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. IPR2024-00280

U.S. Patent No. 10,894,011

DECLARATION OF DR. NICOLAS BU-SABA REGARDING CLAIMS 1-2, 5, 8-10, 12, AND 14 OF U.S. PATENT NO. 10,894,011

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I, Nicolas Y. Bu-Saba, M.D., declare as follows:

I. INTRODUCTION

1. My name is Nicolas Y. Bu-Saba.

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 provide testimony pertinent to Petitioners' Petition for *Inter Partes* Review of U.S. Patent No. 10,894,011 (the "'011 patent"). I understand that Petitioners are challenging the patentability of claims 1-2, 5, 8-10, 12, and 14 of the '011 patent ("Challenged Claims").

II. QUALIFICATIONS AND EXPERIENCE

3. I have been involved in the in the field of otolaryngology, and in particular rhinology, for over 28 years.[1] My qualifications for forming the opinions set forth in this declaration are summarized below. My curriculum vitae, which

[1] Otolaryngology is a field of medicine focused on treating the ear, nose, and throat. An otolaryngologist is often called an ear, nose, and throat doctor (or ENT). A sub-field of otolaryngology is rhinology, which focuses on treating nasal conditions such as rhinitis.

describes my education, experience, professional activities, and lists, among other things, my publications and patents, is attached as **Appendix A**.

4. I received a Bachelor of Science in biology-chemistry with distinction (in 1981), and a Doctor of Medicine ("M.D.") with distinction (in 1985), from the American University of Beirut. From 1985-1986, I was an intern in the Department of Surgery at the American University of Beirut Medical Center. From 1986-1989, I completed a residency in the Department of Otolaryngology, American University of Beirut Medical Center. From 1989-1990, I completed a fellowship in general otolaryngology at the Massachusetts Eye and Ear and Harvard Medical School. From 1990-1991, I completed a residency in the Department of Surgery of Beth Israel-Deaconess Hospital and Harvard Medical School. From 1991-1995, I completed a residency in the Department of Otolaryngology-Head and Neck Surgery of the Massachusetts Eye and Ear and in the Department of Otolaryngology-Head and Neck Surgery of Harvard Medical School.

5. I have worked as an Otolaryngology Surgeon in the VA Boston Healthcare System from 1995 until my retirement from the VA in September 2023. Since 1996, I have worked as a Surgeon at the Massachusetts Eye and Ear and as a Clinical Associate in Surgery at Massachusetts General Hospital in Boston, Massachusetts. My clinical practice encompasses most areas in the field of

otolaryngology including head and neck surgery, rhinology and paranasal sinus disorders, and obstructive sleep apnea (OSA) / sleep-disordered breathing. From 1995 through 2016, I conducted approximately 4,000 outpatient clinic visits and perform approximately 300 operations on an annual basis. I have continued to conduct outpatient clinical visits and operations on a reduced basis since January 2017. I have held numerous other hospital appointments described in further detail in my CV (Appendix A).

6. Since 2010, I have served as an Associate Professor in the Department of Otolaryngology of Harvard Medical School. Between 2010 and September 2023, I have served as an Adjunct Associate Professor in the Department of Otolaryngology—Head and Neck Surgery at the Boston University School of Medicine. I have held numerous other academic appointments described in further detail in my CV (Appendix A). My research interests are in the fields of Rhinology, Paranasal Sinus Disorders, and Sleep-Disordered Breathing. I have co-authored dozens of peer-reviewed articles in the field of otolaryngology, including articles on rhinology, such as: (1) Bu-Saba NY. Same stage nasal and palatopharyngeal surgery for OSA: Is it safe? *Otolaryngol Head Neck Surg* 2002; 126:399-403; (2) Bu-Saba NY, Hossain M. Clinical outcomes of septoplasty and inferior turbinate reduction in the geriatric Veterans population. *Am J Rhinol* 2004; 18: 343-7; (3) Bu-Saba NY,

Sin HJ, Faquin W. Correlation between Middle Turbinate and Ipsilateral Ethmoid Histopathology in Chronic Rhinosinusitis. *Otolaryngology Head Neck Surg* 2006; 134:250-4; (4) Yamasaki A, Levesque PA, Bleier BS, Bu-Saba NY, Gray ST, Holbrook EH, Sedaghat AR, Lindsay RW. Improvement in nasal obstruction and quality of life after septorhinoplasty and turbinate surgery. *Laryngoscope* 2019; 129:1554-1560. Additional articles, case series, case reports, book chapters, editorials, and reviews are described in further detail in my CV (Appendix A).

7. In the course of my clinical and academic practice, I have experience performing and designing methods and devices for the treatment of ear, nose, and throat conditions. Among other methods, I have extensive experience using radiofrequency-based ablation methods for treating target tissue involved in various conditions. For instance, in and around 1999 I popularized radiofrequency soft palate ablation (somnoplasty) as a treatment for snoring and mild obstructive sleep apnea at the Massachusetts Eye and Ear Infirmary. In or around 2000, I also introduced tongue base radiofrequency ablation as a treatment for patients with obstructive sleep apnea at the Boston VA Healthcare System. This treatment allowed us to treat sleep apnea patients who had a site of obstruction in their hypopharynx (tongue base area) who had failed palatopharyngeal surgery and CPAP therapy. Additionally, in 1999, I taught a course titled "Somnoplasty" administered

by Boston University School of Medicine. In this course, I specifically taught other otolaryngology specialists about using radiofrequency treatment of the turbinates and soft palate to treat patients that present sleep-disordered breathing. Thus, I have specifically lectured on using radiofrequency ablation to treat nasal conditions.

8. I am being compensated for my work on this matter at my standard hourly consulting rate of $750 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 this Declaration nor is it dependent on any testimony I give or on the outcome of this proceeding.

9. I have no financial interest in Petitioners or Patent Owner. I similarly have no financial interest in the ’011 patent, and have had no contact with the named inventors of the ’011 patent.

III. LEGAL PRINCIPLES

10. I am not an attorney. For the purposes of this declaration, I have been informed about certain aspects of the law that are relevant to my opinions. My understanding of the law was provided to me by Petitioners’ attorneys.

A. Scope of Opinion

11. I have been informed and understand that the petitioner in an *inter partes* review may request cancellation of claims as unpatentable only on grounds that such claims are anticipated or would have been obvious to a person of ordinary skill in the art at the time of the purported invention, and only on the basis of prior art consisting of patents or printed publications. My opinions in this matter address only such grounds.

B. Anticipation

12. I have been informed by counsel that a patent claim is anticipated and therefore unpatentable if each element of that claim is present in a single prior art reference.

C. Obviousness

13. I understand that a claim is unpatentable if it would have been obvious to a person of ordinary skill in the art at the time the alleged invention was made. I understand that a claim could have been obvious based on the teachings or suggestions of a single prior art reference or from a combination of two or more prior art references. I understand that an obviousness analysis requires an understanding of the scope and content of the prior art, any differences between the alleged

invention and the prior art, and the level of ordinary skill in evaluating the pertinent art.

14. I further understand that a claim would have been obvious if it unites old elements with no change to their respective functions, or alters prior art by mere substitution of one element for another known in the field, and that combination yields predictable results. Also, I understand that obviousness does not require physical combination/bodily incorporation, but rather consideration of what the combined teachings would have suggested to persons of ordinary skill in the art at the time of the alleged invention.

15. In connection with obviousness, I have been informed that there must have been some reason or motivation that would have led a person of ordinary skill in the art to combine or modify the relevant teachings in the prior art to obtain the claimed invention, and one of ordinary skill in the art must have had a reasonable expectation of success in doing so.

16. While it may be helpful to identify a reason for this combination, I understand that there is no rigid requirement of finding an express teaching, suggestion, or motivation to combine within the references. If a person of ordinary skill in the art can implement a predictable variation, obviousness likely bars its patentability. For the same reason, if a technique has been used to improve one

device and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique would have been obvious. I understand that a claim would have been obvious if a person of ordinary skill in the art would have had reason to combine multiple prior art references or add missing features to reproduce the alleged invention recited in the claims.

17. In sum, I understand that a determination of whether a claim would have been obvious is based upon a variety of considerations, including, among others:

- whether the teachings of the prior art references disclose known concepts combined in familiar ways, which, when combined, would yield predictable results;
- whether a person having ordinary skill in the art could implement a predictable variation, and would see the benefit of doing so;
- whether the claimed elements represent one of a limited number of known design choices, and would have a reasonable expectation of success by those skilled in the art;
- whether a person having ordinary skill would have recognized a reason to combine known elements in the manner described in the claim;
- whether there is some teaching or suggestion in the prior art to make the modification or combination of elements claimed in the patent; and

- whether the alleged invention applies a known technique that had been used to improve a similar device or method in a similar way.

18. I also understand that in considering obviousness, it is important not to determine obviousness using the benefit of hindsight derived from the patent being considered. I also understand that one of ordinary skill in the art has ordinary creativity, and is not an automaton.

19. I further understand that certain factors, commonly referred to as secondary considerations, may support or rebut the obviousness of a claim. I also understand that secondary considerations cannot be used to overcome anticipation. I understand that such secondary considerations include, among other things, commercial success of the patented invention, skepticism of those having ordinary skill in the art at the time of invention, unexpected results of the invention, any long-felt but unsolved need in the art that was satisfied by the alleged invention, the failure of others to make the alleged invention, praise of the alleged invention by those having ordinary skill in the art, and copying of the alleged invention by others in the field. I understand that there must be a nexus, that is, a connection, between any such secondary considerations and the alleged invention. I also understand that contemporaneous and independent invention by others is a secondary consideration tending to show obviousness.

20. I reserve the right to respond to any allegations that may be put forth by Patent Owner in this proceeding that any secondary considerations tend to rebut the obviousness of any claim of the ’011 patent discussed in this declaration.

D. Claim Dependency

21. I understand that a patent may include two types of claims, independent claims and dependent claims. An independent claim stands alone and includes only the limitations it recites. A dependent claim can depend from an independent claim or another dependent claim. I understand that a dependent claim includes all the limitations that it recites in addition to all of the limitations recited in the claim or claims from which it depends.

E. Priority

22. I have been informed and understand that for a patent’s claims to receive the benefit of priority of an earlier-filed application, every application in the priority chain between that earlier-filed application and the application in question must support every limitation of the claim. This means every parent application must describe every limitation of every claim and that it is not enough for the parent application to simply render obvious the claims of the patent claims in question.

F. Written Description

23. I have been informed and understand that whether an application describes a patent's claim limitations is known as the "written description requirement." I have been informed and understand that to satisfy the written description requirement, the patent's specification must describe the claimed invention in sufficient detail that a person of ordinary skill in the art could reasonably conclude that the inventor had possession of the claimed invention at the time of filing.

* * *

24. The analysis in this declaration is in accordance with the above-stated legal principles.

IV. MATERIALS CONSIDERED

25. In forming my opinions, in addition to my knowledge and experience, I have considered the materials cited herein and listed in **Appendix B**.

V. LEVEL OF ORDINARY SKILL IN THE ART

26. It is my understanding that when considering the claims of the '011 patent and the prior art, I must do so based on the perspective of one of ordinary skill in the art at the relevant effective priority date.

27. As detailed in Section VII.B (Prosecution History), I understand that the ’011 patent claims priority to a series of patent application, starting with a provisional application filed on July 22, 2005. *See* Ex.1001-USP011, Cover. However, for the reasons I explain in Section IX (Priority Date), it is my opinion that the Challenged Claims do not have written support in any application prior to the filing of the parent to the ’011 patent, U.S. Patent No. 10,610,675 (the “’675 patent”) which was filed on October 22, 2019. As a result, I understand that the ’011 patent would only be entitled to a priority date of October 22, 2019—the filing date of the ’675 patent. *See* Ex.1021-USP675, Cover. For purposes of my analysis, I have considered the level of ordinary skill in the art as of July 2005 and as of October 2019. In my opinion, that level was the same for all relevant times between 2005 and 2019.

28. 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.

29. Based on these factors as well as my experience and expertise, a person of ordinary skill in the art at all relevant times (2005-2019) (hereinafter, a "POSITA") 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.

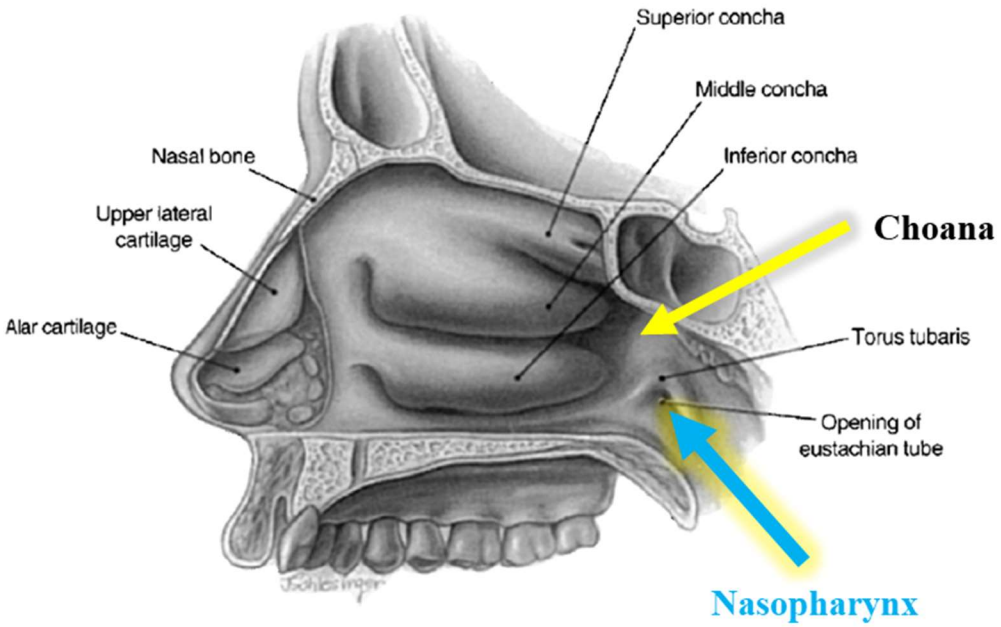
30. Although my qualifications and experience exceeded those of a person of ordinary skill in the art as defined above between 2005 and 2019, my analysis and opinions herein regarding the '011 patent have been based on the perspective of a person of ordinary skill in the art as of the relevant times of the '011 patent (2005-2019).

VI. OVERVIEW OF THE TECHNOLOGY

A. Relevant Anatomy

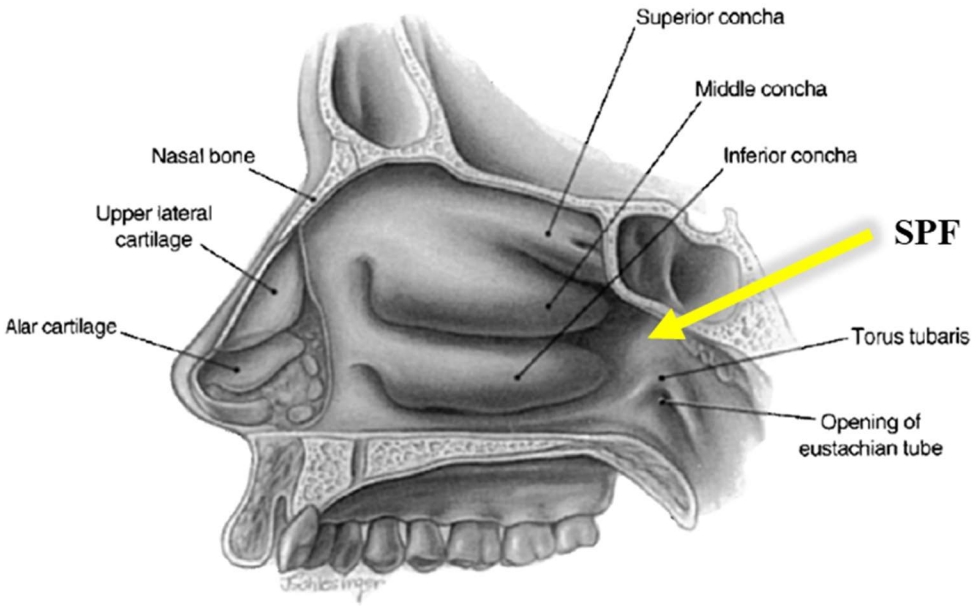
31. By the early 2000s, the anatomy of the nose and upper airways was well understood by those skilled in the art. Although I have selected discrete prior art references to explain the relevant anatomy, many other references describe the same. The left and right nostrils of the nose lead into left and right nasal cavities, and the nasal cavities are separated by the nasal septum. *See, e.g.*, Ex.1005-Makower,

[0001], [0131]. As depicted below, the nasal cavity typically contains three turbinates (i.e., concha)—the superior turbinate (top), the middle turbinate (middle), and the inferior turbinate (bottom). Each turbinate (i.e., concha) is lined with mucosal tissue, and the turbinates, among other things, help increase the total interior surface area of the nasal cavity and transfer moisture and warmth to air that is inhaled. *E.g.*, *id*., [0004]. The left and right nasal cavities terminate at the posterior choana, which as shown below "opens into the nasopharynx." *Id*., [0002]. The nasopharynx is the upper portion of the pharynx (otherwise known as the throat) and is the closest part of the pharynx to the nasal cavities.

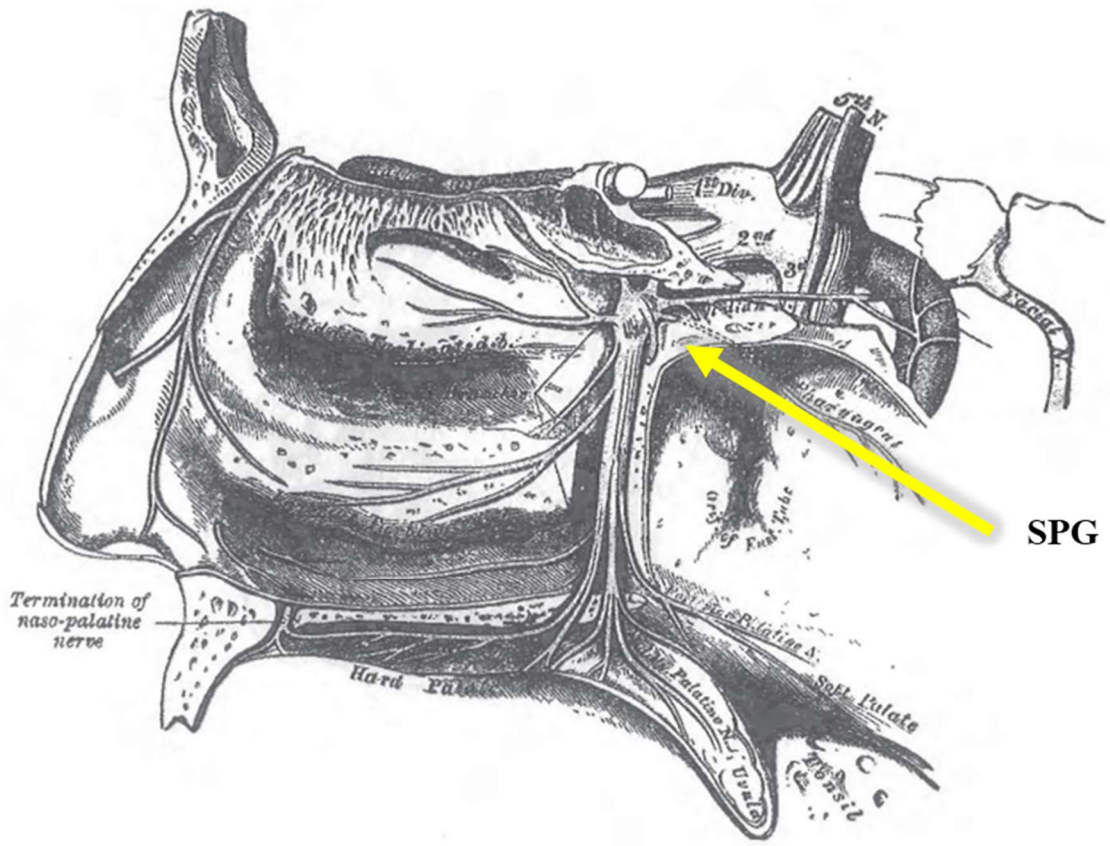


Ex.1064-Lane, 338.

32. By the early 2000s, it was known that nerves located throughout tissue in the nasal cavity and the nasopharynx control cells in that area. Some of those cells are goblet cells, which are cells that, among other functions, generate mucus. *E.g.*, Ex.1052-Fenton, 23 ("The first line of defense is the covering of mucous secretion on the epithelium, as produced by the goblet cells and glands of the mucous membrane.…Mucous glands and goblet cells are found in the walls of the nasopharynx and also in the lungs."). One of the nerves in the area of the nasal cavity and nasopharynx that controls goblet cells is called the posterior nasal nerve which branches from the sphenopalatine ganglion or SPG. The SPG is located at the pterygomaxillary space (pterygopalatine fossa) behind the maxillary bone and to the side of the back of the nasal cavity near the sphenopalatine foramen or SPF. The SPF is highlighted in the following figure.



Ex.1064-Lane, 338; *see also* Ex.1041-Stedman's, 700 (defining "sphenopalatine foramen" as "formed from the sphenopalatine notch of the palatine bone in articulation with the sphenoid bone; it transmits the sphenopalatine artery and accompany nerves"); Ex.1042-PDR, 700 (same). As explained above in this section, the posterior nasal nerve branches from the SPG. Like the SPG, the posterior nasal nerve is located in the area of the nasal cavity and nasopharynx and controls the production of mucus (e.g., by goblet cells). The SPG is highlighted in the following figure, which also shows the posterior nasal nerve branching throughout the nasal cavity and nasopharynx. As I explain below in Section X.A.1.b (Ground I, Claim 1, Element 1[a]), the passageway that includes the nasal cavity and nasopharynx is known as the nasopharyngeal passage.



Ex.1065-Gray, 864. It was well known by the early 2000s that the posterior nasal nerve and other branches of SPG receive contributions from another nerve called the Vidian nerve (which provides autonomic innervation), which is located further posterior and lateral from the SPF. *E.g.*, Ex.1054-Arora, 80.

33. The SPG is part of the parasympathetic nervous system, i.e., part of the body's autonomous nervous system. *E.g.*, Ex.1050-Waxman, 260, 262-263, 266. The nervous system in the nose and nasopharynx functions by having various smaller nerves branch from a larger nerve. Thus, skilled artisans knew by the early

2000s that the SPG had many parasympathetic nerves branching off of it that extended throughout the nasal cavity and nasopharynx. These parasympathetic nerves were known to control cells adjacent to where they had branched, such as goblet cells that generate mucus. Consistent with the knowledge that parasympathetic nerves originating at the SPG and branching throughout the nasal cavity and nasopharynx control mucus production, it was known that the activity of parasympathetic nerves can cause physiological symptoms such as congestion and mucus production. *E.g.*, Ex.1051-Windsor, 284 ("Post-ganglionic parasympathetic neurons from this ganglion then distribute to the lacrimal gland and glands of the nasal cavity, paranasal sinuses, palate, and upper pharynx where they promote secretion."). Indeed, it was known since the 1960s that disrupting the parasympathetic nerves in the Vidian nerve reduced symptoms of rhinitis. *E.g.*, Ex.1003-Saadat, 2:39-47.

B. Therapy Using Neurotoxins

34. As the '011 patent itself states, by the early 2000s, "[c]ontrolled injection of neurotoxins [was] a common procedure…." Ex.1001-USP011, 1:50-51. One known neurotoxin was botulinum neurotoxin, which was and remains commonly known by its brand name, BOTOX®. As explained by the '011 patent, neurotoxins such as BOTOX® "blocks the release of neurotransmitter[s] from the

nerves that control the contraction of…muscles" or disable mucus producing cells, i.e., blocks the secretion of mucus from goblet cells or mucus glands. *Id*., 1:62-2:18, 3:27-36. For example, injecting neurotoxin in muscle treats conditions by "paralyz[ing] or weaken[ing]" muscles that would, e.g., normally signal nerves to cause physiological symptoms. *Id*., 1:62-2:18. Prior to 2005, neurotoxin injection treatment was well-known and had been studied for a wide range of physiological symptoms including rhinorrhea, rhinitis, asthma, arthritis, essential tremor, cardiovascular disease, sinus headache, and tumors, among many others. *Id*., 2:19-48, 3:37-51, 4:1-17; Ex.1057-Sanders, 2:30-38, 10:14-22, claims 1-4 (using BOTOX to treat rhinorrhea); Ex.1059-Rubisnky, [0013] (using a cytotoxic for treating cancer).

35. For instance, it was well-known to persons of ordinary skill in the art that rhinitis symptoms were alleviated by applying neurotoxin "onto the nasal mucosa" either by topical application or injection into the SPG. *E.g*., Ex.1057-Sanders, 2:30-38 ("According to the present invention a variety of autonomic nerve targets. modes of administration of botulinum toxin, and resultant beneficial clinical effects are contemplated. For example, rhinorrhea (including post nasal drip) may be effectively treated either by topical application of botulinum toxin onto the nasal mucosa or injection into the sphenopalatine ganglion."), 10:14-22 ("Rhinorrhea in

humans may be treated by administering botulinum toxin onto the nasal mucosa.…Alternatively, the botulinum toxin may be injected into the sphenopalatine ganglion. Relatively long-term relief (e.g. up to six months) from chronic rhinorrhea is to be expected."), claims 1-4 (claiming a method of administering toxins to nasal cavity or SPG "to cause denervation of the neurons" to treat "at least one symptom of rhinorrhea"); Ex.1001-USP011, 2:19-48, 3:37-51, 4:1-17.

C. Therapy Using Energy

36. Using energy in medical applications has been known since the early 1900s to change the property and function of tissue. For example, a patent published in 1907 discloses cauterizing tissue (i.e., heating tissue) using a "high frequency electrical current…." Ex.1058-De Forest, 1:14-23. Over the last several decades, different types of energy has been applied to tissue. For example, a patent filed in the 1960s discloses applying energy via sound (e.g., ultrasonic). *See* Ex.1061-Fry, 1:67-70 ("By focusing an ultrasonic beam upon a portion of the nerve pathway which leads from the eye to the visual cortex, it is possible to reversibly suppress the transmission of nerve impulses along this pathway."). And a separate patent filed in the 1960s discloses applying energy via light. *See* Ex.1060-Meyer, 1:10-14 ("[I]n accordance with this invention, the laser energy is concentrated at a specified region

of a laser transmission rod terminating in a probe which penetrates the skin to reach the hair follicle."), 1:35-40. By the early 2000s, it was well known that applying energy to tissue could be used to make cells more permeable (e.g., using electroporation) to help facilitate the application of another therapy or could be used to damage or modify tissue (e.g., ablation) to treat a condition.

1. Electroporation

37. Electroporation has been "known for over half a century." E.g., Ex.1059-Rubisnky, [0007]. Electroporation "is defined as the phenomenon that makes cell membranes permeable by exposing them to certain electric pulses," and can be either reversible or irreversible. Ex.1059-Rubinsky, [0004], [0007]. Reversible poration occurs when the cell membrane reseals, and the cell survives. *Id.*, [0007]. Irreversible poration occurs when the cell membrane does not reseal, and the cell breaks down. *Id*. By the early 2000s, reversible "[t]issue electroporation" was "becoming an increasingly popular minimally invasive surgical technique for introducing small drugs and macromolecules into cells in specific areas of the body." *Id*., [0011], [0014]. As one example, scientists studied reversibly electroporating cell membranes to introduce cancer drugs more easily to such cells without permanent damage. *Id*., [0014]. In other words, electroporation energy was used as an adjuvant to cancer drugs that acted as the therapeutic agent.

It was also known that other types of energy, such as ultrasonic (sound) energy or heating could be used to achieve cell poration. *E.g.*, Ex.1001-USP011, 13:29-42 ("[T]he term 'poration' includes various forms of electroporation, such as the use of pulsed electric fields (PEFs), nanosecond pulsed electric fields (nsPEFs), ionophoreseis, electrophoresis, electropermeabilization, as well as other energy mediated permeabilization, including sonoporation (mediated by ultrasonic or other acoustic energy), and/or combinations thereof, to create temporary pores in a targeted cell membrane.").

2. <u>Ablation</u>

38. Ablation has also been known for decades, and as a result, "a wide range of RF generators and electrodes" for accomplishing "RF heat lesion" were known. Ex.1053-McGovern, 3:53-56; Ex.1054-Arora, 80 (1980 publication discussing cryoablation). Unlike electroporation where energy is applied to create pores in cells, ablation involves applying energy to damage or modify tissue for therapeutic effect. The basic principle of ablation was known to have wide applicability and was used in numerous parts of the body such as the brain, stomach, heart, airways, and nose to treat patients. *E.g.*, Ex.1040-Stone, 22:21-31 ("The anatomical structure into which the catheter is placed may be, for example, the esophagus, the oral cavity, the nasopharyngeal cavity, the auditory tube and

tympanic cavity, the sinus of the brain, the arterial system, the venous system, the heart, the larynx, the trachea, the bronchus, the stomach, the duodenum, the ileum, the colon, the rectum, the bladder, the ureter, the ejaculatory duct, the vas deferens, the urethra, the uterine cavity, the vaginal canal, and the cervical canal.”). For each location in the body where ablation is used, tissue causing a condition or symptom is destroyed or modified such that the treatment reduces or stops the ablated tissue’s operation, and thereby addresses the condition or symptom. Thus, ablation has a qualitatively different goal than reversible electroporation. While reversible electroporation is designed to maintain the operation of cells and enhance their treatment by other therapeutic agents, ablation is designed to alter (or destroy) the cells and thereby directly treat the condition or symptom. *E.g.*, Ex.1059-Rubinsky, [0003], [0005].

39. I have personally used and taught ablation techniques for use in the nasal cavity and nasopharynx, among other anatomical locations, since the 1990s. For example, in 1999, I taught a class in which I discussed techniques for using RF ablation in the nasal cavity. Moreover, by the early 2000s, I was routinely using ablation techniques, including RF ablation with temperature-controlled RF delivery, to treat various nasal conditions as a part of my clinical work. By the early 2000s, I

also routinely used RF ablation and tissue reduction techniques to other parts of the upper airway including soft palate and base of tongue.

40. Ablation energy can be delivered in many forms, including by heating or cooling. *E.g.*, Ex.1008-Edwards-535, Abstract ("An apparatus is provided for ablating at least a portion of a nasal concha."), 5:18-45 (ablation is accomplished via heating); Ex.1054-Arora, 80 ("Cryodestruction of the nasal branches of the Vidian nerve in the region of the sphenopalatine foramen has been done in cases of vasomotor rhinitis."). By the early 2000s, radiofrequency ("RF") ablation was well known. RF ablation is accomplished using bi-polar or monopolar electrodes to deliver RF energy, in the form of alternating electrical current, to heat and cauterize tissue. *E.g.*, Ex.1009-Stern, Abstract ("[P]ower is provided on the basis of a switching arrangement which provides either monopolar or bipolar energy to the electrodes."), 1:14-23, 2:11-19 ("RF current is passed through substantially the entire surface of the endometrium by activating the electrodes. The current is sufficient to resistively heat the endometrium in a single operation to a temperature within a range of between 45° C. to 90° C. for a time sufficient to destroy the cells of the lining while maintaining the average temperature of the myometrium at a temperature of substantially 42° C. or less. The RF current has a frequency of at least 250 kHz and less than 100 MHz."), 13:3-20. The functionality of RF delivery

devices was well known and often used by those of ordinary skill in the art. Those of ordinary skill in the art would use an energy source such as a generator (versions of which were commercially available in multiple types as of the early 2000s) and connect it via electrical connections such as cables or wires to RF electrodes. Artisans would configure the generator such that the energy supplied by the generator to the electrodes would be high enough to increase the temperature of the tissue to cause damage.

41. RF electrodes could be powered by generators in this routine manner for use for different purposes by varying the intensity of the energy delivered. Thus, RF administered at ***lower levels*** is used for reversible electroporation because it will "produce no other substantial effect on biological cells than the permeabilization of the cell membrane." In contrast, RF energy delivered at ***higher*** levels is necessary to cause the damage or modification for ablation. *See, e.g.*, Ex.1059-Rubisnky, [0004]. Accordingly, it was well-known that the energy used for RF ablation was "distinctly different from the pulses which produce electroporation." *Id.*, [0005].

42. One well-known mechanism for determining whether RF electrodes are operating for their intended effect is to use sensors deployed on or close to the portion of the device with the electrodes. *E.g.*, Ex.1005-Makower, [0187] ("Additionally, sensing elements may also be attached to the catheter and/or strut

members to monitor various parameters of the catheter and/or surrounding tissue (e.g., temperature, etc.)."); Ex.1047-Flaherty, 17:53-57 ("Other feedback elements may also be provided, for example, a thermocouple or other temperature sensor may be provided on systems including ionophoresis electrodes or ablation devices to monitor the amount of heating being experienced by tissue during a procedure."); *see also* Ex.1046-Lehmann, 5:31-33 ("Thermocouples 35 can be associated with one or more of the elements 34 and the tip 32 [on a cryoablation catheter]."). For example, there were multiple well-known types of temperature sensors, including devices called "thermocouples" that could be connected to monitoring systems such that a physician administering RF energy could get real-time readings of the temperature of the tissue being treated and maintain it within a desired range based on the purpose of the application. *E.g.*, Ex.1008-Edwards-535, 9:24-26 ("In one embodiment, the apparatus includes at least one temperature sensor, such as a thermocouple or thermistor."); Ex.1062-Townley, [0044] ("In certain embodiments, the therapeutic assembly 212 can include one or more sensors (not shown), such as one or more temperature sensors (e.g., thermocouples, thermistors, etc.)…."), [0074]; Ex.1047-Flaherty, 17:53-57. Among other things, such temperature sensing and monitoring assisted physicians with maintaining patient safety, including ensuring temperatures are not too high. *E.g.*, Ex.1008-Edwards-535, 9:24-45 ("The

temperature sensor is coupled to a communication link (such as a conductor), which is coupled to the processor….[T]he processor may control the delivery of RF energy to achieve delivery of a selected amount of energy, to achieve a selected temperature, or to achieve a selected amount of ablation of a section of a nasal concha."); Ex.1062-Townley, [0074] ("The temperature measurements can provide the operator or the system with feedback regarding the effect of the therapeutic neuromodulation on the tissue."); Ex.1005-Makower, [0187].

D. Treating Nasal Conditions

43. Methods and apparatuses for treating nasal conditions were well-known by the early 2000s. Rhinitis is a nasal condition in which the body produces excess mucus. Symptoms of rhinitis include, for example, chronic cough, congestion, and runny nose. Rhinitis may be associated with the common cold, allergies (allergic rhinitis, e.g., due to seasonal allergies), and year-round chronic rhinitis (e.g., allergic and non-allergic including vasomotor rhinitis). Chronic rhinitis can impair a patient's quality of life and result in serious health consequences if left untreated.

44. By the early 2000s, rhinitis was a well-known nasal condition and the subject of extensive medical research. Because it was also understood that parasympathetic nerves branching from the SPG, which derives from the Vidian nerve, have a role in controlling the tissue in the nasal mucosa—and, specifically,

goblet cells that produce mucus—that is involved in causing the symptoms of rhinitis, medical researchers developed techniques that involved controlling or changing those parasympathetic nerves in order to treat rhinitis.

45. One well-known class of techniques involved injection of ***neurotoxin*** to block parasympathetic-controlled mucus secretion by goblet cells or mucus glands thereby reducing rhinitis. *E.g.*, Ex.1057-Sanders, 2:30-38, 10:14-22, claims 1-4. As discussed below, the ’011 patent was directed to this class of neurotoxin-based techniques. The ’011 patent is directed to using electroporation energy to cause reversible poration of cells, which prepares those cells to receive neurotoxin (which is administered in combination with the electroporation energy) and enhances neurotoxin uptake. *See* Section VII.A.

46. Another well-known technique involved delivering energy to the nose in order to ***ablate*** the cells responsible for controlling or causing rhinitis and its symptoms. *E.g.*, Ex.1005-Makower, [0187]; Ex.1054-Arora, 80; Ex.1006-Fang, 876-877; Ex.1044-Chen, 240. Thus, but the early 2000s, scientists and clinicians had developed and utilized devices that used different types of energy to ablate the parasympathetic nerves branching from the SPG or nasal tissue that are responsible for causing rhinitis symptoms. For instance, in Fang, the medical researchers described using RF energy to “block[] the parasympathetic pathway of the nasal

mucosa," which "reduce[ed] glandular secretion, and thus achieve[d] the therapeutic purpose[]" of treating rhinitis. Ex.1006-Fang, 877. A similar technique was described in Chen—scientists used RF energy to block parasympathetic nerve activity to treat rhinitis. Ex.1044-Chen,[2] 240 ("The use of radiofrequency thermocoagulation of the posterior inferior nasal nerve, anterior ethmoidal nerves, and inferior turbinate…can widely block the source of the parasympathetic nerves in the nasal cavity and reduce the excitability of the parasympathetic nerves [to

[2] *See* Ex.1071 (translation declaration for Chen). Moreover, I understand there are two translations of Chen (Ex.1044-Chen and Ex. 1079). I have reviewed both translations. The minor differences between the two translations (see, e.g., Ex.1044-Chen, 240 ("Follow-up examination was carried out half a year after treatment **concerning** the improvement of nasal symptoms and the findings from nasal examination."); Ex.1079, 39 ("Follow-up examination was carried out at half a year after treatment, **including** the improvement of nasal symptoms and findings from nasal examination.")) do not impact my opinions as set forth herein. Therefore, although I cite to Ex.1044-Chen in my declaration, my analysis and opinions applies equally to Ex.1079.

eliminate symptoms such as nasal congestion and runny nose]."); *see also* Ex.1043-Kong,[3] 214-215 (using "radiofrequency ablation" to treat "perennial allergic rhinitis"); Ex.1046-Liang,[4] 341-342 ("The increased activity of the parasympathetic nervous system in the nasal cavity is an important factor in the onset of allergic rhinitis. From October 1996 to September 1997, we used radiofrequency hyperthermia devices under nasal endoscopy to treat 88 cases of ethmoidal nerve with allergic rhinitis by thermocoagulation. After 1 year of follow-up, the therapeutic effect was significant."). Arora performed a similar technique using a different method, using cryotherapy (or cooling) to ablate tissue or branches of the Vidian nerve (e.g., the SPG) to treat rhinitis. Ex.1054-Arora, 80 ("Cryodestruction of the nasal branches of the Vidian nerve in the region of the sphenopalatine foramen has been done in cases of vasomotor rhinitis.").

[3] *See* Ex.1074 (translation declaration for Kong).

[4] *See* Ex.1072 (translation declaration for Liang).

VII. OVERVIEW OF THE '011 PATENT

A. Summary of the '011 Patent

47. The '011 patent is directed to methods and systems that deliver "toxins to defined target areas within the nasal cavities" for treatment of rhinitis. Ex.1001-USP011, 3:58-62, 8:6-23.

48. Figure 23 is an example of the method and system disclosed in the '011 patent. As shown in Figure 23 (below), the '011 patent teaches using a porous balloon catheter (colored orange) that delivers neurotoxin into the nasal cavity at a controlled rate. Ex.1001-USP011, 22:27-33, 23:67-24:6. The porous balloon catheter delivers neurotoxin into the posterior nasal passages adjacent to the nasopharynx to target that area's high concentration of mucus-producing goblet cells. *Id.*, 23:67-24:6. The porous balloon catheter includes ultrasonic transducers to cause "reversible poration" of the target cells and to increase their permeability/their uptake of neurotoxin. *Id.*, 5:45-55; 22:34-38, 22:55-62, 23:67-24:6. The ultrasonic transducers are not shown in Figure 23.

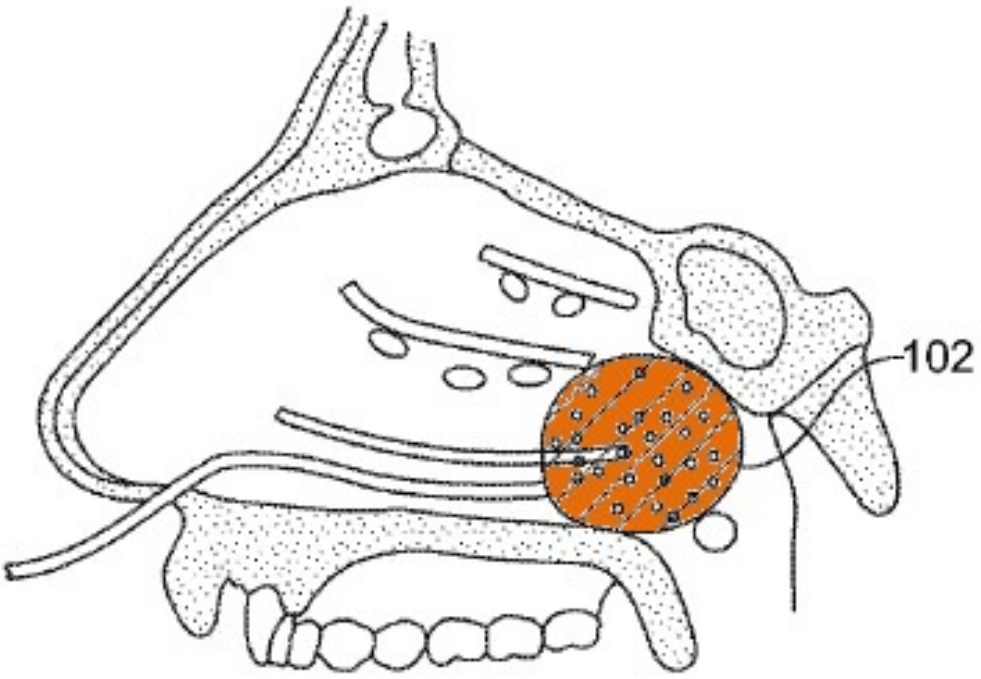


FIG. 23

Ex.1001-USP011, FIG.23.[5]

49. According to the ’011 patent, ultrasonic energy permeabilizes cell membranes to induce reversible poration of the cell membrane (purple), which allows neurotoxins to enter the cell membrane and prevent a muscle’s contraction or

[5] Various annotations have been added to the figures and diagrams in this report. All of these annotations are added unless noted otherwise.

block the secretion of mucus. Ex.1001-USP011, 17:45-51; *see also id.* 4:65-5:6. An example of cell permeabilization and delivering neurotoxins is shown in Figures 2-4. As shown in Figure 2A and 2B (below), the target cell includes a cell membrane that prevents the neurotoxins (green)—labeled LC—from entering the inside of the cell. *Id.*, 15:34-40.

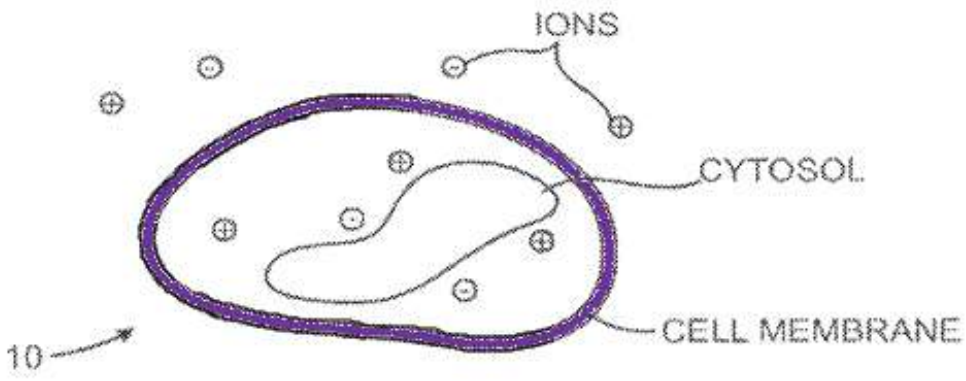


FIG. 2A

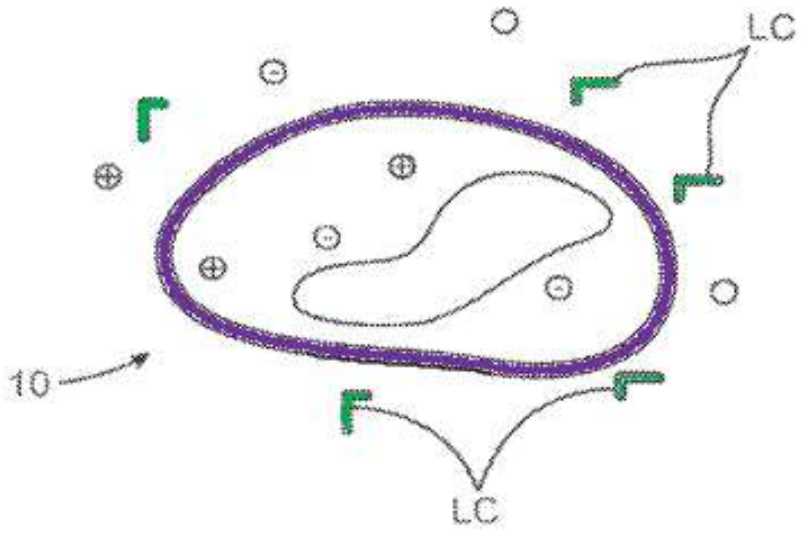


FIG. 2B

Ex.1001-USP011, FIGs.2A-2B. To allow neurotoxins to enter the cell membrane, an energy field can be applied to create temporary pores in the cell membrane for the neurotoxins to pass through, as shown in Figures 3A and 3B. *Id.*, 15:40-43.

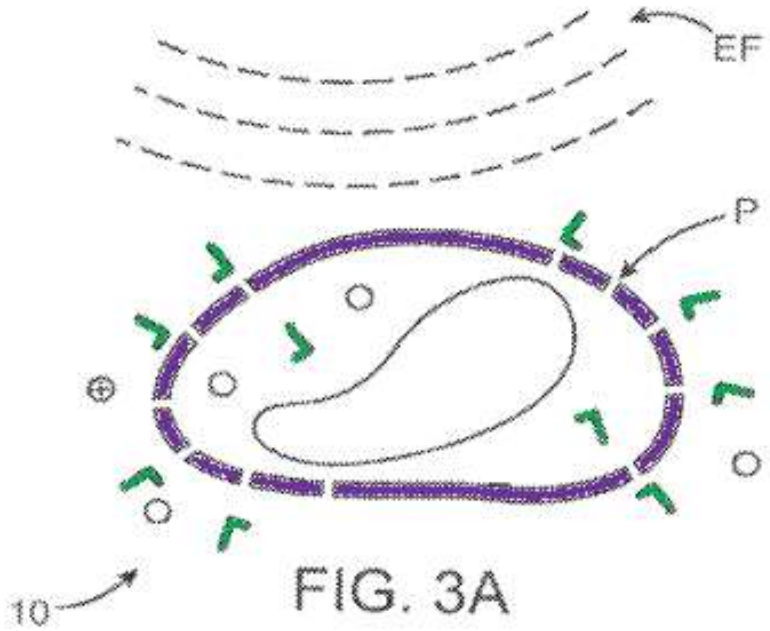


FIG. 3A

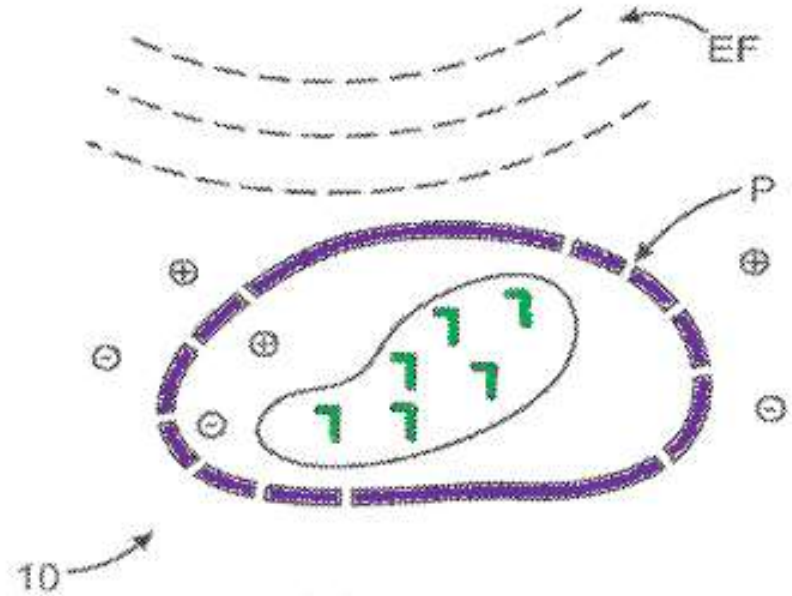


FIG. 3B

Ex.1001-USP011, FIGs.3A-3B. Once the neurotoxins enter, the target cells are "blocked or disrupted" and the cell membrane can recover or close, as shown in Figure 4. *Id.*, 15:43-47.

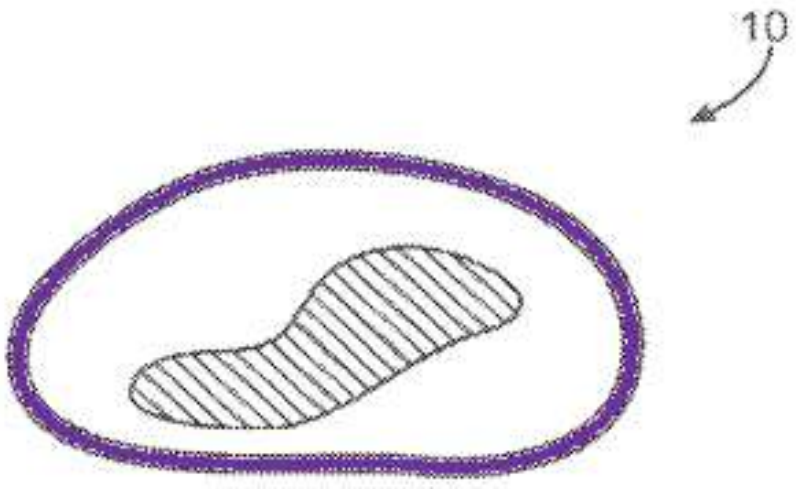


FIG. 4

Ex.1001-USP011, FIG.4. Thus, the device disclosed by the '011 patent uses ultrasonic energy to increase cellular permeability, so that more neurotoxin can go through the cell membranes and into the cells and then change the function of those cells. Ex.1001-USP011, 4:65-5:6; 17:45-51.

50. The '011 patent mentions in passing that other "energy devices" could be used for reversible poration. It lists x-ray, radiofrequency (RF), DC current, AC

current, microwave, and ultrasound as potential "energy source[s]" for reversible poration—i.e., as an adjuvant to the neurotoxin therapy. *Id.*, 13:29-42. The '011 patent does not detail any working embodiment with one of those other sources of reversible poration for use in the nasal cavity or nasopharynx, but merely states that each source would be "adapted and applied in ranges to produce membrane permeabilization in the targeted cell." *Id.* The written description and figures of the '011 patent do not describe using any of those reversible poration energy sources alone, without neurotoxin, to directly treat rhinitis or any other condition. *See generally id.*

51. Claims 1-2, 5, 8-10, 12, and 14 (the "Challenged Claims") are different from the written description and figures of the '011 patent. While the figures and written description of the '011 patent are all directed to systems and methods to deliver ***neurotoxin for treatment*** following electroporation as an adjuvant, the Challenged Claims recite a different technique: the application of ***energy alone for treatment*** (i.e., using energy not as an adjuvant but to directly treat rhinitis symptoms).

B. Prosecution History

52. I understand that U.S. Patent Application No. 16/842,209 (the "'209 Application"), which issued as the '011 patent, was filed on April 7, 2020. Ex.1001-

USP011, Cover; Ex.1024-FH011, 2. I understand that the '209 Application allegedly claims priority to a provisional application that was filed on July 22, 2005. Ex.1024-FH011, 6-7 (showing the priority chain).

53. On May 8, 2020, I understand that the examiner rejected the pending claims of the '209 application as invalid based on claims pending in parent U.S. Patent Application No. 16/036,381 (the "'381 Application"), which issued as U.S. Patent No. 10,729,897 (the "'897 patent"). Ex.1024-FH011, 142-147; Ex.1019-USP897, Cover. I understand that issued claim 1 of the '381 Application (which I understand was claim 21 during prosecution (*see* Ex.1020-FH897, 185)) recited the following:

> 1. A device for altering function of a bronchial airway of a patient by controlling mucus secretion, the device comprising:
>
> a main catheter body configured to extend though a trachea into the bronchial airway; and
>
> at least one energy applicator having at least one energy emitter configured to emit energy relative to the main catheter body,
>
> wherein the device is adapted to deliver energy from the at least one energy emitter to produce an energy field concentrated in a target region in a wall of the bronchial airway in a first lateral direction from the catheter body to alter cells within the target region.

Ex.1019-USP897, claim 1.

54. I understand that in response to this rejection, the Applicant amended the claims of the ’209 application to recite an “[a]pparatus for treatment of a nasal condition by altering function of a nasopharyngeal passage of a patient.” Ex.1024-FH011, 340, 344 (language added in prosecution shown in underline). I understand that as a part of its submission, the applicant argued that the claims in the ’209 Application were different than the claims in the ’381 Application. *Id.*, 340-341. Specifically, the Applicant stated that its amended claims in the ’209 Application were “directed to so-called ‘above the neck’ treatment technology, i.e. application of energy to the nasopharyngeal passage of a patient, which includes [t]he posterior part of the nasal cavity from the posterior limits of the conchae to the choanae,” which were different than the claims in the ’381 Application, which were “directed to ‘below the neck’ treatment technology, i.e. altering the function of the bronchial airway by application of energy to the wall of the bronchial airway of a patient.” *Id.*, 340.

55. The applicant also stated that these two technologies—treatment below the neck in the ’381 Application and treatment above the neck in the ’209 Application—“are necessarily distinct, as is evident in comparing the two claims, and as one of ordinary skill in the art would recognize.” Ex.1024-FH011, 340. It specifically argued that “one of ordinary skill in the art would recognize that the

trachea and bronchial airway can be accessed via the oral cavity, thereby completely bypassing the nasopharyngeal (sic) passage, and that the two bodies have relatively distinct structures." *Id.*

56. For the reasons further discussed in Section IX (Priority Date) below, I agree with applicant's statements that treatment in the bronchial airway and in the nasal cavity are distinct.

57. I understand that after this amendment, the examiner issued a Notice of Allowance on October 15, 2020. Ex.1024-USP011, 378-379.

58. I understand that at least two references that I rely on in this declaration, Saadat (Ex.1003) and Fang (Ex.1006), are not cited on the face of the '011 patent and were not considered by the Examiner during prosecution.

VIII. CLAIM CONSTRUCTION

59. I was informed and I understand that, in my analysis, I should give claim terms their ordinary and customary meaning, as understood by a person of skill in the art at the time of the invention. I was informed and I understand that the words of the patent's claims and the context in which the term is used in the claims are highly instructive in ascertaining the term's meaning. I further understand that the terms of a claim are to be interpreted in the context of the entire patent, including the patent's claims, its specification, and its figures.

60. I have been further instructed that a patent's prosecution history may often provide helpful evidence about how the U.S. Patent and Trademark Office and the applicant understood the patent and its claims. Therefore, I have been instructed that claim terms should also be interpreted in light of the patent's prosecution history.

61. In addition to the claims, the specification, the figures, and the prosecution history, I have been instructed that certain "extrinsic evidence," such as scientific or technical references, may also help inform the way in which a person of ordinary skill in the art understands the claim term. I have been instructed that extrinsic evidence must always be considered in the context of the intrinsic evidence.

62. For the purposes of this declaration, I will give the claim terms their plain and ordinary meaning, including as understood in the field of the '011 patent, and as understood by a person of ordinary skill in the art. To the extent an express claim construction is proposed in this proceeding or in another proceeding involving the '011 patent, I reserve the right to respond to such a construction and/or propose an express construction consistent with the term's plain and ordinary meaning.

IX. PRIORITY DATE

63. I have been provided with the applications in the priority chain of the '011 patent and have considered the date, if any, on which the Challenged Claims

first had written description support in those applications. In my opinion, a person of ordinary skill in the art would have understood that the inventors first described the subject matter of the ’011 patent claims in the applications leading to the ’011 patent no earlier than October 22, 2019, which is the date on which the parent application to the ’011 patent—U.S. Patent No. 10,610,675 (the “’675 patent”)—was filed. I have been informed and understand that this means the ’011 patent is not entitled to a priority date prior to this date.

64. I first provide a brief overview of the ’011 patent’s priority chain. I understand that the first application the ’011 patent claims priority to is Provisional Application No. 60/702,077 (the “’077 Provisional”), which was filed on July 22, 2005. Ex.1001-USP011, Cover. The ’077 Provisional “relates to methods and apparatus for the control of autonomic nerve function comprising delivery via permeabilization of targeted cell membranes a therapeutically effective amount of a portion or fragment of botulinum toxin (BoNT)….” *See* Ex.1010-FH077, [0001], [0024], [0068]-[0070], FIGs.7-8. The ’077 Provisional also discloses using neurotoxins for cosmetic or myofacial applications. *See id.*, [0079], FIG.14. Thus, the ’077 Provisional is directed to using neurotoxins to treat a patient’s respiratory tract or using neurotoxins for cosmetic or myofacial applications. This is not what is claimed in the ’011 patent. Ex.1001-USP011, claim 1.

65. Following the ’077 Provisional, I understand that the Applicant filed nine patent applications, with the last application being the ’209 Application that led to the ’011 patent. *See* Ex.1001-USP011, Cover.

- Application 1: U.S. Application No. 11/495,090 (the “’090 Application”), which was filed on July 21, 2006 and issued as U.S. Patent No. 7,608,275. Ex.1012-USP275, Cover; Ex.1001-USP011, Cover.
- Application 2: U.S. Application No. 12/559,278 (the “’278 Application”), which was filed on September 14, 2009 and issued as U.S. Patent No. 8,133,497. Ex.1013-USP497, Cover; Ex.1001-USP011, Cover.
- Application 3: U.S. Application No. 13/253,595 (the “’595 Application”), which was filed on October 5, 2011 and issued as U.S. Patent No. 8,338,164. Ex.1014-USP164, Cover; Ex.1001-USP011, Cover.
- Application 4: U.S. Application No. 13/660,629 (the “’629 Application”), which was filed on October 25, 2012 and issued as U.S. Patent No. 8,961,391. Ex.1015-USP391, Cover; Ex.1001-USP011, Cover.
- Application 5: U.S. Application No. 14/601,529 (the “’529 Application”), which was filed on January 21, 2015 and issued as U.S. Patent No. 9,498,283. Ex.1016-USP283, Cover; Ex.1001-USP011, Cover.

- Application 6: U.S. Application No. 15/358,187 (the "'187 Application"), which was filed on November 22, 2016 and issued as U.S. Patent No. 10,022,529. Ex.1017-USP529, Cover; Ex.1001-USP011, Cover.
- Application 7: U.S. Application No. 16/036,381 (the "'381 Application"), which was filed on July 16, 2018 and issued as U.S. Patent No. 10,729,897. Ex.1019-USP897, Cover; Ex.1001-USP011, Cover.
- Application 8: The '893 Application, which was filed on October 22, 2019 and issued as the '675 patent. Ex.1021-USP675, Cover; Ex.1001-USP011, Cover.
- Application 9: The '209 Application, which was filed on April 7, 2020 and issued as the '011 patent. Ex.1001-USP011, Cover.

Each of these applications contains substantially the same words and figures as the '077 Provisional Application. Stated differently, each of these applications contains the same disclosure relating to applying neurotoxins to the respiratory tract or using neurotoxins in cosmetic applications. Moreover, until the parent '675 patent was filed on October 22, 2019, each application included claims directed to treating the bronchial tubes. For example, claim 1 of the '283 patent, reproduced below, is directed to treating the bronchial airway.

> 1. A nerve modification device for altering nerve function ***in a bronchial airway of a patient***, the nerve modification device comprising:
>
> a main catheter body configured to extend though a trachea into the bronchial airway;
>
> at least one energy applicator having at least one energy emitter configured to emit energy laterally relative to the main catheter body; and
>
> a movable mechanism to move the at least one energy applicator laterally within the bronchial airway such that the at least one energy emitter contacts a first portion of a circumference of the airway wall,
>
> wherein the nerve modification device is adapted to deliver energy from the at least one energy emitter to produce an energy field concentrated in a target region in the wall of the bronchial airway in a first lateral direction from the catheter body to alter nerve cells within the target region.

Ex.1016-USP283, claim 1. None of the claims in the applications prior to the ’675 patent were directed to treating the nasopharyngeal passage or rhinitis symptoms.

66. In my opinion, none of these applications, including the written description and figures of the ’011 patent and parent ’675 patent, convey to a person of ordinary skill in the art that the inventors were in possession of the alleged invention in the Challenged Claims. Each Challenged Claim requires an “[a]pparatus for treatment of a nasal condition by altering function of a nasopharyngeal passage,” “a hand-held elongate body having proximal and distal

portions, the distal portion being configured for positioning in a nasopharyngeal passage of a patient with the proximal portion positioned outside the nasopharyngeal passage," "an energy transmission element in the distal portion configured to deliver energy to target tissue in the nasopharyngeal passage," and "an energy source operatively coupled to the energy transmission element for supplying energy thereto according to one or more parameters selected so as to alter nasopharyngeal cells in the target tissue such that nasal congestion is reduced." Ex.1001-USP011, claim 1 (elements 1[pre], 1[a], 1[b], 1[c]). The '077 Provisional or following applications do not describe each limitation of the Challenged Claims. Instead, these applications only disclose applying neurotoxins to the bronchial tubes (i.e., respiratory tract) "via permeabilization of targeted cell membranes" (*e.g.*, Ex.1001-USP011, Abstract, FIG.7, FIGs.9-10, FIG.13, 17:22-24) or using neurotoxins for cosmetic applications on the surface of the skin (*e.g.*, *id.*, FIG.14, 19:65-20:17).

67. A person of ordinary skill in the art would have understood that using a neurotoxin in the bronchial tubes or facial skin are distinctly different from positioning a treatment device in the nasopharyngeal passage and applying energy without a neurotoxin to treat rhinitis. For example, a person of ordinary skill in the art would have understood that the mechanisms of treatment are fundamentally different. As explained in Section VI.B (Therapy Using Neurotoxins), neurotoxins

treat conditions by "block[ing] the release of neurotransmitter[s] from the nerves that control the contraction of…muscles" or "disabling" cells responsible for mucus production. Ex.1001-USP011, 1:62-2:18, 3:27-36. That is, neurotoxins block or disable cells that would otherwise cause physiological symptoms. *Id*., 1:62-2:27. A person of ordinary skill in the art would have understood that applying energy to achieve a therapeutic benefit, on the other hand, is different. When applying energy such as RF energy to treat tissue, toxins or other substances are not injected to or applied on the tissue to achieve a therapeutic benefit. Instead, energy itself is applied as therapy to permanently damage or modify tissue. Thus, a person of ordinary skill in the art would have understood that applying neurotoxins to the bronchial tubes or facial skin was distinctly different from positioning a treatment device in the nasopharyngeal passage and applying energy without a neurotoxin to treat rhinitis.

68. Moreover, a person of ordinary skill in the art would have understood that the use of energy for poration (e.g., electroporation) to facilitate the delivery of neurotoxins to bronchial tubes or facial skin (as disclosed in the '077 Provisional) is distinctly different from the use of energy ***without*** neurotoxins to treat tissue. As I explained in Section VI.C.1 (Electroporation), electroporation creates pores in cells that allows neurotoxins to enter. To ensure that neurotoxins enter the bronchial tubes and facial skin (as disclosed in the '077 Provisional) and treat tissue, the applied

energy must cause reversible poration. Otherwise, the target cells would die and the therapeutic benefit of the neurotoxins would not be achieved. In contrast, energy for RF ablation is specifically designed and intended to permanently damage tissue. As a result, it was well-known that the energy used for RF ablation was "distinctly different from the pulses which produce electroporation." Ex.1059-Rubisnky, [0005]. Thus, a person of ordinary skill in the art would have understood that energy for poration as disclosed in the '077 patent was distinctly different than energy for treating tissue without neurotoxins.

69. I have reviewed the'077 Provisional, and I understand that the written description and figures of the '077 Provisional has been copied into following applications. I have also reviewed the claims of each of these applications. In my opinion, nothing in the '077 Provisional or following applications describes that the inventors possessed applying energy in the bronchial tubes (or anywhere else) without a neurotoxin to treat any condition. In particular, nothing in those applications describes that the inventors possessed applying energy in the nasopharyngeal passage without a neurotoxin to treat rhinitis. Thus, in my opinion, the '077 Provisional and subsequent applications do not provide written description support for the Challenged Claims.

70. As I explained in Section VII.B (Prosecution History), I understand that while pursuing the ’209 Application, the Applicant amended the claims of the ’209 Application to recite an “[a]pparatus for treatment of a nasal condition <u>by altering function of a nasopharyngeal passage of a patient.</u>” Ex.1024-FH011, 340, 344 (language added in prosecution shown in underline). I understand that as a part of its submission, the applicant argued that the claims in the ’209 Application were different than the claims in the ’381 Application. *Id.*, 340-341. Specifically, the applicant stated that its amended claims in the ’209 Application were “directed to so-called ‘above the neck’ treatment technology, i.e. application of energy to the nasopharyngeal passage of a patient, which includes [t]he posterior part of the nasal cavity from the posterior limits of the conchae to the choanae,” which were different than the claims in the ’381 Application, which were “directed to ‘below the neck’ treatment technology, i.e. altering the function of the bronchial airway by application of energy to the wall of the bronchial airway of a patient.” *Id.*, 340.

71. The applicant also stated that these two technologies—treatment below the neck in the ’381 Application and treatment above the neck in the ’209 Application—“are necessarily distinct, as is evident in comparing the two claims, and as one of ordinary skill in the art would recognize.” Ex.1024-FH011, 340. It specifically argued that “one of ordinary skill in the art would recognize that the

trachea and bronchial airway can be accessed via the oral cavity, thereby completely bypassing the nasopharyngeal (sic) passage, and that the two bodies have relatively distinct structures." *Id.*

72. The arguments made by the Applicant in the '209 Application are consistent with and confirm my opinion that treatment in the bronchial tubes described in the '077 Provisional and subsequent applications does not provide written description of treatment in the nasopharyngeal passage.

73. I also understand that when the Applicant filed the '893 Application on October 22, 2019, it added the written description and figures from another provisional application—U.S. Provisional Application No. 60/747,771, filed May 19, 2006 (the "'771 Provisional")—into the '893 Application's specification. I also understand that when the '893 Application was filed, the Applicant added method claims with limitations directed to applying energy to tissue in the nasopharyngeal passage. *See* Ex.1021, USP675, claims 1, 17.

74. In my opinion, the '771 Provisional, which I understand is copied into the '893 Application ('675 patent) and '209 Application ('011 patent), does not convey to a person of ordinary skill in the art that the inventors were in possession of the alleged invention in the Challenged Claims. The subject matter of the '771 Provisional is methods and systems for delivering neurotoxins such as BOTOX® in

a nasal cavity under conditions that cause reversible poration of cell membranes. *E.g.*, Ex.1011-FH771, [0002] ("[T]he present invention relates to methods and systems for delivering toxins, such as botulinum toxin light chain fragments, to target cells in a nasal cavity."), [0013] ("According to the present invention, [neurotoxins are] delivered to a patient's nasal membrane while applying energy to target cells within the membrane under conditions which cause a reversible…poration of the cell membranes to enhance delivery of the toxin into the cells."); *see also* Ex.1001-USP011, 8:6-13 ("According to the present invention, [toxins] are delivered to a patient's nasal membrane while applying energy to target cells…under conditions which cause a reversible…poration of the cell membrane to enhance delivery of the toxin").

75. Disclosure of the use of energy (e.g., RF energy) in the '771 Provisional relating to using energy to porate cells to enhance the delivery of toxins is different than the use of energy in the Challenged Claims. The '771 Application (and the '675 patent and '011 patent) does not describe using energy ***without a neurotoxin*** to treat any conditions—in each instance, energy is exclusively used to facilitate and enhance the delivery of toxins. *E.g.*, Ex.1011-FH771, [0075]-[0083], FIGs.10-16; Ex.1001-USP011, 22:23-24:12, FIGs.18-24. As I discussed above, using energy for poration in connection with delivery of a drug (like neurotoxin) is different than

using energy for ablation. A person of ordinary skill in the art would not have understood that the description of the former in the '771 Provisional (and corresponding disclosure in the '675 patent and '011 patent) described delivering energy to the target tissue "according to one or more parameters selected so as to alter nasopharyngeal cells in the target tissue such that nasal congestion is reduced" as claimed. Ex.1001-USP011, claim 1; *see also id.* (claiming an "[a]pparatus for treatment of a nasal condition by altering function of a nasopharyngeal passage of a patient"). A person of ordinary skill in the art would have instead understood that the applicant only disclosed and possessed using energy for purposes of electroporation.[6]

76. I also understand that Applicant pursued claims directed to the disclosure of the '771 provisional in a separate chain. In this chain, the applicant

[6] Moreover, the '771 Provisional and '011 patent do not disclose or suggest that neurotoxins ***alone*** are "energy" or change the temperature of tissue. Thus, a person of ordinary skill in the art would not have understood that the disclosure of neurotoxins in the '771 Provisional (and corresponding disclosure in the '675 patent and '011 patent) described delivering energy to tissue. Ex.1001-USP011, claim 1.

included the figures and written description of the ’771 Provisional in the specification. *See generally* Ex.1026-USP243; Ex.1029-USP817; Ex.1030-USP684; Ex.1031-Pub.233; Ex.1032-USP707; Ex.1033-USP465. In these applications, the applicant obtained claims directed to treating nasal conditions ***with neurotoxins*** and did not obtain claims directed to treating nasal conditions ***without neurotoxins***. For example, U.S. Patent No. 7,655,243 specifically claimed “[a] method for delivering toxins to target cells in a nasal membrane of a patient.” Ex.1026-USP243, claim 1.

77. Moreover, I understand that in these applications, the Applicant presented to the Office that the disclosure of the ’771 provisional discloses that neurotoxins reduce mucus production and congestion and energy electroporates cells to enhance the delivery of neurotoxins to cells. For example, in U.S. Application No. 13/328,203 (the “’203 Application”), which issued as U.S. Patent No. 8,636,684 (the “’684 patent”, Ex.1030) and is related to the ’675 patent, the Applicant only identified that the specification supported that neurotoxin reduces mucus and application of energy causes electroporation to facilitate the delivery of neurotoxin. *E.g.*, Ex.1028-FH684, 16-18, 21-22, 74-86. This is consistent with my review of the ’771 Provisional and ’675 patent—there is no disclosure that describes treating a nasal condition (such as rhinitis or reducing mucus) without neurotoxin. *See*

generally, Ex.1021-USP675; Ex.1011-FH771. To be clear, there is no disclosure in the specification using energy (alone) to treat rhinitis or reduce mucus secretions. The applicant's actions in this separate chain further support that the '771 Provisional (and '675 patent) only described and the named inventors only possessed using energy to facilitate the delivery of toxins as of the time of filing of that application.

78. I also understand that Aerin Medical Inc. ("Aerin") has represented that it is the exclusive licensee of the '011 patent and '675 patent and that Aerin is co-plaintiff to Patent Owner in litigation asserting the '011 patent. I understand that when Aerin was prosecuting a patent application before the Patent Office, it received a rejection over U.S. Patent No. 7,655,243 to Deem (the "'243 patent"). Ex.1034-FH221-Aerin, 786. I also understand that the '243 patent claims priority to the '771 Provisional and includes the figures and written description of the '771 Provisional. *See generally* Ex.1026-USP243. When arguing that the rejection was improper, Aerin represented that "the sole purpose of applying energy as described in Deem [(i.e., the '243 patent)] is to porate target cells to enhance uptake of a nerve toxin." Ex.1034-FH221-Aerin, 786. I understand that the '243 patent's disclosure contains the '771 Provisional's disclosure. Aerin's representation that the sole purpose of energy in the '771 provisional is to porate cells to enhance the uptake of neurotoxins

is consistent with and confirms my opinion that a person of ordinary skill in the art would have understood that the ’771 Provisional (and ’675 patent and ’011 patent) only described and the named inventors only possessed using energy to facilitate the delivery of toxins as of the time of filing of that application.

79. As I explain in Section VI.C (Therapy Using Energy), energy used for ablation is “distinctly different from the pulses which produce electroporation.” Ex.1059-Rubisnky, [0005]. Because the ’771 Provisional (and ’675 patent and ’011 patent) only describe using energy to porate cells, a person of ordinary skill in the art would have understood that the description of the use of energy was, at best, related only to poration and not direct use of energy for treatment on its own (e.g., via ablation). *E.g.*, Ex.1011-FH011, [0049] (“[T]he term ‘electrode’ or ‘energy source’ used herein, encompasses the use of various types of energy producing devices, including x-ray, radiofrequency (RF), DC current, AC current, microwave, ultrasound, adapted and applied in ranges to produce membrane permeabilization in the targeted cell.”); Ex.1001-USP011, 13:36-42.

80. Accordingly, it is my opinion that the priority applications do not provide written description for the Challenged Claims. As a result, I understand that the Challenged Claims are therefore, at best, only entitled to claim priority to no earlier than the date in which the ’675 patent was filed, which was October 22, 2019.

X. GROUNDS FOR FINDING THE CHALLENGED CLAIMS INVALID

81. It is my opinion that the Challenged Claims are unpatentable on the following grounds.192

- **Ground I**: Claims 1-2, 5, 8-10, 12, and 14 are anticipated by Saadat.
- **Ground II**: Claims 12 and 14 are rendered obvious by Saadat.
- **Ground IV**: Claims 1-2, 5, 8-10, 12, and 14 are rendered obvious by the combination of Makower, Fang, and Edwards-535.

The below discussion demonstrates in detail that claims 1-2, 5, 8-10, 12, and 14 of the ’011 patent are unpatentable as anticipated and/or obvious. A copy of the Challenged Claims are attached as **Appendix C**.

82. Before discussing the specific grounds, I provide below a brief overview of the references in the grounds:

83. **Saadat:** I understand that U.S. Patent No. 10,307,200 to Saadat (“Saadat”) was filed on May 17, 2018 and issued on June 4, 2019, i.e., before the ’893 Application was filed on October 22, 2019. Ex.1003-Saadat, Cover; Ex.1001-USP011, Cover. Saadat discloses “devices and methods for ablating regions of tissue…within the nasal cavity for treating conditions such as rhinitis.” Ex.1003-Saadat, 1:21-26. Saadat explains that ablation of posterior nasal nerves, i.e., nerves that originate from the SPG, “leads to a decrease in or interruption of

parasympathetic nerve signals that contribute to congestion and rhinorrhea in patients with chronic rhinitis…" *Id.*, 3:6-14, 16:44-48. Figure 20E depicts one of Saadat's RF ablation probes that is "configured for ablation of the parasympathetic nervous function…." *Id.*, 30:34-38, 31:10-19.

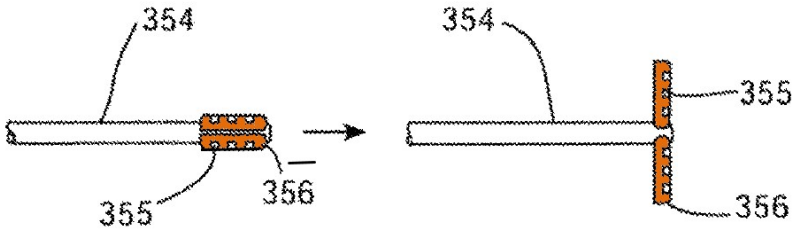


Figure 20E

Ex.1003-Saadat, FIG.20E. Figure 30 of Saadat shows the placement of the device shown in Figure 20E. As shown below in Figure 30, Saadat teaches that the "T" shaped RF ablation probe can be positioned in the posterior area that includes the nasal cavity and the nasopharynx such that the "T" shaped RF ablation probe targets nerves posterior to the turbinates. *Id.*, 14:8-10, 16:20-22, 27:10-20, 33:41-49, FIG.14B, FIG.30.

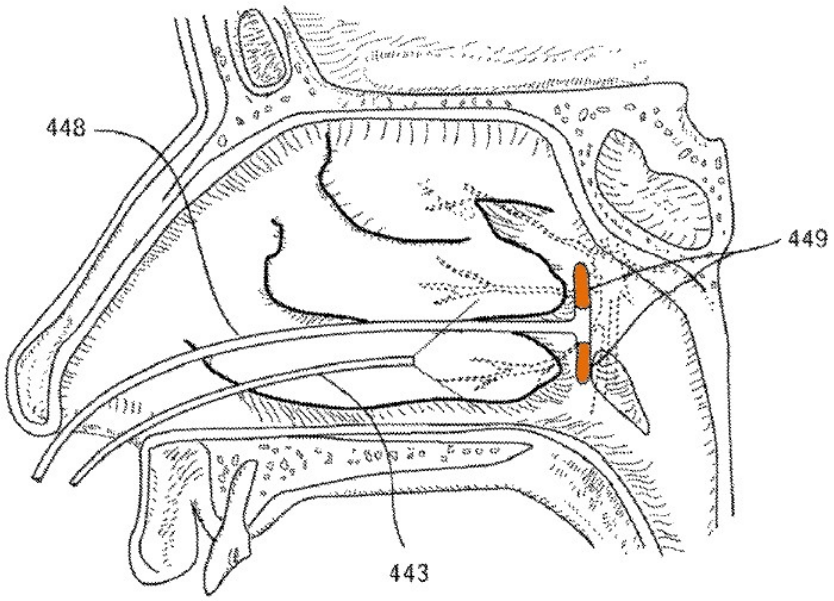
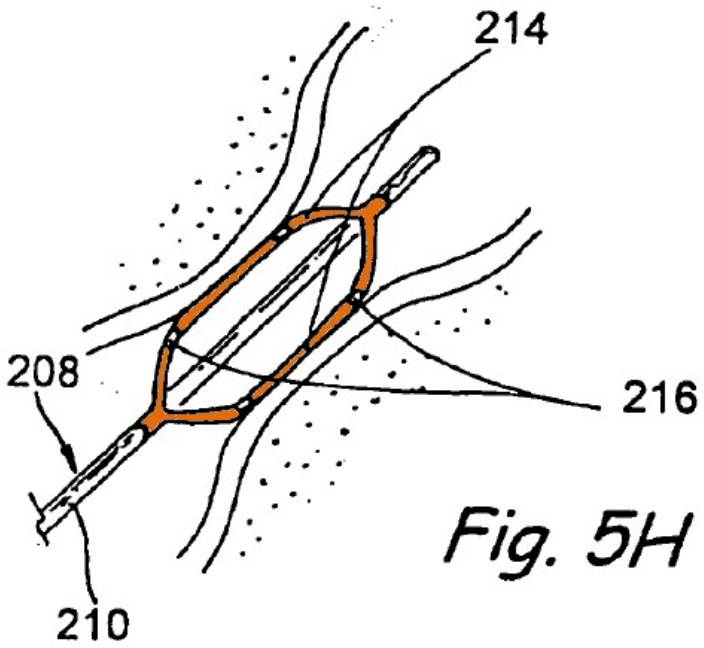


Figure 30

Ex.1003-Saadat, FIG.30.

84. **<u>Makower:</u>** I understand that U.S. Pub. 2005/0240147 to Makower ("Makower") was filed on April 21, 2004 and published on October 27, 2005, i.e., before the '077 Provisional was filed on July 22, 2005. Ex.1005-Makower, Cover; Ex.1001-USP011, Cover. Makower discloses "medical devices and methods…for treating sinusitis and other ear, nose & throat disorders." Ex.1005-Makower, [0001]. In particular, Makower discloses electrosurgical devices that can be inserted in the passage that includes the nasal cavity and nasopharynx "to perform diagnostic or therapeutic procedures." *Id.*, [0161]. Figure 5H described one such electrosurgical

device that is inserted into the nasal cavity and nasopharynx. As shown below, the electrosurgical device in Figure 5H includes strut members 214 with multiple monopolar or bipolar electrodes 216. *Id.*, [0043], [0161], [0187].



Ex.1005-Makower, FIG.5H. Makower explains that the strut members 214 expand from a collapsed state to touch the adjacent nasopharyngeal tissue, and "current is [then] applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated." *Id.*, [0187]. "Sensing elements" can also be attached to Makower's electrosurgical device so that the physician can "monitor various parameters of the catheter and/or surrounding tissue (e.g., temperature, etc.)." *Id.*

85. **Fang:** I understand that Fang is an article that was published on July 20, 2005, i.e., before the '077 Provisional was filed on July 22, 2005. *See* Ex.1006-Fang; Ex.1073 (translation declaration for Fang);[7] Ex.1001-USP011, Cover. Fang teaches performing "nasal endoscopic surgery combined with multiple radiofrequency" to treat "perennial allergic rhinitis." Ex.1006-Fang, 876-877. Fang performs surgery by aligning the "firing head" of an "SHP-I five-organ radiofrequency therapy instrument" "with the sphenopalatine foramen [nasal wall] on both sides" and "carry[ing] out radiofrequency at the anterior upper part of the nasal septum on both sides…." *Id.*, 876. A "SHP-I five-organ radiofrequency

[7] I understand there are two translations of Fang (Ex.1006-Fang and Ex.1079). I have reviewed both translations. The minor differences between the two translations (*see, e.g.*, Ex.1006-Fang, 876 ("All the patients complied with the diagnostic criteria for perennial rhinitis [1], and were accompanied by **deviated** nasal septum."); Ex.1079, 31 ("All the patients complied with the diagnostic criteria for perennial rhinitis [1], and were accompanied by **deflected** nasal septum.")) do not impact my opinions as set forth herein. Therefore, although I cite to Ex.1006-Fang in my declaration, my analysis and opinions applies equally to Ex.1079.

therapy instrument" is a commercially available RF treatment device that comes with many factory pre-set settings. It is an example of an off-the-shelf device, of which there were many available in the 2000s, that those of ordinary skill in the art would routinely use and know how to operate. Fang explains that its procedure "block[s] the posterior parasympathetic fibers of the sphenopalatine nerve" and "blocks the parasympathetic pathway of the nasal mucosa," which "reduces the vascular tension, reduces glandular secretion, and thus achieves the therapeutic purposes" of reducing rhinitis symptoms. *Id.*, 877.

86. **Edwards-535:** I understand that U.S. Patent No. 6,517,535 to Edwards ("Edwards-535") was filed on November 9, 1999 and issued on February 11, 2003, i.e., before the '077 Provisional was filed on July 22, 2005. Ex.1008-Edwards-535, Cover; Ex.1001-USP011, Cover. Edwards-535 discloses "an apparatus for ablating a nasal concha," i.e., an apparatus ablating a turbinate in the nasal cavity. Ex.1008-Edwards-535, 7:28-29; *see also id.*, 4:33-51, FIG.1. Edwards-535's apparatus, shown below, includes a "catheter body 126" that includes a "catheter distal portion 128" and "an energy delivery device 134 for delivering ablative energy." *Id.*, 7:29-36, 8:17-25. Edwards-535 teaches that "the energy delivery device includes one or more ring electrodes 156," and that "ablative energy is supplied to the energy delivery device [(i.e., the electrodes 156)] by an energy source 162." *Id.*, 8:17-25,

8:47-53, FIGs.5-6. Edwards-535 further teaches that the "the energy source 162 includes an energy source 163 (or a power regulator coupled to a standard energy source such as a wall socket or battery), a signal generator 165 (such as a generator for pulses, sine waves, square waves, or some combination of these wave forms with each other or with some other wave form), and a processor 167 for controlling the signal generator." *Id.*, 8:54-60. As one example, Edwards-535 explains that "the signal generator can generate pulses of RF energy which provide between about 5 and about 30 watts of RF energy" to tissue, and explains that those skilled in the art would understand how to modify such parameters. *Id.*, 9:1-13, 11:46-12:4. Thus, Edwards-535's generator (shown below) generates RF energy pulses to be applied via the electrodes 156 according to various parameters.

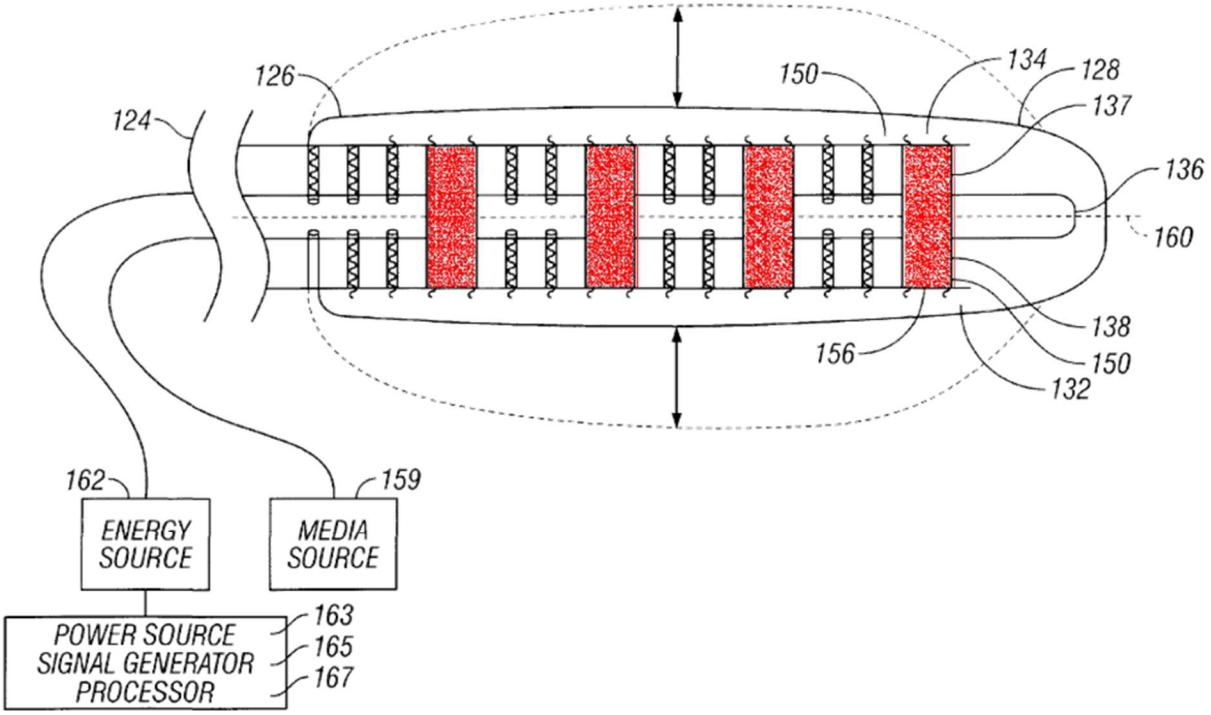


FIG. 6

Ex.1008-Edwards-535, FIG.6.

A. GROUND I: Challenged Claims 1-2, 5, 8-10, 12, and 14 are Anticipated by Saadat

87. As detailed below, Saadat taught each limitation of the Challenged Claims.

1. <u>Claim 1</u>

a. Element 1[pre]: Apparatus for treatment of a nasal condition by altering function of a nasopharyngeal passage of a patient, the apparatus comprising:

88. Saadat discloses an "[a]pparatus for treatment of a nasal condition by altering function of a nasopharyngeal passage of a patient."

89. Saadat discloses "apparatus[es] and methods for treating conditions such as rhinitis." Ex.1003-Saadat, Abstract, Title ("[M]ethods for treating rhinitis"), *see id.*, 1:21-26, 2:16-24 ("Rhinitis is…characterized by nasal symptoms, including…rhinorrhea, and/or nasal congestion."), 3:6-14 ("methods…for ablating one or more [nerve] branches to reduce or eliminate rhinitis…."), 10:16-26, 10:41-11:14, claims 1 ("method for treating nerve tissue within a nasal cavity of a patient"), 6 ("delivering…energy-based treatment…such that at least one symptom of rhinitis is reduced"), FIG.20E, FIG.30. A "nasal condition[] of a patient" includes rhinitis. *See, e.g.*, Ex.1001-USP011, 3:9-12 (rhinitis is "condition" in the "nasal cavity"). Thus, Saadat discloses *an apparatus for treatment of a nasal condition*.[8]

90. Saadat also discloses that its apparatus treats a nasal condition *by altering function of a nasopharyngeal passage of a patient*. Specifically, Saadat discloses an RF ablation probe with a distal end that includes "a bi-polar electrode ablation element 355 on a user deployable 'T' shaped structure 356." Ex.1003-Saadat, 30:34-38 ("FIG. 20A is a schematic illustration of radiofrequency (RF) ablation probe 338 configured for ablation of the parasympathetic nervous

[8] Unless I indicate otherwise, italicized text to refers to the claim language.

function…."), 31:10-19 ("FIG. 20E is a schematic illustration of the distal end of alternative embodiment 354 of RF ablation probe 338 comprising a bi-polar electrode ablation element 355 on a user deployable 'T' shaped structure 356.").

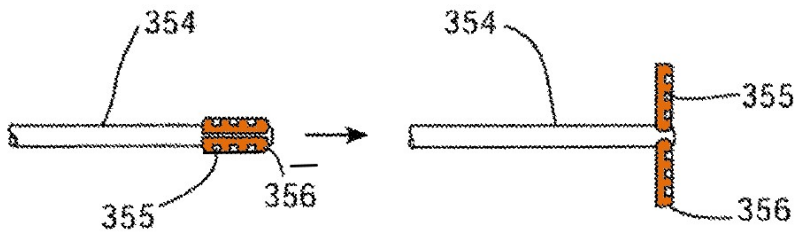


Figure 20E

Ex.1003-Saadat, FIG.20E; *see also id.*, 10:16-26, 11:1-14, 33:41-49 ("FIG. 30 is an in situ illustration of the ablation of the posterior nasal nerve using a generic 'T' tipped ablation device 448. Generic 'T' tipped ablation device 448 is shown with ablation elements 449, which could be cryo ablation elements, RF ablation elements, or some other type of thermal ablation elements.").

91. Figure 30 (shown below) depicts the T-shaped ablation device (annotated in orange) of Figure 20E positioned to target the "posterior nasal nerve" (i.e., the *target tissue*). Ex.1003-Saadat, 16:20-22 ("FIG. 30 is an in situ illustration of the ablation of the posterior nasal nerves at the ablation target area depicted in FIG. 14B."), 33:41-49. The posterior nasal nerve is annotated below in green. Although I understand that patent figures are merely illustrations, the illustration in

Figure 30 showing that the posterior nasal nerve is posterior to the turbinate and then branches through the nasal cavity and nasopharynx is consistent with my experience with human anatomy.

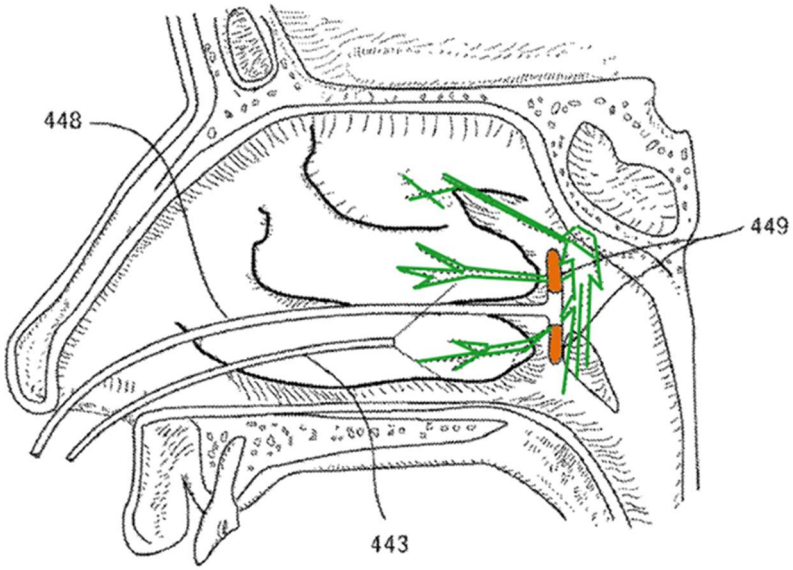


Figure 30

Ex.1003-Saadat, FIG.30.

92. Saadat specifically explained what was well known in the art, which is that these posterior nasal nerves, which I have also annotated in green in Saadat's Figure 14B below, branch from the SPG and control parasympathetic nerve function. Ex.1003-Saadat, 16:39-51, 27:10-20, FIG.14B. As detailed in Section VI.A, the parasympathetic nerves that branch from the SPG and throughout the nasal cavity and nasopharynx (as shown in Figures 14B and 30) control cells (e.g., goblet cells)

that produce mucus. Thus, Saadat's treatment device targets tissue with parasympathetic nerves.

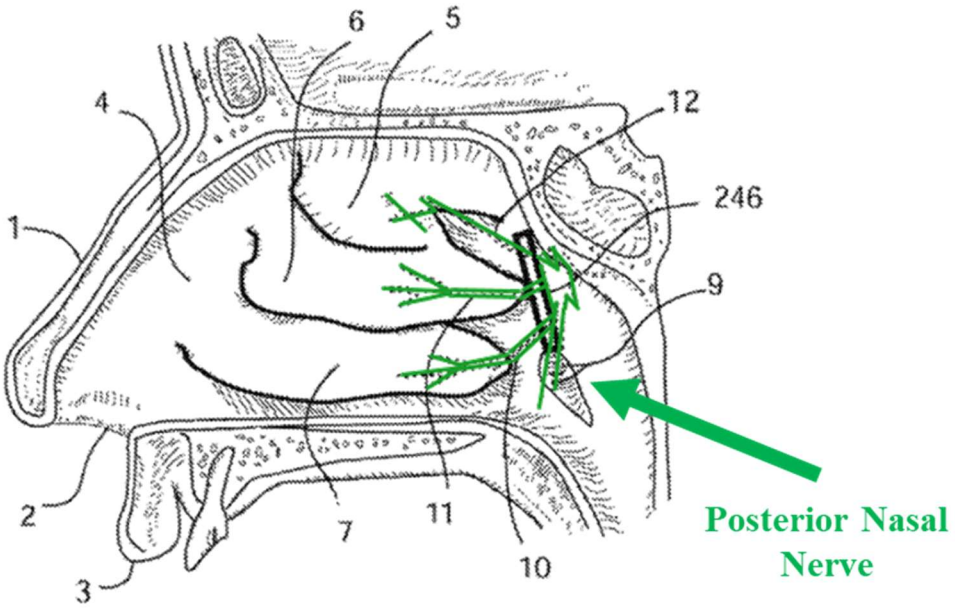


Figure 14B

Ex.1003-Saadat, FIG.14B.

93. Consistent with the knowledge of a person of ordinary skill in the art, Saadat teaches that "[a]blating these nerves leads to a decrease in or interruption of parasympathetic nerve signals that contribute to congestion and rhinorrhea in patients with chronic rhinitis…." Ex.1003-Saadat, 1:62-66 ("The turbinates are autonomically innervated by nerves arising from the Vidian nerve which contains sympathetic and parasympathetic afferents that can modulate the function of the turbinates to either increase (parasympathetic) or decrease (sympathetic) activity of

the submucosal layer."), 3:6-10. Saadat discloses numerous devices that "ablate a single nerve branch or multiple nerve branches," including the "posterior nasal nerve," to "reduce or eliminate rhinitis…." *Id.*, 3:10-14 ("Ablating these nerves leads to a decrease in or interruption of parasympathetic nerve signals that contribute to congestion and rhinorrhea in patients with chronic rhinitis (allergic or vasomotor)."), 4:17-21 ("Any of the ablation devices herein can be used to ablate a single nerve branch or multiple nerve branches."). In the embodiment from Figure 30, reproduced above, the distal end of the "T" shaped device of Figure 20E is positioned proximate to tissue that contains the posterior nasal nerve (i.e., target tissue) to ablate parasympathetic nerves and thereby reduce their activity. *Id.*, 30:34-38, 31:10-19, 33:41-49.

94. Because the distal end of the "T" shaped device is positioned proximate to tissue that contains the posterior nasal nerve and Saadat discloses that ablating such nerves reduces the symptoms of rhinitis, Saadat discloses that its "T" shaped ablation device treats rhinitis *by altering function of a nasopharyngeal passage of a patient*.

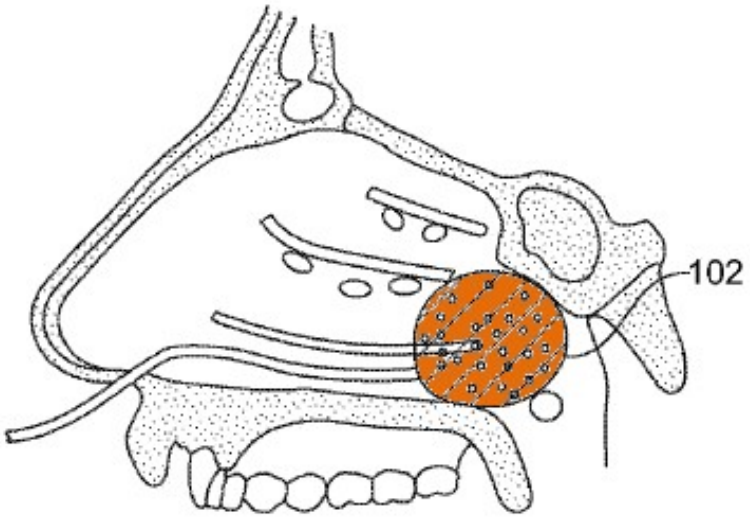
95. A person of ordinary skill in the art would have understood that the plain and ordinary meaning of *nasopharyngeal passage* is the passage that includes both the nasal cavity and the pharynx.

96. This plain and ordinary meaning of *nasopharyngeal passage* is consistent with the knowledge of a person of ordinary skill in the art, the claims, figures, and written description of the ’011 patent, dictionary definitions, and other filings by the Patent Owner. ***First***, at all relevant times for the ’011 patent (2005-2019), it was well-known in the field of otolaryngology that “nasopharyngeal passage” referred to the nasal cavity and nasopharynx (i.e., naso- for nasal cavity and -pharyngeal for pharynx).

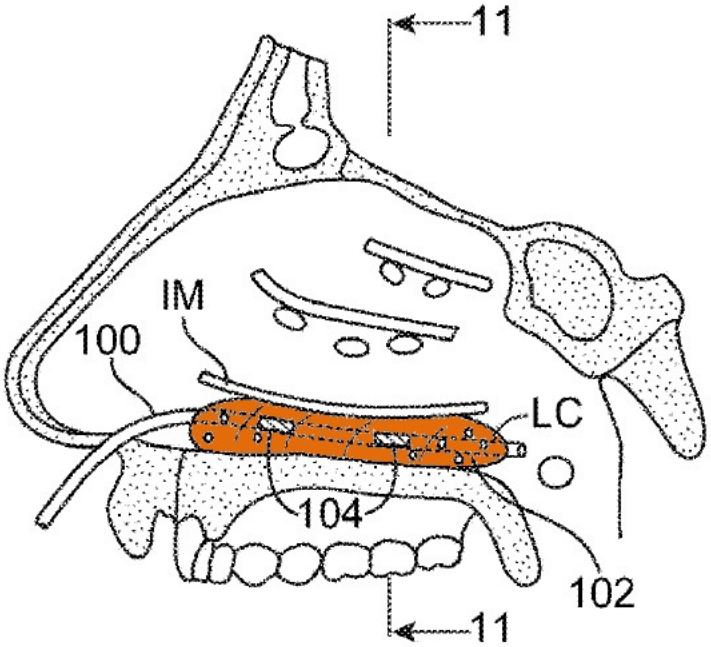
97. ***Second***, the Challenged Claims recite an “[a]pparatus for treatment of a nasal condition.” Ex.1001-USP011, claim 1. This indicates that nasal tissue is within the scope of the target tissue.

98. ***Third***, the ’011 patent specification explains that the balloon catheter shown in Figure 23 (shown below) is “positioned to target an area of high goblet cell (G) concentration, for example, in the back of the nasal passages in the area of the nasopharynx.” Ex.1001-USP011, 23:66-24:6, FIG.23. The ’011 patent explains in another example that the balloon catheter shown in Figure 18 is positioned to “deliver toxin to the nasopharynx” and “ultrasonic poration energy can be delivered to the adjacent nasal membranes which are receiving…toxin[s]….” *Id.*, 10:64-65, 22:34-38, FIGs.18-19. Thus, the ’011 patent refers to the nasopharyngeal passage

as including the nasal cavity and nasopharynx because it discusses targeting the nasal cavity and nasopharynx with the same balloon catheter.



Ex.1001-USP011, FIG.23.



Ex.1001-USP011, FIG.18.

99. ***Fourth***, dictionary definitions from prior to 2005 define "nasopharyngeal" as referring to the nasal cavity and pharynx (i.e., nasopharynx). Ex.1048-Stedman's, 1177 (defining "nasopharyngeal" as "[r]elating to the nose or nasal cavity and the pharynx"); Ex.1049-Webster's, 1504 (defining "nasopharyngeal" as "of or relating to the nose and pharynx or the nasopharynx"). This too shows that *nasopharyngeal passage* refers to both the nasal cavity and nasopharynx and is consistent with the understanding of that term by those of ordinary skill in the art at the time.

100. ***Finally***, I understand that the owner of the '011 patent, Foundry, has used the term "nasopharyngeal" to refer to the nasal cavity and nasopharynx in other patent filings. For example, in Figure 7B of Morriss (filed by Foundry and below), a "delivery device 230 has been advanced into the nasal cavity via a nostril, and sheath 232 has been proximally retracted, thereby allowing the foam contact element [(numbered 234 and colored in orange)] to expand into engagement with **nasopharyngeal mucosa tissue**." Ex.1055-Morriss, [0077]; *see also id.*, [0014]-[0020], [0073]-[0076], [0078], FIGs.5A-5F, FIG.7A. Thus, Foundry has represented in other patent filings that positioning a device in the nasal cavity means that such device is contacting nasopharyngeal tissue, i.e., contacting tissue in the

nasopharyngeal passage. This also confirms my opinion that *nasopharyngeal passage* refers to both the nasal cavity and nasopharynx.

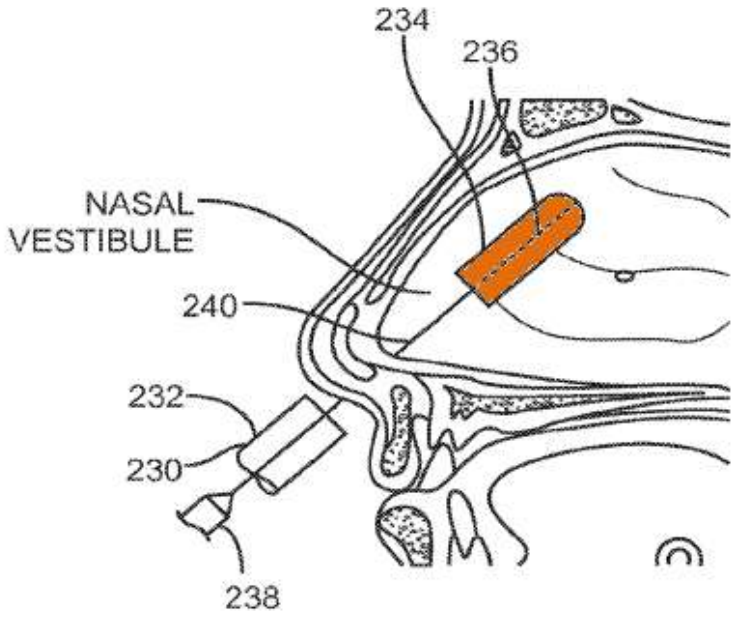


FIG. 7B

Ex.1055-Morriss, FIG.7B.

101. A person of ordinary skill in the art would have recognized that because the distal end of Saadat's ablation device is positioned to target and ablate the posterior nasal nerve, it is positioned *in the nasopharyngeal passage*. *E.g.*, Ex.1003-Saadat, FIG.14B, FIG.30, 30:34-38, 31:10-19, 33:41-49.

102. Saadat also claims positioning the distal end of a treatment device in the nasopharyngeal passage to target and ablate tissue. For example, claim 1

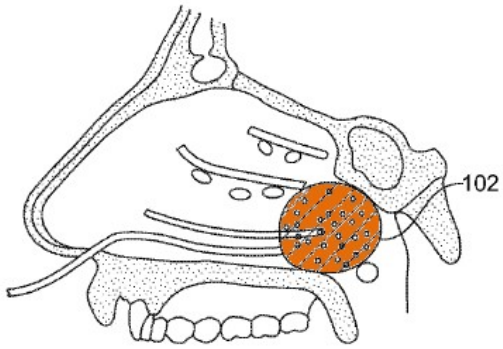
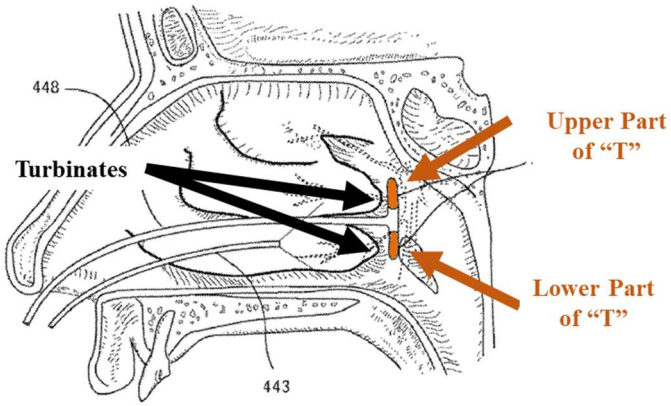
specifically claims a method for treating tissue in the nasal cavity (i.e., *nasopharyngeal passage*):

> 1. **A method for treating nerve tissue within a nasal cavity of a patient,** the method comprising:
>
> **advancing a treatment delivery portion of an energy-based treatment device into a nostril of the patient**;
>
> contacting a mucosal surface of the nasal cavity with the treatment delivery portion; and
>
> **delivering an energy-based treatment from the treatment delivery portion to treat the nerve tissue underlying the mucosal surface**, wherein the delivering of the energy-based treatment comprises delivering energy in a form selected from the group consisting of ultrasound, **radiofrequency**, and electrical energy.

Id., claim 1. Claim 7 also specifies that the treated nerves include "a posterior nasal nerve, a branch of a [V]idian nerve, a parasympathetic nerve, a greater palatine nerve, a maxillary nerve, a sphenopalatine ganglion nerve, or a posterolateral nerve." *Id.*, claim 7. And claim 6 specifies that "the delivering of the energy-based treatment to treat the nerve tissue underlying the mucosal surface comprises ablating the nerve tissue such that at least one symptom of rhinitis is reduced." *Id.*, claim 6. Because the nerves identified in claim 7 innervate the nasal cavity and nasopharynx and claim 6 discloses that ablating tissue with such nerves reduces at least one symptom of rhinitis, Saadat thus claims treating target tissue in nasopharyngeal passage with the

distal end of a treatment device to treat rhinitis, i.e., *treating a nasal condition by altering function of a nasopharyngeal passage of a patient*.

103. Additionally, a person of ordinary skill in the art would have understood that the distal end of Saadat's ablation device is used in the same location the '011 patent identifies as the "nasopharynx" and "nasal passage" (i.e., *nasopharyngeal passage*). As noted, the '011 patent explains that the balloon catheter shown in Figure 23 (shown below) is "positioned to target an area of high goblet cell (G) concentration, for example, in the back of the nasal passages in the area of the nasopharynx." Ex.1001-USP011, 23:66-24:6, FIG.23. As shown in the chart below, a person of ordinary skill in the art would have understood that the upper part of Saadat's ablation device's "T" is positioned proximate to tissue in the posterior nasal cavity, and the lower part Saadat's ablation device's "T" is positioned in and proximate to tissue in the nasopharynx.

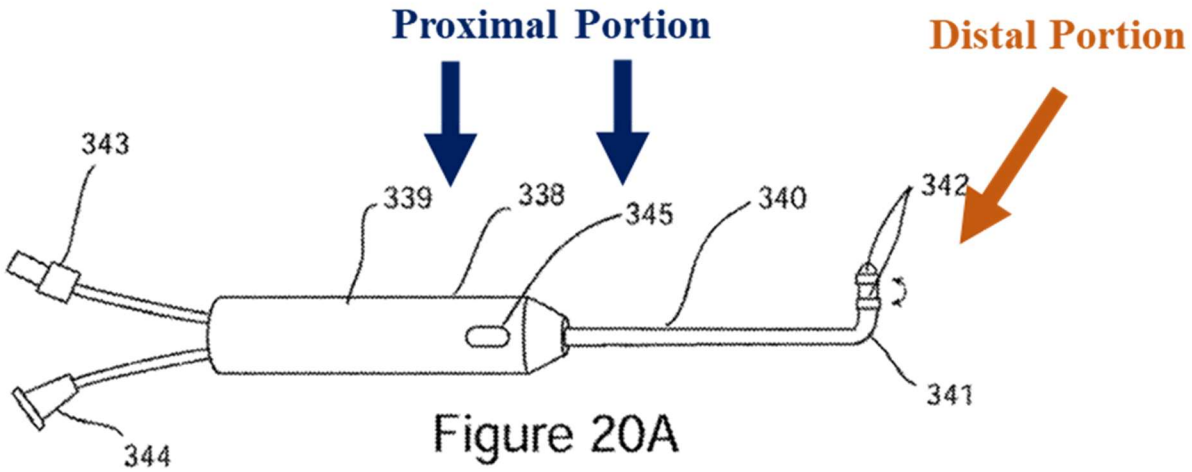
’011 Patent, FIG.23	Saadat, FIG.30
	

Thus, because Saadat’s ablation device’s “T” is positioned in the nasopharyngeal passage to ablate tissue to treat rhinitis, Saadat discloses an *apparatus for treatment of a nasal condition by altering function of a nasopharyngeal passage of a patient*.

b. Element 1[a]: a hand-held elongate body having proximal and distal portions, the distal portion being configured for positioning in a nasopharyngeal passage of a patient with the proximal portion positioned outside the nasopharyngeal passage;

104. Saadat discloses “a hand-held elongate body having proximal and distal portions, the distal portion being configured for positioning in a nasopharyngeal passage of a patient with the proximal portion positioned outside the nasopharyngeal passage.”

105. As shown in Figure 20A (below), Saadat discloses a "radiofrequency (RF) ablation probe 338 configured for ablation of the parasympathetic nervous function." Ex.1003-Saadat, 30:34-38, FIG.20E. Saadat's RF ablation probe includes a "handle 339, probe shaft 340" and a "probe tip" that includes RF electrodes. *Id.*, 30:38-41. Because the RF ablation probe includes a handle, the RF ablation probe is a *handheld elongate body*, with the "handle 339" and "probe shaft 340" being the *proximal portion* of the RF ablation device and the "probe tip" being the *distal portion* of the RF ablation device. *Id.*, 30:34-41; *see also id.*, 10:15-11:14 ("[A]n electrosurgical probe apparatus for ablation of PNN comprising a handle at the proximal end, a probe shaft with a radiofrequency (RF) ablation element comprising at least one radiofrequency (RF) electrode mounted in the vicinity of the distal end of the shaft….").



Ex.1003-Saadat, FIG.20A.

106. Saadat discloses multiple versions of its RF ablation probe, and in particular, multiple versions of the tip, i.e., the *distal portion*. One variation of the tip, shown in Figure 20A (above), has a "'J' shaped probe tip." Ex.1003-Saadat, FIG.20A, 30:38-41. Another variation of the tip is shown in Figure 20E (below), which includes a tip, i.e., *distal portion*, that is a "deployable 'T' shaped structure 356." *Id.*, 31:10-16 ("FIG. 20E is a schematic illustration of the distal end of alternative embodiment 354 of **RF ablation probe 338**…"); *see also* Section X.A.1.a (Ground I, Claim 1, Element 1[pre]).

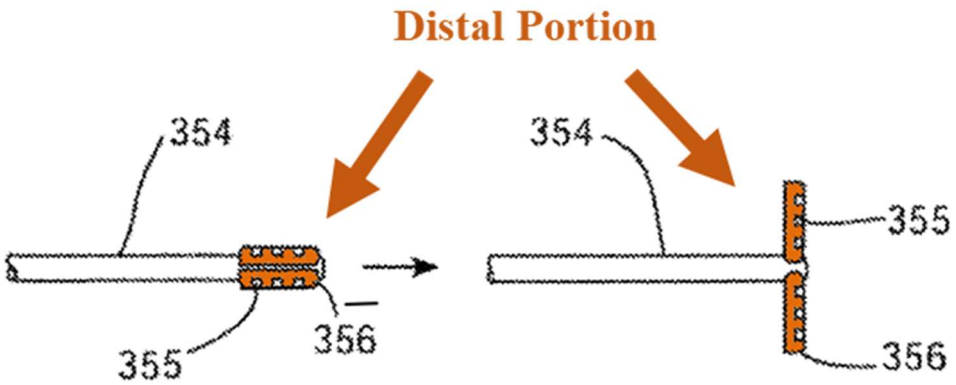


Figure 20E

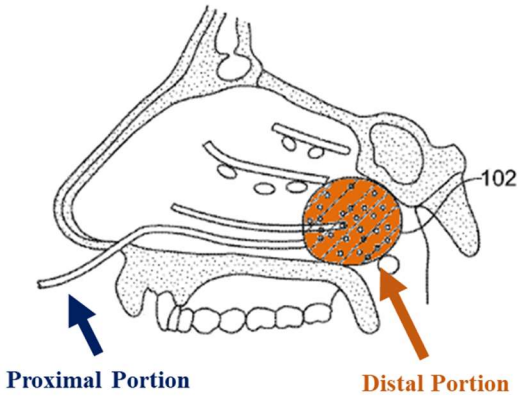
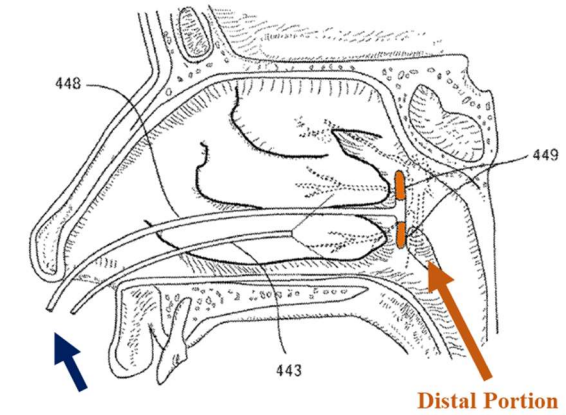
Ex.1003-Saadat, FIG.20E. Like the probe shown in Figure 20A, the handle and shaft of the RF ablation probe are the *proximal portion* and the "T" shaped distal end is the *distal portion*.

107. As I explained in Section X.A.1.a (Ground I, Claim 1, Element 1[pre]), Saadat discloses that the "T" shaped distal end, i.e., *distal portion*, is positioned proximate to tissue in the nasopharyngeal passage, i.e., the nasal cavity and nasopharynx. *See, e.g.*, Ex.1003-Saadat, FIG.14B, FIG.20E, FIG.30, 30:34-38, 31:10-19, 33:41-49. Thus, Saadat discloses that the "T" shaped tip of its RF ablation probe, i.e., the *distal portion*, is configured for positioning in a nasopharyngeal passage of a patient.

108. A person of ordinary skill in the art would also have understood that when a physician would use Saadat's RF ablation probe, the physician would hold the handle of the probe outside of the patient's body, and then advance the "T" shaped distal end of Saadat's RF ablation probe through a patient's nostril such that the distal end is positioned proximate to tissue in the nasopharyngeal passage of a patient. The physician would then use the portion outside of the body to remove the device after treatment. This positioning is shown in Figure 30 of Saadat, which depicts the "T" shaped distal end of Saadat's RF ablation probe in the nasopharyngeal passage of the patient, and shows that the shaft of the probe is advanced through the patient's nostril such that the "T" shaped distal end, i.e., *distal portion*, is *positioned in the nasopharyngeal passage* and a portion of the shaft and the handle the physician is holding, i.e., *proximal portion*, is positioned outside of

the patient's body, i.e., *outside the nasopharyngeal passage*. *See* Ex.1003-Saadat, FIG.30, 33:41-49; *see also id.*, 30:34-41, 31:10-19. Saadat's disclosure is consistent with known RF ablation probes that were used to treat tissue in the nasal cavity or nasopharynx. In particular, it was well-known in the art that when a physician used an RF ablation probe to treat tissue in the nasal cavity or nasopharynx, such as the RF ablation probe disclosed by Saadat, the physician would hold part of the device outside of the patient's body, i.e., *outside the nasopharyngeal passage*, and insert the end of the RF ablation probe with ablation elements into the body such that it would be positioned next to the target tissue in the nasal cavity or nasopharynx, i.e., *positioned in the nasopharyngeal passage*. Indeed, this is exactly how RF ablation probes that I have used since the 1990s operated.

109. Additionally, a person of ordinary skill in the art would have understood that the proximal and distal portions of Saadat's RF ablation device are positioned in the same locations shown in Figure 23 of the '011 patent. As shown in the chart below, just like Figure 23 of the '011 patent, the *proximal portion* of Saadat's RF ablation device is positioned *outside the nasopharyngeal passage* and the *distal portion*, which is advanced through the patient's nostril, is positioned proximate to tissue *in the nasopharyngeal passage*. *See* Ex.1003-Saadat, 11:1-14, 30:34-41, 31:10-19, 33:41-49, FIG.30; Ex.1001-USP011, FIG.23.

’011 Patent, FIG.23	Saadat, FIG.30
 FIG. 23	 Figure 30

110. Saadat also claims positioning a proximal portion of an RF ablation device outside the nasopharyngeal passage and a distal portion of an RF ablation in the nasopharyngeal passage. For example, claim 1 recites advancing a treatment device into a nostril of the patient (i.e., from outside the nostril) and contacting tissue in the nasal cavity or nasopharynx with treatment delivery portion:

> 1. A method for treating nerve tissue within a nasal cavity of a patient, the method comprising:
>
> **advancing a treatment delivery portion of an energy-based treatment device into a nostril of the patient**;
>
> **contacting a mucosal surface of the nasal cavity with the treatment delivery portion**; and
>
> **delivering an energy-based treatment from the treatment delivery portion to treat the nerve tissue underlying the mucosal**

> **surface**, wherein the delivering of the energy-based treatment comprises delivering energy in a form selected from the group consisting of ultrasound, **radiofrequency**, and electrical energy.

Id., claim 1; *see also id.*, claims 2-4, 6-7, 11-12. Saadat thus discloses *a hand-held elongate body having proximal and distal portions, the distal portion being configured for positioning in a nasopharyngeal passage of a patient with the proximal portion positioned outside the nasopharyngeal passage*.

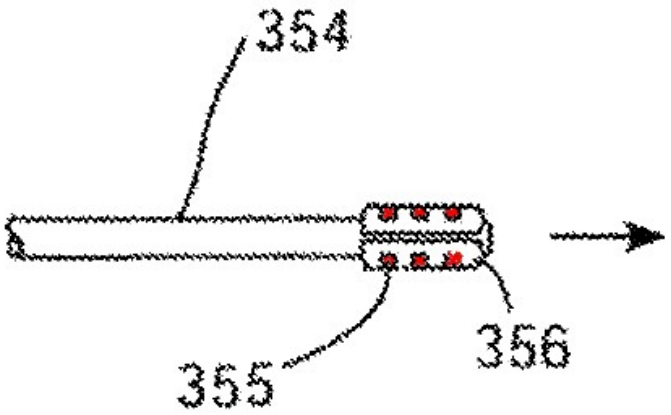
c. Element 1[b]: an energy transmission element in the distal portion configured to deliver energy to target tissue in the nasopharyngeal passage; and

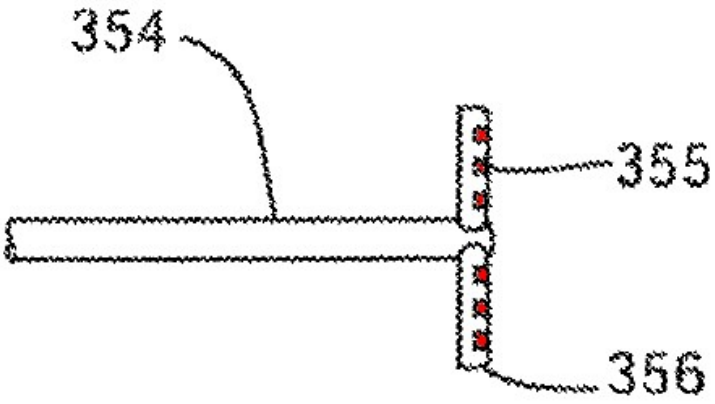
111. Saadat discloses "an energy transmission element in the distal portion configured to deliver energy to target tissue in the nasopharyngeal passage."

112. As I discussed above in Section X.A.1.a-b (Ground I, Claim 1, Elements 1[pre]-[a]), Saadat discloses that the distal end of its "T" shaped **RF ablation probe** is positioned proximate to tissue in the nasopharyngeal passage of a patient. *E.g.*, Ex.1003-Saadat, FIG.14B, FIG.30, 30:34-38, 31:10-19, 33:41-49.

113. The distal end of Saadat's RF ablation probe includes "electrode ablation element[s] 355", i.e., electrodes, that are "configured for ***ablation of the parasympathetic nervous function***…." Ex.1003-Saadat, 30:34-38, 31:10-19, 33:41-29; *see also id.*, 3:6-14 ("The devices and methods described herein are configured to be used for ablating one or more of these branches to reduce or

eliminate rhinitis, e.g., ablating the Posterior Nasal Nerves (PNN)."), 10:16-26, 11:1-14 ("RF ablation element are optimally configured for RF ablation of PNN…."), 30:47-49, 32:62-33:3. Saadat explains the electrodes 355 "operate in a monopolar, bipolar or multipolar fashion…." *Id.*, 31:10-19, 33:41-49. The electrodes are colored in red in Figure 20E below:





Ex.1003-Saadat, FIG.20E.

114. Moreover, Saadat claims that the energy delivery portion of its RF ablation device includes electrodes. For example, claim 3 recites that "the delivering of the energy-based treatment comprises delivering radiofrequency energy from a first electrode on a tissue contact surface to a second electrode on the tissue contact surface." Ex.1003-Saadat, claims 1, 3; *see also id.*, claims 4 (claiming "the first electrode and second electrode comprise dome shaped electrodes on the tissue contact surface, and wherein contacting the mucosal surface comprises contacting the dome shaped electrodes on the tissue contact surface with the mucosal surface"), 9 (claiming "the treatment delivery portion comprises a plurality of electrodes and the delivering of the energy-based treatment comprises delivering radiofrequency energy"), 10 (claiming "the plurality of electrodes [of claim 9] comprise eight electrodes arranged in two lateral arrays"), 11-12. Thus, Saadat discloses *an energy transmission element*, e.g., electrodes, *in the distal portion configured to deliver energy to target tissue in the nasopharyngeal passage*.

d. Element 1[c]: an energy source operatively coupled to the energy transmission element for supplying energy thereto according to one or more parameters selected so as to alter nasopharyngeal cells in the target tissue such that nasal congestion is reduced.

115. Saadat discloses "an energy source operatively coupled to the energy transmission element for supplying energy thereto according to one or more parameters selected so as to alter nasopharyngeal cells in the target tissue such that nasal congestion is reduced."

116. As I explained in Section X.A.1.a-c (Ground I, Claim 1, Elements 1[pre]-1[b]), Saadat discloses that the distal end of its "T" shaped RF ablation probe is positioned in the nasopharyngeal passage of a patient and the distal end includes multiple electrodes that are "configured for ablation of the parasympathetic nervous function…." *E.g.*, Ex.1003-Saadat, 10:16-26, 11:1-14, 30:34-38, 31:10-19, 33:41-49, FIG.14B, FIG.30, claims 1, 6, 7.

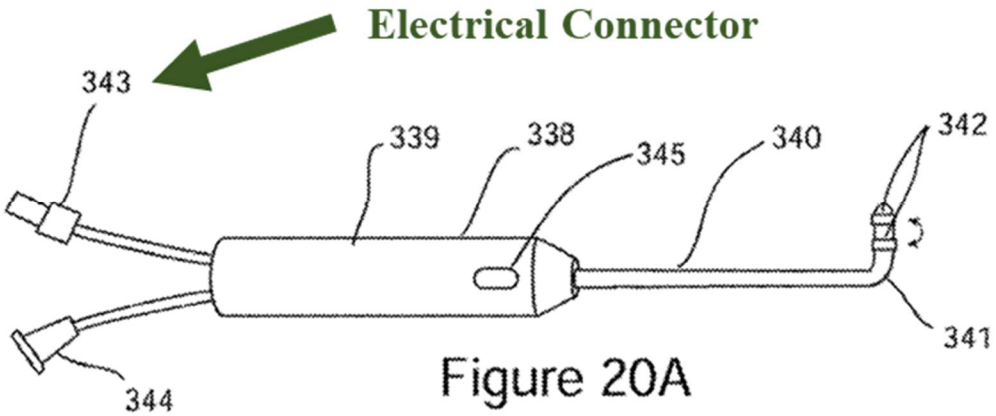
117. Saadat further discloses that its "T" shaped RF ablation probe *alters nasopharyngeal cells in the target tissue such that nasal congestion is reduced*. Consistent with the knowledge of a person of ordinary skill in the art, Saadat explains that nerves branching out from the SPG "are responsible for the parasympathetic control of the nasal mucosa." Ex.1003-Saadat, 16:44-51. Also consistent with the knowledge of a person of ordinary skill in the art, Saadat teaches that "ablating one

or more…branches" of these nerves "leads to a decrease in or interruption of parasympathetic nerve signals that contribute to congestion and rhinorrhea and will "reduce or eliminate rhinitis." *Id.*, 3:6-14. Thus, Saadat specifically teaches that RF ablation disrupts neural activity such that mucus secretion or congestion is reduced.

118. As I discussed in this section and above in Section X.A.1.a-c (Ground I, Claim 1, Element 1[pre]-[b]), Saadat discloses performing RF ablation with the distal end of its "T" shaped RF ablation probe within the *nasopharyngeal passage*. Thus, because Saadat discloses performing RF ablation with the distal end of its RF ablation probe in the nasopharyngeal passage and that doing so disrupts neural activity to reduce the symptoms of rhinitis, Saadat discloses that its RF ablation probe *alters nasopharyngeal cells* when it applies RF energy and that doing so *reduces nasal congestion*.

119. Saadat also discloses *an energy source that is operatively coupled to the energy transmission element for supply energy thereto*. In particular, Saadat's RF ablation probe (below) includes an "**electrical connector 343** [that] is configured for connection to a radiofrequency energy generator, for which there are many commercially available." Ex.1003-Saadat, 30:47-49, FIG.20A. Saadat explains that the "**electrical connector** in the vicinity of the handle **[is] configured to connect the RF ablation element to a source of radiofrequency energy**." *Id.*, 10:16-11:14;

see also id., 12:5-14 ("Another embodiment of this invention is an electrosurgical probe apparatus for ablation of PNN comprising a handle at the proximal end, a probe shaft comprising a distal and proximal end, and an integrated circuit comprising an RF generator disposed in the vicinity of the handle and an RF ablation element disposed in the vicinity of the distal end of the shaft, whereby the geometric parameters of the probe shaft and RF ablation element are optimally configured for RF ablation of PNN according to the surgical methods disclosed here within.").



Ex.1003-Saadat, FIG.20A. Thus, Saadat specifically explains that electrodes (i.e., RF ablation elements) at the distal end of its probe are coupled to an RF energy generator that supplies energy to ablate tissue. Saadat's disclosure or this basic functionality of an RF ablation device is consistent with RF ablation devices that I have used since the 1990s, which include an electrical connector at the device's

handle that connects the electrodes at the device's tip to an RF generator such that RF energy can be supplied by the generator to the electrodes.

120. Saadat further discloses that its RF generator supplies energy to the electrodes at the distal end *according to one or more parameters selected so as to alter nasopharyngeal cells in the target tissue*. As I explained in this section and in Section X.A.1.a-c (Ground I, Claim 1, Element 1[pre]-[b]), Saadat discloses that the distal end of its RF ablation probe includes RF electrodes that supply energy to ablate nasopharyngeal cells. Saadat emphasizes that "[t]hose skilled in the art of RF ablation probes are familiar with the many possible configurations and construction techniques for RF electrodes and probes (Ex.1003-Saaadat, 30:41-47), and explains that the electrodes at the distal end of the RF ablation probe are connected to an RF generator via an electrical connector that supplies power to such electrodes (*id.*, 10:16-11:14, 12:5-14, 30:41-47). In order to successfully ablate tissue in the nasal cavity and nasopharynx as Saadat teaches, a person of ordinary skill in the art would have understood that Saadat's RF electrodes would be configured with its RF generator to supply energy according to one or more parameters, such as within a chosen frequency range.

121. Indeed, it was well known that RF energy was supplied by generators to electrodes according to one or more parameters such as frequency. For example,

Edwards-535 discloses an energy source that delivers RF energy to electrodes. *E.g.*, Ex.1008-Edwards-535, 7:28-36, 8:17-25, 8:54-9:13, 11:46-12:4, FIGs.5-6. As one example, Edwards-535 teaches that its "the signal generator can generate pulses of RF energy which provide between about 5 and about 30 watts of RF energy" for tissue ablation (i.e., to alter cells), and Edwards-535 emphasizes that modifications will readily occur to those skilled in the art." *Id.*, 9:1-13, 11:46-12:4. Relatedly, Stern discloses an RF generator that delivers RF current to electrodes that "has a frequency of at least 250 kHz and less than 100 MHz" for tissue ablation (i.e., to alter cells), and teaches that those skilled in the art would understand that "modifications and variations" of its teachings are possible. *E.g.*, Ex.1009-Stern, 2:6-19.

122. The '011 patent itself correctly assumes that a person of ordinary skill in the art would have understood that an RF generator generates and delivers energy to electrodes according to one or more parameters. The '011 patent generically describes that "[v]arious waveforms or shapes of pulses may be applied to achieve electroporation, including sinusoidal AC pulses, DC pulses, square wave pulses, exponentially decaying waveforms or other pulse shapes such as combined AC/DC pulses, or DC shifted RF signals…." Ex.1001-USP011, 14:19-31. The '011 patent also generically states that "[t]he parameters of applied energy may be varied,

including all or some of the following: waveform shape, amplitude, pulse, duration, interval between pulses, number of pulses, combination of waveforms and the like." *Id.* In other words, the '011 patent generically states that the frequency, power, and other waveform parameters (which are defined by waveform, amplitude, and duration, among other characteristics) may be varied. *Id.* Thus, the '011 patent does not provide any implementation details regarding setting or adjusting any parameters of an RF generator that applies RF energy to electrodes to ablate tissue in the nasal cavity or nasopharynx, which is consistent with the fact that a person of ordinary skill in the art would have understood how to configure an RF generator to apply energy to electrodes according to one or more parameters.

123. As a result, because Saadat discloses that the distal end of its RF ablation probe is configured to ablate nerve cells in the nasopharyngeal passage, ablating nerves in the nasopharyngeal passage reduces the symptoms of rhinitis, and discloses a radiofrequency generator that supplies energy to the electrodes at the distal end of the RF ablation probe that can be configured for this purpose, Saadat discloses an RF generator, i.e., *an energy source*, that is *operatively coupled* to the electrodes, i.e., *energy transmission element*, and *supplies energy thereto according to one or more parameters selected so as to alter nasopharyngeal cells in the target tissue such that nasal congestion is reduced*.

124. Saadat also claims applying RF energy to nerves in the nasopharyngeal passage to treat the symptoms of rhinitis. For example, claim 1 claims applying RF energy to nerves in the *nasopharyngeal passage.*

> 1. **A method for treating nerve tissue within a nasal cavity of a patient,** the method comprising:
>
> **advancing a treatment delivery portion of an energy-based treatment device into a nostril of the patient**;
>
> contacting a mucosal surface of the nasal cavity with the treatment delivery portion; and
>
> **delivering an energy-based treatment from the treatment delivery portion to treat the nerve tissue underlying the mucosal surface**, wherein the delivering of the energy-based treatment comprises delivering energy in a form selected from the group consisting of ultrasound, **radiofrequency**, and electrical energy.

Id., claim 1; *see also id.*, claims 2, ("The method of claim 1, wherein the delivering of the energy-based treatment to treat the nerve tissue underlying the mucosal surface comprises ablating the nerve tissue."), 7 (claiming that the nerve tissue includes "a posterior nasal nerve, a branch of a [V]idian nerve, a parasympathetic nerve, a greater palatine nerve, a maxillary nerve, a sphenopalatine ganglion nerve, or a posterolateral nerve"), 8 ("The method of claim 1, wherein the delivering of the energy-based treatment comprises delivering bipolar radiofrequency energy."). And claim 6, which depends from claim 1, specifies that "the delivering of the energy-

based treatment to treat the nerve tissue underlying the mucosal surface comprises ablating the nerve tissue such that at least one symptom of rhinitis is reduced." *Id.*, claim 6.

2. Claim 2: "The apparatus of claim 1, wherein the energy transmission element comprises at least one electrode."

125. Claim 2 depends from claim 1. Therefore, I incorporate by reference my discussion of Claim 1 in Section X.A.1 (Ground I, Claim 1). Saadat further discloses that "the energy transmission element comprises at least one electrode."

126. As I discussed in Section X.A.1.c (Ground I, Claim 1, Element 1[b]), the distal end of Saadat's RF ablation probe includes multiple electrodes that deliver energy. *E.g.*, Ex.1003-Saadat, 30:34-38, 31:10-19, 33:41-29; *see also id.*, 10:16-26, 30:47-49, 32:62-33:3, FIG.20E, FIG.30, claims 3-4, 9, 10-12.

3. Claim 5: "The apparatus of claim 1, wherein the energy supplying means comprises an RF generator."

127. Claim 5 depends from claim 1. Therefore, I incorporate by reference my discussion of Claim 1 in Section X.A.1 (Ground I, Claim 1). Saadat further discloses that "the energy supplying means comprises an RF generator."

128. As I discussed in Section X.A.1.d (Ground I, Claim 1, Element 1[c]), Saadat's RF ablation probe includes an "**electrical connector 343** [that] is configured for connection to **a radiofrequency energy generator**, for which there

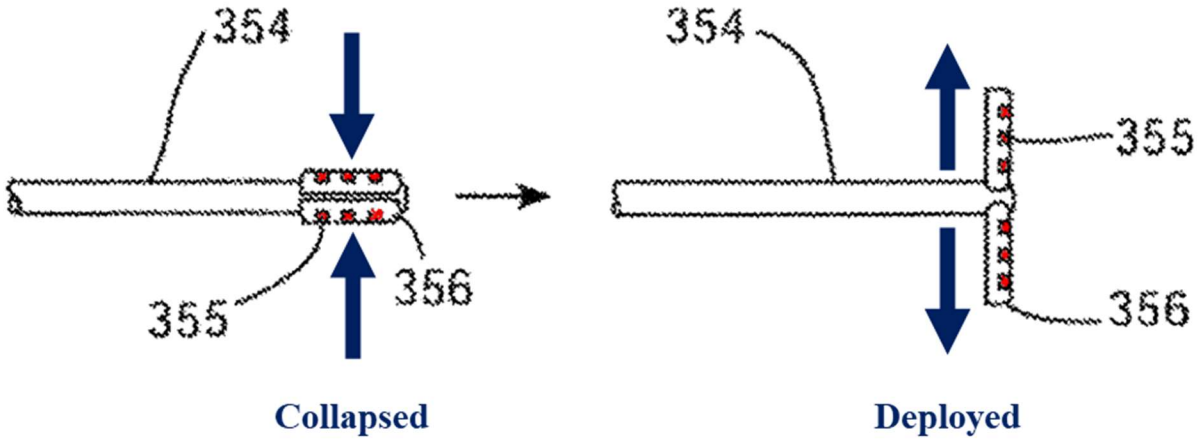
are many commercially available," and Saadat's **radiofrequency energy generator** delivers energy to the electrodes at the distal end of Saadat's RF ablation probe to ablate tissue in the nasopharyngeal passage to reduce mucus production and congestion, i.e., the symptoms of rhinitis. *E.g.*, Ex.1003-Saadat, 30:47-49, FIG.20A.

4. Claim 8: "The apparatus of claim 1, wherein the energy transmission element is movable relative to the distal portion of the body."

129. Claim 8 depends from claim 1. Therefore, I incorporate by reference my discussion of Claim 1 in Section X.A.1 (Ground I, Claim 1). Saadat also discloses that "the energy transmission element is movable relative to the distal portion of the body."

130. Saadat discloses that its "T" shaped tip is a deployable structure that "is comprised of two halves which can alternately be collapsed and deployed as in FIG. 20E." Ex.1003-Saadat, 31:10-16. Saadat elaborates that "the two halves of the electrode structure 356 are pivoted to allow them to move laterally relative to the catheter shaft 354," and each half includes multiple electrodes 355 that are monopolar or bipolar electrodes. *Id.*, 31:16-19; *see also id.*, Abstract ("Once suitably positioned, the distal end may be reconfigured from the first configuration to a second configuration which is shaped to contact and follow the tissue region and the post nasal nerve may then be ablated via the distal end."), 15:17-21, 33:41-49,

FIG.30. As shown in Figure 20E reproduced below, the "T" shaped structure is first in a collapsed state such that the electrode structures 356 with electrodes 355 are parallel to the catheter shaft 354. *Id.*, 31:10-19. The "T" shaped structure is then deployed such that the electrode structures 356 with electrodes 355 move relative to the catheter shaft 354.



Ex.1003-Saadat, FIG.20E. Thus, Saadat discloses that its electrodes, i.e., *energy transmission element*, *is movable relative to the distal portion of the body*.

5. <u>Claim 9: "The apparatus of claim 8, wherein the energy transmission element is configured to deliver energy laterally relative to the distal portion of the body."</u>

131. Claim 9 depends from claim 8. Therefore, I incorporate by reference my discussion of Claim 8 in Section X.A.4 (Ground I, Claim 8). Saadat also discloses that "the energy transmission element is configured to deliver energy laterally relative to the distal portion of the body."

132. As I discussed in Section X.A.1.c (Ground I, Claim 1, Element 1[b]) and Section X.A.4 (Ground I, Claim 8), the distal end of Saadat's "T" shaped RF ablation probe includes multiple bipolar electrodes 355 that deliver RF energy. *See, e.g.*, Ex.1003-Saadat, 31:10-19, 33:41-49, FIG.20E, FIG.30, claims 1, 3-4, 9, 10-12. It was well-known that bipolar electrodes are conductors that facilitate RF current traveling from one electrode to another. For example, Figure 17 of Stern, reproduced below, shows RF current traveling from one bipolar electrode to another bipolar electrode. Ex.1009-Stern, 5:54-55 ("FIG. 17 shows electric field lines outside a bipolar electrode pair."), 13:11-20 ("In contrast, a bipolar operation is shown in FIG. 17. The balloon 256 includes electrodes 258 and 260. The electric field lines proceed between the two electrodes. With a bipolar electrode, the current paths are more easily controllable by appropriate placement and activation of the electrodes….").

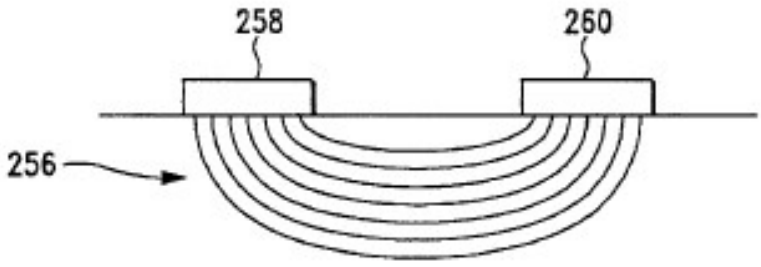
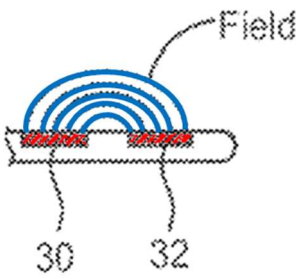
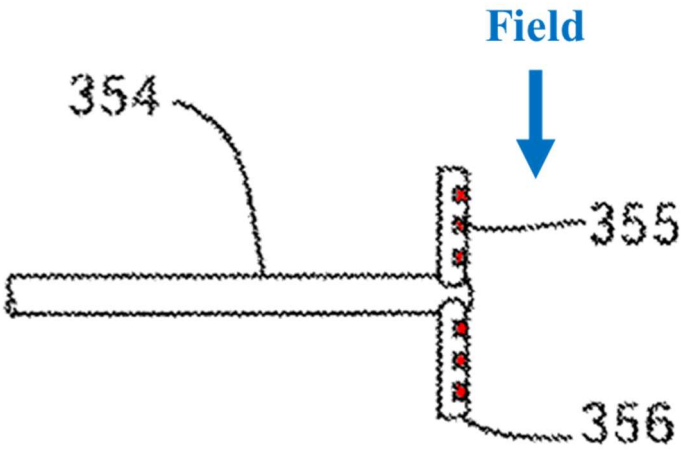


FIG.–17

Ex.1009-Stern, FIG.17.

133. In view of this common knowledge, a person of ordinary skill in the art would have understood that electrical current would travel from one of Saadat's electrodes to another of Saadat's electrodes to create an electrical field between the two electrodes that is concentrated through the contacted tissue. A person of ordinary skill in the art would have understood the current in the electrical field created by Saadat's electrodes includes current, i.e., *energy*, that is directed laterally relative to the axis of the distal portion of the RF ablation probe. In other words, a person of ordinary skill in the art would have understood that current traveling between Saadat's bipolar electrodes would create electrical fields that concentrate current lateral relative to the axis of the distal portion of the RF ablation probe (e.g., the target tissue above and below the probe). Additionally, the concentration of current in Saadat is the same as the energy concentration depicted in the '011 patent in Figure 5A by similarly arranged electrodes. Ex.1001-USP011, 16:30-58 ("FIG. 5A depicts an arrangement of electrodes 30 and 32 that produces an electric field concentrated in a lateral direction from the catheter body…."), FIG.5, FIGs.5A-5B; Ex.1003-Saadat, 30:34-55, 31:10-19, FIG.20E. Thus, Saadat discloses that its "T" shaped RF ablation probe *delivers energy laterally relative to the distal portion of the body*.

’011 Patent, FIG.5A	Saadat, FIG.20E
 FIG. 5A	

6. Claim 10: “The apparatus of claim 9, wherein the energy transmission element is configured to extend laterally from the distal portion of the body.”

134. Claim 10 depends from claim 9. Therefore, I incorporate by reference my discussion of Claim 9 in Section X.A.5 (Ground I, Claim 9). Saadat further discloses that “the energy transmission element is configured to extend laterally from the distal portion of the body.”

135. As I explained in Section X.A.4 (Ground I, Claim 8), Saadat’s “T” shaped RF ablation probe includes two electrode structures that each have multiple electrodes that collapse and expand outward, as shown in Figure 20E. Because each electrode structure 356 extends from the catheter body 354, the electrode structure

356 with electrodes 355 is thus *configured to extend laterally from the distal portion of the body*.

7. Claim 12: "The apparatus of claim 1, further comprising: a sensing element on the distal portion of the body."

136. Claim 12 depends from claim 1. Therefore, I incorporate by reference my discussion of Claim 1 in Section X.A.1 (Ground I, Claim 1). Saadat further discloses "a sensing element on the distal portion of the body."

137. Saadat explains that its probe "may also be configured with at least one temperature sensor disposed in the vicinity of the distal end." Ex.1003-Saadat, 6:35-37; *see also id.*, 17:56-59 ("In one embodiment, a temperature sensor may be disposed in the vicinity of distal end effector 30 (e.g., spring-like structure) and used to measure, display, or control a temperature of surgical interest."). Moreover, Saadat claims that its RF ablation probe includes a "thermocouple disposed in a vicinity of the treatment delivery portion." *Id.*, claim 5 ("The method of claim 1, further comprising measuring energy-based treatment delivery using a thermocouple disposed in a vicinity of the treatment delivery portion." It was well-known that a thermocouple is a type of temperature sensor. *E.g.*, Ex.1047-Flaherty, 17:53-57 ("Other feedback elements may also be provided, for example, a thermocouple or other temperature sensor may be provided on systems including ionophoresis

electrodes or ablation devices to monitor the amount of heating being experienced by tissue during a procedure."); Ex.1062-Townley, [0044] ("In certain embodiments, the therapeutic assembly 212 can include one or more sensors (not shown), such as one or more temperature sensors (e.g., thermocouples, thermistors, etc.), impedance sensors, and/or other sensors."). Because a thermocouple/ temperature sensor monitors temperature and Saadat explains that its thermocouple/ temperature sensor is disposed at the end of the device, i.e., on the RF ablation probe, Saadat discloses *a sensing element on the distal portion of the body*.

8. Claim 14: "The apparatus of claim 12, further comprising: a monitoring system operatively coupled to the sensing element for indicating a degree of treatment of the target tissue."

138. Claim 14 depends from claim 12. Therefore, I incorporate by reference my discussion of Claim 1 in Section X.A.7 (Ground I, Claim 12). Saadat further discloses "a monitoring system operatively coupled to the sensing element for indicating a degree of treatment of the target tissue."

139. As I discussed in Section X.A.7 (Ground I, Claim 12), Saadat disclosed an RF ablation probe including a temperature sensor and specifically a thermocouple that monitors temperature. Saadat explained that the "temperature sensor" or "thermocouple" "monitors the…temperature of the tissue region…under treatment."

Ex.1003-Saadat, 23:1-6. Thus, Saadat teaches the well-known concept that temperature sensors and thermocouples *indicate* to a physician *a degree of treatment of the tissue* being ablated. *See, e.g.*, Ex.1047-Flaherty, 17:53-57 ("Other feedback elements may also be provided, for example, a thermocouple or other temperature sensor may be provided on systems including ionophoresis electrodes or ablation devices **to monitor the amount of heating being experienced by tissue during a procedure**."); Ex.1062-Townley, [0047] ("For example, the evaluation/feedback algorithm 220, in conjunction with the controller 218, can be configured to monitor temperature at the treatment site during therapy and automatically shut off the energy delivery when the temperature reaches a predetermined maximum (e.g., when applying RF energy)….").

B. Ground II: Challenged Claims 12 and 14 are Obvious in view of Saadat

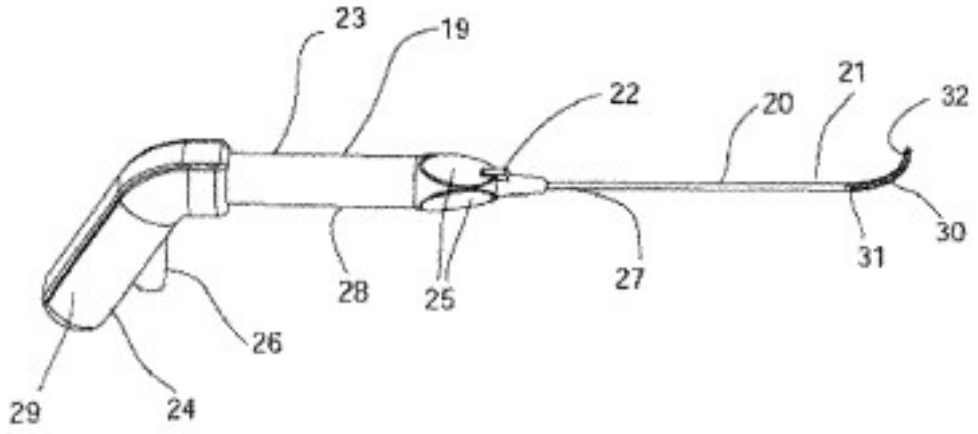
140. As detailed in Ground I, Saadat anticipates claims 12 and 14. To the extent Patent Owner argues that Saadat does not anticipate claims 12 and 14, Saadat also renders these claims obvious.

1. <u>Claim 12: "The apparatus of claim 1, further comprising: a sensing element on the distal portion of the body."</u>

141. Claim 12 depends from claim 1. Therefore, I incorporate by reference my discussion of Claim 1 in Section X.A.1 (Ground I, Claim 1). I also incorporate

by reference my discussion of Claim 12 in the context of Ground I. *See* Section X.A.7 (Ground I, Claim 12).

142. To the extent Patent Owner contends that Saadat does not expressly disclose "a sensing element on the distal portion of the body," it would have been obvious to a person of ordinary skill in the art in view of Saadat's teachings to include a sensing element on the distal end of Saadat's RF ablation probe. As I explained in Section X.A.7 (Ground I, Claim 12), Saadat explained that its RF ablation probe "may also be configured with at least one temperature sensor disposed in the vicinity of the distal end." Ex.1003-Saadat, 6:35-37. Further, Figure 2 of Saadat illustrates an ablation probe for cryoablating posterior nasal nerves, and the probe includes "a temperature sensor may be disposed in the vicinity of **distal end effector 30** (e.g., spring-like structure) and used to measure, display, or control a temperature of surgical interest." *Id.*, 16:51-54, 17:56-59, 17:62-64.



Ex.1003-Saadat, FIG.2. As I also explained in Section X.A.7 (Ground I, Claim 12), Saadat claims that its RF ablation probe includes a "thermocouple disposed in a vicinity of the treatment delivery portion," and a person of ordinary skill in the art would have understood that a thermocouple measures temperature. *Id.*, claim 5 ("The method of claim 1, further comprising measuring energy-based treatment delivery using a thermocouple disposed in a vicinity of the treatment delivery portion."); Ex.1047-Flaherty, 17:53-57; Ex.1062-Townley, [0044]; Ex.1005-Makower, [0187].

143. A person of ordinary skill in the art would have been motivated to position a thermocouple (i.e., a *sensing element*) on the distal end of Saadat's "T" shaped RF ablation probe to measure the tissue temperature as taught by Saadat. A person of ordinary skill in the art would have understood that monitoring tissue

temperature when applying RF ablation energy is a way to monitor for patient safety. As I explain in Section VI.C.2 (Ablation), RF ablation involves applying energy to tissue to heat the tissue and cause damage. If too much energy is applied, the tissue temperature can increase such that heat is subsequently transferred to adjacent tissue that is not within the scope of treatment. For example, tissue in the nasopharyngeal passage is near many significant organs, arteries, and nerves (i.e., tissue adjacent to the target tissue). If too much energy is applied to tissue in the nasopharyngeal passage, adjacent tissue would become damaged, i.e., the temperature would increase such that there is more tissue damage than desired or necessary for the therapeutic objective of treating rhinitis. Thus, a person of ordinary skill in the art would have understood that including a thermocouple at the end of Saadat's "T" shaped RF ablation would allow the physician to monitor the tissue temperature and confirm that the appropriate amount of energy is applied. For at least this reason, it was well-known and routine to include temperature sensors on RF ablation probes to ensure that the temperature of the target tissue remained in a proper range. *See, e.g.*, Ex.1062-Townley, [0044] ("In certain embodiments, the therapeutic assembly 212 can include one or more sensors (not shown), such as one or more temperature sensors (e.g., thermocouples, thermistors, etc.), impedance sensors, and/or other sensors."); Ex.1005-Makower, [0187] ("Additionally, sensing elements may also be

attached to the catheter and/or strut members to monitor various parameters of the catheter and/or surrounding tissue (e.g., temperature, etc.)."). Saadat itself teaches both a device and a thermocouple for use with the device. *E.g.*, Ex.1003-Saadat, 16:51-54, 17:56-59, 17:62-64, claims 1, 5.

144. A person of ordinary skill in the art would have had a reasonable expectation of success at including a temperature sensor (e.g., thermocouple) on the distal end of Saadat's "T" shaped RF ablation probe. As I discuss above in this Section, Saadat specifically teaches including temperature sensors on ablation devices, and doing so was well-known in the art. *E.g.*, Ex.1003-Saadat, 16:51-54, 17:56-59, 17:62-64, claims 1, 5; Ex.1062-Townley, [0044]; Ex.1005-Makower, [0187]; Ex.1047-Flaherty, 17:53-5. Thus, a person of ordinary skill in the art would have understood that including a thermocouple (i.e., temperature sensor) on Saadat's "T" shaped RF ablation probe was simply using one known device, a thermocouple, with another known device, an RF ablation probe, to obtain the predictable result of measuring the temperature of target tissue when applying RF energy.

145. The '011 patent itself assumes (correctly) that a person of ordinary skill in the art would have understood how to implement a sensing element. The '011 patent generically describes that "any of [its] foregoing systems may include electrodes or other monitoring systems" without implementation details. Ex.1001-

USP011, 18:34-39. In my opinion, this too is consistent with the fact that a person of ordinary skill in the art would have had a reasonable expectation of success at including a temperature sensor (e.g., thermocouple) on the distal end of Saadat's "T" shaped RF ablation probe.

2. Claim 14: "The apparatus of claim 12, further comprising: a monitoring system operatively coupled to the sensing element for indicating a degree of treatment of the target tissue."

146. Claim 14 depends from claim 12. Therefore, I incorporate by reference my discussion of Claim 12 in Section X.A.7 (Ground I, Claim 12) and Section X.B.1 (Ground II, Claim 12). I also incorporate by reference my discussion of Claim 14 in the context of Ground I. *See* Section X.A.8 (Ground I, Claim 14).

147. To the extent Patent Owner contends that Saadat does not expressly disclose "a monitoring system operatively coupled to the sensing element for indicating a degree of treatment of the target tissue," it would have been obvious to a person of ordinary skill in the art in view of Saadat's teachings to include a monitoring system operatively coupled to the sensing element on the distal end of Saadat's RF ablation probe for indicating a degree of treatment of the target tissue. As I discussed in Section X.A.7 (Ground I, Claim 12) and Section X.B.1 (Ground II, Claim 12), Saadat discloses or at least renders obvious including a sensing

element such as a thermocouple on the distal end of Saadat's RF ablation probe to measure the tissue temperature during the application of RF energy.

148. A person of ordinary skill in the art would have been motivated to couple a thermocouple on the distal end of Saadat's RF ablation probe to a monitoring system because a monitoring system allows the thermocouple to be used for its intended temperature monitoring purpose by informing the physician of the temperature of the tissue when RF ablation is being applied. Indeed, as I explained in Section X.B.1 (Ground II, Claim 12), it was well-known and routine to monitor tissue temperature with sensing elements as a method of protecting patient safety. *E.g.*, Ex.1062-Townley, [0114] ("The therapeutic assembly 1212 can also include a temperature sensor 1252 (e.g., a thermocouple) and/or other type of sensor to detect various properties at the treatment site before, during, and/or after applying therapeutic neuromodulation energy, and provide feedback that may be used to control the operation of the therapeutic assembly 1212."); Ex.1005-Makower, [0187] ("Additionally, sensing elements may also be attached to the catheter and/or strut members to monitor various parameters of the catheter and/or surrounding tissue (e.g., temperature, etc.).").

149. A person of ordinary skill in the art would have had a reasonable expectation of success at coupling a temperature sensor, i.e., thermocouple, on the

distal end of Saadat's RF ablation probe to a monitoring system. As noted in this section, it was well-known to use monitoring systems when applying RF energy so physicians could monitor the temperature of tissue determined by temperature sensors. And Saadat specifically teaches this well-known concept—Saadat teaches including a "temperature sensor" "to monitor…a temperature of the tissue region…under treatment." *E.g.*, Ex.1003-Saadat, 23:1-6. As a result, a person of ordinary skill in the art would have understood that including a monitoring system to indicate a degree of treatment of the target tissue was simply using one known device, a monitoring system, with another, an RF ablation probe with a thermocouple, to obtain the predictable result of monitoring the temperature of tissue when applying RF energy.

C. Ground IV: Challenged Claims 1-2, 5, 8-10, 12, and 14 are Obvious Over the Combination of Makower, Fang, and Edwards-535

150. As detailed below, the combination of Makower, Fang, and Edwards-535 renders the Challenged Claims obvious.

1. Claim 1

a. Element 1[pre]: Apparatus for treatment of a nasal condition by altering function of a nasopharyngeal passage of a patient, the apparatus comprising:

151. The combination of Makower and Fang teaches an "[a]pparatus for treatment of a nasal condition by altering function of a nasopharyngeal passage of a patient."

152. Makower teaches "**medical devices** and methods and more particularly…**minimally invasive, catheter based devices, systems** and methods for treating sinusitis and other ear, **nose** & throat **disorders**." Ex.1005-Makower, [0001]; *see also id.* [0043] ("In accordance with the present invention, there are provided methods wherein one or more flexible catheters or other flexible elongate devices as described herein are inserted in to the nose, nasopharynx, paranasal sinus, middle ear or associated anatomical passageways to perform an interventional or surgical procedure."), [0161] ("The present invention provides a variety of apparatus that may be inserted into the nasal cavity, paranasal sinus, nasopharynx or middle

ear to perform diagnostic or therapeutic procedures."), [0187]. Claim 1 of Makower also claims a method of treating a nasal condition using a working device:

> **A method for diagnosing and/or treating** sinusitis or **another disorder affecting the nose**, paranasal sinuses **or other anatomical structures of the** ear, **nose** or throat, said method comprising the steps of:
>
> (A) placing a port device in the nostril or nasal cavity on at least one side of the intranasal septum, said port device comprising a device insertion port and a valve that is operative to allow a working device to be inserted through said device insertion port while preventing blood or other fluid from backflowing out of the device insertion port at least when no working device is inserted therethrough;
>
> (B) advancing at least one working device through the port device to a location within the nose, nasopharynx or paranasal sinus; and
>
> (C) using the working device to perform a diagnostic or therapeutic procedure.

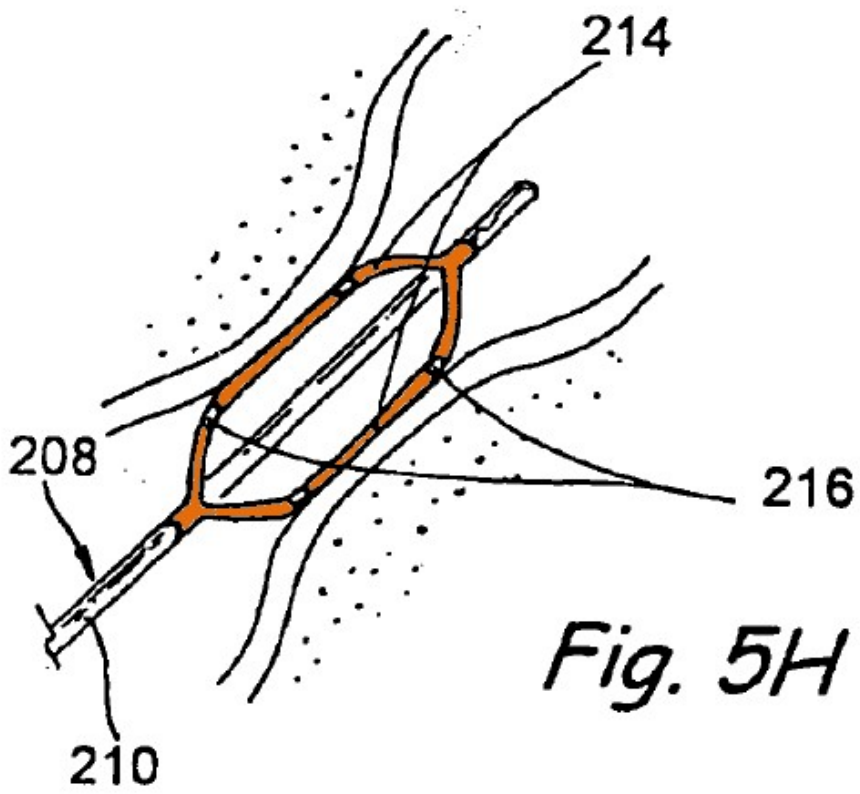
Id., claim 1. Claim 2 of Makower specifies that the procedure includes "ablating" tissue with the working device. *Id.*, claim 2. Thus, Makower teaches an *apparatus for treatment of a nasal condition*.

153. Makower also discloses *altering function of a nasopharyngeal passage of a patient*. As I explained in Section X.A.1.a (Ground I, Claim 1, Element 1[pre]), a person of ordinary skill in the art would have understood that the plain and ordinary

meaning of *nasopharyngeal passage* is the passage that includes both the nasal cavity and the pharynx.

154. Makower teaches positioning "one or more flexible catheters or other flexible elongate devices as described herein…into the **nose, nasopharynx**, paranasal sinus, middle ear or associated anatomical passageways to perform an interventional or surgical procedure." Ex.1005-Makower, [0043]. In particular, Makower discloses "working devices" that are "inserted into the **nasal cavity**, paranasal sinus, **nasopharynx** or middle ear to perform diagnostic or therapeutic procedures." *Id.*, [0161]. One such device is shown in Figure 5H. *Id.*, [0161], [0187]. Figure 5H of Makower depicts "an electrosurgical device 208 comprising a flexible shaft 210 (e.g., a catheter or solid shaft) having arched strut members 214 attached thereto." *Id.*, [0187]. Makower explains that "[e]lectrodes 216 are located on the strut members 214," and that "current is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated. *Id.*, [0164], [0187], FIG.5H; *see also id.* ("The electrodes 216 may be bipolar, monopolar…."). Makower also explains that such electrodes are "radiofrequency electrodes." *Id.*, [0164] ("[T]he working devices shown in FIGS. 5A-5Y" and described herein incorporate assemblies, components or mechanisms (e.g.,…radiofrequency electrodes)."). Although I understand that patent figures are merely illustrations,

Figure 5H shows the electrodes on the strut members 214 contacting the surrounding tissue (e.g., tissue in the nasal cavity or nasopharynx), which is consistent with my experience treating tissue in the nasal cavity and nasopharynx.



Ex.1005-Makower, FIG.5H, [0161], [0164], [0187]. Thus, because Makower teaches that the electrodes on the strut members 214 apply current to tissue in the nasal cavity or nasopharynx to heat tissue, Makower discloses that the strut members 214 with electrodes of its electrosurgical device *alters function of a nasopharyngeal*

passage of a patient when applying current to the tissue in the nasal cavity or nasopharynx.

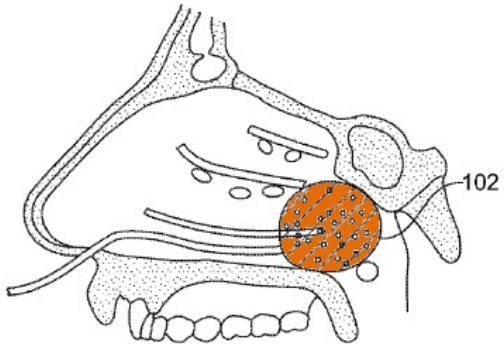
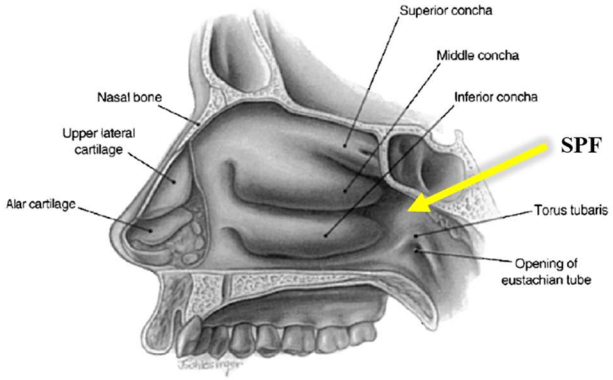
155. Fang also teaches an *apparatus for treatment of a nasal condition*. Fang teaches performing "nasal endoscopic surgery combined with multiple radiofrequency in the treatment of perennial allergic rhinitis." Ex.1006-Fang, 876. Fang explains that "[u]nder nasal endoscopy, the SHP-I five-organ radiofrequency therapy instrument (manufactured by Guangzhou Medical Instrument Factory) was firstly used, with the Level 3 intensity selected, and the firing head aligned with the sphenopalatine foramen on both sides, to carry out radiofrequency…." *Id.* Fang explains that "[t]he use of radiofrequency technique completely blocks the parasympathetic pathway of the nasal mucosa," which "reduces glandular secretion, and thus achieves the therapeutic purposes" of treating "perennial allergic rhinitis." *Id.*, 876-877. Because rhinitis is a nasal condition, Fang thus teaches an *apparatus for treatment of a nasal condition*.

156. Fang teaches that it treats a nasal condition *by altering function of a nasopharyngeal passage of a patient*. As I explain in this section, Fang teaches aligning the firing head of the "SHP-I five-organ radiofrequency therapy instrument" with the sphenopalatine foramen "to carry out radiofrequency" ablation, and that doing so achieves the therapeutic purposes" of treating rhinitis. Ex.1006-Fang, 876-

877. Thus, Fang teaches aligning the "firing head" of the "SHP-I five-organ radiofrequency therapy instrument" with the "sphenopalatine foramen" to perform radiofrequency ablation to treat rhinitis. *Id.*

157. As I explained in Section VI.A (Relevant Anatomy), the SPF is located in the posterior nasal cavity, that is, in the *nasopharyngeal passage*. *See* Section X.A.1.a (Ground I, Claim 1, Element 1[pre]) (explaining a person of ordinary skill in the art would have understood that the plain and ordinary meaning of *nasopharyngeal passage* is the passage that includes both the nasal cavity and the pharynx). Additionally, the SPF is located in same location that the '011 patent identifies as the "nasal passage" and "nasopharynx," i.e., *nasopharyngeal passage*. As I explained in Section X.A.1.a (Ground I, Claim 1, Element 1[pre]), the '011 patent explains that the balloon catheter shown in Figure 23 (shown below) is "positioned to target an area of high goblet cell (G) concentration, for example, in the back of the nasal passages in the area of the nasopharynx." Ex.1001-USP011, 23:66-24:6, FIG.23. As shown in the chart below, a person of ordinary skill in the art would have understood that the SPF is in the same location that the '011 patent identifies as the nasal passage and nasopharynx, i.e., the *nasopharyngeal passage.* The '011 patent thus confirms that Fang—which places its device at the SPF and in

same location as the balloon in ’011 patent Figure 23—positions its “firing head” *proximate to target tissue in the nasopharyngeal passage*. Ex.1006-Fang, 876-877.

’011 Patent, FIG.23	**SPF**
	

158. Moreover, as I explained in Section VI.A (Relevant Anatomy), the SPF is where nerve branches of the SPG that contain parasympathetic nerves enter the nasal cavity to innervate the nasal cavity and nasopharynx. Fang therefore teaches that applying radiofrequency energy to target tissue in the nasopharyngeal passage will block (i.e., alter) activity of the parasympathetic nerves, which in turn reduces the symptoms of rhinitis. In other words, because Fang teaches targeting tissue and nerves surrounding the SPF with its radiofrequency device and that applying radiofrequency ablation to such nerves alters the function of the nerves to treat rhinitis, Fang teaches an *apparatus for treatment of a nasal condition by altering function of a nasopharyngeal passage of a patient*.

159. As I explain in this section and Section X.C.1.e (Motivation to Combine with a Reasonable Expectation of Success), Fang teaches the obvious result of applying RF energy via current to tissue in the nasal cavity and nasopharynx (i.e., *nasopharyngeal passage*) with Makower's electrodes. A person of ordinary skill in the art would have been motivated to use Makower's electrosurgical device to reduce nasal congestion and mucus production (i.e., symptoms of rhinitis) in the nasal cavity and nasopharynx by disrupting neural activity as taught by Fang with a reasonable expectation of success because, among other reasons, Makower and Fang teach treating nasal conditions by applying RF energy in the same place, where parasympathetic nerves innervating from the SPG are located.

b. Element 1[a]: a hand-held elongate body having proximal and distal portions, the distal portion being configured for positioning in a nasopharyngeal passage of a patient with the proximal portion positioned outside the nasopharyngeal passage;

160. Makower and Fang teach "a hand-held elongate body having proximal and distal portions, the distal portion being configured for positioning in a nasopharyngeal passage of a patient with the proximal portion positioned outside the nasopharyngeal passage."

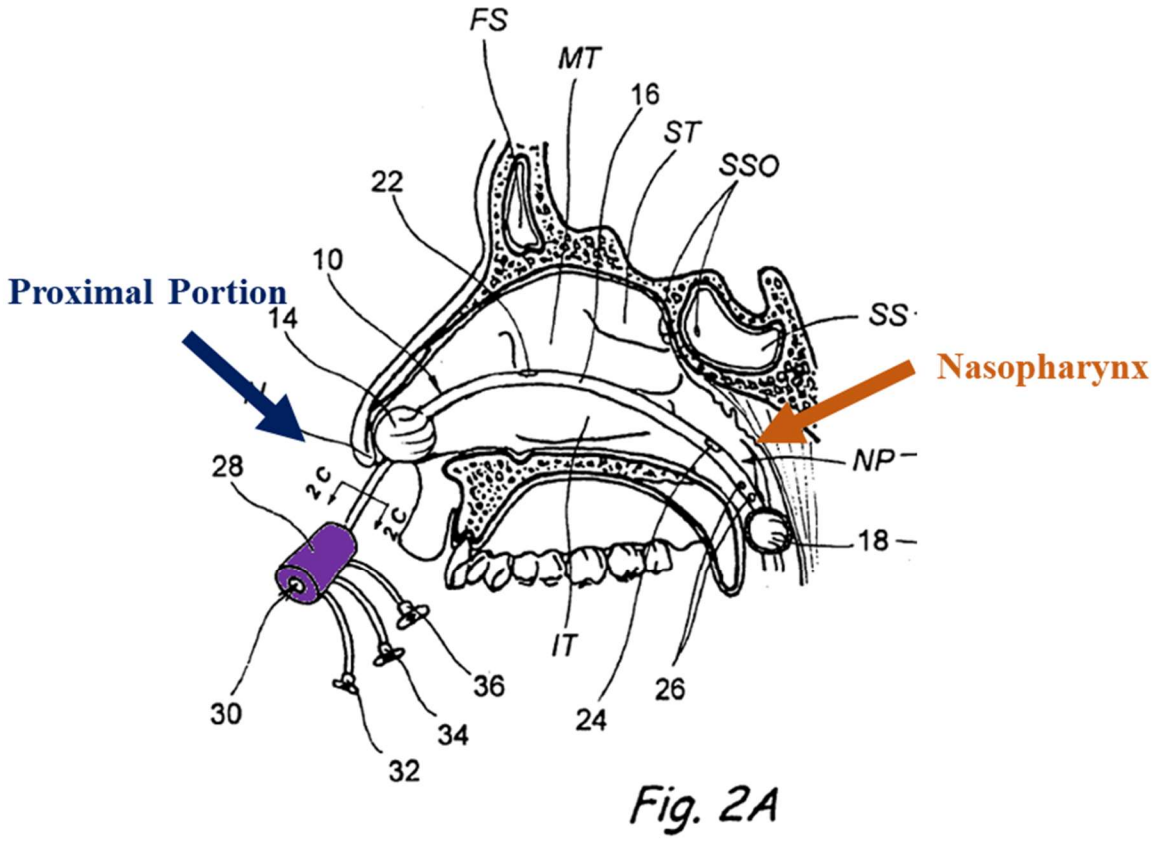
161. As I explained in Section X.C.1.a (Ground IV, Claim 1, Element 1[pre]), Makower teaches an electrosurgical device that includes "a flexible shaft

210 (e.g., a catheter or solid shaft)" with multiple electrodes on strut members, and that such electrodes are "radiofrequency electrodes." *E.g.*, Ex.1005-Makower, [0161], [0164] ("[T]he working devices shown in FIGS. 5A-5Y" and described herein incorporate assemblies, components or mechanisms (e.g.,…radiofrequency electrodes)."), [0187], FIG.5H. Makower also teaches that the multiple electrodes on the strut members contact surrounding tissue in the nasal cavity or nasopharynx to apply current to heat tissue. *Id.*, [0161], [0164], [0187, FIG.5H. And Makower also explains that the "flexible shaft 210" "allows [the electrosurgical device] to be delivered and positioned to perform the desired diagnostic or therapeutic procedures…." *Id.*, [0161]. Makower's teachings are consistent with known RF ablation probes that were used to treat tissue in the nasal cavity or nasopharynx. In particular, it was well-known in the art that when a physician used an RF ablation probe to treat tissue in the nasal cavity or nasopharynx, such as the RF ablation probe disclosed by Makower, the physician would hold the device outside of the patient's body, i.e., *outside the nasopharyngeal passage*, and the end of the RF ablation probe with ablation elements would be positioned next to the target tissue in the nasal cavity or nasopharynx, i.e., *positioned in the nasopharyngeal passage*. After the procedure was completed, the physician would then use the portion outside of the body to remove the device after treatment. Indeed, this is how RF ablation probes

that I have used since the 1990s operated. Thus, because Makower's electrosurgical device is a type of catheter, a person of ordinary skill in the art would have understood that Makower's electrosurgical device is a handheld device, i.e., *hand-held elongate body*, that includes a portion that is held by the physician outside of the patient's body, i.e., *a proximal portion positioned outside the nasopharyngeal passage*, and a portion (e.g., the strut members with electrodes) that is inserted by the physician into the patient's nasal cavity or nasopharynx, i.e., *a distal portion configured for positioning in the nasopharyngeal passage*.

162. Figure 2A of Makower confirms that the electrosurgical device is a hand-held elongate body that has a proximal portion outside the nasopharyngeal passage and a distal portion position in the nasopharyngeal passage. Figure 2A, shown below, teaches an occluder and access device that facilitates inserting the flexible shaft 210 into a patient's nasal cavity and nasopharynx. Ex.1005-Makower, [0133]-[0135], [0162] ("[T]hese working devices (and/or the catheters used to deliver them) may be inserted through lumens of the occluder & access devices 10, 12, 300, 301, 400, 430, etc. as shown in FIGS. 2A-2R…."). In particular, Figure 2A depicts an occluder and access device 10 that includes a "device insertion opening 30," tube 16, and outlet openings 22 and 24. *Id.*, [0135]; *see also id*, [0134] ("To facilitate the insertion and proper positioning of such catheters and/or other elongate

working devices and to prevent undesirable drainage of blood or debris from the operative site, the present invention includes a number of different occluder and/or access port devices….”). Makower explains that the electrosurgical device can be inserted through the “device insertion opening 30” and tube 16 and “out of a selected” outlet opening 22 or 24 “to a position within the nose, nasopharynx or paranasal sinus.” *Id.*, [0135]. In other words, the flexible shaft 210 of the electrosurgical device can be inserted through the “device insertion opening 30” and tube 16 such that the strut members with electrodes enter the patient’s body and exit one of the outlet openings 22 or 24 such that the strut members with electrodes are positioned in the nasal cavity or nasopharynx. *Id.* For example, the physician holds the electrosurgical device outside of the patient’s body, advances the flexible shaft through the outlet opening, then through outlet opening 22, and positions the strut members with electrodes in the nasal cavity. Relatedly, the physician holds the electrosurgical device outside of the patient’s body, advances the flexible shaft through the outlet opening, then through outlet opening 24, positions the strut members with electrodes in the nasopharynx.



Ex.1005-Makower, FIG.2A. This supports and confirms my opinion that Makower's electrosurgical device is a handheld device, i.e., *hand-held elongate body*, that includes a portion that is held by the physician outside of the patient's body, i.e., *a proximal portion positioned outside the nasopharyngeal passage*, and a portion (e.g., the strut members with electrodes) that is inserted by the physician into the patient's nasal cavity or nasopharynx, i.e., *a distal portion configured for positioning in the nasopharyngeal passage*.

163. As I explained in Section X.C.1.a (Ground IV, Claim 1, Element 1[pre]), Fang teaches that the physician treating a patient aligns the "firing head" of the "SHP-I five-organ radiofrequency therapy instrument" with the "sphenopalatine foramen" to perform radiofrequency ablation to treat rhinitis. Ex.1006-Fang, 876-877. Fang's description of its RF device is consistent with how physicians used known RF ablation probes to treat tissue in the nasal cavity or nasopharynx. In particular, it was well-known in the art that when a physician used an RF ablation probe to treat tissue in the nasal cavity or nasopharynx, such as the RF ablation probe disclosed by Fang, the physician would hold the device outside of the patient's body, i.e., *outside the nasopharyngeal passage*, and the end of the RF ablation probe with ablation elements would be positioned next to the target tissue in the nasal cavity or nasopharynx, i.e., *positioned in the nasopharyngeal passage*. Indeed, as explained above in this section, this is how RF ablation probes that I have used since the 1990s operated. Thus, Fang teaches the well-known concept of *a hand-held elongate body* that includes a portion held by the physician outside the patient's body, i.e., *proximal portion position outside the nasopharyngeal passage*, and a portion that is advanced by the physician into the patient's such that the end of the device that delivers energy is positioned proximate to the tissue being treated, i.e., *distal portion configured for positioned in the nasopharyngeal passage*.

c. Element 1[b]: an energy transmission element in the distal portion configured to deliver energy to target tissue in the nasopharyngeal passage; and

164. Makower and Fang teach "an energy transmission element in the distal portion configured to deliver energy to target tissue in the nasopharyngeal passage."

165. As I explained in Section X.C.1.a (Ground IV, Claim 1, Element 1[pre]), Makower and Fang each teach positioning a distal portion of a treatment device proximate to tissue in the *nasopharyngeal passage*.

166. As I explained in Sections X.C.1.a-b (Ground IV, Claim 1, Elements 1[pre]-1[a]), Makower teaches an electrosurgical device that includes multiple electrodes on strut members, and that such electrodes are "radiofrequency electrodes," i.e., *energy transmission element*s. *E.g.*, Ex.1005-Makower, [0161], [0164] ("[T]he working devices shown in FIGS. 5A-5Y" and described herein incorporate assemblies, components or mechanisms (e.g.,…radiofrequency electrodes)."), [0187], FIG.5H. Makower explains that its electrodes are bipolar electrodes, and that once the device is positioned in the nasal cavity or nasopharynx, i.e., nasopharyngeal passage, "current is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated." *Id.*, [0043], [0161] ("The present invention provides a variety of apparatus that may be inserted into the nasal cavity, paranasal sinus, nasopharynx or middle ear to perform diagnostic or

therapeutic procedures."), [0187]. Makower also teaches the well-known concept of using multiple electrodes for ablation in its claims. In particular, claims 1 and 2 of Makower teach advancing a working device (e.g., electrosurgical device shown in Figure 5H) to the nose or nasopharynx, i.e., nasopharyngeal passage, and ablating tissue.

> 1. A method for diagnosing and/or treating sinusitis or another disorder affecting the nose, paranasal sinuses or other anatomical structures of the ear, nose or throat, said method comprising the steps of:
>
> (A) placing a port device in the nostril or nasal cavity on at least one side of the intranasal septum, said port device comprising a device insertion port and a valve that is operative to allow a working device to be inserted through said device insertion port while preventing blood or other fluid from backflowing out of the device insertion port at least when no working device is inserted therethrough;
>
> (B) **advancing at least one working device through the port device to a location within the nose, nasopharynx** or paranasal sinus; and
>
> (C) **using the working device to perform a diagnostic or therapeutic procedure**.
>
> 2. A method according to claim 1 wherein **the working device is used to perform a procedure selected from the group consisting of**:…cutting, **ablating**, debulking, cauterizing, heating, lasing, dilating **or otherwise modifying tissue**….

Id., claims 1-2. Therefore, because Makower teaches the well-known concept of an electrosurgical device with bipolar electrodes that administers energy such as RF

energy via electrical current to treat tissue and Makower teaches positioning the strut members with electrodes in the nasal cavity or nasopharynx, i.e., Makower teaches electrodes that are *configured to deliver energy to target tissue in the nasopharyngeal passage*.

167. As I explained in Sections X.C.1.a-b (Ground IV, Claim 1, Elements 1[pre]-1[a]), Fang likewise teaches using RF energy to heat and thus treat tissue by using an energy transmission element. In particular, Fang teaches aligning the "firing head" of the "SHP-I five-organ radiofrequency therapy instrument" with the "sphenopalatine foramen" to perform radiofrequency ablation. Ex.1006-Fang, 876. Fang explains that "the radiofrequency ablation of sphenopalatine foramen…block[s] the posterior parasympathetic fibers of the sphenopalatine nerve." *Id.*, 877. Fang also explains that "the parasympathetic nerves in the nasal cavity…regulate the vascular dilation and contraction of the nasal mucus membrane and the secretion of glands," and that "use of radiofrequency technique completely blocks the parasympathetic pathway of the nasal mucosa," which "reduces glandular secretion, and thus achieves the therapeutic purposes" of treating rhinitis, i.e., reducing mucus production and congestion. *Id.*, 876-877. Thus, Fang teaches that its "firing head" is aligned with tissue near the SPF and delivers radiofrequency energy to treat tissue. Because Fang's "firing head" delivers RF energy, a person of

ordinary skill in the art would have understood that Fang's "firing head" included one or more electrodes. Indeed, it was well-known for decades that RF energy was applied to tissue via electrodes. *See* Section VI.C.2 (Ablation); Ex.1009-Stern, 2:11-19 ("RF current is passed through substantially the entire surface of the endometrium by activating the electrodes."). Thus, Fang discloses that its firing head, i.e., *energy transmission element*, is *configured to deliver energy to target tissue in the nasopharyngeal passage*.

d. Element 1[c]: an energy source operatively coupled to the energy transmission element for supplying energy thereto according to one or more parameters selected so as to alter nasopharyngeal cells in the target tissue such that nasal congestion is reduced.

168. The combination of Makower, Fang, and Edwards-535 teaches "an energy source operatively coupled to the energy transmission element for supplying energy thereto according to one or more parameters selected so as to alter nasopharyngeal cells in the target tissue such that nasal congestion is reduced."

169. As I discussed in Sections X.C.1.a-c (Ground IV, Claim 1, Elements 1[pre]-1[b]), Makower teaches an electrosurgical device that includes RF electrodes that deliver RF energy via current to tissue in the nasal cavity or nasopharynx to cause "heat[ing]" and treat a nasal condition. *E.g.*, Ex.1005-Makower, [0001], [0043], [0161], [0187], FIG.5H, claim 1. As I also discussed in Sections X.C.1.a-c

(Ground IV, Claim 1, Elements 1[pre]-1[b]), Fang relatedly teaches an RF device that delivers RF energy to tissue near the SPF, i.e., tissue in the nasopharyngeal passage, to "block the posterior parasympathetic fibers of the sphenopalatine nerve" to treat the symptoms of rhinitis, e.g., mucus production and congestion. *E.g.*, Ex.1006-Fang, 876-877. Thus, as discussed in Sections X.C.1.a (Ground IV, Claim 1, Element 1[pre]) and Section X.C.1.e (Motivation to Combine with a Reasonable Expectation of Success), a person of ordinary skill in the art would have found it obvious that the combination of Makower and Fang teach RF electrodes that *supply energy* to tissue in the nasopharyngeal passage *so as to alter nasopharyngeal cells in the target tissue such that nasal congestion is reduced*.

170. It was well-known by those in the art that electrodes that deliver RF energy to tissue are coupled to an energy source that creates and delivers energy to the electrodes. In other words, it was well-known that electrodes are coupled to an energy source (e.g., a generator) via electrical connections such that energy is supplied to the electrodes from the energy source. It was further well-known that to create and deliver energy by energy sources for ablating tissue, a person of ordinary skill in the art would select one or more parameters for that purpose. For example, as discussed below in this section, Edwards-535 teaches a "signal generator [that, for example,] generate[s] pulses of RF energy which provide between about 5 and

about 30 watts of RF energy" for tissue ablation (i.e., to alter cells), and that modifications to these parameters "will readily occur to those skilled in the art." Ex.1008-Edwards-535, 9:1-13, 11:46-12:4. Relatedly, Stern teaches an RF generator that delivers RF current to electrodes that "has a frequency of at least 250 kHz and less than 100 MHz" for tissue ablation (i.e., to alter cells), and that those skilled in the art would understand that "modifications and variations" of its teachings are possible. *E.g.*, Ex.1009-Stern, 2:6-19. Thus, a person of ordinary skill in the art would have understood that the energy to be delivered via Makower and Fang's RF electrodes was selected according to parameters chosen for the intended purpose of ablating nasopharyngeal cells to reduce congestion.

171. The '011 patent recognizes these basic and fundamental principles regarding the operation of electrodes and RF generators. The '011 patent admits that generators that created energy for electroporation were well-known and commercially available. Ex.1001-USP011, 16:37-53 ("[E]lectroporation catheter system 20 further comprises a pulse generator 24 such as those generators available from Cytopulse Sciences, Inc. (Columbia, Md.) or the Gene Pulser Xcell (Bio-Rad, Inc.), or IGEA (Carpi, Italy), electrically connected to a catheter having a proximal end and a distal end and adapted for minimally invasive insertion into the desired region of the body as described herein."). The '011 patent also assumes that a person

of ordinary skill in the art would have understood the steps for determining the parameters of energy that is delivered to tissue. The '011 patent generically describes that "[v]arious waveforms or shapes of pulses may be applied to achieve electroporation, including sinusoidal AC pulses, DC pulses, square wave pulses, exponentially decaying waveforms or other pulse shapes such as combined AC/DC pulses, or DC shifted RF signals…." Ex.1001-USP011, 14:19-31. The '011 patent also generically states that "[t]he parameters of applied energy may be varied, including all or some of the following: waveform shape, amplitude, pulse duration, interval between pulses, number of pulses, combination of waveforms and the like." *Id.* In other words, the '011 patent generically states that the frequency, power, and other waveform parameters (which are defined by waveform, amplitude, and duration, among other characteristics) may be varied. *Id.* The '011 patent does not provide any implementation details regarding setting or adjusting any parameters of an RF generator that applies RF energy to electrodes to ablate tissue in the nasal cavity or nasopharynx, which is consistent with the fact that a person of ordinary skill in the art would have understood how to configure an RF generator to apply energy to electrodes according to one or more parameters.

172. As a result, a person of ordinary skill in the art would have understood that because Makower and Fang teach delivering RF energy for a specific purpose,

i.e., ablating tissue (e.g., cells) in the nasopharyngeal passage to treat a nasal condition, Makower and Fang each teach that RF energy is supplied to tissue vie electrodes and the electrodes receive such energy from an energy source (e.g., a generator) that is coupled to the electrodes and generates energy according to one or more parameters to accomplish the purpose of ablating tissue to treat a nasal condition.

173. To the extent the Patent Owner argues that Makower and Fang do not expressly teach an *energy source* (e.g., RF generator), Edwards-535 teaches an example of the well-known concept of using an RF generator to generate RF energy to ablate tissue according to one or more parameters. Edwards-535 teaches "an apparatus for ablating a nasal concha." Ex.1008-Edwards-535, 7:28-29. "Nasal concha" refers to a turbinate, and as discussed in Section VI.A, turbinates are located in the nasal cavity, i.e., within the *nasopharyngeal passage*. *See also* Section X.A.1.a (Ground I, Claim 1, Element 1[pre]) (explaining the plain and ordinary meaning of *nasopharyngeal*). Edwards-535's "apparatus 124 includes a catheter body 126 which has a distal portion 128 with dimensions configured for introduction through a nostril of a patient into a nasal meatus of a patient." Ex.1008-Edwards-535, 7:29-32. The distal portion 128 includes "an energy delivery device 134 for delivering ablative energy." *Id.*, 7:33-36, 8:17-25. As shown in Figure 6 (below),

the "energy delivery device 134" "includes one or more ring electrodes 156" for delivering the ablative energy. *Id.*, 8:17-25. Edwards-535 explains that the "ablative energy is supplied to the energy delivery device by an energy source 162," and that the energy is "RF energy which ablates the turbinate [(i.e., tissue)] by heat and cell destruction." *Id.*, 8:47-53. In other words, Edwards-535 explains that an *energy source* 162 *is operatively coupled* to its electrodes and delivers RF energy according to parameters that ablate the tissue "by heat and cell destruction." *Id.*, 8:47-53, FIGs.5-6. Edwards-535 further explains that its energy source 162 includes "a signal generator 165 (such as a generator for pulses, sine waves, square waves, or some combination of these wave forms with each other or with some other wave form)" that generates RF energy. *Id.*, 8:54-9:13. Edwards-535 provides multiple examples of energy that is created according to one or more parameters to ablate tissue, i.e., to alter cells. For example, Edwards-535 teaches that "the signal generator can generate pulses of RF energy which provide between about 5 and about 30 watts of RF energy." *Id.*, 9:1-13. Edwards-535 also emphasizes that "modifications will readily occur to those skilled in the art." *Id.*, 11:46-12:4.

174. Moreover, it was well-known that one parameter for RF energy was frequency. Edwards-535 teaches exemplary ranges for RF frequency, which includes "RF radiation frequency between about 300 megahertz and about 700

megahertz, such as preferably about 465 megahertz…." Ex.1008-Edwards-535, 8:61-67. Edwards-535 uses "megahertz" as the unit for this energy. The typical range for RF energy for tissue ablation was "kilohertz." *See, e.g.*, Ex.1056-Sackenheim, 90 (explaining that for RF ablation systems, one company "use[s] a 460-kHz generator," a second company uses a "uses 480 kHz" generator, and a third company "uses 460 kHz of power"); Ex.1066-Edwards-886, 36:66-37:7 ("In the illustrated embodiment, the integrated generator 38 has four independent radio frequency channels. Each channel is capable of Supplying up to 15 watts of radio frequency energy with a sinusoidal waveform at 460 kHz."). Thus, a person of ordinary skill in the art would have understood that Edwards-535's use of "megahertz" was potentially a typographical error. Regardless, and in any event, Edwards-535's use of this exemplary range does not alter my opinions regarding 's because as discussed in this section and Section X.C.1.e (Motivation to Combine with a Reasonable Expectation of Success), Edwards-535 teaches the well-known concept of an RF generator for generating RF energy according to various parameters and "modifications will readily occur to those skilled in the art," including modifications to a desired range for RF ablation. *E.g.*, Ex.1008-Edwards-535, 8:54-9:13, 11:46-12:4.

175. Thus, Edwards-535 teaches an energy source that delivers energy to electrodes according to one or more parameters selected to alter tissue, and its device is shown, for example, in Figure 6 (below).

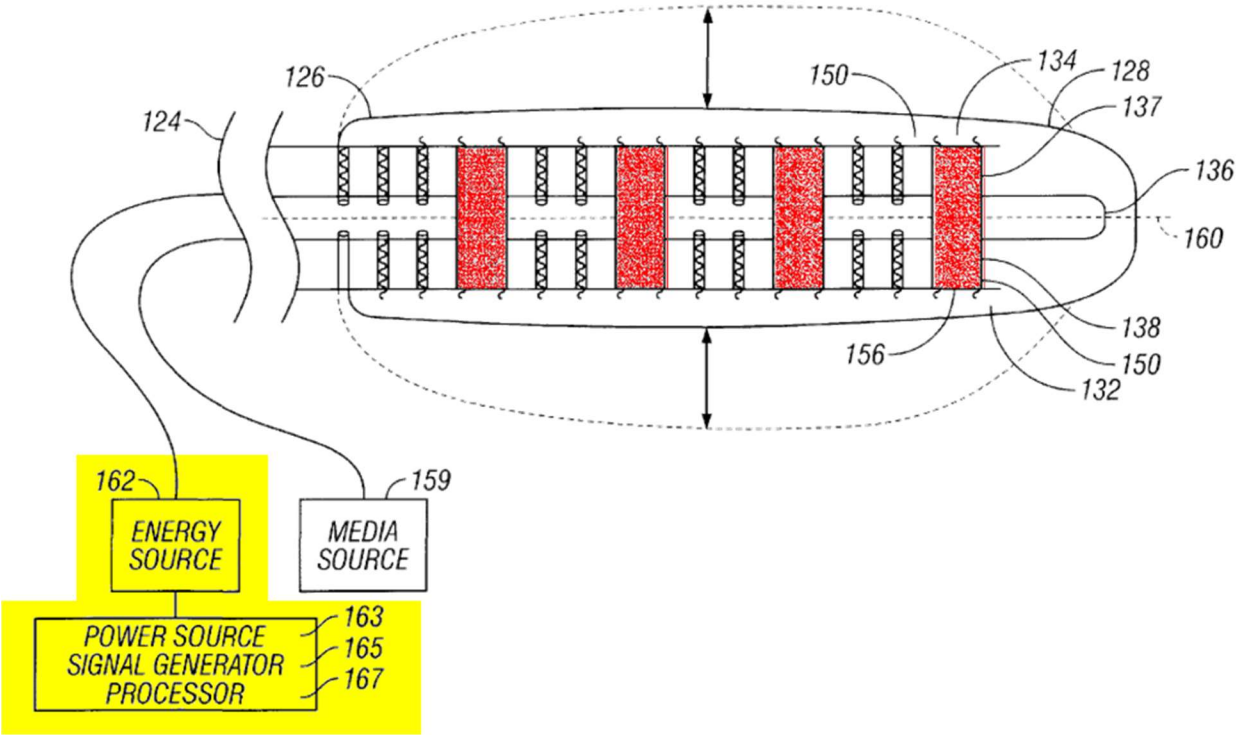


FIG. 6

Ex.1008-Edwards-535, FIG.6

176. As I explain in this section and Section X.C.1.e (Motivation to Combine with a Reasonable Expectation of Success), Edwards-535 teaches operating RF electrodes using an RF generator and a person of ordinary skill in the art would have found it obvious to apply Edwards-535's teaching of an RF generator to the combination of Makower and Fang. In other words, it is my opinion that a person

of ordinary skill in the art would have been motivated to use an RF generator as taught by Edwards-535 with the RF electrodes on the electrosurgical device taught by Makower using RF energy with parameters set to reduce rhinitis symptoms in the nasopharyngeal passage by altering tissue as taught by Fang with a reasonable expectation of success.

e. Motivation to Combine with a Reasonable Expectation of Success

177. As I explained in Section III.C (Legal Principles – Obviousness), I have been informed and understand that a person of ordinary skill in the art must have had a reason or motivation to combine or modify the relevant teachings in the prior art to obtain the claimed invention, and one of ordinary skill in the art must have had a reasonable expectation of success in doing so. It is my opinion that a person of ordinary skill in the art would have had a motivation to combine Makower, Fang, and Edwards-535 with a reasonable expectation of success.

178. **First**, it is my opinion that Makower, Fang, and Edwards-535 are in the same field as the claims of the ’011 patent and are reasonably pertinent to solving the problems addressed by the claims of the ’011 patent. The claims of the ’011 patent are related to the problem of treating tissue by applying energy. *See, e.g.*, Ex.1001-USP011, claim 1. Similarly, Makower, Fang, and Edwards-535 are each

directed to the problem of treating tissue. Ex.1005-Makower, [0001] ("The present invention relates generally to medical devices and methods and more particularly to minimally invasive, catheter based devices, systems and methods for treating sinusitis and other ear, nose & throat disorders."), [0043], [0164], [0187]; Ex1006-Fang, 876-877 (using "radiofrequency" to treat tissue near the "sphenopalatine foramen"); Ex.1008-Edwards-535, Abstract ("An apparatus is provided for ablating at least a portion of a nasal concha."), 2:53-3:36, 4:19-32. Makower, Fang, and Edwards-535 also teach devices that use the same method to treat tissue, which is applying RF energy. Ex.1005-Makower, [0043], [0161], [0164], [0187] ("[C]urrent is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated."); Ex.1006-Fang, 876-877 ("[T]he SHP-I five-organ radiofrequency therapy instrument (manufactured by Guangzhou Medical Instrument Factory) was firstly used, with the Level 3 intensity selected, and the firing head aligned with the sphenopalatine foramen…."); Ex.1008-Edwards-535, Abstract, 2:53-3:36, 8:47-9:13 ("[A]blative energy is supplied to the energy delivery device by an energy source 162….The energy used is preferably RF energy which ablates the turbinate by heat and cell destruction.").

179. **Second**, in my opinion, a person of ordinary skill in the art would have been motivated to apply Fang's teaching of disrupting neural activity using ablation

with Makower's device and method (applying energy in the nasal cavity or nasopharynx) to reduce the symptoms of rhinitis (e.g., mucus production and congestion), including as recited in claim 1 elements 1[pre] and 1[c]. In particular, it is my opinion that a person of ordinary skill in the art would have understood in view of Fang that the electrodes on Makower's electrosurgical device would treat rhinitis (i.e., a nasal condition) by disrupting neural activity in the same manner taught by Fang—applying RF energy to ablate tissue (i.e., increase tissue temperature) that contains parasympathetic nerves that innervate from the SPG and Vidian nerve to inhibit the signaling of such parasympathetic nerves that cause mucus production (i.e., signal to goblet cells to produce mucus). Makower's device would not require any modifications to achieve this result because Makower specifically teaches that its device applies energy to the nasal cavity and nasopharynx using electrodes, the same mechanism as Fang. Indeed, Makower expressly teaches that its device treats a nasal disorder (*e.g.*, Ex.1005-Makower, [0001]), and it is my opinion that a person of ordinary skill in the art would have understood that Fang simply clarifies that Makower's device achieves the same therapeutic effect in the same manner as claimed in the '011 patent.

180. It is also my opinion that a person of ordinary skill in the art would have been motivated to combine Makower's method and device with the teachings of

Fang. Makower teaches "Working Devices for Delivering Substances or for Cutting, Ablating, Remodeling or Expanding Bone or Soft Tissue." Ex.1005-Makower, [0160] (title of section of Makower that describes working devices). Makower teaches procedures for using such devices, and Figure 5H of Makower depicts one working device, which is an electrosurgical device with electrodes that deliver energy to tissue. *See, e.g.*, *id.*, [0043], [0161], [0164], [0187]. Makower also explains, consistent with my experience, that "designs and constructions of such components and assemblies are w[e]ll known in the art," and a person of ordinary skill in the art would have thus been motivated to look to other references to provide additional details. *Id.*, [0164]. Fang provides additional details about the well-known design, construction, and operation of the Makower's electrosurgical device that delivers RF energy.

181. More specifically, as I explained in Sections X.C.1.a-d (Ground IV, Claim 1, Elements 1[pre]-1[c]), Figure 5H of Makower teaches an electrosurgical device that includes bipolar electrodes on strut members. Ex.1005-Makower, [0161], [0187], Fig5H. Makower further teaches that its strut members with electrodes are positioned in the nasal cavity or nasopharynx (i.e., nasopharyngeal passage), and energy is then applied via the electrodes to heat the surrounding tissue to treat nasal disorders. *Id.*, [0001], [0043], [0161], [0164], [0187], FIG.5H, claim

1. Relatedly, as I discuss in Sections X.C.1.a-d (Ground IV, Claim 1, Elements 1[pre]-1[c]), Fang teaches applying energy to tissue in the nasal cavity (i.e., nasopharyngeal passage) to treat nasal disorders. Ed.1006-Fang, 876-877. In particular, Fang teaches that applying energy to tissue near the SPF disrupts the SPG and branching parasympathetic nerves to treat rhinitis. *Id.* Fang explains that "[n]umerous studies have shown that the parasympathetic nerves in the nasal cavity…regulate the vascular dilation and contraction of the nasal mucus membrane and the secretion of glands," and that "[t]he use of radiofrequency technique completely blocks the parasympathetic pathway of the nasal mucosa," "reduces glandular secretion, and thus achieves the therapeutic purposes" of treating rhinitis." *Id.* Fang thus teaches the well-known concept that parasympathetic nerves regulate mucus production (e.g., by goblet cells), and disrupting such nerves will decrease mucus production. *Id.*; *see also id.* Ex.1044-Chen, 240-241 (teaching that disrupting parasympathetic nerves reduces the symptoms of rhinitis).

182. It is my opinion that Fang's teachings are consistent with the knowledge of a person of ordinary skill in the art prior to 2005. As I explained in Section VI.A (Relevant Anatomy), it was well-known to those skilled in the art prior to 2005 that parasympathetic nerves and goblet cells, which are discussed in Fang, are located throughout the nasal cavity and nasopharynx, i.e., the nasopharyngeal passage. For

example, it was well-known to those skilled in the art that the SPG is a ganglion located downstream of the Vidian nerve where parasympathetic fibers synapse and is located lateral to the posterior nasal cavity near the SPF. *See* Section VI.A (Relevant Anatomy). It was also well-known to those skilled in the art that parasympathetic nerves connect to the SPG and branch from the SPG throughout the nasal cavity and nasopharynx, i.e., the nasopharyngeal passage, and that the Vidian nerve, SPG, and parasympathetic nerve branches regulate mucus production and congestion because such nerves control the activity of mucus glands and goblet cells, which are responsible for mucus production. *See id.*; Ex.1051-Windsor, 284 ("Post-ganglionic parasympathetic neurons from this ganglion then distribute to the lacrimal gland and glands of the nasal cavity, paranasal sinuses, palate, and upper pharynx where they promote secretion…."); Ex.1052-Fenton, 23 ("The first line of defense is the covering of mucous secretion on the epithelium, as produced by the goblet cells and glands of the mucous membrane…. Mucous glands and goblet cells are found in the walls of the nasopharynx and also in the lungs."). As a result, a person of ordinary skill in the art would have understood prior to the '011 patent that nerves in the nasopharyngeal passage, i.e., nerves in the nasal cavity and nasopharynx, regulate the production of mucus (e.g., by goblet cells).

183. Moreover, prior to 2005, it was also well-known to those skilled in the art that disrupting the Vidian nerve, SPG, or associated parasympathetic nerve branches would reduce the symptoms of rhinitis, i.e., mucus production, mucus secretion, and congestion. For example, as early as the 1960s, it was known that "cutting the parasympathetic nerve fibers in the [V]idian canal," i.e., cutting the Vidian nerve, reduced the symptoms of rhinitis. *E.g.*, Ex.1003-Saadat, 2:39-47. As I explained in Section VI.D (Treating Nasal Conditions), references such as Chen and Arora taught that ablating branches of the Vidian nerve or parasympathetic nerves in the nasopharyngeal passage reduced the symptoms of rhinitis. *See, e.g.*, Ex.1044-Chen, 240 ("The use of radiofrequency thermocoagulation of the posterior inferior nasal nerve, anterior ethmoidal nerves, and inferior turbinate…can widely block the source of the parasympathetic nerves in the nasal cavity and reduce the excitability of the parasympathetic nerves [to eliminate symptoms such as nasal congestion and runny nose]."); Ex.1054-Arora, 80 ("Cryodestruction of the nasal branches of the Vidian nerve in the region of the sphenopalatine foramen has been done in cases of vasomotor rhinitis."). Consistent with the knowledge of those skilled in the art, Fang taught that applying RF energy to parasympathetic nerves in the nasopharyngeal passage disrupts such nerves and thus reduces rhinitis symptoms. In other words, Fang teaches that applying RF energy to tissue

surrounding the SPF (which includes the SPG and parasympathetic nerves) "completely blocks the parasympathetic pathway of the nasal mucosa," which "reduces glandular secretion, and thus achieves the therapeutic purposes" of treating "perennial allergic rhinitis" while minimizing adverse effects. Ex.1006-Fang, 876-877.

184. Although Fang teaches ablating tissue near the SPF, Fang does not limit its teachings to any particular location, but instead teaches the effects of ablating the SPF nerve or associated parasympathetic nerves. *See* Ex.1006-Fang, 876-877. Fang thus teaches that applying RF energy to parasympathetic nerves disrupts such nerves to treat rhinitis, without limiting its teachings to only parasympathetic nerves located near the SPF. A person of ordinary skill in the art would thus have understood based on Fang's teaching that ablating parasympathetic nerves that innervate mucus producing cells (e.g., goblet cells) known to be located in the nasopharynx (*see* Section VI.A (Relevant Anatomy)) using RF energy would disrupt such nerves and reduce the symptoms of rhinitis.

185. Given Makower expressly states that further details regarding its disclosed working devices were well known to those skilled in the art, a person of ordinary skill in the art would have been motivated (including based on Makower's invitation) to combine Fang's teachings regarding the known outcome of applying

RF energy in the nasopharyngeal passage with Makower's electrosurgical device and methods. Indeed, Makower and Fang each teach delivering energy to the same part of the body, the nasopharyngeal passage, and for the same purpose, treating nasal conditions, and Fang simply explains the therapeutic result and outcome of Makower's device and method. Ex.1005-Makower, [0001], [0043], [0161], [0164], [0187], FIG.5H, claim 1; Ex.1006-Fang, 876-877. Accordingly, it is my opinion that a person of ordinary skill in the art would have been motivated to combine the teachings of Makower and Fang.

186. **Third**, in my opinion, a person of ordinary skill in the art would have been motivated to use an energy source as taught by Edwards-535 with the combination of Makower and Fang, including as recited in claim 1 element 1[c]. As I have explained in this section and Section X.C.1.d (Ground IV, Claim 1, Element 1[c]), Makower and Fang each teach delivering RF energy to tissue in the nasopharyngeal passage using electrodes, and Fang teaches that applying RF energy to tissue in the nasopharyngeal passage reduces the symptoms of rhinitis (e.g., nasal congestion and mucus production). In my opinion, a person of ordinary skill in the art would have been motivated to use Makower and Fang according to their intended purposes of treating nasal conditions, and Edwards-535 teaches the well-known details regarding how to deliver RF energy to tissue via electrodes as taught by

Makower and Fang. For example, it was well-known that electrodes were coupled to an energy source (e.g., a generator), which generated the energy that would be applied to tissue via the electrodes. It was also well known that energy generated to ablate tissue would be generated according to one or more parameters to ablate (i.e., alter) such tissue (e.g., tissue in the nasal cavity or nasopharynx). For example, it was well-known that the frequency (hertz) or power (Watts) (which are defined by waveform, amplitude, and duration, among other characteristics) would be set such that the generated energy would alter the desired tissue. *See, e.g.*, Ex.1008-Edwards-535, 8:61-9:13, 11:46-12:4; Ex.1009-Stern, 2:6-19.

187. Makower correspondingly acknowledges that the design and operation of RF ablation devices was well-known in the art and the implementation details would be known to those skilled in the art. Makower specifically describes "Working Devices for…Ablating…Soft Tissue," "therapeutic procedures" using the disclosed working devices, and provides specific examples of a working devices (e.g., electrosurgical device in Figure 5H), and states that "[t]he designs and constructions of such components and assemblies are w[e]ll known in the art." Ex.1005-Makower, [0001], [00043], [0132], [0160]-[0164], [0187], claim 1. In my opinion, a person of ordinary skill in the art would have understood that Edwards-535 provides a specific example of the well-known design, construction, and

operation of an RF energy source for use with the combination of Makower and Fang. In other words, Edwards-535 teaches a well-known energy source that is operatively connected to RF electrodes to deliver RF energy set to frequencies and wattages (i.e., parameters) for nasal tissue ablation. *E.g.*, Ex.1008-Edwards-535, 8:54-9:13, 11:46-12:4, FIGs.5-6. As a result, in my opinion, a person of ordinary skill in the art would have been motivated to use an energy source taught by Edwards-535 (e.g., RF generator) to generate and deliver RF energy to RF electrodes to treat nasal tissue with Makower and Fang because Edwards-535, Makower, and Fang each teach delivering energy (e.g., RF energy) to ablate tissue in the nasal cavity or nasopharynx, i.e., nasopharyngeal passage, and Edwards-535 teaches well-known, specific, routine, implementation details for doing so.

188. **Fourth**, in my opinion, a person of ordinary skill in the art would have had a reasonable expectation of success at combining the teachings of Makower, Fang, and Edwards-535. In particular, a person of ordinary skill in the art would have reasonably expected that Makower's electrosurgical device, which applies energy to the nasopharyngeal passage (*see, e.g.*, Sections X.C.1.c (Ground IV, Claim 1, Element 1[b]), would obtain the clinical result taught by Fang. Indeed, Makower disclosed an electrosurgical device that applies RF energy to treat nasal conditions (*see* Sections X.C.1.a-d (Ground IV, Claim 1, Elements 1[pre]-1[c])). And Fang and

others specifically taught that applying RF energy to tissue in the nasopharyngeal passage would reduce the symptoms of rhinitis. For example, Chen taught that "radiofrequency thermocoagulation of the sphenopalatine nerve" reduced the symptoms of rhinitis. Ex.1044-Che, 239. In particular, Chen taught that "parasympathetic nerves in the nasal cavity mainly originate from the sphenopalatine nerves," and that applying "radiofrequency thermocoagulation," i.e., "RF energy" to such nerves "block[s] the source of the parasympathetic nerves in the nasal cavity and reduce the excitability of the parasympathetic nerves, the sensitivity of the nasal mucosa to sensitive areas, and the sensory-parasympathetic reflex." *Id.*, 240. Like Fang, Chen also taught that the disruption of the parasympathetic nerves reduces the symptoms of rhinitis. *Id.*, 240-241.

189. Moreover, Fang does not teach a specialized RF device was required to reduce the symptoms of rhinitis. Ex.1006-Fang, 876. Instead of using a specialized device, Fang used a "SHP-I five-organ radiofrequency therapy instrument (manufactured by Guangzhou Medical Instrument Factory)" "with the Level 3 intensity selected" to perform its disclosed method. In other words, Fang used a generic catheter with factory settings to treat rhinitis. A person of ordinary skill in the art would have understood that Makower's electrosurgical device with electrodes to deliver RF energy would operate in a similar manner as Fang's generic catheter,

particularly since Makower expressly states that the design of RF devices was well-known to those skilled in the art.

190. Accordingly, because Makower and Fang are each directed to the same problem of treating nasal conditions and each disclose solutions of using devices to deliver RF energy to tissue to treat nasal conditions, it is my opinion that a person of ordinary skill in the art would have been motivated to combine their teachings and would have had a reasonable expectation of successfully using Makower's electrosurgical device to deliver RF energy according to known methods to tissue in the nasopharyngeal passage to reach the predictable result taught by Fang.

191. Additionally, in my opinion, a person of ordinary skill in the art would have had a reasonable expectation of success at using an *energy source* (e.g., RF generator) as taught by Edwards-535 to connect to (i.e., *operatively coupled to*) and apply energy to Makower's RF electrodes *according to one or more parameters* to achieve the therapeutic results taught by the combination of Makower and Fang (i.e., *alter nasopharyngeal cells in the target tissue such that nasal congestion is reduced*). As I explained in this section and Section X.C.1.d (Ground IV, Claim 1, Element 1[c]), Edwards-535 teaches an energy source that is an RF generator that can provide RF energy to electrodes at different frequencies and wattages, and specifically states that "modifications will readily occur to those skilled in the art."

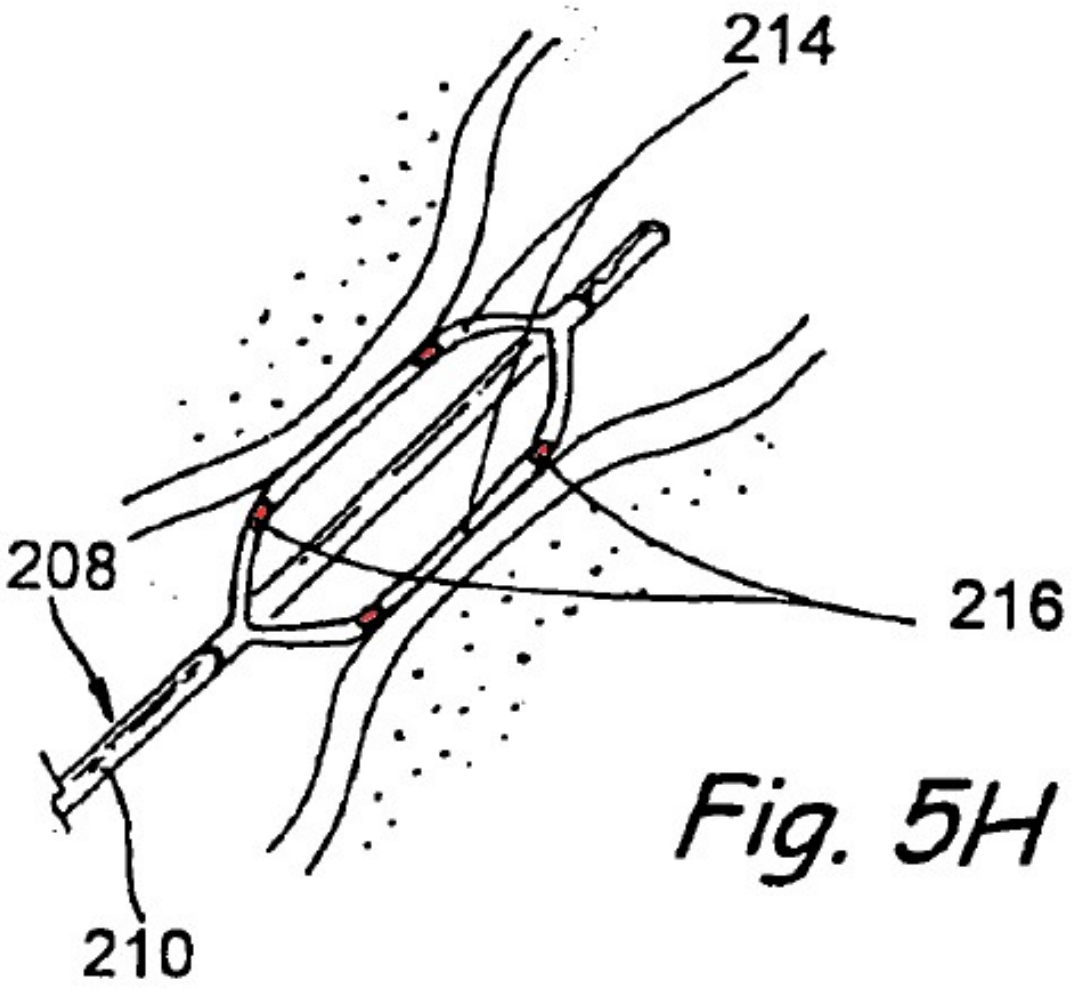
E.g., Ex.1008-Edwards-535, 8:47-9:13, 11:46-12:4, FIGs.5-6. Relatedly, Makower specifically states that the design and construction of RF ablation devices was well-known to those skilled in the art. Ex.1005-Makower, [0164] ("The designs and constructions of such components and assemblies are w[e]ll known in the art."). Makower and Fang do not teach or suggest that a specialized RF energy source or electrical connection is needed to successfully apply tissue in the nasal cavity or nasopharynx (i.e., nasopharyngeal passage) to treat the symptoms of rhinitis. Indeed, each reference is indifferent regarding the type of energy source that is required, leaving the implementation details to those skilled in the art. *See generally* Ex.1005-Makower; Ex.1006-Fang. And as I discussed in Section X.C.1.d (Ground IV, Claim 1, Element 1[c]), the '011 patent assumes that a person of ordinary skill in the art would have understood the operation of energy sources and the parameters required to alter tissue because it does not provide any specific implementation details regarding generators. Ex.1001-USP011, 16:37-53. Consistent with this, in my opinion, a person of ordinary skill in the art would have had a reasonable expectation of success using a known energy source (e.g., RF generator) as taught by Edwards-535 with Makower's and Fang's known RF ablation devices to reach the predictable result of treating rhinitis as taught by Fang.

192. In conclusion, it is my opinion that the combination of Makower, Fang, and Edwards-535 teach each limitation of claim 1, and that a person of ordinary skill in the art would have been motivated to combine the teachings of Makower, Fang, and Edwards-535 with a reasonable expectation of success. Thus, it is my opinion that claim 1 would have been obvious over the combination of Makower, Fang, and Edwards-535.

2. Claim 2: "The apparatus of claim 1, wherein the energy transmission element comprises at least one electrode."

193. Claim 2 depends from claim 1. Therefore, I incorporate by reference my discussion of Claim 1 in Section X.C.1 (Ground IV, Claim 1). The combination of Makower, Fang, and Edwards-535 further teaches that "the energy transmission element comprises at least one electrode."

194. As I explained in Section X.C.1.c (Ground IV, Claim 1, Element 1[b]), Makower's electrosurgical device includes strut members 214 that include multiple "bipolar" or "monopolar" electrodes 216. Ex.1005-Makower, [0187], FIG.5H. Makower explains that "current is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated." *Id.*, [0187].



Ex.1005-Makower, FIG.5H. Thus, Makower teaches that delivering energy includes delivering energy from a bipolar or monopolar electrodes. Furthermore, as I explained in Section X.C.1.c (Ground IV, Claim 1, Element 1[b]), Fang teaches applying RF energy with an RF ablation device, and a person of ordinary skill in the art would have understood that Fang's RF ablation device used RF electrodes to deliver the energy from the device's firing head. Ex.1006-Fang, 876-877.

3. Claim 5: "The apparatus of claim 1, wherein the energy supplying means comprises an RF generator."

195. Claim 5 depends from claim 1. Therefore, I incorporate by reference my discussion of Claim 1 in Section X.C.1 (Ground IV, Claim 1). The combination of Makower, Fang, and Edwards-535 further teaches that "the energy supplying means comprises an RF generator."

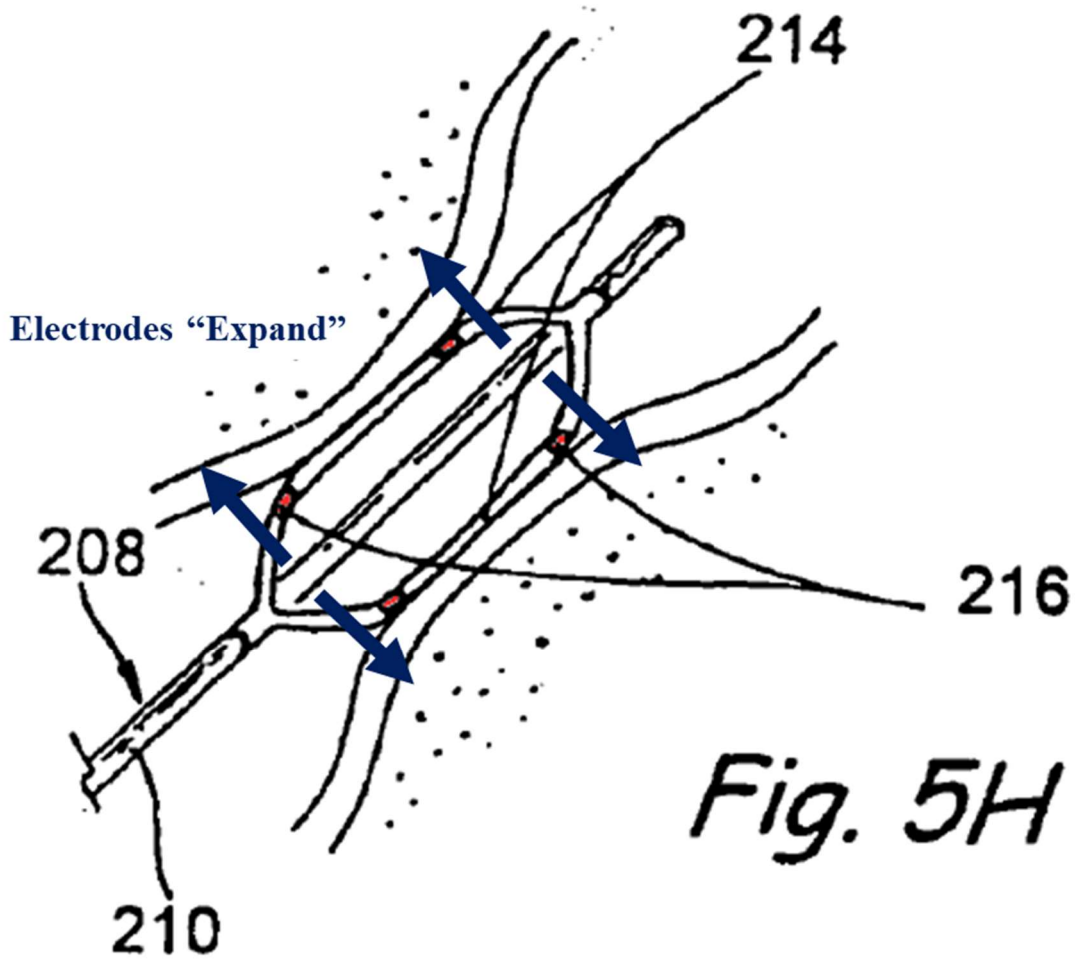
196. As I explained in Section X.C.1.d (Ground IV, Claim 1, Element 1[c]) and Section X.C.1.e (Motivation to Combine with Reasonable Expectation of Success), Makower, Fang, and/or Edwards-535 teach an RF generator that is operatively coupled to RF electrodes. *E.g.*, Ex.1008-Edwards-535, 7:28-36, 8:17-25, 8:47-9:13, 11:46-12:4, FIGs.5-6.

4. Claim 8: "The apparatus of claim 1, wherein the energy transmission element is movable relative to the distal portion of the body."

197. Claim 7 depends from claim 1. Therefore, I incorporate by reference my discussion of Claim 1 in Section X.C.1 (Ground IV, Claim 1). The combination of Makower, Fang, and Edwards-535 further teaches that "the energy transmission element is movable relative to the distal portion of the body."

198. Makower teaches that its "strut members 214 may be collapsible and expandable." Ex.1005-Makower, [0187]. In other words, Makower teaches that the

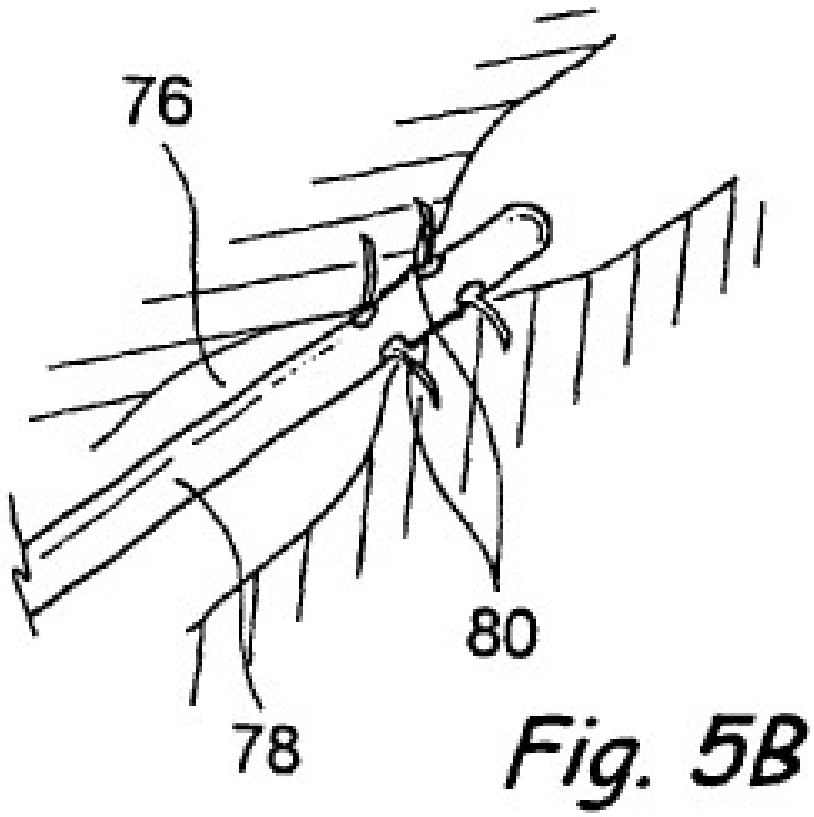
strut members with electrodes of its electrosurgical device start in a collapsed position and can then be expanded to contact tissue, as shown in Figure 5H below.



Ex.1005-Makower, FIG.5H. Thus, Makower discloses that the strut members with electrodes, i.e., *energy transmission elements*, are *movable relative to the distal portion of the body*.

199. Additionally, Makower teaches other variations of its working device that include electrodes which move out from a distal portion of the flexible catheter

shaft. For example, in Figure 5B (below), Makower discloses a catheter that is positioned in the nasal cavity or nasopharynx, i.e., nasopharyngeal passage, that includes a "flexible catheter shaft 78" and "injectors 80" that are "are advanced" out of the shaft and deliver RF energy. Ex.1005-Makower, [0167]. In other words, the injectors 80 move out from a distal portion of the "flexible catheter shaft 78" and deliver energy. Thus, Figure 5B of Makower also teaches *energy transmission elements* that are *movable relative to the distal portion of the body.*



Ex.1005-Makower, FIG.5B.

5. Claim 9: "The apparatus of claim 8, wherein the energy transmission element is configured to deliver energy laterally relative to the distal portion of the body."

200. Claim 9 depends from claim 8. Therefore, I incorporate by reference my discussion of Claim 8 in Section X.C.4 (Ground IV, Claim 8). The combination of Makower, Fang, and Edwards-535 further teaches that "the energy transmission element is configured to deliver energy laterally relative to the distal portion of the body."

201. As I explained in Section X.C.1.c (Ground IV, Claim 1, Element 1[b]) and Section X.C.2 (Ground IV, Claim 2), Makower teaches that its electrosurgical device includes strut members 214 that include multiple "bipolar" electrodes 216 that deliver "current…causing tissue adjacent to the struts 214 to be cauterized or heated." Ex.1005-Makower, [0187]. As I explained in Section X.A.5 (Ground I, Claim 9), it was well-known that bipolar electrodes are conductors and cause RF current to travel from one electrode to another. For example, Figure 17 of Stern, reproduced below, shows RF current traveling from one bipolar electrode to another bipolar electrode. Ex.1009-Stern, 5:54-55 ("FIG. 17 shows electric field lines outside a bipolar electrode pair."), 13:11-20 ("In contrast, a bipolar operation is shown in FIG. 17. The balloon 256 includes electrodes 258 and 260. The electric field lines proceed between the two electrodes. With a bipolar electrode, the current

paths are more easily controllable by appropriate placement and activation of the electrodes….”).

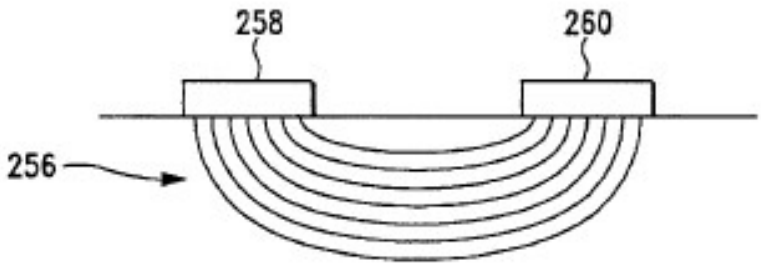
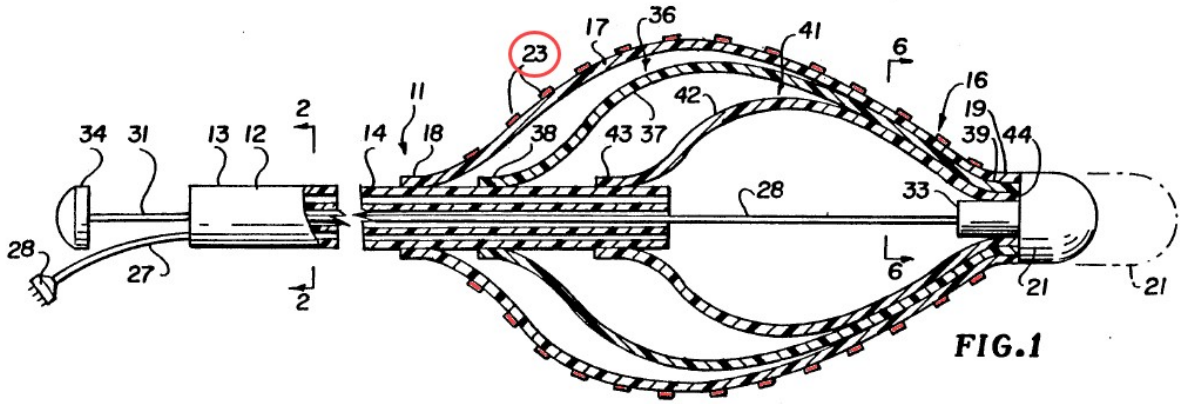


FIG.–17

Ex.1009-Stern, FIG.17.

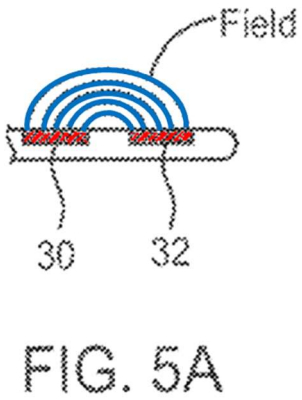
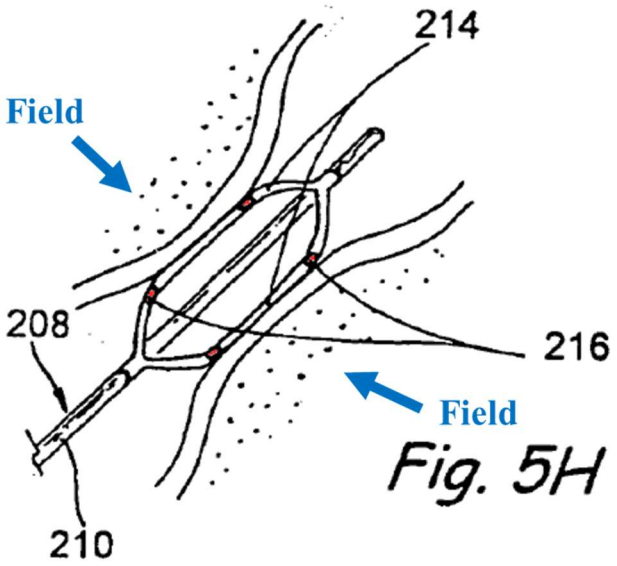
202. In view of this common knowledge, a person of ordinary skill in the art would have understood that electrical current would travel from one of Makower’s bipolar electrodes to another of Makower’s bipolar electrodes to create an electrical field between the two electrodes that travels through the contacted tissue. A person of ordinary skill in the art would have understood the concentration of current, i.e., *energy*, in Makower is directed laterally relative to the strut members of the electrosurgical device. In other words, a person of ordinary skill in the art would have understood that current traveling between Makower’s bipolar electrodes would create electrical fields that concentrate current lateral relative to the axis of the distal portion of the RF ablation probe and into the targeted tissue. With respect to implementation, Makower teaches that Figure 5H incorporates well-known

components and assemblies, including for example U.S. Patent No. 5,255,679 to Imran. Ex.1005-Makower, [0164] ("[T]he working devices shown in FIGS. 5A-5Y"" and described herein incorporate assemblies, components or mechanisms….The designs and constructions of such components and assemblies are w[e]ll known in the art. Non-limiting examples of some such designs and constructions are set forth in… U.S. Pat. No. 5,255,679 (Imran)…."). Imran Figure 1 (below) teaches electrodes 23, shown in red, that are disposed on the lateral side of a strut on the distal portion of the treatment device. Ex.1068-Imran, claim 1, 62-66, 2:57-64, 3:2-7.



Ex.1068-Imran, FIG.1. Thus, Imran teaches electrodes disposed on a lateral side of the treatment device, and a person of ordinary skill in the art would have understood that current traveling from or between such electrodes would create electrical fields that concentrate current lateral relative to the axis of the distal portion of the RF ablation probe. In my opinion, and as Makower contemplates, implementation of

laterally disposed electrodes like those in Imran in Makower's Figure 5H device would have been routine and well within the skill of a skilled artisan. It confirms that the combination of Makower, Fang and Edwards-535 would have rendered claim 9 obvious. Additionally, the concentration of current in Makower is the same as the energy concentration depicted in the '011 patent in Figure 5A by similarly arranged electrodes. Ex.1001-USP011, 16:30-58 ("FIG. 5A depicts an arrangement of electrodes 30 and 32 that produces an electric field concentrated in a lateral direction from the catheter body…."), FIG.5, FIGs.5A-5B; Ex.1005-Makower, [0161], [0164], [0187], FIG.5H. Thus, Makower discloses that the electrodes on the strut members of its electrosurgical device *deliver energy laterally relative to the distal portion of the body*.

’011 Patent, FIG.5A	Makower, FIG.5H
	

6. Claim 10: “The apparatus of claim 9, wherein the energy transmission element is configured to extend laterally from the distal portion of the body.”

203. Claim 10 depends from claim 9. Therefore, I incorporate by reference my discussion of Claim 9 in Section X.C.5 (Ground IV, Claim 9). The combination of Makower, Fang, and Edwards-535 further teaches that “the energy transmission element is configured to extend laterally from the distal portion of the body.”

204. As I explained in Section X.C.4 (Ground IV, Claim 8), Makower teaches that its “strut members 214 may be collapsible and expandable.” Ex.1005-Makower, [0187]. In other words, Makower teaches that the strut members with electrodes of its electrosurgical device start in a collapsed position and can then be

expanded to contact tissue, as shown in Figure 5H. *See id.*, FIG.5H. Thus, because the electrodes on the strut members extend outward from the distal end of the shaft, the electrodes, i.e., *energy transmission elements*, are configured to extend laterally from the distal portion of the body. Moreover, as also discussed in Section X.C.4 (Ground IV, Claim 8), Makower teaches other variations of its working device, such as Figure 5B, that include electrodes that move out *laterally* from a distal portion of the flexible catheter shaft. *Id.*, [0167], FIG.5B.

7. Claim 12: "The apparatus of claim 1, further comprising: a sensing element on the distal portion of the body."

205. Claim 12 depends from claim 1. Therefore, I incorporate by reference my discussion of Claim 1 in Section X.A.1 (Ground I, Claim 1). The combination of Makower, Fang, and Edwards-535 further teaches "a sensing element on the distal portion of the body."

206. Makower teaches that "sensing elements may also be attached to the catheter and/or strut members to monitor various parameters of the catheter and/or surrounding tissue (e.g., temperature, etc.)." Ex.1005-Makower, [0187]. Makower further teaches that "any of the devices described within this document may be further modified to include…electromagnetic positioning sensor/detector…, RF sensor/transmitter…, [or a] thermal sensor," among others, and that the "designs and

constructions of" RF devices was well-known in the art. *Id.*, [0164], [0192]. Thus, Makower teaches a *sensing element on the distal portion of the body*.

8. Claim 14: "The apparatus of claim 12, further comprising: a monitoring system operatively coupled to the sensing element for indicating a degree of treatment of the target tissue."

207. Claim 14 depends from claim 12. Therefore, I incorporate by reference my discussion of Claim 1 in Section X.C.7 (Ground IV, Claim 12). The combination of Makower, Fang, and Edwards-535 further teaches "a monitoring system operatively coupled to the sensing element for indicating a degree of treatment of the target tissue."

208. As I explained in Section X.C.7 (Ground IV, Claim 12), Makower teaches that "sensing elements may also be attached to the catheter and/or strut members to monitor various parameters of the catheter and/or surrounding tissue (e.g., temperature, etc.)." Ex.1005-Makower, [0187]. Makower further teaches that "any of the devices described within this document may be further modified to include…electromagnetic positioning sensor/detector…, RF sensor/transmitter…, [or a] thermal sensor," among others, and that the "designs and constructions of" RF devices was well-known in the art. *Id.*, [0164], [0192]. Inclusion of such sensors/monitors was well-known and routine. Those of ordinary skill in the art

would include such sensors/monitors as one means of ensuring that the device was operating in a manner that would have the desired result, for example, by monitoring the tissue temperature. In other words, those of ordinary skill in the art would include such sensors/monitors to monitor the degree to which the tissue was being treated to ensure the device was operating in a manner that would obtain the desired result of safely ablating tissue. Indeed, Edwards-535 taught "an apparatus for ablating a nasal concha," i.e., turbinates, that included "sensors" "to monitor the amount of energy delivered and the amount of heat generated." Ex.1008-Edwards-535, 7:28-29, 9:14-16. Thus, Makower teaches that the *sensing elements* are *coupled* to *a monitoring system* that indicates the tissue temperature, i.e., *degree of treatment*.

XI. AVAILABILITY FOR CROSS-EXAMINATION

209. 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.

XII. RIGHT TO SUPPLEMENT

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

XIII. JURAT

211. 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, 2024

/s/ Nicolas Bu-Saba
Nicolas Bu-Saba, M.D.

APPENDIX A

Curriculum Vitae

Date Prepared: **10/22/2023**

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Place of Birth: Lebanon

Education:

06/1981 B.Sc. Biology-Chemistry, American University of Beirut, Beirut, Lebanon (With Distinction).

06/1985 M.D., School of Medicine, American University of Beirut, Beirut, Lebanon (With Distinction).

Postdoctoral Training:

Internships and Residencies:

07/85 - 06/86 Intern, Department of Surgery, American University of Beirut Medical Center, Beirut, Lebanon.

07/86 - 06/89 Resident, Department of Otolaryngology, American University of Beirut Medical Center, Beirut, Lebanon.

07/89 - 06/90 Clinical/Research Fellowship in General Otolaryngology, Massachusetts Eye and Ear Infirmary and Harvard Medical School, Boston, MA.

07/90 - 06/91 Resident, Department of Surgery, Beth Israel-Deaconess Hospital and Harvard Medical School, Boston, MA.

7/91 -6/95 Resident, Department of Otolaryngology, Massachusetts Eye and Ear Infirmary and Department of Otology and Laryngology, Harvard Medical School, Boston, MA.

Specialty Advanced Educational Courses:

2003-2004: Daiichi Clinical Scholars Program in Evidence Based Medical Research, American Academy of Otolaryngology- Head and Neck Surgery Foundation and Duke University.

Academic Appointments:

1995-1996 Assistant Professor, Department of Otolaryngology- Head and Neck Surgery, Boston University Medical School, Boston, Massachusetts.
1996-1998 Instructor, Department of Otology and Laryngology, Harvard Medical School, Boston, Massachusetts.
1998-2009: Assistant Clinical Professor, Department of Otology and Laryngology, Harvard Medical School, Boston, Massachusetts.
2009-2014: Associate Clinical Professor, Department of Otology and Laryngology, Harvard Medical School, Boston, Massachusetts.
2010: Adjunct Associate Professor, Department of Otolaryngology – Head and Neck Surgery, Boston University School of Medicine (non-voting).
2014: Associate Professor, Department of Otolaryngology, Harvard Medical School.
2020- Member, Division of Sleep Medicine, Harvard Medical School

Hospital Appointments:

07/95-Current Otolaryngology Surgeon; VA Boston HealthCare System, West Roxbury, MA.
08/96-08/99 Assistant in Otolaryngology, Massachusetts Eye and Ear, Boston, Massachusetts.
08/96-Current Clinical Associate in Surgery, Massachusetts General Hospital, Boston, Massachusetts.
08/99-08/01 Assistant Surgeon in Otolaryngology, Massachusetts Eye and Ear, Boston, Massachusetts.
08/01-02/06 Associate Surgeon in Otolaryngology, Massachusetts Eye and Ear, Boston, Massachusetts.
02/06-Current Surgeon in Otolaryngology, Massachusetts Eye and Ear, Boston, Massachusetts.
01/2016- Member, Division of Rhinology, Massachusetts Eye and Ear, Boston, Massachusetts
01/2019- Member, Division of Sleep Medicine and Surgery, Massachusetts Eye and Ear, Boston, Massachusetts
09/2023- Director, Otolaryngology Emergency Services, Massachusetts Eye and Ear, Boston, Massachusetts
09/2023- Chief, Division of Comprehensive Otolaryngology, Massachusetts Eye and Ear, Boston, Massachusetts

Other Professional Positions:

1997-1997	Consultant in Otolaryngology; Lahey-Hitchcock Clinic, Peabody, Massachusetts.
1997-1997	Otolaryngology Staff, East Boston Neighborhood Health Center, Winthrop MA.
1997-1999	Otolaryngology Staff, Harvard Vanguard Medical Associates, Boston, MA.
1999-Current	Otolaryngology Consultant for Telemedicine Service at Partner's Health Care System, Boston, MA

Major Administrative Responsibilities:

Local:

1988-1989	Chief Resident, Department of Otolaryngology, American University of Beirut, Beirut, Lebanon.
1994-1995	Chief Resident; Department of Otolaryngology, Massachusetts Eye and Ear Infirmary, Boston, Massachusetts.
1995-2000	Chief, Division of Otolaryngology, Brockton/West Roxbury VA Medical Center, West Roxbury, Massachusetts.
2000	Co-Director. Radiofrequency In-Service Course for Otolaryngology staff, Massachusetts Eye and Ear Infirmary. My role was to organize the course, lecture on related topics, and provide hands-on instruction to the otolaryngology staff.
2000-Present	Associate Chief of Otolaryngology-Head and Neck Surgery, Boston VA Healthcare System, Boston, Massachusetts.
2008-present:	Member, Board of Surgeons. Massachusetts Eye and Ear, Boston, Massachusetts
2012-2021	Coordinator, Rhinology Journal Club, Massachusetts Eye and Ear Infirmary.
2012-2021	Coordinator, Special Problems in Rhinology Conference, Massachusetts Eye and Ear, Boston, Massachusetts
2015-2018	Member, Executive Board of Massachusetts Eye and Ear Associates
2017-Present	Director. Comprehensive Otolaryngology Update CME course. My role was to set the course's educational goals, curriculum, and agenda, assign and invite faculty, coordinate with Harvard CME office, and partner with industry for educational grant support. Massachusetts Eye and Ear, Boston, Massachusetts
2015-Present	Co-Director. Snoring and Sleep Disordered Breathing CME course. My role was to closely work with the primary course coordinator to set the course's educational goals, curriculum, and agenda, assign and invite faculty. Massachusetts Eye and Ear, Boston, Massachusetts
2019-2021	International Outreach Coordinator, Massachusetts Eye and Ear
2023-	Director, Otolaryngology Emergency Services, Massachusetts Eye and Ear, Boston, Massachusetts
2023-	Chief, Division of Comprehensive Otolaryngology, Massachusetts Eye and Ear, Boston, Massachusetts

Regional and National:

1998-2000	Secretary/Treasurer, Otolaryngology Chapter, American University of Beirut Alumni Association of North America.

1998-2000 Treasurer, New England Chapter, American University of Beirut Alumni Association of North America.
2000-2002 President, New England Chapter, American University of Beirut Alumni Association of North America.
2006-2011 Member of Board of Governors, American Academy of Otolaryngology- Head and Neck Surgery Foundation.
2007-2012 Member of Board of Directors, Massachusetts Society of Otolaryngology.
2009-2010 Chairman, Carrier Relations Committee, Massachusetts Society of Otolaryngology – Head and Neck Surgery.
2010-2012 Legislative Chairperson, Massachusetts Society of Otolaryngology – Head and Neck Surgery.
2020-pesent: Member, Medical Specialty Policy Advisory Committee for Sleep Medicine, Point32Health
2020-present: Member, Medical Specialty Policy Advisory Committee for ENT, Point32Health

International:

2017: Organizer; Rhinology World Congress, Hong Kong.
2018: Co-Director, 5th Croatian Rhinology Congress, Zagreb, Croatia. Attendees were rhinologists from Croatia, surrounding Balkan countries, Turkey, Austria, and USA.

Committee Service:

Local

1996-1998: Utilization Review Committee, (Member), Physician Reviewer from the Department of Surgery, VA Boston HealthCare System, West Roxbury, MA.
1997-2019: Tumor Board, (Member), VA Boston HealthCare System, West Roxbury, MA.
1998-Present: Infection Control Committee, (Member), Massachusetts Eye and Ear Infirmary, Boston, MA.
1999-2015: Cancer Committee, (Member), VA Boston HealthCare System, West Roxbury, MA.
2008-present: Member, Board of Surgeons. Massachusetts Eye and Ear
2008-2010: Otolaryngology Service Executive Committee, (Member), Massachusetts Eye and Ear Infirmary, Boston, MA.
2017-2020: Clinical Operation Group Committee (Member), Massachusetts Eye and Ear Infirmary, Boston, MA

National

2006-2011: Legislative Representative, (Member), American Rhinologic Society and American Academy of Otolaryngology- Head and Neck Surgery Foundation.

2020-present: Member, Medical Specialty Policy Advisory Committee for Sleep Medicine, Point32Health
2020-present: Member, Medical Specialty Policy Advisory Committee for ENT, Point32Health

Professional Societies:

1985-1989: Lebanese Medical Association.
1991-2000: American Medical Association.
1991-present: Massachusetts Medical Society.
1996-present: American Board of Otolaryngology.
1996-present: American Academy of Otolaryngology-Head and Neck Surgery.
- 1994 - 1995: Resident's Committee (Member),
- 1997-2000: Speech, Voice and Swallowing Disorders Committee, (Member)
- 1997-2003: Sleep Disorders Committee, (Member)
- 2004-2006: Slide Lecture Series Committee, (Member)
- 2007-2010: Rhinology and Allergy Education Committee, (Member)
- 2010-2016: International Otolaryngology Committee
- 2013-2016: Credentials and Membership Committee
- 2016-: Rhinology and Paranasal Sinus Committee
- 2016-: Sleep Disorders Committee

1996-present: Association of Research in Otolaryngology.
1996-present: Association of Veterans' Administration Otolaryngologists.
1997-present: Society of Veterans' Administration Surgeons.
1997-present: New England Otolaryngology Society.
1998-present: Massachusetts Society of Otolaryngology-Head and Neck Surgery.
- 2007-2012: Board of Directors, (Member)
- 2009-2012: Carrier Relations Committee
- 2010-2012: Legislative Chairperson
- 2015-2016: Board of Directors, (Member)

1999-present: American Rhinologic Society.
- 2011-present: Fellow
- 2005-2011: Research Grant Committee, (Member)
- 2005-2011: Corporate Liaison Committee, (Member)
- 2011-2012: Program Committee, Annual Meeting
- 2011-2014: Chair, International Liaison Committee
- 2014-2017: Education Committee
- 2017: Program Committee, ARS Fall Meeting

2000-present: American Broncho-Esophalogical Association.
2004-present: American College of Surgeons.
2004-present: American Academy of Otolaryngic Allergy.
2007-present: Triologic Society.
- 2015- Fellow
- 2015: Program Committee (Abstract review and grading), Combined Section Meeting

2016-present: American Academy of Otolaryngic Allergy

2019-present: Member, European Rhinologic Society
2019-present: Honorary Member, Bulgarian Rhinologic Society

Editorial Positions:

Ad Hoc Reviews:

2004-: The Laryngoscope journal.
2008-: Otolaryngology – Head and Neck Surgery journal.
2010-: American Journal Rhinology Allergy.
2013-: International Forum for Allergy and Rhinology journal.
2019-: American Journal of Otolaryngology- Head and Neck Medicine and Surgery.

Other Editorial Positions:
2009-: Editorial Advisory Board, Türkiye Klinikleri Journal of Medical Sciences.

Awards, Honors and Prizes:

1978 –1985 Dean's Honor List, American University of Beirut, Beirut, Lebanon
1979 - 1984 University Scholarship, American University of Beirut, Beirut, Lebanon
1992 Resident Travel Award, Association of Research in Otolaryngology
1993 Resident Travel Award, Association of Research in Otolaryngology
1994 Resident Presentation Award, New England Otolaryngology Society Meeting.
1995 Resident Travel Award; Association of Research in Otolaryngology.
2002 Daiichi Clinical Scholars Program in Evidence Based Medical Research
2006 Honor Award, American Academy of Otolaryngology-Head and Neck Surgery Foundation.
2009 First Prize; Best Poster presentation at the Eastern Section Meeting of the Triologic Society, Boston, MA.

Report of Funded and Unfunded Research Projects

Past Funding:

2007-2008: MEEI Career Development Grant. I served as PI. Research project title: The role of connexin genes mutations in the pathogenesis of chronic rhinosinusitis. The results were published in two papers (2008 and 2014).

Merck Medical School Grant – Daniel L. Hamilos, PI. I served as an investigator. The title of the research project: IL-13 and cysteinyl-leukotriene effects on nasal polyp epithelial cells: relevance to nasal polyp pathogenesis.

2015- 2017: MEEI Foundation Clinical Research Grant. I serve as an investigator. Research project title: The efficacy of Nifedipine in the treatment of refractory rhinosinusitis with nasal polyposis.

2015-2017: MEEI Foundation Clinical Research Grant. I serve as an investigator. Research Project Title: Prospective Evaluation of Quality of Life, Objective, and Anatomic Outcomes in Patients with Nasal Obstruction and Identification of Specific Anatomic Factors Associated with Persistent Nasal Obstruction after Septoplasty or Nasal Valve Correction.

2019-2021: OptiNose US, Inc; Industry Funded. I serve as an investigator for a multi-institutional study. Project Title: A 24-Week Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study Evaluating the Efficacy and Safety of Intranasal Administration of 186 and 372 µg of OPN-375 Twice a Day (BID) in Subjects with Chronic Rhinosinusitis With or Without the Presence of Nasal Polyps.

Unfunded Projects

2004-2007. I served as PI. Research project title: Predictors of prolonged length of stay following elective major head and neck surgery. The research findings and report served as my thesis for induction as a fellow to the Triologic society and was published in a peer-reviewed specialty journal in 2007.

2015-2017. I serve as PI. Correlation of CT based cross-sectional and volumetric analysis of the nasal and pharyngeal airway with the outcome of nasal surgery in patients with sleep disordered breathing.

Report of Teaching:

Teaching of Students in Courses:

1997-2002 Evaluation and Management of Sleep Apnea. In: Clinical Aspects of Speech and Hearing Course; Hearing and Speech Therapy Ph.D. Graduate course, MIT. Lecturer. PhD graduate students (15 students). Contact time was 2 hours.

1998-2000 Diagnosis and Management of Sinusitis. Physician Assistant Studies Program, Massachusetts College of Pharmacy and Health Sciences, Boston, MA (30-40 physician assistant students). Lecturer. Contact time was 2 hours.

2001 Acute and Chronic Rhinosinusitis. Physician Assistant Studies Program, Massachusetts College of Pharmacy and Health Sciences, Boston, MA. (30-40 physician assistant students). Lecturer. Contact time was 2 hours.

Formal Teaching of Residents, Clinical Fellows, and Research Fellows

1995 Temporal Bone Dissection Course for Otolaryngology Residents, Boston University. Attending and Tutor. Otolaryngology residents (8 residents). Contact time was 3 hours.

1995-1996 Head and Neck Anatomy Dissection Course for Otolaryngology Residents, Boston University. Attending and Tutor. Otolaryngology residents (8 residents). Contact time was 6 hours.

1996: "Ossicular Reconstruction: A Temporal Bone Workshop" Instructional Course, Boston University School of Medicine. Target audience was staff Otolaryngologists, residents, and fellows. Faculty, lecturer, and instructor.

1998-2001 Emergencies of the Nose. Introductory Summer Course for Otolaryngology Residents; Massachusetts Eye and Ear Infirmary and Harvard Medical School (total of 8 residents). Lecturer. Contact time was 2 hours.

1999: Clinical Evaluation of Sleep Disordered Breathing. In: Somnoplasty Course, Boston University School of Medicine. Target audience was staff Otolaryngologists, residents, and fellows. Faculty, lecturer, and instructor.

2012-2016 Medical Management of Rhinosinusitis. Faculty; Boston Resident Sinus Dissection Course. The target audience for the course are ORL residents at Boston medical school (Harvard, Boston University and Tufts University) ORL residency programs. Contact time was 1 hour

2012-2019 Live Cadaveric Dissection / Basic and Advanced Endoscopic Sinus Surgery. Boston Resident Sinus Dissection Course. The target audience for the course are ORL residents at Boston medical school (Harvard, Boston University and Tufts University) ORL residency programs. Contact time was 3 hours.

Clinical Supervisory and Training Responsibilities:

1996- Outpatient MEE 4 half days/week
Supervising medical students ~2 months/year

1996- Operating room MEE 1 day/week
Learners present include residents and rhinology fellows

1995- Outpatient Boston VA 2 half days/week
3rd year HMS students; rotating residents from ENT, anesthesia, oral maxillofacial surgery

1995- Operating room Boston VA 1 day/week
PGY 4 resident always present; additional learners sometimes present

Formally Supervised Trainees

2004-2006: Dr. Hyei Jung Shin (otolaryngologist from South Korea): Research Fellow in Otolaryngology, Massachusetts Eye and Ear Infirmary. Dr. Shin published papers and completed research projects in the field of rhinosinusitis (studying the impact of gender and age on the clinical presentation of chronic rhinosinusitis and studying the histopathology basis for the term "rhinosinusitis". Dr. Sin is currently an active academic staff in the Department of Otolaryngology, Ewha Woman's University, Mok-Dong Hospital, Seoul, Korea.

2006-2007: Dr. Kajohnkiat Prasittivatechakool (Otolaryngologist and army officer from Thailand): Research Fellow in Otolaryngology, Massachusetts Eye and Ear Infirmary. Dr. Prasittivatechakool was involved in research projects related to rhinosinusitis (evidence based review of endoscopic frontal sinus surgery and the role of osteoplastic frontal sinus obliteration in the era of endoscopic sinus surgery). This research was presented at national specialty meetings. Lt. Col. Dr.

Prasttivatechakool is currently an active academic and clinical staff in the Department of Otolaryngol Phramongkutklao College of Medicine, Rajavithi Road, Rajathavee, Bangkok 10400, Thailand. He is involved in the training of otolaryngology residents in addition to being a surgeon with the Thai army.

2009-2010: Dr. Lorice Mahfoud: Research Fellow in Otolaryngology, Massachusetts Eye and Ear Infirmary. Dr. Mahfoud completed a residency in otolaryngology at the American University of Beirut, Beirut, Lebanon. Dr. Mahfoud is involved in a research project to determine the value of sinus CT imaging quantifying the severity of nasal septum deviation. In addition, Dr. Mahfoud co-authored a review paper on the work-up and surgical treatment of nasal septum perforation. The review is part of "Patient of the Month Program" sponsored by the American Academy of Otolaryngology – Head and Neck Surgery Foundation. Dr. Mahfoud plans to return to her home country (Lebanon) and start an academic career in Rhinology.

2014-2015: Dr. Luciano Gregorio (Otolaryngologist and Rhinologist from Sao Paulo, Brazil). Research Fellow in Otolaryngology / Rhinology, Massachusetts Eye and Ear Infirmary. Dr. Gregorio participated in several clinical research projects pertaining to chronic rhinosinusitis and rhinologic disorders, epistaxis, and sleep-disordered breathing. He moved back to Sao Paulo in July 2015 and currently holds an academic appointment at Universidade Federal de São Paulo, São Paulo.

2015-2016: Dr. Danmo Cui, Medical Doctor and aspiring otolaryngology from Beijing, China. Dr. Cui is participating in a research project that aims to correlate the surgical outcome of nasal surgery in curing sleep-disordered breathing with objective changes in the cross-sectional and volumetric analysis of the nasal and pharyngeal airway using pre- and post-operative CT. Dr. Cui moved back to China, presented and successfully defended her medical school thesis at Capital Medical University, Beijing, China based on her research work.

2017-2018 Dr. Abdulaziz BinHossan (Jeddah, Saudi Arabia). Dr. BinHossan is a practicing otolaryngologist at the military hospital in Jeddah, Saudi Arabia. The one-year fellowship in Rhinology and Allergy enabled Dr. BinHossan to provide evidence-based clinical care and design and conduct clinical research at his facility. Dr BinHossan joined an academic practice in Kkamis Mushait, Saudi Arabia

Formal Teaching of Peers

1996: Rhlinologic Manifestations of Systemic Diseases. In: Sinus Surgery and Rhinology Update. Instructional Courses, Boston University School of Medicine. Target audience was staff Otolaryngologists, residents, and fellows. Faculty and Lecturer.

1998: Treatment of Obstructive Sleep Apnea. AMIL Study Group Continuing Education Program, Massachusetts General Hospital, Boston, MA. The audience consisted of practicing physicians from Brazil (20 physicians). Contact time was 1 hour.

2003: Sleep-disordered Breathing: Diagnosis and Treatment. Partners HealthCare Telemedicine Lecture Series (CME), ARAMCO, Dhahran, Saudi Arabia (lecture given at Boston via telemedicine/videoconference). Target audience was staff physicians. Lecturer.

2016: Co-Director, Snoring and Sleep Disordered Breathing Evaluation and Management. HMS CME course, Massachusetts Eye and Ear Infirmary (2.5-day course). Target audience was Medical Sleep Medicine Specialists, Oral-Maxillofacial surgeons, and Otolaryngologists.

2016: How important is the nose in sleep disordered breathing therapy. Faculty / Speaker. Snoring and Sleep Disordered Breathing Evaluation and Management; HMS CME course, Massachusetts Eye and Ear Infirmary (2.5-day course). Target audience was Medical Sleep Medicine Specialists, Oral-Maxillofacial surgeons, and Otolaryngologists.

2016: Benefits of staging therapy for obstructive sleep apnea patients. Faculty/ Speaker. Snoring and Sleep Disordered Breathing Evaluation and Management; HMS CME course, Massachusetts Eye and Ear Infirmary (2.5-day course). Target audience was Medical Sleep Medicine Specialists, Oral-Maxillofacial surgeons, and Otolaryngologists.

2016: The airway in motion, DISE evaluation. Panelist. Snoring and Sleep Disordered Breathing Evaluation and Management; HMS CME course, Massachusetts Eye and Ear Infirmary (2.5-day course). Target audience was Medical Sleep Medicine Specialists, Oral-Maxillofacial surgeons, and Otolaryngologists.

2017: Director, Otolaryngology Update; HMS CME course, Massachusetts Eye and Ear Infirmary (2.5-day course). Target audience was General Otolaryngologists, Otolaryngology Nurse Practitioners and Physician Assistants, Otolaryngology Residents and Fellows.

2017: Role of Nasal Surgery in OSA. Faculty/ Speaker. Otolaryngology Update; HMS CME course, Massachusetts Eye and Ear Infirmary (2.5-day course). Target audience was General Otolaryngologists, Otolaryngology Nurse Practitioners and Physician Assistants, Otolaryngology Residents and Fellows.

2017: Challenging FESS Cases- Panel. Panelist/Faculty. Otolaryngology Update; HMS CME course, Massachusetts Eye and Ear Infirmary (2.5-day course). Target audience was General Otolaryngologists, Otolaryngology Nurse Practitioners and Physician Assistants, Otolaryngology Residents and Fellows.

2017: OSA and Snoring- Panel. Panelist/Faculty. Otolaryngology Update; HMS CME course, Massachusetts Eye and Ear Infirmary (2.5-day course). Target audience was General Otolaryngologists, Otolaryngology Nurse Practitioners and Physician Assistants, Otolaryngology Residents and Fellows.

2018: Co-Director, Snoring and Sleep Disordered Breathing Evaluation and Management. HMS CME course, Massachusetts Eye and Ear Infirmary (2.5-day course). Target audience was Medical Sleep Medicine Specialists, Oral-Maxillofacial surgeons, and Otolaryngologists.

2018: Importance of the Nasal Septum in obstructive sleep apnea patients. Faculty/ Speaker. Snoring and Sleep Disordered Breathing Evaluation and Management; HMS CME course, Massachusetts Eye and Ear Infirmary. Target audience was Medical Sleep Medicine Specialists, Oral-Maxillofacial surgeons, and Otolaryngologists.

2018: Approach to Surgical Management of Snoring / Sleep Disordered Breathing / Staging Surgery- Panel. Panelist/Faculty. Snoring and Sleep Disordered Breathing Evaluation and Management; HMS CME course, Massachusetts Eye

and Ear Infirmary. Target audience was Medical Sleep Medicine Specialists, Oral-Maxillofacial surgeons, and Otolaryngologists.

2018: Drug-Induced Sleep Endoscopy- Panel. Panelist/Faculty. Snoring and Sleep Disordered Breathing Evaluation and Management; HMS CME course, Massachusetts Eye and Ear Infirmary. Target audience was Medical Sleep Medicine Specialists, Oral-Maxillofacial surgeons, and Otolaryngologists.

2018: Cost Benefit of Surgical Intervention in OSA. Faculty/ Speaker. Snoring and Sleep Disordered Breathing Evaluation and Management; HMS CME course, Massachusetts Eye and Ear Infirmary. Target audience was Medical Sleep Medicine Specialists, Oral-Maxillofacial surgeons, and Otolaryngologists.

2019: Director, Comprehensive Otolaryngology 2019; HMS CME course, Massachusetts Eye and Ear Infirmary (2.5-day course). Target audience was General Otolaryngologists, Otolaryngology Nurse Practitioners and Physician Assistants, Otolaryngology Residents and Fellows.

2019: Role of Nasal Surgery in OSAS. Faculty/ Speaker. Comprehensive Otolaryngology 2019; HMS CME course, Massachusetts Eye and Ear Infirmary. Target audience was General Otolaryngologists, Otolaryngology Nurse Practitioners and Physician Assistants, Otolaryngology Residents and Fellows.

2020: Co-Director, Snoring and Sleep Disordered Breathing - Evaluation and Management. HMS CME course, Massachusetts Eye and Ear Infirmary (2.5-day course). Target audience was Medical Sleep Medicine Specialists, Oral-Maxillofacial surgeons, Otolaryngologists, Pulmonary specialists, and Allied Health Professionals (Nurse practitioners and physician assistants).

2020: Nasal Patency (nasal septum and turbinates) in OSAS. Faculty/ Speaker. Snoring and Sleep Disordered Breathing - Evaluation and Management. HMS CME course, Massachusetts Eye and Ear Infirmary. Target audience was Medical Sleep Medicine Specialists, Oral-Maxillofacial surgeons, Otolaryngologists, Pulmonary specialists, and Allied Health Professionals (Nurse practitioners and physician assistants).

2020: Cost Benefit of Surgical Intervention in OSAS. Faculty/ Speaker. Snoring and Sleep Disordered Breathing - Evaluation and Management. HMS CME course, Massachusetts Eye and Ear Infirmary. Target audience was Medical Sleep Medicine Specialists, Oral-Maxillofacial surgeons, Otolaryngologists, Pulmonary specialists, and Allied Health Professionals (Nurse practitioners and physician assistants).

2021: Director, Comprehensive Otolaryngology Update 2021; HMS CME course, Massachusetts Eye and Ear Infirmary (3-day course). Target audience was General Otolaryngologists, Otolaryngology Nurse Practitioners and Physician Assistants, Otolaryngology Residents and Fellows.

2021: Role of Nasal Obstruction in Sleep Disordered Breathing. Faculty/ Speaker. Comprehensive Otolaryngology Update 2021. HMS CME course, Massachusetts Eye and Ear Infirmary. Target audience was General Otolaryngologists, Otolaryngology Nurse Practitioners and Physician Assistants, Otolaryngology Residents and Fellows.

2022: Co-Director, Snoring and Sleep Disordered Breathing - Evaluation and Management. HMS CME course, Massachusetts Eye and Ear (2.5-day course).

Target audience was Medical Sleep Medicine Specialists, Oral-Maxillofacial surgeons, Otolaryngologists, Pulmonary specialists, and Allied Health Professionals (Nurse practitioners and physician assistants).

2022: Role of the Nasal Septum in Snoring and OSAS. Faculty/ Speaker. Snoring and Sleep Disordered Breathing - Evaluation and Management. HMS CME course, Massachusetts Eye and Ear. Target audience was Medical Sleep Medicine Specialists, Oral-Maxillofacial surgeons, Otolaryngologists, Pulmonary specialists, and Allied Health Professionals (Nurse practitioners and physician assistants).

2022: Cost Benefit of Surgical Intervention in OSAS. Faculty/ Speaker. Snoring and Sleep Disordered Breathing - Evaluation and Management. HMS CME course, Massachusetts Eye and Ear. Target audience was Medical Sleep Medicine Specialists, Oral-Maxillofacial surgeons, Otolaryngologists, Pulmonary specialists, and Allied Health Professionals (Nurse practitioners and physician assistants).

2022: Pharyngeal Wall Surgery, Hyoid Suspension, Geniotubercle Advancement, Tongue Ligature for OSA. Panel. Faculty/ Panelist. Snoring and Sleep Disordered Breathing - Evaluation and Management. HMS CME course, Massachusetts Eye and Ear. Target audience was Medical Sleep Medicine Specialists, Oral-Maxillofacial surgeons, Otolaryngologists, Pulmonary specialists, and Allied Health Professionals (Nurse practitioners and physician assistants).

2022: Latest Advances in Palate Surgery for OSA. Panel. Faculty/ Panelist. Snoring and Sleep Disordered Breathing - Evaluation and Management. HMS CME course, Massachusetts Eye and Ear. Target audience was Medical Sleep Medicine Specialists, Oral-Maxillofacial surgeons, Otolaryngologists, Pulmonary specialists, and Allied Health Professionals (Nurse practitioners and physician assistants).

2022: Tongue Evaluation and Management in OSA Patients. Panel. Faculty/ Panelist. Snoring and Sleep Disordered Breathing - Evaluation and Management. HMS CME course, Massachusetts Eye and Ear. Target audience was Medical Sleep Medicine Specialists, Oral-Maxillofacial surgeons, Otolaryngologists, Pulmonary specialists, and Allied Health Professionals (Nurse practitioners and physician assistants).

2023: Director, Comprehensive Otolaryngology Update 2023; HMS CME course, Massachusetts Eye and Ear Infirmary (3-day course). Target audience was General Otolaryngologists, Otolaryngology Nurse Practitioners and Physician Assistants, Otolaryngology Residents and Fellows.

2023: Role of Nasal Obstruction in Sleep Disordered Breathing. Faculty/ Speaker. Comprehensive Otolaryngology Update 2023. HMS CME course, Massachusetts Eye and Ear Infirmary. Target audience was General Otolaryngologists, Otolaryngology Nurse Practitioners and Physician Assistants, Otolaryngology Residents and Fellows.

Local Invited Teaching Presentations:

1995: Surgical Management of Obstructive Sleep Apnea. Grand Round, Department of Surgery, VA Boston HealthCare System. Lecturer.

1999: Surgical Management of the Neck in Patients with Head and Neck Cancer. Grand Round, Department of Surgery, VA Boston HealthCare System. Lecturer

1999: Nasal sarcoidosis and maxillary sinus mucoceles. Clinicopathologic Conference. Department of Otolaryngology, Massachusetts Eye and Ear Infirmary. Lecturer.

2000: Diagnosis and Management of Rhinosinusitis. Grand Round, Spinal Cord Injury Service, VA Boston HealthCare System Lecturer.

2000: Patient workup and selection for sleep-disordered breathing. In: Radiofrequency In-Service Course for Otolaryngology Staff, Massachusetts Eye and Ear Infirmary.

2000: Turbinate and base of tongue applications of radiofrequency volume reduction. In: Radiofrequency In-Service Course for Otolaryngology staff, Massachusetts Eye and Ear Infirmary.

2002: Obstructive Sleep Apnea: Diagnosis and Treatment. Grand Round, Spinal Cord Injury Service, VA Boston HealthCare System Lecturer.

2002: Evolution of sleep-disordered breathing and update on radiofrequency treatment. Grand Round, Department of Otolaryngology, Massachusetts Eye and Ear Infirmary Lecturer.

2002: Surgical Management of Inferior Turbinate Hypertrophy. Grand Round, Division of Allergy and Immunology, Massachusetts General Hospital Lecturer.

2003: Clinical Evaluation and Management of Sleep-Disordered Breathing. Grand Round, Division of Allergy and Immunology, Massachusetts General Hospital Lecturer.

2009: Evolution of Snoring Surgery. Bulfinch Medical Group Seminar, Massachusetts General Hospital, Boston, MA. Lecturer.

2010: Advances in Snoring and Sleep Apnea Surgery. Saudi Aramco Medical Service Organization – Telemedicine Department, Massachusetts General Hospital (Physician and Health Care Providers in Saudi Arabia).

2013: Management of Challenging Rhinology Cases. Panelist, Panel Discussion; Rhinology Lecture Series. Massachusetts Eye and Ear Infirmary

2014: Managing Complications of Endoscopic Sinus Surgery. Panelist, Panel Discussion; Rhinology Lecture Series. Massachusetts Eye and Ear Infirmary.

2014: Surgical Management of Sleep-Disordered Breathing – Palatopharyngeal Surgery. Sleep-Medicine Service Lecture Series, Sleep Medicine Service, Massachusetts General Hospital, Boston, MA.

2014: Endoscopic Sinus Surgery: Indications and Techniques. Allergy Grand Rounds, Division of Allergy and Immunology, Massachusetts General Hospital, Boston MA.

2015: Medical Management of Chronic Rhinosinusitis. Panelist, Panel Discussion (Work-Up and Management of Chronic Rhinosinusitis); Rhinology Lecture Series. Massachusetts Eye and Ear Infirmary.

2015: The Role of Nasal Obstruction in Obstructive Sleep Apnea and CPAP non-compliance. Panelist, Panel Discussion (Management of Obstructive Sleep

Apnea); General Otolaryngology Lecture Series. Massachusetts Eye and Ear Infirmary

2015: Management of Challenging Obstructive Sleep Apnea Patients. Panelist, Panel Discussion (Management of Obstructive Sleep Apnea); Rhinology Lecture Series. Massachusetts Eye and Ear Infirmary.

2016: Sinonasal Involvement with Systemic Inflammatory Disease; Panelist, Panel Discussion, Rhinology Lecture Series, Massachusetts Eye and Ear Infirmary

2017: Endoscopic Sinus Surgery: Indications and Techniques. Grand Round, Division of Allergy and Immunology, Massachusetts General Hospital.

2019: Endoscopic Sinus Surgery: Indications and Techniques. Grand Round, Division of Allergy and Immunology, Massachusetts General Hospital.

2020: Evaluation and Management of Sleep Disorders. Panelist, Panel Discussion; Sleep Division Lecture Series. Massachusetts Eye and Ear.

2020: Risks of Reopening During COVID-19: What we know and what we want to know. Panelist, Panel Discussion, Rhinology Lecture Series, Massachusetts Eye and Ear.

2021: Management of Recalcitrant Nasal Polyposis. Panelist, Panel Discussion, Rhinology Lecture Series, Massachusetts Eye and Ear.

2022: Endoscopic Sinus Surgery: Indications and Techniques. Grand Round, Division of Allergy and Immunology, Massachusetts General Hospital.

2022: Tonsil Trouble: Tonsil Mass with Hematemesis. Panelist, Panel Discussion, Medical Forum Conference, Department of Internal Medicine, Boston VA HealthCare System. Invited faculty

Report of Regional National and International Invited Presentations:

"No presentations below were sponsored by outside entities."

Regional:

2003: Surgical Treatment of Sleep-Disordered Breathing. Grand Round, Emerson Hospital, Concord, MA (For Staff). Lecturer.

2004: Panel and Case Presentations: Controversies in Snoring and Sleep Apnea. New England Otolaryngology Society (NEOS) meeting, Boston MA. Target audience was otolaryngologist, otolaryngology residents, and otolaryngology fellows from New England. Panelist.

2009: Chronic Rhinosinusitis: Is It Anatomy, Infection or Inflammation. Annual Meeting of Rhode Island Society of Otolaryngology, Providence, Rhode Island.

2015: Chronic Rhinosinusitis: Work-Up and the Role of Endoscopic Sinus Surgery. The NESA Allied Health Update, Westford, MA. Target audience was Allied Health Professional and Nurses for New England and the rest of the United States.

2017: OSA: Work-up and How to Decide on the Appropriate Surgery. Clinical Sleep Grand Rounds. Center for Life Science, Beth Israel Deaconess Medical Center. Harvard-Wide and Boston-Wide Grand Round. Target audience was sleep medicine faculty and clinical fellows.

2019: The Upper Airway in Sleep Apnea". Clinical Sleep Grand Round, Beth Israel Deaconess Medical Center, Boston MA. Target Audience sleep medicine clinical fellows and sleep medicine faculty, Beth Israel Medical Center, Massachusetts General Hospital, and Yale University Medical Center.

National

2002: Little Falls Hospital Grand Round: "RTIs: A Focus on the Diagnosis and Management of Sinusitis". Little Falls, New York. Lecturer.

2002: Medical History for the Sleepy Patient. In: "Diagnosis and Medical Treatment of The Sleepy Patient". Interactive Committee Presentation, Sleep Disorders Committee, American Academy of Otolaryngology-Head and Neck Surgery Foundation annual meeting, San Diego, California. Panelist.

2002: Medical Center Hospital Grand Round: "The Management of RTIs: Chronic Sinusitis: Management, Pathophysiology, and Clinical Presentation." Odessa, Texas. Lecturer.

2003: University of Nevada School of Medicine, Department of Family and Community Medicine Grand Round: "Respiratory Tract Infections: A Focus on Bacteriology of Sinusitis". Las Vegas, Nevada. Lecturer.

2012: Role of nasal obstruction in sleep-disordered breathing. Invited Panelist: "Sleep-Disordered Breathing: what to do about the nose?". 2013 Summer Sinus Symposium, American Rhinologic Society Meeting, Chicago IL.

2013: The role of nasal obstruction in obstructive sleep apnea. Invited Panelist: "Sleep-Disordered Breathing: what to do about the nose?". 2013 Summer Sinus Symposium, American Rhinologic Society Meeting, Chicago IL.

2013: Evidence based review of endoscopic frontal sinus surgery. American Academy of Otolaryngology – Head and Neck Surgery Foundation and Egyptian Otolaryngology Society Satellite Symposium, Vancouver, Canada.

2018: Evaluation of nasal obstruction in the setting of OSA. Panelist: "Current Management of Obstructive Sleep Apnea and Sleep Disordered Breathing: Don't Forget the Nose". AAO-HNSF Annual Meeting, Atlanta Georgia

2019: Plasticity of Route of Breathing. Panel: "First in Line: The Nose". 10th International Surgical Sleep Society Meeting, New York, NY, USA. Panelist / Invited Faculty

2019: Moderator. Panel: Managing Intraoperative Bleeding During Endoscopic Sinus Surgery. RhinoWorld / ARS / IRS/ ISIAN meeting, Chicago IL. Invited Faculty

2022: Moderator. Panel: The Role of the Nose in OSA and Snoring. International Surgical Sleep Society Annual Meeting / American Academy of Otolaryngic Allergy Annual Meeting, Philadelphia, PA. Invited Faculty.

National Invited Presentations as Selected Oral Abstracts

1991: Laser Doppler measurements and electrocochleography during ischemia of the guinea pig cochlea: Implications for hearing preservation in acoustic neuroma surgery. ARO Meeting, St Petersburg, FL. (Abstract).

1991: The Significance of a false-positive auditory brainstem response: A prospective study. Eastern Section Meeting of Triologic Society, Philadelphia, PA. (Abstract).

1999: Maxillary sinus mucoceles: Clinical presentation and long-term results of endoscopic surgical treatment. Eastern Section Meeting of the Triologic Society, Providence RI. (Abstract).

1999: Sarcoidosis presenting as recurrent nasal polyps. Eastern Section Meeting of the Triologic Society, Providence RI. (Abstract).

1999: Chronic invasive fungal sinusitis: Does it exist? American Rhinologic Society meeting, New Orleans, LA. (Abstract).

2000: Bacteriology of maxillary sinus mucoceles versus chronic sinusitis. Eastern Section Meeting of the Triologic Society, Pittsburgh, PA. (Abstract).

2000: Are imaging studies necessary in the work-up of anosmia? IX International Rhinologic Society Congress, The Nose 2000…And Beyond, Washington, DC. (Abstract).

2001: Same stage nasal and palatopharyngeal surgery for OSA: Is it safe? Annual meeting of the American Academy of Otolaryngology-Head and Neck Surgery Foundation, Denver, Colorado. (Abstract).

2002: Endoscopic sinus surgery for inflammatory maxillary sinus pathology. Eastern Section of the Triologic Society, Philadelphia, Pennsylvania. (Abstract).

2002: Ethmoid mucocele as a late complication of endoscopic ethmoidectomy. Annual Meeting of the American Academy of Otolaryngology-Head and Neck Surgery Foundation, San Diego, California. (Abstract).

2003: Clinical outcomes of septoplasty in the geriatric population. Eastern Section of the Triologic Society meeting, Boston, Massachusetts. (Abstract).

2004: Correlation between clinical diagnosis and histopathologic findings in patients with sinunasal disease. Eastern Section of the Triologic Society meeting, NY, NY. (Abstract).

2005: Correlation between Middle Turbinate and Ipsilateral Ethmoid Histopathology in Chronic Rhinosinusitis. Annual meeting of the American Academy of Otolaryngology – Head and Neck Surgery, Los Angeles, CA. (Abstract).

2006: The Impact of Gender on the Clinical Presentation of Inflammatory Paranasal Sinus Disease. Eastern Section of the Triologic Society meeting, Toronto, Canada. (Abstract).

2007: Evidence Based Review of Endoscopic Frontal Sinus Surgery. The annual meeting of the American Academy of Otolaryngology-Head and Neck Surgery Foundation, Washington DC. (Abstract).

2008: The role of frontal sinus obliteration in the era of FESS. The annual meeting of the American Academy of Otolaryngology-Head and Neck Surgery Foundation, Chicago, IL. (Abstract).

2013: The Role of Nasal Obstruction in Obstructive Sleep Apnea. Invited Panelist: "Sleep-Disordered Breathing: what to do about the nose?". 2013 Summer Sinus Symposium, American Rhinologic Society Meeting, Chicago IL.

2014: Radiographic evaluation of nasal septal deviation from computed tomography correlates poorly with physical exam findings. American Rhinologic Society (ARS) meeting, Orlando, FL.

2016: General antibiotic exposure is associated with an increased risk of developing chronic rhinosinusitis without nasal polyps: A case control study. Triologic Society Annual Meeting, Chicago, IL.

2016: A cost effectiveness analysis of nasal surgery to increase CPAP adherence in sleep apnea patients with nasal obstruction. Triologic Society Annual Meeting, Chicago, IL.

2019: Long-Term Improvement in Nasal Obstruction and General Health-Related Quality of Life after Functional Septorhinoplasty with and without Inferior Turbinate Reduction." Combined Sectional Meeting of Triologic Society, San Diego CA.

2019: Managing Intraoperative Bleeding During Endoscopic Sinus Surgery: Panel. Moderator. RhinoWorld / ARS / IRS/ ISIAN meeting, Chicago IL

International:

2004: Surgery for Sleep-disordered Breathing. Invited Speaker, Grand Round, Department of Otolaryngology-Head and Neck Surgery, University of Nueva Leon School of Medicine, Monterrey, Mexico. Invited Speaker/ Visiting Professor.

2004: Paranasal Sinus Mucocele: Pathophysiology and Surgical Treatment. Curso Internacional Theorico-Practico de Cirugia Y Diseccion Endoscopica de Nariz Y Senos Paranasales."Theorical- Practical Endoscopic Surgery Course", Universidad Autonoma De Nuevo Leon, Monterrey, Mexico. Faculty / Invited Speaker.

2004: Rhinosinusitis: Is it Anatomic, Infectious, or Inflammatory Disease? Curso Internacional Theorico-Practico de Cirugia Y Diseccion Endoscopica de Nariz Y Senos Paranasales."Theorical- Practical Endoscopic Surgery Course", Universidad Autonoma De Nuevo Leon, Monterrey, Mexico. Faculty / Invited Speaker.

2004: Nasal Polyposis: Clinical Presentation, Pathophysiology and Treatment. Curso Internacional Theorico-Practico de Cirugia Y Diseccion Endoscopica de Nariz Y Senos Paranasales. "Theorical- Practical Endoscopic Surgery Course", Universidad Autonoma De Nuevo Leon, Monterrey, Mexico. Faculty / Invited Speaker.

2004: Headache and Facial Pain: Is It Sinus Disease? Does ESS Help? Curso Internacional Theorico-Practico de Cirugia Y Diseccion Endoscopica de Nariz Y Senos Paranasales. "Theorical- Practical Endoscopic Surgery Course", Universidad Autonoma De Nuevo Leon, Monterrey, Mexico. Faculty / Invited Speaker.

2004: Curso Internacional Theorico-Practico de Cirugia Y Diseccion Endoscopica de Nariz Y Senos Paranasales. "Theorical- Practical Endoscopic Surgery Course", Universidad Autonoma De Nuevo Leon, Monterrey, Mexico. Instructor, endoscopic sinus surgery on cadavers. Faculty / Invited Speaker.

2004: Laryngopharyngeal Reflux: Implications, Diagnosis and Treatment. Annual Meeting of the Society of Otolaryngology-Head and Neck Surgeons (Colegio de Especialistas en Cirugia de Oido, Nariz Y Garganta de Monterrey, A.C), Monterrey, Mexico. Faculty / Invited Speaker.

2004: Panel Discussion. "Sobre Dilemas en Sinusitis Y Cirugia Endoscopica de Senos Paranasales". Sesiones Mensuales Del Colegio de Especialistas en Cirugia de Oido, Nariz Y Garganta de Monterrey, A.C., Monterrey, Mexico. Faculty / Invited Speaker.

2008: The Evolution of Snoring Surgery. 8th International Otolaryngology Head and Neck Surgery Congress and Ankara Otolaryngology and Head and Neck Surgery Society Meeting, Ankara, Turkey. Faculty / Invited Speaker.

2008: Transnasal Endoscopic Control of Epistaxis. 8th International Otolaryngology Head and Neck Surgery Congress and Ankara Otolaryngology and Head and Neck Surgery Society Meeting, Ankara, Turkey. Faculty / Invited Speaker.

2008: Management of Frontal Sinus Disease. 8th International Otolaryngology Head and Neck Surgery Congress and Ankara Otolaryngology and Head and Neck Surgery Society Meeting, Ankara, Turkey. Faculty / Invited Speaker.

2008: Facial Pain: Is Endoscopic Sinus Surgery Curative? 8th International Otolaryngology Head and Neck Surgery Congress and Ankara Otolaryngology and Head and Neck Surgery Society Meeting, Ankara, Turkey. Faculty / Invited Speaker.

2008: Obstructive Sleep Apnea Syndrome. Panel Discussion. 8th International Otolaryngology Head and Neck Surgery Congress and Ankara Otolaryngology and Head and Neck Surgery Society Meeting, Ankara, Turkey. Faculty / Invited Speaker.

2010: Which Surgical method for Which Patient with OSAS (Obstructive Sleep Apnea Syndrome). Panel Discussion. Second Congress of Sleep Disordres, Turkish Sleep Society, Famagusta, Turkish Republic of Northern Cyprus. Panelist/ Faculty / Invited Speaker.

2010: Surgical Techniques in the Treatment of Snoring; New Approaches in Obstructive Sleep Apnea Surgery. Second Congress of Sleep Disordres, Turkish Sleep Society, Famagusta, Turkish Republic of Northern Cyprus. Faculty / Invited Speaker.

2010: Advances in Snoring and Sleep Apnea Surgery. Saudi Aramco Medical Service Organization – Telemedicine Department, Massachusetts General Hospital (Physician and Health Care Providers in Saudi Arabia). Invited Speaker.

2011: Facial Pain. 33rd Turkish National Otorhinolaryngology and Head and Neck Surgery Congress, Antalya, Turkey. Faculty / Invited Speaker.

2011: Office Procedures to Treat Snoring. Invited Speaker, 33rd Turkish National Otorhinolaryngology and Head and Neck Surgery Congress, Antalya, Turkey. Faculty / Invited Speaker.

2011: Paranasal Sinus Mucoceles. 33rd Turkish National Otorhinolaryngology and Head and Neck Surgery Congress, Antalya, Turkey. Faculty / Invited Speaker.

2011: Endoscopic Management of Epistaxis. 33rd Turkish National Otorhinolaryngology and Head and Neck Surgery Congress, Antalya, Turkey. Faculty / Invited Speaker.

2011: Work-up and Management of Obstructive Sleep Apnea: Panel Discussion. 33rd Turkish National Otorhinolaryngology and Head and Neck Surgery Congress, Antalya, Turkey. Panelist / Faculty / Invited Speaker.

2012: Management of Frontal Sinus Disease: Endoscopic versus Open. Second Croation Rhinologic Congress, Zagreb, Croatia. Faculty / Invited Speaker.

2012: Transnasal Endoscopic Management of Epistaxis. Second Croation Rhinologic Congress, Zagreb, Croatia. Faculty / Invited Speaker.

2012: Endoscopic Management of Epistaxis. First Bulgarian-Italian Rhinology Friendship Meeting, Plovdiv, Bulgaria. Faculty / Invited Speaker.

2012: Pathophysiology and Management of Paranasal Sinus Mucoceles. First Bulgarian-Italian Rhinology Friendship Meeting, Plovdiv, Bulgaria. Faculty / Invited Speaker.

2012: Stroz Lunch Symposium: The Last Word in Otolaryngology with Surgical Video Demonstrations. First Bulgarian-Italian Rhinology Friendship Meeting, Plovdiv, Bulgaria. Faculty / Invited Speaker.

2012: An Evidence Based Review of Endoscopic Frontal Sinus Surgery. 3rd Macedonian ORL Congress, Ohrid, Macedonia (FYROM). Faculty / Invited Speaker.

2012: Chair, three hour "Rhinology Session", 3rd Macedonian ORL Congress, Ohrid, Macedonia (FYROM). Participating otolaryngologists presented their clinical and basic research papers in the field of Rhinology. I moderated the sessions. Invited Faculty / Moderator.

2012: Panelist; Pearls of Management of Fungal Rhinosinusitis. Panel Discussion. Invited Speaker. 3rd Pan-Arab Rhinology Society Conference, Sultan Qaboos University, Muscat, Oman. Panelist / Faculty / Invited Speaker.

2012: Endoscopic Management of Epistaxis. 3rd Pan-Arab Rhinology Society Conference, Sultan Qaboos University, Muscat, Oman.

2012: Management of the Frontal Sinus: Endoscopic versus Open Approach. 3rd Pan-Arab Rhinology Society Conference, Sultan Qaboos University, Muscat, Oman. Faculty / Invited Speaker.

2012: Chair and Moderator, one and half hour "Rhinology Session". Participating otolaryngologists presented their clinical and basic research papers in the field of Rhinology. I chaired and moderated the session. 3rd Pan-Arab Rhinology Society Conference, Sultan Qaboos University, Muscat, Oman. Faculty / Invited Speaker.

2013: Medical Management of Chronic Rhinosinusitis with Nasal Polyposis. Panel title: Nasal Polyposis: Etiology and Treatment. International Federation of Otolaryngologic Societies (IFOS) meeting, Seoul, South Korea. Panelist / Invited Speaker.

2013: Evidence based review of endoscopic frontal sinus surgery. American Academy of Otolaryngology – Head and Neck Surgery Foundation and Egyptian Otolaryngology Society Satellite Symposium, Vancouver, Canada. Faculty / Invited Speaker.

2013: Endoscopic Frontal Sinusotomy: An Evidence- Based Review. 2nd Bulgarian – Italian Meeting in Rhinology and 6th Endoscopic Sinus Surgery Course, Trieste, Italy. Faculty / Invited Speaker.

2013: Medical Therapy of Chronic Rhinosinusitis with Nasal Polyposis. 2nd Bulgarian – Italian Meeting in Rhinology and 6th Endoscopic Sinus Surgery Course, Trieste, Italy. Faculty / Invited Speaker.

2013: Parnasal Sinus Mucoceles: Pathogenesis and Management. 2nd Bulgarian – Italian Meeting in Rhinology and 6th Endoscopic Sinus Surgery Course, Trieste, Italy. Faculty / Invited Speaker.

2013: How to Deal with Complications of Surgical Treatment of Chronic Rhinosinusitis. Panel Discussion. 2nd Bulgarian – Italian Meeting in Rhinology and 6th Endoscopic Sinus Surgery Course, Trieste, Italy. Panelist / Invited Speaker.

2014: Clinical Algorithm for the Management of Epistaxis: The Role of Endoscopic Control. 11th International Congress of Otorhinolaryngology- Head and Neck Surgery, Ankara, Turkey. Faculty / Invited Speaker.

2014: Medical Management of Chronic Rhinosinusitis with Nasal Polyposis: Otolaryngology Perspective. Invited Speaker, 11th International Congress of Otorhinolaryngology- Head and Neck Surgery, Ankara, Turkey. Faculty / Invited Speaker.

2014: Management of Frontal Sinus Disease: Endoscopic vs Open Approaches. 11th International Congress of Otorhinolaryngology- Head and Neck Surgery, Ankara, Turkey. Faculty / Invited Speaker.

2014: Frontal Sinus Mucoceles: Pathogensis and Surgical Management. 2nd Bulgarian – Italian Meeting on Rhinology and 6th Endoscopic Sinus Surgery Course, Trieste, Italy. Invited Faculty / Speaker.

2014: What Causes Facial Pain in Sinusitis. Facial Pain and Headache Symposium, 25th Congress of the European Rhinologic Society (ERS) and 32nd International Symposium of Infection and Allergy of the Nose (ISIAN) meetings, Amsterdam, Netherlands. Invited Speaker.

2014: Are There Still Indications for External Approach to Frontal Sinus Disease? External Approaches to the Sinus Symposium, 25th Congress of the European Rhinologic Society and 32nd International Symposium of Infection and Allergy of the Nose (ISIAN) meetings, Amsterdam, Netherlands. Invited Speaker.

2014: Paranasal Sinus Mucoceles: Pathogenesis and Management. Bulgarian Rhinologic Society Meeting, Pomotir, Bulgaria. Faculty / Invited Speaker.

2014: The Role of Medical Therapy in Chronic Rhinosinusitis with and without Polyposis. Invited Speaker. 3rd Bulgarian-Italian Meeting on Rhinology. Rovereto, Italy. Invited Faculty / Speaker.

2014: Evidence-Based Review of Endoscopic Frontal Sinus Surgery. Invited Speaker. 3rd Bulgarian-Italian Meeting on Rhinology. Rovereto, Italy. Invited Faculty / Speaker.

2014: What Causes Facial Pain in Rhinosinusitis. Invited Speaker. 3rd Bulgarian-Italian Meeting on Rhinology. Rovereto, Italy. Invited Faculty / Speaker.

2015: Challenging Cases in Rhinology: How I Solved the Problem. Scientific Panel Sponsored by ARS (American Rhinology Society). 16th World Congress of

Rhinology / 34th ISIAN (International Society of Inflammation and Allergy of the Nose) / 16th IRS (International Rhinology Society) Meeting, Sao Paulo, Brazil. Panelist / Invited Faculty.

2015: Chronic Rhinosinusitis Treatment: Medical vs Surgical. Sunset Debate Panel, 16th World Congress of Rhinology / 34th ISIAN (International Society of Inflammation and Allergy of the Nose) / 16th IRS (International Rhinology Society) Meeting, Sao Paulo, Brazil. Panelist / Invited Faculty.

2015: Etiology and Work-Up of Sinugenic Facial Pain / Headache. 16th World Congress of Rhinology / 34th ISIAN (International Society of Inflammation and Allergy of the Nose) / 16th IRS (International Rhinology Society) Meeting, Sao Paulo, Brazil. Invited Faculty / Speaker.

2015: DISE (Drug Induced Sleep Endoscopy) and its Utilization in Surgical Planning. Invited Speaker, Round Table Discussion (Jointly Sponsored by AAO-HNSF and European ORL- HNS): Innovative Therapies for Obstructive Sleep Apnea. 3rd Congress of European ORL – HNS Society, Prague, Czech Republic. Invited Faculty / Speaker.

2015: Advances in the Pathogenesis of, and Surgery for Chronic Rhinosinusitis: Evidence Based Review Plus Current Opinion. Moderator; Round Table Discussion Panel (Jointly Sponsored by AAO-HNSF and European ORL- HNS). 3rd Congress of European ORL – HNS Society, Prague, Czech Republic. Invited Faculty / Speaker.

2015: Endoscopic Frontal Sinus Surgery: An Evidence-based Review of its Efficacy and the Current Role of Osteoplastic Frontal Sinus Obliteration. XXVI Congreso SOCMNO (Sociedad De Otorrinolaringologia Del Centro Medico Nacional De Occidente A.C.), Puerto Vallarta, Mexico. Invited Faculty / Speaker.

2015: Paranasal Sinus Mucoceles: Pathogenesis and Surgical Management. XXVI Congreso SOCMNO (Sociedad De Otorrinolaringologia Del Centro Medico Nacional De Occidente A.C.), Puerto Vallarta, Mexico. Invited Faculty / Speaker.

2015: Sinugenic Facial Pain: What Causes It and The Appropriate Work-Up. XXVI Congreso SOCMNO (Sociedad De Otorrinolaringologia Del Centro Medico Nacional De Occidente A.C.), Puerto Vallarta, Mexico. Invited Faculty / Speaker.

2015: The Nasal Airway and OSAS: Work-Up and Role of Surgery. XXVI Congreso SOCMNO (Sociedad De Otorrinolaringologia Del Centro Medico Nacional De Occidente A.C.), Puerto Vallarta, Mexico. Invited Faculty / Speaker.

2016: Paranasal Sinus Mucoceles: Pathogenesis and Surgical Treatment. Hospital Leon Bacerra de Guayaquil, Guayaquil, Ecuador. Visiting Professor.

2016: Nasal Surgery for Obstructive Sleep Apnea. Hospital Leon Bacerra de Guayaquil, Guayaquil, Ecuador. Visiting Professor.

2016: Medical Management of Chronic Rhinosinusitis: an Otolaryngic Prospective. Hospital Leon Bacerra de Guayaquil, Guayaquil, Ecuador. Visiting Professor.

2016: Facial Pain and Sinusitis: The Role of Endoscopic Sinus Surgery. Hospital Leon Bacerra de Guayaquil, Guayaquil, Ecuador. Visiting Professor.

2016: Same Day Discharge and Safety of Concurrent Nasal and Oropharyngeal Surgery. Panel Title: OSA and the Nose in Adults. 7th International Surgical Sleep Society (ISSS) Symposium – Surgery, Sleep, and Breathing, Sao Paolo, Brazil.

2016: Lessons from Frontal Sinus Surgery Cases. Panelist, Round Table. 26th Congress of the European Rhinologic Society (ERS), 35th Congress of the International Society of Inflammation and Allergy of the Nose (ISIAN), 17th Congress of the International Rhinologic Society (IRS), Stockholm, Sweden. Invited Faculty / Panelist.

2016: Volumetric Analysis of Nasal Surgery in Patients with Obstructive Sleep Apnea. 26th Congress of the European Rhinologic Society (ERS), 35th Congress of the International Society of Inflammation and Allergy of the Nose (ISIAN), 17th Congress of the International Rhinologic Society (IRS), Stockholm, Sweden. Oral Presentation

2016: Expanding the Limits of Endoscopic Intraorbital Tumor Resection Using 3-Dimensional Reconstruction. 26th Congress of the European Rhinologic Society (ERS), 35th Congress of the International Society of Inflammation and Allergy of the Nose (ISIAN), 17th Congress of the International Rhinologic Society (IRS), Stockholm, Sweden. Oral Presentation

2016: Nasal Surgery and OSA: Volumetric Analysis and Economic Impact. International Conference Rhinology and Rhinoallergy & 5th Bulgarian Italian Rhinology Meeting, Senigallia, Italy. Invited Faculty / Speaker

2016: Master Class / Round Table: How to Deal with Complications of Endoscopic Sinus Surgery. Complications of FESS: How Bad Can It Be? International Conference Rhinology and Rhinoallergy & 5th Bulgarian Italian Rhinology Meeting, Senigallia, Italy. Panelist / Invited Faculty

2016: Moderator: Pediatric Rhinology Session. International Conference Rhinology and Rhinoallergy & 5th Bulgarian Italian Rhinology Meeting, Senigallia, Italy. Invited Faculty

2017: Controversies: Is nasal obstruction to be considered for snoring / OSAS treatment. IFOS (International Federation of Otolaryngology Societies), Paris France. Speaker / Invited Faculty

2017: Novel Medical Therapies for Chronic Rhinosinusitis; In: Uncontrolled rhinitis and rhinosinusitis: Where do we stand today? Panel. IFOS (International Federation of Otolaryngology Societies), Paris, France. Panelist / Invited Faculty

2017: Drug Induced Sleep Endoscopy (DISE): Panel. Rhinology World Congress, Hong Kong. Moderator

2017: Role of Drug Induced Sleep Endoscopy in the Workup for OSA. Rhinology World Congress, Hong Kong. Invited Faculty

2017: Nasal Surgery and OSA: Volumetric Analysis and Economic Impact. Rhinology World Congress. Hong Kong. Invited Faculty

2017: Organizer / Scientific Committee. Rhinology World Congress. Hong Kong

2017: Choosing the Right Therapy for Your OSA Patient. 4th Congress of European ORL-HNS, Barcelona, Spain. Invited Faculty

2017: Diagnosis of OSA: Is PSG Still the Gold Standard? 4th Congress of European ORL-HNS, Barcelona, Spain. Invited Faculty

2018: Role of Nasal Surgery in OSA. 5th Croatian Rhinology Congress, Zagreb, Croatia. Invited Faculty

2018: Endoscopic Sinus Surgery: 35+ Years Later. 5th Croatian Rhinology Congress, Zagreb, Croatia. Invited Faculty

2018: Co-Director, 5th Croatian Rhinology Congress, Zagreb, Croatia. Attendees were rhinologists from Croatia, surrounding Balkan countries, Turkey, Austria, and USA.

2018: Moderator: Chronic Rhinosinusitis (CRS) medical management. 27th Congress of the European Rhinologic Society (ERS), 37th Congress of the International Society of Inflammation and Allergy of the Nose (ISIAN), 18th Congress of the International Rhinologic Society (IRS), London, United Kingdom.

2019: Surgical Therapy for Obstructive Sleep Apnea. Otolaryngology College of Guadalajara, Cámara de Comercio: Guadalajara, Mexico. Invited Faculty

2019: Multilevel Surgery in OSA. XXI Congreso Internacional Avances En Medicina, Hospital Civil De Guadalajara / University of Guadalajara, Guadalajara, Mexico. Invited Faculty

2019: Hypoglossal Nerve Stimulation in the Treatment of Obstructive Sleep Apnea. XXI Congreso Internacional Avances En Medicina, Hospital Civil De Guadalajara / University of Guadalajara, Guadalajara, Mexico. Invited Faculty

2019: Sleep Surgery Complications. XXI Congreso Internacional Avances En Medicina, Hospital Civil De Guadalajara / University of Guadalajara, Guadalajara, Mexico. Invited Faculty

2019: Panel: Future Perspectives in Sleep Medicine. XXI Congreso Internacional Avances En Medicina, Hospital Civil De Guadalajara / University of Guadalajara, Guadalajara, Mexico. Invited Faculty/Panelist

2019: Advances in the Medical Management of Chronic Rhinosinusitis. 2nd Balkan Rhinoforum, Belgrade, Serbia. Invited Faculty

2019: Plasticity of Route of Breathing. Panel: “First in Line: The Nose”. 10th International Surgical Sleep Society Meeting, New York, NY, USA. Panelist / Invited Faculty

2019: Up To Date in Surgical Treatment of OSA. XII International Symposium on Snoring and Sleep Apnea”, Hospital Albert Einstein, São Paulo, Brazil. Invited Faculty

2019: OSA: Clinical Work-up and Surgical Planning. V Panamerican Association of Otolaryngology Conference Course and VII Paraguayan Congress of Otolaryngology, Head and Neck Surgery, Asuncion, Paraguay. Invited Faculty

2019: Sleep Apnea Surgery: Selection of the Patient for Surgery. Webinar, Mexican Society of Otolaryngology, Mexico City, Mexico. Invited Faculty

2019: Silent Sinus Syndrome. 15th Bulgarian Rhinology Society Annual Meeting, Starosel, Bulgaria. Invited Faculty

2019: Paranasal Sinus Mucoceles: Pathogenesis and Surgical Managment. 15th Bulgarian Rhinology Society Annual Meeting, Starosel, Bulgaria. Invited Faculty

2019: Moderator: FESS – an Update. 15th Bulgarian Rhinology Society Annual Meeting, Starosel, Bulgaria. Invited Faculty

2022: Silent Sinus Syndrome: Pathogenesis, Clinical Presentation, and Treatment. Rinology World Congress 2022, Rhinoworld 2022, IRS / ISIAN 2022, St Petersburgh, Russia. Invited Faculty

2022: Role of Nasal Surgery in the Treatment of Snoring and OSA. Rinology World Congress 2022, Rhinoworld 2022, IRS / ISIAN 2022, St Petersburgh, Russia. Invited Faculty

2022: Complications of Sleep Surgery: Lessons Learned. Round Table Discussion. Confederation of European ORL- Head and Neck Surgery (CEORL-HNS), Milan, Italy. Invited Faculty

2022: Septal Surgery: Clinical Implications of Septal Deformity. Confederation of European ORL- Head and Neck Surgery (CEORL-HNS), Milan Italy. Invited Faculty / Moderator

2022: Paranasal Sinus Mucoceles: Pathogenesis, Clinical Presentation and Management. Annual International Conference "XIV Marius Plouzhnikov Memorial Lecturing", St Petersburgh, Russia. Invited Faculty

2023: CPAP versus Surgery for OSA. International Federation of Otolaryngology Societies (IFOS), Dubai, UAE. Invited Faculty / Moderator

2023: Work-up of Patients Who Present with Sleep Disordered Breathing. Federation of Otolaryngology Societies (IFOS), Dubai, UAE. Invited Faculty

2023: Nasal Surgery for Sleep Disordered Breathing. International Federation of Otolaryngology Societies (IFOS), Dubai, UAE. Invited Faculty

2023: Metabolic Syndrome and Obstructive Sleep Apnea. Hospital Ángeles del Carmen, Guadalajara, Mexico. Visiting Professor / Invited Faculty

2023: Intraoperative Navigation during Endoscopic Sinus Surgery. International Medical Imaging Congress, Unidad de Patologia Clinica, Guadalajara, Mexico. Invited Faculty

2023: Obstructive Sleep Apnea: Scope of the Disease. International Medical Imaging Congress, Unidad de Patologia Clinica, Guadalajara, Mexico. Invited Faculty

2023: Silent Sinus Syndrome: Pathogenesis, Clinical Presentation, and Treatment. Grand Round, Department of Otolaryngology, University of Sao Paulo, Sao Paulo, Brazil. Invited Faculty

2023: Intraoperative Navigation during Endoscopic Sinus Surgery. XI International Interdisciplinary Congress of Head and Neck Diseases. St Petersburgh Russia. Invited Faculty

2023: Silent Sinus Syndrome: Pathogenesis, Clinical Presentation, and Treatment. 7th Congress of Romanian Rhinologic Society and 13th International Symposium on Rhinosinusitis and Nasal Polyposis. Sibiu, Romania. Invited Faculty

2023: Highlights on Chronic Rhinosinusitis Pathophysiology: Non-Type 2 Inflammation. 29th Congress of European Rhinologic Society (ERS), 40th Congress of International Society of Inflammation and Allergy of the Nose (ISIAN), and 22nd Congress of the International Rhinologic Society (IRS), Sofia, Bulgaria. Invited Faculty

2023: Acute Rhinosinusitis. Abstract Session. 29th Congress of European Rhinologic Society (ERS), 40th Congress of International Society of Inflammation and Allergy of the Nose (ISIAN), and 22nd Congress of the International Rhinologic Society (IRS). Session Chair / Moderator, Sofia, Bulgaria. Invited Faculty

2023: Silent Sinus Syndrome: Pathogenesis, Clinical Presentation, and Treatment. SANTO-RHINO III-Santorini Sinus Skull Base and Rhinoplasty Workshop, 12-14 October 2023, Santorini, Greece. Invited Faculty

Report of Clinical Activities and Innovations:

Licensure and Certification:

1984:	FMGEMS parts I and II.
1985:	Lebanese Medical License.
1989:	FLEX parts I and II (State of New York)
1991:	Massachusetts Medical License
1996:	Diplomate in Otolaryngology- Head and Neck Surgery, American Board of Otolaryngology – Head and Neck Surgery.
2004:	Fellow, American College of Surgery

Clinical Activities

1996-	Outpatient MEE	4 half days/week
1996-	Operating room MEE	1 day/week
1995-	Outpatient Boston VA	2 half days/week
1995-	Operating room Boston VA	1 day/week

My clinical practice encompasses most areas in the field of otolaryngology – head and neck surgery, but with special emphasis on rhinology, paranasal sinus disorders, and obstructive sleep apnea (OSA) / sleep-disordered breathing. I have offices at both the Massachusetts Eye and Ear Infirmary, and the VA Boston Healthcare System. At both facilities, I work in close association with the sleep disorders clinics and laboratories. I see close to 4000 outpatient clinic visits and perform 300 operations on an annual basis at both facilities.

I get patient referrals locally, regionally, nationally, and internationally for treatment of sleep disordered breathing and rhinosinusitis. Veteran patients diagnosed with sleep-disordered breathing and advanced sinonasal disease are referred to me from the various VA hospitals and clinics in VISN-I.

Clinical Innovations:

- Established a surgical Otolaryngology service at the West Roxbury VA. We have been able to provide a fully array of otolaryngology clinical care at the West Roxbury Campus, including supporting role to other surgical and medical services, until the merger with Jamaica Plain VA
- Popularized radiofrequency soft palate ablation (somnoplasty) as a treatment for snoring and mild obstructive sleep apnea at the Massachusetts Eye and Ear Infirmary. This led to an increase in patient volume and the surgical treatment of patients who suffer from snoring or mild obstructive sleep apnea in the office setting. Patients are typically able to

resume their regular daily activities on the day of surgery with minimal discomfort and low morbidity.

- Introduced tongue base radiofrequency ablation as a treatment for patients with obstructive sleep apnea at the Boston VA HealthCare System. This treatment allowed us to treat sleep apnea patients where the site of obstruction is the hypopharynx (tongue base area) and have failed palatopharyngeal surgery and CPAP therapy. This surgery has low morbidity and a short hospital stay (patients are either discharged on the day of surgery or monitored for 23 hours).
- Introduced palate implant as a treatment for patients with snoring and mild obstructive sleep apnea syndrome at the Massachusetts Eye and Ear Infirmary. This is another office procedure intended to treat patients with snoring or mild sleep apnea. This procedure is fairly successful and with very low morbidity.
- Introduced DISE (drug-induced sleep endoscopy) in the surgical planning for patients with obstructive sleep apnea at the Massachusetts Eye and Ear Infirmary. DISE can be instrumental in surgical planning for patients with obstructive sleep apnea. Awake fiberoptic laryngoscopy can have several shortcomings, major among them is the fact that the patient is being examined while awake and hence the findings might not reflect the anatomic changes during natural sleep.
- Co-founded the Harvard wide sleep apnea multispecialty service which aims at providing comprehensive medical and surgical care for patients suffering from sleep disordered breathing across Harvard Affiliated Hospitals. In addition, we organized the first CME course which is scheduled in the last week of September 2016.

Report of Education of Patients and Service to the Community:

Local Community Activities:

2007, 2008: Medical Management of Rhinosinusitis. In: Public Forum on Rhinosinusitis, Massachusetts Eye and Ear Infirmary. Lay people (50 persons attended). Lecturer.

2007-2011: Medical Management of Rhinosinusitis: Public Forum on Rhinosinusitis. Massachusetts Eye and Ear, Boston, MA

2013-2017: Medical Management of Rhinosinusitis: Public Forum on Rhinosinusitis. Massachusetts Eye and Ear, Boston, MA

2018: Medical Management of Rhinosinusitis: Health Sense 2018 – Know You Nose. Public Form, Massachusetts Eye and Ear, Boston MA

International Humanitarian Missions / Activities:

2002: Staff Surgeon, Medical Missions for Children, Quito, Ecuador. The mission lasted for 1 week. We evaluated approximately 90 patients and performed approximately 50 operations.

2008: Staff Surgeon, Medical Missions for Children, Guayaquil, Ecuador. The mission lasted for 1 week. We evaluated approximately 85 patients and performed approximately 55 operations.

2009: Staff Surgeon, Global Smile Foundation, Guayaquil, Ecuador. The mission lasted for 1 week. We evaluated approximately 115 patients and performed 60 surgical procedures on 45 patients.

2016: Staff Surgeon, Global Smile Foundation, Guayaquil, Ecuador. The mission lasted for 1 week. We evaluated approximately 250 patients with congenital cleft lip and / or palate deformity. We performed 57 surgical procedures on 48 patients.

Report of Scholarship

Peer Reviewed Research Publications:

1) Levine R, **Busaba NY**, Brown C. Laser Doppler measurements and electrocochleography during ischemia of the guinea pig cochlea: Implications for hearing preservation in acoustic neuroma surgery. Ann Otol Rhinol Laryngol 1993; 102: 127-36.

2) **Busaba NY**, Rebeiz E, Salman S, Thornton A, West C. The Significance of a false-positive auditory brainstem response: A prospective study. Am J Otol 1994; 15: 233-6.

3) **Busaba NY**, Rauch S. The Significance of ABR and gadolinium-enhanced MRI for idiopathic sudden sensorineural hearing loss (ISSHL). Otolaryngol Head Neck Surg 1995; 113: 271-5.

4) **Busaba NY**. Clinical presentation and management of labyrinthine fistulas caused by chronic otitis media. Ann Otol Rhinol Laryngol 1999; 108: 435-9.

5) **Busaba NY**, Fabian R. Extent of lymphadenectomy achieved with various modifications of neck dissection: A pathologic study. Laryngoscope 1999; 109:212-15.

6) **Busaba NY**, Salman SD. Maxillary sinus mucoceles: Clinical presentation and long-term results of endoscopic surgical treatment. Laryngoscope 1999; 109: 1446-9.

7) **Busaba NY**, Siegel N, Salman SD. Bacteriology of non-traumatic maxillary sinus mucoceles versus chronic sinusitis. Laryngoscope 2000; 110:969-71.

8) **Busaba NY**, Ishoo E, Kieff D. Open Zenker's diverticulectomy using stapling techniques. Annal Otol Rhinol Laryngol 2001; 110:498-501.

9) **Busaba NY**. Is imaging necessary in the evaluation of the patient with an isolated complaint of anosmia? Ear Nose Throat J 2001; 80:892-6.

10) **Busaba NY**. Same stage nasal and palatopharyngeal surgery for OSA: Is it safe? Otolaryngol Head Neck Surg 2002; 126:399-403.

11) **Busaba NY**, Kieff D. Endoscopic sinus surgery for inflammatory maxillary sinus pathology. Laryngoscope 2002; 112:1378-83.

12) Kieff D, **Busaba NY**. Treatment of isolated sphenoid sinus inflammatory disease by endoscopic sphenoidotomy without ethmoidectomy. Laryngoscope 2002; 112:2186-8.

13) Kieff DA, **Busaba NY**. Same-day discharge for selected patients undergoing combined nasal and palatal surgery of obstructive sleep apnea. Ann Otol Rhinol Laryngol 2004; 113:128-31.

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Thesis (Triologic Society):

Predictors of prolonged length of stay after major elective head and neck surgery. This thesis was reviewed and accepted by the Triologic Society Board for induction as a fellow into the society in 2007.

Abstracts:

1) 2012: Ting J, Wu A, Holbrook E, Metson R, Gray S, **Busaba NY**, Bleier B. Choice of Nasal Packing Following Skull Base Reconstruction: Analysis by Subsite. American Rhinologic Society Meeting / COSM, San Diego, CA. (Poster Presentation).

Narrative Report:

I am involved in several professional activities, which include running a busy clinical practice, teaching of medical students and other health care professionals, training and mentoring of residents and fellows, and conducting clinical as well as basic science research.

Clinical: My clinical practice encompasses most areas in the field of otolaryngology – head and neck surgery, but with special emphasis on rhinology, paranasal sinus disorders, and obstructive

sleep apnea (OSA) / sleep-disordered breathing. I have offices at both the Massachusetts Eye and Ear Infirmary and the VA Boston Healthcare System. I am a member of the Division of Rhinology and the Division of General Otolaryngology at the Massachusetts Eye and Ear Infirmary and the Division of Otolaryngology at the Boston VA HealthCare System. I work in close association with the sleep disorders clinics and laboratories and I a member of the sleep apnea multispecialty services at both medical facilities and their affiliated institutions.

Administrative: The Division of Otolaryngology at the West Roxbury/Brockton VA was rejuvenated under my leadership when I joined the department of surgery and was appointed the chief of the division in July 1995. I expanded the Division to encompass all aspects of Otolaryngology including head and neck oncology service. The division was transformed into a major clinical service at the VA providing inpatient consultations, outpatient clinic service, and surgical service. I later helped integrate the divisions of otolaryngology at the Boston and West Roxbury/Brockton campuses following the merger of the two VA's and currently serve as the Associate Chief of Otolaryngology at the VA Boston HealthCare System. The Division of Otolaryngology at the VA Boston HealthCare System serves at the major tertiary center for Otolaryngic disease in VA- VISN I. In addition, I served for two years as the Assistant Director, Snoring and Sleep Apnea Center, at the Massachusetts Eye and Ear Infirmary.

Teaching: I have teaching responsibilities at Harvard Medical School, Massachusetts Eye and Ear Infirmary, and Boston VA HealthCare System. I am involved in the education of third year HMS students who rotate at the Massachusetts Eye and Ear Infirmary and second year HMS students who spend a clerkship rotation at the Boston VA HealthCare System. In addition, I train Harvard University Otolaryngology residents and Rhinology Fellows. I have participated in several instructional courses for Otolaryngology residents at both Harvard and Boston University medical schools, given several Grand Rounds at my primary hospitals as well as regional hospitals, and served as a faculty on multiple regional Specialty Instructional Courses (CME courses).

I started a Division of Rhinology (Massachusetts Eye and Ear Infirmary) monthly Journal Club alternating with Special Problems in Rhinology sessions in 2012.

The American Academy of Otolaryngology – Head and Neck Surgery and the American Rhinologic Society appointed me to the Rhinology and Allergy Education Committee and the Education Committee respectively. These committees are in charge of developing educational material in related clinical fields to their worldwide membership such as Academy-U that was developed by the American Academy of Otolaryngology – Head and neck Surgery.

I mentor international research fellows at the Massachusetts Eye and Ear Infirmary. These fellows can be otolaryngologists who are already in practice, to fresh graduates of residency training programs, to medical school graduates. The mentees participate in clinical and basic science research as well as shadow me in the outpatient clinic and operating rooms. Several went back to their home countries and joined academic centers

I participated in several international meetings and instructional courses (as a lecturer, panelist, or faculty) in Mexico, Brazil, Sultanate of Oman, Turkey, and multiple European countries.

In addition, I served as an Invited Professor at several national and international institutions where I gave lectures and ran discussion groups with their trainees and faculty. These included Little Falls Hospital (Little Falls, New York), Medical Center Hospital (Odessa, Texas), University of Nevada School of Medicine, Department of Family and Community Medicine (Las Vegas, Nevada), Universidad Autonoma De Nuevo Leon, (Monterrey, Mexico), and hôpital Notre-Dame du Liban (Jounieh, Lebanon).

Research: My research interests are in the fields of Rhinology and Paranasal Sinus Disorders, and Sleep-Disordered Breathing. I authored and co-authored several peer-reviewed papers and chapters in Otolaryngology textbooks in the fields of obstructive sleep apnea, surgery for paranasal sinus disease, and anatomy and histology of the nasopharynx. I served as a PI on a project to correlate outcome of nasal surgery in patients with sleep-disordered breathing with CT based volumetric measurements of the nasal and pharyngeal airway. I was an investigator on a project looking into the efficacy of Nifedipine in the treatment of recalcitrant chronic rhinosinusitis with nasal polyposis, and an investigator on a project exploring the clinical predictors of surgical success for septoplasty alone vs septoplasty with nasal valve reconstruction.

APPENDIX B

Appendix B: Materials Considered

No.	Description
1001	U.S. Patent No. 10,894,011
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
1010	U.S. Provisional Appl. No. 60/702,077
1011	U.S. Provisional Appl. No. 60/747,771
1012	U.S. Patent No. 7,608,275
1013	U.S. Patent No. 8,133,497
1014	U.S. Patent No. 8,338,164
1015	U.S. Patent No. 8,961,391
1016	U.S. Patent No. 9,498,283
1017	U.S. Patent No. 10,022,529
1019	U.S. Patent No. 10,729,897
1020	Prosecution History for 10,729,897
1021	U.S. Patent No. 10,610,675
1024	Prosecution History for U.S. Patent No. 10,894,011
1026	U.S. Patent No. 7,655,243
1028	Prosecution History for U.S. Patent No. 8,636,684
1029	U.S. Patent No. 8,105,817
1030	U.S. Patent No. 8,636,684
1031	U.S. Patent Pub. No. 2014/0114233
1032	U.S. Patent No. 9,700,707
1033	U.S. Patent No. 10,052,465
1034	File History for U.S. Patent No. 10,335,221 assigned to Aerin
1040	U.S. Patent No. 8,939,970 to Stone
1041	Stedman's Medical Dictionary (27th ed. 2001)
1042	PDR Medical Dictionary (2nd ed. 2000)

No.	Description
1043	Kong Yonggang, *Low-temperature plasma ablation of inferior turbinate for the treatment of perennial allergic rhinitis*, 19(5) J Clin. Otorhinolaryngol 214 (Mar. 2005) (Translation) ("Kong")
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")
1045	Liang Jianping, *Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy*, 13(8) J Clin. Otorhinolaryngol 341 (Aug. 1999) (Translation) ("Liang")
1046	U.S. Patent No. 6,669,689 to Lehmann
1047	U.S. Patent No. 6,685,648 to Flaherty
1048	Stedman's Medical Dictionary (26th ed. 1995)
1049	Webster's Third New International Dictionary (2002)
1050	Seth Waxman, *Correlative Neuroanatomy* (23rd ed. 1996)
1051	Robert E. Windsor and Scott Jahnke, *Sphenopalatine Ganglion Blockage: A Review and Proposed Modification of the Transnasal Technique*, Pain Physician 7:283-286 (2004)
1052	Ralph Fenton, *Current Evaluation of Nasopharyngeal Defense Mechanisms* (1955)
1053	U.S. Patent No. 6,517,534 to McGovern
1054	M.M. L. Arora, *Cryodestruction of Vidian Nerve Branches*, 32:3 Indian J. Otolaryngology 80 (Sept. 1980)
1055	U.S. Patent Pub. No. 2014/0243793 to Morriss
1056	Maureen Sackenheim, *Radio Frequency Ablation*, JDMS 19:88-92 (March/April 2003)
1057	U.S. Patent No. 5,766,605 to Sanders
1058	U.S. Patent No. 874,178 to De Forest
1059	U.S. Patent Pub. No. 2005/0171574 to Rubinsky
1060	U.S. Patent No. 3,538,919 to Meyer
1061	U.S. Patent No. 3,117,571 to Fry
1062	International Pub. No. 2016/183337 to Townley

No.	Description
1064	Andrew Lane, *Nasal anatomy and physiology*, Facial Plast. Surg. Clin. N. Am. 12:387-395 (2004)
1065	Gray's Anatomy (2003)
1066	U.S. Patent No. 6,273,886 to Edwards
1068	U.S. Patent No. 5,255,679 to Imran
1071	Translator Declarations for Chen
1072	Translator Declarations for Liang
1073	Translator Declarations for Fang
1074	Translator Declarations for Kong
1079	Munford Appendices for Shanghai

APPENDIX C

Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
1[pre]	Apparatus for treatment of a nasal condition by altering function of a nasopharyngeal passage of a patient, the apparatus comprising:	**Ground I** **Ground IV**
1[a]	a hand-held elongate body having proximal and distal portions, the distal portion being configured for positioning in a nasopharyngeal passage of a patient with the proximal portion positioned outside the nasopharyngeal passage;	
1[b]	an energy transmission element in the distal portion configured to deliver energy to target tissue in the nasopharyngeal passage; and	
1[c]	an energy source operatively coupled to the energy transmission element for supplying energy thereto according to one or more parameters selected so as to alter nasopharyngeal cells in the target tissue such that nasal congestion is reduced.	
2	The apparatus of claim 1, wherein the energy transmission element comprises at least one electrode.	**Ground I** **Ground IV**
5	The apparatus of claim 1, wherein the energy supplying means comprises an RF generator.	**Ground I** **Ground IV**
8	The apparatus of claim 1, wherein the energy transmission element is movable relative to the distal portion of the body.	**Ground I** **Ground IV**
9	The apparatus of claim 8, wherein the energy transmission element is configured to deliver energy laterally relative to the distal portion of the body.	**Ground I** **Ground IV**

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
10	The apparatus of claim 9, wherein the energy transmission element is configured to extend laterally from the distal portion of the body.	**Ground I** **Ground IV**
12	The apparatus of claim 1, further comprising: a sensing element on the distal portion of the body.	**Ground I** **Ground II** **Ground IV**
14	The apparatus of claim 12, further comprising: a monitoring system operatively coupled to the sensing element for indicating a degree of treatment of the target tissue.	**Ground I** **Ground II** **Ground IV**