

**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 IPR2024-00669
Patent No. 11,679,077

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

Table of Contents

I.	INTRODUCTION	1
A.	My Background, Qualifications, Publications, and Testimony	2
B.	Compensation.....	7
II.	SUMMARY OF MY OPINIONS	8
III.	LEGAL PRINCIPLES.....	10
A.	Legal Standard for Claim Construction	10
B.	Legal Standard for Obviousness	11
IV.	THE BASES FOR MY OPINIONS	12
V.	PERSON OF ORDINARY SKILL IN THE ART	13
VI.	OVERVIEW OF THE '077 PATENT AND THE CHALLENGED CLAIMS	15
VII.	OVERVIEW OF THE ASSERTED PRIOR ART	18
A.	U.S. Patent App. Pub. No. 2005/0240147 (“Makower”) (Ex-1005).....	18
B.	Fang (Ex-1006).....	20
C.	U.S. Patent No. 5,562,720 (“Stern”) (Ex-1009).....	21
VIII.	CLAIM CONSTRUCTION	22
IX.	GROUND 5: PETITIONERS HAVE FAILED TO SHOW THAT MAKOWER IN VIEW OF, <i>INTER ALIA</i> , FANG RENDERS CHALLENGED CLAIMS 1-3, 5-8, AND 11 OBVIOUS	22
A.	A POSITA Would Not Have Had A Reasonable Expectation Of Success In Treating Target Tissue With The Makower FIG. 5H Device.....	22
B.	Claim 7: Makower’s Fig. 5H Electrodes Are Not Configured To “Deliver Energy Laterally”	31

X.	GROUND 6: PETITIONERS HAVE FAILED TO SHOW THAT STERN DISCLOSES “MULTIPLE PAIRS OF BIPOLAR ELECTRODES”	36
XI.	DECLARATION IN LIEU OF OATH	40

EXHIBIT LIST

Exhibit	Description
1001	U.S. Patent No. 11,679,077
1002	Declaration of Dr. Nicolas Bu-Saba
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”)
1007	Declaration of Gregory T. Martin
1008	U.S. Patent No. 6,517,535 to Edwards
1009	U.S. Patent No. 5,562,720 to Stern
1022	Prosecution History for U.S. Patent No. 10,610,675
1025	Prosecution History for U.S. Patent No. 11,679,077
1068	U.S. Patent No. 5,255,679 to Imran
2001	Lewis, David, and Nicolas Y. Busaba. “Surgical Management.” Sinusitis. CRC Press, 2006. 233-268.
2002	October 17, 2024 deposition transcript of Dr. Nicolas Bu-Saba
2003	Declaration of Dr. Howard L. Levine
2004	CV of Dr. Howard L. Levine
2005	[N/A – This Declaration]
2006	CV of Dr. Marom Bikson
2007	Brook, Itzhak. “ <i>Sinusitis: From Microbiology To Management</i> ” 2006
2008	September 24, 2024 Deposition transcript of Dr. Gregory T. Martin
2009	September 25, 2004 Deposition transcript of Dr. Gregory T. Martin

I, Dr. Marom Bikson, declare as follows:

I. INTRODUCTION

1. My name is Dr. Marom Bikson. I have been retained by counsel for Patent Owner The Foundry, LLC (“Patent Owner” or “Foundry”) to provide my independent analysis regarding various issues concerning the validity of challenged claims in three related *inter partes* review (“IPR”) petitions filed by Neurent Medical Inc. & Neurent Medical Ltd. (“Petitioners”) against three patents owned by Foundry. These matters are identified below:

- IPR2024-00279 regarding U.S. Patent No. 10,610,647 (the “’675 patent”);
- IPR2024-00280 regarding U.S. Patent No. 10,894,011 (“the ’011 patent”);
- and
- IPR2024-00669 regarding U.S. Patent No. 11,679,077 (“the ’077 patent”).

While this Declaration focuses on the ’077 patent IPR, I am submitting similar declarations in the IPRs for the ’675 and ’011 patents.

2. For the ’077 patent IPR, I understand that Petitioners have challenged the patentability of the following claims: 1-8 and 11 (the “Challenged Claims”) across four proposed invalidity Grounds.

3. I have been asked to provide my opinions with respect to certain issues on Grounds 4-5, in which Petitioners assert that Makower (Ex-1005) in combination with, *inter alia*, Fang (Ex-1006) render obvious all Challenged Claims.

4. I have also been asked to provide my opinions with respect to certain issues on Ground 5 in which Petitioners assert that Makower (Ex-1005) in combination with, *inter alia*, Stern (Ex-1009) renders obvious Challenged Claim 4.

A. My Background, Qualifications, Publications, and Testimony

5. My background, qualifications, and educational and employment history are set forth in my curriculum vitae, which I understand has been filed in this proceeding as **Exhibit 2006**.

6. I am a tenured Professor in the College of Engineering at The City College, where I began as an Associate Professor in 2003. I serve as the University's (Shames) Professor of Biomedical Engineering, a position I have held since 2014.

7. I have reviewed the '077 patent, its file history, and the Challenged Claims and understand that the Challenged Claims are directed to an "apparatus for treatment of a nasal condition by altering a function of a nasopharyngeal passage of a patient" having "an energy delivery element in the distal portion configured to delivery energy to target tissue in the nasopharyngeal passage" and "an energy source" for "supplying energy" to the "energy delivery element" "so as to alter nasopharyngeal cells in the target tissue such that nasal congestion is reduced." I have significant experience in the area of medical devices that deliver energy to tissue using, for example, radiofrequency electrodes.

8. I earned my Bachelor of Science in Biomedical Engineering, with a concentration in Electrical Engineering, from Johns Hopkins University in 1995. I earned my Ph.D. in Biomedical Engineering from Case Western Reserve University in 2000. The primary emphasis of my doctoral research pertained to the mechanisms by which electrical stimulation effects the body including leading to excitation of tissue, how parameters of a stimulation device impact the effects of stimulation, and experience with a range of technology used to stimulate the body and quantify the effects of stimulation.

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

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

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

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

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

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

15. I have received numerous grants in the fields of electrical and biomedical engineering. I am currently in receipt of, or was involved in work associated with: a \$44.5K grant for developing new protocols for read-write Neuromodulation from General Patent Corporation; a \$1.7m grant from the National Institute of Health (“NIH”) for developing a new mechanism of brain stimulation

via the coupled vascular hypothesis for transcranial direct current stimulation (“tDCS”); a \$2.2m grant from the NIH for developing automatic modeling software regarding tDCS; a \$955K grant from New York University and the City College of New York for advancing technology for home Neuromodulation in multiple sclerosis; a \$174K grant from the U.S. Department of Education for designing a device to assist visually impaired children; a \$485K grant from the NIH for enhancing drug delivery to brain tumors; a \$1.7m grant from the NIH for evaluating the effects of tDCS on neuronal plasticity in brain slices; a \$4m grant from the NIH for evaluating neural oscillatory patterns underlying auditory cognitive impairments in schizophrenia; a \$384K grant from Boston Scientific for researching high frequency spinal cord stimulation; a \$3.7m grant from the New York State Department of Health for developing translational models for electrotherapy of spinal cord injuries; and a \$3m grant from the NIH to Soterix Medical for supporting a clinical trial on DCS for rehabilitation.

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

17. I have written and published widely in the fields of electrical and biomedical engineering, including, without limitation, papers on cranial nerve stimulation, which discuss procedures involving electrodes inserted into the human head through the nose. I have published, or currently have in press, at least 322

articles with various academic journals across the world. I have written and published at least an additional 120 abstracts, in addition to being featured in at least 99 selected news and features in the press. My works have been cited over 42,940 times in scientific publications. The topics of my publications include:

- a. Electrical stimulation of excitable tissue: Design of efficacious and safe protocols. *Journal of Neuroscience Methods*, 141(2), 171-198 (2005);
- b. Bio-heat transfer model of deep brain stimulation-induced temperature changes. *Journal of Neural Engineering*, 3(4) (2006);
- c. Temperature control at DBS electrodes using a heat sink: Experimentally validated FEM model of DBS lead architecture. *Journal of Neural Engineering*, 9(4) (2012);
- d. Bio-heat model of kilohertz-frequency deep brain stimulation increases brain tissue temperature. *Neuromodulation*, 23(4), 489-495 (2020);
- e. Electrical stimulation of cranial nerves in cognition and disease. *Brain Stimulation*, 13(3), 717-750 (2020);
- f. Transcranial electrical and magnetic stimulation (tES and TMS) for addiction medicine: A consensus paper on the present state of the science and the road ahead. *Neuroscience and Biobehavioral Reviews*, 104, 118-140 (2019);

- g. Higher-order power harmonics of pulsed electrical stimulation modulates corticospinal contribution of peripheral nerve stimulation. *Scientific Reports*, 7 (2017);
 - h. Moreno-Duarte, I., Morse, L. R., Alam, M., Bikson, M., Zafonte, R., & Fregni, F. Targeted therapies using electrical and magnetic neural stimulation for the treatment of chronic pain in spinal cord injury. *NeuroImage*, 85, 1003-1013 (2014);
 - i. Comparing cortical plasticity induced by conventional and high-definition 4×1 ring tDCS: A neurophysiological study. *Brain Stimulation*, 6(4), 644-648 (2013) (doi:10.1016/j.brs.2012.09.010);
 - j. Fundamentals of transcranial electric and magnetic stimulation dose: Definition, selection, and reporting practices. *Brain Stimulation*, 5(4), 435-453 (2012); and
 - k. Electrical stimulation of excitable tissue: Design of efficacious and safe protocols. *Journal of Neuroscience Methods*, 141(2), 171-198 (2005).
18. I am a named inventor on a U.S. patent regarding neurocranial electrostimulation models, systems, devices, and methods, in addition to two foreign patents. I am a named inventor on an additional nine U.S. patent applications and five international patent applications.

B. Compensation

19. My compensation in this case is at my normal hourly rate. My compensation is not related to the outcome of this proceeding, i.e., I will not receive any additional compensation based on the outcome of any IPR or other proceeding involving the '077 patent.

20. I am not, and never have been, an employee of Foundry or Aerin Medical, who I understand is the exclusive licensee of the '077 patent.

II. SUMMARY OF MY OPINIONS

21. I have been asked to opine on certain issues related to the validity of the Challenged Claims. Specifically, I understand that Petitioners allege that the Challenged Claims are unpatentable over the combination of Makower (U.S. Patent Publication No. 2005/0240147; Ex-1005) in view of Fang—a journal publication purporting to disclose a treatment method for perennial allergic rhinitis using, *inter alia*, RF energy (Ex-1006-Fang) and Edwards (U.S. Patent No. 6,517,535; Ex-1008) (Ground 5) and further in view of Stern (U.S. Patent No. 5,562,720; Ex-1009) (Ground 6). I understand that Petitioner focuses on Makower's device depicted in FIG. 5H and alleges that a person of ordinary skill in the art ("POSITA") would have been motivated by Fang to use Makower's FIG. 5H device to treat perennial allergic

rhinitis by applying RF energy to tissue in the nasopharyngeal passage¹ and would have had a reasonable expectation of success in doing so.

22. I have been asked to provide my opinion regarding (1) whether a POSITA would have been motivated to use/would have had a reasonable expectation of using Makower's FIG. 5H device to treat perennial allergic rhinitis in the nasopharyngeal passage; and (2) whether the electrodes of Makower's FIG. 5H device are configured to deliver energy laterally relative to the distal portion of the treatment device, as recited in Challenged Claim 7; and (3) whether Stern discloses multiple pairs of bipolar radiofrequency electrodes, as recited in Challenged Claim 4.

23. In sum, as I explain in this declaration, it is my opinion that a POSITA would not have had a reasonable expectation of success to use Makower's FIG. 5H device to treat target tissue in the nasopharyngeal passage at least because the arrangement of Makower's FIG. 5H device would cause energy to be drawn away from the target tissue instead of towards the target tissue.

¹ I understand that the nasopharyngeal passage includes the nasal cavity and nasopharynx. (Ex-1002 at ¶¶32-33.)

24. In addition, as I explain in this declaration, it is my opinion that Makower fails to disclose any arrangement of electrodes that would deliver energy laterally relative to the distal portion of the treatment device, as required by Challenged Claim 7.

25. Finally, as I explain in this declaration, it is my opinion that Stern fails to disclose multiple pairs of bipolar radiofrequency electrodes, as required by Challenged Claim 4.

III. LEGAL PRINCIPLES

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

A. Legal Standard for Claim Construction

27. It is my understanding that the purpose of the claim construction process is to determine the meaning of the terms in the Challenged Claims of the '077 patent to a person of ordinary skill in the art ("POSITA") as of the time that the claimed invention was filed. I also understand that the words of the claims, the specification, and the prosecution history are to be primarily considered in order to construe the claims. These three sources are commonly referred to as "intrinsic evidence," while everything else is referred to as "extrinsic evidence."

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

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

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

B. Legal Standard for Obviousness

31. I understand that a patent claim may be unpatentable if the invention recited in the claim would have been obvious to one of ordinary skill in the art at the time the invention was made. In considering whether the Challenged Claims of the '077 patent are obvious, I have been asked to consider (a) the level of ordinary skill in the art at the time of the claimed invention, (b) the scope and content of the prior

art, and (c) any differences between the prior art and the Challenged Claims of the '077 patent.

32. I understand that a patent claim composed of several elements is not necessarily proved obvious merely by demonstrating that each of its elements was independently known in the prior art. I also understand that obviousness should not be analyzed using the benefit of hindsight. Instead, it must be analyzed from the standpoint of what was known and understood by a POSITA at the time of the claimed invention. I further understand that a party seeking to invalidate a patent claim as obvious must demonstrate that a skilled artisan would have had reason to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.

IV. THE BASES FOR MY OPINIONS

33. I have reviewed the '077 patent, including the Challenged Claims and the prosecution history of the '077 patent. (Ex-1001 and Ex-1025.) I have also reviewed the prosecution history of the '675 patent (Ex-1022), which I understand Petitioners refer to as support for their use of Makower. (*See, e.g.*, Petition at 67 (citing to Ex-1022).)

34. I have also reviewed the Petition for *Inter Partes* Review filed by Petitioners Neurent Medical Inc. and Neurent Medical Ltd. ("Petitioners" or

“Neurent”), the attached Declaration of Dr. Bu-Saba (Ex-1002), the transcript of the deposition of Dr. Bu-Saba (Ex-2002), the declaration of Dr. Martin (Ex-1007), the transcript of the deposition of Dr. Martin (Ex-2008 and Ex-2009) as well as Makower (Ex-1005), Fang (Ex-1006), Stern (Ex-1009), and Patent Owner’s Exhibit 2001, which I understand is a chapter Dr. Bu-Saba’s co-authored in the 2006 book entitled “Sinusitis.”

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

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

37. I have also relied on a conversation that I had on October 23, 2024, with Patent Owner’s other expert, Dr. Howard L. Levine, M.D., who is an expert in the treatment of the nasopharyngeal passage using devices that apply radiofrequency energy.

V. PERSON OF ORDINARY SKILL IN THE ART

38. I am informed that prior art and any opinions related to the prior art are to be analyzed from the perspective of a POSITA who would be involved in the same field as the ’077 patent at the time of the invention of the Challenged Claims.

39. I understand that Petitioners' definition of a POSITA is: "(1) a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline and (2) at least three years of experience in the clinical use, design, development, and/or testing of medical devices, including medical devices that deliver energy to tissue." (Petition at 18-19.)

40. I also understand that Patent Owner's definition of a POSITA is: "(1) a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline;" and (2) at least three years of experience in the **design and development**, of **nasal** medical devices, including **nasal** medical devices that deliver energy to the nasopharyngeal passage."

41. I have been asked to apply Patent Owner's definition of POSITA, which I agree with. My opinions would not change if Petitioner's definition of POSITA is adopted.

42. My opinions offered here are based on my extensive experience in the development of medical devices for all areas of the body, including the head, plus my conversation with Dr. Levine, who is an expert in nasal medical devices.

43. I have been asked to assume the priority date for this the '077 patent is July 21, 2006.

44. All of the opinions that I express in this declaration have been made from the standpoint of a POSITA as of July 21, 2006.

VI. OVERVIEW OF THE '077 PATENT AND THE CHALLENGED CLAIMS

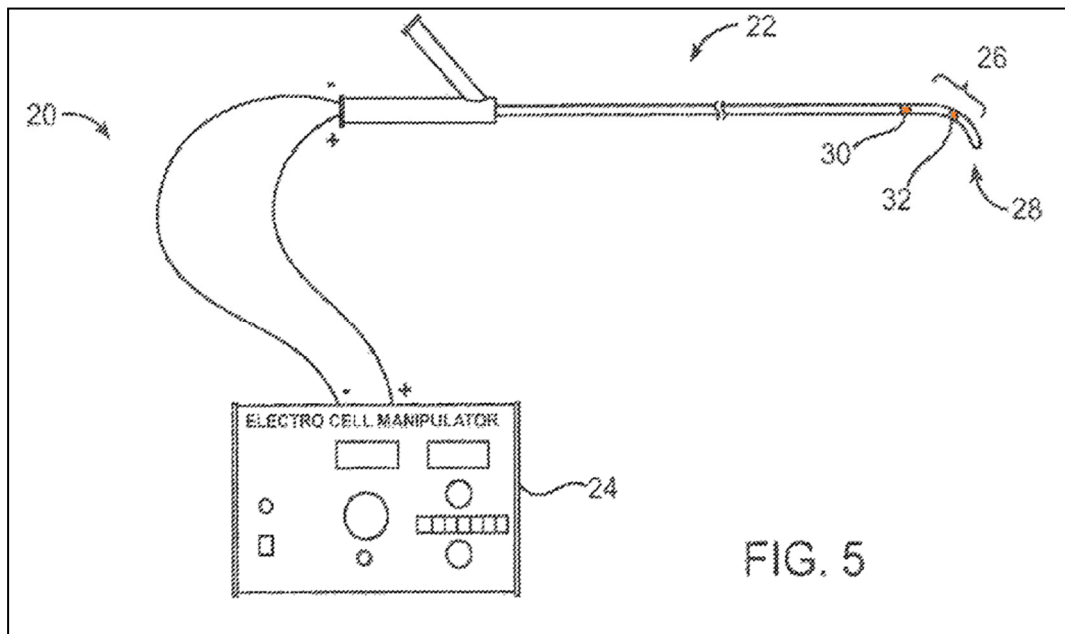
45. The '077 patent is entitled “Systems and Methods for Delivery of a Therapeutic Agent,” and issued on June 20, 2023, from U.S. Patent Application No. 17/151,938, filed on January 19, 2021. (Ex-1001.)

46. The '077 patent discloses methods and apparatuses “for the control of autonomic nerve function” of target cells in the nasal passageway. (Ex-1001, 1:38-47.) The '077 patent discloses the use of a treatment device for implementing a two-step treatment method. Specifically, first, an apparatus uses “an electric field or ultrasonic energy generated by a pulse or pulses of a designated duration and amplitude to alter tissue at the cellular level via permeabilization of the cell membrane.” (Ex-1001, 4:59-65.) Second, an active neurotoxin, *e.g.*, BoNT-LC, is delivered to permeabilized cells. (*Id.*)

47. While many embodiments of the '077 patent disclose energy delivery to achieve reversible poration, the '077 patent specifically states that the energy delivery may be reversible or non-reversible. (Ex. 1001, 8:10-18.) The '077 patent also discloses that “the energy may be applied to regions of the nasal membrane which are the same or different from the regions where the toxin has been introduced.” (Ex-1001, 8:33-36.)

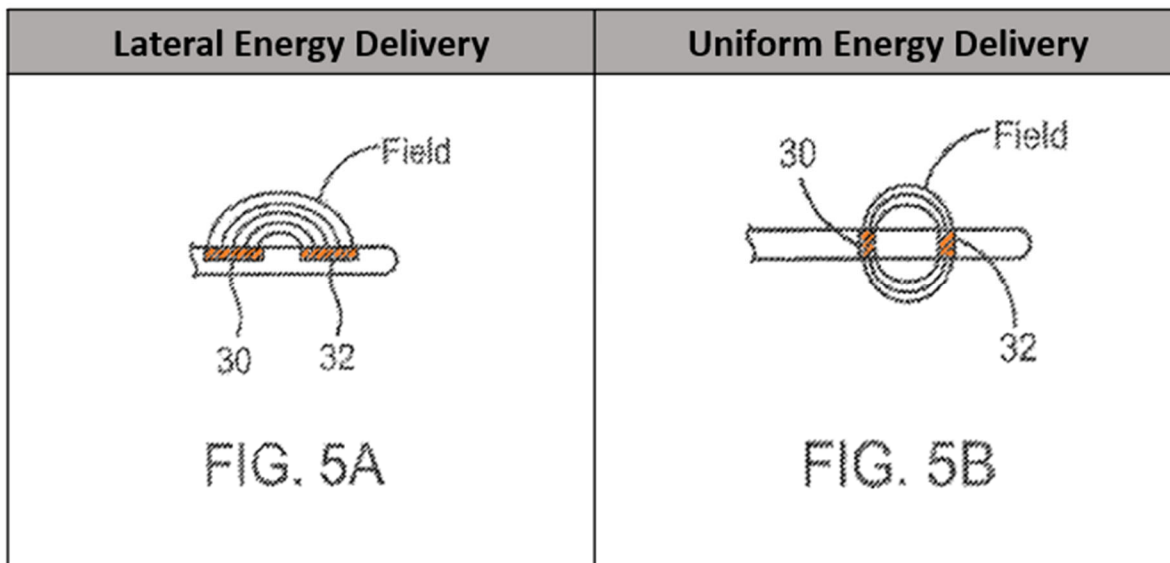
48. The '077 patent also discloses the treatment device for carrying out the treatment method. An example of the '077 patent's treatment device is shown in

FIG. 5 (below). The '077 patent refers to the treatment device as an “electroporation catheter system 20” and explains that the device includes a “pulse generator 24” and a “catheter 22.” The catheter 22 includes a distal end 28 with electrodes 30, 32 (orange).



(Ex-1001, FIG. 5 (annotated)).

49. The '077 patent describes at least two types of electrode arrangements for the treatment device in FIGS. 5A and 5B, which I have shown below. The '077 patent discloses that in FIG. 5A the electrodes are arranged to “produce[] an electric field concentrated in a lateral direction from the catheter body,” and in FIG. 5B the electrodes are arranged “to create a more uniform electric field about the shaft of the catheter body.” (Ex. 1001, 16:59-63).



(Ex. 1001, FIGS. 5A-B (annotated).)

50. There is one independent Challenged Claim (Claim 1), which is reproduced below:

Claim 1

1. Apparatus for treating rhinitis in a nasal cavity, the apparatus comprising:

1[a] an elongate body, comprising: a proximal portion; and a distal portion configured for positioning in the nasal cavity;

1[b] multiple radio frequency electrodes coupled with the distal portion of the elongate body; and

1[c] a radiofrequency generator coupled with the proximal portion of the elongate body for supplying radiofrequency energy to the multiple radiofrequency electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis.

51. The Challenged Claims also include claims 2-8 and 11, which depend from claim 1. Relevant to my opinions are claim 2, which depends from claim 1, and claim 4, which depends from claim 2, and claim 7, which depends from claim 1:

2. The apparatus of claim 1, wherein the multiple radio frequency electrodes comprise at least two bipolar radiofrequency electrodes.

4. The apparatus of claim 2, wherein the at least two bipolar radiofrequency electrodes comprise multiple pairs of bipolar radiofrequency electrodes.

7. The apparatus of claim 1, wherein the multiple radiofrequency electrodes are configured to deliver energy laterally relative to the distal portion of the elongate body.

VII. OVERVIEW OF THE ASSERTED PRIOR ART

52. I understand that Petitioners assert the Challenged Claims are unpatentable over multiple prior art references. Below I summarize the prior art relevant to my opinions in this declaration, namely, Makower (Ex-1005), Fang (Ex-1006), and Stern (Ex-1009).

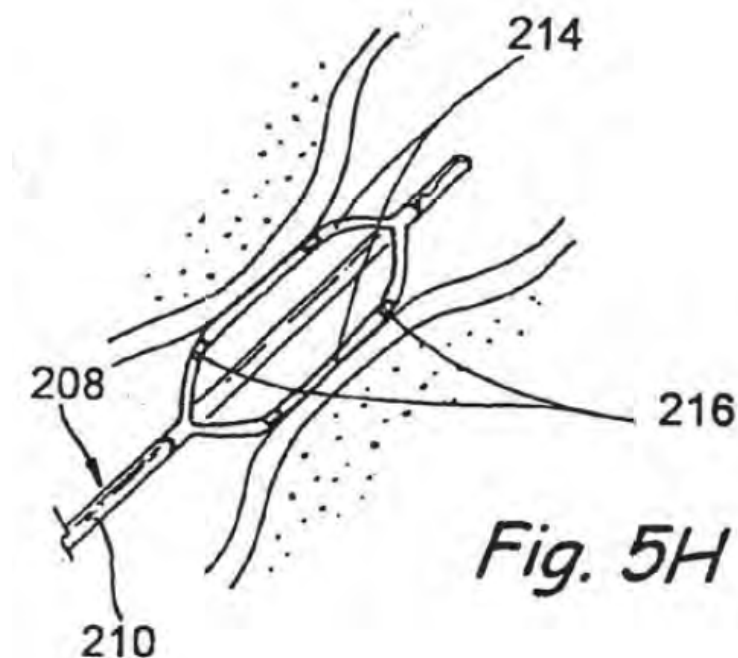
A. U.S. Patent App. Pub. No. 2005/0240147 (“Makower”) (Ex-1005)

53. I have reviewed Makower, which is generally directed to “minimally invasive, catheter based devices, systems and methods for treating sinusitis and other ear, nose & throat disorders.” (Ex-1005 at [0001], [0042].) Makower discloses numerous device embodiments. (*Id.* at [0161]; *see also id.* at [0049]-[0128].)

54. In Ground 5, Petitioners contend that Makower's FIG. 5H embodiment discloses nearly all of the structural and functional elements of the Challenged Claims.

55. Makower's FIG. 5H shows "a partial perspective view of a tissue shrinkage electrode device being used in accordance with the present invention." The FIG. 5H embodiment (reproduced below) comprises an electrosurgical device 208 comprising a catheter 210 with arched strut members 214 attached thereto. (*Id.* at [0187].) Electrodes 216 are located on the strut members 214. (*Id.*) In operation, the device 208 is advanced "into a passageway such as a nostril, nasal cavity, meatus, ostium, interior of a sinus, etc." and then current is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated. (*Id.*) Makower discloses that the electrodes 216 may be "bipolar, monopolar or facilitated by any other suitable form of energy such as gas or plasma arc."² (*Id.* at [0187].)

² While bipolar and monopolar electrodes are well-known concepts to a POSITA, it is unclear how Makower's electrodes could be "facilitated by . . . gas or plasma arc." Makower provides no disclosure regarding a device with such electrodes that could provide clarity to a POSITA.



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

B. Fang (Ex-1006)

56. Fang is a journal article titled “Nasal endoscopy combined with multiple radiofrequency for perennial allergic rhinitis.” (Ex-1006.) Fang purports to describe a method for treating perennial allergic rhinitis by, *inter alia*, applying RF energy to tissue in the nasopharyngeal passage. (Ex-1006 at 876.)

57. Fang describes part of its treatment method as including the use of a “SHP-I five-organ radiofrequency therapy instrument” to ablate “the bilateral sphenopalatine foramen, anterior ethmoidal nerve, and inferior nasal concha.” (Ex-1006 at 876, abstract.) Fang does not disclose the structure of the “SHP-I five-organ radiofrequency therapy instrument.” I have not heard of this device prior to reading Fang. I understand that neither Dr. Levine nor Petitioners’ expert, Dr. Bu-Saba, have

ever seen or used this device and they also had not heard of this device prior to reading Fang. (Ex-2002 at 181:1-184:21.)

C. U.S. Patent No. 5,562,720 (“Stern”) (Ex-1009)

58. I have reviewed Stern. Stern is generally directed to a device for the “selective destruction of the endometrium,” the thin layer of tissue lining the uterus. (Ex-1033-Stern at 1:17-22, 6:56-59.) Stern explains that its “goal” is “destruction of the endometrial cells.” (*Id.* at 6:60-62.) Stern describes destroying the endometrium using ablative radiofrequency energy while maintaining the average temperature of the myometrium, the tissue beneath the endometrium surrounding the uterine cavity. (*Id.* at 2:11-18, 6:66-7:6, 7:29-33.)

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

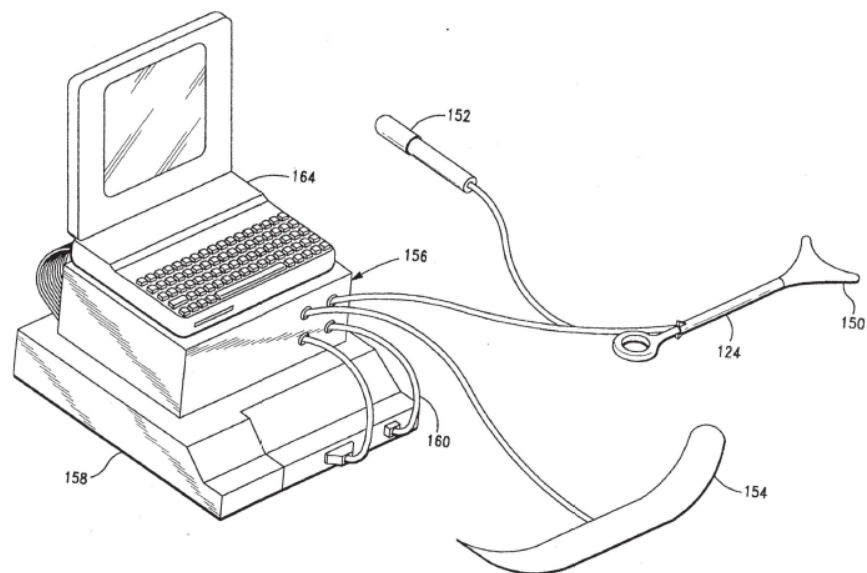


FIG. - 12

(*Id.* at FIG. 12.)

VIII. CLAIM CONSTRUCTION

60. For the purposes of this declaration, I will give the claim terms their plain and ordinary meaning as understood by a POSITA as of July 21, 2006. To the extent an express claim construction is proposed in this proceeding or in another proceeding involving the '077 patent, I reserve the right to respond to such a construction and/or propose an express construction.

IX. GROUND 5: PETITIONERS HAVE FAILED TO SHOW THAT MAKOWER IN VIEW OF, *INTER ALIA*, FANG RENDERS CHALLENGED CLAIMS 1-3, 5-8, AND 11 OBVIOUS

A. A POSITA Would Not Have Had A Reasonable Expectation Of Success In Treating Target Tissue With The Makower FIG. 5H Device

61. I understand that Petitioners' Ground 5 contends that a POSITA would have been motivated to use the Makower device shown in FIG. 5H to apply RF energy to tissue in the nasopharyngeal passage as part of a proposed method for treating perennial allergic rhinitis as per Fang. (Petition at 74-75 ("a POSITA would have found it obvious that the combination of Makower and Fang discloses RF electrodes that apply RF energy *to treat a target tissue in the nasal cavity and thus treat rhinitis* (emphasis in original); Petition at 78 ("a POSITA would have been motivated and would have found it obvious to apply Fang's method (disrupting neural activity using ablation) with Makower's device (electrosurgical device for the nasopharynx) to treat rhinitis").) I understand that Petitioners' proposed combination does not include any modification to Makower's FIG. 5H device.

62. I also understand that one of Petitioners' bases for their motivation to combine Makower and Fang is that a POSITA would have had a reasonable expectation of success in using Makower's FIG. 5H device according to Fang's treatment method of delivering energy to target tissue in the nasal cavity and thus treat rhinitis (as required by claim 1). For the reasons explained below, I disagree.

63. First, I have been asked by counsel to assume that "supplying radiofrequency energy" to the target tissue as per claim 1 of the '077 patent reads on

supplying ablative radiofrequency energy to that target tissue.³ Thus, to read on the claims, Makower's FIG. 5H device must reasonably be expected to ablate the target tissue.

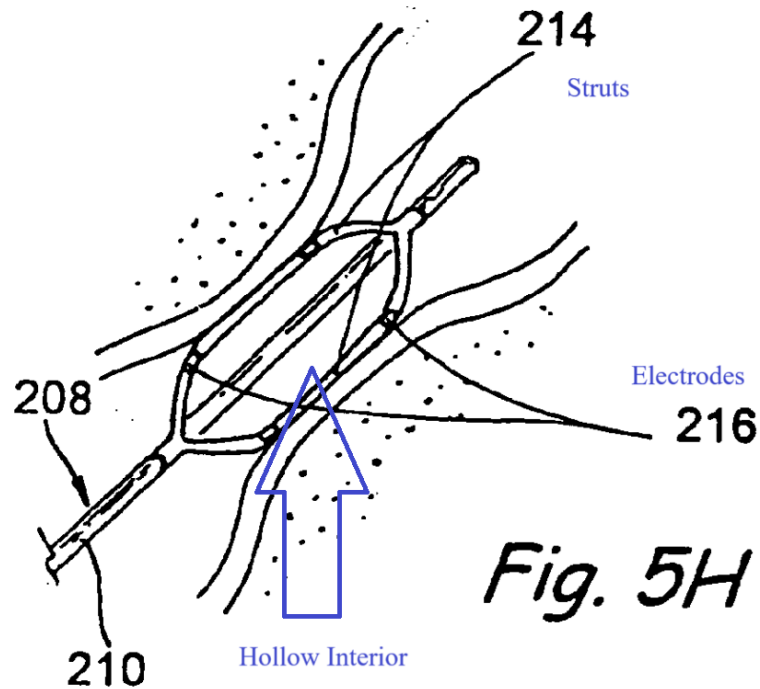
64. Second, prior to reviewing Makower (Ex. 1005), I had never seen or used a device like the FIG. 5H device of Makower to deliver energy to the nasopharyngeal passage. I also understand that neither Dr. Levine nor Dr. Bu-Saba have ever seen or used a device that like that of Makower's FIG. 5H for delivering RF energy delivery to the nasopharyngeal passage. (Ex. 2002 at 303:13-18.) As shown below, this may be because the RF device proposed by Makower is unsuited to treat tissue in the nasopharyngeal passage.

65. Specifically, a POSITA would have understood that, for ablation to be effective, RF energy must be applied to the target tissue for a sufficient amount of time and at a sufficient energy level in order to destroy the target tissue. A POSITA would have understood that if tissue does not receive the requisite amount of energy, then the tissue will not be ablated. Thus, when determining which device to use in a procedure where the goal is to destroy the target tissue, a POSITA would want to choose a device that it knows can deliver the threshold amount of energy to the target tissue during the therapeutic procedure.

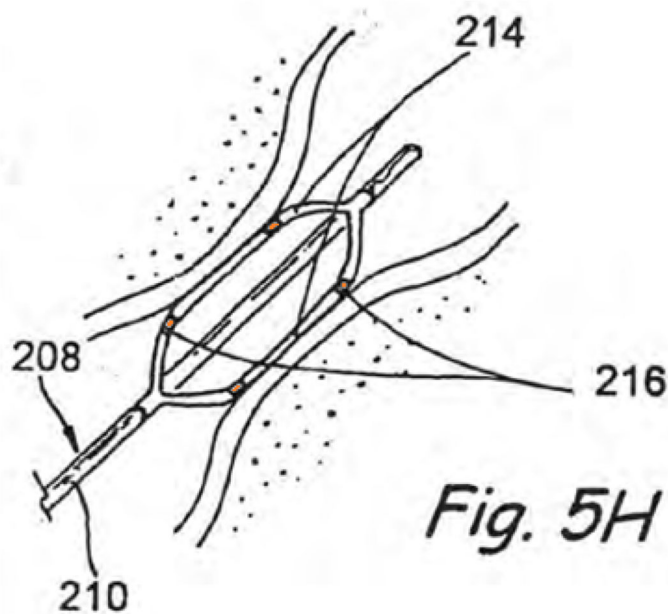
³ Claim 1 recites "supplying radiofrequency energy to multiple radiofrequency electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis."

66. In determining whether a device would reasonably be expected to deliver the threshold amount of energy to the target tissue, a POSITA would consider, without limitation, the structure of the treatment device, the type, number, and placement of the electrodes on the treatment device, the location where the treatment device is being used, and the medium surrounding the treatment device so as to assess whether the energy emitted from the electrodes can effectively treat the target tissue to achieve the desired result. In view of at least these considerations, it is my opinion that a POSITA would not have had a reasonable expectation of successfully using Makower's FIG. 5H device to ablate target tissue in the nasopharyngeal passage.

67. Specifically, as I explain in detail below, a POSITA would not have had a reasonable expectation of success in the Makower-Fang combination because a POSITA would have understood that the FIG. 5H structure, which includes a hollow interior, has the undesirable effect of preferentially applying RF energy to fluids located in the interior of the device, i.e., away from the targeted tissue, and thus the FIG. 5H device would not have been expected to be able to properly ablate target tissue in the nasopharyngeal passage. A POSITA would have had this understanding at least due to Makower's FIG. 5H arrangement (shown below), including (1) its ring electrodes, which are capable of emitting energy about their entire circumference, and (2) its hollow interior, which allows electrolytic fluids therein.



68. Specifically, a POSITA would have understood that Makower FIG. 5H device illustrates four ring electrodes (216) on its struts (214). Makower's electrodes are shown in *orange* below in annotated FIG. 5H.



69. A POSITA would have understood Makower's FIG. 5H electrodes to be ring electrodes for several reasons. First, Makower discloses that FIG. 5H is a "partial perspective view" of the device. A POSITA would have understood that a perspective view, is a two-dimensional representation of device. It is not, for example, a figure showing a slice of the device, as is common in cross-sectional illustrations. As shown in FIG. 5H, the electrodes appear ring like, and, as is common with ring electrodes, only a portion of the electrodes are in contact with adjacent tissue⁴ while the majority of the surface area of each electrode is illustrated as being *not* in contact with tissue. A POSITA would understand based on the perspective view of in FIG. 5H and the depictions of the electrodes in relation to the struts 216 that the electrodes (*orange*) wrap around the struts, which is also consistent with a POSITA's understand of ring electrodes.

70. As it relates to operation of the FIG. 5H electrodes, Makower is extraordinarily light on details, merely disclosing:

"In operation, the device 208 is advanced into a passageway such as a nostril, nasal cavity, meatus, ostium, interior of a sinus, etc. Thereafter, current is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated. The electrodes 216 may be bipolar, monopolar or facilitated by any other suitable form of energy such as a gas or plasma arc." (Ex. 1005 at 0187.)

⁴ At least the top left electrode of FIG. 5H is illustrated as *not* being in contact with tissue.

As shown above, Makower states current is applied to the electrodes, and that the electrodes may be bipolar, monopolar or facilitated by any other suitable form of energy such as gas or plasma arc.

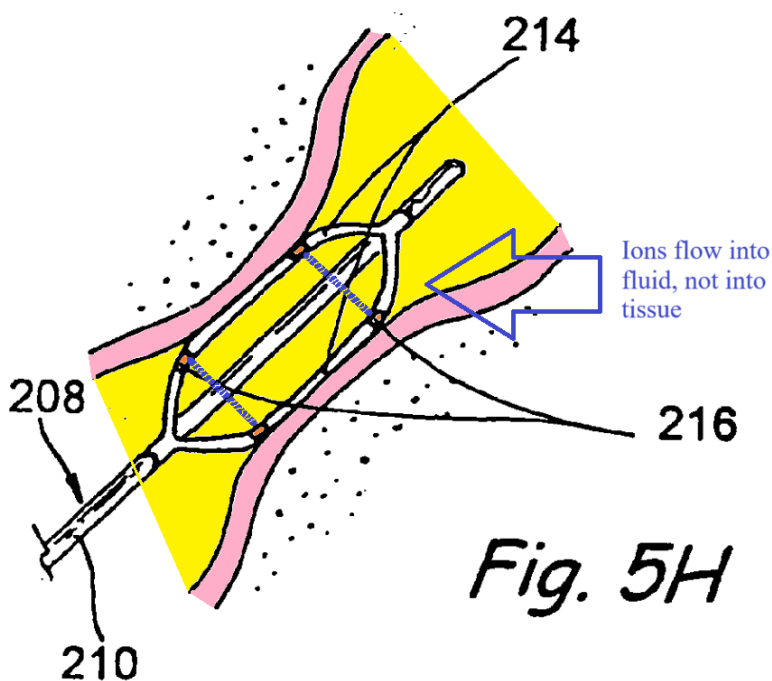
71. A POSITA would have known that monopolar electrode configurations typically consist of an active electrode that is positioned inside the body adjacent the target tissue and a return electrode placed outside of the patient's body. In use, the energy flows from the active electrode inside the body to the return electrode.

72. A POSITA would have known that bipolar electrode configurations, on the other hand, typically consist of two or more closely spaced active electrodes that are positioned inside the body, adjacent the target tissue. In use, the energy current flows between the closely spaced bipolar electrodes.

73. Irrespective of whether the ring electrodes on Makower's FIG. 5H device are monopolar or bipolar, a POSITA would not have been motivated to use Makower's FIG. 5H device to ablate target tissue in the nasopharyngeal passage because a POSITA would not have had a reasonable expectation of success of effectively treating the targeted tissue.

74. Specifically, when Makower's FIG. 5H device is placed in the nasopharyngeal passage, electrolytic fluids within the nose (e.g., mucus, blood,

saline)⁵ will flow into and reside in the interior space of FIG. 5. Further, when current is applied to Makower's ring electrodes, instead of the RF energy being preferentially applied to the tissue, because electrolytic fluid is present in the nose and, thus, in the interior space of Makower's FIG. 5H device, a POSITA would have known that the most conductive pathway (path of least resistance for ions) is through the electrolytic fluid—not through the tissue, as I illustrate below⁶:



⁵ I understand from my conversation with Dr. Levine that these types of fluid are generally present during operation of an RF device designed to treat the nasopharyngeal passage.

⁶ The below illustration presents one potential pathway for the ions to flow; it will be appreciated that, irrespective of which electrodes of Makower are energized, the ions will preferentially flow through the electrolytic fluid and not into the tissue.

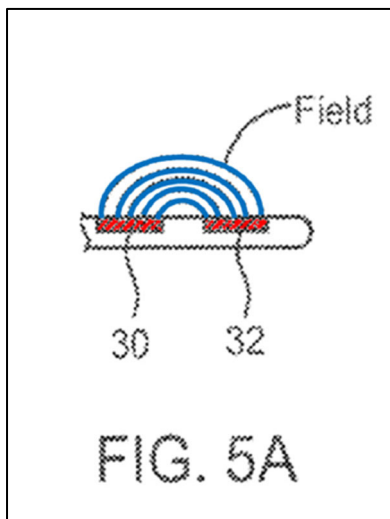
75. Indeed, it was well-known to a POSITA that RF energy will be drawn to the path that it can travel through with the least resistance. A POSITA would have understood that, as between tissue and an electrolytic fluid, such as a mucus, blood, or saline, the path of least resistance would be the electrolytic fluid due to the conductive property of that medium. In the context of bodily fluids and saline, a POSITA would have understood that when RF energy encounters these fluids, the ions will be draw to that medium. This is because these fluids are highly conductive to current due to, for example, their salt content (e.g. the fluid is an electrolyte).

76. Given the foregoing, a POSITA would have recognized that Makower's proposed FIG. 5H device would not be suited to ablatively treat target tissue. Instead, the energy would predominantly flow into the interior of Makower's device, which is not the target tissue thereby inefficiently dispersing current away from the target tissue, which in turn produces an undesirable (and uncontrolled) pattern of heating. A POSITA would find this design unacceptable as it would not accomplish the goal of effectively ablating target tissue. Indeed, given the issues with electrolytic fluids present in its hollow interior, the heating thereof, and the inability to properly control ion flow to tissue, a POSITA would have concluded that there was too much risk of using Makower's proposed FIG. 5H device in operations involving the nasopharyngeal passage and would have sought an alternative device.

B. Claim 7: Makower's Fig. 5H Electrodes Are Not Configured To "Deliver Energy Laterally"

77. Dependent claim 7 recites that the "multiple radiofrequency electrodes are configured to deliver energy laterally relative to the distal portion of the" apparatus' "elongate body." I understand that Petitioners contend that Makower's FIG. 5H device discloses this claim. For the reasons explained below, I disagree.

78. Initially, I note that Petitioners identify FIG. 5A in the '077 patent as showing electrodes that are configured to deliver energy laterally. (Petition at 90-91 (including annotated FIG. 5A (below))).

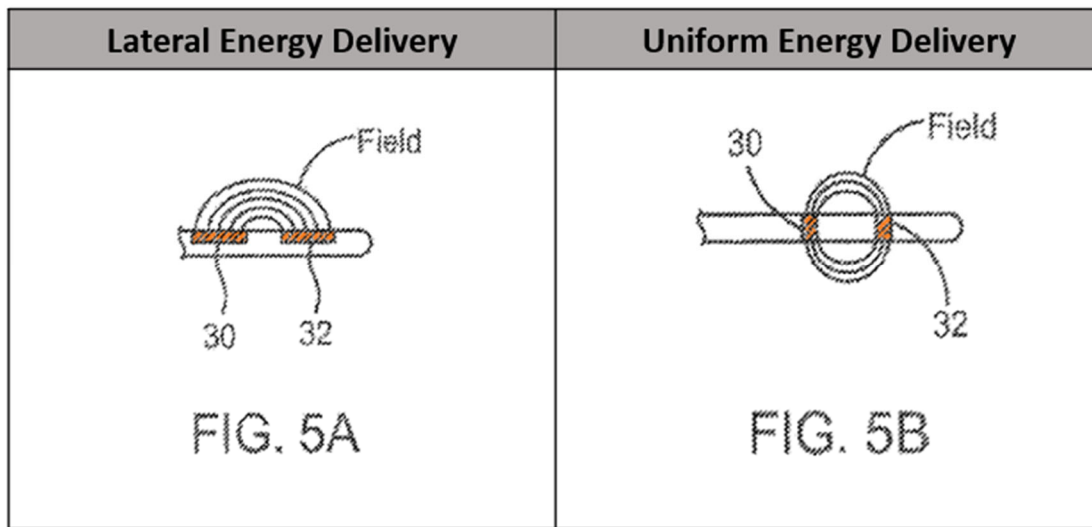


79. I agree with Petitioners that FIG. 5A (above) depicts lateral energy delivery. This is because a POSITA would have understood that the bottom and side surfaces of the FIG. 5A electrodes are insulated, whereas the top of the electrodes are exposed, resulting in energy delivery from only the exposed surface of each electrode and in one direction, i.e., laterally through the electrode's top surfaces.

80. According to Petitioners, “[i]n Makower, a POSITA would have understood current travels from one bipolar electrode to another electrode to create an electric field that travels through contacted tissue.” (Petition at 89.) I disagree that a POSITA would have understood the electrodes on Makower’s FIG. 5H device to deliver energy laterally.

81. Unlike the FIG. 5A electrodes in the ’077 patent, Makower’s FIG. 5H electrodes are ring electrodes, which are designed to emit energy about their entire circumference.⁷ Such current flow is akin to electrode arrangement shown in FIG. 5B of the ’077 patent, which is *not* described as lateral energy delivery but rather is described as “uniform” energy delivery. (Ex-1001 at 16:54-58 (“FIG. 5A depicts and arrangement of electrodes 30 and 32 that produces an electric field concentrated in a lateral direction from the catheter body *whereas, FIG. 5B shows a device constructed to create a more uniform electric field about the shaft of the catheter body.*”).))

⁷ As noted above, this does not mean Makower’s device would preferentially treat tissue; instead ions would preferentially flow into electrolytic fluid present in the nose, as explained previously.

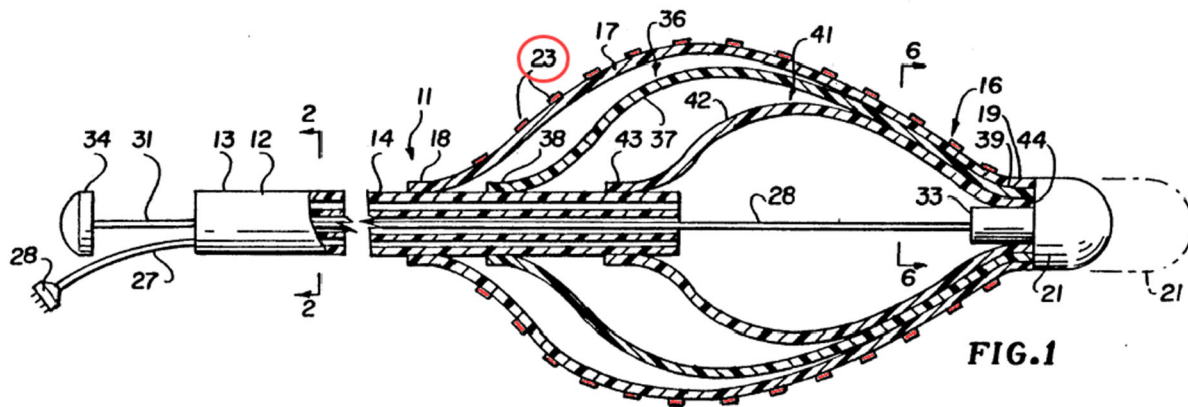


82. Nevertheless, citing to Ex-1068-Imran and Dr. Bu-Saba (Ex-1002-Bu-Saba at ¶¶207-209), Petitioners argue that the electrodes in Makower’s FIG. 5H device are configured to deliver energy laterally based on the assertion that Makower teaches “delivering laterally just as similarly arranged electrodes do in ’077 Figure 5A.” (Petition at 89.)

83. I reviewed Imran, which is Ex-1068 and understand Petitioners to have identified Imran in view of Makower’s disclosure in paragraph [0164]. In that paragraph Makower identifies twenty patents numbers and says these twenty patents “designs and constructions of...components and assemblies” purportedly known in the art that may be incorporated into “*some of the working devices* shown in FIGS. 5A-5Y’”.” (Ex-1005-Makower, [0164].)

84. Initially, I note that Makower does not tie any of these twenty incorporated patents or features thereof to FIG. 5H. In addition, I am unaware of any

explanation in the Petition or Dr. Bu-Saba explaining why a POSITA would have chosen to implement features Imran into the FIG. 5H device, as opposed to any of the other structures in the other identified patents. Instead, Dr. B-Saba asserts that Imran discloses electrodes that deliver energy laterally because FIG. 1 shows electrodes “that are disposed on the lateral side of the distal portion of the treatment device.” (Ex-1002-Bu-Saba at ¶209.) Dr. Bu-Saba cites to annotated FIG. 1 of Imran, which I reproduced below.

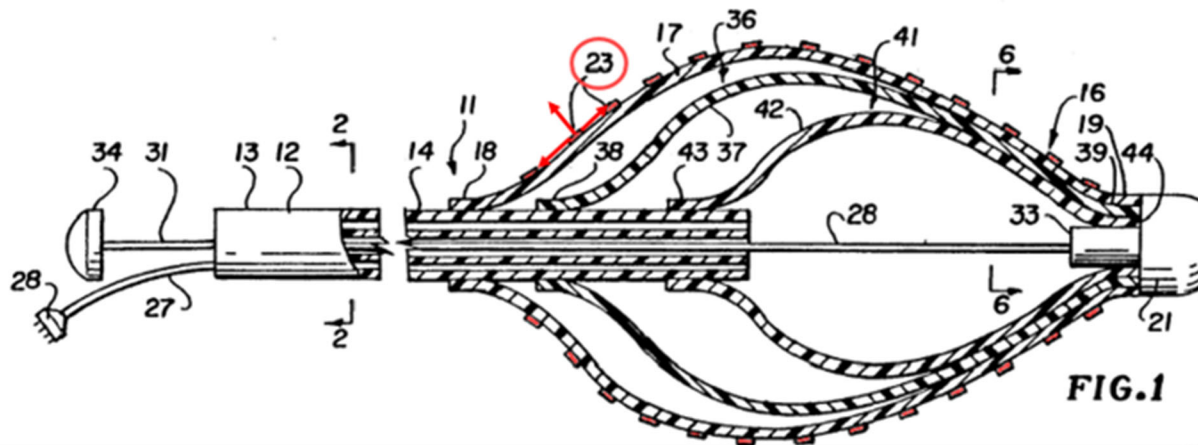


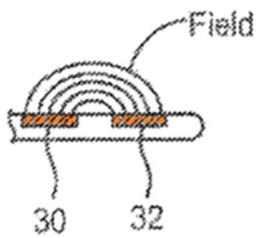
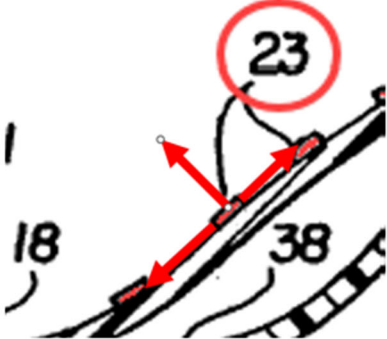
(Annotated FIG. 1 of Imran from Ex-1002-Bu-Saba at ¶209.)

85. I disagree that with Petitioners and Dr. Bu-Saba. As explained below, a POSITA would not have understood Imran’s electrodes to be configured to deliver energy laterally.

86. Imran discloses that FIG. 1 “is a cross-sectional view of the distal extremity of an endocardial catheter for mapping and/or ablation...” As shown in FIG. 1, the electrodes extend above the surface of the struts. Thus, a POSITA would

have understood that, unlike the electrodes laterally delivering energy in FIG. 5A of the '077 patent, which have only a single exposed, top surface, the electrodes in Imran deliver energy in multiple directions, through each, exposed (i.e., non-insulated) surface.



'077 Patent: Lateral Energy Delivery Through Top Electrode Surface	Imran: Energy Delivery Through Multiple Exposed Electrode Surface
 FIG. 5A	

87. In addition, Imran’s written specification does not describe the electrodes in FIG. 1 as delivering energy laterally. Nor does it describe the electrodes as having the lateral surface configuration that a POSITA would understand could be configured to deliver energy laterally.

88. In sum, in my opinion, neither Makower’s FIG. 5H nor Imran disclose the requirement of claim 7, i.e., “wherein the energy delivery element is configured to concentrate energy laterally relative to the distal portion of the treatment device.”

X. GROUND 6: PETITIONERS HAVE FAILED TO SHOW THAT STERN DISCLOSES “MULTIPLE PAIRS OF BIPOLAR ELECTRODES”

89. I understand that in Ground 6, Petitioners allege that Challenged Claim 4 is unpatentable as obvious over Makower in combination with Fang and Edwards as per Ground 5, and further in view of Stern.

90. Challenged Claim 4 depends from Challenged Claim 2, which depends from Challenged Claim 1, and recites, among other things, “wherein the at least two bipolar radiofrequency electrodes comprise multiple pairs of bipolar radiofrequency electrodes.” (Ex-1001 at claim 4.)

91. Petitioners assert that Stern’s Figure 15 teaches “multiple pairs of bipolar radiofrequency electrodes” because Stern Figure 15 depicts “circuitry for *two pairs of bipolar radiofrequency electrodes.*” (Petition at 52 (emphasis in original) Ex-1007-Martin, ¶56; Ex-1009 at FIG. 15, 12:41-13:2.)

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

93. A POSITA would have understood a “pair” of bipolar electrodes to be two electrodes located near each other that have opposite polarities.

94. Stern’s Figure 15, which is reproduced below, discloses a voltage source 228, four electrodes 220, 222, 224, and 226, a grounding pad 230, and nine switches 232, 234, 236, 238, 240, 242, 244, 246, and 248. (Ex-1009-Stern at FIG. 15; *id.* at 12:46-13:2.)

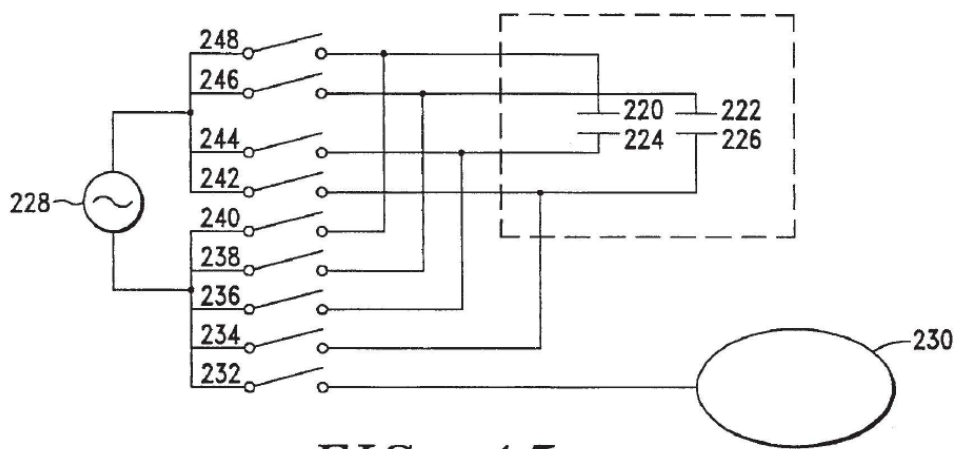


FIG. – 15

(Ex-1009-Stern at FIG. 15.)

95. Stern describes its electrodes as “an array of separate electrodes.” (Ex-1009-Stern at 2:26-29, 2:39-40, 2:59-60.) Depending on which switches are closed, any of electrodes 220, 222, 224, and 226 in Figure 15 can be a monopolar electrode.

(*Id.* at FIG. 15, 12:46-55.) Similarly, depending on which switches are closed, any of electrodes 220, 222, 224, and 226 can be a positive electrode or a negative electrode. (*Id.* at FIG. 15, 12:55-13:2.)

96. None of the electrodes in Stern's Figure 15 have opposite polarities when all the switches are open, and thus there are no bipolar electrode "pairs" in Figure 15 when all the switches are open. (Ex-1009-Stern at FIG. 15, 12:37-13:2.) Rather, a bipolar electrode "pair" is formed in Stern's Figure 15 only when certain switches are closed. (Ex-1009-Stern at FIG. 15, 12:37-13:2.)

97. To form multiple pairs of bipolar electrodes in Stern's Figure 15, three or more of Figure 15's switches must be closed at the same time. However, Stern does not teach this. Instead, Stern teaches that its device is configured to have at most a single pair of bipolar electrodes. Specifically, Stern teaches at most closing one of switches 242, 244, 246, and 248 and one of switches 234, 236, 238, and 240 to form a single pair of bipolar electrodes. (Ex-1009-Stern at 12:55-13:2.) This teaching is consistent with Stern's teaching that its electrodes "are independently and sequentially energized." (*Id.* at 2:31-33, 2:49-53, 10:48-52, 17:54-55.) To energize Stern's electrodes "independently and sequentially," at most two of Stern's switches would be closed at a time.

98. Petitioners likewise fail to identify where Stern teaches closing three or more switches at the same time. At most, Petitioners identify two examples where

Stern's Figure 15 device is configured to have a single pair of electrodes (*i.e.*, electrodes 220 and 224) by closing switches 248 and 236 or by closing switches 246 and 234. (Petition at 52-53 (citing Ex-1009-Stern at 12:55-13:2); Ex-1004-Martin, ¶56 (same).) The deficiency in Petitioners' analysis is illustrated in Petitioners' own annotations to Stern's Figure 15 (reproduced below), which shows two examples of when Stern's device is configured to have a single pair of electrodes:

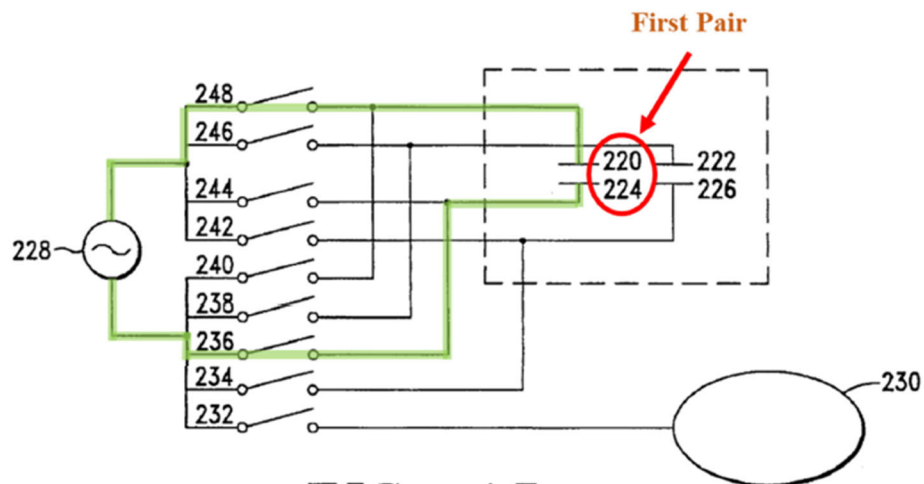


FIG.-15

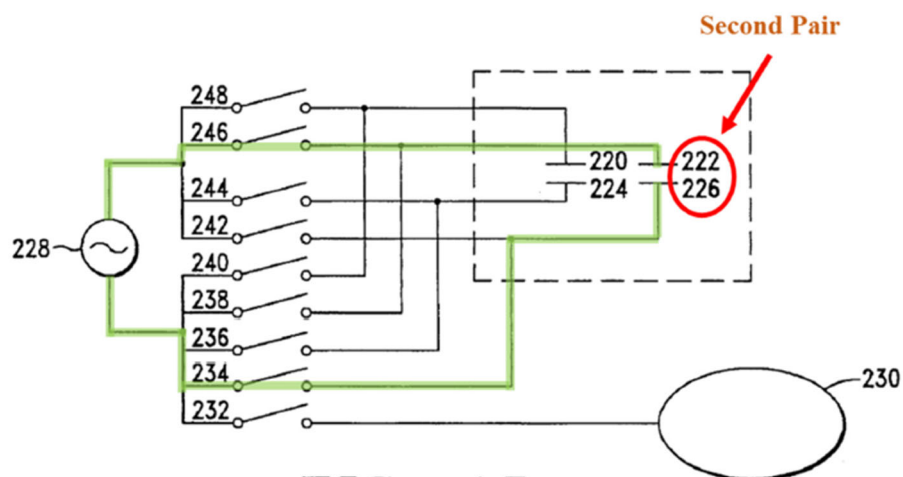


FIG.-15

(Petition at 52-53 (annotations in original).)

99. Accordingly, Petitioners have failed to show that Stern discloses “multiple pairs of bipolar radiofrequency electrodes,” as required by Challenged Claim 5.

XI. DECLARATION IN LIEU OF OATH

100. I hereby 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 § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon. If called to testify as to the truth of the matters stated herein, I could and would testify competently.

101. I declare under penalty of perjury that the foregoing is true and correct.



Dated: October 25, 2024

Dr. Marom Bikson