Bikson also opines that Petitioners’ interpretation of the claims allows for random arrangements because you could “simply draw an imaginary line between two electrodes and label the imaginary line a row.” Ex.2001-Bikson-Decl., ¶78. I disagree with this opinion. As explained in my previous declaration, Stern shows two ordered rows of bipolar electrode pairs at least by showing a 2x2 array where the rows are parallel to one another.

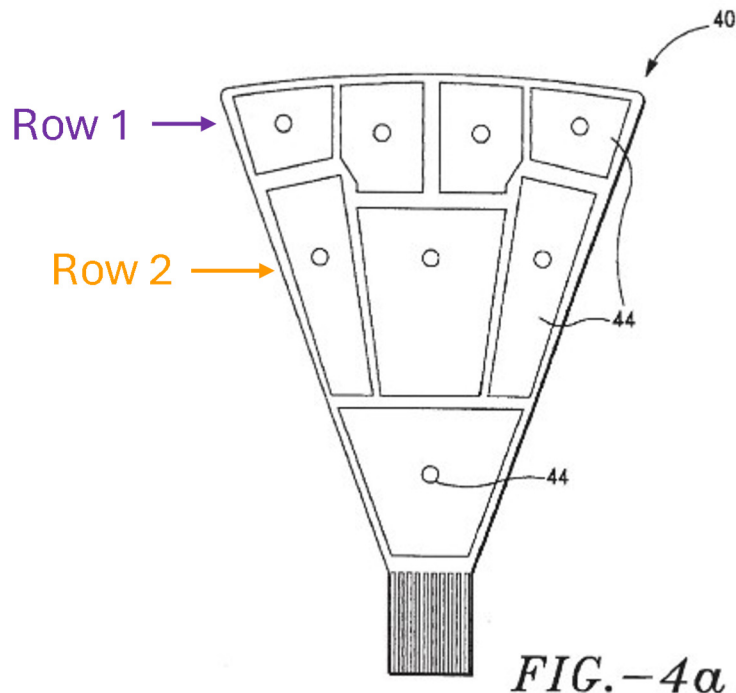
34. Dr. Bikson also opines that “two rows of electrodes” must have different requirements than “two rows of electrode pairs.” Ex.2001-Bikson-Decl., ¶79. “Two rows of electrodes” could exist where there are two rows of monopolar electrodes that are not paired together. “Two rows of electrode pairs” connotes that you have two rows of electrodes where there are electrode pairs. Therefore, this distinction further supports my opinion that “two rows of electrode pairs” does not require multiple pairs in each row.

2. Stern discloses “two rows of bipolar electrode pairs” that have multiple pairs in each row

35. Although I disagree that “two rows of bipolar electrode pairs” requires multiple pairs in each row for the reasons explained above, Stern teaches two rows

of bipolar electrode pairs with multiple pairs in each row. For this reason, it is my opinion that Stern discloses “two rows of bipolar electrode pairs” even under Dr. Bikson’s interpretation.

36. As I explained in my first Declaration, Stern discloses various arrangements of electrodes on the surface of a bladder along with techniques for selectively energizing certain electrode pairs in the array. Ex.1002, ¶92 (citing Ex.1033-Stern, 2:36-40). One such arrangement is shown in Stern’s Figure 4a, which shows an ordered arrangement of electrodes that can be configured as a first row with four electrodes (Row 1, purple) and a second row with three electrodes (Row 2, orange).



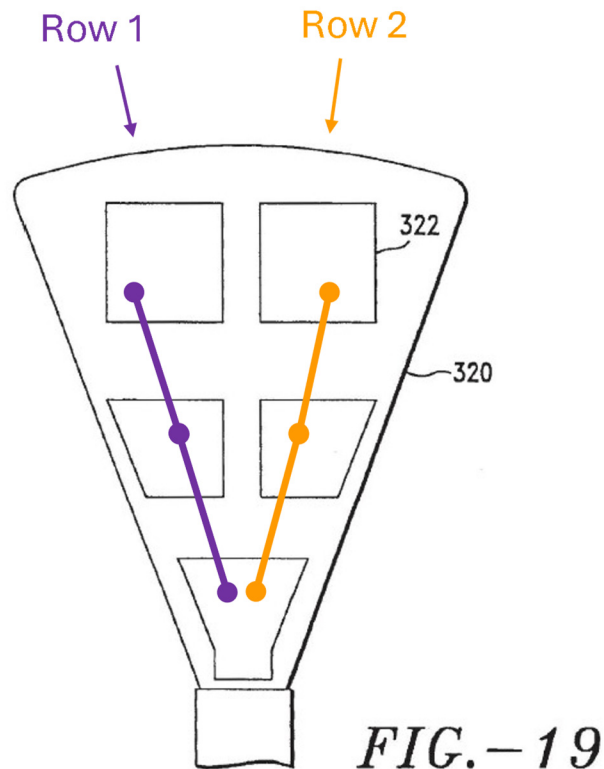
Ex.1033-Stern, Figure 4a (annotated).

37. Stern discloses operating the electrodes in Figure 4a “utilizing a bipolar construction.” Ex.1033-Stern 12:7-25 (explaining that Figure 5 can be operated using a bipolar construction); *see also id.* 8:66-9:2 (explaining that Figure 5 is the circuitry used to control Figure 4a). Stern discloses the details for how to implement bipolar operation by referring to Figure 15, which illustrates how to configure a “plurality of electrodes” for “either monopolar or bipolar operation.” Ex.1033-Stern, 5:48-50, 12:49-52, 13:39-43. Although Figure 15 illustrates configurable bipolar operation using a 2x2 array of electrodes, a person of ordinary skill in the art would have readily applied these teachings to the ordered arrangement in Figure 4a. The only difference is the number of electrodes in each row. I note the '271 patent does not describe how to implement bipolar operation at all, which further suggests that it would have been trivial to adapt Figure 15 to match the number of electrodes shown in Figure 4a.

38. In my first Declaration, I explained that a person of ordinary skill in the art would have been motivated to combine the teachings of Stern and Edwards-'535. Ex.1002, ¶¶93-94. I note that my analysis applies equally to the various arrangements of electrodes in Stern, including Figure 4a. For example, the benefits of even heating and precise energy delivery control would be present as much as, if

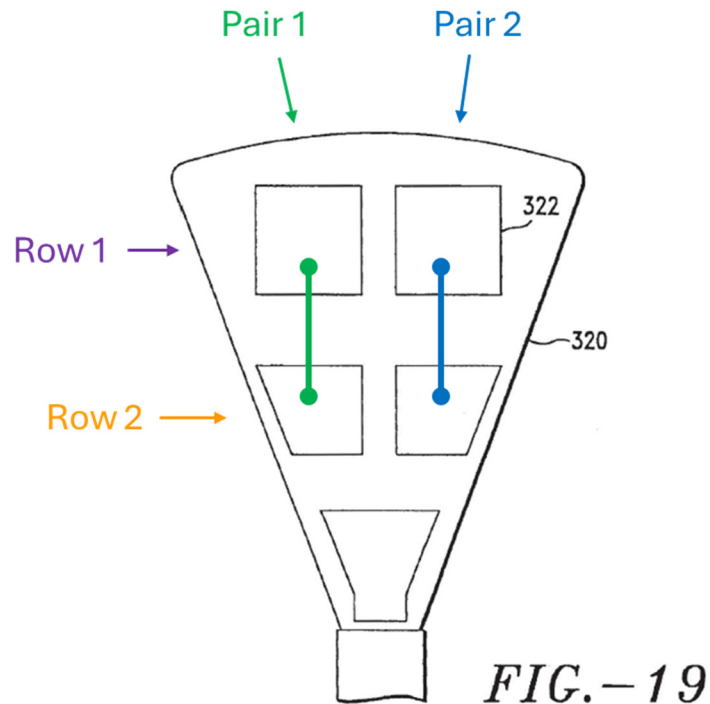
not more, when using the arrangement of Figure 4a compared to Figure 19 given the greater number of controllable electrodes in Figure 4a.

39. In addition to Figure 4a, Stern discloses various other arrangements of electrodes that satisfy Dr. Bikson's interpretation. For example, in configurations where the fifth electrode at the bottom of Figure 19 is activated, there is a third electrode for each of the rows, such that the rows can be configured to contain two pairs within each row.



Ex.1033-Stern, Figure 19 (annotated).

40. Furthermore, to the extent that Dr. Bikson opines that forming bipolar pairs between two rows (such that each row contains a single electrode from each pair) satisfies its interpretation, Stern discloses multiple pairs within each row under this interpretation as well. For example, as shown below, each row can be configured to include one electrode from a first pair and one electrode from a second pair.



Ex.1033-Stern, Figure 19 (annotated).

D. Stern teaches “applying radiofrequency energy with the bipolar electrode pairs” (limitation 1[B])

41. I have reviewed Dr. Bikson’s declaration and deposition transcript. Based on this review, I understand it is his opinion that limitation 1[B] requires bipolar electrode pairs that apply radiofrequency energy at the same time. Ex.2001-Bikson-Decl., ¶¶80-83. I again disagree with his interpretation, but even if this interpretation was correct, that would not change my opinion that Stern discloses “applying radiofrequency energy with the bipolar electrode pairs.” Ex.1002, ¶¶95-96.

1. “Bipolar electrode pairs” do not need to apply radiofrequency energy at the same time

42. Dr. Bikson’s opinions for the “bipolar electrode pairs” term of limitation 1[B] are similar to those I addressed previously for the “bipolar electrode pairs” term of limitation 1[A]. Ex.2001-Bikson-Decl., ¶¶80-83; *see* Section II.B. Specifically, Dr. Bikson opines that applying energy with “bipolar electrode pairs” requires applying energy through multiple bipolar pairs at the same time. Accordingly, for similar reasons stated above and incorporated herein, I disagree with Dr. Bikson’s opinions. For example, just as claim 1 does not require bipolar electrode pairs to be active “at the same time,” the claim also does not require bipolar pairs to be active at the same time when applying radiofrequency energy. Rather,

the claim encompasses arrangements where any one or more of the pairs is active at a time. As I explained above, Dr. Bikson's interpretation is inconsistent with the specification, which describes applying energy using independently controlled bipolar electrode pairs and does not require using multiple electrode pairs at the same time. *See, supra*, Section II.B; Ex.1001-USP271, 23:40-43, 23:64-24:3.

2. Stern discloses “bipolar electrode pairs” that apply radiofrequency energy at the same time

43. As I explained above in Section II.B and incorporate herein, Stern teaches activating multiple bipolar electrode pairs “at the same time.” Because the pairs can be active at the same time, they apply radiofrequency energy to the tissue at the same time.

E. A person of ordinary skill in the art would have been motivated to combine Edwards-'535 and Stern

44. Dr. Bikson opines that a person of ordinary skill in the art would not have been motivated to modify Edwards-'535's teaching of a single row bipolar electrode pairs in view of Stern's teaching of two rows of bipolar electrode pairs. Ex.2001-Bikson-Decl., ¶¶84-89. I note, however, that he appears to disagree with only a subset of the multiple reasons that I identified in my first Declaration for why a person of ordinary skill in the art would have been motivated to arrange Edwards-'535's electrodes into two rows in view of Stern. Ex. 1002, ¶¶93-94. He also does

not address many of the reasons identified in Dr. Martin's declaration, *see* Ex.1004-Martin-Decl., ¶¶75-97, which I reviewed in the course of preparing my first Declaration. The reasons that I (and Dr. Martin) identified and that Dr. Bikson has not addressed continue to support my opinion that a person of ordinary skill in the art would have been motivated to arrange Edwards-'535's electrodes into two rows in view of Stern. Moreover, for the limited subset of reasons that Dr. Bikson does address, I disagree with his analysis.

45. First, Dr. Bikson appears to disagree with Dr. Martin's explanation that by referring to Baker – a reference that describes a non-nasal ablation device with embodiments similar to those of Stern – Edwards-'535 establishes that a person of ordinary skill in the art would have been motivated to look to non-nasal ablation devices like those described in Stern to improve Edwards-'535's nasal ablation device. Ex.1004-Martin-Decl., ¶89; Ex.2001-Bikson-Decl., ¶¶85-87. However, the focus of Dr. Bikson's disagreement appears to be whether Edwards-'535 incorporates Baker by reference “in its entirety.” Ex.2001-Bikson-Decl., ¶87. I understand that whether a patent incorporates another patent by reference “in its entirety” versus some smaller portion of the cited reference is a legal question. Whether or not the entire Baker reference was incorporated by reference into Edwards-'535, because Edwards-'535 (a reference describing a nasal ablation

device) points a person of ordinary skill in the art to Baker (a reference describing a non-nasal ablation device with attributes similar to Stern), it would have motivated a person of ordinary skill in the art to use the teachings like those found in Baker in Edwards-'535. *See* Ex.1004-Martin-Decl., ¶89.

46. Second, Dr. Bikson appears to disagree with Dr. Martin's explanation that Stern's electrode arrangement provides "simplified spatial resolution of the applied energy" such that a person of ordinary skill in the art would have been motivated to combine its teachings with those of Edwards-'535. Ex.2001-Bikson-Decl., ¶88; Ex.1004-Martin-Decl., ¶95. According to Dr. Bikson, Stern's arrangement of two rows of bipolar electrode pairs is just one possible "ordered arrangement[]" out of many possibilities. Ex.2001-Bikson-Decl., ¶88. I disagree. My first Declaration explains why a person of ordinary skill in the art would have chosen to apply Stern's teaching of two rows of bipolar electrode pairs to the teachings of Edwards-'535, Ex.1002, ¶¶93-94, and my discussion with Dr. Martin and my review of his declaration confirmed those reasons. For example, Dr. Martin explained that Stern's arrangement of two rows of bipolar electrode pairs provides even heating and precise energy control, and I explained how this benefit would have contributed to a person of ordinary skill in the art's motivation to combine the references. Ex.1002, ¶94. Dr. Bikson does not appear to disagree that Stern's

technique using two rows of bipolar electrode pairs provides even heating and precise energy control, and instead simply opines that there are other possible arrangements of the electrodes that could potentially achieve similar benefits.

47. However, the existence of other potential arrangements (e.g., a single row of electrodes) would not have discouraged a person of ordinary skill in the art from choosing Stern's embodiment that uses two rows of electrode pairs. In general, a person of ordinary skill in the art would not have understood a medical device to have a single optimal configuration that overrides the benefits of other configurations. Medical devices are often designed to be used on a range of anatomical structures, and patient anatomy and physiology differs from one patient to the next, so what is optimal for one patient may be different for another patient. For example, when treating a smaller portion of a turbinate (or a turbinate of a smaller patient), one row of electrodes may be sufficient to provide the desired even heating and precise control, but when treating a larger portion or a larger patient, two or more rows may be preferred to give control over a larger area of the anatomy. For this reason, medical devices—such as bipolar forceps—often come in different variants that can be selected for a given patient. The '271 patent itself discloses over 30 variants of its energy delivery device, including arrangements with one row (Figure 8G) and two rows (Figure 8F) of electrodes, and does not suggest that a

person of ordinary skill in the art would have needed to pick just one variant as being optimal across all use cases. Ex.1001-USP271, Figures 4B, 4C, 4D, 5A, 5B, 8F, 8G, 9A, 9B, 10A, 11A, 11B, 12A, 12B, 13A, 13C, 13D, 14A, 15B, 16, 17A, 18, 19A, 20A, 21A, 22A, 22B, 22C, 22F, 23A, 23D, 25A, 25B, 26, 27, 29, and 31A.

48. Finally, Dr. Bikson appears to disagree with Dr. Martin's explanation that combining the teachings of Edwards-'535 and Stern could have been accomplished by mere "duplication of parts." Ex.2001-Bikson-Decl., ¶89. However, Dr. Bikson only addresses Edwards-'535's ring electrode embodiments in providing this opinion, contending that the ring electrodes cannot be modified to form two rows of electrode pairs (as taught by Edwards-'535) by duplication of parts alone. *Id.* Dr. Bikson does not address Edwards-'535's surface electrode embodiments, which Dr. Martin explained can be modified to form two rows of electrode pairs by a duplication of parts. Ex.1004-Martin-Decl., ¶87 (citing Ex.1010-Edwards-'535, 8:19-33 (covering both ring electrode and surface electrode embodiments)). Moreover, even for the ring electrode embodiments, Dr. Martin identified other reasons beyond duplication of parts that a POSITA would have had a reasonable expectation of success in combining Edwards-'535 with Stern, which I reviewed in the course of preparing my first Declaration. Ex.1004-Martin-Decl.,

¶¶84-88, 92-93, 96-97. Dr. Bikson does not address those other reasons supporting a reasonable expectation of success.

IV. IT IS MY OPINION THAT DEPENDENT CLAIM 11 IS OBVIOUS

49. Claim 11 recites, in part, “before removing the treatment element from the nasal airway: repositioning the treatment element to contact a different portion of nasal mucosa.” Dr. Bikson appears to disagree that a person of ordinary skill in the art would have understood disclosures that teach using treatment elements to apply energy to different portions of the nasal mucosa, as taught by multiple references (*see* Ex.1010-Edwards-’535, FIGs.3D, 3B; Ex.1040-Kong, 214, Ex.1056-Liang, 341), to mean that the treatment element is repositioned without first removing treatment element from the nasal airway. Ex.2001-Bikson-Decl., ¶¶92-100. I previously explained that a person of ordinary skill in the art would have understood that the treatment element is repositioned before removing it from the nasal airway, as this is a well-understood sequence for a clinical procedure and is consistent with how similar procedures in the nose have been carried out since long before the ’271 patent was filed. Ex.1002-Decl., ¶133.

50. The background knowledge of a person of ordinary skill in the art confirms that a such a person would have understood that the references’ teachings to mean that the treatment element is repositioned without first removing treatment

element from the nasal airway. One of the general objectives when carrying out procedures in the nose is to minimize insertion and removal of the treatment element. Doing so minimizes patient discomfort and trauma to tissue, and maximizes efficiency of the procedure. Therefore, procedures that involve contacting multiple areas within the nose are designed to contact each of the target areas before removing the treatment element from the nose. That is, the treatment element is generally only removed at the end of the procedure, unless unplanned circumstances arise that may require earlier removal of the treatment element (e.g., patient reports discomfort, excessive bleeding occurs, or the like). I routinely perform procedures in this way in my practice as an otolaryngologist—and have since the late 1990s. I would not expect Dr. Bikson to have knowledge of these nuances of clinical practice, given that he has no clinical experience and has not applied energy into a patient's body, let alone to nasal mucosa of a nasal airway. Ex.1084-Bikson-Tr., 24:13-22, 46:2-16, 82:13-84:5. These are the types of “things that a doctor knows that [he does] not know.” *Id.*, 46:15-16.

51. To illustrate how this works in a practical example, the following is a description of a typical procedure carried out using Somnoplasty, a device that delivers RF energy to the turbinates in a manner similar to the claimed method of the '271 patent. I have been using the Somnoplasty device since the late 1990s.

First, I apply anesthesia. Then, I advance the treatment element into the nose and insert a needle into a first entry point of the inferior turbinate. I apply energy for about 3-4 seconds, advance the needle about one centimeter further into the turbinate, and apply energy for another 3-4 seconds. Next, I remove the needle from the first entry point (but not from the nose), reposition the treatment element, insert the needle into a second entry point of the inferior turbinate, and apply energy at two more locations. I repeat this process until I have inserted the needle into three entry points and created six lesions (two per entry point). All of these steps are performed before removing the treatment element from the nose. This procedure is also described in prior art articles. *See* Ex.1092-Cavaliere, 257-258 (“under microscopic vision, the active 10-mm portion of the electrode and at least 2 mm of the insulation were inserted submucosally, and the energy was delivered into three different sites of each turbinate (anterior, middle, and posterior portion).”). I use this approach (as would any person of ordinary skill in the art) because it is a logical, safe, and efficient way to apply energy to different parts of the mucosa, particularly when compared to the Dr. Bikson’s interpretation that the needle is removed from the nasal passages each time there is a need to apply energy at a different location.

52. Removing the treatment element from the nose in between applying energy to different portions of the same nasal cavity as Dr. Bikson proposes would have several negative adverse effects. First, inserting a foreign object into the nose is an uncomfortable process for the patient. There is the risk that the object bumps into tissue and causes trauma. As a clinician, I endeavor to keep my patients as comfortable as possible. A person of ordinary skill in the art would therefore not remove and re-insert a device unless it was necessary. Second, the problems with re-insertion are compounded by Edwards-'535's device. While balloon devices like that described in Edwards-'535 are often neatly folded into a small cross section to permit easy initial insertion, once inflated, the balloons often occupy a larger cross-sectional footprint. This makes reinsertion somewhat more challenging. A person of ordinary skill in the art would therefore be less inclined to remove and then re-insert a device like that in Edwards-'535 than another device that has a consistent form factor.

53. Dr. Bikson also misinterprets the prior art references I relied on in my first Declaration. First, Dr. Bikson opines that Edwards-'535 only delivers energy to one "singular" portion of the nasal concha. Ex.2001-Bikson-Decl., ¶97. I disagree. For example, Edwards-'535 plainly states that the device delivers energy to all three of the nasal concha by using the term "and/or" rather than simply "or."

Ex.1010-Edwards-'535, 6:38-42 (“The nasal meatus into which the apparatus is delivered may be the inferior, middle *and/or* superior nasal meatus and 40 is preferably the inferior nasal meatus. The nasal concha ablated may be the inferior, middle *and/or* superior nasal concha and is preferably the inferior nasal concha”). Delivering energy to only one of the concha is only “one embodiment” of Edwards-'535. *Id.*, 6:42-44 (“In one embodiment, energy is delivered to a selected section of one of the nasal concha.”).

54. Second, Dr. Bikson similarly opines that Kong only teaches “applying energy to a single portion of nasal mucosa.” Ex.2001-Bikson-Decl., ¶98. I also disagree. Dr. Bikson appears to suggest that the making of holes in Kong is different from the application of energy within one single hole. This interpretation is not supported by Kong’s teachings. Kong discloses that the holes are made using the RF electrode. Ex.1040-Kong, 214 (“The RF electrode was inserted into the inferior turbinate and pushed along the longitudinal direction to an appropriate depth (approximately 1.5-2.0 cm) under the mucosa; after making the hole to the required depth...”). Kong does not describe any other clinical purpose for making such holes. Therefore, a person of ordinary skill in the art would have understood each of the holes to be a location where RF energy is delivered. This interpretation is consistent with my experience with the Somnoplasty procedure I described

above. For the reasons I describe above, a person of ordinary skill in the art would have applied energy to the multiple regions described by Kong before removing the device.

55. I note that Dr. Bikson does not suggest Liang applies energy to only one single portion of the nasal cavity. That is consistent with my reading of the Liang reference, which plainly describes performing thermocoagulation in at least two locations. Ex.1056-Liang, 341 (“Under direct nasal endoscopy, the emitter was used to perform thermal coagulation treatment on the bilateral nasal ridge and the corresponding nasal septum mucosa.”).

56. Thus, a person of ordinary skill in the art would have understood (or at least found obvious) that the references’ disclosure of contacting multiple portions of the mucosa means that each of those multiple portions will be contacted before removing the treatment element from the nose.

V. IT IS MY OPINION THAT DEPENDENT CLAIM 16 IS OBVIOUS

57. Claim 16 recites “bending a shaft of the nasal airway treatment device before contacting the treatment element with the nasal mucosa.” In my first declaration, I explained that this limitation would have been obvious in view of Edwards-’535’s teaching of a shaft of a nasal airway treatment device where the

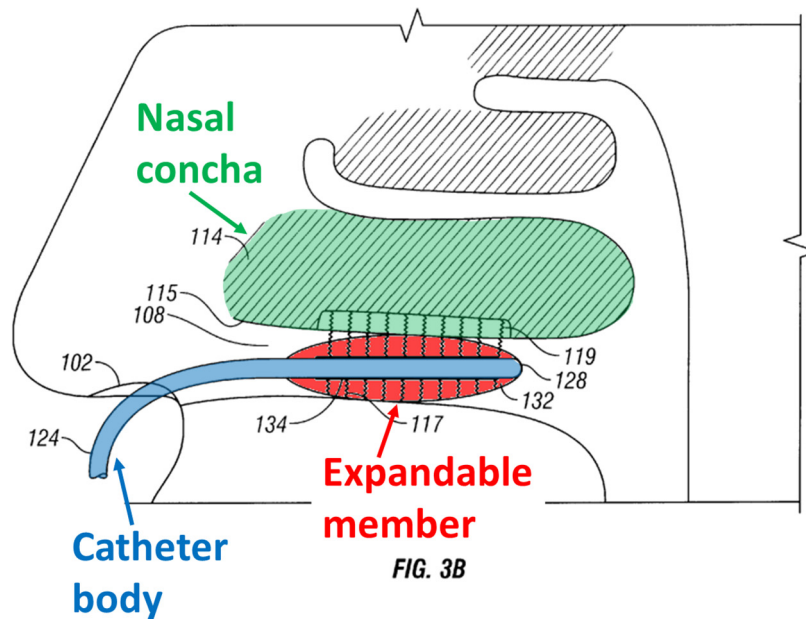
shaft is bent, as common sense dictates that the shaft would have been bent before contacting the treatment element with the mucosa. Ex. 1002, ¶¶144-147.

58. Nevertheless, Dr. Bikson opines that Edwards-'535's shaft could have been bent after contacting the treatment element with the mucosa, and that bending the shaft before contacting the treatment element with the mucosa is neither taught by nor obvious in view of Edwards-'535's teachings. Ex.2001-Bikson-Decl., ¶¶102-104. I disagree. A person of ordinary skill in the art with clinical experience treating the nasal passages would have understood that bending the shaft after the treatment element is already in contact with the mucosa is impractical and, at best, creates significant challenges that are not present when the shaft is pre-bent. Accordingly, a person of ordinary skill in the art would have understood Edwards-'535's teachings to mean that the shaft is bent before contacting the treatment element with the mucosa.

59. One problem with Dr. Bikson's theory is that it requires the shaft to be straight while the treatment element is being inserted into the nose and guided to the target location. However, Dr. Bikson's interpretation is problematic from a clinical standpoint and does not accurately reflect a person of ordinary skill in the art's understanding of how nasal treatment devices are designed. One intuitive reason that the shafts of nasal treatment devices are bent is that a clinician must be

able to see up the patient's nose when inserting the device. If the shaft were straight, the handle, shaft, and treatment element would form a straight line such that the clinician's hand (on the handle) would block the line of sight to the treatment element (at the end of the shaft). The practical challenge that this presents is readily ascertainable to a person of ordinary skill in the art and can easily avoided by using a bent shaft. Accordingly, it is understood that a nasal treatment device would have a bent shaft (i.e., a shaft that is bent *before* the treatment element contacts the mucosa) so that the clinician's hand is out of the way during the procedure and the clinician can see up the nostril.

60. Another reason the shaft cannot be straight is that, with no flexibility in movement, many structures within the nose would be inaccessible. As shown in Figure 3B of Edwards-'535's, for example, many portions of the inferior turbinate (like the target location shown in Figure 3B, and portions distal to that target location) are accessible from the opening of the nostril only by bending the shaft—any attempt to reach those locations with a straight shaft would encounter structures between the nostrils and the target location, resulting in likely tissue or bone damage. Such damage and discomfort can easily be avoided by using a bent shaft, which is why in practice the shaft is bent before the treatment element contacts the mucosa.



Ex.1010-Edwards-'535, FIG.3B.

61. Moreover, even if the target location in Edwards-'535 was accessible using a straight shaft, a person of ordinary skill in the art still would not have understood the disclosed bend to be formed after the treatment element contacted the mucosa. Bending a shaft that is already in contact with the mucosa would place pressure on the mucosa and risk uncontrolled movement of the treatment element (causing potential trauma and damage, and general discomfort to the patient). This approach would also provide less control over the ultimate shape of the shaft. Again, in practice, clinicians easily avoid these issues simply by bending the shaft before it is in contact with the tissue (and even before insertion into the nose). This

understanding is reflected in the typical examples of nasal treatment devices shown below, all of which have pre-bent shafts to “allow the [device] to be used within the recesses of the nose and sinuses.”

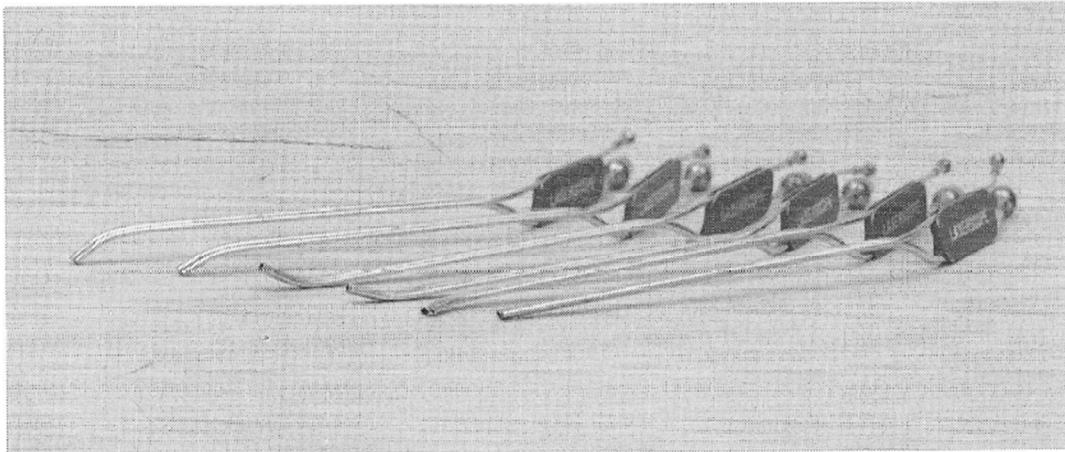


Figure 1. Various laser handpieces of differing angles allow the laser to be used within the recesses of the nose and sinuses.

Ex. 1093-Levine, Figure 1.¹

62. This interpretation of the Edwards-’535 reference is consistent with my clinical practice. Since the late 1990s, I have used the Somnoplasty device, which has been used to treat sleep apnea and for other procedures in the nose using

¹ The above examples are from a paper authored by Dr. Howard Levine, who I understand is testifying as an expert on behalf of The Foundry in related IPR proceedings IPR2024-00279, IPR2024-00280, and IPR2024-00281.

ablation. The Somnoplasty device is manufactured and sold with a bend the shaft of the device before insertion into the patient.

63. Thus, a person of ordinary skill in the art would have understood or at least found obvious that the bend in Edwards-'535's shaft was formed before the treatment element contacted the mucosa.

VI. AVAILABILITY FOR CROSS-EXAMINATION

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

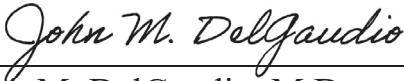
VII. RIGHT TO SUPPLEMENT

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

VIII. JURAT

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

Dated: January 17, 2025



John M. DelGaudio, M.D.

APPENDIX A

Appendix A: Materials Considered

Exhibit	Description
1001	U.S. Patent No. 11,241,271 (“’271 patent”)
1003	File History of U.S. Patent No. 11,241,271
1004	Declaration of Dr. Gregory Martin
1010	U.S. Patent No. 6,517,535 (“Edwards-’535”)
1011	U.S. Patent No. 5,575,788 (“Baker”)
1012	U.S. Patent No. 5,891,134 (“Goble”)
1013	WO 2010/077980 (“Baker-’980”)
1015	U.S. Patent No. 6,033,397 (“Laufer”)
1016	U.S. Patent No. 6,273,886 (“Edwards-’886”)
1017	Chen et al., “Radiofrequency treatment of nasal posterior-under nerve, ethmoidal nerve and infratubinal for perennial allergic rhinitis under nasal endoscope,” 11:3 China J. Endoscopy 239 (March 2005) (English translation) (“Chen”)
1019	U.S. Patent App. No. 2007/0219600 (“Gertner”)
1021	U.S. Patent App. No. 2005/0240147 (“Makower”)
1023	Coste et al., Radiofrequency Is a Safe and Effective Treatment of Turbinate Hypertrophy, Laryngoscope, 111(5) (2001) (“Coste”)
1024	WO1999030655A1 (“Hovda”)
1025	U.S. Patent No. 874,178 (“De Forest”)
1026	U.S. Patent No. 3,538,919 (“Meyer”)
1027	U.S. Patent No. 3,117,571 (“Fry”)
1029	Arora, et al., “Cryodestruction of Vidian nerve branches” (“Arora”)
1031	Hytönen et al., Radiofrequency thermal ablation for patients with nasal symptoms: a systematic review of effectiveness and complications, 266 Eur Arch Otorhinolaryngol 1257 (February 3, 2009)

Exhibit	Description
1033	U.S. Patent No. 5,562,720 (“Stern”)
1035	M. Philippson, Principles of Electrical Resistance of Living Tissue, Bull. Cl. Sci. Acad. R. Belg. ser. 5, vol. 7 (July 1921) (English Translation)
1037	Chung, Cough: Causes, Mechanisms and Therapy, Blackwell Publ’g Ltd (2003) (“Chung”)
1038	U.S. Patent No. 6,109,268 (“Thapliyal”)
1039	Banhiran, Quality of life in patients with chronic rhinitis after radiofrequency inferior turbinate reduction, J. Med Assoc Thai, Vol. 93 No.8 (2010) (“Banhiran”)
1040	Kong et al., “Clinical observation on radiofrequency ablation treatment in perennial allergic rhinitis” J. Clin Otorhinolaryngol (China) Vol.19, No.5 (March 2005)(English translation) (“Kong”)
1041	Snow, Blessed Days of Anesthesia (Oxford U. Press, 2008) (available at: http://ndl.ethernet.edu.et/bitstream/123456789/3165/1/360.pdf)
1042	Bäck et al., Submucosal Bipolar Radiofrequency Thermal Ablation of Inferior Turbinates: A Long-Term Follow-up With Subjective and Objective Assessment, 112 Laryngoscope 1806 (October 2002).
1043	Ilgner et al., Feasibility of coblation versus laser resection in recurrent nasal polyps, 5686 Proc. of SPIE 322 (April 25, 2005)
1044	Lee et al., Surgical Management of Turbinate Hypertrophy in the Office: Three Mucosal Sparing Techniques, 12:2 Operative Techniques in Otolaryngology--Head and Neck Surgery 107 (June 2001)
1046	U.S. Patent No. 3,941,121 (“Olinger”)
1047	U.S. Patent No. 4,271,848 (“Turner”)
1048	Nomura et al., Distribution and Clinical Significance of Autonomic Nervous System in the Human Nasal Mucosa, 73 Acta Otolaryng 493 (1972) (“Nomura”)

Exhibit	Description
1049	Akiyoshi Konno, Historical, Pathophysiological, and Therapeutic Aspects of Vidian Neurectomy, 10 Curr Allergy Asthma Rep 105 (2010) (“Konno”)
1055	Fang et al., Nasal endoscopy combined with multiple radiofrequency for perennial allergic rhinitis, 25:7 J. First Mil Med Univ 876 (2005) (English translation) (“Fang”)
1056	Liang et al., Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy, 13:8 J. Clin Otorhinolaryngol (China) 341 (August 1999) (English translation) (“Liang”)
1057	Excerpts from File History for U.S. Patent No. 10,398,489
1058	U.S. Patent App. No. 2002/0016588 (“Wong”)
1059	Chinese Patent No. 2225227 (English translation) (“Liang ’227”)
1060	Andrew P. Lane, Nasal anatomy and physiology 12 Facial Plast Surg Clin N Am 387 (2004) (“Lane”)
1064	G.A.G. Mitchel, The Automatic Nerve Supply of the Throat, Nose, and Ear, J. of Laryngology & Otology (August 1954)
1066	U.S. Patent App. No. 2004/0230188 (“Cioanta”)
1084	Transcript of the January 7, 2025, Deposition of Dr. Marom Bikson
1085	Exhibit A to the Deposition of Dr. Marom Bikson
1086	Exhibit B to the Deposition of Dr. Marom Bikson
1093	Howard L. Levine, Lasers in Endonasal Surgery, 30:3 OTOLARYNGOLOG. CLINICS OF N. AM. (June 1997) (“Levine”).
/	Patent Owner’s Preliminary Response
/	Institution Decision
/	Patent Owner’s Response
2001	Declaration of Dr. Marom Bikson
2002	Curriculum Vitae of Dr. Marom Bikson
2003	Transcript of the September 24, 2024, Deposition of Dr.

Exhibit	Description
	Gregory T. Martin
2004	Transcript of the September 25, 2024, Deposition of Dr. Gregory T. Martin
2007	Transcript of the October 10, 2024, Deposition of Dr. John M. DelGaudio