

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.

Petitioners,

v.

AERIN MEDICAL INC.,
Patent Owner.

Case No. IPR2024-00277

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

**DECLARATION OF DR. JOHN DELGAUDIO REGARDING
CLAIMS 1-4, 6-12, 16 OF U.S. PATENT NO. 11,241,271**

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I, John DelGaudio, declare as follows:

I. INTRODUCTION

1. My name is John DelGaudio. I am a Professor in the Department of Otolaryngology at Emory University School of Medicine. I also serve as director of Emory Sinus, Nasal, & Allergy Center. I am also the Chief of Rhinology, Sinus, and Skull Base Surgery.

2. I have been retained as an expert in this proceeding by counsel for Neurent Medical Inc. and Neurent Medical Ltd. (collectively, “Neurent” or “Petitioners”). I have been asked for my expert conclusions regarding the validity of claims 1-4, 6-12, 16 of U.S. Patent No. 11,241,271 (the “’271 patent”) (Exhibit 1001-USP271). For the reasons set forth below, it is my conclusion that claims 1-4, 6-12, and 16 of the ’271 patent are invalid.

II. QUALIFICATIONS AND EXPERIENCE

3. My curriculum vitae, which describes my education, experience, professional activities, and which lists, *inter alia*, my publications and patents, is attached as **Appendix A**. Below is a summary of my education, work experience, and other qualifications.

4. I received a Bachelor of Arts from LaSalle University in 1985 and a Medical Doctorate from Jefferson Medical College in 1989. After receiving my

medical degree, I completed an internship in general surgery at Lankenau Hospital in Philadelphia, PA, from 1989 to 1990, and a residency in the Department of Otolaryngology at the University of Michigan Hospital, Ann Arbor, from 1990 to 1995. During my residency, I received a National Institutes of Health-funded research fellowship for research on laryngeal muscles.

5. Following my residency, I joined the faculty of the Emory University School of Medicine in the Department of Otolaryngology – Head and Neck Surgery. I was an assistant professor from 1995 to 2004 and an associate professor from 2004 to 2009, and I have been a full professor since 2009. From 2010 to 2021, I served as vice chair of the department and have also served as the Chief of Rhinology, Sinus, and Skull Base Surgery since 2004.

6. As a professor, the focus of my research is in the field of rhinology, i.e., conditions of the nose and sinus. Ongoing clinical studies focus on topics including office rhinologic surgery (performing surgical procedures on the nose and sinus structures in the office setting), central compartment atopic disease (I described and characterized a new subset of chronic sinusitis with nasal polyps that is related to allergy), nasal allergy (including allergic rhinitis and its symptoms, e.g., post nasal drip and chronic cough), nasal polyps, idiopathic intracranial

hypertension and skull base defects (repairing defects between the brain and nose/sinuses), and endoscopic orbital surgery.

7. I have regularly published my research findings in academic journals and conferences. To date, I have published over 150 articles in peer-reviewed journals and presented at over 100 national and international conferences. I have also served as a manuscript reviewer for journals including all of the major Otolaryngology journals in the US, and I currently serve on the editorial board for the International Forum of Allergy and Rhinology.

8. I have received numerous accolades and honors for my research. For example, in 2019 my collaborators and I were awarded Best Clinical Research Paper at the International Society for Inflammation and Allergy of the Nose (ISIAN) Rhinoworld conference for a study entitled “Central Compartment Involvement in AERD: The Role of Allergy and Previous Surgery” (first paper to describe the presence of allergy mediated polyps in patients with a condition that includes asthma, aspirin sensitivity, and polyps). I have been awarded the Golden Head Mirror Award by the American Rhinologic Society. This is an award given no more than once yearly and is for meritorious teaching at the national level. I have been awarded both the Gerald Gussack Award and the Lester Brown Award by the Georgia Society of Otolaryngology. These are teaching and service awards.

9. In addition to my academic research, I have almost three decades of experience in clinical practice as an otolaryngologist. I received my medical license in Georgia in 1995 and was admitted to the American Board of Otolaryngology – Head and Neck Surgery in 1996. Since 1995, I have practiced as an attending physician for Atlanta-area clinics and hospitals, including the Emory Clinic, Egleston Children’s Hospital, Grady Memorial Hospital, and Atlanta Veteran’s Administration Hospital. These include basic conditions such as nasal congestion, allergic and non-allergic rhinitis, and anatomic obstruction such as deviated nasal septum and internal nasal valve collapse. Some of these conditions can be treated with medications and office surgeries. More complex conditions that I treat in my practice are sinus and nasal tumors (benign and malignant), cerebrospinal fluid leaks and meningoencephaloceles (connections between the brain and nose/sinuses), orbital tumors and other orbital conditions (such as bulging eyes from thyroid eye disease).

10. I have been practicing Otolaryngology and Rhinology since 1995. As part of my practice I have frequently used radiofrequency (RF) energy for the treatment of nasal conditions such as inferior turbinate hypertrophy and rhinitis, and to treat the tongue and palate for sleep apnea and snoring.

11. Throughout my career, I have been deeply engaged in professional organizations in the field of otolaryngology. From 2016 to 2017, I was the president of the American Rhinologic Society, the world's largest physician organization focused on the treatment of patients with diseases of the nose and paranasal sinuses. Outside of my term as president, I have served in various other senior roles with the American Rhinologic Society, including vice president, board member, and representative to the International Forum of Allergy and Rhinology LLC. I also served as the president of the Georgia Society of Otolaryngology from 2009-2010, and I currently serve on its board of directors. Since 2010, I have been on the editorial board of the International Forum of Allergy and Rhinology.

12. I am being compensated for my work on this matter, but my opinions are based on my own views of the prior art and patented technology. To the best of my knowledge, I have no financial interest in either party or in the outcome of this proceeding.

III. LEGAL PRINCIPLES

13. 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

14. 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

15. 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

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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 '271 patent discussed in this declaration.

D. Claim Dependency

24. 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.

* * *

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

IV. MATERIALS CONSIDERED

26. In preparing this declaration, I reviewed and considered the materials identified in **Appendix B** as well as any document cited in this declaration. I have

also relied on a conversation with Dr. Gregory Martin and have reviewed his declaration.

V. LEVEL OF ORDINARY SKILL IN THE ART

27. It is my understanding that when considering the claims of the '271 patent and the prior art, I must do so based on the perspective of one of ordinary skill in the art at the relevant effective filing date.

28. I understand 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.

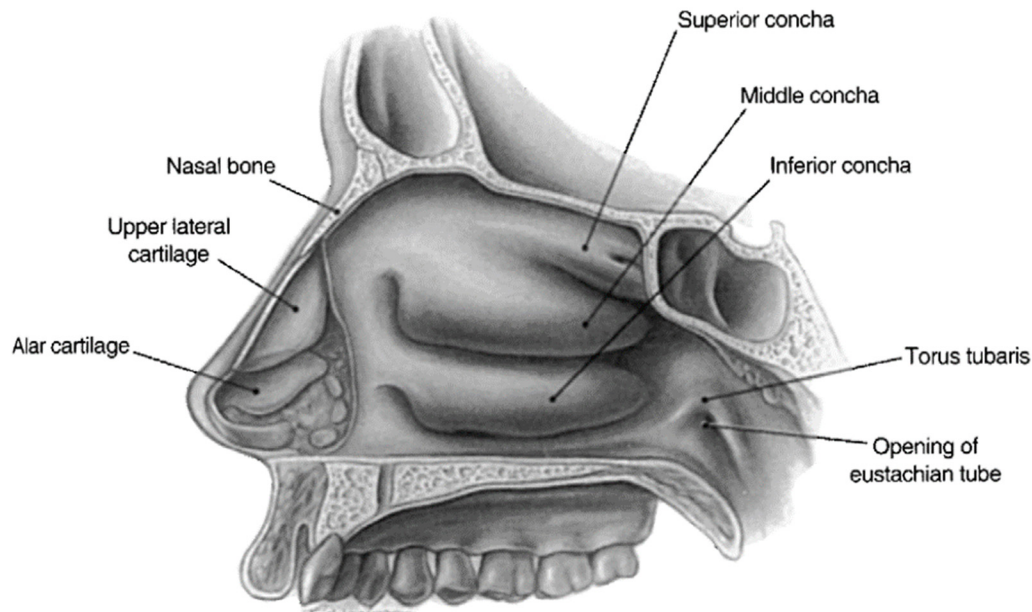
29. Based on these factors as well as my experience and expertise, a person of ordinary skill in the art at all relevant times (2011-2019) would have had (1) a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline and (2) at least three years of experience in the clinical use, design, development, and/or testing of medical devices, including medical devices that deliver energy to tissue. A higher level of education may compensate for less work experience, and vice versa. Before June 14, 2011, which

is the claimed priority date of the '271 patent, I would have qualified at least as a person of ordinary skill in the art under this standard.

VI. OVERVIEW OF THE TECHNOLOGY

A. Anatomical Features of the Nose and Upper Airways

30. The nose is roughly symmetrical, with the same anatomical features present on (or within) the left and right sides of the nose. Air enters the nose through the left and right nostrils. The figure below is a simplified depiction of the internal anatomy of the right side of the nose and nasopharynx.



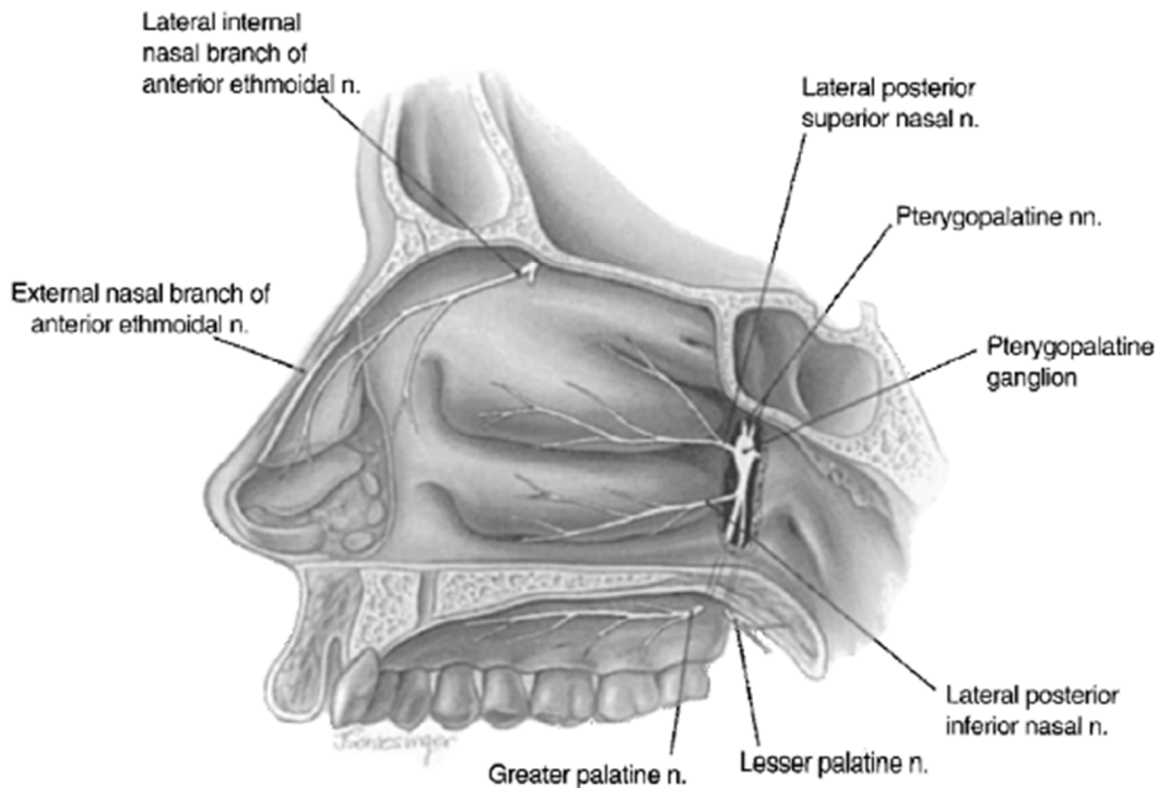
Ex.1060-Lane, FIG.1 (“Lateral nasal wall anatomy. Left side of the nose [*sic*]¹ with nasal septum removed”). Below, I describe certain anatomical features of the nose between the nostrils at the front (or anterior) of the nose and the nasopharynx at the back (or posterior) of the nose.

- Nasal cavity is the large space located behind the external nose that is accessed through the nostrils, in which the anatomical structures below are located. The nasal cavity and the structures within it function to “lubricate and humidify inspired air while removing airborne particles before they reach the lower airway.” *Id.*, 393. The nasal cavity also “warms inspiratory air through ... flow that maximizes contact with the available mucosal surface area.” *Id.*
- Nasal septum is situated between the left and right side of the nose and partitions the nasal cavity into two sides). *See id.*, 387-388.

¹ Although the caption states “left side,” the figure shows the right side of the nose, which is consistent with other similar figures in the paper being identified in their captions as showing the right side of the nose. *See* Ex.1060-Lane, FIGs.2, 4.

- Upper lateral cartilage is a roughly triangular shaped structure that forms the roof (upper boundary) of the middle portion of the nose. *See id.*, 394.
- Internal nasal valve is the narrowest part of the nasal airway and is located at the junction of the upper lateral cartilage, septum, and anterior part of the inferior turbinate (although those structures are not part of the valve itself and only define its boundaries). *See id.*, 388.
- Turbinates (sometimes called “concha”) protrude from the lateral wall of the nasal cavity and are located posterior to the internal nasal valve. Typically there are three turbinates – inferior, middle, and superior – with the inferior turbinate being the bottommost and largest turbinate. The turbinates increase the interior surface area of the nose and help transfer heat and moisture to inhaled air. Ex.1021-Makower, [0004].
- Mucosal tissue lines the interior surfaces of the upper airways, performing the functions of producing and draining mucus (i.e., mucociliary transport), which serves as a filter and lubricator for the nose and airway. *Id.*

31. The nerve supply of the lateral wall of the right side of the nose is illustrated below.

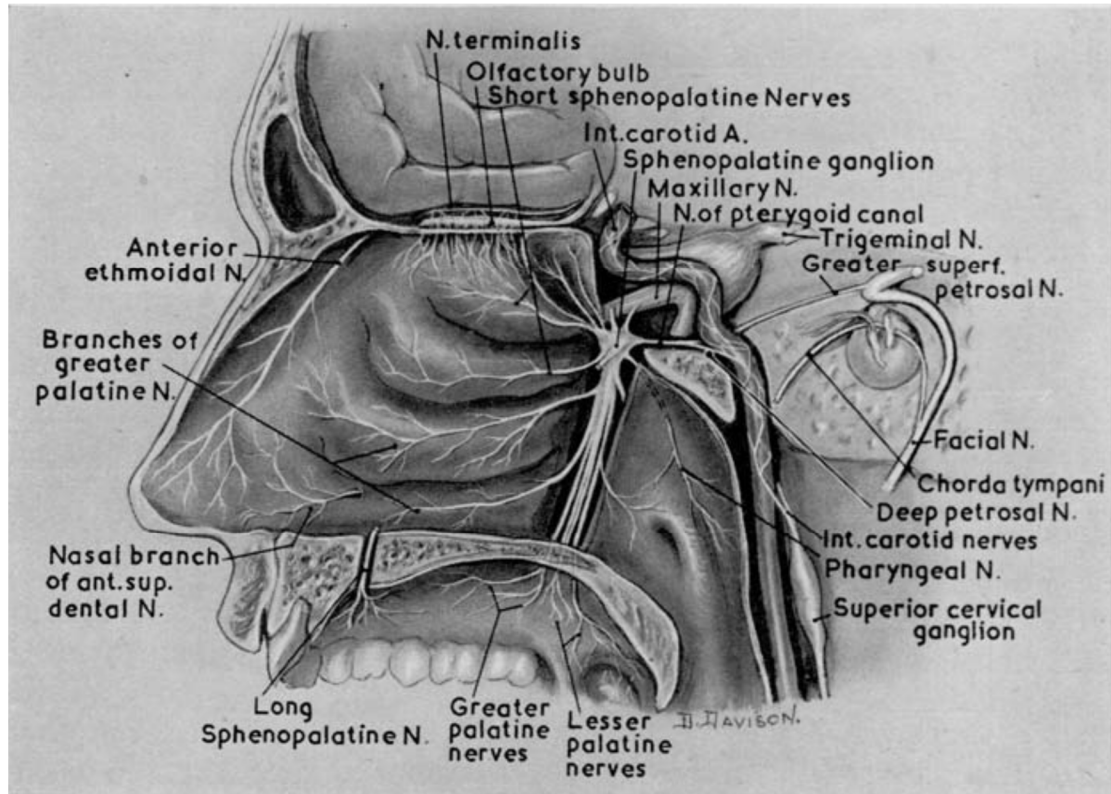


Ex.1060-Lane, FIG.4 (“Right lateral wall of the nose showing nerve supply.”).

Branches of the ophthalmic and maxillary divisions of cranial nerve supply sensation to mucosal tissue lining the nasal passages. *Id.*, 390. For example, the illustration above depicts the posterior inferior lateral nasal nerve, which is a branch of the maxillary division that innervates the inferior turbinate. *Id.*

(“Posteroinferior nasal branches give sensation to the mucosa of the turbinates and lateral nasal wall”).

32. The posterior nasal nerves, such as the inferior lateral nasal nerve discussed above, are branches of the Vidian nerve, also called the nerve of the pterygoid canal (labeled “N. of pterygoid canal” in the illustration below).



Ex.1064-Mitchel, FIG.7. The figure shows that the Vidian nerve extends through the pterygoid canal and reaches a structure called the sphenopalatine ganglion. This structure is located in the pterygopalatine fossa, which connects to the nasal cavity by an opening on the lateral nasal wall called the sphenopalatine foramen. *Id.*, 505-507. The nerves branch out from the sphenopalatine ganglion into other locations throughout the upper airways through the sphenopalatine foramen,

including the turbinates, which are innervated by the posterior nasal nerve branches. As I explained above, the posterior nasal nerve branches include the posterior inferior nasal nerves located behind and within the inferior turbinate. The posterior nasal nerve branches also include posterior superior nasal nerves of the upper and middle turbinates. Another nerve—the nasociliary nerve—descends from a different path and branches into the ethmoidal nerve branches, which innervate the anterior portions of the turbinates. *Id.*, 507

33. It was well known that nerves, including the Vidian nerve and its branches, have a significant role in the production of mucus in the upper airways and the eyes. Ex.1060-Lane, 392; Ex.1064-Mitchel, 505-06. In particular, mucus production is a function of the autonomic nervous system that regulates involuntary physiologic processes. The autonomic nervous system is divided into the sympathetic, parasympathetic, and enteric divisions, of which the Vidian nerve and its branches are part of both the sympathetic and parasympathetic divisions. Functions of the sympathetic nervous system include increasing heart rate, suppressing the immune system, and increasing sweat gland secretions (often described as “fight or flight” functions). Functions of the parasympathetic nervous system include decreasing heart rates, activating the immune system, and releasing

mucosal and salivary glandular secretions (often described as “rest and digest” functions).

34. The structure and function of these and many other anatomical structures of the nose and upper airways would have been standard textbook knowledge to a person of skill in the art long before the claimed priority date of the '271 patent.

B. Rhinitis and Its Symptoms, Including Excessive Mucus Production

35. Medical conditions affecting the nose and upper airways have been extensively studied for decades prior to the '271 patent. One commonly diagnosed and well-understood condition is allergic rhinitis, an inflammation of mucosal tissue triggered by allergies. Ex.1037-Chung, 110 (“The concept of rhinitis implies inflammation of the nasal mucosa.”), 111 (“Allergic rhinitis is characterized by nasal obstruction, rhinorrhoea, sneezing, nasal pruritus and postnasal drip.”). Allergic rhinitis and its symptoms typically arise from “stimulation of the sensory [nerve] endings distributed” within the nose and the body’s response to that stimulation, which is carried out through parasympathetic nerves. Ex.1049-Konno, 108 (“[N]asal hypersecretion observed in allergic rhinitis is considered to be caused by histamine-induced stimulation of the sensory endings

distributed in the nasal epithelium.”), 111; Ex.1048-Nomura, 493 (“The characteristic sym[p]toms of allergic rhinitis are rhinorrhea, nasal obstruction and sneezing, the first two of which are due to the predominant manifestation of parasympathetic nerve stimulation.”).

36. Overactive parasympathetic nerves (which include the posterior inferior lateral nasal nerve) in particular have also been identified as an underlying cause of excess mucus production associated with vasomotor rhinitis and other conditions of the upper airways. Ex.1048-Nomura, 498 (describing how “nasal glands” are controlled by autonomic nervous system including parasympathetic nerves), Abstract (“over-stimulated” nerves “produce profuse nasal secretion”); Ex.1049-Konno, 106 (“Since the 1950s, vasomotor rhinitis has been thought to result from an imbalance in the autonomic input, particularly from overstimulation of the parasympathetic nervous system of the nasal mucosa.”).

C. Techniques for Treating Rhinitis and Its Symptoms, Including Excessive Mucus Production

37. Known treatments for rhinitis and its symptoms often target nerves within the nose. For example, a “posterior nasal neurectomy,” in which posterior nasal nerves are cut or removed, has been described as offering “superb clinical effectiveness.” Ex.1049-Konno, 110, Abstract (“Considering the long-term side

effects of inhibition of lacrimation and possible partial recurrence of hyperreactive nasal symptoms observed after vidian neurectomy, less invasive endoscopic posterior nasal neurectomy [(i.e., treatment of posterior nasal nerves)] is considered the treatment of choice for patients with allergic rhinitis who require surgical intervention.”). Other clinicians have also reported that targeting the ethmoidal nerve to treat rhinitis was very successful. *See* Ex.1056-Liang, Abstract (“Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy has such advantages as significant therapeutic effect, convenient operation, and accurate treatment site, and has good clinical application values.”); Ex.1017-Chen, Abstract (“treating PAR [perennial allergic rhinitis] with nasal posterior-under nerve, ethmoidal nerve and infratubinal radiofrequency under nasal endoscope is highly effective, easy to perform and [has] few complications, so it is a good way to treat PAR.”).

38. The posterior nasal neurectomy is based on the “Vidian neurectomy” (surgically cutting/transecting the Vidian nerve), which has been used to treat rhinitis and its symptoms (including excessive mucus production) since at least the 1970s. *See, e.g.*, Ex.1048-Nomura, 493-95 (discussing Vidian neurectomy for treating rhinitis in 1972); Ex.1049-Konno, 105-106 (describing history of Vidian

neurectomies dating back to the 1970s); Ex.1029-Arora, Abstract (describing destruction of the Vidian nerve as the “treatment of choice” for rhinitis in 1980).

39. As I explained previously, branches of the Vidian nerve extend to many locations outside of the mucus-producing regions of the nose, including the eyes. As a result, patients who received Vidian neurectomies occasionally reported complications such as severe dry eye. *See* Ex.1049-Konno, 110. Accordingly, by the early 2000s the popularity of Vidian neurectomies was eclipsed by procedures like the posterior nasal neurectomy (described at the beginning of this section), which targets parasympathetic branches of the Vidian nerve closer to the target mucus-producing regions of the nose. *Id.* Another example of such a procedure is described in Kong, in which RF energy is delivered to nerve branches downstream from the sphenopalatine ganglion to “damage[e]...the parasympathetic nerve fibers from the inferior turbinate”—i.e., the posterior inferior nasal nerves—thereby “reducing gland secretion.” Ex.1040-Kong, 215.

D. Using Energy to Treat Medical Conditions

40. A common technique for treating medical conditions is to deliver various forms of energy (e.g., light, sound, heat, etc.) to target tissue within the body. Illustrative examples of energy based treatments, some of which pre-date the '271 patent by as much as a century, include the following:

- Ex.1025-De Forest (U.S. patent issued in 1907), 1:8-23 (“My invention relates to devices for producing burning effects by means of high frequency electrical currents, and more particularly to cauteries employed in surgery.... I have discovered that when a conductor is attached to any part of a high-frequency oscillating circuit, the high frequency electrical current passing into a body, for example, a human body, will produce a heating or burning effect at the point of contact of the electrode conveying such currents to said body...”)
- Ex.1026-Meyer (U.S. patent issued in 1970), 1:35-40 (“In this illustration depilation is accomplished by inserting the probe 6 into the follicle 9 of hair 10 to terminate at the papilla, and transmitting a metered amount of laser energy through the laser beam transmitting rod 11 to destroy the tissue immediately surrounding the terminal end 12 of the laser probe 6.”)
- Ex.1027-Fry (U.S. patent issued in 1964), 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.”)
- Ex.1046-Olinger (U.S. patent issued in 1976), 3:32-40 (“The invention is particularly useful for inspecting, studying and treating the nervous system

and particularly the spinal cord, as, for example, in making radiofrequency lesions in nerve tracts, under direct visual supervision, in patients with intractable pain or spasticity. Now, for the first time, an electrode may be inserted percutaneously into the spinal pathways under direct visual control to make radiofrequency lesions in patients with intractable pain.”)

- Ex.1047-Turner (U.S. patent issued in 1981), 5:55-60 (“As seen in FIG. 1, a broadband electromagnetic radiation (EMR) system or apparatus 10 for irradiation of living tissue or tissue simulating material comprises generally an EMR or microwave generator or source 12 to which is electrically connected, by a transmission means or line 16, EMR irradiating means 14.”)

E. Using Energy to Treat Conditions of the Nose and Upper Airways

41. It was also known to deliver energy based treatment, such as those described in the previous section, to mucosal and submucosal tissue of the nose to treat conditions of the nose and upper airways. For example, prior to the claimed priority date of the '271 patent, energy based treatments had been disclosed for treating upper airway conditions including the following:

- Sinusitis; *see, e.g.*, Ex.1021-Makower, Abstract (“Sinusitis ... and other disorders of the ear, nose and throat are diagnosed and/or treated using minimally invasive approaches and, in many cases, flexible catheters as

opposed to instruments having rigid shafts. Various diagnostic procedures and devices are used ... to facilitate insertion of working devices (e.g.,...energy emitting devices[])]”);

- Rhinitis; *see, e.g.*, Ex.1019-Gertner, [0066] (“The particular nasal cavity being treated may determine the energy density or dosage requirements.... In the case where the nasal cavity is being treated and rhinitis is the disease, the dosage from the tip 118 may be chosen appropriately”); Ex.1017-Chen, 239-40 (“From September 2002 to March 2003, 40 patients with [perennial allergic rhinitis] (observation group) were treated with radiofrequency thermocoagulation of the posterior inferior nasal nerve, anterior ethmoidal nerve, and inferior turbinate under nasal endoscopy”); Ex.1013-Baker, 5:15-19 (“Methods and systems of the present invention employ the application of acoustic energy ... to address a range of pathophysiological processes that accumulate, and interact, to cause various illnesses and conditions, and to produce undesired symptoms.”), 26:7-8 (“The methods and devices may be used for treating common colds, nasal congestion and allergic rhinitis, as well as sinusitis and other nasal conditions.”); Ex.1056-Liang, 341 (“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.”); Ex.1040-Kong, 214 (“From March 2003 to April 2004, low-temperature ablation plasma surgical system under nasal endoscopy was used in our department to treat 35 cases of perennial allergic rhinitis using inferior turbinate perforation and achieving satisfactory results”);

- Obstruction of a nasal meatus; *see, e.g.*, Ex.1010-Edwards-’535, 4:19-32 (“The present invention provides a method and apparatus for ablating at least a portion of a nasal concha (turbinate)... By reducing the size of a nasal concha, obstruction of a nasal meatus can be reduced.”), 5:33-35 (“Sufficient energy 117 is delivered through the surface 115 of the nasal concha 114 to ablate at least a portion 119 of the nasal concha 114”).

These treatments targeted the tissue located throughout the upper airways, including “mucous membranes [(i.e., mucosal tissue)] and nasal turbinates [(e.g., the superior, middle, and/or inferior turbinates)].” Ex.1013-Baker, 17:11-13.

42. In addition, energy based treatments had been disclosed for treating upper airway conditions using various forms of energy including the following:

- Electrical energy; *see, e.g.*, Ex.1038-Thapliyal, 7:56-8:15 (“The present invention provides systems and methods for selectively applying electrical energy to a target location within...[the] nasal cavity and sinuses. These

procedures may be performed through the mouth or nose....These procedures may include the removal of swollen tissue, chronically-diseased inflamed and hypertrophic mucus linings, polyps and/or neoplasms from the various anatomical sinuses of the skull, the turbinates and nasal passages.”);

- Light energy; *see, e.g.*, Ex.1019-Gertner, [0013] (“[A] therapy device for providing therapeutic light to a target region of tissue within a nasal cavity is provided.”);
- Radiofrequency (RF) energy; *see, e.g.*, Ex.1039-Banhiran, 950 (“[T]emperature-controlled radiofrequency volumetric reduction (RFVTR) has been applied to treat several upper airway diseases especially chronic rhinitis and obstructive sleep apnea. Its major mechanism is to produce thermal coagulation necrosis in the submucosal tissue by releasing specific radiofrequency (460 kHz) energy through a special probe under well-controlled temperature (60°-90°C).”);
- Acoustic energy (e.g., ultrasound); *see, e.g.*, Ex.1013-Baker, 16:19-22 (“[D]evices of the present invention [are used] for delivery of generally high frequency acoustic energy (e.g., ultrasound energy, including high intensity ultrasound (HIU) and high intensity focused ultrasound (HIFU) to tissue sites such as nasal passages.”).

It was known that applying these types of energy to tissues within the nasal passages could result in various desirable effects, including ablation of tissue, disruption of the normal function of the tissue (which can be desirable when seeking to reduce symptoms), and/or other forms of treatment. *Id.*, 8:17-24 (“Various systems and methods for delivery [of] acoustic energy to internal body sites for purposes of treatment, disruption, ablation and/or removal of undesired tissue or obstructions, and the like, are known in the art.”).

F. Using RF Energy to Treat Conditions of the Nose and Upper Airways

43. As I explained in the previous section, one form of energy used to treat conditions in the nose was RF energy, and by 2011, I personally was routinely treating patients using RF energy for upper airway conditions such as inferior turbinate hypertrophy, rhinitis, snoring, and sleep apnea. Consistent with my experience, various publications that pre-date the '271 patent describe using RF energy to treat many types of nasal conditions, including nasal polyps (Ex.1024-Hovda, 11:13-12:4), snoring, nasal obstruction secondary to non-allergic or allergic rhinitis (Ex.1031-Hytönen, Abstract), or to remove a blockage or shrink enlarged tissue (Ex.1010-Edwards-'535, Abstract; Ex.1023-Coste, 894; Ex.1024-Hovda, 11:13-31; Ex.1031-Hytönen, Abstract).

44. Devices used to deliver RF energy to the nose had been commercialized before the 2010s and were being used for clinical applications such as reducing the size of a patient's nasal turbinates to improve airflow. Ex.1021-Makower, [0020]-[0021], [0038]-[0040] (“One example of a radio frequency procedure that may be used to shrink enlarged inferior turbinates is radiofrequency volumetric tissue reduction (RFVTR) using the Somnoplasty® system (Somnus Medical Technologies, Sunnyvale, Calif.).”); *see also* Ex.1042-Bäck, Abstract, 1808 (describing “bipolar radiofrequency thermal ablation of the inferior turbinates in patients with nasal obstruction” with “ENTec Hummingbird wand”); Ex.1044-Lee, Abstract, 108-09 (same with Hummingbird wand and Reflex 45 wand from Arthrocare); Ex.1010-Edwards-'535, 4:53-67. The clinical results reported in these publications suggested that turbinate reduction using RF energy treatment was a promising option for reducing mucus production. Ex.1042-Bäck, 1808-10.

45. In the same timeframe of the late 1990s and early 2000s, other groups were using RF energy delivery devices to ablate nerves in the inferior turbinate and to thereby treat rhinitis to mitigate its symptoms, such as excess mucus production by. Ex.1040-Kong, 215; Ex.1017-Chen, 240; Ex.1055-Fang, 876; Ex.1056-Liang,

341; *see generally* Ex.1031-Hytönen (surveying effectiveness of RF ablation for various indications, including both nasal obstruction and rhinitis).

46. With respect to terminology, I note that various prior art references use the terms “radiofrequency” or “radio frequency” and the acronym “RF” interchangeably. *See, e.g.*, Ex.1040-Kong, Abstract (describing “radiofrequency ablation”), Title (same), 214 (describing use of an “RF electrode”); Ex.1033-Stern, 3:12-16 (describing “applying RF energy” using “a radio frequency power means”). Accordingly, in the context in which these terms are used throughout this declaration, a person of ordinary skill in the art would have understood references to “radiofrequency” energy to refer to “RF” energy and vice versa.

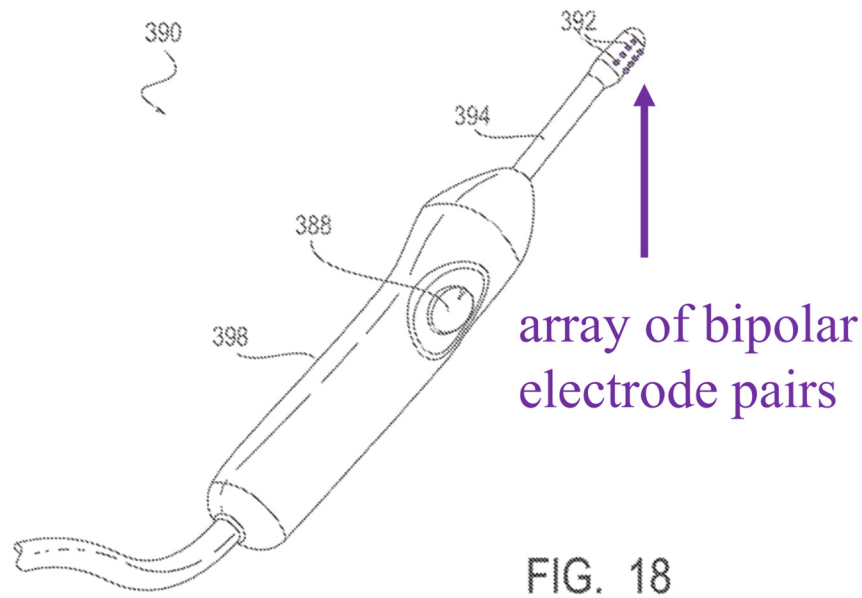
VII. OVERVIEW OF THE '271 PATENT

A. Overview of the '271 Patent

47. The '271 patent states in its introductory section, titled “Field of the Invention,” that the patent relates to “treating structures within the nose and upper airway” to “improve airflow.” Ex.1001-USP271, 1:34-43. Embodiments of the '271 patent place “emphasis...on structure and function of the nasal valve,” for example by “altering a structure, shape or conformation of...nasal structures...to modify, by reshaping, tissue at or adjacent the nasal valve.” *Id.*, 48:4-7, 5:56-61.

48. The challenged claims, however, do not recite limitations related to the structure and function of the nasal valve, and are instead directed to a method that “reduce[s] mucus production” by “applying radiofrequency energy ... to a target tissue underlying the nasal mucosa.” *Id.*, Clm.1. The ’271 patent does not elaborate on how applying radiofrequency energy can achieve the claimed reduction of mucus production; for example, it does not disclose details about the specific target tissue, RF energy delivery device, power level, target temperature range, or time of treatment, to achieve the intended outcome of reducing mucus production. Rather, the ’271 patent’s specification merely states in general terms that “any of the embodiments described above may be [used] to reduce mucus production...around any treated areas....[M]ucus reduction may also be part [of] the beneficial result of any treatment, in some embodiments.” *Id.*, 48:1-7.

49. One embodiment of a treatment device is depicted in Figure 18, reproduced below.



Id., FIG.18.² Figure 18 shows “pairs of bipolar electrodes 392” at a distal end of the treatment device. *Id.*, 26:63-67. The challenged claims require the claimed treatment device to have “two rows of bipolar electrode pairs.” *Id.*, Clm.1. The claims or specification do not further explain how such a configuration of the treatment device facilitates the goal of reducing mucus production. *Id.*, 48:1-7.

B. Examination of the '271 Patent Before the United States Patent and Trademark Office

50. The '271 patent was filed as a continuation patent application on July 17, 2019. Ex.1001-USP271, Cover. On July 25, 2019, the applicant filed a

² Annotations added unless otherwise noted.

preliminary amendment replacing as-filed claims 1-15 with new claims 16-31 (which correspond to the now-issued claims 1-16). Ex.1003-USP271FH, 416-22.

51. On July 19, 2021, the examiner issued a non-final office action rejecting each of then-numbered claims 16-31 for double patenting over the issued claims of the parent application. *Id.*, 47-49. The office action further stated, without elaboration, that claims 16-31 “would be allowable subject to filing an acceptable Terminal Disclaimer.” *Id.*, 49. In response, on October 11, 2021, the applicant filed a terminal disclaimer to overcome the double patenting rejection. *Id.*, 42-44. The applicant did not make any amendments to the challenged claims and did not present any substantive arguments contesting the examiner’s findings in the office action. *Id.*

52. Subsequently, on November 3, 2021, the examiner issued a notice of allowance, which did not include any statement of the examiner’s reasons for allowance. *Id.*, 7-11.

53. I understand and have been informed that there may be circumstances where the examination of a parent application provides additional information about the examiner’s reasons for allowing the challenged claims. However, in this case, the examiner’s apparent basis for allowing the parent application’s claims does not provide any basis for distinguishing the challenged claims from the

references in the Grounds below. During the examination of the parent application, the examiner issued a non-final office action in which certain claims of the parent application were rejected as being anticipated by U.S. Patent No. 6,109,268 (“Thapliyal”). Ex.1057-US489FH, 60-62. The applicant filed a response on June 6, 2019, in which the applicant amended the rejected claims to recite additional limitations including “*contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway.*” *Id.*, 47-50, 43-45. The applicant argued that the additional limitations were distinguishable from Thapliyal because, according to the applicant, “[a] primary objective of the Thapliyal device and method is to apply energy to fluid and not directly to tissue, in an attempt to reduce unwanted damage of the tissue.” *Id.*, 44. Subsequently, on July 5, 2019, the examiner issued a notice of allowance for the parent application, stating without elaboration that the applicant “filed significant reasons for allowance over the prior art [in] the response dated 6/6/2019.” *Id.*, 1-7.

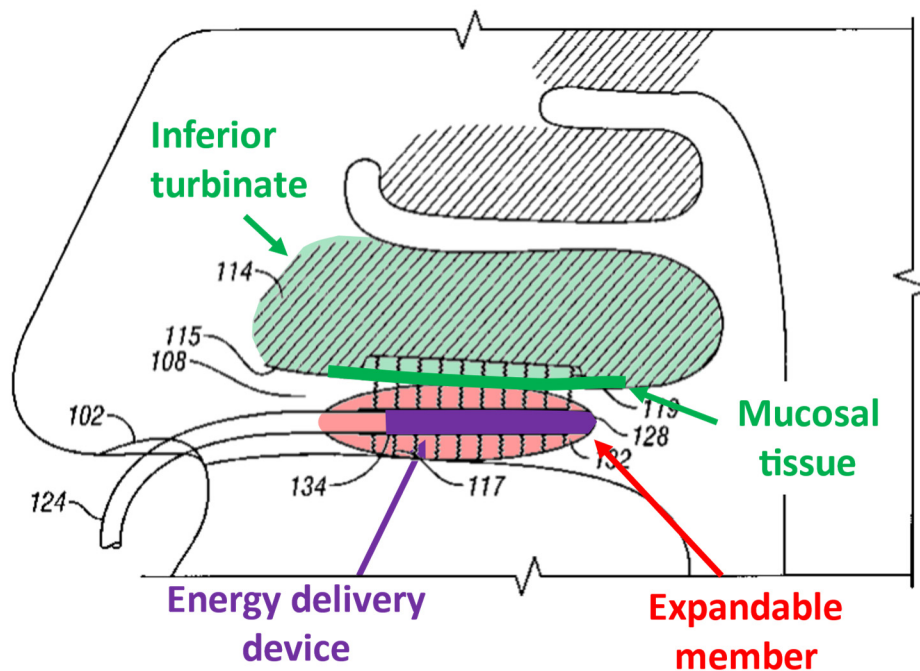
54. The challenged claims are similar to the allowed claims of the parent application, and the examiner identified both sets of claims as being “not patentably distinct from each other.” Ex.1003-USP271FH, 48. The challenged claims recite the same limitation that was added to the parent application’s claims to overcome Thapliyal: “*contacting a treatment element of a nasal airway*

treatment device directly with nasal mucosa of the nasal airway.” However, as I explain in further detail below, the challenged claims are unpatentable over prior art references that were not before the examiner during examination of the ’271 patent, including Edwards-’535 which discloses contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway as claimed.

VIII. OVERVIEW OF THE PRIOR ART REFERENCES

A. Edwards-’535

55. Edwards-’535 is directed to systems and methods used to treat conditions in the nasal passaged by application of RF energy. Ex.1010-Edwards-’535, 1:22-26, 5:45-51, 6:66-7:17,. Figure 3B of is reproduced below.



Id., FIG.3B. Figure 3B shows a distal portion 128 of an apparatus 124. The distal portion 128 includes an energy delivery device 134 (purple) positioned within an expandable member 132 (red). *Id.*, 5:18-35, 8:8-33. Energy delivery device 134 can also be positioned “on the surface” of expandable member 132. *Id.* After being inserted “through a nostril,” energy delivery device 134 is used to deliver “RF energy which ablates [nasal tissue such as that of the inferior turbinate (green)] by heat and cell destruction.” *Id.*, 5:18-45, 8:18-25, 8:51-53.

B. Kong

56. Kong is a scientific journal article describing a clinical study in which patients with perennial allergic rhinitis were treated by applying RF energy to the

inferior turbinate. Ex.1040-Kong, Abstract, 214 (“From March 2003 to April 2004, low-temperature ablation plasma surgical system under nasal endoscopy was used in our department to treat 35 cases of perennial allergic rhinitis using inferior turbinate perforation and achieving satisfactory results.”). The authors explained that the results of the study were promising, with a demonstrated effectiveness of 94.3%. *Id.*, 214. The patients in Kong’s study were treated using a “Hummingbird or ReFlex 45 RF electrode” device to apply RF energy through holes “at the lower or medial edge of the inferior turbinate.” *Id.* The holes were located in two (“anterior and posterior”) or three (“anterior, middle, and posterior”) parts of the inferior turbinate, with “1-2 holes made in each part.” *Id.*

57. Kong also includes a detailed discussion of its clinical results (Section 3 titled “Discussions”), which sets forth the authors’ explanation for why the disclosed treatment technique was effective at treating rhinitis. *Id.*, 214-15. The authors explain that “by removing some parasympathetic nerve fibers,” symptoms of rhinitis including excess “nasal mucus” can be reduced. *Id.* By applying RF energy, the “parasympathetic nerve fibers from the inferior turbinate” are “damage[ed]” which results in “reducing the sensitivity of nerve endings, reducing gland secretion, and improving nasal ventilation.” *Id.*, 215.

C. Liang

58. Similar to Kong, Liang is a scientific journal article describing a clinical study in which patients with perennial allergic rhinitis were treated by applying RF energy to the ethmoidal nerve (a nerve branch located throughout the anterior portion of the nose and the septum). Ex.1056-Liang, 341 (“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.”). The authors explained that the results of the study were promising. *Id.* (explaining that the clinical results demonstrated a “significant” “therapeutic effect”). The patients in Liang’s study were treated using “radiofrequency electromagnetic waves ... to generate strong endogenous heat effects in local cells, causing thermal coagulation...to treat diseases.” *Id.* Liang explains that applying radiofrequency energy to the specified locations of the nose “can cause varying degrees of damage to the deep ethmoidal nerve, reducing its sensitivity to adverse external physical and chemical stimuli, reducing the secretion of vasoactive peptides, inhibiting sneezing reflex, reducing runny nose, and improving nasal ventilation, thus achieving the goal of treating allergic rhinitis.” *Id.*, 341-42.

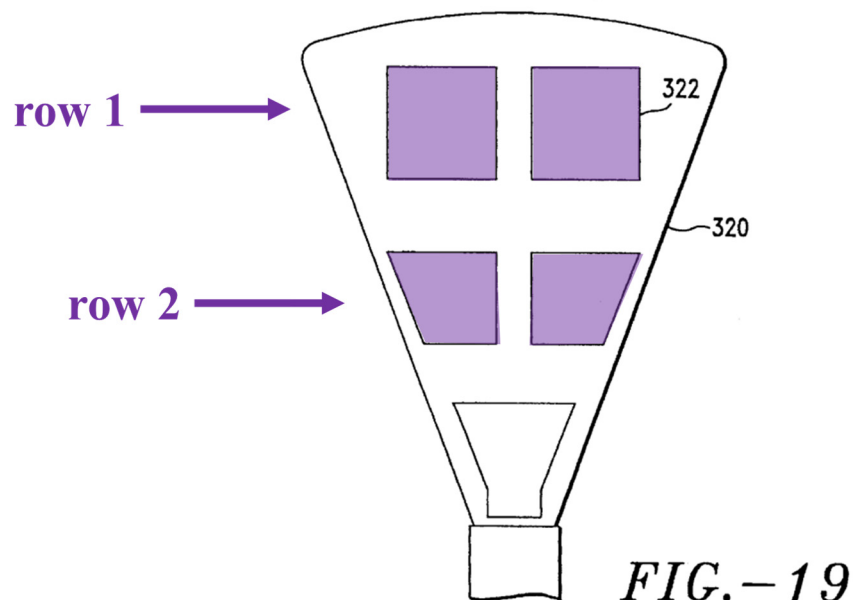
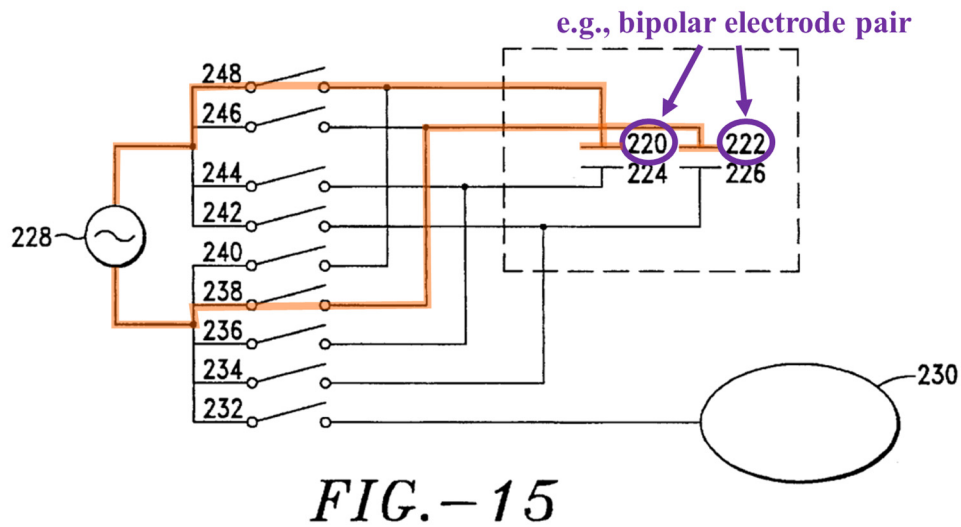
59. For example, Liang teaches that its methods use “the SHP-I radiofrequency treatment device for facial organs (manufactured by Guangzhou Medical Device Factory)...with the negative electrode connected to the lower part of the patient's chin...to perform thermal coagulation treatment.” *Id.*, 341. A description of the SHP-I is found in a Chinese utility model, CN 2225227 (Ex.1059-Liang’227). The Chinese utility model explains that the SHP-I contacts and applies energy to the surface of the mucosa, e.g., the SHP-I is described as “contact[ing]...patient’s tissue to produce an internal thermal effect..., which causes protein tissues to heat coagulate, dehydrate, shrink, harden, form blood clots, and gradually subside or disappear, leading to necrosis and detachment....” Ex.1059-Liang’227, 1.

D. Stern

60. Stern teaches systems and methods that use “a bipolar/monopolar application of RF energy” to selectively destroy body tissues such as the endometrium (mucosal tissue lining the uterus). Ex.1033-Stern, 1:15-23; *see also id.*, Abstract, 2:6-18, 18:27-40 (“One of the more obvious variations based upon the above disclosure is the utilization of [the disclosed techniques] for treatment of other body organs or tissues either externally or internally [(i.e., tissues other than the endometrium)].”). Stern’s techniques destroy body tissue using an ablation

device having an expandable member with RF electrodes on its surface. *Id.*, 2:26-35.

61. Figures 15 and 19 of Stern, reproduced below, depict embodiments of Stern's ablation device.



Id., FIGs.15, 19 (annotated). Figures 15 and 19 disclose a configuration of the ablation device having two rows of pairs of bipolar RF electrodes (shown in purple in Figure 19) and corresponding switching circuitry (orange) for energizing the electrode pairs (shown in Figure 15). *Id.*, 2:36-40, 3:29-40, 12:7-13:55.

E. Edwards-'886

62. Edwards-'886 teaches systems and methods for “treating interior tissue regions of the body” by “supply[ing] energy to an electrode structure to heat” the target tissue. Ex.1016-Edwards'886, 1:12-17, 2:60-65. For example, the energy can be supplied by a radiofrequency generator that “appl[ies] bursts of low level radio frequency energy through each electrode selected for operation.” *Id.*, 39:35-40:3. In certain configurations, the generator provides RF energy “with a sinusoidal waveform at 460 kHz.” *Id.*, 36:66-37:2.

IX. CLAIM CONSTRUCTION

63. 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 can be 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.

64. I have been further instructed that a patent's "prosecution history" may often provide helpful evidence about how the Patent 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.

65. 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 the person of ordinary skill in the art might understand the claim term. I have been instructed that extrinsic evidence must always be considered in the context of the intrinsic evidence.

66. In my opinion, the prior art discloses all of the limitations of the challenged claims under any plausible construction and/or under the apparent interpretation of the claims advanced by the Patent Owner in the parallel litigation. I have been informed and understand that in such circumstances, there is no need to construe the terms in the challenged claims.

X. ANALYSIS OF GROUNDS

67. It is my opinion that the challenged claims are unpatentable on the following grounds.

- Ground I: Claims 1-3, 6-12, and 16 are rendered obvious by Edwards-'535, Kong, and Stern under 35 U.S.C. §103.
- Ground II: Claim 4 is rendered obvious by Edwards-'535, Kong, Stern, and Edwards-'886 under 35 U.S.C. §103.
- Ground III: Claims 1-3, 6-12, and 16 are rendered obvious by Edwards-'535, Liang, and Stern under 35 U.S.C. §103.
- Ground IV: Claim 4 is rendered obvious by Edwards-'535, Liang, Stern, and Edwards-'886 under 35 U.S.C. §103

These grounds demonstrate in detail that claims 1-4, 6-12, and 16 are unpatentable as obvious. A copy of the challenged claims are provided as **Appendix C**.

A. Ground I: Claims 1-3, 6-12, 16 Are Invalid as Obvious Over Edwards-'535 in View of Kong and Stern

1. Claim 1

- a. 1[pre]: A method for treating a nasal airway to reduce mucus production, the method comprising:**

68. I have been informed and understand that, in general, there are circumstances where the preamble of a claim does not limit the scope of the claim, and there are circumstances where the preamble does limit the scope of the claim. In any event, even if the preamble of claim 9 is limiting, the combination of

Edwards-'535 and Kong teaches a method for treating a nasal airway (e.g., ablating interior section of a turbinate / ablating inferior turbinate) to reduce mucus production (e.g., reduce glandular secretions and nasal mucus).

69. Edwards-'535 discloses techniques that aim to treat nasal conditions and improve air flow through the nasal passages using “a method...for treating airway obstructions.” Ex.1010-Edwards-'535, 1:22-50, 1:60-66, 4:19-32, 6:66-7:4, 7:12-25, Clm.1.

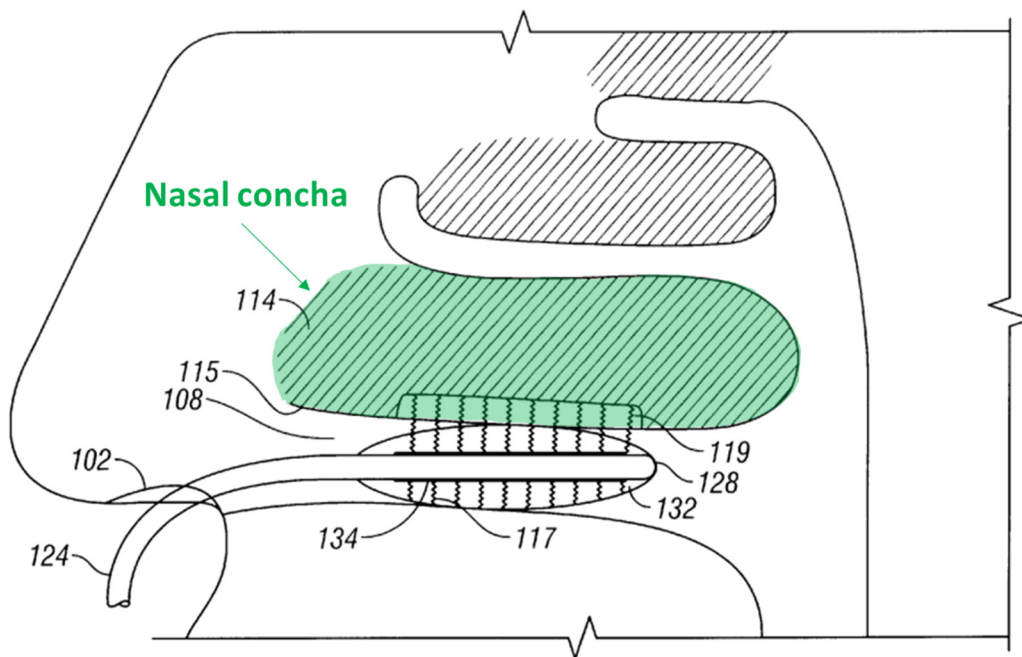


FIG. 3B

Id., FIG.3B. Figure 3B illustrates how Edwards-'535's method seeks to deliver treatment to the nasal concha (another term for turbinate) (green) by “ablating at

least a portion of a nasal concha (turbinate).” *Id.*, 4:19-32; *see also id.*, Abstract, 1:22-41, 4:41-43 (“the nasal concha, also referred to as the turbinates”), 4:63-67, 5:9-15, 6:59-7:4, 7:12-25, Clm.1. For example, the treatment can include applying RF energy to ablate tissue located in the “anterior or posterior sections of the inferior nasal concha.” *Id.*, 6:9-65. Additionally or alternatively, the treatment can be applied to other turbinates (concha) including the superior and middle concha. *Id.*, Abstract, 1:60-2:29, 4:19-52, 6:39-42.

70. Although not necessary to carry out Edwards-’535’s method, I note that Edwards-’535 discloses an optional cooling technique as an additional measure to facilitate ablating tissue underlying the mucosal tissue. This technique involves “cooling the surface of the nasal concha being ablated” such that “ablation can be performed to remove an internal section of a nasal concha without damaging the surface of the nasal concha.” *Id.*, 4:60-67, 6:10-37.

71. Kong also discloses techniques that aim to treat upper airway conditions (and thereby carry out a method of treating a nasal airway, as claimed) by applying RF energy to the turbinates. Ex.1040-Kong, 214-15, Abstract; *see also* Ex.1010-Edwards-’535, 4:33-5:15, 6:9-7:4. For example, Kong teaches that the RF energy is applied using a “bipolar” “RF electrode,” and Kong targets the same anatomical structures as Edwards-’535 (e.g., tissue located “under the

mucosa” of the “anterior, middle, and posterior part[s]” of the “lower or medial edge of the inferior turbinate”). Ex.1040-Kong, 214-15, Abstract; *see also* Ex.1010-Edwards-’535, 4:33-5:15, 6:9-7:4.

72. Moreover, Kong’s method is used for “reducing gland secretion” and “reducing nasal mucus” (i.e., the claimed reduction in mucus production).

Ex.1040-Kong, 215. For example, a person of ordinary skill in the art would have understood from background knowledge of nasal anatomy that the nasal glands include the serous, seromucous, and intraepithelial glands in the submucosa of the turbinates. Ex.1060-Lane, 392 (“In the epithelium and submucosa, there are three different types of glands: serous, seromucous, and intraepithelial.”). Each of these types of glands contributes to mucus production in the nose, with the “bulk of the mucus in the nose [being] generated by the submucosal seromucous glands.” *Id.*, 392-393. Accordingly, a person of ordinary skill in the art would have understood Kong’s teaching of “reducing gland secretion” to refer to reducing mucus production, as claimed. Kong further teaches that the mechanism by which reduction in mucus production is achieved includes “damaging the cholinergic microganglia and parasympathetic nerve fibers from the inferior turbinate, the unmyelinated sensory nerve fibers (SP energy nerves) and parasympathetic nerve

endings from the pterygoid and anterior ethmoidal nerves in the nose.” Ex.1040-Kong, 215.

i. *Motivation to Combine the Teachings of Edwards-’535 and Kong*

73. As I explained above, Edwards-’535 teaches a method in which RF energy is applied to tissue underlying the mucosa of the inferior turbinate. *See, e.g., §§ X.A.1.a-c.* Additional details about RF energy based treatment applied to tissue within the inferior turbinate are found in Kong. For example, Kong teaches methods that apply RF energy to specific tissues and structures of the upper airways to treat allergic rhinitis. In view of these teachings, a person of ordinary skill in the art would have been motivated to combine Edwards-’535 and Kong such that Edwards-’535’s method and device would have been applied to deliver RF energy to specific tissues to treat allergic rhinitis, as taught by Kong. Below, I explain why a person of ordinary skill in the art would have been motivated to combine Edwards-’535 and Kong in this manner with a reasonable expectation of success.

74. As an initial matter, a person of ordinary skill in the art would have understood that Edwards-’535 and Kong are in the same field as the ’271 patent and are reasonably pertinent to solving the problems addressed in the ’271 patent

(e.g., treating tissue in a body cavity) with the same types of solutions (e.g., applying RF energy to tissue). *See, e.g.*, Ex.1010-Edwards, Abstract, 5:43-51, 8:47-53, 10:25-31, 10:51-57; Ex.1040-Kong, 214-15.

75. In addition, Kong supplies ample reasons to treat specified tissues within the inferior turbinate (e.g., nerve tissue underlying the mucosa of the “lower or medial edge of the inferior turbinate”) using RF energy. Kong states (and supports with real-world clinical data) that its approach based on targeting specified tissues using RF energy to treat allergic rhinitis achieved a “total effective rate [of] 94.3%” and “[n]o surgical complications or other discomfort were observed.” Ex.1040-Kong, 214; *see also id.*, Abstract (applying “radiofrequency ablation [in accordance with Kong’s techniques] is a simple and safe [technique] to treat perennial allergic rhinitis”), 215 (“[T]his method has the advantages of minimal damage to the inferior turbinate, mild pain, fast postoperative recovery, and minimal postoperative care.”). More specifically, Kong includes a detailed analysis to explain why ablating the particular tissues targeted in the study, e.g., nerves within the inferior turbinate, results in “reducing the glandular secretion, its sensitivity to external physical and chemical adverse stimuli, and the secretion of vasoactive peptides,” which in turn has the effect of “inhibiting sneezing reflex, reducing nasal mucus[,]” “reducing the sensitivity of

nerve endings, reducing gland secretion, and improving nasal ventilation.” *Id.*,

215. A person of ordinary skill in the art would have therefore recognized that combining Edwards-’535’s teachings in connection with a method for treating the inferior turbinate with RF energy with Kong’s teaching of particular target tissues would have improved Edwards-’535’s method by enabling treatment of rhinitis effectively and with few side effects or risks of complications.

76. Moreover, Kong acknowledges certain deficiencies of its own treatment methods that are not present in Edwards-’535’s methods, which provides an additional express motivation for a person in the ordinary skill in the art to combine the teachings of Edwards-’535 and Kong. For example, Kong observes that its method of targeting particular nerve tissues was highly effective at treating allergic rhinitis but that the use of a piercing RF energy delivery device was damaging, “[reduced] the surgical field of view ..., and [increased] the difficulty of surgery.” Ex.1040-Kong, 215. Edwards-’535’s method achieves the same objective of Kong whereby “an interior portion of a nasal concha is ablated,” but unlike Kong accomplishes this goal “without ablating the surface of the nasal concha.” Ex.1010-Edwards-’535, 6:10-22. For example, unlike Kong’s piercing device, Edwards-’535’s device includes a pliable balloon at its distal end that does not pierce the mucosal tissue. Certain embodiments of Edwards-’535 further apply

cooling to the tissue surface to avoid damaging the mucosa when targeting the underlying tissue. Edwards-'535 discloses that the benefits of its approach include the ability to "remove an internal section of a nasal concha without damaging the surface of the nasal concha," and to carry out the procedure "bloodlessly and without the need to penetrate tissue, thereby significantly reducing the risk of infection." *Id.*, 4:53-67. Accordingly, Kong's teachings regarding the limitations of piercing RF energy delivery devices would have motivated a person of ordinary skill in the art to use Edwards-'535's method of using a non-piercing RF energy delivery device to target the nerve tissue identified in Kong.

77. Combining Edwards-'535 and Kong in the above-described manner would have yielded predictable results, particularly given that each of the references is directed to applying energy to nasal tissues to treat various conditions. Ex.1010-Edwards-'535, 5:36-44 (Edwards-'535's methods deliver "ablative energy...capable of causing the ablation of tissue."), 1:22-23 ("The present invention relates to a method and apparatus for treating airway obstructions."); Ex.1040-Kong, 214 ("low-temperature ablation plasma surgical system under nasal endoscopy was used in our department to treat 35 cases of perennial allergic rhinitis."). Another similarity between Edwards-'535 and Kong is that they each teach that the applied energy is used to ablate tissue of the upper airways, such as

tissue within the inferior turbinate. Ex.1010-Edwards-'535, 5:27-38 (“Sufficient energy 117 is delivered through the surface 115 of the nasal [turbinate] 114 to ablate at least a portion 119 of the nasal [turbinate] 114.”); Ex.1040-Kong, Abstract (describing “ablation of the inferior turbinate”), 214 (applying RF energy to the “anterior, middle, and posterior part[s]” of the “lower or medial edge of the inferior turbinate.”). Given that Edwards-'535 and Kong are each focused on treating upper airway conditions by ablating nasal tissue using energy, a person of ordinary skill in the art would have found their teachings to be readily combinable in a manner that would have yielded predictable results.

78. Consistent with this understanding, practitioners often used the same commercial RF treatment devices used in Kong’s clinical study of allergic rhinitis patients to perform turbinate reduction (the procedure disclosed by Edwards-'535). For example, Kong teaches that the patients in its study were treated using “a Hummingbird or ReFlex 45 electrode of ENTec plasma surgical system (Jesse Company, USA). Ex.1040-Kong, 214. These electrodes were also routinely used to carry out turbinate reduction procedures. *See, e.g.*, Ex.1042-Bäck, 1808 (Hummingbird for turbinate reduction); Ex.1043-Ilgner, 323 (Reflex 45 for removing nasal polyps), Ex.1044-Lee, 108-109 (Hummingbird and Reflex 45 for turbinate reduction). When using these devices to carry out turbinate reduction (as

in Edwards-'535), researchers observed a similar reduction in nasal discharge also accomplished by Kong. Ex.1042-Bäck, 1808, FIG.2 (showing roughly 25% reduction in nasal discharge); Ex.1040-Kong, 215. The similarity between the procedures disclosed in Edwards-'535 and Kong is further reinforced by survey studies of RF-energy based treatments that included results of both RF-based rhinitis treatments (including Kong's) and RF-based turbinate reduction treatments (like that of Edwards-'535). *See generally* Ex.1031-Hytönen. Given that devices used to achieve the clinical outcomes of Edwards-'535 and Kong were known to be compatible and useful for both types of treatment, it would have been obvious to a person of ordinary skill in the art to use a device and method like that disclosed in Edwards-'535's to ablate tissue to target the particular tissue identified in Kong to obtain predictable results of reducing mucus production without damaging mucosal tissue.

79. A person of ordinary skill in the art would have understood that combining Edwards-'535 and Kong in the manner described above would have been reasonably likely to improve Edwards-'535's method by targeting particular tissues that Kong identifies as likely to treat rhinitis and reduce mucus production. In addition, the combination would have been straightforward and predictable given that the techniques of Kong would have been used to improve Edwards-

'535's similar method in the same way. For example, Kong's teachings would have been applied to Edwards-'535's in the same way those teachings are used in Kong itself: Kong teaches that using RF energy to ablate nerve tissue and/or turbinates is a promising way to treat rhinitis, Ex.1040-Kong, 215, and Edwards-'535's method delivers RF energy to ablate tissue, Ex.1010-Edwards-'535, 5:36-51.

80. Other clinical studies from the same timeframe as Kong further support that a person of ordinary skill in the art would have had a reasonable expectation of success. For example, the following additional studies support Kong's teaching that RF ablation of nasal tissue is a promising treatment for allergic rhinitis (and therefore likely to reduce mucus production). *See* Ex.1055-Fang, 876 ("From March 1998 to January 2003, various methods such as nasal endoscopic surgery for submucous resection of the nasal septum combined with radiofrequency ablation of the sphenopalatine foramen, anterior ethmoidal nerve, and inferior nasal concha were used in our department for the treatment of 63 patients with perennial allergic rhinitis. After some time, patients were followed up, and the results were good."); Ex.1056-Liang, 341 ("From October 1996 to September 1997, we used radiofrequency hyperthermia equipment 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.”); Ex.1017-Chen, 239-241 (“From September 2002 to March 2003, 40 patients with PAR (observation group) were treated with radiofrequency thermocoagulation of the posterior inferior nasal nerve, anterior ethmoidal nerve, and inferior turbinate under nasal endoscopy, and comparison was made with another group (control group) of 40 patients with PAR treated with only radiofrequency thermocoagulation of the sphenopalatine nerve under nasal endoscopy in order to study the new method to improve the therapeutic effect of PAR. After six months of follow-up, the therapeutic effect was significant.”). Accordingly, combining Edwards-’535 and Kong would have yielded the predictable result of Edwards-’535’s method being used to deliver RF energy to treat rhinitis, as taught by Kong, with a reasonable expectation of success. Implementing the combination would have been straightforward and well within the capabilities of a person of ordinary skill in the art.

81. The lack of implementation details described in the ’271 patent further supports that a person of ordinary skill in the art would have found obvious and readily implemented the combination of Edwards-’535 and Kong. For example, the ’271 patent claims the use of an energy based therapy to reduce mucus production but the disclosure does not explain how such a reduction in mucus

production is accomplished. In fact, the '271 patent states that “any of [its] embodiments” are capable of reducing mucus production but does not disclose how to actually achieve this capability. Ex.1001-USP271, 48:1-7; *see also id.*, 10:44-53. Given the range of devices and techniques to reduce mucus production that the '271 patent considers to be within the level of ordinary skill, a person of ordinary skill in the art would have similarly had a reasonable expectation that combining Edwards-'535 and Kong would successfully reduce mucus production. The examiner of the '271 patent appears to have agreed with this assessment, stating that “causing a reduction in mucus production in the nasal airway is an obvious result from the claimed radio frequency energy passing through the nasal mucosa to underlying submucosal tissue.” Ex.1003-USP217FH, 48.

82. Accordingly, a person of ordinary skill in the art would have been motivated to combine the teachings of Edwards-'535 and Kong and would have done so with a reasonable expectation of success. Moreover, as I explain in further detail below with reference to limitations 1[a]-1[c], the combined teachings would have resulted in a method for treating a nasal airway to reduce mucus production, as claimed.

- b. 1[a]: contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the**

**nasal airway, wherein the treatment element
comprises two rows of bipolar electrode pairs;**

83. The combined method of Edwards-'535 and Kong, in further view of the teachings of Stern, includes the claimed step of contacting a treatment element (e.g., expandable member 132 and energy delivery device 134, as taught by Edwards-'535 and modified according to the teachings of Stern) of a nasal airway treatment device (e.g., apparatus 124, as taught by Edwards-'535 and modified according to the teachings of Stern) directly with nasal mucosa of the nasal airway (e.g., tissue lining the lower or medial edge of the inferior turbinate, as taught by Kong), wherein the treatment element comprises two rows of bipolar electrode pairs (e.g., plurality of bipolar energy delivery devices, as taught by Stern).

- i. ***Edwards-'535 in view of Kong teaches contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises [a row] of bipolar electrode[s].***

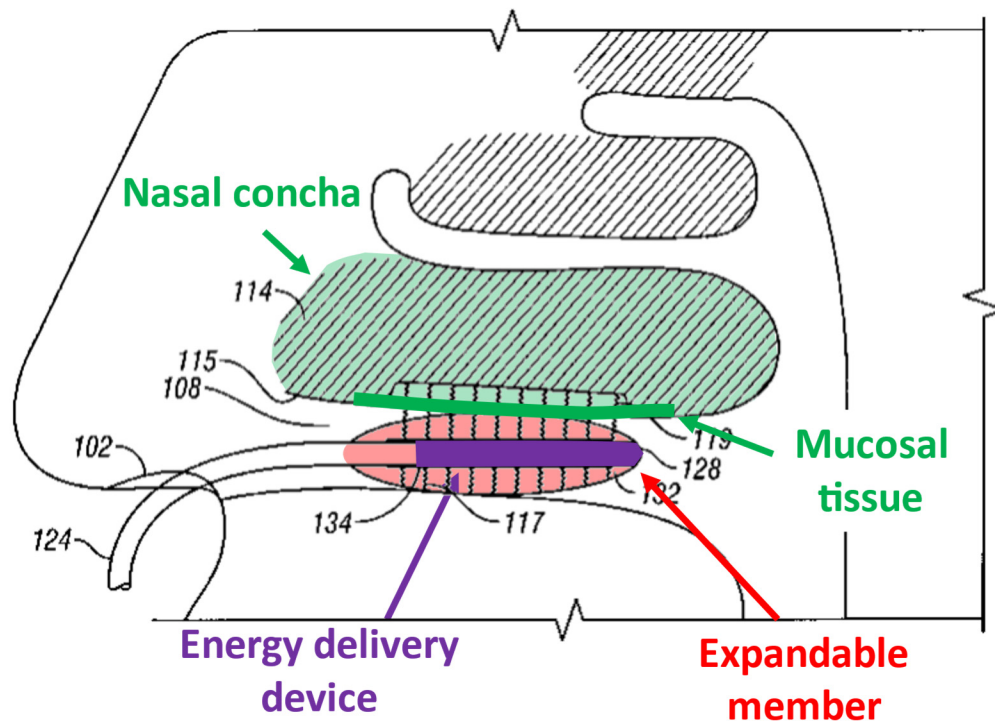
84. Edwards teaches that treatment is delivered to the nasal airway using “an apparatus 124 having a distal portion 128 with an expandable member 132 and an energy delivery device 134.” Ex.1010-Edwards, 5:20-26; *see also id.*, 5:27-35 (e.g., applying expandable member 132 to a “nasal concha 114 to be treated”), 5:51-61, 7:33-53, FIGs.3A-C. Distal portion 128 “for delivering ablative energy is introduced through a nostril 102 [and] into a nasal meatus adjacent a surface of a

nasal concha.” *Id.*, 5:20-26. A person of ordinary skill in the art therefore would have understood Edwards-’535’s apparatus 124 to be a nasal airway treatment device, as claimed, and distal portion 128 (including expandable member 132 and energy delivery device 134) to be a treatment element of the nasal airway treatment device.

85. Combining Edwards-’535 and Kong would have resulted in Edwards-’535’s distal portion 128 (i.e., the claimed treatment element) directly contacting the nasal mucosa lining the inferior turbinates, as taught by Edwards-’535 and Kong. In fact, this step is performed when carrying out the combined method using any one of multiple device arrangements disclosed by Edwards-’535. For example, as I explain in further detail below, the combined method satisfies this limitation when using either (a) a device that includes Edwards-’535’s energy delivery device 134 within expandable chamber 132 or (b) a device that includes Edwards-’535’s energy delivery device 134 on the surface of expandable chamber 132.

86. In either design, distal portion 128 is used as a treatment element, as claimed, given that energy delivery device 134 and expandable member 132 apply “ablative energy” to the nasal concha (turbinates), i.e., the claimed nasal airway, in order to treat the turbinates. Ex.1010-Edwards-’535, 5:18-27, FIGs.3A-4A.

87. When configured like the first design (i.e., energy delivery device 134 is positioned within expandable member 132), distal portion 128 of apparatus 124 includes an energy delivery device 134 within an expandable member 132 as shown in Figure 3B, below. *Id.*, 4:53-67, 5:18-35, 8:8-17, Clm.1, FIGs.3A-3C.



Id., FIG.3B. Figure 3B shows that “the expandable member 132 [(red)] is expanded within the nasal meatus 108 so that the expandable member 132 is brought into [direct] contact with the surface 115 of the nasal concha 114 [(green)] to be treated.” *Id.*, 5:27-35; *see also id.*, 4:53-67, 5:46-61, 7:18-25, 8:18-25, Clm.1, FIG.3B. A person of skill in the art would have understood from Edwards-

'535's teachings and textbook knowledge of nasal anatomy that mucosal tissue lines the surface 115 of the nasal concha 114 and is therefore directly contacted by the treatment element. Ex.1021-Makower, [0004] ("The nasal turbinates [(i.e., part of the nasal passages)]...extend inwardly from the lateral walls of the nose and are covered with mucosal tissues"); Ex.1060-Lane, 392 ("At the limen vestibuli [(i.e., within the nasal passages beyond the area in the immediate vicinity of the nostril openings)], the epithelium begins to change over to a pseudostratified respiratory epithelium [in which] [r]espiratory mucosal cells rest on a basement membrane that overlies a loose lamina propria.").

88. When configured like the second design (i.e., energy delivery device 134 is positioned on the surface of expandable member 132), distal portion 128 includes an energy delivery device 134 "positioned on a surface" of expandable member 132. *Id.*, 8:8-33, FIGs.5-6. Because the surface of expandable member 132 is in direct contact with mucosal tissue lining a nasal concha 114, as shown above in Figure 3B, the electrodes of energy delivery device 134 are likewise in direct contact with the mucosal tissue.

89. Edwards-'535 discloses a variety of ways to position energy delivery device 134 on the surface of expandable member 132, including using "ring electrodes 156 disposed on the surface of the expandable member 132," *id.*, 8:17-

25, FIG.6, and by using known “surface energy delivery devices,” *id.*, 8:30-33 Consistent with this disclosure, Edwards-’535 incorporates by reference another patent, Baker ’788, that discloses examples of a “suitable surface” for expandable member 132. *Id.*, 8:27-30 (incorporating by reference the disclosures of Baker ’788 and describing the teachings as “[a]n example of a suitable surface for disposition on the membrane”). For example, Baker ’788 teaches that the surface can be “implanted with...ions” and/or “coated with a material that improves its conductivity.” Ex.1011-Baker-’788, 7:45-65 (“Conforming member 20 is made of a material that suitably conforms to a surface to be ablated.... Conforming member 20 can be implanted with conductive ions, and conductive surface 24 can be coated with a material that improves its conductivity.”).

90. As I explained in Section VII.B, *supra*, the applicant argued during examination of the parent application of the ’271 patent that the limitation of “*contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway*” rendered the claims distinguishable from the prior art cited by the examiner. Specifically, the applicant argued that Thapliyal did not teach these limitations because “[a] primary objective of the Thapliyal device and method is to apply energy to fluid and not directly to tissue, in an attempt to reduce unwanted damage of the tissue.” Ex.1057-US489FH, 44.

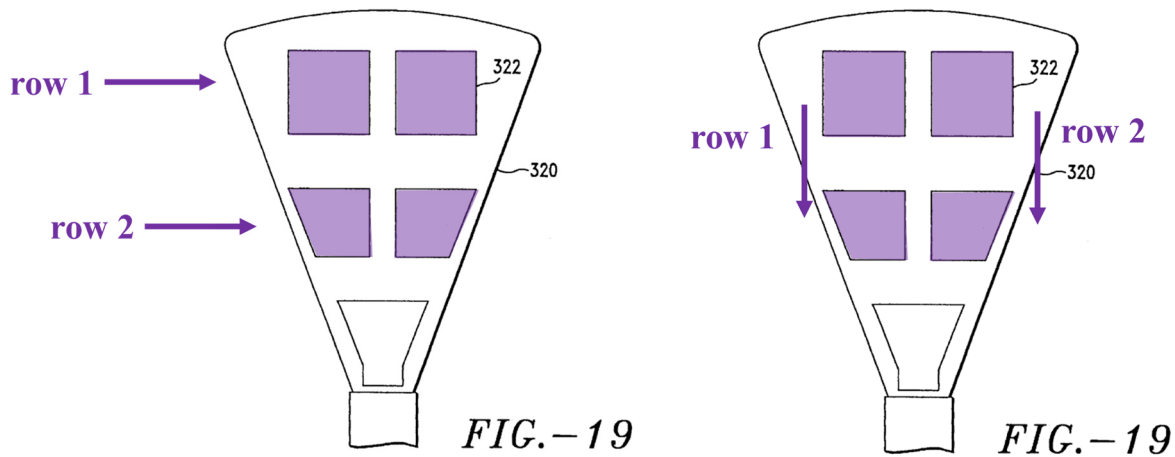
However, even assuming that limitation 1[a] does not cover energy transfer through a fluid in accordance with the applicant's characterization of Thapliyal's teachings, a person of ordinary skill in the art would have understood that at least when using Edwards-'535's second configuration (which uses surface electrodes), RF energy is not transferred through a fluid but rather propagates directly from the surface electrode into tissue in contact with the surface electrode. *See* Ex.1010-Edwards-'535, 8:12-33.

91. Edwards-'535 teaches that in certain arrangements, energy delivery device 134 is made up of "a plurality of energy delivery devices," which allows for "bipolar...energy delivery." *Id.*, 8:12-32, 10:52-61; *see also id.*, 8:50-54, 10:30-32, FIGs.3A-3B, 3D, 4A, 6. For example, Edwards teaches that the plurality of electrodes can be arranged in rows, as claimed, e.g., by arranging them "in parallel with their axes aligned with a long axis 160 of the catheter body 126." *Id.*, 8:19-33, FIG.6. However, Edwards-'535 does not provide further implementation details regarding rows of electrodes that deliver bipolar energy. A person of ordinary skill in the art would have turned to other references, such as Stern, for these details.

- ii. ***Stern teaches wherein the treatment element comprises two rows of bipolar electrode pairs,***

and it would have been obvious to combine Stern and Edwards-'535.

92. Referring to Figure 19, reproduced below, Stern teaches an RF treatment element that includes two rows of bipolar electrode pairs.



Ex.1033-Stern, FIG.19. Figure 19 shows that “a plurality of electrodes 322 [(purple)] are formed on the surface of the bladder 320.” *Id.*, 14:26-28.

Specifically, Figure 19 depicts four electrodes 322 arranged in a two-by-two array.

Stern teaches that “bipolar RF energy” can be selectively delivered to “chosen pairs [within the] array.” *Id.*, 2:36-40, 13:1-44. A person of ordinary skill in the art would have recognized that pairing the electrodes of a two-by-two array, as taught by Stern, results in two rows of bipolar electrode pairs. For example, as shown in Figure 19 above, different pairings can result in two horizontal rows of bipolar electrode pairs (left) or two vertical rows of bipolar electrode pairs (right).

93. It would have been obvious to combine the Stern's teaching of two rows of bipolar electrode pairs with Edwards-'535's technique for treating a nasal airway. As an initial matter, a person of ordinary skill in the art would have understood that Edwards-'535 and Stern are in the same field as the '271 patent and are reasonably pertinent to solving the problems addressed in the '271 patent (e.g., treating tissue in a body cavity) with the same types of solutions (e.g., applying RF energy to tissue). *See, e.g.*, Ex.1010-Edwards, Abstract, 5:43-51, 8:47-53, 10:25-31, 10:51-57; Ex.1033-Stern, Abstract, 1:15-23, 10:4-10, 10:40-65, 12:38-45. Moreover, as I explained above, Edwards-'535's omission of implementation details regarding its bipolar energy delivery embodiments would have motivated a person of ordinary skill in the art to seek out the teachings of a reference like Stern, which teaches specific configurations of bipolar electrode pairs (e.g., the configurations shown in Figure 19). A person of ordinary skill in the art would have had found the use of bipolar electrodes in the arrangement taught by Stern to be reasonably likely to successfully ablate the nasal tissues targeted using the combined method. This is consistent with my experience treating patients using RF treatment elements with bipolar electrodes, which by 2011 were widely available to clinicians and came in a variety of different configurations.

94. In addition, I have spoken with Dr. Gregory Martin and reviewed his declaration. Dr. Martin's analysis confirms and supports my conclusions that Stern teaches a treatment element that comprises two rows of bipolar electrode pairs, as claimed, and that a person of ordinary skill in the art would have been motivated to combine Edwards-'535 and Stern with a reasonable expectation of success. For example, Dr. Martin explains that Stern's technique provides even heating and precise energy delivery control. These are attributes that a person of ordinary skill in the art would have regarded as beneficial, particularly when delivering treatment to the nasal passages (e.g., when using the combined method of Edwards-'535 and Kong) given the uneven morphology of nasal cavity tissue and the proximity of the RF energy delivery to a patient's brain and other critical tissues within the head. For example, a person of ordinary skill in the art would have understood that the morphology of the nasal turbinates has significant variation, e.g., due to the presence (or absence) of polyps, uneven mucus coatings, variable thickness of the tissue covering the bone, and the like. Consistent with this understanding, Kong suggests the importance of precise control of energy delivery by explaining that its techniques are preferably carried out by skilled operators with a "foundation in endoscopic surgery" and that a "good conductive layer" should be provided. Ex.1040-Kong, 215.

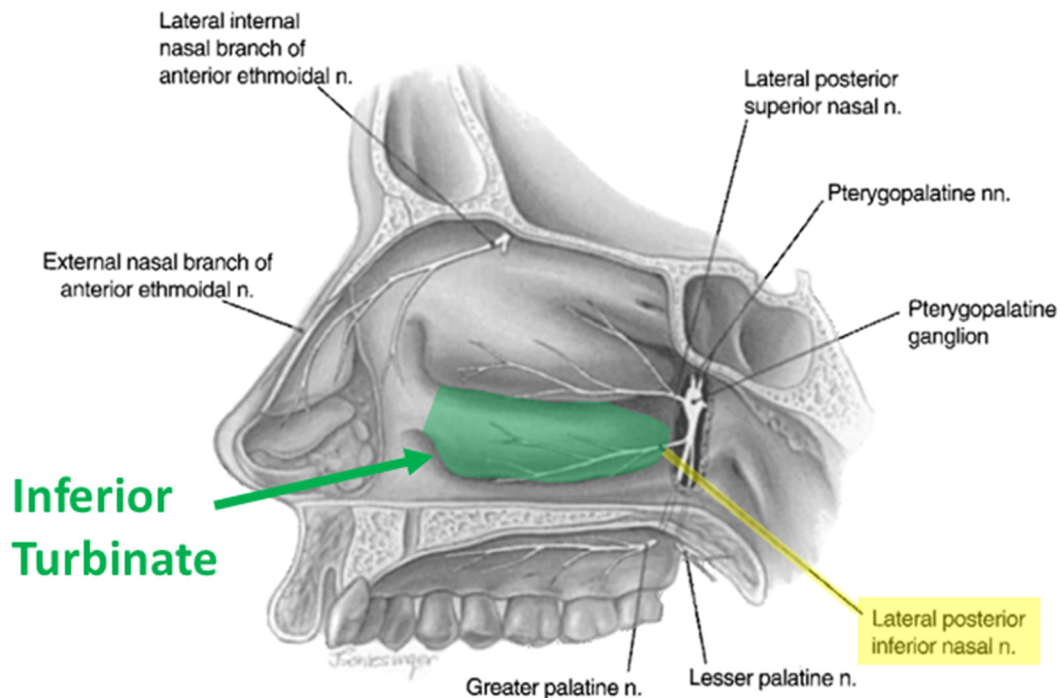
- c. 1[b]: applying radiofrequency energy with the bipolar electrode pairs through the nasal mucosa to a target tissue underlying the nasal mucosa for an amount of time to heat the target tissue; and**

95. The combined method of Edwards-'535 and Kong, in further view of Stern, includes the claimed step of applying radiofrequency energy with the bipolar electrode pairs (e.g., Edwards-'535's energy delivery device 134 modified to include bipolar electrode pairs, as taught by Stern) through the nasal mucosa to a target tissue underlying the nasal mucosa (e.g., parasympathetic nerves and/or submucosa within the inferior turbinate, as taught by Kong) for an amount of time to heat the target tissue (e.g., the time needed to ablate tissue by heating, as taught by Edwards-'535).

96. As I explained above with reference to limitations 1[pre] and 1[a], combining the teachings of Edwards-'535 and Stern would have resulted in Edwards-'535's RF treatment method being modified to apply radiofrequency energy with bipolar electrode pairs, as claimed. As I further explained above with reference to limitations 1[pre] and 1[a], combining the teachings of Edwards-'535 and Kong would have resulted in the radiofrequency energy being applied to parasympathetic nerves and/or submucosa (i.e., the claimed target tissue), as these are the tissues Kong targets in its method for treating rhinitis. *See* Ex.1040-Kong,

215 (explaining that Kong’s treatment involves “damaging the cholinergic microganglia and parasympathetic nerve fibers from the inferior turbinate” and “causing protein coagulation and denaturation in the nasal mucosa and submucosal tissues”).

97. A person of ordinary skill in the art would have understood from background knowledge of nasal anatomy that, within the nasal passage, nerves are a type of tissue underlying the mucosal tissue. For example, the figure below shows that the inferior turbinate is innervated by the lateral posterior inferior nasal nerve.



Ex.1060-Lane, FIG.4. Moreover, although the simplified figure above does not show the tissue overlying the nerves for illustrative purposes, a person of ordinary skill in the art would have understood that nerves (such as the lateral posterior inferior nasal nerve depicted above) branch out underneath the mucosal tissue, e.g., within the submucosa. *Id.*, 392 (“The submucosa contains blood vessels, venous plexi, plexi, glandular elements, sensory *nerves*, and immune cells”) (emphasis added); *see also id.*, FIG.1 (showing the same portion of the anatomy as shown in FIG.4 with the overlying mucosa). Accordingly, in the combined method of Edwards-’535 and Kong, the RF energy treatment would be delivered through the nasal mucosa to target tissue underlying the nasal mucosa, as claimed. *See also* Ex.1010-Edwards-’535, 4:53-67, 5:27-35 (explaining that energy is “delivered through the surface 115 of the nasal concha 114 to ablate at least a portion 119 of the nasal concha 114”), 6:9-7:17, 11:23-44, FIGs.4A-4C; Ex.1040-Kong, 214-15 (disclosing that RF energy is applied through holes in the “anterior, middle, and posterior part[s]” of the “lower or medial edge of the inferior turbinate”).

98. Given that Edwards-’535’s method “caus[es] the ablation of tissue by heating at least a portion of the nasal concha being treated to a temperature above about 40°C.,” Ex.1010-Edwards-’535, 5:35-38, a person of ordinary skill in the art would recognize that the RF energy is necessarily applied for some amount of time

sufficient to heat the target tissue and thereby cause ablation. Consistent with this understanding, Edwards-'535 teaches that a "feedback control system" can be used to "maintain[] tissue adjacent to an energy delivery device at a desired temperature for a selected period of time." *Id.*, 9:65-10:3.

99. Further details regarding the target duration and temperature for known RF ablation treatments are found in Stern, which states that the RF energy is applied "for a time sufficient to destroy the...cells by elevating the temperature of the endometrium [(i.e., the tissue lining the uterus, which like the tissue lining the nasal passages includes a layer of mucosa)] to between 45° C. and 90° C. and preferably within 10 seconds." Ex.1033-Stern, 6:66-7:3; *see also id.*, 2:6-19 (discussing time), 7:21-34 (same), Abstract (discussing heating tissue), 2:41-49 (same), 3:13-37 (same), 10:54-11:7 (uniform heating), 12:25-36 (precise control of heating), 13:21-38 (controlling heated area), 1:25-61 (destroying tissue). "The temperature is maintained until the endometrial tissue is destroyed which is optimally accomplished by a temperature between 55° C. to 65° C. for up to 10 minutes." *Id.*, 7:3-7, 1:25-61, 2:41-49. These timing and temperature parameters were also understood by a person of ordinary skill in the art to treat nasal tissue as of 2011. Ex.1039-Banhiran, 950 ("[T]emperature-controlled radiofrequency volumetric reduction (RFVTR) has been applied to treat several upper airway

diseases especially chronic rhinitis and obstructive sleep apnea. Its major mechanism is to produce thermal coagulation necrosis in the submucosal tissue by releasing specific radiofrequency (460 kHz) energy through a special probe under well-controlled temperature (60°-90°C).”) (citations omitted).

d. 1[c]: removing the treatment element from the nasal airway,

100. The combined method of Edwards-’535 and Kong includes the claimed step of removing the treatment element (e.g., expandable member 132 having energy delivery device 134, as taught by Edwards-’535 and modified according to the teachings of Stern) from the nasal airway.

101. A person of ordinary skill in the art would readily understand that the combined method involves removing the treatment element after the treatment is delivered, as it would be impractical for patients to keep the device of Edwards-’535 (as modified in view of Stern) – a large externally operated device which is not intended as an implant – inserted in their nasal passages indefinitely.

Consistent with this understanding, Edwards-’535 discloses two figures (Figures 4B and 4C) depicting a patient’s nasal passages after the procedure. Unlike Figure 4A, which illustrates the device inserted into the patient’s nasal airway during the ablation procedure, Figures 4B and 4C demonstrate that the device has been

removed from the patient's nasal airway as claimed. Ex.1010-Edwards-'535, 6:66-7:25.

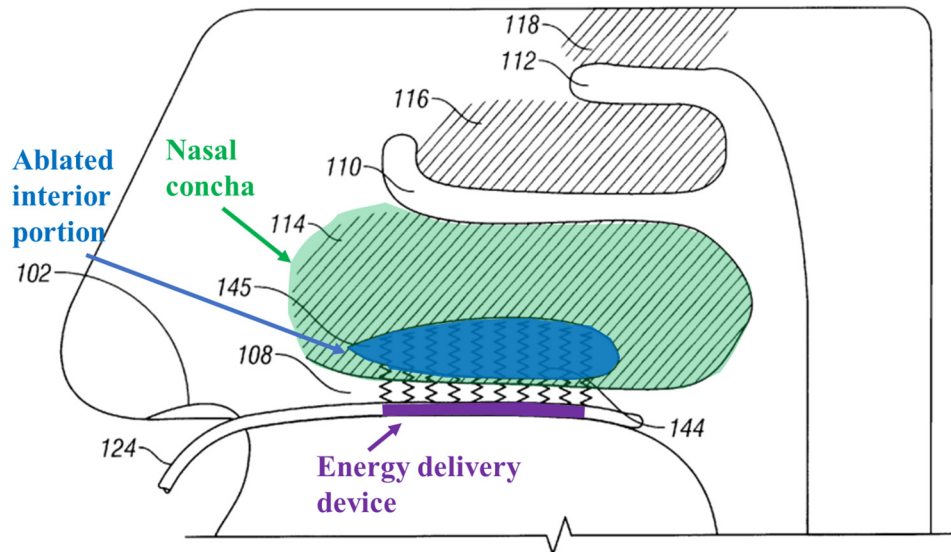


FIG. 4A

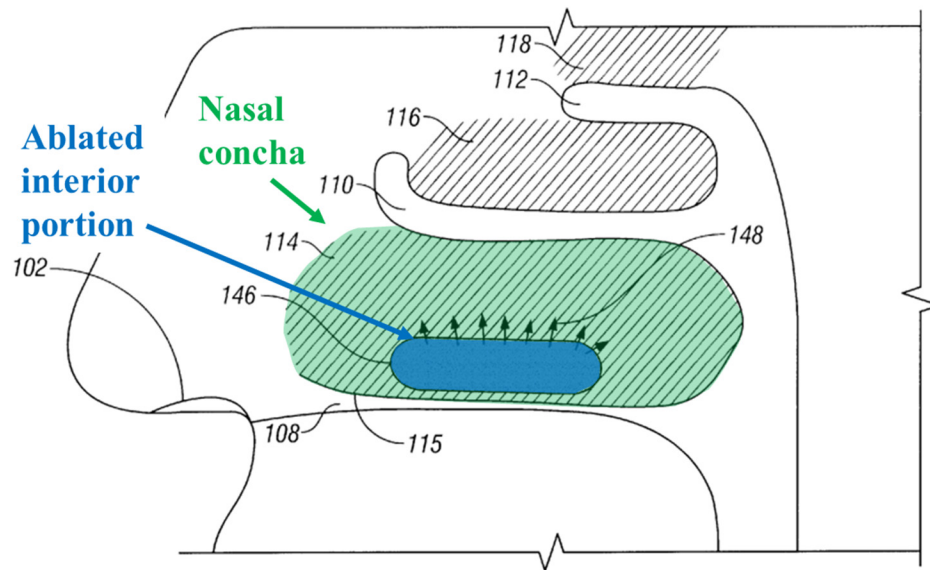


FIG. 4B

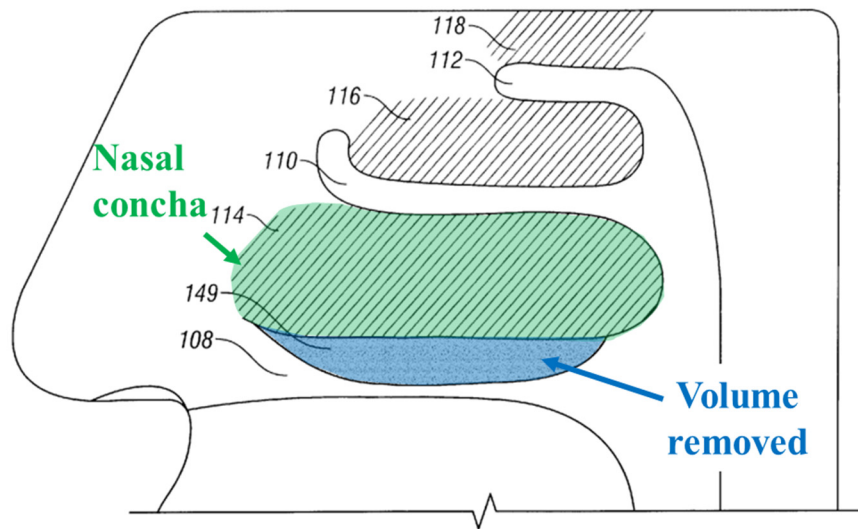


FIG. 4C

Id., FIGs.4A-4C.

102. Kong likewise discloses that “the electrode was slowly removed” after applying energy, and a person of ordinary skill in the art would have similarly understood this teaching to apply to the combined method. Ex.1040-Kong, 214.

- e. **1[d]: wherein heating the target tissue with the applied radiofrequency energy modifies at least one property of the target tissue, and**

103. The combination of Edwards-’535 and Kong teaches that the claimed step of heating the target tissue with the applied radiofrequency energy, as recited by limitation 1[b], modifies at least one property of the target tissue (e.g., the target nerve tissue, as taught by Kong, is removed via ablation (and therefore its

properties are modified), as taught by Edwards-'535 and similarly taught by Kong).

104. A person of ordinary skill in the art would have understood that the treatment delivered by the RF energy delivery device in the combined method of Edwards-'535 and Kong modifies a property of the mucosal tissue, as claimed. For example, Edwards-'535 discloses that the applied RF energy ablates tissue by heating (thermocoagulation), which removes all or a portion of (and thus modifies) the tissue. Ex.1010-Edwards-'535, 5:35-39 (explaining that the ablative RF energy “caus[es] the ablation of tissue [(i.e., modifying a property of the tissue by removing all or a portion of the tissue)] by heating at least a portion of the nasal [turbinate] being treated”). In particular, an interior portion of the nasal concha is removed. *Id.*, 1:20-26, 3:18-36 (describing applying energy “into an internal section” to “cause ablative heating therein”), 4:19-32, 4:53-67, 5:9-15, 5:36-45 (describing heating tissue to above 40° C), 6:59-7:25, 8:46-53 (“RF energy which ablates the turbinate by heat and cell destruction”), Abstract, FIGs.4A-4C, Clm.1.

105. Further properties of the target tissue that are modified are described in Kong. For example, Kong explains that:

[C]ells in the target tissues...gradually disintegrate on a molecular basis, causing protein coagulation and denaturation in the nasal mucosa

and submucosal tissues, gland atrophy, and vascular closure, thereby reducing the degranulation process of mast cells (reducing the release of histamine), damaging the cholinergic microganglia and parasympathetic nerve fibers from the inferior turbinate, the unmyelinated sensory nerve fibers (SP energy nerves) and parasympathetic nerve endings from the pterygoid and anterior ethmoidal nerves in the nose....

Ex.1040-Kong, 215. A person of ordinary skill in the art would have understood that these or similar effects on the target tissue would arise in the combined method of Edwards-'535 and Kong, as Edwards-'535 shares Kong's objective of removing submucosal tissue such as nerve fibers. *See, e.g.*, Ex.1010-Edwards-'535, 8:46-53 ("RF energy which ablates the turbinate by heat and cell destruction").

f. 1[e]: wherein the modified at least one property of the target tissue causes a reduction in mucus production in the nasal airway.

106. The combination of Edwards-'535 and Kong teaches that the modified at least one property of the target tissue, as recited by limitation 1[d], causes a reduction in mucus production (e.g., reducing gland secretion and/or reducing nasal mucus, as taught by Kong) in the nasal airway.

107. As I explained above with reference to limitation 1[pre], the combined method of Edwards-'535 and Kong would have resulted in applying RF energy to the inferior turbinate to ablate (modify) target tissue, thereby “damaging the cholinergic microganglia and parasympathetic nerve fibers from the inferior turbinate, the unmyelinated sensory nerve fibers (SP energy nerves) and parasympathetic nerve endings from the pterygoid and anterior ethmoidal nerves in the nose.” Ex.1040-Kong, 215. Kong explains that the effects of this treatment include “reducing gland secretion” and “reducing nasal mucus,” which in turn “achiev[es] the objective of treating perennial allergic rhinitis.” *Id.*, 214-215. As I further explained with reference to limitation 1[pre], Kong’s references to “reducing gland secretion” and “reducing nasal mucus” would have been understood to refer to reducing mucus production in the nasal airway, as claimed.

108. For these reasons, it is my opinion that claim 1 would have been obvious in view of Edwards-'535, Kong, and Stern.

2. Claim 2: The method of claim 1, wherein the target tissue is selected from the group consisting of mucosa, submucosa, cartilage, muscle, ligament, and tendon.

109. The combination of Edwards-'535 and Kong teaches, or at least renders obvious, that the target tissue, as recited by limitations 1[b], 1[d], and 1[e], is selected from the claimed group (e.g., mucosa and/or submucosa). For example,

as I explained above with reference to limitation 1[b], combining the teachings of Edwards-'535 and Kong would have resulted in the radiofrequency energy being applied to the submucosa, as this is one of the tissues Kong targets in its method for treating allergic rhinitis. *See* Ex.1040-Kong, 215 (explaining that Kong's treatment involves "causing protein coagulation and denaturation in the nasal mucosa and submucosal tissues"). Edwards-'535 likewise teaches that RF energy is applied to an interior portion of the concha, which includes the submucosa, *see, e.g.,* Ex.1010-Edwards-'535, 4:53-67, 5:27-35, 6:9-7:17, 11:23-44, FIGs.4A-4C, and further discloses arrangements in which RF energy is applied to the surface of the nasal concha, which includes mucosa, *see, e.g., id.*, 2:63-3:6 ("delivering ablative energy to the surface of the nasal concha"), FIGs.3B-3D.

110. For these reasons, it is my opinion that claim 2 would have been obvious in view of Edwards-'535, Kong, and Stern.

3. Claim 3: The method of claim 1, further comprising controlling at least one characteristic of the applied radiofrequency energy with a control system coupled with the nasal airway treatment device.

111. The combined method of Edwards-'535 and Kong includes the claimed step of controlling at least one characteristic of the applied radiofrequency energy (e.g., amount of energy output, duty cycle, wattage, and/or use of

monopolar and/or bipolar energy) with a control system (e.g., feedback control system coupled with the nasal airway treatment device).

112. A person of ordinary skill in the art would have understood, or at least found obvious, that the treatment device of Edwards-'535 includes a suitable control system to regulate the amount of ablative RF energy delivered to the target tissue. Such control systems have long been commonplace in RF energy delivery devices given that their purpose is to deliver RF energy with characteristics sufficient to achieve the intended clinical outcome, which can vary from patient to patient, for different sides of the nose for a given patient, and for different target locations on a given side of the nose. For example, a common characteristic of the applied RF energy that can be controlled is the total amount of RF energy delivered (e.g., in units of Joules): too little energy will not ablate the target tissue as intended, whereas too much may damage tissues outside of the target area causing unintended consequences and side effects. Accordingly, delivering an uncontrolled or fixed amount of RF energy would be unsuitable; instead, control systems are used to ensure that the intended amount of RF energy for a given patient or target location is delivered to the tissue. I personally have used a number of RF energy delivery devices and each one has had a control system that allows control over energy delivery.

113. Consistent with this understanding, Edwards-'535's RF energy delivery device is coupled to a "feedback control system" that uses "feedback" from sensors (e.g., temperature or impedance sensors) to "control[] the operation of an [RF] energy source which delivers energy to the energy delivery device." Ex.1010-Edwards-'535, 9:65-10:3, 9:14-23; *see also id.*, 9:24-9:64, 10:4-11:22 (describing feedback control system), 11:23-44 (describing temperature/impedance feedback system), 8:54-9:13 (describing processor-based control of an amount of energy delivered), FIGs.5-6, 8-10. The feedback control system enables "the delivery of RF energy can be reduced, modified or interrupted" in response to the measured impedance of the tissue to be ablated, thereby controlling at least one characteristic of the applied radiofrequency energy, as claimed. *Id.*, 11:12-22, FIG.8; *see also id.*, 9:1-64 (describing determining and adjusting an "amount of energy being delivered"), 10:46-51 (same), FIG.10. Edwards-'535's feedback control system can change other attributes of the applied RF energy including "chang[ing] (i) the selected energy (ii) the duty cycle (on-off and wattage) [of the applied energy], [and] (iii) bipolar or monopolar energy delivery...." *Id.*, 10:52-61. In this manner, the feedback control system is able to "control the delivery of RF energy...to achieve a selected temperature" in response to the output from a temperature sensor. *Id.*, 9:24-44.

114. For these reasons, it is my opinion that claim 3 would have been obvious in view of Edwards-'535, Kong, and Stern.

- 4. Claim 6: The method of claim 1, further comprising displaying one or more parameters of treatment on a console attached to the nasal airway treatment device while the radiofrequency energy is applied, the one or more parameters selected from the group consisting of treatment time, power level, temperature sensed by the treatment element, electric impedance, electric current, and depth of treatment.**

115. The combined method of Edwards-'535 and Kong includes the claimed step of displaying one or more parameters of treatment on a console (e.g., user interface and display 196, as taught by Edwards-'535) attached to the nasal airway treatment device while the radiofrequency energy is applied, the one or more parameters selected from the claimed group (e.g., power level, temperature sensed by the treatment element, and electric impedance).

116. Similar to the above analysis that I provided for claim 3, a person of ordinary skill in the art would have understood, or at least found obvious, that the treatment device of Edwards-'535 includes a suitable console to display one or more parameters of the RF energy based treatment. Such consoles have long been commonplace in RF energy delivery devices given their purpose is to deliver RF energy with characteristics sufficient to achieve the intended clinical outcome,

which can vary from patient to patient, for different sides of the nose for a given patient, and for different target locations on a given side of the nose. This variability means that a user of the treatment device must be able to control the relevant parameters of the treatment, and this control is most commonly carried out using a console attached to the treatment device that displays the relevant parameters to facilitate such control. For example, a typical parameter that may be controlled and displayed via the console is the total amount of RF energy delivered (e.g., in units of Joules), e.g., a larger target structure (e.g., a large turbinate) may require more total RF energy than a smaller structure (e.g., a small turbinate). Based on the parameters and are controlled and displayed via the console, control systems of the treatment device are used to ensure that the intended amount of RF energy for a given patient or target location is delivered to the tissue, as I explained for claim 3. I personally have used a number of RF energy delivery devices and each one has had a console that displays one or more parameters of the energy delivery treatment.

117. Consistent with this understanding, Edwards-'535 teaches that its RF energy delivery device (i.e., the claimed nasal airway treatment device) is attached to a console having a user interface and display 196, as shown below in Figure 8.

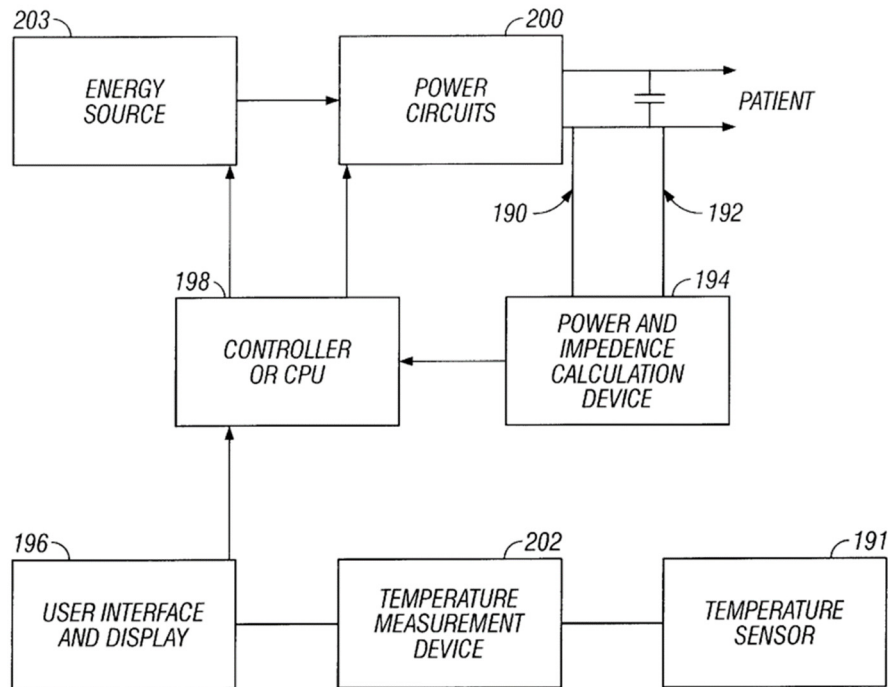


FIG. 8

Ex.1010-Edwards-'535, FIG.8. Figure 8 shows that user interface and display 196 receives and displays various parameters derived from sensors of apparatus 124. The displayed parameters include calculated energy values (i.e., the claimed power level), calculated impedance values, and temperature. *Id.*, 10:4-11 (displaying energy and impedance), 10:18-22 (displaying temperature), 10:32-45 (describing display), 11:12-22 (displaying energy and impedance), FIGs.8-9; *see also id.*, 9:14-53 (discussing sensors of the apparatus). Given that these parameters (e.g., energy, impedance, and temperature) are displayed continuously, including when the user

is adjusting control signals and monitoring for limits, the parameters are displayed while the radiofrequency energy is applied, as claimed. *See id.*

118. Edwards-'535's user interface and display 196 is attached to the nasal airway treatment device, e.g., the user interface and display 196 is used to control the energy source 203 that provides energy to the nasal airway treatment device. For example, user interface and display 196 communicates detected temperature information with a controller or CPU 198, which in turn controls how much energy the energy source 203 provides to the electrodes 191. *Id.*, FIGs.8-9, 10:4-31, 10:45-11:3, 11:12-22, 11:23-26.

119. For these reasons, it is my opinion that claim 6 would have been obvious in view of Edwards-'535, Kong, and Stern.

5. Claim 7: The method of claim 1, further comprising applying local anesthesia to at least one of the nasal mucosa or the target tissue before applying the radiofrequency energy.

120. The combined method of Edwards-'535 and Kong includes the claimed step of applying local anesthesia to at least one of the nasal mucosa or the target tissue before applying the radiofrequency energy. For example, Kong discloses applying “[s]urface anesthesia” using a “spray in the nasal cavity” (i.e., on the nasal mucosa) and “infiltration anesthesia” “under the bilateral inferior

turbinate mucosa (i.e., the target tissue). Ex.1040-Kong, 214; *see also id.*, Abstract (discussing anesthesia), 215 (same).

121. More generally, using local anesthesia has long been a routine aspect of delivering treatment within the nose, particularly in circumstances where, as here, the treatment causes ablation and removal of tissue and could stimulate sensory tissue (e.g., nerves). Delivering such treatment without local anesthesia would have been extremely painful and, at the very least, deeply uncomfortable to the patient. Accordingly, a person of ordinary skill in the art would have found it obvious to apply local anesthesia to the target tissues and/or the overlying mucosa before applying radiofrequency energy to (or through) the tissue, as taught by Kong. Moreover, a person of ordinary skill in the art would have had understood that applying local anesthesia would have been reasonably likely to reduce the patient's level of pain and discomfort, particularly given that local anesthesia has been successfully used for more than a century for a wide range of medical procedures including those within the nose. *See, e.g.*, Ex.1041-Snow, xi-xii (discovery in 1846), 153 (discussing "local anaesthetic" in 1859), 190 (describing proliferation of "local anaesthesia"); Ex.1055-Fang, 876 (using anesthesia when applying RF energy in the nose); Ex.1017-Chen, 240 (same); Ex.1056-Liang, 341 (same).

122. For these reasons, it is my opinion that claim 7 would have been obvious in view of Edwards-'535, Kong, and Stern.

6. Claim 8: The method of claim 1, wherein the radiofrequency energy is produced by a radiofrequency energy source configured to run between 1 Watt and 100 Watts.

123. The combination of Edwards-'535 and Kong teaches that the radiofrequency energy is produced by a radiofrequency energy source configured to run between 1 Watt and 100 Watts, as claimed. For example, Edwards-'535 teaches that energy source 203 (i.e., the claimed radiofrequency energy source) produces “pulses of RF energy which provide between about 5 and about 30 watts of RF energy to at least a portion of the turbinate.” Ex.1010- Edwards-'535, 9:1-11, *see also id.*, 5:48-51, 10:52-58.

124. In addition, I have spoken with Dr. Gregory Martin and reviewed his declaration. Dr. Martin's analysis confirms and supports my conclusions that, in the combined method of Edwards-'535 and Kong, radiofrequency energy is produced by a radiofrequency energy source configured to run between 1 Watt and 100 Watts.

125. For these reasons, it is my opinion that claim 8 would have been obvious in view of Edwards-'535, Kong, and Stern.

7. Claim 9: The method of claim 1, wherein applying the radiofrequency energy comprises heating the target tissue to a temperature between 50 degrees Celsius to 70 degrees Celsius.

126. The combination of Edwards-'535 and Kong, in further view of Stern, teaches, or at least renders obvious, that the claimed step of applying the radiofrequency energy, as recited by limitation 1[b], includes heating the target tissue to a temperature between 50 degrees Celsius to 70 degrees Celsius. For example, Edwards-'535 teaches "heating at least a portion of the nasal concha being treated to a temperature above about 40° C." Ex.1010- Edwards-'535, 5:35-44. Although Edwards-'535 does not teach a more specific temperature range, Stern teaches that an optimal temperature range for tissue destruction is "between 55° C. to 65° C." Ex.1033-Stern, 6:63-7:6. Given that Edwards-'535 and Stern share the same objective of destroying target tissue, and given that Edwards-'535's suggested range (over 40° C) overlaps with Stern's suggested range (55° C. to 65° C), a person of ordinary skill would have found it obvious to heat tissue to 55° C. to 65° C, as taught by Stern, when carrying out the combined method of Edwards-'535 and Kong, and doing so would have been reasonably likely to achieve the clinical benefits associated with destroying the target tissue. In fact, other references describe successfully ablating tissue within the nose to treat rhinitis

using a similar temperature range. *See* Ex.1039-Banhiran, 950 (“[T]emperature-controlled radiofrequency volumetric reduction (RFVTR) has been applied to treat several upper airway diseases especially chronic rhinitis and obstructive sleep apnea. Its major mechanism is to produce thermal coagulation necrosis in the submucosal tissue by releasing specific radiofrequency (460 kHz) energy through a special probe under well-controlled temperature (60°-90°C).”) (citations omitted).

127. In addition, I have spoken with Dr. Gregory Martin and reviewed his declaration. Dr. Martin’s analysis confirms and supports my conclusions that the combination of Edwards-’535, Kong, and Stern discloses that applying the radiofrequency energy includes heating the target tissue to a temperature between 50 degrees Celsius to 70 degrees Celsius.

128. For these reasons, it is my opinion that claim 9 would have been obvious in view of Edwards-’535, Kong, and Stern.

8. Claim 10: The method of claim 1, wherein the amount of time the radiofrequency energy is applied to the target tissue is between fifteen seconds and one minute.

129. The combination of Edwards-’535 and Kong, in further view of Stern, teaches, or at least renders obvious, that the amount of time the radiofrequency energy is applied to the target tissue is between fifteen seconds and one minute, as claimed. For example, Edwards-’535 teaches that the RF energy is applied to the

target tissue for a “selected period of time.” Ex.1010- Edwards-’535, 9:65-10:3.

Although Edwards-’535 does not teach a more specific range of times, a person of ordinary skill in the art would have understood that typical lengths of times for RF energy delivery treatments were well established and included the claimed range of 15 seconds to one minute. *See, e.g.*, Ex.1058-Wong, [0053] (disclosing that it takes 3-30 seconds of bipolar RF energy application to denature protein, which is representative of other tissue); Ex.1033-Stern, 6:63-7:6 (disclosing applying RF electric current to heat tissue surface for 10 seconds to 10 minutes); Ex.1016-Edwards’886, FIG.79 (showing temperature in tissue rising to stable temperatures at times between 15 seconds to 1 minute). These time ranges are consistent with my own experience delivering RF energy treatment to patients in my clinical practice—the amount of time varies from patient to patient, within a given patient, and further depends on the energy delivery device being used, but can fall within the claimed range of 15 seconds to one minute. In some instances, shorter durations of RF energy application are effective.

130. In addition, I have spoken with Dr. Gregory Martin and reviewed his declaration. Dr. Martin’s analysis confirms and supports my conclusions that the combination of Edwards-’535, Kong, and Stern discloses that the amount of time

the radiofrequency energy is applied to the target tissue is between fifteen seconds and one minute.

131. For these reasons, it is my opinion that claim 10 would have been obvious in view of Edwards-'535, Kong, and Stern.

9. Claim 11:

- a. 11[a]: The method of claim 1, further comprising, before removing the treatment element from the nasal airway: & 11[b]: repositioning the treatment element to contact a different portion of nasal mucosa; and**

132. The combined method of Edwards-'535 and Kong includes the claimed step of repositioning the treatment element to contact a different portion of nasal mucosa (e.g., anterior, middle, or posterior part of the turbinate) before removing the treatment element from the nasal airway.

133. A person of ordinary skill in the art would have understood, or at least found obvious, that Edwards-'535's treatment element generally would not have delivered treatment to just one location in the nasal airway at a time but would have instead been repositioned (perhaps multiple times) to deliver treatment to multiple locations each time it is inserted into the nostril. This is particularly the case where, as here, the treatment is being delivered to the parasympathetic nerves of the inferior turbinate, as taught by Kong, because these nerves form a plexus, i.e., a branching network that provides multiple signaling pathways through the

turbinate. Delivering spot treatment to a single location within a nerve plexus is unlikely to have significant clinical benefits, as the nerve signals can simply bypass the affected area. To significantly disrupt the signaling in the nerve plexus and thereby achieve the desired clinical effects, treatment is delivered to nerve tissue spanning a large area of the turbinates. Practically, this is accomplished by having multiple bipolar electrodes and by repositioning the RF treatment element to target nerve tissue multiple locations. For example, in my clinical practice I will often reposition an RF treatment element six or more times to deliver treatment to different areas of the turbinate. Moreover, although Edwards-'535's use of an inflatable balloon with a large surface area may reduce the number of times the treatment element is repositioned relative to a smaller electrode, a person of ordinary skill in the art nevertheless would have understood at least some repositioning of the balloon to be beneficial given the large size of the inferior turbinate.

134. Consistent with this understanding, Edwards-'535 teaches that its treatment element is placed in different positions to contact different portions of the inferior turbinate. For example, Figures 3B and 3D, reproduced below, depict the treatment element contacting the anterior or middle portion of the inferior turbinate, respectively, where the treatment element is repositioned depending on which

portion is being contacted (i.e., the balloon is not large enough to encompass the entire surface inferior turbinate without being repositioned).

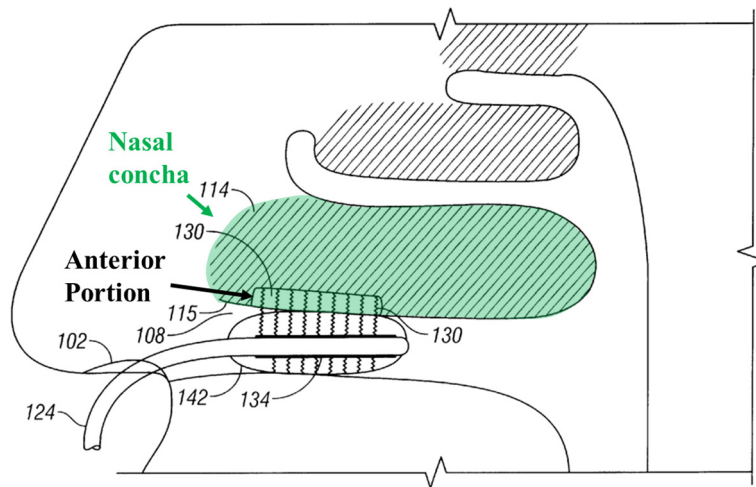


FIG. 3D

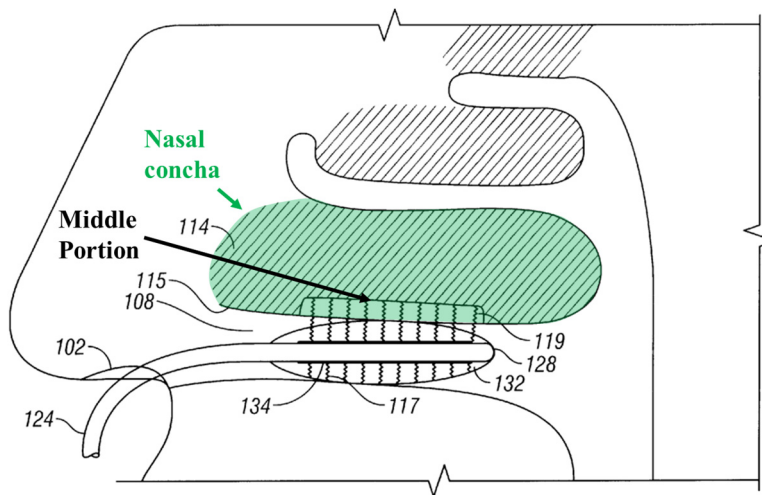


FIG. 3B

Ex.1010-Edwards-'535, FIGs.3D, 3B (annotated); *see also id.*, 6:38-48 (“[E]nergy is delivered to a selected section of one of the nasal concha. For example, energy

may be selectively delivered to the anterior or posterior sections of the inferior nasal concha. Delivery of energy to a selected section of a nasal concha may be accomplished by the placement of the apparatus within the nasal meatus.”).

135. Moreover, Kong teaches that energy is delivered to a plural number of locations “at the lower...edge of the inferior turbinate,” including “the anterior, middle, and posterior part.” Ex.1040-Kong, 214. These multiple locations are targeted in a single pass (i.e., by repositioning the treatment element) before the “electrode [is] slowly removed.” *Id.*

136. Accordingly, in the combined method of Edwards-’535 and Kong, it would have been obvious to reposition the treatment element (e.g., Edwards-’535’s expandable member 132) to contact different portions of the nasal mucosa (e.g., the mucosa lining the anterior, middle, and posterior part of the inferior turbinate, as taught by Kong) before removing the treatment element from the nasal airway. Moreover, a person of ordinary skill in the art would have found repositioning the treatment element to be reasonably likely to successfully treat allergic rhinitis in view of Kong’s teachings that repositioning the treatment element to target tissue within three different portions of the inferior turbinate yielded promising clinical results.

- b. 11[c]: applying radiofrequency energy with the bipolar electrode pairs through the different portion of nasal mucosa to a different portion of target tissue for the amount of time to heat the different portion of target tissue.**

137. The combined method of Edwards-'535 and Kong includes the claimed step of applying radiofrequency energy with the bipolar electrode pairs through the different portion of nasal mucosa to a different portion of target tissue (e.g., the anterior, middle, or posterior part) for the amount of time to heat the different portion of target tissue before removing the treatment element from the nasal airway.

138. As I explained above with reference to limitations 11[a] and 11[b], combining the teachings Edwards-'535 and Kong results in a method that includes repositioning Edwards' expandable member 132 (i.e., the claimed treatment element) at different locations (e.g., the anterior, middle, and posterior part of the turbinate, as taught by Kong) to deliver similar treatment (e.g., RF energy based treatment) at each location before removing the treatment element from the nasal airway. Moreover, as I explained above with reference to limitation 1[b], the combined method would have delivered treatment at each of the different locations by applying RF energy with the bipolar electrode pairs through the nasal mucosa to

a target tissue underlying the nasal mucosa for an amount of time to heat the target tissue.

139. For these reasons, it is my opinion that claim 11 would have been obvious in view of Edwards-'535, Kong, and Stern.

10. Claim 12: The method of claim 1, wherein the modified at least one property of the target tissue is selected from the group consisting of shrinking, tightening, stiffening, and deactivating the target tissue.

140. The combination of Edwards-'535 and Kong teaches that the modified at least one property of the target tissue, as recited by limitations 1[d] and 1[e], is selected from the claimed group (e.g., shrinking and/or deactivating the target tissue). For example, as I explained above with reference to limitations 1[pre], 1[d], and 1[e], Edwards-'535 teaches that the target tissue is modified by destroying and/or reducing its size, thereby shrinking the target tissue, as claimed.

141. Moreover, as I explained above with reference to limitations 1[pre], 1[a], 1[d], and 1[e], using the combined method to ablate the particular target tissue identified in Kong (e.g., nerve and/or submucosal tissue) results in “damaging the cholinergic microganglia and parasympathetic nerve fibers from the inferior turbinate, the unmyelinated sensory nerve fibers (SP energy nerves) and parasympathetic nerve endings from the pterygoid and anterior ethmoidal nerves in

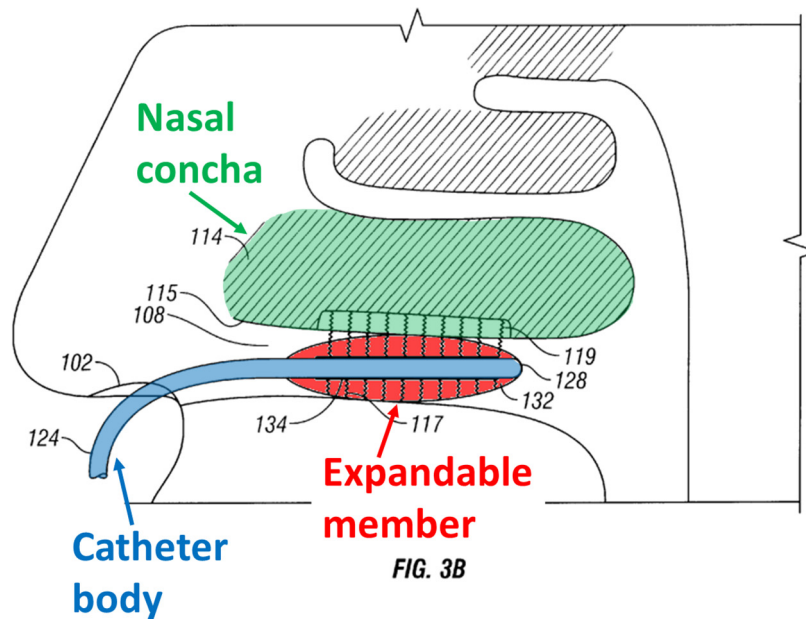
the nose.” Ex.1040-Kong, 215. Damaging the nerves would have been understood to result in deactivation, as claimed, particularly given that Kong’s purpose is to deliver treatment that prevents over-active nerves from triggering symptoms of allergic rhinitis.

142. For these reasons, it is my opinion that claim 12 would have been obvious in view of Edwards-’535, Kong, and Stern.

11. Claim 16: The method of claim 1, further comprising bending a shaft of the nasal airway treatment device before contacting the treatment element with the nasal mucosa.

143. The combined method of Edwards-’535 and Kong includes the claimed step of bending a shaft of the nasal airway treatment device before contacting the treatment element with the nasal mucosa.

144. Figure 3B of Edwards-’535 is reproduced below.



Ex.1010-Edwards-'535, FIG.3B. Figure 3B shows that apparatus 124 (i.e., the claimed nasal airway treatment device) includes a catheter (blue) (i.e., the claimed shaft) used to position expandable member 132 at a target site within the nasal passages of a patient. *Id.*, FIG.3B, 2:63-3:6 (“the apparatus includes a catheter having a distal portion with a dimension configured for positioning the catheter distal portion through a nostril of a patient”). The catheter has a bend along its length, which a person of ordinary skill in the art would have recognized is necessarily formed at some time, and is often formed during the medical procedure itself for the purpose of reaching around contours and bends in the patient’s nasal passages.

145. Edwards-'535 does not provide details about when or how the bend shown in Figure 3B was formed, which is consistent with the fact that forming bends in catheter shafts has long been routinely performed in the context of delivering treatment to the nasal passages. By way of example, the following references disclose further details of forming bends in catheter shafts when treating upper airway conditions.

- Ex.1013-Baker, 22:21-35 (“[T]he energy delivery member may comprise a flexible, steerable structure 48.... A distal end of the energy delivery member 46, 48 is preferably navigable to target tissue sites or target blocked sites within cavities, such as nasal passages and blocked ostia, where it can be activated to provide mechanical and cavitation effects that promote recanalization of obstructed passages.”), 23:9-13 (“In some embodiments, a guidance member, such as a guidewire-type member, may be provided and operated separately from an energy delivery member. In this embodiment, the guidance member may be advanced and positioned at a desired operating site, and the energy delivery member may then be advanced over, along-side or through the guidance member for positioning and activation at the desired operating site.”), FIGs.7-8D;

- Ex.1019-Gertner, [0072] (“In one embodiment, the insertion member 106 is flexible so that its shape and orientation with respect to the housing or hand piece 102 may be adjusted. A flexible material, such as rubber, plastic, or metal may be used to construct the insertion member 106, and to provide flexibility thereto. In one embodiment, a goose-neck tube, or spiral wound coil is used to provide a flexible insertion member 106.”), [0077] (“The insertion member 106 may be made of flexible materials so that it can bend, or be steered around corners, or conform to the shape of the cavity, as required.”);
- Ex.1021-Makower, [0195] (“It is to be further understood that any of the catheters, scopes, elongate working devices or other devices disclosed in this patent application may be rendered steerable or volitionally bendable, unless to do so would make such device inoperative for its intended purpose. Steerable catheters and scopes are well known in the art and may utilize mechanical steering assemblies (e.g., pull wires, hinges, etc.) or shape memory materials (e.g., nickel titanium alloys, shape memory polymers, etc.) to induce the device to undergo the desired bending or curvature after it has been inserted into the body. Examples of apparatus and construction that may be used to render these devices steerable or volitionally bendable

include but are not limited to those described in U.S. Pat. No. 5,507,725 (Savage et al.), U.S. Pat. No. 5,656,030 (Hunjan et al.), U.S. Pat. No. 6,183,464 (Webster), U.S. Pat. No. 5,251,092 (Qin et al.), U.S. Pat. No. 6,500,130 (Kinsella et al.), U.S. Pat. No. 6,571,131 (Nguyen), U.S. Pat. No. 5,415,633 (Lazarus et al.), U.S. Pat. No. 4,998,916 (Hammerslag et al.), U.S. Pat. No. 4,898,577 (Badger et al.), U.S. Pat. No. 4,815,478 (Buchbinder et al.) and published U.S. Patent Applications No. 2003/0181827A1 (Hojeibane et al.) and 2003/0130598A1 (Manning et al.), the entities [sic] of which are expressly incorporated herein by reference.”).

146. A person of ordinary skill in the art therefore would have readily applied background knowledge regarding how to use and manipulate catheters to form the bend in Edwards-’535’s catheter shaft, and would have found it obvious to do so. For example, forming a bend in Edwards-’535’s catheter shaft would have been a matter of using a known technique (i.e., one or more well-known techniques for forming a bend in a catheter shaft) to improve a similar device (Edwards’ apparatus 124, which includes a bent catheter shaft) in the same way.

147. Edwards-’535 lack of specificity about the catheter shaft (e.g., the material that the shaft is made of is not specified) further supports that a person of ordinary skill in the art would have recognized that Edwards-’535 is ready for

improvement and would have been motivated to turn to background knowledge to implement Edwards-'535's teachings. For example, a person of ordinary skill in the art would have selected a suitable technique for forming the bend in Edwards-'535's catheter shaft as a matter of routine implementation, yielding the predictable result of a catheter having a desired shape for delivering treatment to the nose. A person of ordinary skill in the art also would have had a reasonable expectation of success, as forming a bend in the catheter shaft would have facilitated accurate placement of the distal end of Edwards-'535's catheter shaft at a target location and would have allowed the distal end to reach otherwise hard-to-reach locations of the nose, e.g., posterior surfaces of a nasal turbinate.

148. For these reasons, it is my opinion that claim 16 would have been obvious in view of Edwards-'535, Kong, and Stern.

B. Ground II: Claim 4 Is Invalid as Obvious Over Edwards-'535 in View of Kong and Stern in Further View of Edwards-'886

1. Claim 4: The method of claim 1, wherein the radiofrequency energy is applied in the form of a 460 kHz sinusoid wave.

149. The combination of Edwards-'535 and Kong, in further view of Edwards-'886, teaches that the radiofrequency energy is applied in the form of a 460 kHz sinusoid wave. For example, Edwards-'886 teaches an RF energy delivery device that applies energy in the form of a "sinusoidal waveform at 460

kHz.” Ex.1016-Edwards-’886, 36:66-37:6. Like the combined method of Edwards-’535 and Kong, Edwards-’886’s technique ablates tissue (such as nerve tissue), supplies “up to 15 watts of radio frequency energy,” and operates in a “bipolar mode.” *Id.*, 22:41-56, 36:66-37:6; *cf.* Ex.1040-Kong, 215 (explaining that the treatment ablates “nerve fibers from the inferior turbinate”); Ex.1010-Edwards-’535, 9:1-11 (explaining that the treatment supplies “between about 5 and about 30 watts of RF energy” to the target tissue), 10:52-61 (explaining that the treatment includes “bipolar...energy delivery”). I further note that Edwards-’535 and Edwards-’886 share the same first named inventor, Stuart Edwards.

150. In view of these similarities, a person of ordinary skill in the art would have readily applied Edwards-’886’s teaching of a 460 kHz sinusoid wave to the combined method of Edwards-’535 and Kong and would have found the use of such a waveform to be reasonably likely to successfully ablate the nasal tissues targeted using the combined method. In fact, other references describe successfully ablating tissue within the nose to treat rhinitis using radiofrequency energy at 460 kHz. *See* Ex.1039-Banhiran, 950 (“[T]emperature-controlled radiofrequency volumetric reduction (RFVTR) has been applied to treat several upper airway diseases especially chronic rhinitis and obstructive sleep apnea. Its major mechanism is to produce thermal coagulation necrosis in the submucosal

tissue by releasing specific radiofrequency (460 kHz) energy through a special probe under well-controlled temperature (60°-90°C).”).

151. In addition, I have spoken with Dr. Gregory Martin and reviewed his declaration. Dr. Martin’s analysis confirms and supports my conclusions that the combination of Edwards-’535, Kong, Stern, and Edwards-’886 teaches that the radiofrequency energy is applied in the form of a 460 kHz sinusoid wave.

152. For these reasons, it is my opinion that claim 4 would have been obvious in view of Edwards-’535, Kong, Stern, and Edwards-’886.

C. Ground III: Claims 1-3, 6-12, 16 Are Invalid as Obvious Over Edwards-’535 in View of Liang and Stern

1. Claim 1

a. 1[pre]: A method for treating a nasal airway to reduce mucus production, the method comprising:

153. As I explained above in my analysis of limitation 1[pre] in Ground I, Edwards-’535 teaches a method for treating a nasal airway by applying RF energy to the turbinates. Moreover, although Ground I focused on the treatment of the inferior turbinate, Edwards-’535’s method is equally applicable to techniques for treating the middle turbinate. Ex.1010-Edwards-’535, 6:40-42 (“The nasal concha ablated may be the inferior, middle and/or superior nasal concha.”).

154. Liang also discloses techniques that aim to treat upper airway conditions (and thereby carry out a method of treating a nasal airway, as claimed) by applying RF energy to the turbinates. Ex.1056-Liang, 341. For example, Liang targets the same anatomical structures as Edwards-'535, e.g., tissue located within the "middle turbinate," which Liang also refers to as the "nasal ridge." *Id.* Moreover, Liang's method results in "damage[ing]...the deep ethmoidal nerve," which "reduc[es] runny nose" (i.e., the claimed reduction in mucus production) and mitigates other symptoms of allergic rhinitis. *Id.*, 341-42.

155. In Liang's study, patients with allergic rhinitis were treated with "thermocoagulation." *Id.*, 341-42. Thermocoagulation refers to the use of energy to heat tissue and thereby ablate the tissue. *See* Ex.1066-Cioanta, [0061] ("thermal ablation is carried out by causing the targeted tissue to thermocoagulate"). This is the same mechanism that Edwards-'535 describes for ablating tissue. Ex.1010-Edwards-'535, 5:35-45 ("[A]blative energy...caus[es] the ablation of tissue by heating at least a portion of the nasal [turbinates] being treated.").

i. *Motivation to Combine Edwards-'535 and Liang*

156. As I explained above, Edwards-'535 teaches a method in which RF energy is applied to tissue underlying the mucosa of the middle turbinate. *See, e.g.,* §§ X.A.1.a-c. Additional details about RF energy based treatment applied to

tissue within the middle turbinate are found in Liang. As an initial matter, a person of ordinary skill in the art would have understood that Liang, like Edwards-'535 and Stern, are in the same field as the '271 patent and are reasonably pertinent to solving the problems addressed in the '271 patent (e.g., treating tissue in a body cavity) with the same types of solutions (e.g., applying RF energy to tissue).

Ex.1056, 341-42. Additionally, Liang teaches methods that apply RF energy to specific tissues and structures of the upper airways to treat allergic rhinitis and its symptoms. In view of these teachings, a person of ordinary skill in the art would have been motivated to combine Edwards-'535 and Liang such that Edwards-'535's method and device would have been applied to deliver RF energy to specific tissues to treat allergic rhinitis, as taught by Liang. Below, I explain why a person of ordinary skill in the art would have been motivated to combine Edwards-'535 and Liang in this manner with a reasonable expectation of success.

157. For one, Liang supplies ample reasons to treat specified tissues within the middle turbinate (e.g., nerve tissue underlying the mucosa of the “anterior part of the middle turbinate”) using RF energy. Liang states (and supports with real-world clinical data) that its approach based on targeting specified tissues using RF energy to treat allergic rhinitis achieved a “overall effective rate [of] 95.5%” and “[n]o complications such as nasal septum perforation, nasal dryness, or decreased

olfactory function occurred.” Ex.1056-Liang, 341, Abstract; *see also id.*, 342 (explaining that Liang’s technique “has no obvious side effects or serious complications, has significant therapeutic effects, and has good clinical application values”). More specifically, Liang includes a detailed analysis to explain why ablating the particular tissues targeted in the study, e.g., nerves within the middle turbinate, results in “damage to the deep ethmoidal nerve, reducing its sensitivity to adverse external physical and chemical stimuli, reducing the secretion of vasoactive peptides, inhibiting sneezing reflex, reducing runny nose, and improving nasal ventilation, thus achieving the goal of treating allergic rhinitis.” *Id.*, 342. A person of ordinary skill in the art would have therefore recognized that combining Edwards-’535’s teachings in connection with a method for treating the middle turbinate with RF energy with Liang’s teaching of particular target tissues would have improved Edwards-’535’s method by enabling treatment of allergic rhinitis effectively and with few side effects or risks of complications.

158. Moreover, Liang acknowledges certain deficiencies of its own treatment methods that are not present in Edwards-’535’s methods, which provides an additional express motivation for a person in the ordinary skill in the art to combine Edwards-’535 and Liang. For example, Liang observes that its method of targeting particular nerve tissues was highly effective at treating allergic rhinitis

but that its methods resulted in “bloody secretions due to nasal reactions” after treatment and that some patients “developed nasal adhesion” (where two surfaces damaged during the procedure heal together). *Id.*, 341-42. Edwards-’535’s method achieves the same objective of Liang whereby “an interior portion of a nasal concha is ablated,” but unlike Liang accomplishes this goal “bloodlessly” and “without the formation of a wound on the surface of the nasal concha.” Ex.1010-Edwards-’535, 4:53-66. For example, Edwards-’535’s device includes a pliable balloon at its distal end, and certain embodiments further apply cooling to the tissue surface to avoid damaging the mucosa when targeting the underlying tissue. Accordingly, Liang’s teachings regarding the unwanted side effects of its clinical methods would have motivated a person of ordinary skill in the art to use Edwards-’535’s method of using an RF energy delivery device and/or an active cooling technique to target the nerve tissue identified in Liang.

159. Combining Edwards-’535 and Liang in the above-described manner would have yielded predictable results, particularly given that each of the references is directed to applying RF energy to nasal tissues to treat various conditions. *Id.*, 5:36-50 (Edwards-’535’s methods deliver “ablative energy...capable of causing the ablation of tissue.”), 1:22-23 (“The present invention relates to a method and apparatus for treating airway obstructions.”);

Ex.1056-Liang, 341 (“we used radiofrequency hyperthermia devices under nasal endoscopy to treat 88 cases of ethmoidal nerve with allergic rhinitis by thermocoagulation”). Another similarity between Edwards-’535 and Liang is that they each teach that the applied energy is used to ablate and heat tissue of the upper airways, such as tissue within the middle turbinate. Ex.1010-Edwards-’535, 5:27-38 (“Sufficient energy 117 is delivered through the surface 115 of the nasal [turbinate] 114 to ablate at least a portion 119 of the nasal [turbinate] 114.”), 6:40-42 (“The nasal concha ablated may be the inferior, middle and/or superior nasal concha.”); Ex.1056-Liang, 341 (“Under direct nasal endoscopy, the emitter was used to perform thermal coagulation treatment on the bilateral nasal ridge [(middle turbinate)] and the corresponding nasal septum mucosa.”). Given that Edwards-’535 and Liang are each focused on treating upper airway conditions by ablating nasal tissue using RF energy, a person of ordinary skill in the art would have found their teachings to be readily combinable in a manner that would have yielded predictable results.

160. As I explained above in Ground I (*see* Section X.A.1.a.i), survey studies of RF-energy based treatments included results of both RF-based rhinitis treatments (like that of Liang) and RF-based turbinate reduction treatments (like that of Edwards-’535). *See generally* Ex.1031-Hytönen. Given that devices used

to achieve the clinical outcomes of Edwards-'535 and Liang were known to be compatible and useful for both types of treatment, it would have been obvious to a person of ordinary skill in the art to use Edwards-'535's method for ablating tissue to target the particular tissue identified in Liang to obtain predictable results of reducing mucus production without damaging mucosal tissue.

161. A person of ordinary skill in the art would have understood that combining Edwards-'535 and Liang in the manner described above would have been reasonably likely to improve Edwards-'535's method by targeting particular tissues that Liang identifies as likely to treat allergic rhinitis and reduce mucus production. In addition, the combination would have been straightforward and predictable given that the techniques of Liang would have been used to improve Edwards-'535's similar method in the same way. For example, Liang's teachings would have been applied to Edwards-'535's in the same way those teachings are used in Liang itself: Liang teaches that using RF energy to ablate nerve tissue and/or turbinates is a promising way to treat allergic rhinitis, Ex.1056-Liang, 341-342, and Edwards-'535's method delivers RF energy to ablate tissue, Ex.1010-Edwards-'535, 5:36-51.

162. As I explained in Ground I (*see* Section X.A.1.a.i), other clinical studies from the same timeframe as Liang further demonstrate that applying RF

energy to the nose is a promising way to treat rhinitis and support that a person of ordinary skill in the art would have had a reasonable expectation of success.

Accordingly, combining Edwards-'535 and Liang would have yielded the predictable result of Edwards-'535's method being used to deliver RF energy to treat allergic rhinitis, as taught by Liang, with a reasonable expectation of success. Implementing the combination would have been straightforward and well within the capabilities of a person of ordinary skill in the art.

163. Accordingly, a person of ordinary skill in the art would have been motivated to combine the teachings of Edwards-'535 and Liang and would have done so with a reasonable expectation of success. Moreover, as I explain in further detail below with reference to limitations 1[a]-1[c], the combined teachings would have resulted in a method for treating a nasal airway to reduce mucus production, as claimed.

- b. 1[a]: contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises two rows of bipolar electrode pairs;**

164. The combined method of Edwards-'535 and Liang, in further view of the teachings of Stern, includes the claimed step of contacting a treatment element (e.g., expandable member 132 and energy delivery device 134, as taught by

Edwards-'535 and modified according to the teachings of Stern) of a nasal airway treatment device (e.g., apparatus 124, as taught by Edwards-'535 and modified according to the teachings of Stern) directly with nasal mucosa of the nasal airway (e.g., tissue lining middle turbinate, as taught by Liang), wherein the treatment element comprises two rows of bipolar electrode pairs (e.g., plurality of bipolar energy delivery devices, as taught by Stern).

- i. ***Edwards-'535 in view of Liang teaches contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises [a row] of bipolar electrode[s].***

165. As I explained above in my analysis of limitation 1[a] in Ground I, Edwards-'535 discloses contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises a row of bipolar electrodes. Liang also teaches that the treatment element used in its clinical methods directly contacted mucosal tissue of the middle turbinate. For example, Liang teaches that its methods use “the SHP-I radiofrequency treatment device for facial organs (manufactured by Guangzhou Medical Device Factory)...with the negative electrode connected to the lower part of the patient's chin...to perform thermal coagulation treatment.” Ex.1056-Liang, 341. A person of ordinary skill in the art would have recognized that the SHP-I

directly contacts the mucosa, as the SHP-I is described as “contact[ing]...patient’s tissues to produce an internal thermal effect..., which causes protein tissues to heat coagulate, dehydrate, shrink, harden, form blood clots, and gradually subside or disappear, leading to necrosis and detachment....” Ex.1059-Liang’227, 1.

ii. *Stern teaches wherein the treatment element comprises two rows of bipolar electrode pairs, and it would have been obvious to combine Edwards-’535 and Stern.*

166. As I explained above in my analysis of limitation 1[a] in Ground I, based on my discussion with Dr. Martin and my review of his declaration, I understand that Stern discloses two rows of bipolar RF electrodes and that the combination of Edwards-’535 and Stern would have been obvious. As I explained above with reference to the combination of Edwards-’535, Stern, and Kong, the benefits offered by Stern’s teachings would have been particularly beneficial when combined with the teachings of Liang for the same reasons, which would have been relevant to Liang’s technique. Additionally, Liang teaches that one outcome to avoid is a perforated nasal septum. Ex.1056-Liang, 342. Stern’s teachings to use two rows of bipolar electrode pairs that can individually control and direct energy would have been useful tools to help a clinician avoid perforating the nasal septum.

- c. 1[b]: applying radiofrequency energy with the bipolar electrode pairs through the nasal mucosa to a target tissue underlying the nasal mucosa for an amount of time to heat the target tissue; and**

167. The combined method of Edwards-'535 and Liang, in further view of Stern, includes the claimed step of applying radiofrequency energy with the bipolar electrode pairs (e.g., Edwards-'535's energy delivery device 134 modified to include bipolar electrode pairs, as taught by Stern) through the nasal mucosa to a target tissue underlying the nasal mucosa (e.g., the ethmoidal nerve within the middle turbinate, as taught by Liang) for an amount of time to heat the target tissue (e.g., the time needed to ablate tissue by heating, as taught by Edwards-'535).

168. As I explained above in my analysis of limitation 1[b] in Ground I, the combined teachings of Edwards-'535 and Stern disclose applying radiofrequency energy with bipolar electrode pairs, as claimed. Moreover, the combined method of Edwards and Liang would have resulted in the RF energy being applied through the surface of the mucosa of the middle turbinate to "damage...the deep ethmoidal nerve" (i.e., the claimed target tissue underlying the nasal mucosa) by heating the target tissue (e.g., by causing "thermocoagulation"). Ex.1056-Liang, 341-42; *see also id.*, 342 (discussing damaging "deep tissues"); Ex.1059-Liang'227, 1 (describing results from SHP-I).

169. Moreover, as I explained above in my analysis of limitation 1[b] in Ground I, Edwards-'535 and Stern each disclose that the RF energy is applied for an amount of time to heat the target tissue, as claimed.

d. 1[c]: removing the treatment element from the nasal airway,

170. As I explained above in my analysis of limitation 1[c] in Ground I, Edwards-'535 teaches that expandable member 132 having energy delivery device 134 (i.e., the claimed treatment element) is removed from the nasal airway. In addition, for the reasons I discussed above, it would have been obvious to combine Edwards-'535 with Liang so as to remove the treatment element. A person of ordinary skill in the art would have had a reasonable expectation of success in doing so for the same reasons.

e. 1[d]: wherein heating the target tissue with the applied radiofrequency energy modifies at least one property of the target tissue, and

171. As I explained above in my analysis of limitation 1[d] in Ground I, Edwards-'535 teaches that heating the target tissue with the applied radiofrequency energy ablates the target tissue a thereby modifies at least one property of the target tissue.

172. Further modifications that occur when heating the target tissue according to the combined method of Edwards-'535 and Liang are described in Liang:

[G]enerat[ing] strong endogenous heat effects in local cells, causing thermal coagulation of protein..., tissue degeneration, and atrophy.... Radiofrequency treatment can not only cause degeneration and atrophy of the sensitive mucosa..., as well as damage to the glands, but also can cause varying degrees of damage to the deep ethmoidal nerve, reducing its sensitivity to adverse external physical and chemical stimuli..., [and] reducing runny nose..., thus achieving the goal of treating allergic rhinitis.

Ex.1056-Liang, 341-42; *see also* Ex.1059-Liang'227, 1 (describing effects of SHP-I).

173. For the reasons I discussed above, it would have been obvious to combine Edwards-'535 with Liang so as to heat and modify a property of the target tissue. A person of ordinary skill in the art would have had a reasonable expectation of success in doing so for the same reasons.

f. 1[e]: wherein the modified at least one property of the target tissue causes a reduction in mucus production in the nasal airway.

174. The combination of Edwards-'535 and Liang teaches that the modified at least one property of the target tissue, as recited by limitation 1[d], causes a reduction in mucus production in the nasal airway.

175. As I explained above with reference to limitation 1[pre], the combined method of Edwards-'535 and Liang would have resulted in applying RF energy to the middle turbinate to ablate (modify) target tissue, thereby “damage[ing]...the deep ethmoidal nerve.” Ex.1056-Liang, 341-42. Liang explains that the effects of this treatment include “reducing runny nose,” which in turn “achiev[es] the goal of treating perennial allergic rhinitis.” *Id.*, 342. As I further explained with reference to limitation 1[pre], Liang’s reference to “reducing runny nose” would have been understood to refer to reducing mucus production in the nasal airway, as claimed.

176. For these reasons, it is my opinion that claim 1 would have been obvious in view of Edwards-'535, Liang, and Stern.

2. Claim 2: The method of claim 1, wherein the target tissue is selected from the group consisting of mucosa, submucosa, cartilage, muscle, ligament, and tendon.

177. The combination of Edwards-'535 and Liang teaches that the target tissue, as recited by limitations 1[b], 1[d], and 1[e], is selected from the claimed

group (e.g., mucosa and/or submucosa). For example, as I explained above with reference to limitation 1[b], combining the teachings of Edwards-'535 and Liang would have resulted in the radiofrequency energy being applied to the to the surface of the middle turbinate (i.e., the claimed mucosa) and to the underlying ethmoidal nerve (i.e., the claimed submucosa). Ex.1056-Liang, 341-42 (describing damaging mucosa and underlying ethmoidal nerve), 341 (causing "white spots of local mucosa"). Moreover, as I explained above in my analysis of claim 2 in Ground I, Edwards-'535 similarly teaches that the target tissue includes the mucosa and/or the submucosa.

178. For these reasons, it is my opinion that claim 2 would have been obvious in view of Edwards-'535, Liang, and Stern, and that a person of ordinary skill in the art would have had a reasonable expectation of success in such a combination.

3. Claim 3: The method of claim 1, further comprising controlling at least one characteristic of the applied radiofrequency energy with a control system coupled with the nasal airway treatment device.

179. As I explained above in my analysis of claim 3 in Ground I, a person of ordinary skill in the art would have understood that Edwards-'535 teaches, or at least renders obvious, the additional limitations of claim 3. For these reasons, it is

my opinion that claim 3 would have been obvious in view of Edwards-'535, Liang, and Stern, and a person of ordinary skill in the art would have had a reasonable expectation of success in such a combination.

4. **Claim 6: The method of claim 1, further comprising displaying one or more parameters of treatment on a console attached to the nasal airway treatment device while the radiofrequency energy is applied, the one or more parameters selected from the group consisting of treatment time, power level, temperature sensed by the treatment element, electric impedance, electric current, and depth of treatment.**

180. As I explained above in my analysis of claim 6 in Ground I, a person of ordinary skill in the art would have understood that Edwards-'535 teaches, or at least renders obvious, the additional limitations of claim 6. For these reasons, it is my opinion that claim 6 would have been obvious in view of Edwards-'535, Liang, and Stern, and a person of ordinary skill in the art would have had a reasonable expectation of success in such a combination.

5. **Claim 7: The method of claim 1, further comprising applying local anesthesia to at least one of the nasal mucosa or the target tissue before applying the radiofrequency energy.**

181. As I explained above in my analysis of claim 7 in Ground I, a person of ordinary skill in the art would have found it obvious to apply local anesthesia to the target tissues and/or the overlying mucosa before applying radiofrequency

energy to (or through) the tissue with a reasonable expectation of success in doing so, as the procedure would have been unduly painful without it and many known and reliable local anesthesia techniques existed long before the 2010s. Consistent with this understanding, Liang teaches that local anesthesia (e.g., 2% dicaine epinephrine) was applied to the surface of middle turbinate before applying the radiofrequency energy. Ex.1056-Liang, 341 (“The patient was put in the supine or semi-reclining position and was subjected to nasal mucosal anesthesia using a 2% dicaine epinephrine sponge, focusing on the anterior part of the middle turbinate (nasal ridge) and its corresponding nasal septum. Then, the SHP-I radiofrequency treatment device for facial organs (manufactured by Guangzhou Medical Device Factory) was used....”).

182. For these reasons, it is my opinion that claim 7 would have been obvious in view of Edwards-’535, Liang, and Stern, and that a person of ordinary skill in the art would have had a reasonable expectation of success in such a combination.

6. **Claim 8: The method of claim 1, wherein the radiofrequency energy is produced by a radiofrequency**

energy source configured to run between 1 Watt and 100 Watts.

183. As I explained above in my analysis of claim 8 in Ground I, a person of ordinary skill in the art would have understood that Edwards-'535 teaches, or at least renders obvious, the additional limitations of claim 8. Moreover, I have spoken with Dr. Gregory Martin and reviewed his declaration, and analysis confirms and supports my conclusions. For these reasons, it is my opinion that claim 8 would have been obvious in view of Edwards-'535, Liang, and Stern, and a person of ordinary skill in the art would have had a reasonable expectation of success in such a combination.

7. Claim 9: The method of claim 1, wherein applying the radiofrequency energy comprises heating the target tissue to a temperature between 50 degrees Celsius to 70 degrees Celsius.

184. As I explained above in my analysis of claim 9 in Ground I, a person of ordinary skill in the art would have understood that Edwards-'535 in view of Stern teaches, or at least renders obvious, the additional limitations of claim 9. Moreover, I have spoken with Dr. Gregory Martin and reviewed his declaration, and analysis confirms and supports my conclusions. For these reasons, it is my opinion that claim 9 would have been obvious in view of Edwards-'535, Liang, and Stern, and a person of ordinary skill in the art would have had a reasonable

expectation of success in such a combination. My conclusion is bolstered by the fact that the SHP-I device discussed in Liang heats tissue to a temperature within the range of 60-80°C. Ex.1059-Liang-'227, 1.

8. Claim 10: The method of claim 1, wherein the amount of time the radiofrequency energy is applied to the target tissue is between fifteen seconds and one minute.

185. As I explained above in my analysis of claim 8 in Ground I, a person of ordinary skill in the art would have understood that Edwards-'535 teaches, or at least renders obvious, the additional limitations of claim 10. Moreover, I have spoken with Dr. Gregory Martin and reviewed his declaration, and analysis confirms and supports my conclusions. For these reasons, it is my opinion that claim 10 would have been obvious in view of Edwards-'535, Liang, and Stern, and a person of ordinary skill in the art would have had a reasonable expectation of success in such a combination.

9. Claim 11:

a. 11[a]: The method of claim 1, further comprising, before removing the treatment element from the nasal airway & 11[b]: repositioning the treatment element to contact a different portion of nasal mucosa; and

186. As I explained above in my analysis of limitations 11[a] and 11[b] in Ground I, the claimed step of repositioning the treatment element to contact a different portion of nasal mucosa before removing the treatment element from the

nasal airway would have been obvious when using a device like Edwards-'535's treatment device to treat a nerve plexus like the ethmoidal nerve, as taught by Liang. Ex.1056-Liang, 341 (discussing applying RF energy to multiple locations, such as the nasal septum mucosa in addition to the middle turbinate). A person of ordinary skill in the art would have been motivated to move the device from the middle turbinate to the nasal septum mucosa (or vice versa) and had a reasonable expectation of success in doing so for the reasons I discussed with regard to limitation 1[pre] above and limitations 11[a] and 11[b] in Ground I.

b. 11[c]: applying radiofrequency energy with the bipolar electrode pairs through the different portion of nasal mucosa to a different portion of target tissue for the amount of time to heat the different portion of target tissue.

187. As I explained above in my analysis of limitation 11[c] in Ground I, the claimed step of applying radiofrequency energy with the bipolar electrode pairs through the different portion of nasal mucosa to a different portion of target tissue for the amount of time to heat the different portion of target tissue before removing the treatment element from the nasal airway would have been obvious when using a device like Edwards-'535's treatment device (as modified according to the teachings of Stern) to treat a nerve plexus like the ethmoidal nerve, as taught by Liang. A person of ordinary skill in the art would have understood that all

treatment locations of Liang involve nasal mucosa, and thus that the same application time would be usable to heat the tissue to the same temperature. A person of ordinary skill in the art therefore would have been motivated to apply energy to both the middle turbinate to the nasal septum mucosa in the same way and had a reasonable expectation of success in doing so for the reasons I discussed with regard to limitation 1[pre], 11[a], and 11[b] above and limitations 11[a]-11[c] in Ground I.

188. For these reasons, it is my opinion that claim 11 would have been obvious in view of Edwards-'535, Liang, and Stern.

10. Claim 12: The method of claim 1, wherein the modified at least one property of the target tissue is selected from the group consisting of shrinking, tightening, stiffening, and deactivating the target tissue.

189. The combination of Edwards-'535 and Liang teaches that the modified at least one property of the target tissue, as recited by limitations 1[d] and 1[e], is selected from the claimed group (e.g., shrinking and/or deactivating the target tissue). For example, as I explained above with in my analysis of claim 12 in Ground I, Edwards-'535 teaches that the target tissue is modified by destroying and/or reducing its size, thereby shrinking the target tissue, as claimed.

190. Moreover, as I explained above with reference to limitations 1[pre], 1[a], 1[d], and 1[e], using the combined method to ablate the particular target tissue identified in Liang (e.g., nerve and/or submucosal tissue) results in “damag[ing]...the deep ethmoidal nerve.” Ex.1056-Liang, 341-42. Damaging the nerves would have been understood to result in deactivation, as claimed, particularly given that Liang’s purpose is to deliver treatment that prevents over-active nerves from triggering symptoms of allergic rhinitis.

191. For these reasons, it is my opinion that claim 12 would have been obvious in view of Edwards-’535, Liang, and Stern, and that a person of ordinary skill in the art would have had a reasonable expectation of success in such a combination.

11. Claim 16: The method of claim 1, further comprising bending a shaft of the nasal airway treatment device before contacting the treatment element with the nasal mucosa.

192. As I explained above in my analysis of claim 16 in Ground I, a person of ordinary skill in the art would have understood that Edwards-’535 teaches, or at least renders obvious, the claimed step of bending a shaft of the nasal airway treatment device before contacting the treatment element with the nasal mucosa. For these reasons, it is my opinion that claim 16 would have been obvious in view

of Edwards-'535, Liang, and Stern, and that a person of ordinary skill in the art would have had a reasonable expectation of success in such a combination.

D. Ground IV: Claim 4 is Invalid as Obvious Over Edwards-'535 in View of Liang and Stern in Further in View of Edwards-'886

1. Claim 4: The method of claim 1, wherein the radiofrequency energy is applied in the form of a 460 kHz sinusoid wave.

193. As I explained above in my analysis of claim 4 in Ground II, a person of ordinary skill in the art would have understood that Edwards-'535 in view of Edwards-'886 teaches, or at least renders obvious, the additional limitations of claim 4. Moreover, I have spoken with Dr. Gregory Martin and reviewed his declaration, and analysis confirms and supports my conclusions. For these reasons, it is my opinion that claim 4 would have been obvious in view of Edwards-'535, Liang, Stern, and Edwards-'886, and that a person of ordinary skill in the art would have had a reasonable expectation of success in such a combination.

XI. AVAILABILITY FOR CROSS-EXAMINATION

194. 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

195. 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

196. 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

/John M. DelGaudio, MD/
John M. DelGaudio, M.D.

APPENDIX A

**EMORY UNIVERSITY SCHOOL OF MEDICINE
CURRICULUM VITAE**

10/27/23

1. Name: John M. DelGaudio, M.D.
2. Office Address: Department of Otolaryngology
The Emory Clinic
550 Peachtree St., NE
Suite 1135
Atlanta, GA 30308
Telephone: (404) 778-2178
Fax: (404) 778-4295
3. E-mail Address: jdelgau@emory.edu
4. Home Address:
3615 Habersham Rd. NW
Atlanta, GA 30305
Phone: (404) 788-7004
5. Current Titles and Affiliations:
 - a. Academic appointments:
 1. Primary appointments:

Gerald S. Gussack, MD Endowed Professor of Otolaryngology-Head and Neck Surgery. August 1, 2014 – present.

Vice Chair, Department of Otolaryngology- Head and Neck Surgery, Emory University School of Medicine, October 2010- 2021.

Professor, Department of Otolaryngology-Head and Neck Surgery, Emory University School of Medicine, September 2009- present.

Residency Program Director, Department of Otolaryngology- Head and Neck Surgery, Emory University School of Medicine, January 2007-July 2015.

Chief of Rhinology, Sinus, and Skull Base Surgery, Department of Otolaryngology Head and Neck Surgery, Emory University School of Medicine, September 2004-present.
 - b. Clinical Appointments:

Attending Physician, Department of Otolaryngology-Head and Neck Surgery, The Emory Clinic, July 1995-present

Attending Physician, Egleston Children's Hospital, July 1995-present

John M. Del Gaudio, M.D.

Attending Physician, Grady Memorial Hospital, July 1995-present

Attending Physician, Atlanta Veterans Administration Hospital, August 2003-present

c. Administrative appointments:

Executive Committee, Ambulatory Surgery Center, Emory Healthcare, June 2011-present

Ambulatory Surgery Block Utilization Committee, Emory Healthcare, 2017-present

Physician Steering Committee for Clinical Redesign, Emory Healthcare, December 2008-2012

CEO Advisory Committee, The Emory Clinic, February 2003-2008

Ambulatory Surgery Committee, The Emory Clinic, 1996-present

Otolaryngology Physician Liaison, The Emory Clinic Electronic Medical Record Project 2002

Otolaryngology Physician Liaison, Charge Capture, 2002

d. Other positions:

Board of Directors, Oral, Head and Neck Cancer Advocacy Foundation

7. Previous Academic and Professional Appointments:

Associate Professor, Department of Otolaryngology-Head and Neck Surgery, Emory University School of Medicine, September 1, 2004- September 1, 2009.

Assistant Professor, Department of Otolaryngology-Head and Neck Surgery, Emory University School of Medicine, July 1995- September 2004.

8. Previous Administrative and/or Clinical Appointments:

Lakes Community Urgent Care; Pinckney, MI; July 1993 – June 1995

Hartland Urgent Care; Hartland, MI; June 1992 – July 1993

Deputy Medical Examiner; Washtenaw County, MI; January 1992 – June 1995

Chelsea Community Hospital Emergency Room, Chelsea, MI; October 1991 – June 1995

McPherson – McAuley Urgent Care, Brighton, MI; August 1991 – June 1995

Physician Contractor, Emergency Department; Emergency Physicians Medical Group, Ann Arbor, MI; July 1991 – June 1995

John M. Del Gaudio, M.D.

9. Licensures/Boards:

Georgia – license# 039772, issued April 6, 1995

10. Specialty Boards:

American Board of Otolaryngology-Head and Neck Surgery - March 26, 1996

11. Education:

1985-1989, M.D., Jefferson Medical College, Philadelphia, PA (Maxima Cum Laude)

NBME Part I 6/09/87

NBME Part II 9/28/88

NBME Part III 3/07/90

Certification Date 7/01/90

1981-1985, B.A., LaSalle University, Philadelphia, PA (Honors Program; Magna Cum Laude)

1977-1981, Diploma, West Catholic Boys High School, Philadelphia, PA

12. Postgraduate Training:

Residency, Department of Otolaryngology-Head and Neck Surgery, University of Michigan Hospitals, Ann Arbor, Michigan, 1990-1995

Fellowship, N.I.H. Funded Research Fellowship (Topic: Muscle Fiber Types and Myosin Heavy Chain Isoforms in Normal and Denervated Rat Laryngeal Muscles), 1991-1992

Internship, General Surgery, Lankenau Hospital, Department of Surgery, Philadelphia, PA, 1989-1990

13. Military or Government Service:

14. Committee Memberships:

a. National and international:

American Rhinologic Society representative to International Forum of Allergy and Rhinology LLC, January 2018- December 2021

President, American Rhinologic Society, September 2016- September 2017

President Elect, American Rhinologic Society, September 2015- September 2016

Program Chair, American Rhinologic Society, September 2015- September 2016

1st Vice President, American Rhinologic Society, September 2014-September 2015

John M. Del Gaudio, M.D.

2nd Vice President, American Rhinologic Society, September 2013-September 2014

Board Member- Board of Directors, American Rhinologic Society, 9/2011-9/2013

Consultant to the Board of Directors – American Rhinologic Society, 9/2009-9/2011

ENToday- Literature Review Committee, 2009-2016.

Chair- Credentials Committee, American Rhinologic Society, September 2007-2011

Education Committee, American Academy of Otolaryngology- Head and Neck Surgery, 2007-2010

Scientific Program Committee, American Rhinologic Society, 2007-2010

Member at Large, Board of Directors, American Rhinologic Society, 9/2007-9/2008

Member-at-Large to Nominations Committee, American Rhinologic Society, 2007-2008

Credentials Committee, American Rhinologic Society, December 2002-2007

Scientific Program Committee, American Rhinologic Society, 2004-2006

Education Committee, American Rhinologic Society, 2005-2008

Self- Instructional Package Committee, American Academy of Otolaryngology- Head and Neck Surgery, 2005-2008

Centralized Otolaryngology Research Experience (Consultant), American Academy of Otolaryngology- Head and Neck Surgery, 2007

b. Regional and state:

Board of Directors, Georgia Society of Otolaryngology, 2006-present

President 2009-2010

President-Elect, 2008-2009

Treasurer- 2007-2008

Secretary, 2006-2007

Metro Atlanta Otolaryngology - Head & Neck Surgery Society

President, 1998-1999

President Elect, 1997-1998

Secretary, 1996-1997

15. Consultantships:

John M. Del Gaudio, M.D.

Medtronic- 2018-present
Pro-Dex- 2019- present

16. Editorships and Editorial Boards:

International Forum of Allergy and Rhinology, 2010-present

17. Manuscript Reviewer:

Ophthalmic Plastic and Reconstructive Surgery 2015

Cephalalgia 2013

International Forum of Allergy and Rhinology, 2010-present

American Journal of Rhinology & Allergy, 2002- present

Otolaryngology Head and Neck Surgery, 2004-present

Archives of Otolaryngology-Head and Neck Surgery, 1997- present

Laryngoscope, 2005-present

Annals of Otolaryngology, Rhinology, Laryngology, 1998-present

Skull Base Surgery, 1999

18. Honors and Awards:

Best Clinical Research Paper. International Society for Inflammation and Allergy of the Nose (ISIAN). Rhinoworld Chicago June 6-9, 2019. Central Compartment Involvement in AERD: The Role of Allergy and Previous Surgery.

Lester Brown Award from the Georgia Society of Otolaryngology for distinguished service in Otolaryngology in the State of Georgia. 7/2016

Certificate of Honor- American Academy of Otolaryngology- Head and Neck Surgery 9/2010

The Gerald S. Gussack Award from The Georgia Society of Otolaryngology for teaching in the field of Otolaryngology, July 27, 2007

The Golden Head Mirror Award from The American Rhinologic Society for teaching and service in the field of Rhinology, September 16, 2006

John M. Del Gaudio, M.D.

Fellow, The Triological Society, 2005

Emory University Woodruff Leadership Academy Class of 2005

John L. Kemink Award (Clinical Research Award), University of Michigan Department of Otolaryngology- Head and Neck Surgery 1995

The Gilson Colby Engel Award (Intern of the Year), Lankenau Hospital, Philadelphia, PA 1989-1990

The Alumni Prize, Jefferson Medical College, 1989

James J. Cooper Scholarship, Jefferson Medical College, 1988-1989

AOA, 1987

Hobart Amory Hare Medical Honor Society, 1987

Lange Medical Publication Prize, Jefferson Medical College, 1986, 1987, 1988

Melvin I. Katzman Pathology Award, Jefferson Medical College, 1986-1987

McGraw-Hill Book Company Prize, Jefferson Medical College, 1985-1986

Physiology Award, Jefferson Medical College, 1985-1986

19. Society Memberships:

North American Skull Base Society, 2022

American College of Surgeons, Fellow 1998

American Academy of Otolaryngology - Head and Neck Surgery, Member 1991, Fellow 1996

The Triologic Society, Fellow 2005

American Rhinologic Society, Member 1997, Fellow 2002

Georgia Society of Otolaryngology, 1996

Secretary, 2006-2007

Treasurer, 2007-2008

President Elect, 2008-2009

President, 2009-2010

Metro Atlanta Otolaryngology - Head & Neck Surgery Society, 1995

Secretary, 1996-1997

President Elect, 1997-1998

President, 1998-1999

John M. Del Gaudio, M.D.

American Medical Association, 1995

Atlanta Medical Society, 1995

Medical Association of Georgia, 1995

National Board of Medical Examiners, Diplomate 1990

Sigma Xi, The Medical Research Society, 1988

20. Organization of National or International Conferences:

a. Administrative positions:

a. Please refer to Course Director and National Position sections

c. Sessions as chair:

a. Please refer to National and International Presentations

21. Research Focus:

The focus of my research is in Rhinology. Ongoing studies focus on office rhinologic surgery, central compartment atopic disease, nasal allergy, nasal polyps, idiopathic intracranial hypertension and skull base defects, and the nasal microbiome.

22. Patents: None

23. Grant Support:

a. Active Support/Clinical Trials

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 Sinusitis With or Without the Presence of Nasal Polyps- Clinical Trial

OptiNose

Co-Investigator (PI Joshua Levy)

2019-

A Phase 2 Multicenter, Double-blind, Randomized, Placebo-Controlled Trial to Evaluate Oral Ifetroban in Subjects with Symptomatic Aspirin Exacerbated Respiratory Disease (AERD)- Clinical Trial

Cumberland Pharmaceutical

Co-Investigator

2019-

SYNAPSE - StudY in NAsal Polyps patients to assess the Safety and Efficacy of mepolizumab- Clinical Trial

John M. Del Gaudio, M.D.

GlaxoSmithKline
Co-Investigator
2019-

CTH-301: An Open-Label, Phase 3 Study Examining the Long-Term Safety, Tolerability and Efficacy of APL-130277 in Levodopa Responsive Patients with Parkinson's Disease Complicated by Motor Fluctuations ("OFF" Episodes)- Clinical Trial
Sunovion
Sub-Investigator
2019-

Office Lateral Nasal Wall Implants for nasal obstruction- Clinical Trial
Spirox
Primary Investigator
2017-2020, \$50,000.

b. Previous support:

Office polypectomy with Coblation vs. microdebrider.
Arthrocare.
Primary Investigator
Unrestricted educational grant, 2012.

Incidence of laryngopharyngeal reflux (LPR) in patients who have failed endoscopic sinus surgery for chronic sinusitis. Use of a 3-channel pH catheter with a nasopharyngeal sensor to detect nasopharyngeal reflux
AstraZeneca Corporation
Primary Investigator
2002 – 2005, \$52,800.

The prevalence of coexistence of laryngopharyngeal/gastroesophageal reflux and obstructive sleep apnea: Correlation of simultaneous 24-hour pH study and overnight polysomnogram
AstraZeneca Corporation
Primary Investigator
2002 – 2005, \$40,000.

c. Collaborator:

Endocannabinoid Activity in Aspirin Exacerbated Respiratory Disease
Triological Society Career Development Award
Collaborator (PI Levy)
7/01/2018-06/30/2020

Wound Healing in Sinonasal Mucosa: Influence of Th2 Inflammatory Mediators
KL2 Scholar, NIH Mentored Clinical and Translational Research Scholars Program
Co-Investigator (PI Sarah K. Wise, MD)
2010–2012, \$25,000 technical per year

John M. Del Gaudio, M.D.

Characterization of Human Sinonasal Intercellular Junctional Proteins

American Rhinologic Society

New Investigator Award

Co-Investigator (PI Sarah K. Wise, MD)

2010-2011, \$25,000

Intercellular Junctional Proteins in Rhinosinusitis – Inflammatory Mediator Effects

Emory University Research Committee

Co-Investigator (PI Sarah K. Wise, MD)

2012, \$30,000

24. Clinical Service Contributions:

25. Formal Teaching:

a. Medical student teaching

1. Clinic and operating room teaching of third and fourth year medical students
2. Research mentoring for multiple medical students on almost yearly basis

b. Graduate program

1. Training programs:

Course Co-Director, Southern States Rhinology Course. Kiawah Island, SC, May 12-14, 2022

Course Co-Director, Southern States Rhinology Course. Kiawah Island, SC, April 22-24, 2021

Course Co-Director, Southern States Rhinology Course. Kiawah Island, SC, May 3-5, 2019

Course Co-Director, Virtual Rhinology IV, American Rhinologic Society. March 16, 2019

Course Co-Director, Southern States Rhinology Course. Kiawah Island, SC, May 3-5, 2018

Course Co-Director, Southern States Rhinology Course. Kiawah Island, SC, March 30-April 1, 2017

Course Co-Director, The Second Oceanic-American Sinus/Skull Base Interactive Symposium (OASSIS II), Atlanta, GA, May 5-7, 2016

Course Co-Director, Southern States Rhinology Course. Kiawah Island, SC, April 21-23, 2016

John M. Del Gaudio, M.D.

Course Co-Director, Southern States Rhinology Course. Kiawah Island, SC, April 31-May 2, 2015

Course Co-Director, Southern States Rhinology Course. Kiawah Island, SC, May 8-10, 2014

Course Co-Director, Southern States Rhinology Course. Kiawah Island, SC, May 1-4, 2013

Course Co-Director, Southern States Rhinology Course. Kiawah Island, SC, May 2-5, 2012

Instructor and Faculty, Intraventricular and Skull Base Neuroendoscopy Hands on Course, Atlanta, GA. June 8-10, 2011

Course Co-Director, Southern States Rhinology Course. Kiawah Island, SC, March 31-April 2, 2011

Instructor and Faculty, Intraventricular and Skull Base Neuroendoscopy Hands on Course, Atlanta, GA. June 9-11, 2010

Course Co-Director, Southern States Rhinology Course. Kiawah Island, SC, April 8-10, 2010

Course Co-Director, South American Endoscopic Sinus Surgery Course, Jacksonville, FL, March 27, 2010

Instructor and Faculty, Intraventricular and Skull Base Neuroendoscopy- A Hands on Course, Atlanta, GA. June 3-5, 2009

Instructor and Faculty, 5th Annual Emory Voice Center Laryngeal Imaging Workshop, Atlanta, GA. February 21-22, 2009

Course Co-Director, Southern States Rhinology Course. Kiawah Island, SC, April 10-12, 2008

Instructor and Faculty, 4th Annual Emory Voice Center Laryngeal Imaging Workshop, Atlanta, GA. February 21-23, 2008

Course Co-Director, South American Endoscopic Sinus Surgery Course (Emory University sponsored course), Jacksonville, FL. February 1-2, 2008

Instructor, Diagnosis and Treatment of Diseases of the Head and Neck (Emory sponsored CME course), Sea Island, GA, July 9-11, 2007

Course Director, Southern States Rhinology Course. Atlanta, GA, March 15-17, 2007

Instructor and Faculty, 3rd Annual Emory Voice Center Laryngeal Imaging

John M. Del Gaudio, M.D.

Workshop, Atlanta, GA, February 22-23, 2007

Course Co-Director, Southern States Rhinology Course, Augusta, GA, October 19-21, 2006

Course Co-Director, South American Endoscopic Sinus Surgery Course, Jacksonville, FL, June 2-3, 2006

Course Co-Director, Southern States Rhinology Course, Charleston, SC, March 28-30, 2006

Instructor and Faculty, 2nd Annual Emory Voice Center Laryngeal Imaging Workshop, Atlanta, GA, February 24-25, 2006

Course Co-Director, Southern States Rhinology Course, Savannah, GA, October 18-20, 2005

Course Co-Director, Southern States Rhinology Course, Birmingham, AL, April 28-30, 2005

Course Director, Emory Otolaryngology Resident's Endoscopic Sinus Surgery Course, March 26, 2005

Instructor and Faculty, 1st Annual Emory Voice Center Laryngeal Imaging Workshop, Atlanta, GA, February 25-26, 2005

Course Director, Otolaryngology in Primary Care Medicine (Emory sponsored CME course), April 17, 2004

Course Director, Southern Regional Endoscopic Sinus Surgery Meeting (Emory University sponsored course), March 18-19, 2004

Course Director, South American Endoscopic Sinus Surgery Course (Emory University sponsored course), September 19-20, 2003

Course Director, Current Concepts in Endoscopic Sinus Surgery (Emory sponsored CME course), Emory University School of Medicine, March 20-21, 2003

Course Director, Otolaryngology in Primary Care Medicine (Emory sponsored CME course), Emory University School of Medicine, April 20, 2002

Course Director, Current Concepts in Endoscopic Sinus Surgery (Emory sponsored CME Course), Emory University School of Medicine, March 7-8, 2002

Instructor, Otolaryngology in Primary Care Medicine (Emory sponsored CME course), Emory University School of Medicine, April 21, 2001

Course Director, Current Concepts in Endoscopic Sinus Surgery (Emory sponsored CME course), Emory University School of Medicine, March 14-15, 2001

John M. Del Gaudio, M.D.

Instructor, Diagnosis and Treatment of Diseases of the Head and Neck (Emory sponsored CME course). Sea Island, GA. July 16-20, 2000

Course Director, Current Concepts in Endoscopic Sinus Surgery (Emory sponsored CME course), Emory University School of Medicine, March 24-25, 2000

Instructor, Diagnosis and Treatment of Diseases of the Head and Neck (Emory sponsored CME course), July 20-23, 1998

2. Residency program:

Course Co-Director. Emory Resident's Sinus Surgical Dissection Course, Atlanta, GA, January 26, 2008

Course Director, Emory Otolaryngology Resident's Endoscopic Sinus Surgery Course, January 27, 2007

Course Director, Emory Otolaryngology Resident's Endoscopic Sinus Surgery Course. February 18, 2006

Course Director, Emory Otolaryngology Resident's Endoscopic Sinus Surgery Course, April 24, 2004

Instructor, Endoscopic Sinus Surgery Course, Emory University, March 11-12, 1998

Instructor, Endoscopic Sinus Surgery Course, Emory University; March 14-15, 1997

26. Supervisory Teaching:

a. Ph.D. students directly supervised:

b. Fellows directly supervised:

Director of Rhinology and Skull Base Fellowship in Department of Otolaryngology 2010-2012.

Faculty member of Emory Rhinology and Skull Base Fellowship, 2010-present.

c. Residency program

Otolaryngology Residency Program Director, January 2007-July 2015

John M. Del Gaudio, M.D.

Chief of Rhinology and Sinus Surgery 2004-present

d. Other

Director of Emory South American Visiting Mini-Fellowships in Rhinology.
One-month fellowships for Latin American Otolaryngologists to observe nasal and sinus surgery and patient care and perform cadaver dissections.
Over 60 fellow observers to date

27. Lectureships, Seminar Invitations, and Visiting Professorships:

Otolaryngology Underwater. October 24-27, 2023. Montego Bay, Jamaica.
Skull Base Reconstruction: Simple to Complex

20th ASEAN ORL-HNS Congress. October 14-15, 2023. Hanoi, Vietnam.
Central Compartment Atopic Disease: An Allergy Mediated Subtype of CRSwNP.

Combined meeting of the Estonian Otolaryngology Society and American Academy of Otolaryngology. August 17-19, 2023. Tallinn, Estonia.
The Relationship between CRSwNP and Allergy.

VI Course of International PanAmerican Society of ORL. Buenos Aires, Argentina. June 24-27, 2023.
CSF Leak Repair: Simple to Complex
The Relationship Between CRSwNP and Allergy

Congreso Nacional Society Mexican Otorhinolaryngology, Head and Neck Surgery (SMORLCCC). Cancun, Mexico. April 30-May 3, 2023.
Central Compartment Atopic Disease
The Relationship between Allergy and CRSwNP

North American Skull Base Society Annual Meeting. Tampa, FL. February 17-19, 2023.
Endoscopic Surgery for Intraconal Tumors

International Federation of Otolaryngology Societies. January 18-22, 2023. Dubai, UAE.
Central Compartment Atopic Disease. Instructional Course.
The Role of Allergy in CRSwNP. Panel Moderator.
Multidisciplinary Management of CRSwNP.

Confederation of European Otorhinolaryngology (CEORL) 6th Meeting. October 30-November 2, 2022. Milan, Italy.
CSF Leak and Skull Base Defect Repair: Keynote Speech

PanAmerican Society of Otorhinolaryngology Meeting. Orlando, FL. June 25-27, 2022.
Surgery for Nasal Polyps: When and how much. Panelist
Endoscopic management of Lacrimal Pathology. Inferior Meatus Surgery.

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12th Balkan Congress of Otorhinolaryngology-Head and Neck Surgery, in conjunction with the AAO-HNS and CEORL-HNS. Ohrid, North Macedonia. June 1-5, 2022.

The Role of Allergy in CRSwNP
Skull Base Defect Repair: Simple to Complex
Central Compartment Atopic Disease

European Skull base Society Meeting. Riva del Garda, Italy. April 20-23, 2022.

Endoscopic Repair of CSF Leaks and Skull Base Defects
Juvenile Nasopharyngeal Angiofibroma. Residual Tumor after Resection:
Resect or Observe.
Moderator: Lateral Skull Base Free Paper Sessions

Hellenic Rhinologic Society. April 8, 2022. (virtual presentation)
Topical Therapies for CRS

North American Skull Base Society Annual Meeting. Phoenix, AZ. February 17-20, 2022.

Endoscopic Surgery for Intraconal Tumors
Proffered Paper Session Moderator

Czech ORL-HNS Meeting. October 23, 2021. Prague, Czech Republic (virtual presentation)
The role of allergy in CRSwNP

European Rhinologic Society. September 26-30, 2021. Thessaloniki, Greece.

Management of Spontaneous CSF Leaks.
Office Revision Sinus Surgery

Virtual Rhinology V. March 13, 2021.

What is the Role of Nasal Endoscopy and Radiology in Allergic Rhinitis (Moderator)

American Rhinologic Society Annual Meeting. September 13-14, 2019. New Orleans, LA.

Treatment for Aspirin Exacerbated Respiratory Disease
CRSwNP allergy and asthma prevalence by endotype

American Academy of Otolaryngic Allergy Annual Meeting. September 13-14, 2019. New Orleans, LA.

Intranasal Findings in Allergy: it's not what you were taught in residency
Office-Based Sinus Procedures
Nasal Polyp Disease (Content Meets Culture Walking Tour)

ASEAN ORL-HNS Congress. August 23-25, 2019. Singapore.

Central Compartment Atopic Disease
Endoscopic Orbital Surgery for Tumors
Managing Challenging Complications: Iatrogenic CSF Leak

Confederation of European Otorhinolaryngology (CEORL) 5th Meeting. June 29-July 3, 2019. Brussels, Belgium.

Central Compartment Atopic Disease
Skull Base Defect Repair: Simple to Complex

Rhinoworld Chicago. Meeting of the American Rhinologic Society, International Society, and

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ISIAN. June 5-9, 2019. Chicago, IL.

- What Nasal Findings Indicate Allergy?
- Would You Do This in Your Office? (Panel Moderator)
- Sinusitis and Nasal Polyps: Where does Allergy Fit In?
- Central Compartment Involvement in Aspirin Exacerbated Respiratory Disease: The Role of Allergy and Previous Surgery
- Surgical Considerations in the Atopic CRS Patient
- Would You Do This in Your Office? Treating Mucocoeles (Panel Moderator)
- Reflux Worsens CRS (Panel Moderator)

69th Congreso Nacional Society Mexican Otorhinolaryngology, Head and Neck Surgery (SMORLCCC). May 1-5, 2019

- Indications and Basic Principles of ESS
- Approaches to the Skull Base
- Central Compartment Atopic Disease

2nd Balkan Rhino-Forum. Sinusitis, Skull Base & Rhinoplasty Symposium. Belgrade, Serbia. April 5-7, 2019.

- Disease Specific Treatment of the Middle Turbinate
- Moderator, Rhinology and Skull Base Section

XXXVI Congreso Panamericano de Otorrolaringología y Cirugía de Cabeza y Cuello. Lima, Peru. November 14-17, 2018.

- Endoscopic Resection of Sinonasal Fibro-osseous Lesions
- Frontal Sinus Surgery (Panel)
- Advances in Endoscopic Sinus Surgery: Office Sinus Surgery (Panel)
- Recurrent Nasal Polyps: Central Compartment Atopic Disease (Panel)
- Surgical Treatment of the Inferior and Middle Turbinates
- Septoplasty and Turbinate Surgery (Dissection)

8th International Update Course: Otolaryngology Underwater. Cozumel, Mexico. October 30-November 2, 2018.

- Nasal Polyps and Aspirin Exacerbated Respiratory Disease
- Stylohyoid Complex Syndrome: A Pain in the Neck
- Office Management of Nasal Polyps

Autumn in New England Otolaryngology Update. Lebanon, NH. September 21, 2018.

- Office Sinus Surgery
- CRS with Nasal Polyps: Not a Single Disease

Sydney Endoscopic Sinus Dissection Course. August 16-18, 2018. Sydney, Australia.

- Chronic Rhinitis. Post-Nasal Drip
- Complications of Sinus Surgery. Lateral Lamella Injury in ESS.
- Disease-Specific Treatment of the Middle Turbinate.

Georgia Society of Otolaryngology Summer Meeting. July 20-22, 2018. Orlando, FL.

- Chronic Rhinosinusitis with Nasal Polyps. Panelist.

EndoBarcelona. 8th World Congress of Endoscopic Surgery of the Paranasal Sinuses, Skull Base, Brain & Spine. July 5-8, 2018. Barcelona, Spain.

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Endoscopic Management of Encephaloceles and CSF Leaks. (Panel Moderator)
Novel Therapies in Treatment of Recalcitrant Chronic Rhinosinusitis. Office Surgery
(Panelist)
Timing and Cost-Effectiveness of Surgery for CRS (Panelist)

Rhinology VII. April 28-30, 2018. Sao Paulo, Brazil. (Keynote Speaker)
Office Sinus Surgery: Advancing Rhinologic Care (Keynote speech)
Nasal Polyposis- What's New? (Panel Moderator)
Does Outcome/Prognosis depend on etiology?
Challenging Cases in Frontal Sinus Surgery (Panelist)
Treatment of the Turbinates
How to treat recalcitrant CRS clinically or surgically (Panel moderator)
Challenging cases of CRS (Panelist)
The appropriate time for sinus surgery
CSF leak repair: simple to complex

27th Congress of the European Rhinologic Society, 36th Congress of the International Society
of Inflammation and Allergy of the Nose, and 18th Congress of the International
Rhinologic Society. April 22-26, 2018. London, England.
Office Rhinologic Surgery: What are the Limits? (Panel presentation)
How I Do It: Office Rhinologic Surgery

5th Croatian Rhinologic Congress. February 23-24, 2018. Zagreb, Croatia.
Office Sinus Surgery
General Rhinology Section Moderator

39th Curso Internacional SMORLCCC. Temas Selectos de Otorrinolaryngologia. February
15-17, 2018.
Chronic Sinusitis with Nasal Polyps: Not a Single Disease
Endoscopic Resection of Fibro-osseous Lesions
Office Rhinologic/Sinus Surgery
Diagnosis and Treatment of Nasal CSF Leaks (Panelist)
Allergy in Rhinology (Panelist)

4th Congress of European ORL-HNS. October 8-11, 2017. Barcelona, Spain.
Office Surgery for Recalcitrant CRS. Panelist
Office Sinus Surgery: the Next Frontier in Rhinology (Keynote Lecture)

2nd Eurasian Respiratory & Allergy Summit. September 21-24, 2017. Budva, Montenegro.
Atopic Findings in the Nasal Cavity
AERD and Nasal Polyps
Advanced Sinus Surgery and Complications in ESS

Rhinology World Congress. Hong Kong. September 1-2, 2017.
Office Rhinologic/Sinus Surgery. Instructional Course.
Management of CSF leaks and Skull Base Defects. Panel Moderator.
Navigating Through Challenges in Sinus and Skull Base Surgery. Panelist.

4th South Pacific ORL Forum. Honolulu, HI. July 10-12, 2017.
Isolated Sphenoid Sinus Opacification.

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ENT World Congress (IFOS). Paris, France. June 24-28, 2017.
When Sinus Surgery is Difficult (Panel). Recalcitrant Polyp Disease (Panelist and Chairperson)
Ambulatory Sinus Surgery (Panel). Office Sinonasal Surgery (Panelist)
Nasal Manifestations of Systemic Disease (Panel). IgG-4 Related Disease (Panelist)
Nasal Polyposis: From Basic Science to New Emerging Therapies (Panel Moderator)

Cranial Base Surgery Course. "A 360° Perspective". Atlanta, GA. April 6, 2017.
Reconstruction of Dural Defects

RhinoForum. December 1-3, 2016. Warsaw, Poland.
Basic Principles and Techniques in ESS.
Office Rhinologic Surgery.
Surgery of the Inferior Meatus: A New Paradigm for the Treatment of Epiphora

15th International Congress of the Iranian Society of Otolaryngology-Head and Neck Surgery.
November 8-11, 2016. Tehran, Iran.
Isolated Sphenoid Sinus Opacification.
Postoperative Care and Complications of FESS (Panelist)
Rhinogenic Headache
Difficult Frontal Sinus Cases (Panelist)
Office Rhinoogic Surgery
CSF Leaks and Skull Base Repair

Northeast Ohio Otolaryngology Society. October 26, 2016. Cleveland, OH.
Office Rhinologic Surgery: What can we do?

The Cleveland Clinic Visiting Professor. October 26, 2016. Cleveland, OH.
Skull Base Defects, CSF Leaks and Meningoencephaloceles: Skull Base Reconstruction.

Annual Traditional Autumn Conference of Ukranian Oto-Rhino-Laryngologic Society. "Modern Methods of Conservative and Surgical Treatment in Otorhinolaryngology". Kiev, Ukraine. October 3-4, 2016.
Ambulatory Rhinosurgery

XI Bulgarian National Congress of Otorhinolaryngology. St. Vlas, Bulgaria. Sept 30-October 2, 2016.
Management of the Middle Turbinate.
Office Rhinologic Surgery.

26th Congress of the European Rhinologic Society, 35th Congress of the International Society of Inflammation and Allergy of the Nose, and 17th Congress of the International Rhinologic Society. July 3-7, 2016. Stockholm, Sweden.
Aggressive Polyp Disease: Demographic, Racial, and Disease Differences.

24th Annual John Q. Adams Lecturer. Visiting Professor. Vanderbilt University Department of Otolaryngology. June 24, 2016.
Office Rhinologic Surgery: How Did I Get Here?

35th PanAmerican Congress of Otolaryngology and Head & Neck Surgery. Havana, Cuba.

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June 13-16, 2016.

Evaluation and Management of CSF Rhinorrhea: Free Grafts in Reconstruction (Miniseminar)
A New Paradigm in Treatment of Epiphora: Surgery of the Inferior Meatus
Surgical Approaches to Chronic Sinusitis with Nasal Polyposis (Panel)

Middle Eastern Congress on Rhinology and Facial Plastic Surgery. Tehran, Iran. April 13-15, 2016.

Contemporary Treatment of the Middle Turbinate
Office Rhinologic Surgery: Sinus Recirculation and Mucocele Drainage
Advanced Frontal Sinus Surgery: Outside-In Lothrop Procedure and Osteoplastic Flap
Endoscopic Resection of Sinonasal Tumors
Iatrogenic Skull Base Defects: Why and What to do?
A New Paradigm for Epiphora: Treatment of the Inferior Meatus
Sinus Headache or Migraine: the Role of the Otolaryngologist

Georgetown University Department of Otolaryngology. Washington D.C. March 31, 2016.
Complications in Endoscopic Sinus Surgery: How to Prevent and What to Do.

University of Michigan Sinus and Skull Base Course. Ann Arbor, MI. January 16-17, 2016.
Surgical Landmarks in ESS.
Surgery of the Orbit and Pterygopalatine Fossa.

Georgia Society of Otolaryngology Fall Meeting. Lake Oconee, GA. December 5, 2015.
Panel Moderator: Difficult Sinus Patients

OESO 13th World Conference. "The Esophagiome". Monaco. August 31-September 3, 2015.
What is the evidence for reflux in chronic sinusitis?
What is the evidence for reflux causing postnasal drip?

Skull Base and Intraventricular Neuroendoscopy- A Hands on Course, Atlanta, GA. December 11, 2014.
Olfactory Neuroblastoma

Georgia Society of Otolaryngology Fall Meeting. Lake Oconee, GA. December 6, 2014.
Stylohyoid Complex Syndrome: A Pain in the Neck.

XXV Congreso Nacional de la Sociedad Mexicana de Rhinología y Cirugía Facial. Acapulco, Mexico. November 7-10, 2014.
Office Rhinologic Surgery
Complications in Endoscopic Sinus Surgery
Inferior Meatus Surgery for Epiphora
Surgery of the Middle and Inferior Turbinates
Pediatric Sinus Surgery (Panel)

Mexico City Rhinologic Society. Mexico City, Mexico. August 27, 2014.
Complications in Sinus and Skull Base Surgery: How to Avoid and Treat

Reunion Annual AOCCCHE. Asociacion de Otorrinolaringologia y Cirugia de Cabeza, A.C. August 28-30, 2014. Guanajuato, Mexico.

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Endoscopic Skull Base Surgery: Skull Base Repair, CSF Leaks and
Meningoencephaloceles
Endoscopic Surgery of the Paranasal Sinuses in Children: Panel
Surgical Anatomy of the Paranasal Sinuses and Skull Base

Skull Base and Intraventricular Neuroendoscopy- A Hands on Course, Atlanta, GA. December 5, 2013.

Olfactory Neuroblastoma

Georgia Society of Otolaryngology Fall Meeting. Atlanta, GA. November 17, 2012.
Polypoid Changes of the Middle Turbinate as an Indicator for Atopic Disease.

OESO. Reflux: LES to UES. Como, Italy. September 1-4, 2012.
What is the Mechanism by which Reflux causes globus pharyngeus?
What is the role of endoscopy in globus?
What objective evidence is there to support a role of reflux in CRS?
Does CRS respond to treatment of reflux? What is best treatment for CRS?

The Open Forum 2012. New York, NY. July 27-28, 2012.
Drug Delivery: the Future is Now. Panel discussion.

Georgia Society of Otolaryngology Summer Meeting, Orlando, FL. July 20-22, 2012.
Frontal Sinus Panel: Discussion of difficult cases (Moderator and Panelist)

Head and Neck Imaging, How the Experts Do It. Atlanta, GA. June 2, 2012.
Radiologic Correlates in Endoscopic Sinus Surgery: Indications and Techniques

Hospital Angeles. A Day with the Master. Mexico City, Mexico. September 29, 2011.
Sinus Headache and Migraine
Reflux and Sinusitis
Inferior Meatus Surgery for Epiphora
Complications and How to Avoid them in Endoscopic Sinus Surgery
Cadaveric Dissection

Mexican Otolaryngology Society, Mexico City, Mexico. September 28-29, 2011.
Office Rhinologic Surgery.
Rhinology: My Experience

Georgia Society of Otolaryngology Summer Meeting, Amelia Island, FL. July 29-31, 2011.
Diagnosis and Treatment of Sinus Headache
What I have learned after 15 years of practice (Panel Discussion)
Getting out of Trouble in Sinus Surgery (Panel Discussion)

Intraventricular and Skull Base Neuroendoscopy- A Hands on Course, Atlanta, GA. June 8-10, 2011.

Endoscopic Approach to the Orbit, Pterygopalatine and Infratemporal Fossa
Skull Base Reconstruction
Hands on Dissection Labs

8th Annual Middle East Update in Otolaryngology- Head and Neck Surgery. Dubai, UAE. May 8-10, 2011.

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Reflux and Sinusitis: Is there a connection?
Rhinologic Headache: Sinusitis vs. Migraine
Office Rhinologic Surgery: How Far Can We Go?
Inferior Meatus Surgery for Nasolacrimal Duct Obstruction
Reflux and the Upper Airway

Intraventricular and Skull Base Neuroendoscopy- A Hands on Course, Atlanta, GA. July 28-30, 2010

Endoscopic Approach to the Orbit, Pterygopalatine and Infratemporal Fossa
Skull Base Reconstruction
Hands on Dissection Labs

Fourth Congress of Venezuelan Rhinology and Facial Plastic Surgery. Margarita Island, Venezuela. May 26-28.

Endoscopic Treatment of Epiphora
Sinus Headache
Endoscopic Treatment of Sinonasal Tumors
Office Rhinologic Surgery
Panel: Skull Base Tumors, Anterior Cranial Fossa

Southern Section Meeting of the Triological Society. Orlando, FL. February 3-6, 2010.
Guidelines, Indications, and best Practices in Sinus Surgery. Panel Discussion.

Patologia Inflamatoria de la Via Aerea Superior. Hospital Angeles del Carmen. Guadalajara, Mexico. January 28-30, 2010.

Medical and Surgical Management of the Turbinates
Preoperative, Postoperative, and Long-term Management of Nasal Polyposis
Pearls in Endoscopic Sinus Surgery
What to do when Surgery and Medical Treatment fail in Chronic Rhinosinusitis
Office Surgery in Rhinology

Technicas y Tecnologia Cirugia Endonasal. Mexico City Mexico. September 8, 2009.

Anatomical Surgical Keypoints in Endoscopic Sinus Surgery
Panel Discussion on Advanced Technologies

XII Reunion Annual AOCCCHE. September 3-6, 2009. VeraCruz, Mexico.

Anatomy and Surgery of the Frontal Recess

Intraventricular and Skull Base Neuroendoscopy- A Hands on Course, Atlanta, GA. June 3-5, 2009

Endoscopic Approach to the Orbit, Pterygopalatine and Infratemporal Fossa
Skull Base Reconstruction, Including Nasal Septal Flap

Rhinology World. Meeting of the American Rhinologic Society, International Rhinologic Society, and International Symposium of Infection and Allergy of the Nose. Philadelphia, PA.

Comprehensive Treatment of the Frontal Sinus. Open Frontal Sinus Surgery.
Debate. Discussing the Role of Reflux in Nasal and Sinus Disease.

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22nd Congress of the European Rhinologic Society, and 27th International Symposium of Infection and Allergy of the Nose. Crete, Greece. June 15-19, 2008

Discussing the Role of Fungi in Chronic Rhinosinusitis. The Role of Surgery.
Debate. Discussing the Role of Reflux in Nasal and Sinus Disease. Presentation.
Round Table. My Worst Case and What I Learned.

Southern States Rhinology Course.

Kiawah Island, SC, May 8-10, 2014. Course Co-Director
Kiawah Island, SC, May 11-13, 2013. Course Co-Director
Kiawah Island, SC, May 3-5, 2012. Course Co-Director
Kiawah Island, SC, April 14-16, 2011. Course Co-Director
Kiawah Island, SC, April 8-10, 2010. Course Co-Director
Kiawah Island, SC, April 10-12, 2008. Course Co-Director
Atlanta, GA. March 16-17, 2007. Course Director
Augusta, GA. October 20-21, 2006. Course Co-Director
Charleston, SC. April 28-29, 2006. Course Co-Director
Savannah, GA. October 20-21, 2005. Course Co-Director
Birmingham, AL. April 29-30, 2005. Course Co-Director
Anatomic cadaver dissections.
Endoscopic Orbital Surgery
Osteoplastic Frontal Sinus Surgery.
Basic Principles of Endoscopic Sinus Surgery.
Reflux and Sinusitis.

Annual Laryngeal Imaging Workshop. The Emory Voice Center, Emory University School of Medicine. Atlanta, GA.

February 19, 2010.
February 20, 2009.
February 21, 2008.
February 23, 2007.
February 24, 2006.
February 25, 2005.
TransNasal Flexible Laryngoscopy. 30-minute presentation.
TransNasal Flexible Laryngoscopy Hands-On Instruction.

3rd Latin American Sinus Surgery Course. Jacksonville, FL. February 2, 2008.

Surgical Dissection Lab.
Complications of Endoscopic Sinus Surgery. 30-minute presentation.
Endoscopic Treatment of Skull Base Defects.
Endoscopic Tumor Resection.

Southern Section of the Triological Society. Naples, FL. January 12, 2008.

Rhinology Panel Discussion: Surgical Failures of FESS for Chronic Sinusitis.

Meeting of the Society of Head and Neck Nurses. Washington, DC. September 17, 2007.

Diagnosis and Management of Zenker's Diverticulum.

"Diagnosis and Treatment of Diseases of the Head and Neck." Emory CME Course. Sea Island, GA. July 9, 2007

Evaluation and Management of Common Nasal Disorders.
Laryngopharyngeal Reflux and Head and Neck Disorders.

John M. Del Gaudio, M.D.

Trans y Post Operatorio de la Cirugia Endoscopica Nasosinusal. Reunion con el experto Dr. John DelGaudio. Sociedad Venezolana de Rinologia y Cirugia Facial. Valencia, Venezuela. June 14-15, 2007

- Perioperative Treatment for Nasal Polyps. El Pre,
- Frontal Sinus Surgery: Navigation, Trephination or Only Endoscopic Treatment.
- Turbinate Surgery: When and How.
- Complications of Endoscopic Sinus Surgery.
- Reasons for Failure in Endoscopic Sinus Surgery.
- Diagnosis and Treatment of Cerebrospinal Fluid Leaks.
- Beyond the Sinuses: Dacryocystorhinostomy and Pterygopalatine Fossa.
- Surgical Anatomy.
- Medical Treatment or Surgery for Chronic Sinusitis.
- Basic Principles of Sinus Surgery. Extended Surgery of the Maxillary Sinus.
- Ethmoid Sinus Lesions: What are the Limits.
- Sphenoid Sinus: Keeping the Route and Avoiding Accidents.
- Postoperative Care: How I do it.

University of Pennsylvania 4th International Update Course: Otolaryngology Underwater. Roatan, Honduras. May 8-11, 2007

- Pharyngeal Suspension Procedures in Obstructive Sleep Apnea.
- Malpractice or Poor Outcome? Panel discussion.
- Skull Base Surgery: Endoscopic and Open Surgical Options.
- Endoscopic Surgery of the Pterygopalatine and Infratemporal Fossae.
- Endoscopic Staple-Assisted Zenker's Diverticulotomy.
- Image-Guidance: Computer Assisted, Ultrasound, Fluoroscopy, Intraoperative CT and MR: Where is it going? Panel discussion.
- Reflux and Chronic Rhinosinusitis: Is there a connection?

Eastern Surgical Society Meeting. Atlanta, GA. May 4, 2007.
Endoscopic Staple-assisted Zenker's Diverticulotomy.

2nd Latin American Sinus Surgery Course. Jacksonville, FL. June 3, 2006. Course Co-Director.
Frontal Recess Anatomy.
Frontal Sinus Surgery.
Endoscopic Repair of CSF Leaks and Meningoceles.
Endoscopic Resection of Sinonasal Tumors.
Postoperative Care.
Anatomic cadaver dissection demonstration and course.

The American Society of Head and Neck Nurses. Chicago, IL. May 21, 2006.
Zenker's Diverticulum: Diagnosis and Treatment.

Georgia Society of Otolaryngology/ Metro Atlanta Educational Society Annual Meeting.
Endoscopic Treatment of Sinonasal Tumors. Atlanta, GA November 19, 2004

Clinical Update for Radiologists. Atlanta, GA. October 28, 2004
Radiologic Correlates in Sinusitis.
Skull Base Defects: CSF Leaks and Meningoencephaloceles.

XII Curso Actualizacion en el Manejo de la Enfermedad Nasosinusal. Caracas, Venezuela. July

John M. Del Gaudio, M.D.

16-17, 2004.

Endoscopic Orbital Decompression and Surgery of the Pterygopalatine and Infratemporal Fossae.

Endoscopic Resection of Sinonasal Tumors.

Case Studies on Sinonasal Disease.

Basic Principles in Endoscopic Sinus Surgery.

Surgery of the Sphenoid Sinus.

University of Pennsylvania 3rd International Update Course: Otolaryngology Underwater.

Cozumel, Mexico. May 21, 2004.

Skull Base Surgery: Endoscopic or Open. Panel discussion.

Frontal Recess Anatomic Variations

Image-Guided Sinus Surgery. Panel discussion.

Visiting Professor. The Cleveland Clinic Foundation, Department of Otolaryngology, Head and Neck Diseases. Cleveland, OH. May 27, 2004.

Reflux and Sinusitis.

Society of Otorhinolaryngology- Head and Neck Nurses, Atlanta Regional Chapter. March 20, 2004.

Laryngopharyngeal Reflux and Associated Head and Neck Disorders.

Georgia Society of Otolaryngology/ Metro Atlanta Educational Society Annual Meeting. November 21, 2003.

Endoscopic Staple-Assisted Zenker's Diverticulotomy. Atlanta, GA.

28. National and International Conferences:

American Academy of Otolaryngology- Head and Neck Surgery Annual Meeting.

Nashville, TN. October 2, 2023.

Understanding Central Compartment Atopic Disease. Panel Moderator.

The American Rhinologic Society. Boston, MA. May 4-5, 2023.

The ABCs of Central Compartment Atopic Disease. Panel Moderator

Colorado Mid-Winter Meeting. Vail, Colorado. January 29-February 2, 2023.

Olfaction: Practice Guidelines and Management Strategies- Panelist

Difficult Cases, Panel Moderator

American Rhinologic Society. Philadelphia, PA. September 9-10, 2022.

Central Compartment Atopic Disease: What do we know?

Colorado Mid-Winter Meeting. Vail, Colorado. January 30-February 3, 2022.

The Impact of Covid on Rhinology- Panelist

New Technologies and Indications for Office Rhinologic Surgery, Panel Moderator

North American Neuro-Ophthalmology Society 46th Annual Meeting. March 8, 2020.

Amelia Island, FL.

John M. Del Gaudio, M.D.

Neuro-Imaging Evidence for Reversible Collapsibility of the Distal Transverse Sinuses in Spontaneous CSF Leak.

Colorado Mid-Winter Meeting. Vail, Colorado. February 2-6, 2020.

A Case I would Like to do over. Panelist
Central Compartment Atopic Disease: Case Examples

Northwest Academy of Otolaryngology Meeting. Whistler, British Columbia. January 10-12, 2020. Keynote Speaker.

Nasal Polyps: The Role of Allergy in Phenotype Specific Treatment
Controversies in Turbinate Surgery (Panelist)

North American Neuro-Ophthalmology Society (NANOS) Annual meeting, March 2019, Las Vegas, NV.

Neuro -ophthalmic evaluation of patients with spontaneous cerebrospinal fluid (CSF) leaks. Bidot S, Levy JM, Narayana KM, Newman NJ, Biousse V, for the CSF leak study group.

Interactive Allergy and Rhinology. American Academy of Otolaryngic Allergy. Dallas, Texas. February 8-10, 2019.

Cystic Fibrosis and Rhinosinusitis
Case-Based Panel: Systemic Diseases in the Rhinologic Patient
Topical and Alternative Therapies for Rhinosinusitis
Fungal Rhinosinusitis
Frontal Sinus Management
Office Rhinologic Surgery
Case-Based Panel: Complications of Sinus Surgery
Benign Sinonasal Neoplasms
Case-Based Panel: If I cCould Do This One Over Again

Colorado Mid-Winter Meeting. Vail, Colorado. February 3-7, 2018.

Revision Sinus Surgery. Panel Moderator
Medicolegal Issues in Rhinology. Panelist

Northwest Academy of Otolaryngology Meeting. Whistler, British Columbia. January 11-13, 2019.

Getting it Right the First Time in Surgery for CRS. Panelist

American Academy of Otolaryngology Annual Meeting. Atlanta, GA. October 7-10, 2018.

Hemostasis in Sinus Surgery. Panelist.
Endonasal Lacrimal Surgery. Inferior Meatus Surgery. Speaker.

American Academy of Otolaryngic Allergy Annual Meeting. Philadelphia, PA.

September 21-23, 2018
CRS with Polyps in the 21st Century
Sinusitis or Allergy? Or both?
Office Rhinologic Surgery

Summer Sinus Symposium of The American Rhinologic Society. Seattle, WA July 12-14, 2018.

John M. Del Gaudio, M.D.

Would You Do This in Your Office? Panelist
Dissection Moderator.

Ultimate Colorado Mid-Winter Meeting. Vail, Colorado. February 4-7, 2018.
What I Do Different Now than When I Started. Panel Moderator
A Case I Would Do Differently. Panelist

Summer Sinus Symposium of The American Rhinologic Society. Washington, DC. July 14-16, 2017.
Would You Do This in Your Office? Panel Moderator
Complications in Sinus Surgery. Panelist

The American Rhinologic Society Meeting at COSM. San Diego, CA. April 26-27, 2017.
Central Compartment Atopic Disease. (Poster)
Radiographic Phenotype of Chronic Sinusitis with Atopic Disposition
Practice Patterns in Office-Based Rhinology: Survey of the American Rhinologic Society

The Triological Society. San Diego, CA. April 27-29. 2017.
Intranasal Tissue Necrosis Associated with Opioid Abuse: A Case Report and Systematic Review

2017 AAOA Interactive Allergy & Rhinology Course. Dallas, TX. February 10-12, 2017.
Topical and Alternative Therapies for CRS
Fungal Rhinosinusitis
Headache for the Otolaryngologist
Benign Sinonasal Tumors
Complications in Sinus Surgery: Panel Moderator
FESS- When and How Much? –Panelist
Systemic Disease in the Rhinologic Patient- Panelist

Ultimate Colorado Mid-Winter Meeting. Vail, Colorado. February 12-15, 2017.

The American Rhinologic Society Meeting. San Diego, CA. September 16-17, 2016.
Age-related changes in nasal mucosal histology of adult patients without inflammatory sinonasal disease.
Silent Sinus Syndrome: A Progressive and Preventable Disease. Poster

The American Academy of Otolaryngic Allergy. San Diego, CA. September 16-17, 2016.
Perceived Compliance and Barriers to Care in Sublingual Immunotherapy.

Summer Sinus Symposium of The American Rhinologic Society. Chicago, IL. July 15-16, 2016.
Uh Oh! What do I do now? Managing Complications. Panel Moderator.
Does Reflux Cause CRS? Panel Moderator.

The American Rhinologic Society Meeting. Chicago, IL. May 19-20, 2016.
Randomized Controlled Trial demonstrating Cost-Effective Method of Olfactory Training in Clinical Practice: Essential Oils at Uncontrolled Concentration.
Successful Repair of Intraoperative Cerebrospinal Fluid Leaks Improves Outcomes In Endoscopic Skull Base Surgery

John M. Del Gaudio, M.D.

Intranasal Volume Increases with Age: Computed Tomography Volumetric Analysis in Adults (Poster)

Second Opinion Rhinology Cases: Is the Degree of surgery consistent with the amount of disease on CT (Poster)

Ultimate Colorado Mid-Winter Meeting. Vail, Colorado. January 25-29, 2016.

Panel: Chronic Cough: "Clearing" Up the Confusion.

Is it a Headache or Sinus Disease?

Panel: Counseling Patients for Surgery

7th International Update Course: Otolaryngology Underwater. Curacao. Nov 3-6, 2015.

Complications in Endoscopic Sinus and Skull Base Injury.

Office Rhinologic Surgery

Panel: Difficult Cases and Controversies in Rhinology

American Academy of Otolaryngology Annual Meeting. Dallas, TX. September 29, 2015.

Patient Centered Care: Does the Press Ganey Correlate to Online Health Grades in a Major Academic Otolaryngology Department?

The American Rhinologic Society at AAO. Dallas, TX. September 25-26, 2015.

Hemostasis in ESS: An Evidence-Based Review. Panel Moderator.

Factors Impacting Cerebrospinal Fluid Leak Rates in Endoscopic Sellar Surgery. Oral Presentation.

Chronic Rhinosinusitis and Obstructive Sleep Apnea: No Association Between Cpap Reservoir Bacterial Colonization And Sinus Culture Results. Poster.

Treatment of "Sinus Headache" In Patients with Concomitant Chronic Rhinosinusitis. Poster.

The American Academy of Otolaryngic Allergy. Dallas, TX. September 25-26, 2015.

Chronic Rhinosinusitis and Obstructive Sleep Apnea: No Association Between Cpap Reservoir Bacterial Colonization and Sinus Culture Results. Oral Presentation.

Treatment Of "Sinus Headache" In Patients with Concomitant Chronic Rhinosinusitis. Oral Presentation.

Immunotherapy Compliance: Comparison of Subcutaneous Versus Sublingual Immunotherapy. Oral Presentation.

Summer Sinus Symposium of The American Rhinologic Society. Chicago, IL. July 17-18, 2015.

Rhinologic Emergencies: Complications of Sinusitis and Sinus Surgery. Panel Moderator.

The Triological Society, Combined Otolaryngology Spring Meeting. Boston, MA. April 25, 2015.

The Place of the Osteoplastic Flap in the Endoscopic Era: Indications and Pitfalls.

The American Rhinologic Society at COSM. Boston, MA. April 24, 2015.

Multi-institutional study of risk factors for perioperative morbidity following endoscopic pituitary surgery.

Australian Society of Otolaryngology-Head and Neck Surgery. Sydney, Australia. March 7-9, 2015. Keynote Speaker, Rhinology.

Post-Nasal Drip Syndrome

John M. Del Gaudio, M.D.

Cough and Chronic Rhinosinusitis: The Unified Airway
Anatomic Variants: What is Important for the Sinus Surgeon

Australian Society of Otolaryngology-Head and Neck Surgery. Pre-Congress Sinus Course.
Sydney, Australia. March 6, 2015.
Anatomy of the Pterygopalatine Fossa.

Ultimate Colorado Mid-Winter Meeting. Vail, Colorado. February 1-5, 2015.
My Favorite Recent Articles in Rhinology. Panel Participant.
Practicing Cost-effective Rhinology. Panel Participant.

Georgia Society of Otolaryngology/ Metro Atlanta Educational Society Annual Meeting. Lake
Oconee, GA. December 7, 2014.
Be Careful What You Publish: Stylohyoid Complex Syndrome is a Pain in the Neck.

American Academy of Otolaryngology Meeting. September 22, 2014. Orlando, FL.
"Sinus headaches": Efficacy of migraine treatment in the otolaryngology office versus
neurology referral

American Rhinologic Society Meeting at AAO. September 20, 2014. Orlando, FL.
MR Cisternogram with Intrathecal Gadolinium (MRCgGd) with delayed imaging for
difficult to diagnose CSF leaks of anterior skull base. (Poster)
Low Grade Sinonasal Sarcoma with Neural and Myogenic Features: a Case Report.
(Poster)
Office Surgery for Paranasal Sinus Recirculation. (Poster)
Management of Non-Invasive Rhinosinusitis in the Immunosuppressed Patient
Population. (Poster)
Decreased Rate of Influenza Vaccination is associated with Increased Subjective
Olfactory Dysfunction. (Poster)
Higher body mass index is associated with subjective olfactory dysfunction. (Poster)

American Rhinologic Society Summer Sinus Symposium. Chicago, IL. July 19, 2014.
Does Reflux Cause Sinusitis?

American Rhinologic Society at COSM. May 16, 2014. Las Vegas, NV.
Non-Allergic Rhinitis Panel. Reflux and Post-Nasal Drip. Panel Presentation.

Triological Society at COSM. May 16, 2014. Las Vegas, NV.
In-Office Drainage of Sinus Mucocoeles: An Alternative to OR Drainage.

2014 Ultimate Colorado Mid-Winter Meeting. Vail, Colorado. February 2-6, 2014.
Peri-operative Management: What Should We Be Doing? Panel Discussion. Panel
Participant.

Southern Section of the Triological Society. January 10-11, 2014. Miami, FL.
Inferior Meatus Endoscopy and Directed Treatment for Epiphora: Long-term followup and
Development of a Treatment Paradigm
My Worst Case Ever. Panel Discussion.

American Academy of Otolaryngic Allergy, September 27-28, 2013. Vancouver, British Columbia.
Polypoid changes of the middle turbinate as an indicator of atopic disease.

John M. Del Gaudio, M.D.

- American Rhinologic Society. September 28, 2013. Vancouver, British Columbia.
Changing Your Practice: Strategies to Manage Your Patients with Recalcitrant Rhinoinusitis. Reflux and Sinusitis: Evidence and Treatment Outcomes. Panel Discussion.
Office Drainage of Fronto-Ethmoid Mucocoeles with Orbital Erosion. Poster.
- American Academy of Otolaryngology Annual Meeting. October 1, 2013. Vancouver, BC.
Laryngeal Inflammation: Diagnosis and Treatment Challenges. Miniseminar/Panel Presentation of AAOA and ALA.
- International Foundation of Otolaryngology Specialties (IFOS). June 1- 5, 2013. Seoul, Korea.
Controversies in Rhinology. Panel Discussion. Panelist.
A New Paradigm for Epiphora. Evaluation and Treatment of the Inferior Meatus.
- American Rhinologic Society Spring Meeting. April 12, 2013.
Everyday Struggles in Our Practice. Panel Discussion. Panelist.
- 2013 Ultimate Colorado Mid-Winter Meeting. Vail, Colorado. February 3-7, 2013.
Patient Selection in ESS: Panel Discussion. Panel Participant.
Cough, Reflux, and the Lower Airway. Panel Discussion. Panel Moderator.
Technology and Innovation in Rhinology. Panel Discussion. Panel Participant.
Performed Demonstration Sinus Dissection.
- 6th International Update Course: Otolaryngology Underwater. Cayman Brac, Cayman Islands. Dec. 4-7, 2012
Office Rhinologic Surgery
Sinus Headache vs. Migraine
Difficult Cases. Panel Discussion. Panelist.
- The Michigan Work Society. Ann Arbor, MI. November 9, 2012.
Common Inferior Meatus Pathology Causing Nasolacrimal Duct Obstruction.
- American Rhinologic Society Summer Symposium. Chicago, IL. July 13, 2012.
Laryngopharyngeal Reflux Disease: Panel Discussion.
Sinus Headache: Panel Discussion
- 2012 Ultimate Colorado Mid-Winter Meeting. Vail, Colorado. February 7, 2012.
Reflux and Sinusitis: What is the Evidence?
- American Academy of Otolaryngic Allergy. San Francisco, CA. September 9, 2011. Office Rhinologic Surgery.
- American Rhinologic Society. San Francisco, CA. September 10, 2011.
Breakfast Symposium. Office Rhinologic Surgery.
Incidental Sinonasal Findings Identified During Preoperative Evaluation for Endoscopic Transsphenoidal Approaches.
Cost Analysis of Office-based and Operating Room Procedures in Rhinology.

John M. Del Gaudio, M.D.

American Academy of Otolaryngology- Head and Neck Surgery Annual Meeting. September 13, 2011. Laryngopharyngeal Reflux. Panel Discussion. Miniseminar sponsored by the AAOA and ALA.

American Rhinologic Society. Chicago, IL. April 28, 2011.
The Great Debate: Sinus Headache or Migraine. Panel discussion and didactic talk.

American Rhinologic Society. Boston, MA. September 25, 2010
Office-based surgical procedures in rhinology: a well-tolerated and cost-effective alternative to operating room treatment (poster)

American Academy of Otolaryngology- Head and Neck Surgery Annual Meeting. September 26-29. Boston, MA.
Reflux Disease- Testing and Treatment. (Miniseminar sponsored by the AAOA and ALA)
Office Polypectomy: Coblator vs. Microdebrider

Pan-American Otolaryngology Meeting. Cancun, Mexico. March 7-10, 2010.
Office Rhinologic Surgery: How Far Can We Go?
Panel: Otolaryngology Residency Training in the United States

American Rhinologic Society. San Diego, CA. October 3, 2009.
Moderator for Scientific sessions.
Endoscopic Sinus Surgery in the Adult Cystic Fibrosis Patient: Effect on Lung Function, Intravenous Antibiotic Use, and Hospitalization.
Radiographic Examination of the Anatomic Relationships of the Posterior Ethmoid Artery.
Choice of Graft Material and Post-Operative Healing in Endoscopic Repair of CSF Leak.
Orbital Involvement in Invasive Fungal Sinusitis: Review of Outcomes and Recommendation of a Treatment Paradigm.

American Academy of Otolaryngology- Head and Neck Surgery. San Diego, CA. October 7, 2009.
Results of Multi-Level Treatment of Moderate and Severe Obstructive Sleep Apnea Utilizing Bone-Anchored Pharyngeal Suspension Sutures.
Common Inferior Meatus Pathologies Causing Epiphora.

American Academy of Otolaryngic Allergy and American Laryngologic Society. San Diego, CA. October 5, 2009.
Rhinogenic Laryngitis, The Role of Reflux- Panel Discussion

Rhinology World (Combined meeting of the American Rhinologic Society, International Rhinologic Society, and International Society of Inflammation and Allergy of the Nose). Philadelphia, PA. April 16-19, 2009.
Laryngopharyngeal Reflux and the Upper Airway- Debate
Comprehensive Management of the Frontal Sinus- Panel
Radiologic Evaluation of Anterior Ethmoid Artery Anatomy in the Non-diseased frontal recess- peer reviewed presentation
Antibiotic Prophylaxis in Sinus Surgery: A Review of Current Practices- peer reviewed presentation

Patologia Inflamatoria de la Nariz y Los Senos Paranasales (Pathologic Inflammation of the Nose and Paranasal Sinuses). Guadalajara, Mexico. January 30-31, 2009.

John M. Del Gaudio, M.D.

Inflammatory disease of the frontal sinus
Headache and facial pain of sinus origin, myth or reality?
Role of surgery in chronic rhinosinusitis
Rhinosinusitis in the immunocompromised adult
Update in extra-esophageal reflux disease, eosinophilic esophagitis and its influence in the nose and paranasal sinuses
Round table discussions:
 Management of massive polyposis
 Management of refractory chronic rhinosinusitis

American Academy of Otolaryngology. Chicago, IL. Sept 22, 2008.
 Computed Tomography Staging System for Allergic Fungal Rhinosinusitis.
 Inferior Meatus Endoscopy and Treatment for Epiphora.

American Rhinologic Society. Chicago, IL. Sept 20, 2008.
 Moderator for Scientific sessions (Inflammatory Mediators).
 The Utility of Cadaver Dissection in Endoscopic Sinus Surgery Training Courses.

American Society of Head and Neck Radiology. Toronto, Canada. Sept 10, 2008.
 Failed ESS in the Frontal Recess: Spectrum of CT Imaging Findings.

American Rhinologic Society. Orlando, FL. May 1, 2008.
 Moderator for Scientific sessions.
 The Role of Desmosomal Junctions in Nasal Polyposis.

American Bronchoesophagologic Society. Orlando, FL. May 1, 2008.
 Comparison of an Oropharyngeal pH Probe and a Standard Dual pH Probe for Diagnosis of Laryngopharyngeal Reflux.

The Annual Meeting of the Triological Society. Orlando, FL. May 1, 2008.
 Empiric Treatment of Sinus Headache as Migraine: The Diagnostic Utility of Triptans.
 An Early Detection Protocol for Invasive Fungal Sinusitis in Neutropenic Patients Successfully Reduces Extent of Disease at Presentation and Long-Term Morbidity.
 The Diagnostic Dilemma of Sinonasal Destructive Lesions. Poster.

Southern Section of the Triological Society. Naples, FL. January 11-12, 2008.
 Intraoperative Computed Tomography: a Valuable Learning Tool for Sinus Surgery. (Poster)

Rhinology Symposium for the Diamond Jubilee National Conference of The Association of Otolaryngologists of India. January 4, 2008. Agra, India.
 Microarray Analysis of Sinonasal Inverting Papilloma.
 Intracranial complications of Sinusitis.

Radiologic Society of North America. Chicago, IL. November 25-29, 2007.
 Sinus CT: Not just axial and coronal images anymore! Using sagittal images to evaluate the frontal recess.
 Failed Endoscopic Sinus Surgery (ESS) in the frontal recess: Spectrum of CT imaging findings.

Georgia Society of Otolaryngology. Atlanta, GA. November 16, 2007.

John M. Del Gaudio, M.D.

Nasolacrimal Duct Obstruction: What can the Otolaryngologist do?

Meeting of the American Academy of Otolaryngology- Head and Neck Surgery. Washington, DC. September 18, 2007.

The role of reflux disease in lingual tonsil hypertrophy.

American Rhinologic Society. Washington, DC. September 15, 2007.

Skull Base Defects After Endoscopic Sinus Surgery: Evaluation of Preoperative Disease Severity at Subsequent Defect Site.

The Voice Foundation. Philadelphia, PA. May 30, 2007

Assessing the effectiveness of Botulinum toxin injections for abductor spasmodic dysphonia.

American Rhinologic Society. San Diego, CA. April 26, 2007.

Identification of Cerebrospinal Fluid Leaks with Preoperative High Resolution CT and Intraoperative Image Guidance Precludes the Need for Intraoperative Fluorescein and Lumbar Drainage for Endoscopic Repair.

Cranial Nerve and Orbital Presentation and Sequelae are Hallmarks of Invasive Fungal Sinusitis Caused by Mucor in Contrast to Aspergillus.

Inferior Meatus Nasolacrimal Duct Cysts in Adults: Initial Report of an Easily Treated yet Previously Unidentified Cause of Epiphora. (Poster)

The use of portable intraoperative computed tomography scanning for real-time image- guidance: a pilot cadaver study.

American BronchoEsophagologic Society. San Diego, CA. April 25, 2007.

Preliminary Comparison of an Oropharyngeal Aerosolized pH Probe and a Standard Dual pH Probe for Diagnosis of Laryngopharyngeal Reflux.

The Triological Society. San Diego, CA. April 25, 2007.

The Diagnostic Dilemma of Sinonasal Destructive Lesions. (Poster)

Southern Section Meeting of the Triologic Society. Marco Island, FL. January 15, 2007.

VRQOL Improvement after Botox Injections for Abductor Spasmodic Dysphonia.

American Rhinologic Society. Toronto, Ontario, Canada. September 16, 2006.

Moderator for Scientific sessions.

Pneumocephalus after Endoscopic Sinus and Microscopic Skull Base Surgery (Poster)

Silent Sinus Syndrome: Lack of Orbital Findings in Early Presentation.

The Georgia Society of Otolaryngology Annual Meeting. Sea Island, GA. July 29, 2006.

Reflux and Rhinosinusitis: Is There a Connection?

The Triological Society. Chicago, IL. May 22, 2006.

Intracranial Complications of Sinusitis: a Five Year Review.

American Rhinologic Society Chicago, IL. May 19-20, 2006

Moderator for Scientific sessions.

Renal Cell Carcinoma: an important consideration in the differential diagnosis of vascular sinonasal masses. A report of 5 cases. (Poster)

John M. Del Gaudio, M.D.

Topical Steroid drops for the treatment of Sinus Ostia Stenosis in the Immediate Postoperative Period.

American Rhinologic Society. Los Angeles, CA. September 24, 2005.
Moderator for Scientific sessions.

American Academy of Otolaryngology- Head and Neck Surgery. Los Angeles, CA. September 24, 2005.

Gastroesophageal and Laryngopharyngeal Reflux in Patients with Sleep-Disordered Breathing.

The Voice Foundation Meeting, Philadelphia, PA. June 12, 2005.

Safety of simultaneous bilateral PCA muscle botulinum toxin injections in abductor spasmodic dysphonia.

American Society of Pediatric Otolaryngology. Toronto, Canada. May 28, 2005.

Head and Neck Manifestations of Pediatric Extracranial carotid Pseudoaneurysms. (Poster).

American Society of Neuroradiology. Toronto, Canada. May 25, 2005.

Cerebrospinal Fluid Leaks: Correlation of High Resolution Multiplanar Reformations with Intraoperative Findings.

The Triological Society. Boca Raton, FL. May 14-15, 2005.

Direct Nasopharyngeal Reflux of Gastric Acid is a Contributing Factor in Refractory Chronic Rhinosinusitis.

Head and Neck Manifestations of Extracranial Carotid Pseudoaneurysms. (Poster)

American Rhinologic Society. Boca Raton, FL. May 13, 2005.

Moderator for Scientific sessions.

Correlation of Nasopharyngeal Reflux and Post-Nasal Drip Symptomatology.

Differences in Skull Base Defect Size: Endoscopy versus Computed Tomography.

Invasive Fungal Sinusitis: What is Appropriate Follow-up?

Orbital Presentation of Invasive Fungal Sinusitis. (Poster)

Southern Section Meeting of the Triological Society. Miami, FL. January 14, 2005.

Safety of Bilateral PCA Injections for Abductor Spasmodic Dysphonia.

American Rhinologic Society Annual Meeting. New York, NY. September 18-20, 2004.

Seminar. Reflux and Sinusitis.

Moderator for Scientific sessions.

Evaluation of Postoperative Pain Following Sinonasal Surgery.

Medical Management of Anosmia Associated with Chronic Sinusitis.

The American Rhinologic Society Annual Meeting. New York, NY. September 19, 2004.

Complications in Endoscopic Sinus Surgery. Lecture and Panel Discussion.

Annual Meeting of the Georgia Society of Otolaryngology. Amelia Island, FL. July 23-25, 2004.

Laryngopharyngeal Reflux: The Unanswered Questions. When to Treat, When to pH Study, When to Refer.

The Frontal Recess. Correlation of Symptoms, Anatomy, and Radiologic Findings.

John M. Del Gaudio, M.D.

American Rhinologic Society. Phoenix, AZ. April 30-May 1, 2004.

Moderator for Scientific sessions.

Correlation of Degree of Frontal Sinus Disease to the Presence of Frontal Headache.

Causes of Frontal Sinus Failure in Endoscopic Sinus Surgery.

Isolated Inflammatory Sphenoid Sinus Disease- a Revisitation of CT Indications
Based Upon Presenting Findings.

American Rhinologic Society. Orlando, FL. September 20, 2003.

Moderator for Scientific sessions.

Presence of Fungus of Sinus Cultures in Cystic Fibrosis Patients.

Race and Gender Differences in Bone Erosion in Allergic Fungal Sinusitis.

Radiologic Variations in Nasofrontal Recess Anatomy.

American Rhinologic Society. Nashville, TN. May 2, 2003.

Glycodelin-a novel immunomodulatory and proangiogenic molecule in chronic
sinusitis

Invasive Fungal Sinusitis: A 15-Year Review from a Single Institution.

Endoscopic Sinus Surgery in Patients with Chronic Hepatic Failure Waiting Liver
Transplant (Poster).

American Rhinologic Society. Denver, CO. September 8, 2001.

Endoscopic Management of Lesions of the Sphenoid Sinus, Orbital Apex, and Clivus,

American Rhinologic Society. Orlando, FL. May 16, 2000.

Computed Tomography Findings in Invasive Fungal Sinusitis.

Malleable Registration Mask for Image-Guided Surgery.

American Rhinologic Society. New Orleans, LA. September 25, 1999.

Paranasal Sinus Meningiomas.

American Head and Neck Society. Palm Desert, CA. April 24-26, 1999.

Immunolocalization of Activated TGF-B1 in Juvenile Nasopharyngeal Angiofibroma.

CT-Guided Needle Biopsy of Head and Neck Lesions.

American Academy of Otolaryngology- Head and Neck Surgery. San Antonio, TX. September 13-
16, 1998.

Stealth Guided Skull Base and Paranasal Sinus Surgery.

Calciophylaxis: A New Head and Neck Manifestation of a Systemic Disorder.

Society for Ear, Nose and Throat Advances in Children (SENTAC). Pittsburgh, PA. December 3-
5, 1993.

Evaluation and Management of Nasal Septal Masses in Children,

22nd European Muscle Conference. Gwatt, Switzerland. October 3-8, 1993.

Muscle Fiber Types in Rat Laryngeal Muscle (Abstract),

29. Other Activities:

John M. Del Gaudio, M.D.

30. Bibliography:

- a. Published and accepted research articles (clinical, basic science, other) in refereed journals:

Kuan EC, et al. International Consensus Statement on Allergy and Rhinology: Sinonasal Tumors. *Int Forum Allrgy Rhinol*.

Bolk KG, Edwards TS, Wise SK, DelGaudio JM. Allergy and Asthma Prevalence and Management Across Nasal Polyp Subtypes.

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APPENDIX B

Appendix B: Materials Considered

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

Dr. DelGaudio Declaration: Appendix B (Materials Considered)

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

Dr. DelGaudio Declaration: Appendix B (Materials Considered)

Exhibit	Description
1049	Akiyoshi Konno, Historical, Pathophysiological, and Therapeutic Aspects of Vidian Neurectomy, 10 Curr Allergy Asthma Rep 105 (2010) (“Konno”)
1055	Fang et al., Nasal endoscopy combined with multiple radiofrequency for perennial allergic rhinitis, 25:7 J. First Mil Med Univ 876 (2005) (English translation) (“Fang”)
1056	Liang et al., Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy, 13:8 J. Clin Otorhinolaryngol (China) 341 (August 1999) (English translation) (“Liang”)
1057	Excerpts from File History for U.S. Patent No. 10,398,489
1058	U.S. Patent App. No. 2002/0016588 (“Wong”)
1059	Chinese Patent No. 2225227 (English translation) (“Liang ’227”)
1060	Andrew P. Lane, Nasal anatomy and physiology 12 Facial Plast Surg Clin N Am 387 (2004) (“Lane”)
1064	G.A.G. Mitchel, The Automatic Nerve Supply of the Throat, Nose, and Ear, J. of Laryngology & Otology (August 1954)
1066	U.S. Patent App. No. 2004/0230188 (“Cioanta”)

APPENDIX C

Appendix C (Challenged Claims)

Ground	35 U.S.C. Section	Claims	References
I	103	1-3, 6-12, 16	Edwards-'535 + Kong + Stern
II	103	4	Edwards-'535 + Kong + Stern + Edwards '886
III	103	1-3, 6-12, 16	Edwards-'535 + Liang + Stern
IV	103	4	Edwards-'535 + Liang + Stern + Edwards '886

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
1[pre]	1. A method for treating a nasal airway to reduce mucus production, the method comprising:	<u>Ground I</u> <u>Ground III</u>
1[a]	contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises two rows of bipolar electrode pairs;	
1[b]	applying radiofrequency energy with the bipolar electrode pairs through the nasal mucosa to a target tissue underlying the nasal mucosa for an amount of time to heat the target tissue; and	
1[c]	removing the treatment element from the nasal airway,	

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
1[d]	wherein heating the target tissue with the applied radiofrequency energy modifies at least one property of the target tissue, and	
1[e]	wherein the modified at least one property of the target tissue causes a reduction in mucus production in the nasal airway.	
2	The method of claim 1, wherein the target tissue is selected from the group consisting of mucosa, submucosa, cartilage, muscle, ligament, and tendon.	<u>Ground I</u> <u>Ground III</u>
3	The method of claim 1, further comprising controlling at least one characteristic of the applied radiofrequency energy with a control system coupled with the nasal airway treatment device.	<u>Ground I</u> <u>Ground III</u>
4	The method of claim 1, wherein the radiofrequency energy is applied in the form of a 460 kHz sinusoid wave.	<u>Ground II</u> <u>Ground IV</u>
6	The method of claim 1, further comprising displaying one or more parameters of treatment on a console attached to the nasal airway treatment device while the radiofrequency energy is applied, the one or more parameters selected from the group consisting of treatment time, power level,	<u>Ground I</u> <u>Ground III</u>

Dr. DelGaudio Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
	temperature sensed by the treatment element, electric impedance, electric current, and depth of treatment.	
7	The method of claim 1, further comprising applying local anesthesia to at least one of the nasal mucosa or the target tissue before applying the radiofrequency energy.	<u>Ground I</u> <u>Ground III</u>
8	The method of claim 1, wherein the radiofrequency energy is produced by a radiofrequency energy source configured to run between 1 Watt and 100 Watts.	<u>Ground I</u> <u>Ground III</u>
9	The method of claim 1, wherein applying the radiofrequency energy comprises heating the target tissue to a temperature between 50 degrees Celsius to 70 degrees Celsius.	<u>Ground I</u> <u>Ground III</u>
10	The method of claim 1, wherein the amount of time the radiofrequency energy is applied to the target tissue is between fifteen seconds and one minute.	<u>Ground I</u> <u>Ground III</u>
11[pre]	The method of claim 1, further comprising, before removing the treatment element from the nasal airway:	<u>Ground I</u> <u>Ground III</u>

Dr. DelGaudio Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
11[a]	repositioning the treatment element to contact a different portion of nasal mucosa; and	
11[b]	applying radiofrequency energy with the bipolar electrode pairs through the different portion of nasal mucosa to a different portion of target tissue for the amount of time to heat the different portion of target tissue.	
12	The method of claim 1, wherein the modified at least one property of the target tissue is selected from the group consisting of shrinking, tightening, stiffening, and deactivating the target tissue.	<u>Ground I</u> <u>Ground III</u>
16	The method of claim 1, further comprising bending a shaft of the nasal airway treatment device before contacting the treatment element with the nasal mucosa.	<u>Ground I</u> <u>Ground III</u>