

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. IPR2024-00278

U.S. Patent No. 11,033,318

**REPLY DECLARATION OF DR. GREGORY T. MARTIN REGARDING
CLAIMS 1, 4-6, 9-10, 12-13, AND 15-17 OF U.S. PATENT NO. 11,033,318**

NEURENT 1083
NEURENT v. AERIN
IPR2024-00278

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I, Gregory T. Martin, Ph.D., declare as follows:

I. INTRODUCTION

1. I am making this declaration at the request of Neurent Medical Inc. and Neurent Medical Ltd. (“Neurent” or “Petitioners”) as an independent expert consultant in this proceeding before the United States Patent and Trademark Office and to address and respond to the arguments made in the Patent Owner’s Patent Owner Response (“POR”) and the declaration submitted by Dr. Marom Bikson (“Bikson Declaration”) (Ex.2001) in support of the POR. I previously submitted a Declaration in support of the Petition, dated January 15, 2024 (Ex.1002) (“First Declaration”).

2. As stated in the First Declaration, I am being compensated for my work on this matter at my standard hourly consulting rate of \$400 per hour, but my opinions are based on my own views and understanding of the prior art, the knowledge of a person of ordinary skill in the art, and the patented technology. My compensation is not dependent on and in no way affects the substance of my statements, opinions, or conclusions in my First Declaration and this Reply Declaration nor is it dependent on any testimony I give or on the outcome of this proceeding.

3. As also stated in my First Declaration, I have no financial interest in Petitioners or Patent Owner. I similarly have no financial interest in the '318 patent and have had no contact with the named inventors of the '318 patent.

II. MATERIALS CONSIDERED

4. In forming my opinions, in addition to my knowledge and experience, I have considered the materials cited in my First Declaration and the documents cited herein, which are listed in **Appendix A**.¹

5. 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-Bikson-Tr.).

¹ Similar to my First Declaration, various annotations have been added to the figures and diagrams in this report. All of these annotations are added unless noted otherwise.

III. SUMMARY OF OPINIONS

6. As I laid out in my First Declaration, my opinion is that claims 1, 4-6, 9-10, 12-13, and 15-17 of the '318 patent would have been obvious to a person of ordinary skill in the art. As I explain in this declaration, my opinion continues to be that claims 1, 4-6, 9-10, 12-13, and 15-17 of the '318 patent would have been obvious over the prior art that I discussed in my First Declaration.

7. I have reviewed the POR, the Bikson Declaration, and the Bikson Deposition—nothing in those has caused me to change my opinions set forth in my First Declaration. Rather, my review of those documents confirms my opinion that claims 1, 4-6, 9-10, 12-13, and 15-17 of the '318 patent would have been obvious.

8. I reviewed the transcript of my deposition² and Dr. Bikson's discussions thereof. Dr. Bikson repeatedly mischaracterizes my opinions, including those on the prior art I discussed in my First Declaration and the reasons why a person of ordinary skill in the art would have interpreted that prior art to teach and render obvious the limitations of the '318 patent claims. Dr. Bikson's opinion is that

² The errata that I submitted for my deposition are included in Exhibits 1094 and 1095.

the '318 patent claims would not have been obvious. I disagree. Moreover, my testimony does not support Dr. Bikson's opinions. I therefore maintain, as I stated in my First Declaration, that the '318 patent claims would have been obvious to a person of ordinary skill in the art and without the use of hindsight. Dr. Bikson only disagrees with a subset of my opinions. I therefore focus on these few areas of dispute in this Reply Declaration.

IV. LEGAL PRINCIPLES

9. In my First Declaration, I set forth the applicable principles of patent law that counsel provided to me, which I incorporate by reference here. Ex.1002, ¶¶10-22. I have continued to apply those principles in providing my opinions in this Reply Declaration.

V. OVERVIEW OF THE TECHNOLOGY AND THE '318 PATENT

10. I discussed the technology background, the '318 patent, and the prosecution history of the '318 patent in paragraphs 29-49 of my First Declaration, which I incorporate by reference here.

11. I have reviewed the section of Dr. Bikson's entitled "Overview of the '318 patent and the Challenged Claims." Ex.2001-Bikson, ¶¶42-48. I note that Dr. Bikson leaves out several aspects of the '318 patent disclosure that are relevant to

how a person of ordinary skill in the art would have interpreted the '318 patent claims. I identify those portions below.

12. As I explained in my First Declaration, I applied the priority date of June 14, 2011 and do not offer any opinion to whether the '318 patent is entitled to a particular priority date. Ex.1002, ¶25. Dr. Bikson applied the same priority date to his analysis. Ex.2001-Bikson, ¶34.

VI. CLAIM CONSTRUCTION

13. In performing my analysis in First Declaration, I applied the plain and ordinary meaning of the claim terms and continue to do so in this Reply Declaration. Ex.1002, ¶¶50-53. Dr. Bikson agrees with me that the plain and ordinary meaning should be applied to the '318 patent claim terms (Ex.2001-Bikson, ¶56), but his analysis does not appear to do so. As I explain below, with respect to claims 1, 6, and 9, instead of applying the plain and ordinary meaning, Dr. Bikson appears to suggest that certain claim terms should be interpreted in a specific manner so as to contain additional requirements. Although I disagree with Dr. Bikson's interpretation of claims 1, 6, and 9, the prior art still discloses the additional requirements that Dr. Bikson seeks to add to the claims.

VII. CHALLENGED CLAIM 1 IS OBVIOUS OVER EDWARDS-'535 AND STERN (GROUND I) AND MAKOWER AND STERN (GROUND IV)

14. For the reasons I explained in my First Declaration, independent claim 1 of the '318 patent would have been obvious over both (1) the combination of Edwards-'535 and Stern (Ex.1002, ¶¶71-156), and (2) the combination of Makower and Stern (Ex.1002, ¶¶254-306).³ In my First Declaration, I explained that a person of ordinary skill in the art would have been motivated to combine Edwards-'535 and

³ In my first declaration, I incorporated my opinions on the combination of Edwards-'535 and Stern into my opinions on the combination of Makower and Stern. *See, e.g.,* Ex.1002, ¶¶258, 261-262, 272-273, 277, 280-283, 286, 291-293, 295-297, 300, 307, 314, 316, 320, 323-325, 327, 328-330. I further incorporated my opinions on the Edwards-'535 and Stern and Makower and Stern into my opinions on other combinations, including those with the Edwards-'886 reference and Patel Reference. *See, e.g.,* Ex.1002, ¶¶234, 241-242, 247, 249-250, 331-333, 335, 338-339, 341-342, My opinions of the Stern reference in combination with Edwards-'535 presented in my Reply Declaration apply equally to the other combinations I addressed in my First Declaration.

Stern (Ex.1002, ¶¶79-80, 102-122, 129-148, 153, 164, 171, 177, 181, 210, 216, 223) and that a person of ordinary skill in the art would have been motivated to combine Makower and Stern (Ex.1002, ¶¶277-288, 292-302, 305, 329, 331), each with a reasonable expectation of success. Dr. Bikson does not appear to disagree with me on these points.

15. Dr. Bikson does, however, appear to disagree with me that Stern teaches limitation 1[d] which requires “multiple pairs of bipolar radiofrequency electrodes” and limitation 1[e] which requires “multiple radiofrequency output channels.” Ex.2001-Bikson, ¶¶57, 68. I disagree with Dr. Bikson for two reasons. First, Dr. Bikson’s opinion is based on his incorrect interpretation of the scope and requirements of claim 1 of the ’318 patent. Second, Dr. Bikson reads the Stern reference too narrowly, which led him to incorrectly conclude that Stern does not teach limitations 1[d] and 1[e] under his (incorrect) interpretation.

16. Dr. Bikson’s arguments do not change my opinion that the claims of the ’318 patent would have been obvious. Therefore, as I explained in my First Declaration and further below in this Reply Declaration, both the combination of Edwards-’535 and Stern and the combination of Makower and Stern teach limitations 1[e] and 1[d].

A. The combinations of Edwards-'535 and Stern (Ground I) and Makower and Stern (Ground IV) teach limitation 1[d]: “multiple pairs of bipolar radiofrequency electrodes”

17. Dr. Bikson opines that Stern does not teach multiple pairs of bipolar radiofrequency electrodes as claimed by the '318 patent because, in his view, limitation 1[d] requires bipolar electrode pairs that are active “at the same time.” Ex.2001-Bikson, ¶¶57-65. I disagree with his interpretation, but even if his interpretation was correct, that would not change my opinion that Stern discloses “multiple pairs of bipolar radiofrequency electrodes.”

1. Limitation 1[d] does not require “multiple pairs of bipolar radiofrequency electrodes” active “at the same time”

18. Dr. Bikson’s opinion is that the prior art does not disclose “an array of multiple pairs of bipolar radiofrequency electrodes” because it does not disclose the multiple pairs being active or delivering energy “at the same time.” Ex.2001-Bikson, ¶¶64-65. The requirement that the electrodes are delivering energy “at the same time” does not appear in claim 1, and the claim does not otherwise recite language requiring the “pairs of bipolar radiofrequency electrodes” to be active at the same time. Rather, the claims recite “multiple pairs of bipolar radiofrequency electrodes,” meaning what is required is more than one bipolar electrode pair. As I explained in my First Declaration, Edwards-'535 or Makower in view of Stern

discloses multiple pairs of bipolar radiofrequency electrodes. Ex.1002, ¶¶97-122, 270-276.

19. Dr. Bikson's interpretation is inconsistent with the '318 patent's description that multiple pairs of bipolar radiofrequency electrodes that can be activated separately *or* individually. For example, the '318 patent teaches that "each pair of electrodes may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately." Ex.1001-USP318, 48:63-49:6. Activating each pair of electrodes "separately" is the opposite of activating pairs "at the same time," which Dr. Bikson says is required by the claims. His opinion is therefore inconsistent with this portion of the specification. The '318 patent gives another example that the "needles or needle pairs of FIG. 8F may be individually controlled to produce an optimal treatment effect." *Id.* 24:45-53. A person of ordinary skill in the art would have understood that individually controlling pairs of electrodes would include controlling pairs to be on while others are off, which is again the opposite of what Dr. Bikson says is required by the claims. As another example, the '318 patent discloses that electrodes can be arranged in a "multiplexed configuration allowing pairing of any of the positive electrodes 963 to any of the negative electrodes 964 to form a complete circuit." *Id.*, 49:18-21; *see also id.*, 49:47-54 ("In some embodiments, the device may include a multiplexed

configuration by providing functionality to allow pairing of any of the positive electrodes 973 to any of the negative electrodes 974 to form a complete circuit.”); 20:30-33 (“The control system 42 may be configured to engage such distributed elements individually or in selected groups so as to treat only targeted areas of the nasal passageway.”). In this embodiment, only one electrode is paired with only one other electrode to form a complete circuit. The ’318 patent does not describe any other complete circuits formed at the same time. Therefore, this embodiment of the ’318 patent discloses only one pair being active at any given time, which is again the opposite of what Dr. Bikson says is required by the claims. The ’318 patent does not describe any arrangements where multiple pairs are active at the same time as being optimal or preferred embodiments, let alone the only embodiment.

20. Dr. Bikson overlooks this disclosure in the ’318 patent in reaching his opinion regarding this claim scope. Ex.2001-Bikson, ¶60. Rather, he simply concludes that “[c]onsistent with the ’318 patent’s description, a POSITA would have understood a ‘pair’ of bipolar radiofrequency electrodes to be two electrodes located near each other that have opposite polarities.” Ex.2001-Bikson, ¶60 (citing Ex-1001, 23:7-11 (“Unless specified otherwise, electrodes described can be monopolar (e.g., used in conjunction with a grounding pad) or bipolar (e.g., alternate polarities within the electrode body, used in conjunction with other tissue-applied

electrodes).”), 49:7-9 (“An electrode pair may include a positive electrode 963 and a negative electrode 964.”), 49:18-24 (“FIG. 40 is a block diagram depicting an electrode array arranged in a multiplexed configuration allowing pairing of any of the positive electrodes 963 to any of the negative electrodes 964 to form a complete circuit. A positive electrode 963 may be paired with the opposite negative electrode 964 or to any of the other negative electrodes 964 regardless of its location in the device.”), 49:35-37 (“An electrode pair may include a positive electrode 973 and a negative electrode 974.”), 49:46-54 (“FIGS. 42A and 42B are block diagrams depicting an array of electrodes of a nasal treatment device. In some embodiments, the device may include a multiplexed configuration by providing functionality to allow pairing of any of the positive electrodes 973 to any of the negative electrodes 974 to form a complete circuit. A positive electrode 973 may be paired with the opposite negative electrode 974, or to any of the other negative electrodes 974 regardless of its location in the device.”)). I have reviewed the portions of the ’318 patent that Dr. Bikson cites, and none disclose multiple pairs of electrodes applying energy at the same time. That disclosure is consistent with pairs of electrodes being activated either at different times (i.e., “separately”) *or* at the same time. I therefore disagree with Dr. Bikson’s conclusion that activation of pairs at the same time is required and that the disclosed embodiments of activating pairs separately are

excluded from “multiple pairs of bipolar electrodes,” as it is inconsistent with the plain and ordinary language of the claim (which does not require one or the other) and this disclosure.

21. I therefore disagree with Dr. Bikson that claim 1 of the '318 patent requires the “multiple pairs of bipolar radiofrequency electrodes” to deliver energy “at the same time.

2. Stern teaches “multiple pairs of bipolar radiofrequency electrodes” that are active “at the same time”

22. As I explain above, I disagree with Dr. Bikson that the claims require activating pairs of electrodes at the same time. However, even if his interpretation was correct, that would not change my opinion that Stern discloses “multiple pairs of bipolar radiofrequency electrodes.” Though I disagree, for the purposes of the following analysis, I assume that limitation 1[d] requires multiple pairs of bipolar radiofrequency electrodes that are active “at the same time,” as Dr. Bikson proposes. Ex.2001-Bikson, ¶¶64-65. Even under this interpretation, Stern teaches activating multiple pairs of bipolar radiofrequency electrodes “at the same time.” For example, Stern states that “any combination of pairs of electrodes [shown in Figure 15] may be utilized together.” Ex.1033-Stern, 13:39-43. A person of ordinary skill in the art would have understood that when pairs of electrodes are used together, they are

active “at the same time.” I note that Dr. Bikson did not discuss Stern’s disclosure of utilizing pairs of electrodes “together” in forming his opinion that Stern does not teach “multiple pairs of bipolar radiofrequency electrodes” that are active “at the same time.”

23. In any event, Stern’s teachings are consistent with the ’318 patent’s discussion of multiple pairs of electrodes. As I explained above, the ’318 patent describes pairs that are activated in groups or sequentially, and does not further state that only one of these activation patterns is required. Ex.1001-USP318, 48:63-49:6; 20:30-33. Dr. Bikson does not identify any disclosure of electrode pairs that are only activated at the same time in the ’318 patent. Consistent with the ’318 patent’s disclosure, Stern discloses pairs that are “utilized together” for the purposes of considering whether there are multiple pairs of bipolar radiofrequency electrodes active at the same time.

24. In view of Stern’s teaching of “multiple pairs of bipolar radiofrequency electrodes” active at the same time, Dr. Bikson is incorrect that “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.2001-Bikson, ¶64. The ability to activate a single pair at a time is just one possible arrangement of Stern’s

pairs. As explained above, Stern also discloses an arrangement that uses multiple pairs “together.”

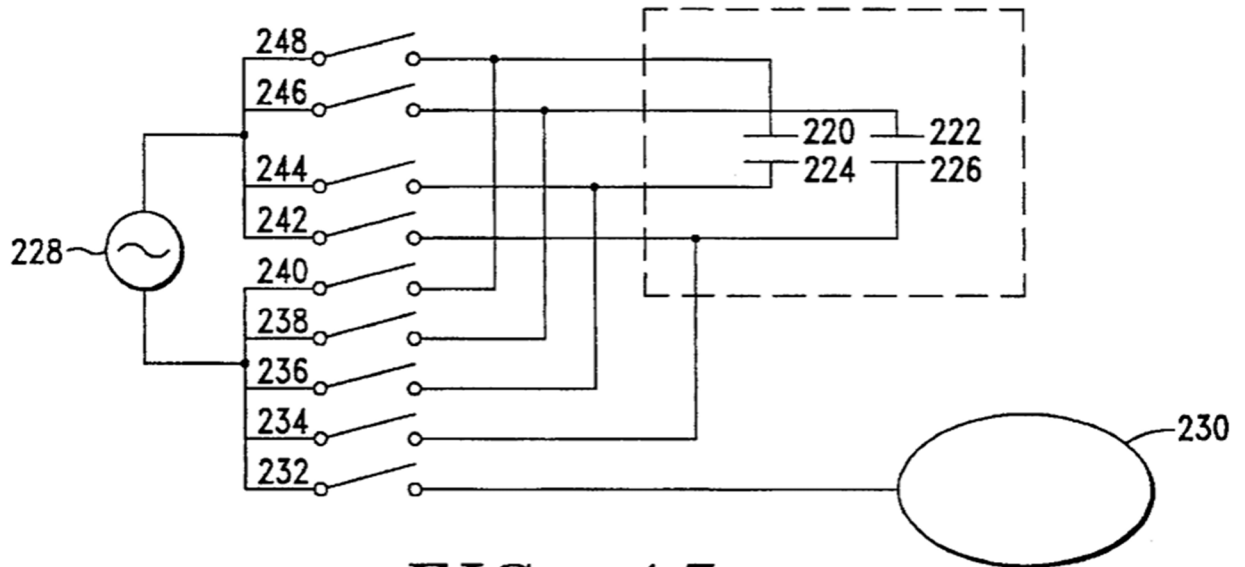


FIG. – 15

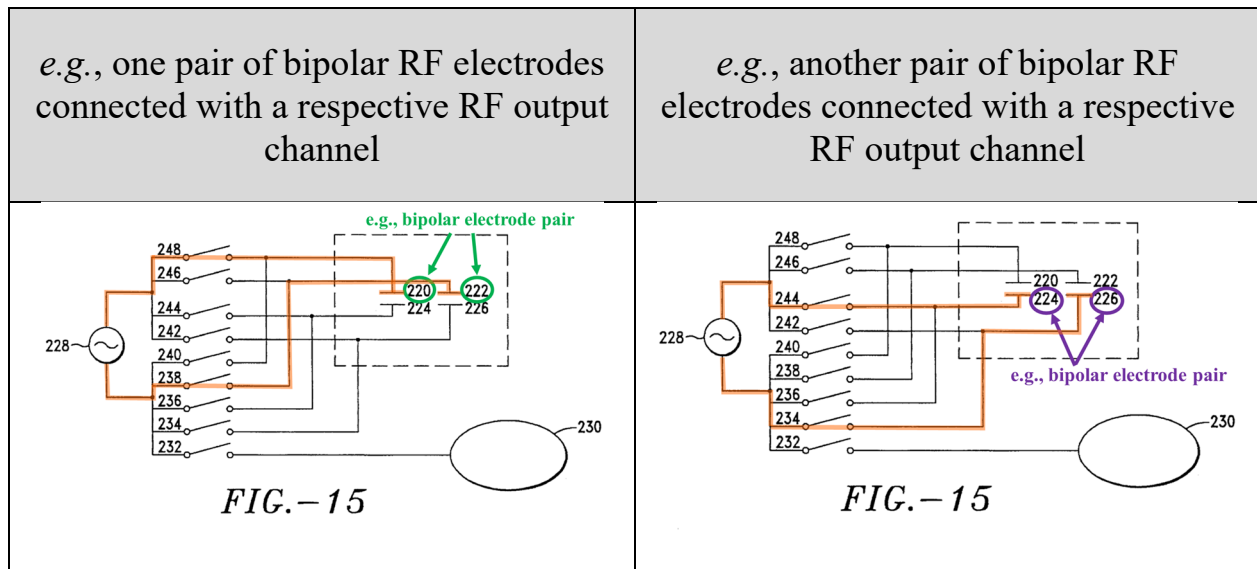
Ex.1033-Stern, FIG.15; 13:39-43 (“[A]ny pair or any combination of pairs of electrodes may be utilized together.”).

25. Dr. Bikson opines that only separate activation or energy delivery of each bipolar pair is contemplated by Stern because Stern teaches that its electrodes “are independently and sequentially energized,” Ex.1033-Stern, 2:31-33, 2:49-53, 10:48-52, 17:54-55, and, according to Dr. Bikson, sequential energization indicates that only two of Stern’s switches would be closed at one time. Ex.2001-Bikson, ¶¶60-64.

26. But in my First Declaration, I explained how **both** activation of pairs of bipolar electrodes at the same time or sequential activation pairs of bipolar electrodes satisfy claim 1 and Stern's stated goal of independent and sequential energization. I described the ability to activate a single pair as an "example[]" of Stern's configuration, and I also explained that Stern more generally discloses configurations where "various combinations of electrodes" are active. Ex.1002, ¶101. I further explained in my First Declaration how the ability to activate multiple pairs at a time contributes to a person of ordinary skill in the art's motivation to combine the teachings of Stern and Edwards-'535. For example, one benefit of Stern's selective control of bipolar pairs is the ability to "direct heat to one particular area and not others." Ex.1002, ¶119; Ex.1033-Stern, 13:21-39 ("The bipolar arrangement allows various pairs of electrodes to be picked in order to heat uneven or rather asymmetrical areas.... That is, any unusual features within an area to be heated may be taken into account in a bipolar operation by selection of different pairs of electrodes for energization utilizing the circuitry of FIG. 15."). For example, all pairs could initially be active, but if one area got too hot, the pairs in that area could be selectively turned off. Another benefit is to allow for "selective tissue destruction across an entire surface of tissue," as opposed to a single discrete portion. Ex.1002, ¶110 (citing Ex.1033-Stern, 2:6-19, 6:44-62, 10:49-65). A person of

ordinary skill in the art would have understood that the desired outcomes of even heating and destruction over an entire area of tissue are accomplished by activating multiple pairs at the same time.

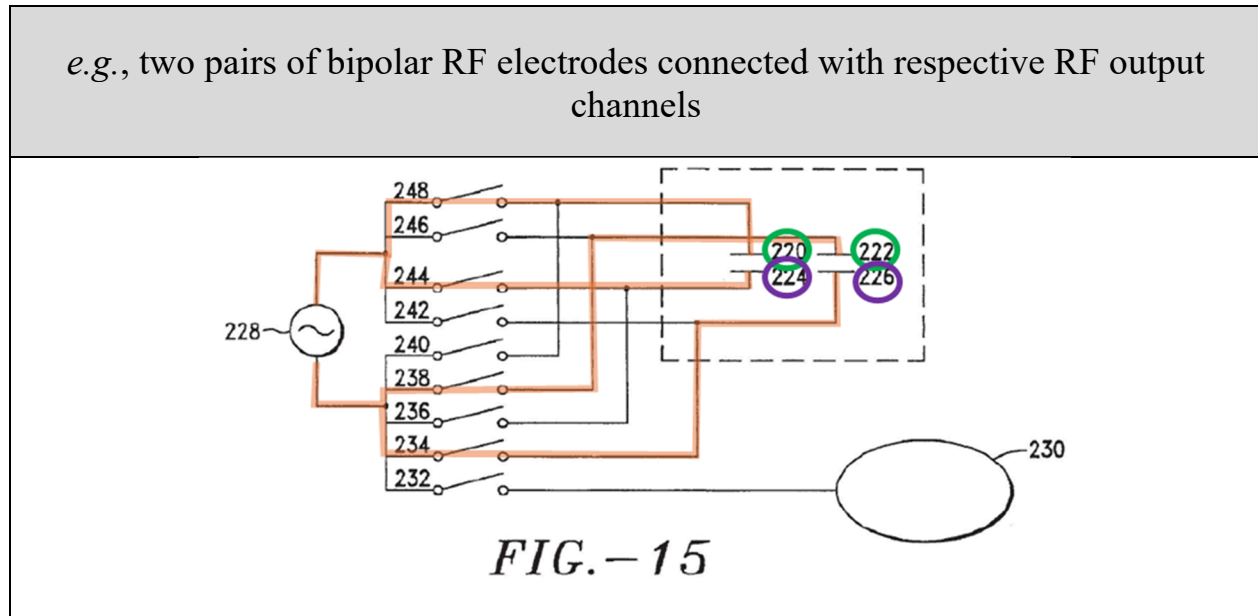
27. Dr. Bikson points to my annotation in my First Declaration where I showed two different ways to configure Stern's device as evidence that Stern teaches only the activation of only a single pair of electrodes at once:



Ex.1002, ¶124. This annotation, however, was exemplary.

28. Consistent with Stern's disclosure and my reading of the Stern reference, and in response to Dr. Bikson's opinion, I offer the following additional annotation, to show how closing switches 248, 238, 244, and 234 would result in the activation of multiple pairs of electrodes at once—this is simply a “combination of

pairs” that are “utilized together” as disclosed by Stern and is a combination of my two previous annotations (Ex.1002, ¶124):



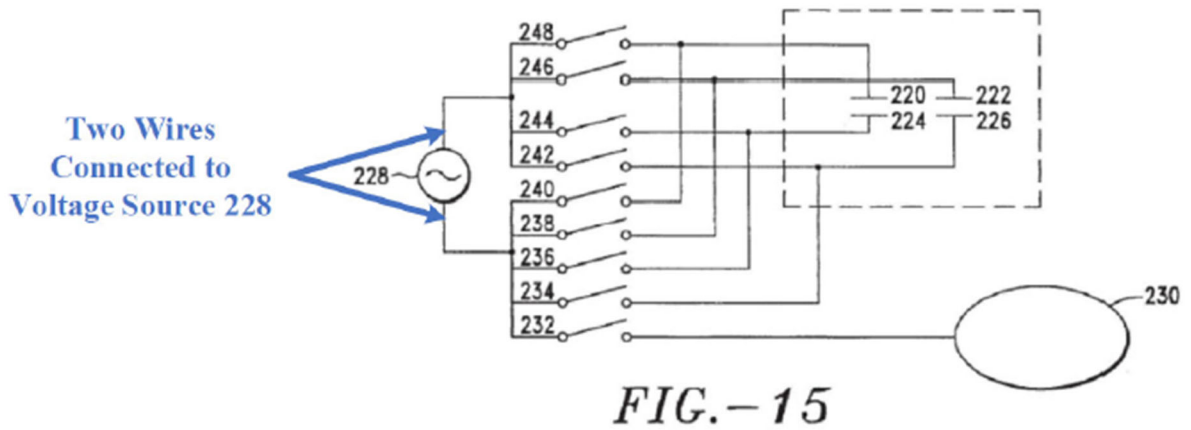
B. The combinations of Edwards-'535 and Stern (Ground I) and Makower and Stern (Ground IV) teach limitation 1[e]: “multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes”

29. Dr. Bikson opines that Stern does not teach the multiple radiofrequency output channels as claimed by the '318 patent because, in his view, the claim requires that each radiofrequency output channel is separately connected directly to the voltage source. Ex.2001-Bikson, ¶¶66-83. Dr. Bikson does not discuss any disclosure of the '318 patent in reaching his opinions regarding this claim scope. Ex.2001-Bikson, ¶¶66, 68-72. I disagree with Dr. Bikson's interpretation, but even

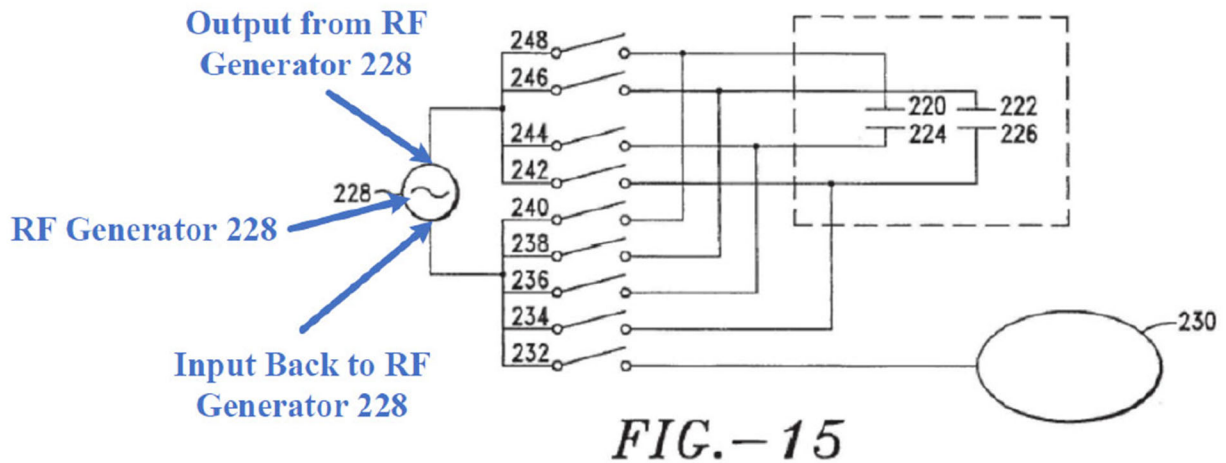
if his interpretation was correct, that would not change my opinion that Stern discloses “multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes.” Ex.1002, ¶115; *id.* ¶¶123-148, 289-302.

1. **Each “radiofrequency output channel” need not be a separate channel “connected directly to the voltage source”**

30. Dr. Bikson appears to interpret limitation 1[e] to require that each claimed radiofrequency output channel is separately *connected directly to the voltage source*. Ex.2001-Bikson, ¶¶68-69. This requirement however is not in the language of claim 1, nor does the term “output channel” mandate such a requirement. Dr. Bikson further opines that the number of radiofrequency output channels depends on how many “terminals or connection points” the radiofrequency generator has. Ex.2001-Bikson, ¶¶71 (opining that a single output channel has two “terminals or connection points”). According to Dr. Bikson, Stern has only one output channel because it shows only two wires connected to the voltage source, which Dr. Bikson opines is equivalent to the generator. Ex.2001-Bikson, ¶¶76-77. Under Dr. Bikson’s view, indicates only two “terminals” or direct “connection points.” Ex.2001-Bikson, ¶¶76-79.



Ex.2001-Bikson, ¶77.



Ex.2001-Bikson, ¶79.

31. The claim does not recite language requiring a direct connection between the channels and the voltage source, nor does it imply any relationship between the output channels and the generator. Indeed, while the claim requires that the “multiple radiofrequency output channels” are “connected with the multiple pairs of bipolar radiofrequency electrodes,” the claim does not recite any other required

connection, much less one to a generator. And it certainly does require that for every output channel there exists a corresponding “terminal[] or connection point[]” on a radiofrequency generator. Ex.2001-Bikson, ¶¶71, 76-77. Rather, the claims recite “multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes,” meaning what is required is a connection to bipolar radiofrequency electrodes. As I explained in my First Declaration, Edwards-’535 in view of Stern discloses this limitation. Ex.1002, ¶¶123-148; *see also* 289-302.

32. Dr. Bikson’s interpretation is inconsistent with the claims of the ’318 patent. Claim 1 focuses on a “device for delivering energy to a nasal airway”—the patent does not claim a radiofrequency generator until claims 9 and 10. Claim 9 clarifies that when the generator is included it needs to be “configured to ...deliver radiofrequency energy separately to each of the multiple radiofrequency output channels.” Nothing about these claims indicates that the radiofrequency output channels need to be directly connected to the voltage source, or even the overall generator, via separate wires. Therefore, the plain language of “output channels” does not indicate any particular output arrangement or connection to the voltage source or radiofrequency generator.

33. Dr. Bikson's interpretation is also inconsistent with the '318 patent's description of radiofrequency output channels. Every time the patent mentions "electrical channel" or "output channel," it is referring to connections to electrodes—a "generator" is not mentioned and there is no specific wiring of channels in the generator that is discussed. Ex.1001-USP318, 24:45-52, 48:63-65, 49:5-10 ("[A]n RF output channel 961 assigned to each electrode pair for feedback"), 49:12-15 ("[A] controlled RF output channel 961 and a thermocouple 962 to allow for independent adjustments"), 49:24-46 ("[A]n RF output channel 961 assigned to each electrode pair for feedback"), 49:65-50:2 ("Each RF output channel may include a positive electrode 983 and the negative electrode 984. While the negative electrode 984 is common, each positive electrode 983 may be independently controlled to achieve the desired treatment."), 50:9-15 ("Each RF output channel may include a positive electrode 993 and the negative electrode 994. While the negative electrode 994 is common, each positive electrode 993 may be independently controlled to achieve the desired treatment."); *see also* FIGs. 39, 40, 42A-42B, 43, 44. Dr. Bikson opines that "a radiofrequency generator with a single radiofrequency output channel will have two terminals or connection points." Ex.2001-Bikson, ¶71. But it does not follow that a radiofrequency generator with multiple output channels will require more than two terminals or connection points.

I note that the '318 patent specification never uses the term “terminal” or “connection points.” Ex.2001-Bikson, ¶71. The claims therefore do not require that the channels be defined by, or have a particular relationship with terminals or connection points.

34. The '318 patent only discusses output channels with reference to block diagrams in Figures 39 to 44. None of these figures show an RF generator, or “terminals” or “connection points” (Ex.2001-Bikson, ¶71) coming from the generator.

35. The patent describes Figure 39 as follows:

“FIG. 39 is a block diagram depicting an array of electrodes of a nasal treatment device *arranged in a multi-channel configuration*. As described above, different target anatomies may have treatment surface areas of varying size and shape. Additionally, users operating a nasal treatment device may vary in skill, dexterity, and habits. Due to these variabilities, each electrode pair of the device may have varying degrees of contact with tissue of the target anatomy. For a configuration in which all pairs of electrodes are controlled by one main electrical *channel*, this may lead to varying magnitudes of treatment energy passing through each electrode pair. The pair(s) of electrodes that have a higher degree of contract with the tissue may experience higher magnitudes of impedance in their individual circuit. Since treatment energy takes the path of least resistance, this may lead to treatment energy being diverted to pairs of electrodes that experience a relatively lower magnitude of impedance due to a relatively lower degree of tissue contact. Thus, it may be advantageous to control the treatment energy through each electrode to ensure repeatable treatments.

In some embodiments, *each pair of electrodes may have a separate, controlled electrical channel to allow for different regions of the treatment*

element to be activated separately. In some embodiments, each electrode pair may be paired with its own thermocouple. By controlling the treatment energy flowing through each pair of electrodes using parameters including, but not limited to, temperature, a greater degree of control and accuracy over the treatment energy may be obtained, such that treatments may be repeatable.

As shown in FIG. 39, the nasal treatment device may include one or more thermocouples 962 and an ***RF output channel 961 assigned to each electrode pair for feedback***. An electrode pair may include a positive electrode 963 and a negative electrode 964. In some embodiments, the positive electrode 963 and the negative electrode 964 may be positioned opposite to one another. Each electrode pair may have its own individual subsystem 960. The individual subsystem 960 may include ***a controlled RF output channel 961*** and a thermocouple 962 ***to allow for independent adjustments***. The thermocouple 962 may act as a feedback control to ensure that proper temperature is maintained at the site of treatment.

Ex.1001-USP318, 48:42-49:17. Figure 39 therefore refers to “an RF output channel 961” that points to the *end* of the “nasal treatment device.” Ex.1001-USP318, 49:5-11. RF output channel 961 is clearly pointing to wires lines carrying both an active signal shown by a “+” sign and a return signal shown by a “-” sign. The ’318 patent never explains, shows, or limits the *beginning* of that output channel, i.e., how the channel connects to the voltage source in the RF generator.

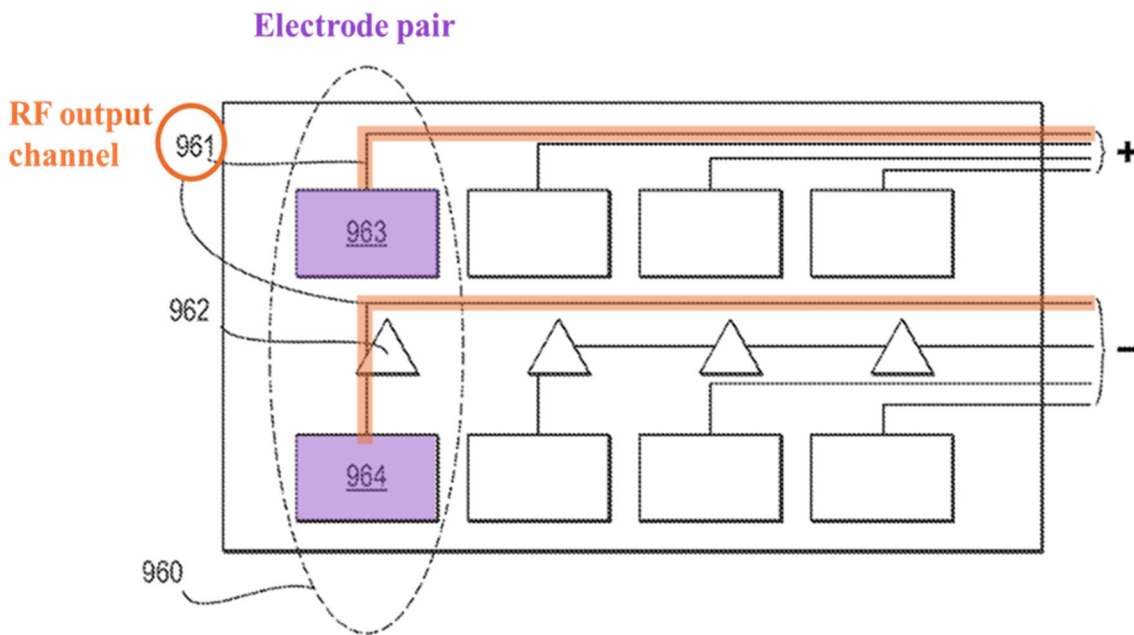


FIG. 39

Ex.1001-USP318, FIG.39.

36. The patent describes Figure 40 as follows:

“FIG. 40 is a block diagram depicting an electrode array *arranged in a multiplexed configuration allowing pairing of any of the positive electrodes 963 to any of the negative electrodes 964 to form a complete circuit.* A positive electrode 963 may be paired with the opposite negative electrode 964 or to any of the other negative electrodes 964 regardless of its location in the device. The device may include a plurality of thermocouples 962 *and an RF output channel 961 assigned to each pair of electrodes for feedback.* Temperature readings from two adjacent thermocouples 962 may be averaged to obtain a temperature reading for the region in which the circuit is located. In some embodiments, the two thermocouples 962 may be the thermocouples in the closest proximity to the positive electrode 963 and the negative electrode 964.”

Ex.1001-USP318, 49:18-32. Similar to Figure 39, Figure 40 refers to “an RF output channel 961” that points to the *end* of the “nasal treatment device.” As in Figure 39, Figure 40 shows RF output channel 961 pointing to wires lines carrying both an active signal shown by a “+” sign and a return signal shown by a “-” sign. The ’318 patent never explains, shows, or limits the *beginning* of that output channel, i.e., how the channel connects to the voltage source in the RF generator. Figure 40’s disclosure regarding its multiplexing capabilities further confirms that the ’318 patent teaches an output channel as something that allows pairing between chosen electrodes to form a complete circuit.

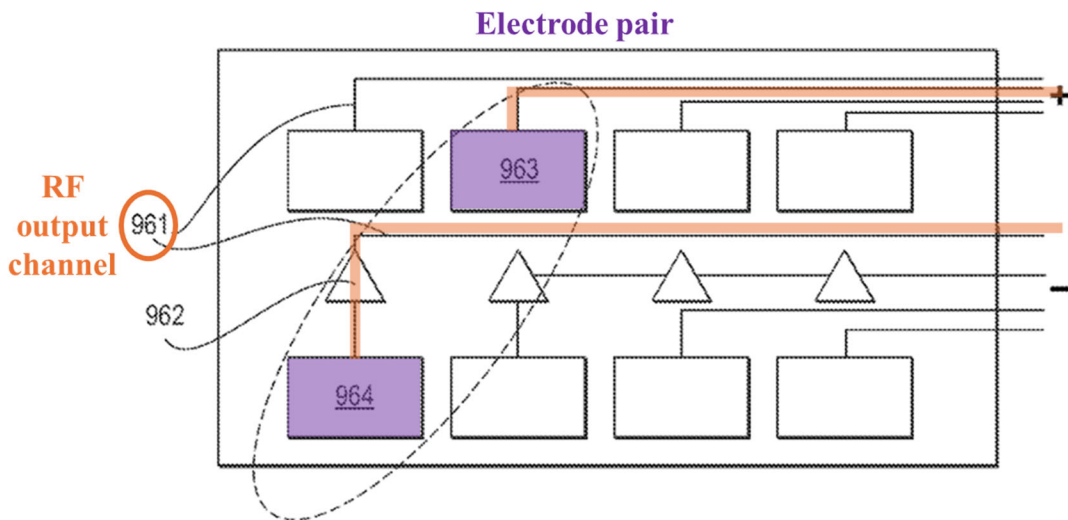


FIG. 40

Ex.1001-USP318, FIG.40.

37.The patent describes Figure 41 as follows:

“FIG. 41 is a block diagram depicting an electrode array arranged such that each electrode pair of the array of electrodes may have its own individual subsystem 970. An electrode pair may include a positive electrode 973 and a negative electrode 974. Each individual subsystem 970 may include controlled ***RF channels 971***, a first thermocouple 972 a, and a second thermocouple 972 b to allow for independent temperature readings. In some embodiments, a temperature reading for an individual subsystem 970 may be obtained from the average temperature input signals of the neighboring thermocouples 972 a and 972 b. The temperature reading may act as a feedback control to ensure that proper temperature is maintained at the site of treatment.”

Ex.1001-USP318, 49:33-45. Figure 41 shows multiple RF channels 971 pointing to all of the wires lines carrying both active signals shown by a “+” sign and return signals shown by a “-” sign. The ’318 patent never explains, shows, or limits the *beginning* of that output channel, i.e., how the channel connects to the voltage source in the RF generator. Figure 41’s disclosure regarding its feedback control system further confirms that the ’318 patent teaches an output channel as something that allows pairing between chosen electrodes to form a complete circuit.

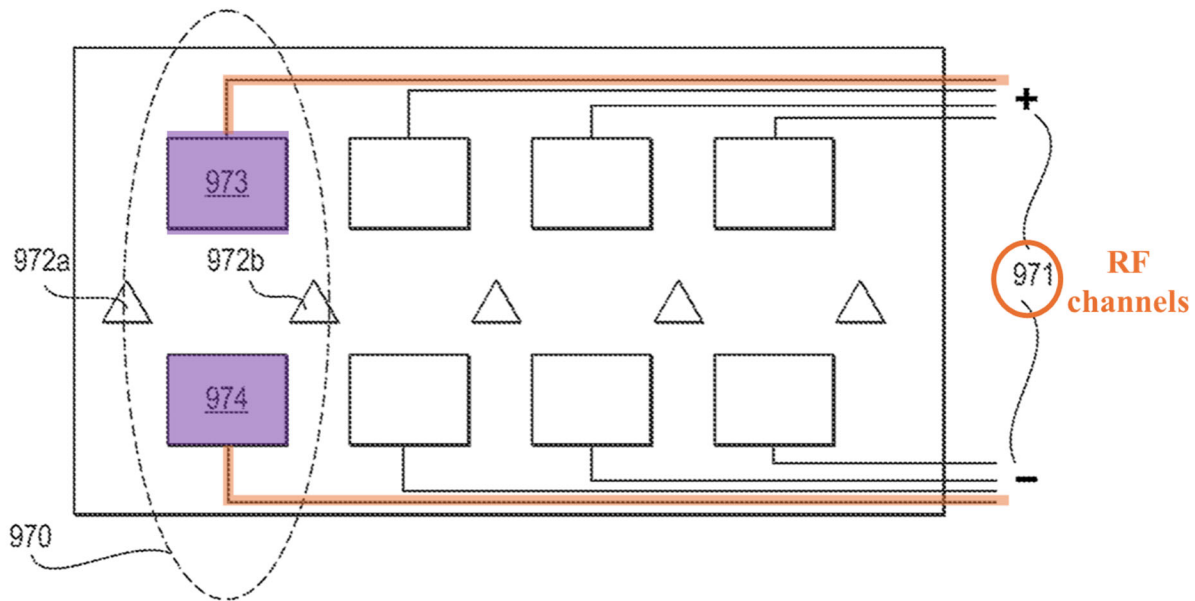


FIG. 41

Ex.1001-USP318, FIG.41.

38.The patent describes Figures 42A and 42B as follows:

“FIGS. 42A and 42B are block diagrams depicting an array of electrodes of a nasal treatment device. In some embodiments, *the device may include a multiplexed configuration by providing functionality to allow pairing of any of the positive electrodes 973 to any of the negative electrodes 974 to form a complete circuit.* A positive electrode 973 may be paired with the opposite negative electrode 974, or to any of the other negative electrodes 974 regardless of its location in the device. FIG. 42A shows one example where temperature readings may be the average of three adjacent thermocouples 972 a, 972 b, and 972 c. FIG. 42B shows one example where temperature reading may be the average of four adjacent thermocouples 972 a, 972 b, 972 c, and 972 d. It will be appreciated that the average of any number of thermocouples may be used to obtain a temperature reading.”

Ex.1001-USP318, 49:46-60. Although not explicitly labeled, these Figures also show output channels:

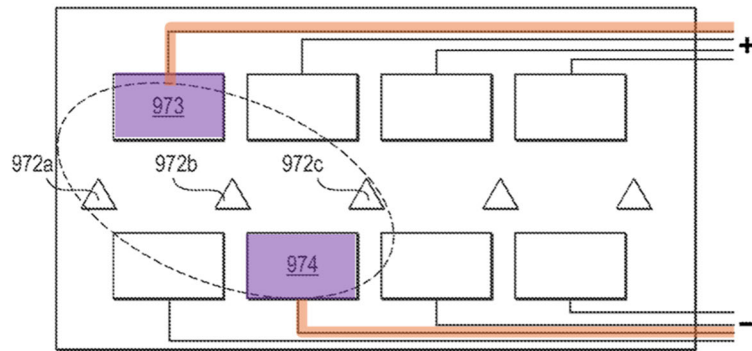


FIG. 42A

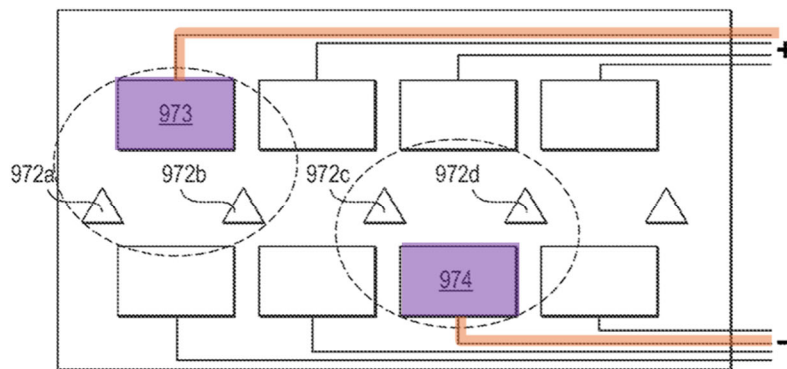


FIG. 42B

Ex.1001-USP318, FIG.42A-42B.

39.The patent describes Figure 43 as follows:

“FIG. 43 is a block diagram depicting an array of electrodes of a nasal treatment device as depicted in FIG. 39. In some embodiments, positive electrodes 983 of the array of electrodes may share a common negative electrode 984. ***Each RF output channel may include a positive electrode 983 and the negative electrode 984.*** While the negative electrode 984 is common, each positive electrode 983 ***may be independently controlled to achieve the desired treatment.*** In some embodiments, a temperature reading may be obtained from temperature input signals sensed from one or more thermocouples 982.”

Ex.1001-USP318, 49:61-50:4. The description of Figure 43 further confirms that the '318 patent teaches an output channel as something that allows pairing between chosen electrodes to control a chosen pairs of electrodes separately from another chosen pair, and gives the example that the negative electrode may be a common electrode.

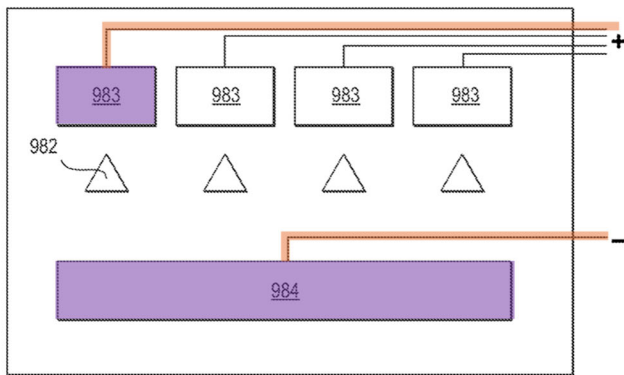


FIG. 43

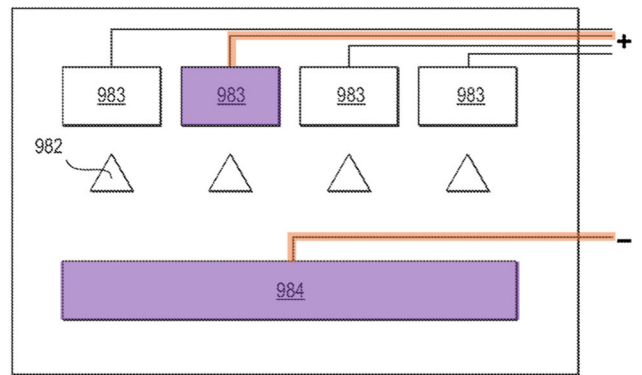


FIG. 43

Ex.1001-USP318, FIG.43. Indeed, with regard to Figure 43, the patent describes multiple channels (“each RF output channel”) despite the fact that there is only one single return line.

40.The patent describes Figure 44 as follows:

“FIG. 44 is a block diagram depicting an array of electrodes of a nasal treatment device as depicted in FIG. 40. In some embodiments, positive electrodes 993 of the array of electrodes may share a common negative electrode 994. ***Each RF output channel may include a positive electrode 993 and the negative electrode 994.*** While the negative electrode 994 is common,

each positive electrode 993 *may be independently controlled to achieve the desired treatment*. In some embodiments, a temperature reading may be obtained from temperature input signals sensed from one or more thermocouples 992.”

Ex.1001-USP318, 50:5-15. Figure 44 is described in a similar manner to Figure 43, again further confirming that a person of ordinary skill in the art would understand output channels in the manner in which it is described in the patent, as an energy connector between electrodes that allows for independent control of bipolar pairs.

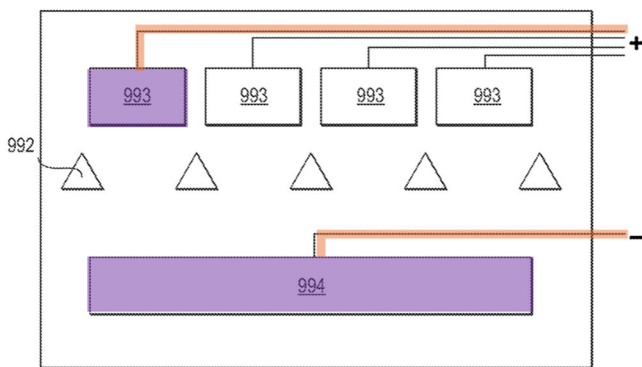


FIG. 44

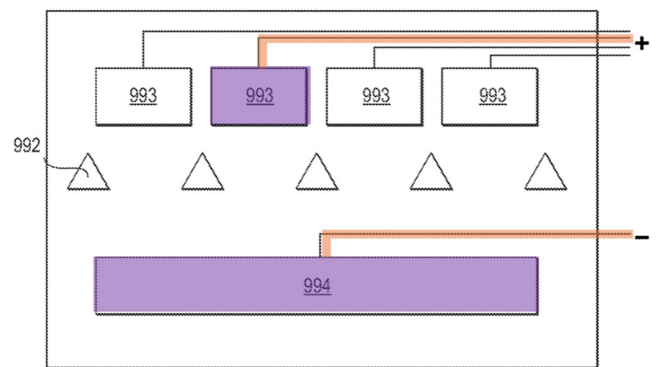


FIG. 44

Ex.1001-USP318, FIG.44.

41. Dr. Bikson’s relies on my deposition testimony and annotations to support his interpretation of “output channels” is my testimony and annotations. But this testimony and these annotations are taken out of context. The context is clear: I testified that Stern shows multiple radiofrequency output channels:

A. If you look at Stern, Stern figure 15 has a number of output channels from their device. *That's how I interpret 'output channel' to mean: output from a radiofrequency generator.*

Q. Okay. So you understand a radiofrequency output channel to be an output from a radiofrequency generator; is that correct?

A. *Yes. Similar to what Stern has in figure 15.*

Ex.2004-Martin-Tr.-Vol.2, 318:3-320:3, 320:8-12, 326:14-327:10, 328:7-329:5, 329:20-330:3; 331:1-9.

42. When I said that “output channel” means “output from a radiofrequency generator,” I meant that the “output channel” must be carrying energy, and that energy is what is output from the radiofrequency generator. This does not mean that the “channel” is required to be directly connected to the generator, or voltage source within a generator, for it to be an “output channel.” Indeed, as Dr. Bikson notes, “it was standard in circuit diagrams to use...[a] circle with a sinusoid wave inside of it...to represent a sinusoidal waveform (e.g., radiofrequency) generator.” Ex.2001-Bikson, ¶74. It was also standard in circuit diagrams to include only two wires extending from the circle, to indicate an output and an input signal. Tellingly, the voltage source symbol, along with the two wires extending from it, are absent from the circuit diagrams in the '318 patent. None of my testimony cited in paragraph 69

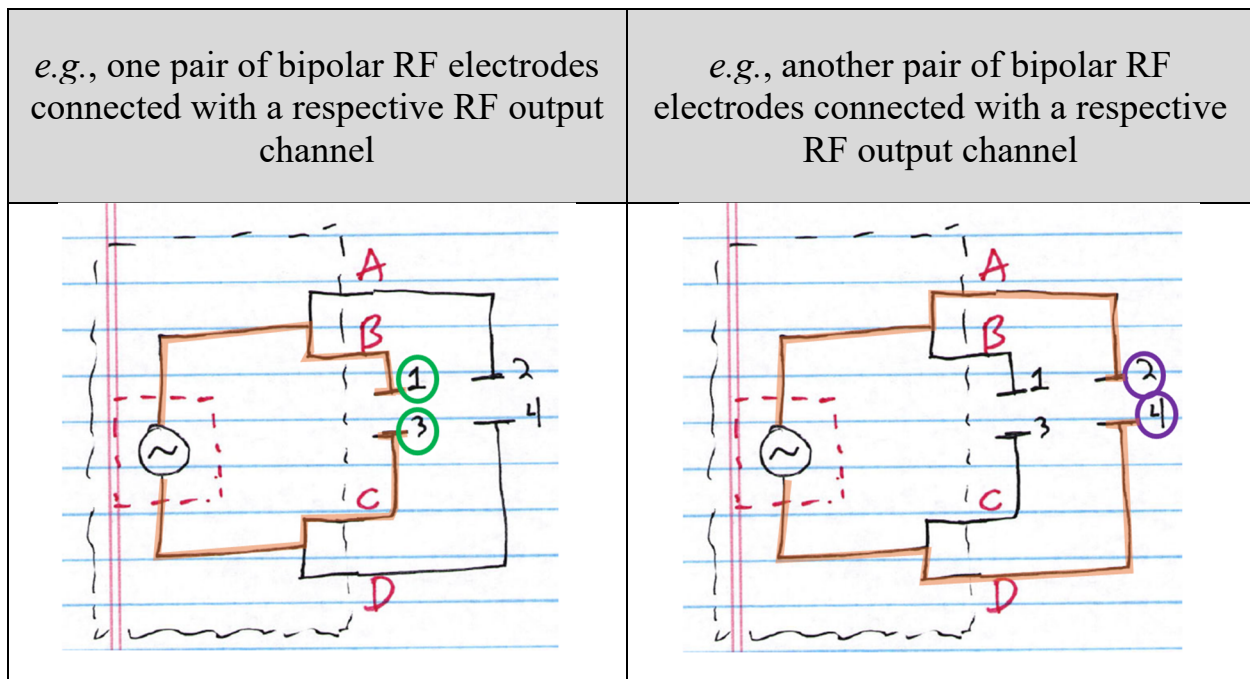
of Dr. Bikson's declaration supports interpreting "radiofrequency output channel" to mean only the direct, physical output from a radiofrequency generator. *See* Ex-2004-Martin-Tr.-Vol.2, 318:12-19, 318:20-319:9, 319:17-320:2, 327:3-4, 329:21-22). The output channel need only be a channel that carries the *output* (i.e., the radiofrequency voltage) from a radiofrequency generator to an electrode pair.

43. Dr. Bikson points to these two wires as proof that Stern taught a single-channel design. But multi-channel circuit designs also tended to show just two wires extending from the sinusoidal voltage source, which is part of the reason why, based on my experience and knowledge, I interpreted Stern's Figure 15 to be a schematic of a multi-channel circuit.

44. Dr. Bikson views the '318 patent as solving the problem faced by single-channel designs where current would be diverted to the electrodes that experience less impedance. *See* Ex.2001-Bikson, ¶80; Ex.1001-USP318, 48:53-62 ("The pair(s) of electrodes that have a higher degree of contact with the tissue may experience higher magnitudes of impedance in their individual circuit. Since treatment energy takes the path of least resistance, this may lead to treatment energy being diverted to pairs of electrodes that experience a relatively lower magnitude of impedance due to a relatively lower degree of tissue contact. Thus, it may be advantageous to control the treatment energy through each electrode to ensure

repeatable treatments.”). But Stern identifies this same problem and offers the circuitry of Figure 15 as a solution: “Th[e] lack of a current between leads is extremely important because the tissue which contacts the electrodes causes an effective shunt current path....In specific instances, it would be more precise to provide a more even heating of a uterus or other body organ if the electrode could have a controlled return path for the current. In such instances, if particular pairs of electrodes were chosen in a bipolar arrangement to receive RF energy, the return path could be controlled selectively by a physician who is performing a visual inspection by means of an x-ray, ultrasound, or other detection device. This precise control can only be afforded in a bipolar arrangement....The device of FIG. 15 provides an apparatus for both bipolar and monopolar application of RF energy with the choice of either bipolar or monopolar being made by control of the switches. Furthermore, not only are the modes selectable by controlling the switches but also within the bipolar mode, for instance, the switches allow for the selective application of RF energy to various combinations of electrodes.”) Ex.1033-Stern, 11:66-12:46. Stern therefore explains the advantages associated with Figure 15, a multi-channel circuit, and clearly shows that the energy is broken down into multiple channels after it is output from the radiofrequency generator—no direct connection to the voltage source is required to form multiple output channels.

45. Consistent with the '318 patent specification and its description of Figures 39 and 40, among others, it is my opinion that an “output channel” connects electrodes and provides the ability to independently control pairs of electrodes. The embodiments in the '318 patent describe exactly what Dr. Bikson opines should be excluded from the scope of the claims—an output wire extending from the voltage source (not shown) which further branches into multiple output channels (shown as reference numeral 961 in Figures 39 and 40 (and others) of the '318 patent). Dr. Bikson also points to my annotation to show a single output channel. Ex.2003. However, as shown below in orange, my original annotation contains at least two output channels under my proper interpretation of “output channel:”



Ex.2007 (annotated). I also testified to this effect:

Q. If you assume that the black dotted rectangle around the circle is the -- designates the radiofrequency generator, in that case how many radiofrequency output channels would you say that this circuit has?

A. Two.

Q. Why do you say that?

A. Well, because this would be one channel, this would be another channel.

Q. So just --

A. So each electrode -- each electrode pair, as you've drawn them, implied, is fed by a channel.

...

A. ...So you could say *A and D form a channel*, and *B and C form a channel*.

Ex.2004-Martin-Tr.-Vol.2, 431:6-432:15. As I explained in my deposition, the above image shows at least two output channels. I note that while I provided the example of A and D forming channel and B and C forming a channel, it is also my opinion that there are other combinations of electrode pairs which would create channels. For example, A and C could form a channel and B and D could form a channel.⁴

⁴ I also note that unlike Figure 15 of Stern, which includes various switches for controlling outputs to various channels and electrodes, the hypothetical drawing that I was asked to construct in my deposition does not have any switches. See Ex.2003.

46. Dr. Bikson also opines that “I understand that Dr. Martin agrees that the demonstrative circuit reproduced above has only one radiofrequency output channel if the red dashed box designates the radiofrequency generator.” Ex.2001-Bikson, ¶72. That was not my testimony. Based on the drawings above, I was asked a hypothetical about how many channels there would be if I were to assume that the radiofrequency generator was contained within the red box. But that was in relation to questions about channels, or “radiofrequency hub[s]” associated with the generator. Ex.2004-Martin-Tr.-Vol.2, 430:20-431:2. Dr. Bikson does not discuss my testimony when I was asked to assume that the radiofrequency generator was contained within the black box, where I clarified that I was talking about output channels from the generator:

Q. If you assume that the black dotted rectangle around the circle is the -- designates the radiofrequency generator, in that case how many radiofrequency output channels would you say that this circuit has?

...

A. Two.

Q. Why do you say that?

A. Well, because this would be one channel, this would be another channel.

Q. So just --

A. So each electrode -- each electrode pair, as you've drawn them, implied, is fed by a channel.

Q. So I guess just since the stenographer can't -- just kind of use like the numbers of electrodes when you're designating a pair. So I'll let you speak.

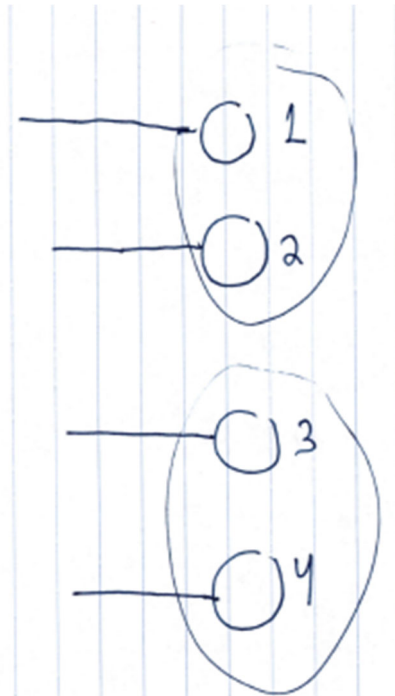
A. So the implication here is this would be *a two-channel RF generator*.

Ex.2004-Martin-Tr.-Vol.2, 431:6-432:4; *see also* 432:16-432:21 (“Q. Okay. So I guess in this diagram the number of output channels depends on how *you’re defining the radiofrequency generator*. Is that fair to say?... A. I would say you’re *correct....*”). As I testified, “the concept of ‘channel’ is not – *there’s no specific definition*” so with reference to this drawing I was discussing a “a one-channel *RF generator*” and “a two-channel *RF generator*.” *Id.* 432:21-433:6. But as I explained above, neither the patent nor the claims define the channels relative to the generator. Rather, they simply recite “radiofrequency output channels.” My answers to questions about how many output channels the hypothetical radiofrequency generators in red and black boxes would have do not support Dr. Bikson’s conclusion that the claimed “radiofrequency output channels” must be direct outputs from a radiofrequency generator.

2. **The prior art discloses “multiple radiofrequency output channels” under either construction**

47. Even if Dr. Bikson’s interpretation was correct, that would not change my opinion that Stern discloses “multiple radiofrequency output channels” because even under Dr. Bikson’s interpretation, Stern teaches “multiple radiofrequency output channels,” as demonstrated by the information Dr. Bikson provided at his deposition.

48. At his deposition, Dr. Bikson was asked to “draw a device that has multiple radiofrequency output channels as required by [claim 1 of the ’318 patent].” Ex.1084-Bikson-Tr.,194:13-15. Dr. Bikson drew the below figure, which I agree with. It does not include a voltage source, and draws output channels as they relate to electrodes:



Ex.1089 (Exhibit E to Dr. Bikson’s deposition). He explained:

And I’m drawing wires going to electrodes one and two. And I’m drawing wires going to electrode three and four. And I guess I’ll put a circle around one and two and around three and four, so each -- this is one bipole and this is another bipole. And the wires coming to them would represent one channel and this would represent another channel.

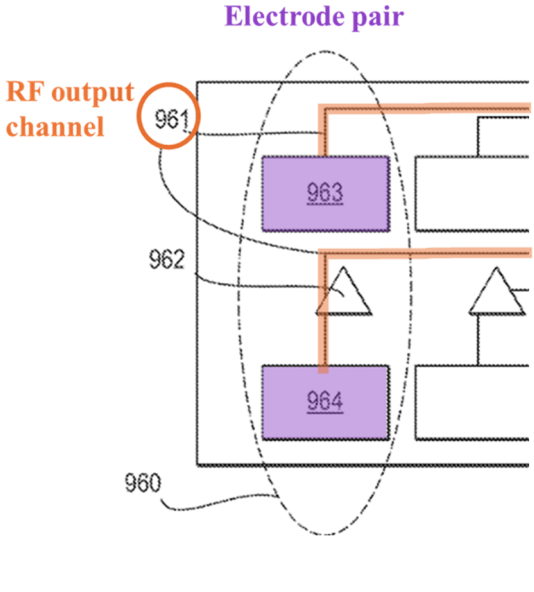
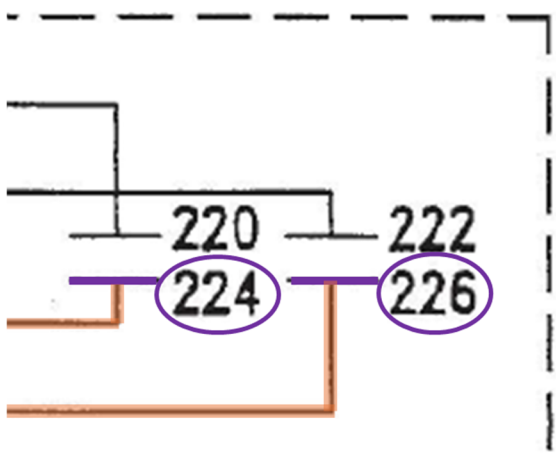
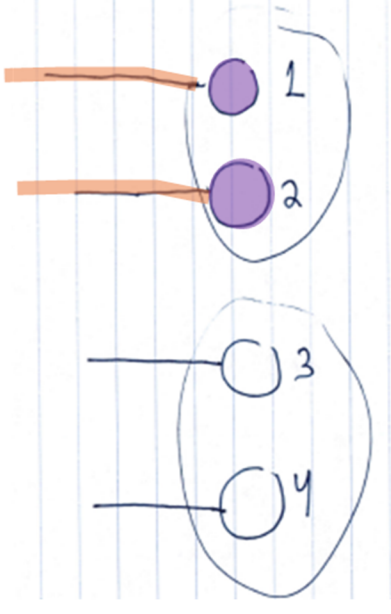
Ex. 1084-Bikson-Tr., 194:19-195:4. He did not draw a voltage source in his depiction of a circuit with multiple radiofrequency output channels, and confirmed that the “voltage source is not shown here.” Ex. 1084-Bikson-Tr.,195:6. Dr. Bikson also agreed that “in the dashed box in Stern Figure 15, it also shows four electrodes and each electrode is connected to its own wire”:

It’s correct that in Figure 15 from Stern you have four electrodes and each electrode is associated with a wire.

Ex. 1084-Bikson-Tr., 96:6-11.⁵ Dr. Bikson’s explanation and drawing confirms that Stern discloses “multiple radiofrequency output channels” under his interpretation.

49. In my opinion, Dr. Bikson’s drawing is also consistent with the ’318 patent’s figures and Stern Figure 15, which shows multiple radiofrequency output channels because, as Dr. Bikson stated, each image shows wires connecting each of the electrode pairs forming an output channel. In the annotated images below, I identify one of the two or more output channels present in each image:

⁵ Dr. Bikson concluded that all of the electrodes are “energized” in his depiction. Ex.1084-Bikson-Tr., 196:18-197:3. For the reasons explained above in Section VII.A.1, the claims do not require the multiple pairs of bipolar electrodes to be active at the same time. Further, it makes little sense why, in Dr. Bikson’s view, the claims require “separate control” of the bipolar electrode pairs while simultaneously requiring multiple bipolar pairs that are active at the same time. Ex.2001-Bikson, ¶80. Separate control would be materially hampered if, for example, an electrode pair that got too hot or applied too much energy could not be turned off without turning off all other electrodes.

Ex.1001-USP318, FIG.39.	Ex.1033-Stern, FIG.15.
 The diagram shows an RF output channel (961) connected to a circuit. A dashed oval labeled "Electrode pair" encloses two rectangular blocks, 963 and 964, connected by a vertical line. A triangle symbol is positioned between these blocks. A horizontal line (962) runs through the middle of the electrode pair. A reference line (960) is at the bottom. The entire circuit is connected to a network of horizontal lines on the right.	 The diagram shows a circuit with two horizontal lines at the top. Below them are two pairs of horizontal lines, each pair enclosed in a purple oval. The top pair is labeled 220 and 222, and the bottom pair is labeled 224 and 226. The lines are connected to a network of horizontal lines on the left and right.
Ex.1087, Ex. B to Dr. Bikson's Deposition.	
 The diagram shows a hand-drawn circuit on lined paper. It consists of two pairs of horizontal lines, each pair connected to a purple circle. The top pair is labeled 1 and 2, and the bottom pair is labeled 3 and 4. The circles are connected to a network of horizontal lines on the left and right.	

Consistent with Dr. Bikson's testimony, Figure 15 of Stern discloses multiple radiofrequency output channels, which would include the one shown above supplying energy to electrodes 224 and 226, and another supplying energy to electrodes 220 and 222. Likewise, Dr. Bikson's drawing shows two similar output channels—one supplying electrodes labeled 1 and 2, and another supplying electrodes labeled 3 and 4. Therefore, Stern discloses multiple radiofrequency output channels even under Dr. Bikson's understanding of the claims.

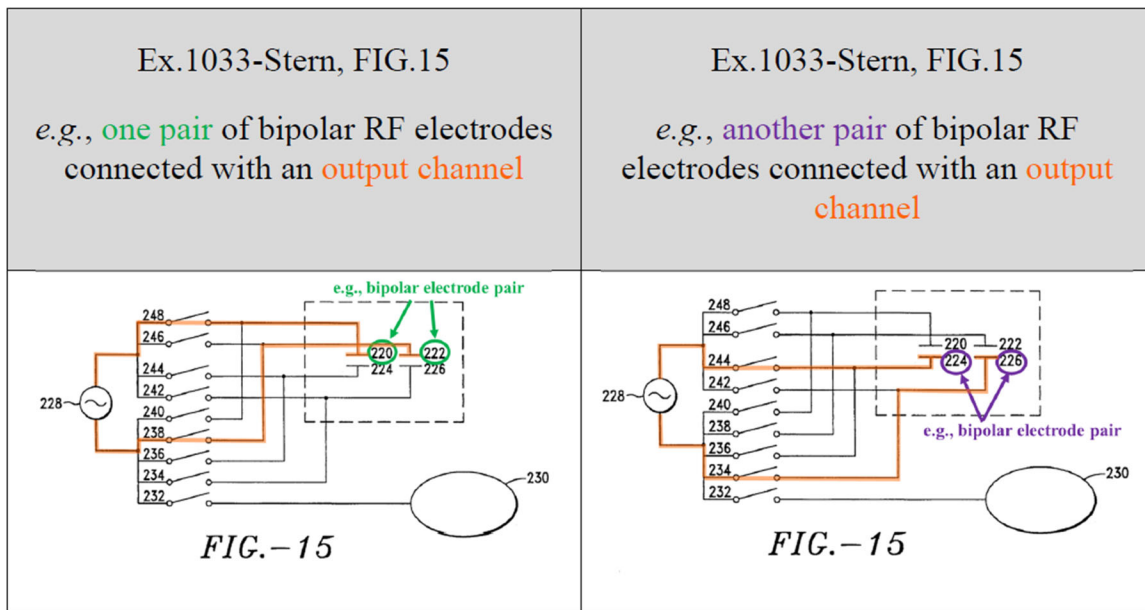
C. The combinations of Edwards-'535 and Stern (Ground I) and Makower and Stern (Ground IV) teach limitation 1[e]: “wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels.”

50. Dr. Bikson appears to disagree that Stern teaches “wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels” because all electrode pairs are coupled to “the same output of Stern's voltage source 228.” Ex.2003-Bikson, ¶¶82-83. Moreover, I understand that the Patent Owner argues that my analysis as to whether “wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels” is conclusory. POR, 26. I disagree with both assertions.

51. **First**, as I explained *supra* Section VII.B, the claims do not require separate outputs from a voltage source to form multiple channels, but that if they do Stern discloses such limitation. Dr. Bikson’s disagreement is therefore a rehashing of his incorrect interpretation of “radiofrequency output channels.”

52. **Second**, my First Declaration was sufficiently detailed and not conclusory. I explained in detail how Stern’s Figure 15 “depicts the circuitry that supplies energy to selected bipolar pairs via separate, controlled electrical channels *to allow each bipolar pair to be activated separately.*” Ex.1002, ¶127. I separately noted in my discussion of Stern that “Stern also teaches that *each pair may be connected to its own output channel.*” Ex.1002, ¶63. I incorporated my analysis of Stern from Ground I into my analysis for the combination of Makower and Stern in Ground IV. Ex.1002, ¶291.

53. Additionally, I offered a chart with two annotated examples showing two separate output channels. One pair of bipolar radiofrequency electrodes is connected with a respective one radiofrequency output channel in the annotated image on the left, and another pair of bipolar radiofrequency electrodes is connected with a different radiofrequency output channel:



Ex.1002, ¶124.

VIII. CHALLENGED CLAIM 5 IS OBVIOUS OVER EDWARDS-’535, AND STERN (GROUND I) AND MAKOWER AND STERN (GROUND IV)

54. Claim 5 recites: “The device of claim 4, wherein at least one pair of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments.” Ex.1001-USP318, cl.5. Claim 4, from which claim 5 depends, recites: “The device of claim 1, wherein the treatment element comprises multiple segments that are expandable from the first configuration to the second configuration.” Ex.1001-USP318, cl.4.

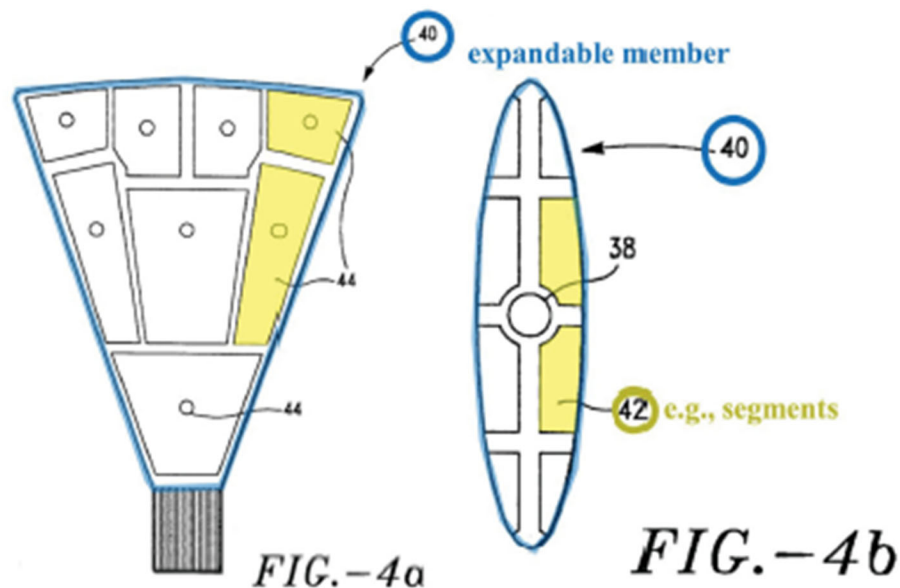
55. For the reasons I explained in my First Declaration, claim 5 of the ’318 patent would have been obvious over both (1) the combination of Edwards-’535 and

Stern (Ex.1002, ¶¶166-173), and (2) the combination of Makower and Stern (Ex.1002, ¶¶312-315). In my First Declaration, I explained that a person of ordinary skill in the art would have been motivated to combine Edwards-'535 and Stern (Ex.1002, ¶¶166-172) and that a person of ordinary skill in the art would have been motivated to combine Makower and Stern, each with a reasonable expectation of success (Ex.1002, ¶¶312-315). Dr. Bikson does not appear to disagree that a person of ordinary skill in the art would have been motivated to make these combinations. Dr. Bikson also does not appear to disagree with me that the combination of Makower in view of Stern renders claim 5 obvious.

56. Dr. Bikson does, however, appear to disagree with me that Edwards-'535 in view of Stern teaches claim 5, which requires “wherein at least one pair of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments.” Ex.2001-Bikson, ¶86. Dr. Bikson explains his opinion in with only one statement in his declaration that expresses his disagreement with my opinion, stating, without explanation, that “Stern teaches that each of its surface segments has one electrode and one thermistor—not two electrodes.” Ex.2001-Bikson, ¶88. I disagree with Dr. Bikson’s reading of Stern.

57. **First**, as I explained in my First Declaration, Stern describes Figures 4A and 4B as having segments 42 that each have a conductive surface and are

electrically connected to a power source. Ex.1002, ¶¶166-172. Stern also explains that these segments are “electrode area segments” and that power can be selectively applied to these segments using the schematic in Figure 15 in a bipolar configuration. Ex.1002, ¶169; Ex.1033-Stern, 5:48-50.



Ex.1033-Stern, FIGs.4a-4b.

58. Dr. Bikson appears to conflate an “electrode area segment” as disclosed by Stern with only one electrode. Ex.2001-Bikson, ¶88. That is not what Stern discloses. Rather, Stern discloses that “power” is delivered “to each segment.” Ex.1033-Stern, 8:55-56. In a monopolar embodiment, a segment may have a single electrode because that is all that’s required to supply energy. However, in a bipolar embodiment, for example one involving the bipolar operation of Stern’s Figure 15

that I identified in my First Declaration (Ex.1002, ¶¶166-172), the segment would have two electrodes. This is confirmed by Stern's disclosure that "[e]ach [conductive] segment 42 is electrically connected through conventional *leads* to a power source." Ex.1033-Stern, 8:56-57. That is, *each singular segment* has *plural leads* to connect to a power source. That makes sense in a bipolar context, where each segment would have two electrodes, and separate leads to connect the segment to the power source. Therefore, Stern discloses that "at least one pair of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments" as required by claim 5.

59. *Second*, my opinion that Stern discloses claim 5 is confirmed by the '318 patent specification. Even assuming, incorrectly, that Stern discloses that segments 42 only have one electrode, the combination of two such segments in a bipolar configuration would have been obvious and would disclose a segment to which a pair of bipolar radiofrequency electrodes is coupled. Such electrodes would be coupled to the segment in two ways: (1) the pair of electrodes is electrically coupled, with one of the two electrodes being physically coupled to a segment 42 and (2) the two segments 42 with separate electrodes, when controlled together, would form a segment as a whole. The '318 patent specification does not support any narrowing of the meaning of "segment" that would exclude these examples from

the scope of claim 5. The term “segment[s]” appears just once in the ’318 patent in this context:

*“With reference to FIGS. 4A-4C, some embodiments of treatment elements 32 may comprise one or more inflatable or expandable sections configured to expand from a collapsed configuration for insertion into the nasal passageway, to an expanded configuration in which some portion of the treatment element 32 contacts and engages an internal surface of a nasal passageway. In some embodiments, an expandable treatment element may comprise an inflation lumen configured to facilitate injection of an inflation medium into an expandable portion of the treatment element. In alternative embodiments, an expandable treatment element may comprise one or more **segments** comprising a shape-memory alloy material which may be configured to expand to a desired size and shape in response to a change of temperature past a transition temperature. In some embodiments, such a temperature change may be brought about by activating an energy-delivery (or removal) element in the treatment element 32.”*

Ex.1001-USP318, 18:13-20. As shown above, the term “segments” appears in a paragraph discussing Figures 4A-4C, which are embodiments of “treatment element shape[s].” See Ex.1001-USP318, 9:1-6.

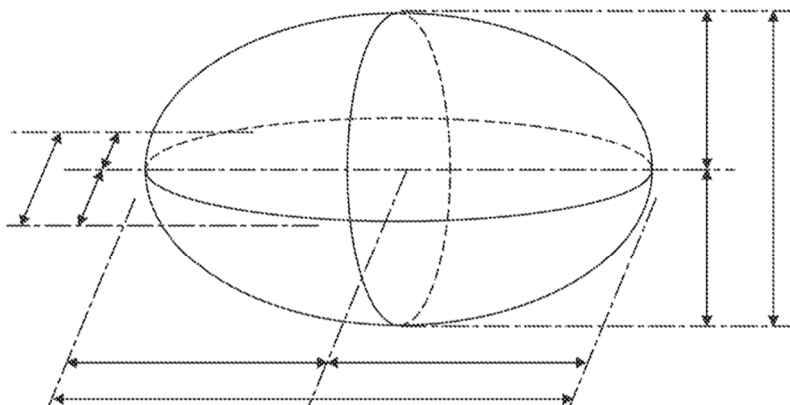


FIG. 4A

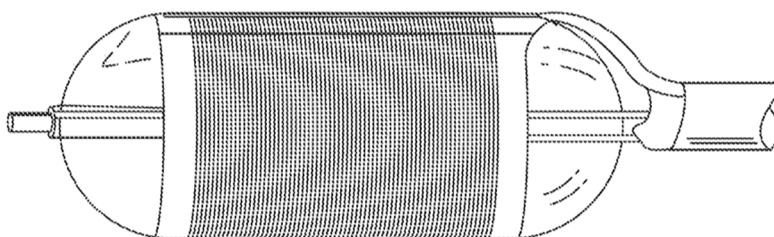
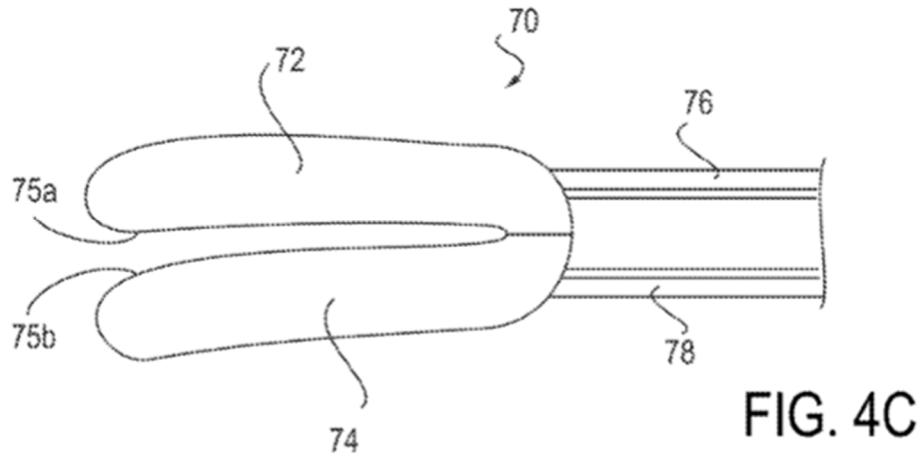


FIG. 4B



Ex.1001-USP318, FIGs.4A-4C. As shown above, there are no reference numerals in Figures 4A and 4B. Figure 4C points to bifurcated “elements 72, 74,” that “may include substantially self-expandable sections” and further indicates that these “halves 72, 75 may also carry energy delivery structures.” *See* Ex.1001-USP318, 17:28-49; FIG.4C. It is unclear whether these “halves” are the described “segments.” The ’318 patent therefore does not show any examples of “at least one pair of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments.” The ’318 patent does not support an interpretation of “segment” that would exclude (1) an electrically coupled bipolar pair of electrodes from being coupled with a segment by virtue of one electrode sitting on or forming a segment or (2) a segment formed by two segments 42 controlled as a bipolar pair.

60. **Third**, in my First Declaration I also incorporated my discussion of claim 4, which did not rely exclusively on Stern. Rather, I explained how Edwards-'535 also discloses the claimed segments. Ex.1002, ¶159, 163-164. When controlling Edwards-'535's electrodes in pairs as taught by Stern, the prior art shows that each pair of electrodes is on a respective segment. And Dr. Bikson does not dispute that Edwards-'535 discloses segments that include two electrodes 156. When the electrodes are delivering energy in bipolar operation, they can be paired such that "at least one pair of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments."

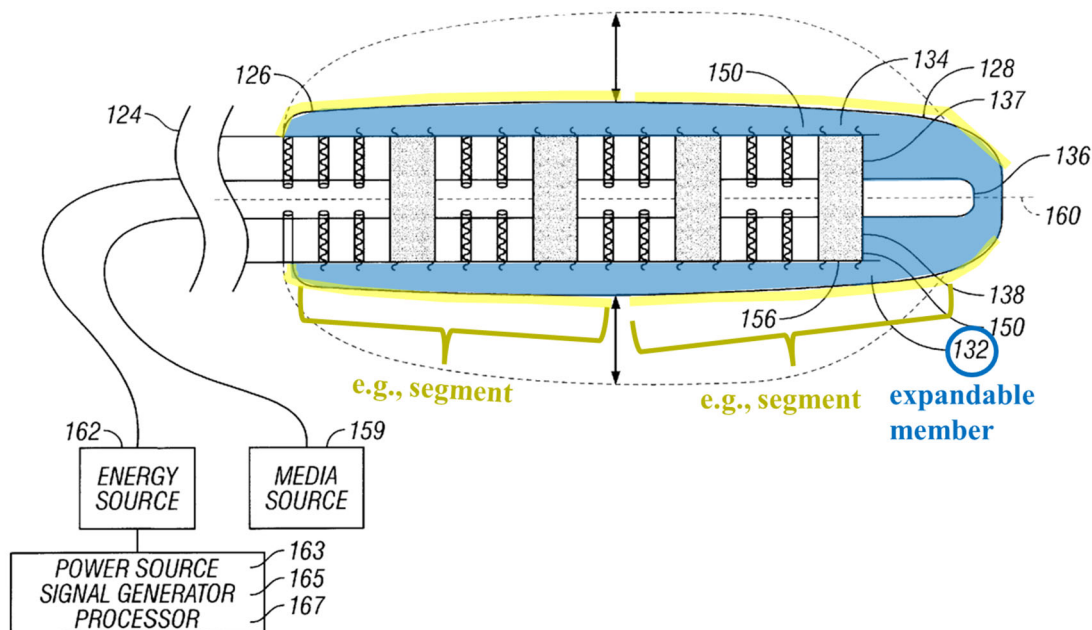


FIG. 6

Ex.1002, ¶¶163-164.

**IX. CHALLENGED CLAIM 6 IS OBVIOUS OVER THE
COMBINATIONS OF EDWARDS-'535, STERN AND PATEL
(GROUND II) AND MAKOWER AND STERN (GROUND IV)**

61. Claim 6 recites: “The device of claim 4, wherein the multiple segments comprise a shape-memory alloy material configured to expand to a desired size and shape.” Ex.1001-USP318, cl.6. Claim 4, from which claim 6 depends, recites: “The device of claim 1, wherein the treatment element comprises multiple segments that are expandable from the first configuration to the second configuration.” Ex.1001-USP318, cl.4.

62. In my First Declaration, I explained that dependent claim 6 of the '318 patent was obvious over both the combination of Edwards-'535 in view of Stern and Patel (Ex.1002, ¶¶233-240), and the combination of Makower and Stern (Ex.1002, ¶¶316-319). Dr. Bikson does not appear to disagree with me that a person of ordinary skill in the art would have been motivated to combine Edwards-'535 and Stern and Patel, or that a person of ordinary skill in the art would have been motivated to combine Makower and Stern, with a reasonable expectation of success. Rather, Dr. Bikson appears to disagree with me that the combinations teach claim 6's limitation that “the multiple segments comprise a shape memory alloy material configured to expand to a desired size and shape.” Ex.2001-Bikson, ¶¶105-112, 118-123. For the reasons explained below, I disagree with Dr. Bikson.

63. Dr. Bikson's arguments do not change my opinion that claim 6 of the '318 patent would have been obvious. Therefore, as I explained in my First Declaration and further below in this Reply Declaration, both the combination of Edwards-'535 in view of Stern and Patel (Ground II) and the combination of Makower and Stern (Ground IV) teach claim 6.

A. The combination of Edwards-'535, Stern, and Patel (Ground I) teaches claim 6: “[t]he device of claim 4, wherein the multiple segments comprise a shape-memory alloy material configured to expand to a desired size and shape.”

64. Dr. Bikson opines that Edwards-'535 in view of Stern and Patel does not teach “wherein the multiple segments comprise a shape-memory alloy material configured to expand to a desired size and shape.” Ex.2001-Bikson, ¶¶105-112. It is Dr. Bikson's opinion that claim 6 prohibits electrodes as being the claimed “segments.” Ex.2001-Bikson, ¶110. I disagree with Dr. Bikson's interpretation of the scope and requirements of claim 6.

65. ***First***, Dr. Bikson opines that the claimed “multiple segments” are different than electrodes because the claims recite both “bipolar radiofrequency electrodes” and “multiple segments” separately, and therefore the two must be distinct elements. Ex.2001-Bikson, ¶¶109-111. Dr. Bikson's interpretation is not supported by the '318 patent's description of segments or the plain language of the

claims because nothing in the '318 patent or in the claims excludes electrodes from being the claimed "segments." The '318 patent only describes these segments only once in this context:

*"With reference to FIGS. 4A-4C, some embodiments of treatment elements 32 may comprise one or more inflatable or expandable sections configured to expand from a collapsed configuration for insertion into the nasal passageway, to an expanded configuration in which some portion of the treatment element 32 contacts and engages an internal surface of a nasal passageway. In some embodiments, an expandable treatment element may comprise an inflation lumen configured to facilitate injection of an inflation medium into an expandable portion of the treatment element. In alternative embodiments, an expandable treatment element may comprise one or more **segments comprising a shape-memory alloy material** which may be configured to expand to a desired size and shape in response to a change of temperature past a transition temperature. In some embodiments, such a temperature change may be brought about by activating an energy-delivery (or removal) element in the treatment element 32."*

Ex.100-USP318, 18:3-20. I have reviewed this disclosure and Figures 4A-4C, and do not see anything that describes the relationship between segments and electrodes, much less any description that requires them to be separate physical components. Rather, the '318 patent explains that the "segments" can "compris[e] a shape-memory alloy material." *Id.*, 18:14-16. Such alloys are well known to be conductive, which is required for electrodes.

66. The other dependent claims in the '318 patent also contradict Dr. Bikson's reading of claim 6. Claim 5 is the only claim that expressly recites a physical relationship between the segments and electrodes. But claim 6 does not depend from claim 5 or recite such a physical relationship. Both claims depend from claim 4, which recites: "[T]he device of claim 1, wherein the treatment element comprises multiple segments that are expandable from the first configuration to the second configuration." Therefore, claim 4 (and thus claim 6) is broader than the physical relationship defined in claim 5, and therefore encompasses electrodes that are not on the segments, such as segments that "comprise" the electrodes. Dr. Bikson's interpretation is inconsistent with the '318 patent claims because it would import the requirements of claim 5 into claims 4 and 6.

67. **Second**, Dr. Bikson opines that Patel's electrodes are not "configured to expand to a desired size and shape" because Patel's electrodes "allow folding or furling of the balloon during insertion," which according to Dr. Bikson, is the opposite of expanding. Ex.2001-Bikson, ¶112. I disagree. As I explained in my First Declaration, Patel describes a balloon that is "inserted into the body in a collapsed state, then inflated with liquid after insertion to expand the balloon, and the balloon's surface is then pressed against tissue." Ex.1002, ¶237; Ex.1034-Patel [0038]. Patel further explains that electrodes 302 and 304 on expandable balloon

106 “are made of thin flexible metallic strips to allow folding or furling of the balloon during insertion.” Ex.1034-Patel, [0090]. In the same paragraph, Patel explains that “[t]ypical cross-section diameter dimension of the device *with the balloon collapsed* may be 2.2 mm *to allow introduction through the channel* of a diagnostic upper endoscope, *on inflation the balloon may expand* to a diameter size of 3.5 mm.” *Id.*; *see also* Ex.1034-Patel, [0085] (“In FIG. 1B, the collapsed balloon has been rolled or furled” but “after the probe has been passed through the channel 112 of the endoscope 108 and is projecting from the distal end of the endoscope the balloon can then be inflated to the shape of a sphere.”). That is, Patel uses the same term as the claim: “expand.” Patel further teaches that the electrodes can be made of “nitinol,” a shape-memory alloy, which facilitates this expansion process. *Id.*, [0090]. Patel’s express disclosure of expanding is consistent with my experience as a medical device designer. In my experience, whenever a balloon is folded or furled during insertion, it necessarily expands from its folded to unfolded state during deployment. As I explained in my First Declaration, Patel therefore renders obvious electrodes “comprise a shape-memory alloy material configured to expand to a desired size and shape.” Ex.1002, ¶¶234-240.

B. The combination of Makower and Stern (Ground IV) teaches claim 6: “[t]he device of claim 4, wherein the multiple segments

comprise a shape-memory alloy material configured to expand to a desired size and shape.”

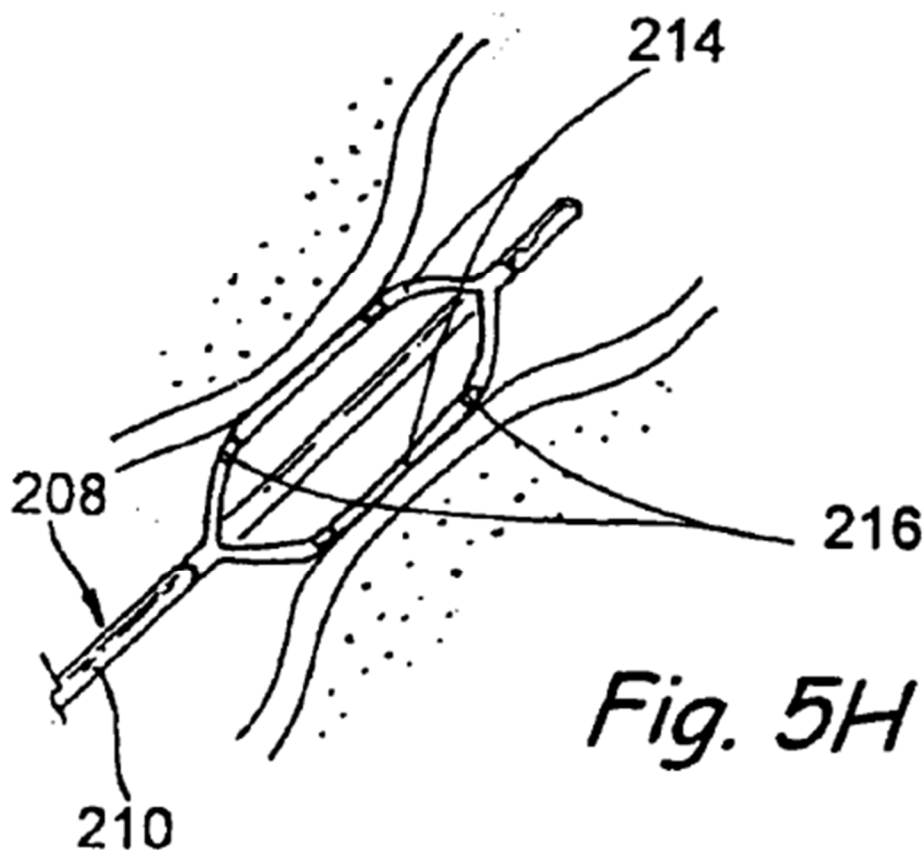
68. Dr. Bikson opines that Makower in view of Stern does not teach “wherein the multiple segments comprise a shape-memory alloy material configured to expand to a desired size and shape” because, in his opinion Makower does not expressly teach that its strut members are made of nitinol. Ex.2001-Bikson, ¶¶118-122. According to Dr. Bikson, Makower’s teaching regarding the deflection of its strut members is unrelated to Makower’s teaching that a shape memory alloy can be used to deflect various sections of the catheter. Ex.2001-Bikson, ¶123. For the reasons I explain below, I disagree.

69. As I explained in my First Declaration, Makower discloses that its “strut members 214 may be collapsible and expandable.” Ex.1021-Makower, [0187], Ex.1002, ¶¶316-318. This collapsing and expansion requires deflection of the strut members 214, which are indisputably found at the end of Makower’s catheter. I also described in my First Declaration Makower’s teachings regarding “shape memory alloys such as nitinol” which “predictably deflect various sections of the catheter.” Ex.1002, ¶318; Ex.1021-Makower, [0194]. I also explained that Makower describes nitinol as a “design element that impacts performance features” like catheter deflections. Ex.1002, ¶318; Ex.1021-Makower, [0194]. Therefore, a

person of ordinary skill in the art would have understood Makower's shape memory alloy would have been used to facilitate the performance feature of deflecting the strut members 214.

70. My opinion was also supported by my discussion with respect to claim 4 for Ground I, which was incorporated into my opinions with regard to claim 6. Ex.1002, ¶316. In my discussion of claim 4 for Ground I, I explained the advantages that nitinol provides in medical devices and how it was well-known to use nitinol inside the body. Ex.1002, ¶¶239, 318. For example, I explained how nitinol has excellent thermal conductivity and biocompatibility and is especially advantageous in the situation where, as Makower describes, a device is inserted into the body in a collapsed state, expanded to deliver treatment, and re-collapsed for removal, because nitinol is flexible, provides easy shape change, and conforms to irregularly shaped tissue. Ex.1002, ¶239. Dr. Bikson does not disagree with me about the prevalence and advantages of using nitinol. Therefore, in light of Makower's disclosure that nitinol "impacts performance features" and helps facilitate "deflect[ion]," Ex.1021-Makower, [0194], and a person of ordinary skill in the art's understanding that nitinol was commonly used to facilitate flexible medical devices, I disagree with Dr. Bikson that a person of ordinary skill in the art would interpret Makower's teaching of using nitinol to exclude the portions of Makower's catheter shown in Figure 5H.

Given the advantages of nitinol, Makower's teaching that its strut members "may be collapsible and expandable," taken in light of the well-known benefits of nitinol, supports my conclusion that Makower teaches that its strut members be made out of nitinol. Ex.1021-Makower, [0187], [0194]; Ex.1002, ¶¶316-318.



Ex.1021-Makower, FIG.5H.

71. My opinion is also bolstered by Makower's disclosure to use nickel titanium alloy (which is indisputably a shape-memory material) elsewhere besides just the catheter shaft. For example, in my First Declaration, I noted that Makower

discloses using nickel titanium alloy for the frame (i.e., *device*) described in paragraph [0149]. Ex.1002, ¶158; Ex-1021-Makower, [0149]. This is just one example. Makower also explains that “any of the catheters, ... [or] working devices or other devices disclosed in this patent may be rendered ... volitionally bendable” by using “shape memory materials (e.g., nickel titanium alloys...) to induce the device to undergo the desired bending or curvature after it has been inserted into the body.” Ex.1021-Makower, [0195]. Likewise, Makower discloses other devices (e.g., an occluder) that are made from nitinol. Ex.1021-Stern, [0150]. Dr. Bikson does not address these disclosures in Makower, and only interprets paragraph [0194] in isolation, rather than reviewing Makower’s disclosure as a whole. The fact that Makower discloses that many components can be made from nitinol or a nickel titanium alloy reinforces my opinion that Makower teaches using a shape memory alloy for other components like the struts of FIG. 5H.

72. Finally, I note that the Examiner, citing to paragraph [0194] of Makower, found that Makower taught this limitation during prosecution. Ex.1003-USP318FH, 509. In response, the Patent Owner’s amended the independent claims. Ex.1002, ¶¶46-49.

X. CHALLENGED CLAIM 9 IS OBVIOUS OVER THE COMBINATIONS OF EDWARDS-’535 AND STERN (GROUND I),

**EDWARDS-'535, STERN AND EDWARDS-'886 (GROUND III) AND
MAKOWER, STERN, AND EDWARDS-'886 (GROUND V)**

73. Claim 9 recites: “The device of claim 1, further comprising: a radiofrequency generator configured to receive sensed signals from the multiple sensors and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels in the form of a 460 KHz sinusoid wave; and a cable coupled to the handle for plugging the handle into the radiofrequency generator.” Ex.1001-USP318, c1.9.

74. In my First Declaration, I explained that dependent claim 9 of the '318 patent would have been obvious over the combination of Edwards-'535 in view of Stern (Ex.1002, ¶¶173-190), Edwards-'535 in view of Stern and Edwards-'886 (Ex.1002, ¶¶241-248), and Makower in view of Stern and Edwards-'886 (Ex.1002, ¶¶333-340). Dr. Bikson does not appear to disagree with me that a person of ordinary skill in the art would have been motivated to combine Edwards-'535 and Stern alone or with Edwards-'886, or that a person of ordinary skill in the art would have been motivated to combine Makower in view of Stern and Edwards-'886. Rather, Dr. Bikson opines that the above combinations do not teach that “a radiofrequency generator configured to...deliver radiofrequency energy separately

to each of the multiple radiofrequency output channels” and “a cable...for plugging the handle into the radiofrequency generator.” Ex.2001-Bikson, ¶¶89-99. I disagree.

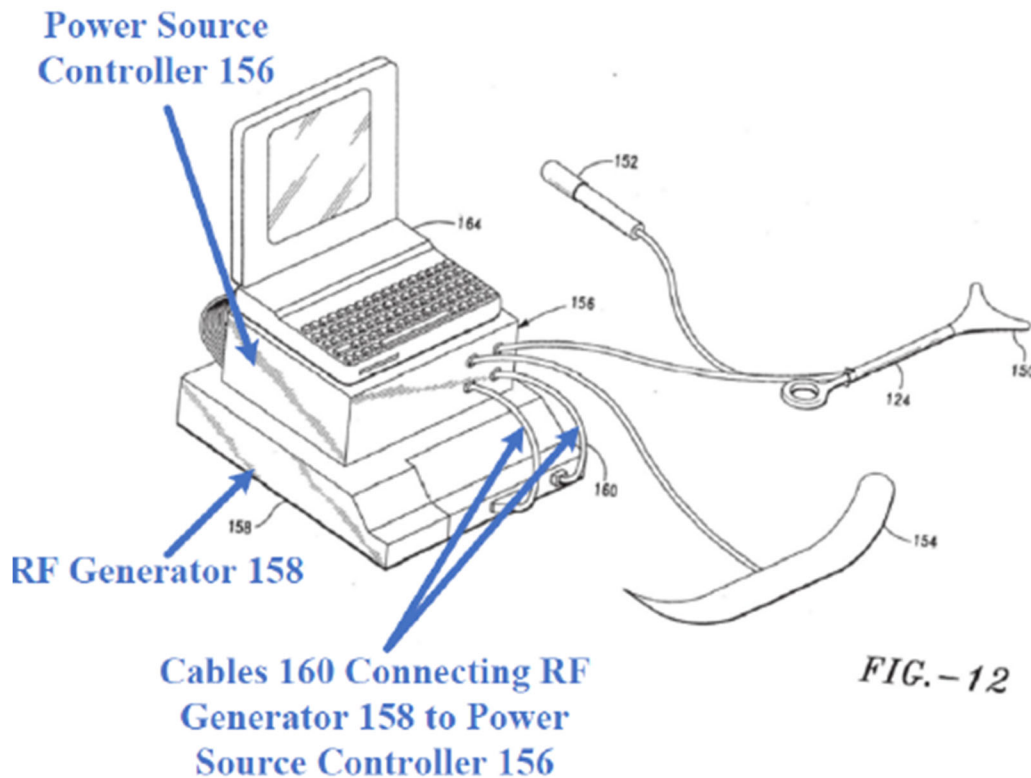
75. Dr. Bikson’s opinions do not change my opinion that the claims of the ’318 patent would have been obvious. Therefore, as I explained in my First Declaration and further below in this Reply Declaration, the above combinations teach the limitations of claim 9.

A. The combinations of Edwards-’535 and Stern (Ground I), Edwards-’535, Stern, and Edwards-’886 (Ground III) and Makower, Stern, and Edwards-’886 (Ground V) teach limitation 9[a]: “a radiofrequency generator configured to receive sensed signals from the multiple sensors and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels in the form of a 460 KHz sinusoid wave.”

76. Dr. Bikson opines that the above combinations do not teach “a radiofrequency generator configured to ... deliver radiofrequency energy separately to each of the multiple radiofrequency output channels” because, in his opinion, Stern’s generator 158 does not deliver radiofrequency energy *directly* to the multiple output channels without any other intervening components. Ex.2001-Bikson, ¶¶89-96, 113-114, 127-129. I disagree with this interpretation of limitation 9[a] and the prior art.

77. **First**, according to Dr. Bikson, the “power source controller 156” in Stern delivers energy to the output channels, not the “RF generator 158.” Ex.2001-

Bikson, ¶91. Dr. Bikson therefore appears to conclude that the claimed “radiofrequency generator” must be “configured to [*directly*] deliver radiofrequency energy,” *i.e.*, that the claimed “radiofrequency generator” cannot generate energy that passes through an intermediate component, like a power source controller, before reaching the device.



Ex.2001-Bikson, ¶92. Additionally, Dr. Bikson opines that Stern does not disclose that the “radiofrequency generator” is configured to “deliver radiofrequency energy separately.” Ex.2001-Bikson, ¶¶90-92. According to Dr. Bikson, Stern’s RF generator 158 is configured to deliver only a single radiofrequency output to the

power source controller 156.” Ex.2001-Bikson, ¶¶92-93. Dr. Bikson points to Stern’s disclosure that its radiofrequency generator is “a conventional electrosurgical power supply” and notes that such power supplies typically had only a single radiofrequency output. Ex.2001-Bikson, ¶94.

78. A person of ordinary skill in the art would have understood Stern’s disclosure to encompass both a configuration where switches directing energy are inside a generator, and a configuration where switches directing energy are inside a power source controller that is connected to the generator. I agree that it appears Figure 12 shows the “power source controller 156” and “RF generator 158” in different boxes, but as I explained, any person of ordinary skill in the art would read Stern’s teaching regarding the energization of RF electrodes to include a configuration where the switches are inside the generator. Regardless, a person of ordinary skill in the art would consider the controller 156 and generator 158 to serve together as a generator.

79. Moreover, these components being separate is in fact contemplated by the ’318 patent. For example, the ’318 patent includes embodiments having a “control system 42 configured to control the timing, location, intensity and/or other properties and characteristics of energy or other treatment applied to targeted regions of a nasal passageway.” Ex.1001-USP318, 16:27-31, FIG.3. This control system is

separate from the power supply 44 that “may be configured to deliver a radio frequency alternating current signal to an RF energy delivery element.” Ex.1001-USP318, 16:55-57. The '318 patent also states that “energy may be produced and controlled via a generator that is either integrated into the electrode handpiece or part of a *separate assembly* that delivers energy or control signals.” Ex.1001-USP318, 34:31-35.

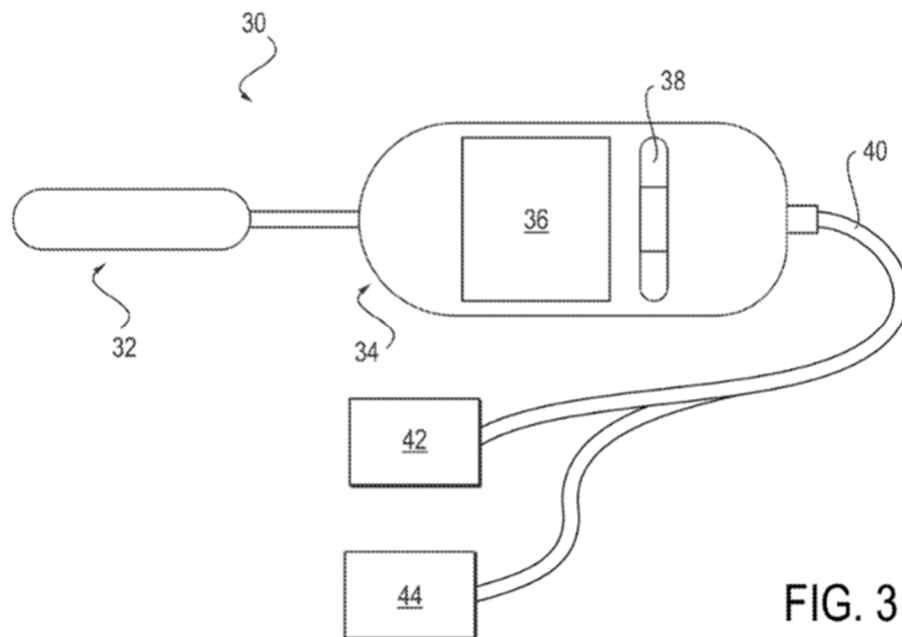


FIG. 3

Ex.1001-USP318, FIG.3.

80. Therefore, even though Stern discloses an RF generator and controller in two different boxes, that configuration is covered by the scope of the claims and is consistent with the '318 patent specification itself. Stern teaches that “RF

generator 158 serves as the RF input power for the controller 156” and that “[o]nce the device 124 and the controller 156 are connected, the RF electrodes are separately, independently and sequentially energized with thermistor temperature feedback to bring the endometrial temperature up to a desired level.” Ex.1033-Stern, 10:39-52. The RF generator 158 is therefore configured to deliver the energy to the electrodes, even if the energy passes through other components before it reaches the electrodes. The ’318 patent also includes other embodiments where other elements, such as an adaptor 554, acts as an intermediary between the RF generator and electrodes. *See* Ex.1001-USP318, FIGs.22A, 45. As shown below, Figure 22A shows the adaptor 544 connected to the treatment device, and Figure 45 shows RF generator 1010 with a break in its cable prior to its connection with the RF generator, clearly indicating that there may be intermediate components between the RF generator and device.

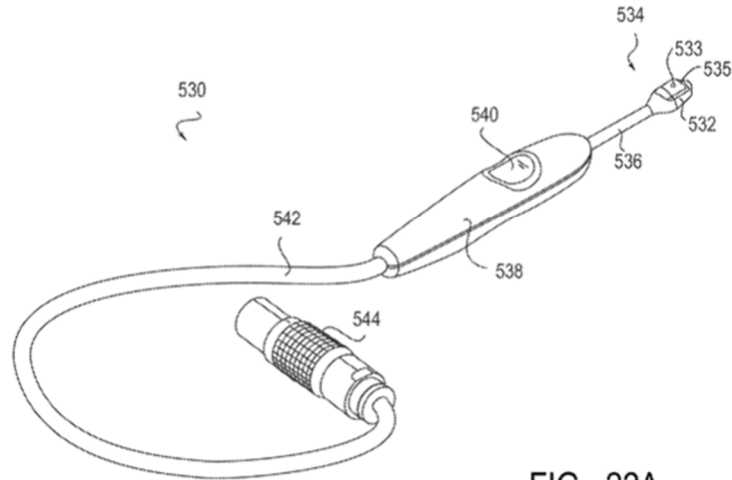


FIG. 22A

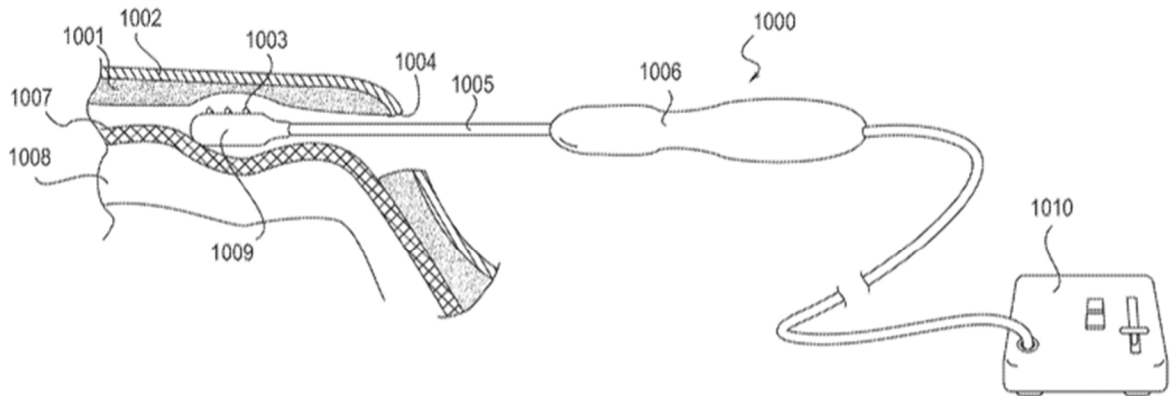


FIG. 45

Ex.1001-USP318, FIG. 45

81. And as I explained in my First Declaration, Stern includes detailed disclosure regarding how it accomplishes independent delivery of energy to the electrodes. Ex.1002, ¶¶123-148. I agree with Dr. Bikson that Stern's generator is a

“conventional electrosurgical power supply.” Ex.2001-Bikson, ¶94. Nothing in the ’318 patent or in the claims expresses that anything other than a conventional power supply would meet the claim limitations. But it is Stern’s clear disclosure regarding how that power supply is routed—i.e., via multiple output channels—that accomplishes the delivery of “radiofrequency energy separately.”

82. *Second*, even if Dr. Bikson’s interpretation was correct, he appears to have fundamentally misunderstood my analysis in Grounds I and III, where I explained the combination of Edwards-’535 and Stern. In my First Declaration, I explained that Edwards-’535’s signal generator—which Dr. Bikson does not dispute is a generator—delivers energy independently to electrodes, and is modified by Stern’s teaching regarding how to do so. Ex.1002, ¶¶175-76, 242-243. That is, Stern’s controller 156 would have supplied the details of how Edwards’535’s signal generator supplies energy. Therefore, Stern’s disclosure of a separate RF generator and controller is irrelevant to the proposed combination of Grounds I and III relied on in the Petition.

B. The combinations of Edwards-535 and Stern (Ground I), Edwards-’535, Stern, and Edwards-’886 (Ground III) and Makower, Stern, and Edwards-’886 (Ground V) teach limitation

9[b]: “a cable...for plugging the handle into the radiofrequency generator”

83. Dr. Bikson opines that the above combinations do not teach “*a cable...for plugging the handle into the radiofrequency generator*” because there are *two* cables leading to the generator, as shown below in Stern’s Figure 12. Ex.2001-Bikson, ¶¶97-99, 113-114, 130-131. Specifically, Dr. Bikson notes that Stern’s RF generator 158 is connected to a separate power source controller 156 via electrosurgical cables 160, and that the handle of the application device 124 is plugged into power source controller 156 via a different cable. Ex.2001-Bikson, ¶99. I disagree with Dr. Bikson’s opinion that the above combinations do not teach limitation 9[b].

84. As I showed in my First Declaration, and reproduced below, Stern discloses a cable connected to the handle.

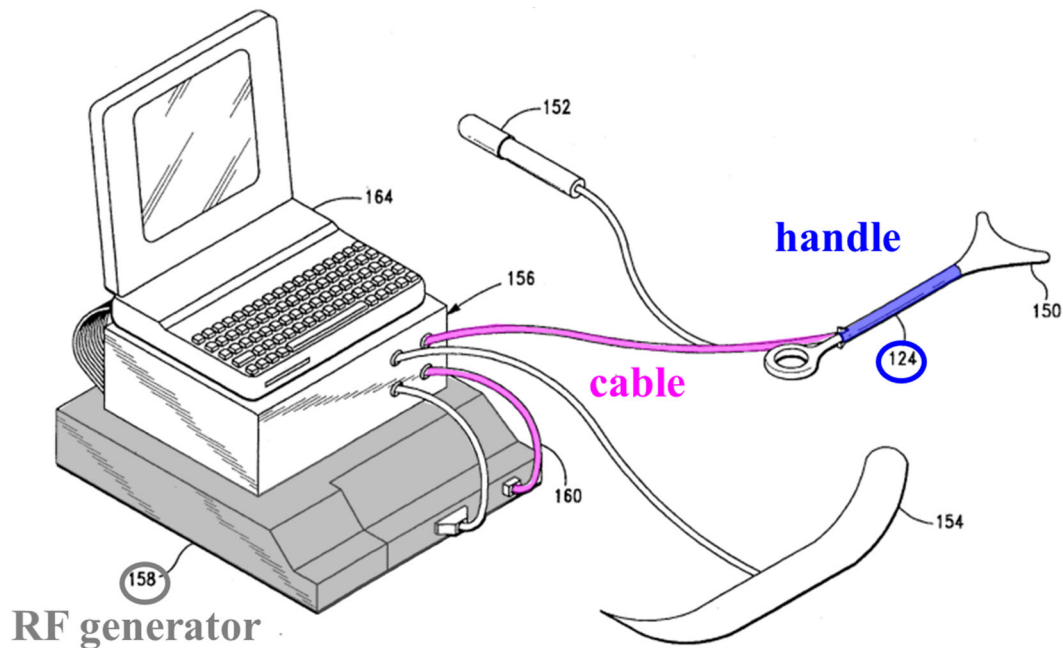


FIG. - 12

Ex.1002, ¶188. Dr. Bikson does not appear to disagree with me that Stern teaches a cable plugged into the handle.

85. I have been informed that when interpreting claim language, the indefinite article “a” does not mean one and only one. Therefore, the fact that Stern’s Figure 12 depicts **two** cables—one connecting the handle to the power source controller 156 and one connecting the power source controller 156 to RF generator 158, does not change my opinion that Stern discloses “a cable...for plugging the handle into the radiofrequency generator.”

86. To the extent that Dr. Bikson misreads the claim language to require a cable that **directly connects** the handle and the radiofrequency generator 158,

without any intermediate components, I disagree with Dr. Bikson's reading of the claim. Claim 9 requires only a cable "for plugging the handle into the radiofrequency generator." That does not imply any direct connection. Rather, either of the cables shown in Stern's Figure 12 above are used to plug the handle into the generator. The '318 patent also does not require any direct connection, noting that generator may be separate from a control system "that delivers energy or control signals." Ex.1001-USP318, 34:33-34, 5:25-30 ("In another aspect, a system is provided comprising a device as described above and further below in combination with one or more other components. ***One such component may be an energy source***, such as an RF energy source. ***Another component may be a control system for controlling the energy source and/or treatment device.***"), 16:27-35 ("In some embodiments the treatment system may comprise an electronic control system 42 configured to control the timing, location, intensity and/or other properties and characteristics of energy or other treatment applied to targeted regions of a nasal passageway. In some embodiments, a control system 42 may be integrally incorporated into the handle section 34. Alternatively, ***the control system 42 may be located in an external device*** which may be configured to communicate with electronics within the handle section 34."), FIG.3. That is, the '318 patent discloses precisely the embodiment that Dr. Bikson concludes is excluded by the claims.

Additionally, Figure 45 clearly shows a break in the cable that connects the RF generator 1010 to the handle portion 1006 of the device, indicating the presence of intermediate components, like the adaptor 544 shown in Figures 22A-22C.

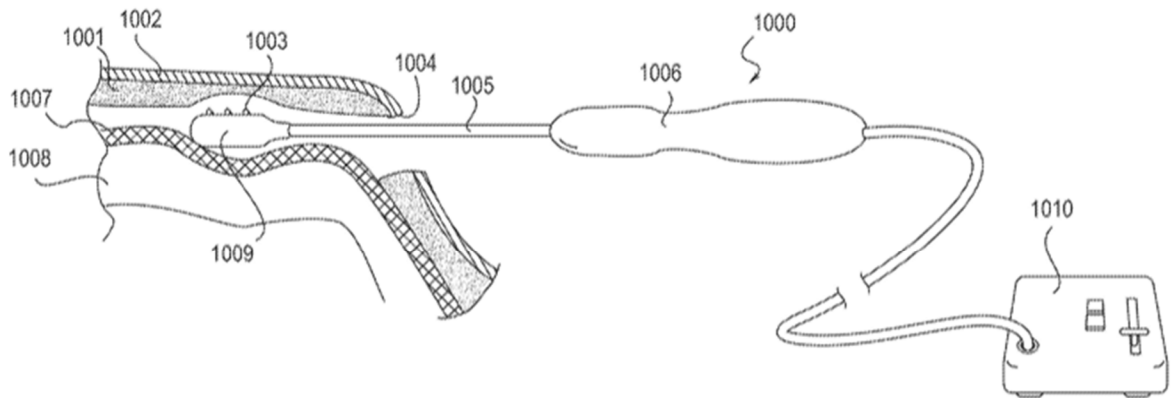


FIG. 45

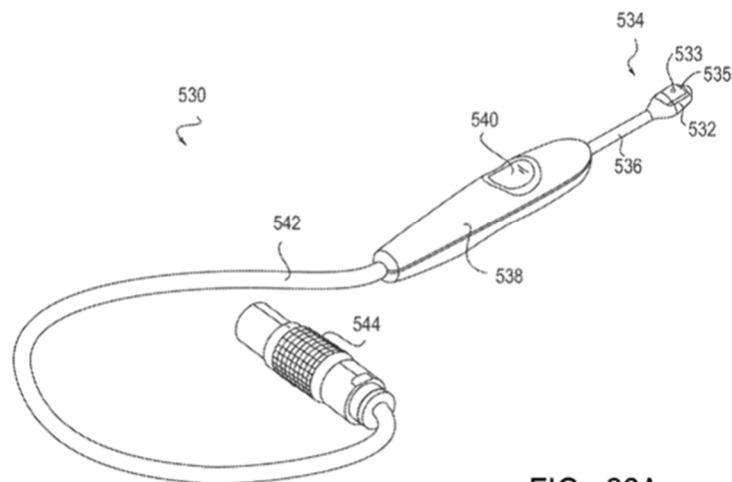


FIG. 22A

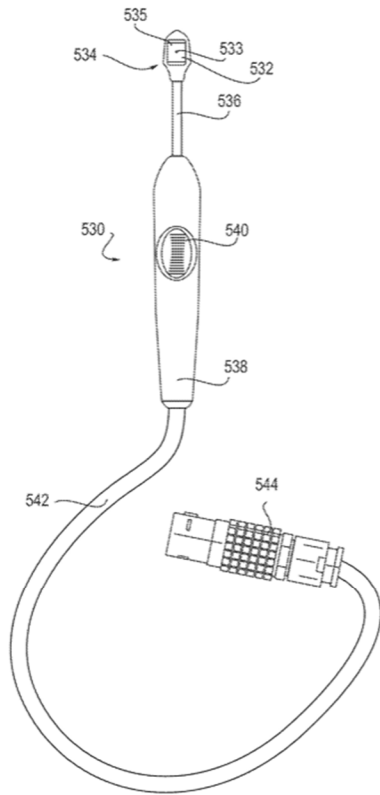


FIG. 22B

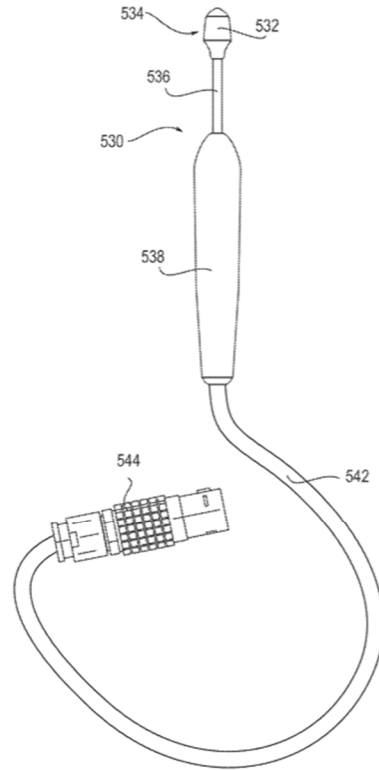


FIG. 22C

Ex.1001-USP318, Figs.45, 22A-22C.

87. Therefore, the '318 patent contemplates an intermediate connection between the generator and handle of the device. And Stern explains that “[o]nce the device 124 and the controller 156 are connected, the RF electrodes are separately, independently and sequentially energized.” Ex.1033-Stern, 10:33-53. As such, Stern teaches the claimed radiofrequency generator and a cable...for connecting the generator to the handle of the device.

88. Additionally, even if Dr. Bikson's interpretation was correct, he appears to have fundamentally misunderstood my analysis in Grounds I and III, where I explained the combination of Edwards-'535 and Stern. In my First Declaration, I explained how Edwards-'535's signal generator would have been modified to include a cable...for plugging Edwards-'535's device into the radiofrequency generator. Ex.1002, ¶189. That is, Stern's controller 156 would have supplied the details of how Edwards'535's signal generator supplies energy, thus there would be no intermediate controller in that combination. I presented the same opinions for the combination of Makower, Stern, and Edwards-'886 (Ground V). Ex.1002, ¶339. Thus, whether Stern discloses a separate RF generator and cable is irrelevant for Grounds I and III.

XI. CHALLENGED CLAIM 15 IS OBVIOUS OVER THE COMBINATIONS OF EDWARDS-'535 AND STERN (GROUND I) AND MAKOWER AND STERN (GROUND IV)

89. Claim 15 recites: "The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes." Ex.1001-USP318, cl.15.

90. In my First Declaration, I explained that dependent claim 15, would have been obvious over the combination of Edwards-'535 in view of Stern (Ex.1002, ¶¶212-218) and Makower in view of Stern (Ex.1002, ¶¶325-327). Dr. Bikson

contends that I did not explain how Stern's Figure 19 disclosure of electrodes 322 arranged in rows would have been obvious to incorporate in Edwards-'535. Ex.2001-Bikson, ¶101. That is incorrect.

91. In my First Declaration, I did address why the electrode configuration of Stern's Figure 19 would have been obvious to incorporate into Edwards-'535. Citing to my discussion in limitations 1[d] and 1[e] I stated that "...such an electrode arrangement would have been obvious to incorporate in Edwards-'535." Ex.1002, ¶216. I also proceeded to explain that "[t]here are only a small number of ways to configure an array of bipolar electrodes." Ex.1002, ¶216. With respect to limitation 1[d], I spent twenty paragraphs explaining how a person of ordinary skill in the art would have been motivated to combine the teachings of Edwards-'535 and Stern (*id.*, ¶¶102-122), including how Stern's disclosure would allow for location control and even heating, which would have been the natural result of including Stern's ordered arrangement in Figure 19 in combination with Stern's bipolar pairing technique. That is, the ordered and even spacing in Stern's Figure 19 would ensure even distribution of energy between pairs of electrodes in an array, as opposed to completely random arrangements. Dr. Bikson does not appear to address any of my analysis for limitation 1[d], which applies directly to the two rows of electrodes required in claim 15.

92. Additionally, Dr. Bikson appears to focus only on my opinion that “there are only a finite number of ways to configure an array of bipolar electrodes” (Ex.2001-Bikson, ¶102)⁶ and ignores the rest of my analysis in that paragraph where I provide additional motivations as to why Stern’s Figure 19 in particular would have been obvious. For example, as I explained in my First Declaration, Stern discloses an “array” of electrodes, which itself implies “an arrangement of bipolar electrodes in rows and columns is appropriate and may even be necessary.” Ex.1002, ¶216. As I explained—more ordered arrangements would have been appropriate, and a person of ordinary skill in the art would have considered ordered arrangements of electrodes and would have had finite choices regarding the arrangement of electrodes in rows and columns. Ex.1002, ¶216.

⁶ Dr. Bikson misinterprets my opinion regarding “finite choices.” I did not say that there were only a finite number of ways to arrange electrodes. Rather, there are only a finite number of ways to guide the arrangement—whether randomly or more ordered in rows. Ex.1002, ¶216.

**XII. CHALLENGED CLAIM 17 IS OBVIOUS OVER THE
COMBINATIONS OF EDWARDS-'535 AND STERN (GROUND I)
AND MAKOWER AND STERN (GROUND IV)**

93. Claim 17 recites: “The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes are connected to one another and to the multiple radiofrequency output channels in a multiplexed configuration.” Ex.1001-USP318, cl.17.

94. In my First Declaration, I explained that dependent claim 17 would have been obvious over the combination of Edwards-'535 in view of Stern (Ex.1002, ¶¶225-232) and Makower in view of Stern (Ex.1002, ¶¶330-331). Dr. Bikson does not appear to disagree with my opinion that Makower in view of Stern render claim 17 obvious. However, Dr. Bikson appears to disagree with me regarding the combination of Edwards-'535 and Stern. Dr. Bikson provides a single sentence stating that I “do not show that Edwards-'535 in view of Stern teaches what is claimed.” Ex.2001-Bikson, ¶104. That is incorrect.

95. I explained in my First Declaration that the combination of Edwards-535 and Stern teach the same kind of multiplexing contemplated by the '318 patent in which *any* two electrodes can be paired. Ex.1002, ¶¶225-232. The '318 patent discloses the same thing: “an electrode array arranged in a multiplexed configuration allowing pairing of any of the positive electrodes 963 to any of the negative

electrodes 964 to form a complete circuit.” Ex.1001-USP318, 10:47-50. Stern discloses the same arrangement as well: “[o]nce the device 124 and the controller 156 are connected, the RF electrodes are separately, independently and sequentially energized with thermistor temperature feedback to bring the endometrial temperature up to a desired level. The system accomplishes this in an automated manner using the RF output from a conventional electrosurgical power supply 158. As discussed previously, the electrodes may have a variety of specific configurations and heating is concentrated in the endometrium near the surfaces of the electrodes. Various electrode configurations provide uniform RF energy distribution to produce uniform heating.” Ex.1033-Stern, 10:48-65.

96. Stern further explains with great detail, how the schematic of Figure 15 can be used in a multiplexed configuration “wherein the multiple pairs of bipolar radiofrequency electrodes are connected to one another”: “the switches allow for the selective application of RF energy to various combinations of electrodes” and that “FIG. 15 illustrates the use of four electrodes 220, 222, 224 and 226.” Ex.1033-Stern, 12:38-45. These electrodes are connected to each other because, for example, “if the switch 232 is opened and if pairs of switches, with one of the pair being selected from the switches 242, 244, 246 and 248 and the other being selected from

switches 234, 236, 238 and 240, are operated in proper conjunction, the electrodes 220, 222, 224 and 226 will provide a bipolar operation.” Ex.1033-Stern, 12:46-13:2.

97. Stern further provides that “[a]s an example, if switch 248 is closed as well as switch 236, then the current will pass from electrode 220 to electrode 224. In a similar manner, if switch 246 is closed as well as switch 234, there will be a bipolar operation with current flowing between electrodes 222 and 226. ***Clearly bipolar operation is not limited to these 220-224 and 222-226 pair couplings.*** If switch 248 and switch 238 are closed there will be bipolar operation between the electrodes 220 and 222.” Ex.1033-Stern, 12:37-13:2. Stern therefore provides more detail regarding how to multiplex electrodes than the ’318 patent.

98. Dr. Bikson does not provide any reason to conclude that Edwards-’535 and Stern’s multiplexing—which matches or exceeds the disclosure of the ’318 patent—should be excluded from claim 17’s requirement that “the multiple pairs of bipolar radiofrequency electrodes are connected to one another and to the multiple radiofrequency output channels in a multiplexed configuration.” Therefore, I maintain that claim 17 would have been obvious over the combination of Edwards-’535 and Stern.

XIII. CHALLENGED CLAIMS 4, 10, 12, 13, AND 16 ARE OBVIOUS.

99. Dr. Bikson's arguments regarding claims 4, 12, 13, and 16 (Grounds I, IV) are based solely on these claims being dependent on claim 1. Dr. Bikson's arguments regarding claim 10 (Grounds I, III, and V) are also based solely on claim 10 being dependent on claim 1. These claims are obvious for the reasons I provided in my First Declaration and the additional reasons provided in this Reply Declaration. *See* Ex.1002, ¶¶157-165 (Claim 4, Ground I), ¶¶307-311 (Claim 4, Ground IV), ¶¶194-202 (Claim 12, Ground I), ¶¶320-322 (Claim 12, Ground IV), ¶¶203-212 (Claim 13, Ground I); ¶¶323-325 (Claim 13, Ground IV), ¶¶218-224 (Claim 16, Ground I); ¶¶328-329 (Claim 16, Ground IV); ¶¶191-195 (Claim 10, Ground I), ¶¶249-251 (Claim 10, Ground III), ¶¶341-343 (Claim 10, Ground V).

XIV. LEVEL OF ORDINARY SKILL IN THE ART

100. As explained in my First Declaration, a person of ordinary skill in the art at all relevant times (2011) would have had (1) a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline and (2) at least three years of experience in the clinical use, design, development, and/or testing of medical devices, including medical devices that deliver energy to tissue. A higher level of education may compensate for less work experience, and vice versa. Ex.1002, ¶27.

101. In his declaration, Dr. Bikson provides a different definition:

“(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.”

Ex.2001-Bikson, ¶40. I understand that the Patent Owner proposes this definition as well. POR, 6-8.

102. Dr. Bikson agrees with me in many regards. For example, he agrees that a person of ordinary skill in the art’s educational background would include “a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline.” Ex.2001-Bikson, ¶40. Moreover, he agrees that a person of ordinary skill would have had three years’ experience. *Id.* However, Dr. Bikson appears to disagree that three or more years of experience in the *clinical use* of medical devices or *testing* of such medical devices would have qualified an individual as a person of ordinary skill in the art. Ex.2001-Bikson, ¶37. Dr. Bikson appears to be of the opinion that a person who has not designed or developed medical devices would not have ordinary skill sufficient to consider issues relevant to the ’318 patent as one skilled in the art. I highlight that difference in blue text below:

My Definition of a Person of Ordinary Skill in the Art (Ex.1002, ¶27)	Dr. Bikson’s Definition of a Person of Ordinary Skill in the Art (Ex.2001-Bikson, ¶40)
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(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.	(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.
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103. I have extensive relevant experience developing and designing medical devices, including those that deliver energy to tissue, nor does he dispute that I would have qualified as a person of ordinary skill in the art under either definition. Indeed, as I explained in my First Declaration, I have been focused on designing and developing technology that delivers energy to tissue, with a particular focus on ablating tissue, throughout almost my entire career. Ex.1002, ¶5. I have offered opinions in this matter consistent with my experience and the experience that a person in the field with ordinary skill would have had as of 2011. As detailed in my First Declaration, my qualifications and experience exceeded those of a person of ordinary skill in the art as defined above in 2011. Ex.1002, ¶28. My opinions in my First Declaration and this Reply declaration remain the same regardless of which definition applies.

XV. AVAILABILITY FOR CROSS-EXAMINATION

104. 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.

XVI. RIGHT TO SUPPLEMENT

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

XVII. JURAT

106. 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



Gregory T. Martin, Ph.D

Martin Declaration: Appendix B (Materials Considered)

APPENDIX A

Appendix A: Materials Considered

Exhibit No.	Description
1001	U.S. Patent No. 11,033,318 (“’318 patent”)
1003	File History of U.S. Patent No. 11,033,318
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”)
1021	U.S. Patent App. No. 2005/0240147 (“Makower”)
1022	U.S. Patent App. No. 2006/0064086 (“Odom”)
1023	Coste et al., Radiofrequency Is a Safe and Effective Treatment of Turbinate Hypertrophy, LARYNGOSCOPE, 111(5) (2001) (“Coste”)
1024	WO1999030655A1 (“Hovda”)
1030	U.S. Patent No. 8,979,841 (“Kunis”)
1031	Hytönen et al., Radiofrequency Thermal Ablation for Patients with Nasal Symptoms: A Systematic Review of Effectiveness and Complications, 266 EUR. ARCH. OTORHINOLARYNGOL. (2009) (“Hytönen”)
1033	U.S. Patent No. 5,562,720 (“Stern”)

Martin Declaration: Appendix B (Materials Considered)

Exhibit No.	Description
1034	U.S. Patent Application No. 2007/0287994 (“Patel”)
1035	M. Philippson, Principles of Electrical Resistance of Living Tissue, BULL. CL. SCI. ACAD. R. BELG. ser. 5, vol. 7 (1921) (English Translation) (“Philippson”)
1045	U.S. Patent No. 5,507,725 (“Savage”)
1050	Hong, Radiofrequency Ablation: Mechanism of Action and Devices, J. VASC. INTERV. RADIOL. 21 (2010) (“Hong”)
1051	Haemmerich, Biophysics of Radiofrequency Ablation, CRITICAL REVIEWS IN BIOMEDICAL ENGINEERING, 38(1) (2010) (“Haemmerich”)
1052	Sackenheim, Radio Frequency Ablation the Key to Cancer Treatment, J. DIAGNOSTIC MEDICAL SONOGRAPHY Vol.19, No. 2 (2003) (“Sackenheim”)
1053	Bronzino, Medical Devices and Systems, Chapter 13, THE BIOMEDICAL ENGINEERING HANDBOOK 3E (2006) (“Bronzino”)
1054	Koyyalagunta et al., Radiofrequency and Cryoablation for Cancer Pain, TECHNIQUES IN REGIONAL ANESTHESIA & PAIN MANAGEMENT Vol.14 (2010) (“Koyyalagunta”)
1056	Liang et al., Radiofrequency Treatment of Ethmoidal Nerve with Allergic Rhinitis Under Nasal Endoscopy, 13:8 J. CLIN OTORHINOLARYNGOL. (China) 341 (August 1999) (English Translation) (“Liang”)
1061	Szold, Nitinol: Shape-Memory and Super-Elastic Materials in Surgery, 20 SURGICAL ENDOSCOPY & OTHER INTERVENTIONAL TECHNIQUES (2006) (“Szold”)
1062	Sedra et al., MICROELECTRONIC CIRCUITS (3d Ed. 1991) (“Sedra”)
1067	U.S. Patent No. 5,505,730 (“Edwards-’730”)
1084	Transcript of the January 7, 2024, Deposition of Dr. Marom Bikson
1089	Exhibit E to the Deposition of Dr. Marom Bikson

Martin Declaration: Appendix B (Materials Considered)

Exhibit No.	Description
1094	Errata Sheet for the Transcript of the September 24, 2024 Deposition of Dr. Gregory Martin (“Martin-Tr.I-Errata”)
1095	Errata Sheet for the Transcript of the September 25, 2024 Deposition of Dr. Gregory Martin (“Martin-Tr.I-Errata”)
/	Patent Owner Preliminary Response in IPR2024-00278
/	Institution Decision in IPR2024-00278
/	Patent Owner Response in IPR2024-00278
2001	Declaration of Dr. Marom Bikson
2002	Curriculum Vitae of Dr. Marom Bikson
2003	Transcript of the September 24, 2024, Deposition of Dr. Gregory T. Martin
2004	Transcript of the September 25, 2024, Deposition of Dr. Gregory T. Martin
2007	Exhibit 8 to the Deposition of Dr. Gregory T. Martin