UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.,

Petitioners,

v.

THE FOUNDRY, LLC.,

Patent Owner.

Case No. IPR2024-00669

U.S. Patent No. 11,679,077

DECLARATION OF DR. GREGORY T. MARTIN REGARDING CLAIM 4 OF U.S. PATENT NO. 11,679,077

Neurent 1099
Neurent v. Foundry
IPR2024-00669

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

I. INTRODUCTION

1. My name is Gregory T. Martin.

2. I am making this declaration at the request of Neurent Medical Inc. and Neurent Medical Ltd. ("Neurent" or "Petitioners") as an independent expert consultant in this proceeding before the United States Patent and Trademark Office and to address and respond to the arguments made in the declarations submitted by Dr. Marom Bikson ("Bikson Declaration") (Ex. 2005) and Dr. Howard Levine ("Levine Declaration") (Ex. 2003) in support of the POR. I previously submitted a Declaration in support of the Petition, dated January 15, 2024 (Ex.1007) ("First Declaration").

3. 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.

4. 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 '077 patent and have had no contact with the named inventors of the '077 patent.

II. MATERIALS CONSIDERED

5. 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]

6. 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 Levine and Bikson Declarations (Exs. 2003 and 2005). I have also reviewed and considered the documents cited by Dr. Bikson and Dr. Levine in their declarations in relation to claim 4 of the '077 patent, and the transcripts of Dr. Bikson's deposition held on January 7, 2025 ("Bikson

[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.

Deposition") (Ex.1091-Bikson-Tr.) and of Dr. Levine's deposition held on January 9, 2025 ("Levine Deposition") (Ex.1089-Levine-Tr.).

III. SUMMARY OF OPINIONS

7. As I laid out in my First Declaration, my opinion is that a person of ordinary skill in the art would have been motivated to combine Sadaat and Stern (Ground III) and Makower, Fang, Edwards-535, and Stern (Ground VI) to arrive at the limitations of claim 4 of the '077. As I explain in this declaration, my opinion continues to be that claim 4 of the '077 patent would have been obvious over the prior art that I discussed in my First Declaration.

8. I have reviewed the POR, the Levine and Bikson Declarations, and the Levine and Bikson Depositions—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 claim 4 of the '077 patent would have been obvious.

9. I reviewed the transcript of my deposition[2] and Dr. Levine's and Dr. Bikson's discussions thereof. They mischaracterize my opinions, including those

[2] The errata that I submitted for my deposition are included in Exhibits 1101 and 1102.

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 claim 4 of the ’077 patent. Dr. Bikson’s and Dr. Levine’s opinion is that ’077 patent claim 4 would not have been obvious in view of Ground VI. I disagree. Moreover, my testimony does not support their opinions. I therefore maintain, as I stated in my First Declaration, that ’077 patent claim 4 would have been obvious to a person of ordinary skill in the art and without the use of hindsight. Dr. Bikson and Dr. Levine only disagree with a subset of my opinions. I therefore focus on these few areas of dispute in this Reply Declaration.

IV. LEGAL PRINCIPLES

10. 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.1007, ¶¶10-20. I have continued to apply those principles in providing my opinions in this Reply Declaration.

V. OVERVIEW OF THE TECHNOLOGY AND THE ’077 PATENT

11. I discussed the technology background, the ’077 patent, and the prosecution history of the ’077 patent in paragraphs 29-38 of my First Declaration, which I incorporate by reference here.

12. I have reviewed the section of Dr. Bikson's declaration entitled "Overview of the '077 patent and the Challenged Claims" (Ex.2005-Bikson, ¶¶45-51) and the section of Dr. Levine's declaration entitled "Overview of the '077 Patent" (Ex.2003-Levine, ¶¶23-27). I note that they leave out several aspects of the '077 patent disclosure that are relevant to how a person of ordinary skill in the art would have interpreted '077 patent claim 4. I identify those portions below.

13. As I explained in my First Declaration, I applied priority dates of July 22, 2005 and October 22, 2019 and do not offer any opinion as to whether the '077 patent is entitled to a particular priority date. Ex.1007, ¶25. Dr. Bikson and Dr. Levine applied the priority date of July 21, 2006 to their analysis. Ex.2005-Bikson, ¶60; Ex.2003-Levine, ¶¶28, 31. My opinions are the same regardless of which priority date is applied.

VI. CLAIM CONSTRUCTION

14. 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.1007, ¶45. Dr. Bikson and Dr. Levine agree with me that the plain and ordinary meaning should be applied to the '077 patent claim terms (Ex.2005-Bikson, ¶60; Ex.2003-Levine, ¶), but their analyses do not appear to do so. As I explain below, with respect to claim 4, instead of applying the plain and ordinary meaning, Dr.

Bikson and Dr. Levine appear 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 and Dr. Levine's shared interpretation of claim 4, the prior art still discloses the additional requirements that Dr. Bikson and Dr. Levine seek to add to the claim.

VII. CHALLENGED CLAIM 4 IS OBVIOUS OVER MAKOWER, FANG, EDWARDS-535, AND STERN (GROUND VI)

15. For the reasons I explained in my First Declaration, claim 4 of the '077 patent would have been obvious over the combination of Makower, Fang, Edwards-535, and Stern. Ex.1007, ¶¶78-108). In my First Declaration, I explained that a person of ordinary skill in the art would have been motivated to combine Makower, Fang, Edwards-535, and Stern with a reasonable expectation of success. Ex.1007, ¶¶55-57, 90-107. Neither Dr. Bikson nor Dr. Levine appears to disagree with me on these points.

16. Dr. Bikson and Dr. Levine do, however, appear to disagree with me that Stern teaches "multiple pairs of bipolar electrodes." Ex.2005-Bikson, ¶¶89-99; Ex.2003-Levine, ¶¶112-121. I disagree with them for two reasons. First, their opinions are based on their incorrect interpretation of the scope and requirements of claim 4 of the '077 patent. Second, Dr. Bikson and Dr. Levine read the Stern

reference too narrowly, which led them to incorrectly conclude that Stern does not teach claim 4 under their (incorrect) interpretation.

17. Neither Dr. Bikson's nor Dr. Levine's arguments change my opinion that '077 patent claim 4 would have been obvious. Therefore, as I explained in my First Declaration and further below in this Reply Declaration, the combination of Makower, Fang, Edwards-535, and Stern teach claim 4.

A. The combination of Makower, Fang, Edwards-535, and Stern (Ground VI) teaches "multiple pairs of bipolar electrodes"

18. Dr. Bikson and Dr. Levine opine that Stern does not teach multiple pairs of bipolar electrodes as claimed by the '077 patent because, in their view, claim 4 requires bipolar electrode pairs that are active "at the same time." Ex.2005-Bikson, ¶¶97-98; Ex.2003-Levine, ¶119. I disagree with their interpretation, but even if their interpretation was correct, that would not change my opinion that Stern discloses "multiple pairs of bipolar electrodes."

1. Claim 4 does not require "multiple pairs of bipolar electrodes" active "at the same time"

19. Dr. Bikson's and Dr. Levine's opinions are that the prior art does not disclose "multiple pairs of bipolar electrodes" because it does not disclose the multiple pairs being active or delivering energy "at the same time." Ex.2005-Bikson, ¶97-98; Ex.2003-Levine, ¶119. The requirement that the electrodes are

delivering energy "at the same time" does not appear in claim 4 (or claims 1 and 2, from which claim 4 depends), and the claim does not otherwise recite language requiring the "pairs of bipolar electrodes" to be active at the same time. Rather, the claims recite "multiple pairs of bipolar electrodes," in plural, meaning what is required is more than one bipolar electrode pair. As I explained in my First Declaration, Makower in view of Stern discloses multiple pairs of bipolar electrodes. Ex.1007, ¶¶55-57, 90-107.

20. Dr. Bikson's and Dr. Levine's interpretation is inconsistent with the '077 patent's description that multiple pairs of bipolar electrodes that are activated separately ***or*** individually. The '077 patent contains only a single sentence that describes multiple pairs of electrodes. That single sentence makes clear that "multiple pairs of electrodes … may be activated in pairs, in groups, or in a ***sequential*** manner." Ex.1001-USP077, 18:42-44. That is, according to the '077 patent, there can be "multiple pairs of [bipolar] electrodes" regardless of whether those pairs are activated "in groups" (i.e., at the same time) or "sequentially" (i.e., at different times). *Id.* The '077 patent does not describe arrangements where multiple pairs are active at the same time as being optimal or preferred embodiments, let alone the only embodiment.

21. Neither Dr. Bikson nor Dr. Levine discusses any disclosure of the '077 patent in reaching their opinions regarding this claim scope. Ex.2005-Bikson, ¶97-98; Ex.2003-Levine, ¶119. Their conclusion that only one of the '077 patent's disclosed embodiments (activation in groups or at the same time) is required and another (activation sequentially) is excluded from "multiple pairs of bipolar electrodes," is inconsistent with the plain and ordinary language of the claim (which does not require one or the other) and this disclosure.

22. I therefore disagree with Dr. Bikson and Dr. Levine's opinions that '077 patent claim 4 requires the "multiple pairs of bipolar electrodes" to deliver energy "at the same time."

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

23. As I explain above, I disagree with Dr. Bikson and Dr. Levine that claim 4 requires activating pairs of electrodes at the same time. However, even if their interpretation was correct, that would not change my opinion that Stern discloses "multiple pairs of bipolar electrodes." Though I disagree, for the purposes of the following analysis, I assume that claim 4 requires multiple pairs of bipolar electrodes that are active "at the same time," as Dr. Bikson and Dr. Levine propose. Even under this interpretation, Stern teaches activating multiple pairs of bipolar

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.1009-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 neither Dr. Bikson nor Dr. Levine discussed Stern's disclosure of utilizing pairs of electrodes "together" in forming their opinion that Stern does not teach "multiple pairs of bipolar electrodes" that are active "at the same time."

24. Stern's teachings are consistent with the '077 patent's discussion of multiple pairs of electrodes. As I explained above, the '077 patent describes pairs that are activated in groups or sequentially, and does not further state that only one is required. Ex.1001-USP077, 18:42-44. Consistent with the '077 patent's disclosure of "groups" of electrode pairs, Stern discloses pairs that are "utilized together." Ex.1009-Stern, 13:39-43. Neither I nor a person of ordinary skill in the art would see a difference between pairs that are "activated … in groups" and pairs that are "utilized together" for purposes of considering whether there are multiple pairs of bipolar electrodes active at the same time.

25. In view of Stern's teaching of "multiple pairs of bipolar electrodes" active at the same time, Dr. Bikson and Dr. Levine incorrectly suggest that Stern only teaches closing one of switches 242, 244, 246, and 248 and one of switches

234, 236, 238, and 240 to form a single pair of bipolar electrodes. Ex-2005-Bikson, ¶97; Ex-2003-Levine, ¶119. 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."

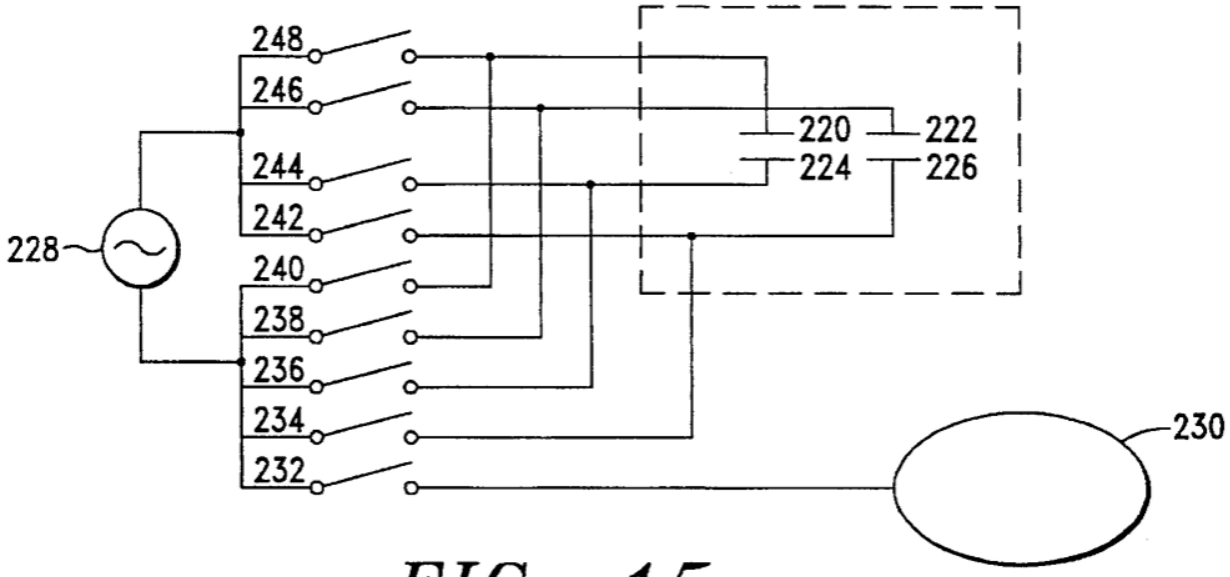


FIG.–15

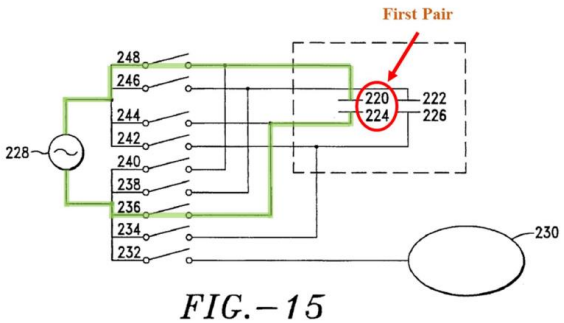
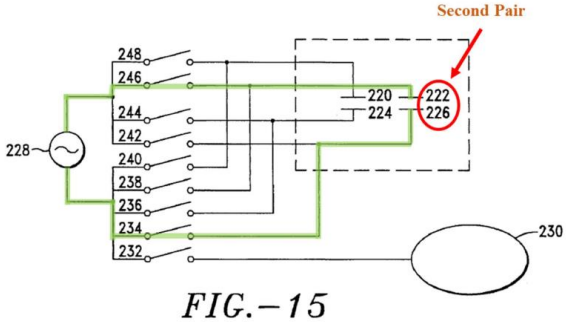
Ex.1009-Stern, Fig.15.

26. Dr. Bikson and Dr. Levine opine that only the first arrangement is contemplated by Stern because Stern teaches that its electrodes "are independently and sequentially energized" (Ex.1009-Stern, 2:31-33, 2:49-53, 10:48-52, 17:54-55) and, according to Dr. Bikson and Dr. Levine, sequential energization indicates that only two of Stern's switches could be closed at one time. Ex.2005-Bikson, ¶¶60-64; Ex.2003-Levine, ¶¶117-121.

27. But in my First Declaration, I explained how ***both*** arrangements (activation at the same time or sequential activation) satisfy claim 4 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.1007, ¶56; *see also id.*, ¶55 (discussing applying energy to "chosen pairs" of electrodes). 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.1007, ¶65; Ex.1009-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.1009-Stern, 2:6-19, 6:44-62, 10:49-65; Ex.1007, ¶¶55-

56, 64. Another benefit is to allow for more even heating of tissue by applying energy for different lengths of time. Ex.1007, ¶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.

28. Dr. Bikson and Dr. Levine point 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:

e.g., one pair of bipolar RF electrodes connected with a respective RF output channel	*e.g.*, another pair of bipolar RF electrodes connected with a respective RF output channel
 FIG.–15	 FIG.–15

Ex.1007, ¶56. This annotation, however, was exemplary.

29. Consistent with Stern's disclosure and my reading of the Stern reference, and in response to Dr. Bikson and Dr. Levine's opinions, 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:

e.g., two pairs of bipolar RF electrodes connected with respective RF output channels

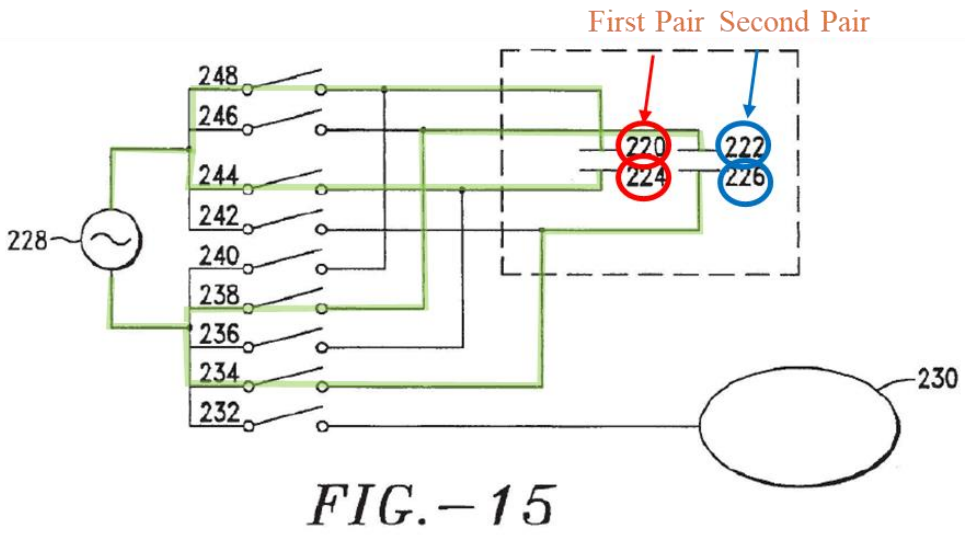


FIG.—15

VIII. LEVEL OF ORDINARY SKILL IN THE ART

30. As explained in my First Declaration, a person of ordinary skill in the art at all relevant times (2005-2019) would have had (1) a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline and (2) at least three years of experience in the clinical use, design, development, and/or

testing of medical devices, including medical devices that deliver energy to tissue. A higher level of education may compensate for less work experience, and vice versa. Ex.1007, ¶27.

31. In his declaration, Dr. Levine 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 nasal medical devices, including medical devices that deliver energy to the nasopharyngeal passage."

Ex.2003-Levine, ¶38.[3] The Patent Owner proposes a similar[4] definition. POR, 19-20.

32. Dr. Levine 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

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[3] Dr. Bikson's declaration indicates that he "understand[s]" the Patent Owner's definition and that he has "been asked to apply" it. Ex.2005-Bikson, ¶¶40-41. However, he does not offer any opinions in support of Patent Owner's definition, and appears to apply the same definition as Dr. Levine. I therefore respond to Dr. Levine regarding the level of ordinary skill in the art. Dr. Bikson states that his opinions are not affected by the definition of POSITA. Ex.2005-Bikson, ¶41.

[4] The Patent Owner's definition differs from Dr. Levine's in that the Patent Owner's definition requires "***nasal*** medical devices that deliver energy to ***tissue***" whereas Dr. Levine's definition requires "medical devices that delivery energy to ***the nasopharyngeal passage***." *Compare* Ex.2003-Levine, ¶38 *with* POR, 19-20. I have not been asked to compare these definitions. My disagreement with Dr. Levine's definition applies equally to Patent Owner's definition.

Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline." Ex.2003-Levine, ¶38; POR, 19-20. Moreover, he agrees that a person of ordinary skill would have had three years' experience. *Id.* However, Dr. Levine 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, and he appears to disagree that experience with medical devices that deliver energy to ***tissue*** without specific experience with ***nasal*** medical devices or those that deliver energy in the ***nasopharyngeal passage*** would have qualified an individual as a person of ordinary skill in the art. Ex.2003-Levine, ¶38. Dr. Levine appears to be of the opinion that a person who has not designed or developed nasal medical devices including those that deliver energy in the nasopharyngeal passage would not have ordinary skill sufficient to consider the issues relevant to the '077 patent as one skilled in the art. I highlight the differences in blue and green text below:

My Definition of a Person of Ordinary Skill in the Art (Ex.1007, ¶27)	**Dr. Levine's Definition of a Person of Ordinary Skill in the Art (Ex.2003-Levine, ¶38)**
(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,**	(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 **nasal**

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.	**medical devices**, including medical devices that deliver energy to **the nasopharyngeal passage**.

33. I have extensive relevant experience developing and designing medical devices, including those that deliver energy to tissue. 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.1007, ¶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 2006.

34. The opinions presented in my First Declaration and those that I provide in this Reply Declaration are informed by my decades of experience designing and developing medical devices, including those that deliver energy to tissue. As I explained in my First Declaration, I have experience with medical devices used throughout the body, including those that apply ablative energy to the endometrial tissue of the uterus (at Hologic) and heart (CryoCath), radiotherapy to breast and brain tissue to treat cancer (at Cytyc Corporation), ultrasound to tumors throughout the body (at Harvard-MIT), and electroporation to the skin (at MIT). *Id*., ¶5, Appx

A, p.67-68. I therefore have experience designing and developing medical devices used throughout the body, including the heart, vascular system, brain, breasts, uterus, skin, and elsewhere, and experience using a device initially used for one part of the body in another part of the body. Moreover, I have taught advanced courses on biomedical engineering design and development at the undergraduate and graduate level that teach principles (including principles regarding ablation) that are applicable throughout the body. Ex.1007, Appx. A, p.65. I consider myself an expert in medical devices generally, and specifically in medical devices that deliver ablative energy to tissue, such as those that use bipolar radiofrequency electrodes. I also consider myself an expert on how tissue responds to external energy sources, as I have studied that topic at length for numerous parts of the body.

35. The opinions I offer in this case are based on my expertise and experience. Based on my expertise and experience, medical doctors or engineers with three years of experience designing devices that deliver energy to tissue as of 2006 would have had the requisite skill to consider the issues that I understand are in dispute with respect to claim 4. Specifically, above, I explain why I disagree with Dr. Levine's interpretation and application of claim 4 to the prior art. Nothing about whether claim 4 requires electrodes activated at the same time or whether Stern teaches such electrodes hinges on any knowledge of any particular portion of nasal

anatomy, much less experience designing or developing devices for use in the nasopharyngeal passage. Instead, an engineer, particularly an engineer with three years' experience with medical devices, including devices applying energy to tissue, would have the skill to consider these issues as of 2006.

36. I disagree with Dr. Bikson's and Patent Owner's proposed definition of a person of ordinary skill in the art, which I believe is unnecessarily constrictive.

37. As explained in my First Declaration, I understand from Petitioners' counsel that several factors are to be considered in determining who would be a person of ordinary skill in the art. These factors include: (1) the types of problems encountered in the art; (2) the prior art solutions to those problems; (3) the rapidity with which innovations are made; (4) the sophistication of the technology; and (5) the educational level of active workers in the field. *See* Ex.1007, ¶26. Dr. Levine's declaration does not reference some of the factors that should be included in determining who would be a person of ordinary skill in the art, nor does he apply any in his analysis. Ex.2003-Levine, ¶¶32-39.

38. **First**, the types of problems and solutions in the art overlap substantially regardless of which part of the body a medical device is indicated for. Throughout my long career designing and developing medical devices for use throughout the body, I routinely drew upon my knowledge of how devices work in

one part of the body and applied that knowledge to other parts of the body. For example, at Cytyc Corporation, I worked on various devices that applied radiotherapy throughout the body, including to the brain and breast tissue. I was able to leverage my knowledge of devices indicated for applying energy to one part of the body to better address the application of energy to others. This is consistent with the prior art disclosures I rely upon in my First Declaration and this Reply Declaration. As one example, the Makower reference explains that its disclosed devices can be used by clinicians throughout the ear, nose, and throat. Ex.1005-Makower, [0043]. For example, while Stern teaches various devices and techniques in the context of uterine ablation, Stern expressly directs a person of skill in the art to apply those teachings to other parts of the body. Ex.1009-Stern, 1:15-23. This is consistent with my experience applying technological advances from one part of the body to another. Dr. Levine agrees that clinicians frequently use devices "off-label" and that he was able to do so based on his clinical experience. Ex.1089-Levine-Tr., 13:10-16, 72:16-75:11, 122:19-124:3. He also wrote in an article about a laser device that he says he worked on (and admitted in his deposition) that safety considerations for using that device safely in the nose were based on safety considerations for the same laser technology elsewhere in the body. Ex.1089-Levine-Tr, 126:3-9; Ex.1107-Levine-Article, 451

39. For the problems and solutions in the field as of 2006, a person of ordinary skill in the art for the '077 patent therefore would not have needed experience with devices that apply energy to tissue in the nose or nasopharyngeal passage in order to understand various operational details and principles that would apply to an apparatus for use in those locations.

40. **Second**, as I have observed in my long career designing and developing medical devices, engineers frequently learned about new areas of the body by consulting relevant literature and doctors, when helpful (and that doctors, likewise, consult engineers, instructions for use, or data generated by engineers when helpful). In my experience, literature and clinicians provided those in the art with the requisite education and general device experience sufficient understanding of the relevant anatomy for treatment without necessitating prior experience in the specific area of the body.

41. My career exemplifies how engineers moved from one treatment area to another without any prior experience in that area. As just one example, I began working on medical devices for use in the brain in 2000 without having ever previously worked on devices indicated for that location. As I explained in my first declaration, "I have routinely consulted with medical practitioners" by "consulting [on] medical journals and discussing design, performance, and treatment criteria."

Ex.1007, ¶6. These sources are sufficient to gain an understanding of new tissue for treatment. Likewise, as I mentioned above, Dr. Levine testified that as a clinician he was able to use devices "off label" and to use experience in one part of the body to inform safety in another part of the body, and that he consulted with engineers on various issues. Ex.1089-Levine-Tr., 13:10-16, 72:16-75:11, 122:19-124:3.

42. A person of ordinary skill in the art for the '077 patent would not have needed specific experience with devices that apply energy to tissue in the nasopharyngeal passage in order to understand the target anatomy ("nasal cavity") of the '077 patent claims and applied their clinical, design, or development experience in that area.

43. **Third**, with regard to ablation specifically, scientific principles of how that energy impacts tissue apply regardless of where the tissue is located. As I explained in my deposition, I have studied the temperature distributions from radiofrequency ablation applied to different volumes of tissue. Ex.2009-Martin-Tr-1, 93:18-22, 94:6-19. To do so, general principles like the tissue's water content (which impacts the tissue impedance) and the size of the tissue volume to be ablated apply regardless of the location of the tissue. In view of this, I have been able to design devices that use similar techniques and electrical energy to ablate tissue throughout the body, including the uterus, ovaries, and heart. And these principles—

that ablation can be used in different parts of the body—would have been taught and conveyed to those with requisite education experience and three years' experience with medical devices, including applying energy to tissue.

44. A person of ordinary skill in the art for the '077 patent would not have needed specific experience with devices that apply energy to tissue in the nasopharyngeal passage to understand based on their clinical, design, or development experience how tissue in the nasal cavity or nasopharyngeal passage would respond to radiofrequency energy.

45. In conclusion, the problems and solutions in the art, experience of those in the art, and technology and innovation at issue all support that a person with a relevant degree and three years' experience with use, design, development, and/or testing of medical devices for applying energy would have had ordinary skill for purposes of considering the subject matter of the '077 patent. I therefore disagree with Dr. Levine's proposed definition of a person of ordinary skill in the art. As detailed in my First Declaration, my qualifications and experience exceeded those of a person of ordinary skill in the art as defined above between 2005 and 2019. Ex.1007, ¶28.

46. I understand that Patent Owner has cited certain of my deposition testimony and suggested my analysis was incomplete or unreliable. I disagree, but in any event address this testimony below.

47. In performing my analysis for my First Declaration and this Declaration, I did consider claims 1 and 2, from which claim 4 depends, which I addressed in my declaration and testified to at my deposition. Ex.2010-Martin-Tr-2, 375:16-18; Ex.1007, Appx. C, p.72. Notably, I was not asked at my deposition whether I considered the claims as a whole in forming my opinions regarding claim 4. In arriving at my analysis of claim 4—which recites a limitation related only to multiple pairs of bipolar electrodes—I considered the claims as a whole in view of the prior art, including Makower, Fang, and Edwards-535, each of which I discussed in my First Declaration. Ex.1002, ¶¶55-56, 89 (Stern), ¶¶79-82 (Makower), ¶¶83-84 (Fang), ¶¶85-88 (Edwards-535), ¶¶90-108 (motivation to combine with reference to all four prior art references). I identified, and Dr. Bikson and Dr. Levine have identified, nothing in claims 1 or 2, or of the teachings of Makower, Fang, and Edwards-535, that impacts or affects my opinions regarding what Stern teaches for Makower's device.

48. At my deposition, I was asked a generic question about the "device" of the combination of Makower, Fang, and Edwards-535. *See, e.g.*, Ex.2010-Martin-

Tr-2, 395:3-4 ("What is the device taught by the combination of Makower, Fang, and Edwards '535?"). This question is not amenable to a single answer because Makower, Fang, and Edwards-535 together teach many different devices with many different potential configurations and components. As I explained in my First Declaration, for purposes of this proceeding, Makower, Fang and Edwards-535, in combination, teach device features relevant to my analysis, that is, an electrode device that would be suitable for, and a person of ordinary skill in the art would have been motivated to use with, Stern's electrodes with a reasonable expectation of success. Ex.1002, 90-108. For example, the combination teaches a device with a generator from Edwards-535 (which I addressed in my First Declaration). Ex.1002, ¶¶92-93. Similarly, it includes a device with bipolar electrodes, consistent with my reliance on Makower's disclosure of an electrosurgical device that has bipolar electrodes. *Id*.

IX. AVAILABILITY FOR CROSS-EXAMINATION

49. 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.

X. RIGHT TO SUPPLEMENT

50. 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.

XI. JURAT

51. 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 16, 2025



Gregory T. Martin, Ph.D.

APPENDIX A

Appendix A: Materials Considered

No.	Description
1001	U.S. Patent No. 11,679,077
1003	U.S. Patent No 10,307,200 to Saadat
1005	U.S. Patent Pub. No. 2005/0240147 to Makower
1006	Fang Chao-xin and Zhen Shao-Shao, *Nasal endoscopy combined with multiple radiofrequency for perennial allergic rhinitis*, 25(07) J. First Mil. Medic Univ. 876 (July 20, 2005) (Translation) ("Fang")
1008	U.S. Patent No. 6,517,535 to Edwards
1009	U.S. Patent No. 5,562,720 to Stern
1044	Chen Shi-qiang et al., *Preliminary study on radiofrequency thermocoagulation of the posterior inferior nerve, anterior ethmoidal nerve, and inferior turbinate under nasal endoscopy for the treatment of perennial allergic rhinitis*, 11(3) China Journal of Endoscopy 239 (Mar. 2005) (Translation) ("Chen")
1056	Maureen McDaniel Sackenhein, *Radio Frequency Ablation*, JDMS 19:88-92 (March/April 2003)
1066	U.S. Patent No. 6,273,886 to Edwards ("Edwards '886")
1067	Joseph D. Bronzino, *Medical Devices and Systems*, The Biomedical Engineering Handbook (3rd ed. 2006)
1069	Dhanalakshmi Koyyalagunta and Danesh Mazloomdoost, *Radiofrequency and cryoablation for cancer pain*, Techniques in Regional Anesthesia and Pain Management 14:3-9 (2010)
1073	Translation Declaration for Fang
1079	Munford Appendices for Shanghai
1080	U.S. Patent No. 5,891,134 to Goble
1081	U.S. Patent No. 5,575,788 to Baker
1082	International Pub. No. 99/30655 to Hovda
1089	Deposition Transcript of Dr. Howard Levine
1091	Deposition Transcript of Dr. Marom Bikson
1101	Martin Day 1 Errata
1102	Martin Day 2 Errata

No.	Description
1007	Howard L. Levine, Lasers in Endonasal Surgery, Ottolaryngologic Clinics of N. Am. 30:3, 451-455 (June 1997)
/	Institution Decision for IPR2024-00669
2003	Declaration of Dr. Howard L. Levine
2004	CV of Dr. Howard L. Levine
2005	Declaration of Dr. Marom Bikson
2006	CV of Dr. Marom Bikson
2009	Transcript of the September 24, 2024, Deposition of Dr. Gregory T. Martin
2010	Transcript of the September 25, 2024, Deposition of Dr. Gregory T. Martin
/	Patent Owner Response in IPR2024-00069