

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. IPR2024-00276

U.S. Patent No. 9,415,194

**DECLARATION OF DR. JOHN DELGAUDIO REGARDING
CLAIMS 1-3, 6, 12, 14, 16, 18, AND 19 OF U.S. PATENT NO. 9,415,194**

Table of Contents

I.	INTRODUCTION	1
II.	QUALIFICATIONS AND EXPERIENCE.....	1
III.	LEGAL PRINCIPLES.....	5
A.	Scope of Opinion.....	6
B.	Anticipation	6
C.	Obviousness.....	6
D.	Claim Dependency	10
IV.	MATERIALS CONSIDERED	10
V.	LEVEL OF ORDINARY SKILL IN THE ART	11
VI.	OVERVIEW OF THE TECHNOLOGY.....	12
A.	Anatomical Features of the Nose and Upper Airways.....	12
B.	Rhinitis and Its Symptoms, Including Post Nasal Drip and Chronic Cough	16
C.	Techniques for Treating Rhinitis and Its Symptoms, Including Post Nasal Drip and Chronic Cough.....	19
D.	Using Energy to Treat Medical Conditions	21
E.	Using Energy to Treat Conditions of the Nose and Upper Airways.....	22
VII.	OVERVIEW OF THE '194 PATENT	26
A.	Overview of the '194 Patent.....	26
B.	Examination of the '194 Patent Before the United States Patent and Trademark Office	29
VIII.	OVERVIEW OF THE PRIOR ART REFERENCES.....	32
A.	Baker.....	32
B.	Edwards-'535	36
C.	Chen.....	37
IX.	CLAIM CONSTRUCTION	38
X.	ANALYSIS OF GROUNDS	39
A.	Ground I: Claims 1-3, 12, 14, 16, and 18 Are Anticipated by Baker	40

B. Ground II: Baker Renders Obvious Claims 1-3, 12, 14, 16, 18, and 19.....	72
C. Ground III: Baker in view of Edwards-’535 and Chen Renders Obvious Claims 1-3, 6, 12, 14, 16, 18, and 19	79
XI. AVAILABILITY FOR CROSS-EXAMINATION	121
XII. RIGHT TO SUPPLEMENT	122
XIII. JURAT	122

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 1-3, 6, 12, 14, 16, 18, and 19 of U.S. Patent No. 9,415,194 (the “’194 patent”) (Exhibit 1001-USP194). For the reasons set forth below, it is my conclusion that claims 1-3, 6, 12, 14, 16, 18, and 19 of the ’194 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 '194 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.

V. LEVEL OF ORDINARY SKILL IN THE ART

27. It is my understanding that when considering the claims of the '194 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.

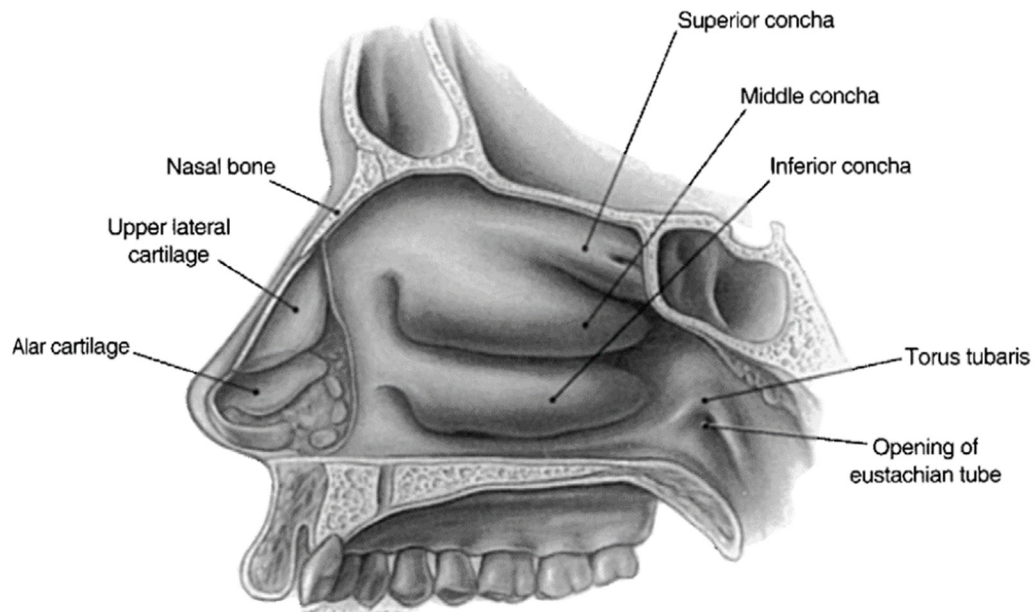
28. I understand that several factors are to be considered in determining who would be a person of ordinary skill in the art. These factors include: (1) the types of problems encountered in the art; (2) the prior art solutions to those problems; (3) the rapidity with which innovations are made; (4) the 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 (2011-2014) 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 '194 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.



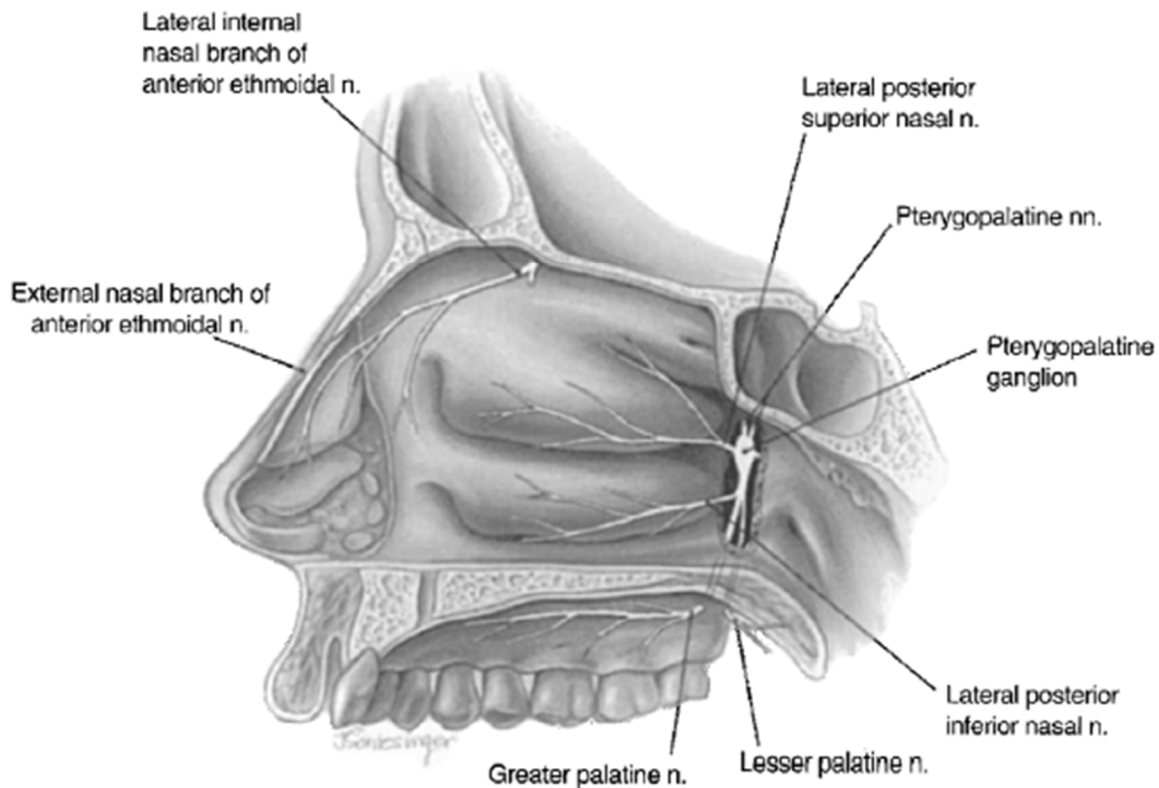
Ex.1060-Lane, FIG.1 (“Lateral nasal wall anatomy. Left side of the nose [*sic*]¹ with nasal septum removed”). Below, I describe certain anatomical features of the nose between the nostrils at the front (or anterior) of the nose and the nasopharynx at the back (or posterior) of the nose.

- 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.*, 387-88.

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 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 '194 patent.

B. Rhinitis and Its Symptoms, Including Post Nasal Drip and Chronic Cough

33. Medical conditions affecting the nose and upper airways have been extensively studied for decades prior to the '194 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.”). Rhinitis and its symptoms typically arise from “stimulation of the sensory [(i.e., nerve)] endings distributed” within the nose. Ex.1049-Konno, 108 (“[N]asal hypersecretion observed in allergic rhinitis is considered to be caused by histamine-induced stimulation of the sensory [(i.e., nerve)] endings distributed in the nasal epithelium.”), 111; Ex.1048-Nomura, 493 (“[C]haracteristic sym[p]toms of allergic rhinitis [include] rhinorrhea [and] nasal obstruction...which are due to the predominant manifestation of parasympathetic nerve stimulation.”).

34. Well-known symptoms of rhinitis include post nasal drip and chronic cough, which I briefly summarize below.

35. Post nasal drip can be characterized as the presence of excess mucus secretion from the nose in the back of the throat. Ex.1037-Chung, 5 (“Postnasal drip is defined as the presence of secretions at the back of the throat associated with frequent throat-clearing.”), 6 (“dripping of secretions rich in inflammatory mediators from the nasopharynx down onto the larynx or trachea (‘postnasal drip’)”). Patients with post nasal drip frequently express sensations of discomfort and need to clear their throats. *Id.*, 286 (“Postnasal drip (‘nasal catarrh’) is characterized by a sensation of nasal secretions or of a ‘drip’ at the back of the throat, accompanied very often by frequent need to clear the throat (‘throat-clearing’). There may be a nasal quality to the voice due to concomitant nasal blockage and congestion, and there may be hoarseness.”). It was well understood that post nasal drip can be caused by various types of rhinitis, such as allergic rhinitis. *Id.*, 247 (“PNDS [post nasal drip syndrome] may be the result of various processes, including seasonal and perennial allergic rhinitis, perennial non-allergic rhinitis, vasomotor rhinitis, postinfectious (postviral) rhinitis and chronic bacterial sinusitis.”), 107 (“A number of conditions can cause PNDS. The differential diagnosis includes...perennial allergic rhinitis.”).

36. Chronic cough can be characterized as a persistent cough that lasts longer than a predetermined amount of time. *Id.*, 11 (“Cough is a universal

experience common to us all. It is also the commonest symptom for which medical advice is sought. For the purpose of classification cough may be divided into defined, acute, self-limiting episodes and chronic persistent cough. This distinction is clinically useful since the aetiology of the two syndromes is very different.”) (citations omitted). For example, studies have used three weeks or eight weeks as the separation between acute (short-term) and chronic cough. *Id.*, 11 (“An arbitrary cut-off of 8 weeks is taken to separate acute from chronic cough.”), 285 (“Chronic cough (cough that persists for more than 3 weeks)”). One of the most frequent causes of chronic cough is post nasal drip. *Id.*, 247 (“Multiple studies have demonstrated PNDS to be the most common cause of chronic cough in adults.”) (citations omitted); *see also id.* 5 (“Postnasal drip, asthma, gastro-oesophageal reflux and bronchitis were the most frequent cause of a chronic productive cough.”), 28, 61, 107 (“In 1998 the *Consensus Panel Report* of the American College of Chest Physicians (ACCP) stated that ‘the most common causes of chronic cough in non-smokers are postnasal drip syndrome (PNDS), asthma and/or gastro-oesophageal reflux disease (GORD), whether or not the cough is described as dry or productive.’”), 285 (“The strong association between postnasal drip (rhinosinusitis) and chronic persistent cough is based on epidemiological evidence, and on a prospective study in adults.”).

C. Techniques for Treating Rhinitis and Its Symptoms, Including Post Nasal Drip and Chronic Cough

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”). Earlier rhinitis treatments dating back as far as

the 1970s targeted the Vidian nerve. *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).

38. Treating rhinitis (e.g., by delivering treatment to nerves, as described above) in turn was known to treat the symptoms of rhinitis, including post nasal drip and chronic cough. For example, the table below indicates that it was known to treat cough (i.e., a symptom of allergic rhinitis and post nasal drip) by treating its underlying cause including allergic rhinitis and post nasal drip.

Table 27.5 Treatments for cough.

1 Treating the specific underlying cause(s)	
Asthma, cough-variant asthma	Bronchodilators and inhaled corticosteroids
Eosinophilic bronchitis	Inhaled corticosteroids; leukotriene inhibitors
Allergic rhinitis and postnasal drip	Topical nasal steroids and antihistamines Topical nasal anticholinergics (with antibiotics, if indicated)
Gastro-oesophageal reflux	Conservative measures Histamine H ₂ -antagonist or proton pump inhibitor
Angiotensin-converting enzyme inhibitor	Discontinue and replace with alternative drug such as angiotensin II receptor antagonist
Chronic bronchitis/chronic obstructive pulmonary disease (COPD)	Smoking cessation Treat for COPD
Bronchiectasis	Postural drainage. Treat infective exacerbation and airflow obstruction
Infective tracheobronchitis	Appropriate antibiotic therapy Treat any postnasal drip

Ex.1037-Chung, 292.

D. Using Energy to Treat Medical Conditions

39. 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 '194 patent by as much as a century, include the following:

- Ex.1025-De Forest (U.S. patent issued in 1907), 1:8-21 (“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

40. 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 '194 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.... Access and occluder devices may be 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.

41. 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).”) (citations omitted);

- 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. Ex.1013-Baker, 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.”).

VII. OVERVIEW OF THE '194 PATENT

A. Overview of the '194 Patent

42. The '194 patent states in its abstract and introductory section, titled “Field,” that the patent relates to “treating structures within the nose and upper

airway” to “alleviate the discomfort of post nasal drip” and/or “chronic cough.”

Ex.1001-USP194, 1:23-28, Abstract.

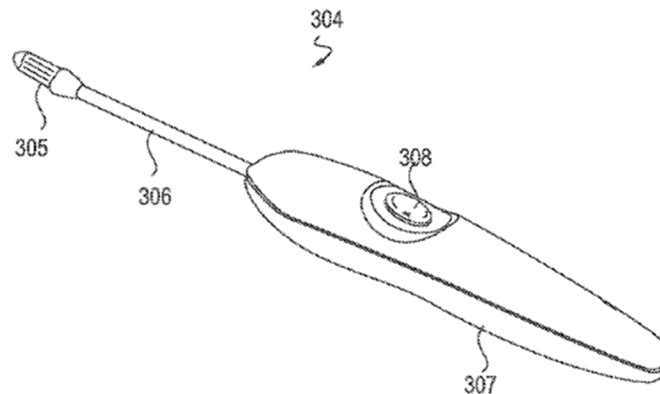
43. The background section of the '194 patent discusses many aspects of post nasal drip and chronic cough that were known at the time the patent was filed. *Id.*, 1:32-45. For example, the background section explains the pathological pathway known to cause post nasal drip and chronic cough as follows: “[m]ucus produced in the nose is transported toward the throat.... [O]verproduction of mucus and/or thicker-than-usual mucus...causes irritation, which is known as post nasal drip syndrome (PNDS) or upper airway cough syndrome (UACS).” *Id.* The '194 patent further explains that post nasal drip was known to be caused by allergies (e.g., allergic rhinitis). *Id.*, 2:4-7 (“[A]llergies[] have...been known to trigger PNDS.”), 2:20-22 (describing known techniques “for controlling the symptoms of moderate-to-severe allergic rhinitis”).

44. According to the '194 patent, existing treatment techniques did not provide “a long lasting, single-treatment or low frequency treatment for PNDS caused by allergies, anatomical causes or other causes.” *Id.*, 2:40-42.

The '194 patent claims require using an “energy-based treatment device” to deliver treatment to nasal tissue, which suggests that claimed energy-based treatment device is intended to address the purported deficiencies of existing treatment

techniques. *Id.*, Claim 1. The patent places few restrictions on the energy-based treatment device: the device can deliver various forms of energy, such as “heat, radiofrequency (RF), laser, light, ultrasound (e.g. high intensity focused ultrasound), [etc.],” *id.*, 9:55-63, and “may have any of a number of different effects on the treated tissue,” *id.*, 2:48-55. The patent also does not disclose details about the specific target tissue, power level, target temperature range, or time of treatment, to achieve the intended outcome of treating post nasal drip or chronic cough.

45. Figure 18 of the patent is reproduced below as one illustration of an embodiment of the claimed energy based therapy device.



Id., FIG.18. Figure 18 depicts a “device 304 for applying energy to upper airway tissues using monopolar electrodes according to one embodiment.” *Id.*, 21:1-3.

However, the challenged claims do not recite any limitations related to monopolar electrodes or otherwise limit the structure of the energy based therapy device.

46. Another purported problem that the '194 patent seeks to address is to treat post nasal drip “without producing severe and/or chronic side effects.” *Id.*, 2:42-44. To address this purported problem, claim 1 requires that the method be performed “without piercing the mucosal tissue.” *Id.*, Claim 1. Other claims that depend from claim 1 further require that the method be performed “without forming an incision in the mucosal tissue and without delivering an implant” (claim 2) or “without changing a shape of the mucosal tissue” (claim 16). *Id.*, Claims 2, 16.

B. Examination of the '194 Patent Before the United States Patent and Trademark Office

47. The '194 patent was filed as a continuation-in-part patent application on March 31, 2015. Ex.1001-USP194, Cover. On November 3, 2015, the examiner issued a non-final office action raising the following rejections and objections:

- Claims 1-4, 20, and 26 were rejected for double patenting over the issued claims of the grandparent application; and

- Claims 5-19, 21-25, and 27-33 were identified as being allowable but were objected to as being dependent upon a rejected base claim.

Ex.1003-USP194FH, 430-435. The examiner also identified a prior art reference, USP 6,416,491, as being “pertinent” to the claims but did not rely on the reference to reject any of the claims. *Id.*, 434. Instead, the examiner simply stated that the applicant “is encouraged to consider the disclosures [of the pertinent reference], including potential combinations thereof.” *Id.*

48. On December 30, 2015, the applicant filed a terminal disclaimer to overcome the double patenting rejection. *Id.*, 456-457. The applicant did not make any substantive amendments to the challenged claims and did not present any substantive arguments contesting the examiner’s findings in the office action. *Id.*, 469 (“With this response, no claims are amended, canceled, or added.”).

49. Subsequently, on April 13, 2016, the examiner issued a notice of allowance, which did not include any statement of the examiner’s reasons for allowance. *Id.*, 484-490.

50. I understand and have been informed that there may be circumstances where the examination of a parent (or grandparent) 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 grandparent

application's claims does not apply to the challenged claims. During the examination of the grandparent application, the examiner issued a non-final office action in which certain claims of the parent application were rejected as being anticipated by USPA 2007/0219600 ("Gertner"). Ex.1018-US594FH, 246-247. The applicant filed a response on September 15, 2014, in which the applicant amended the rejected claims to recite additional limitations including "*applying [a] treatment surface to the nasal tissue with sufficient force to alter a shape of the nasal tissue.*" *Id.*, 262. The applicant argued that the additional limitations were distinguishable from Gertner because, according to the applicant, Gertner's application of light based therapy did not disclose "chang[ing] the shape of nasal tissue." *Id.*, 267-68. Subsequently, on September 30, 2014, the examiner issued a notice of allowance for the parent application, which did not provide a statement of the examiner's reasons for allowance. *Id.*, 273-77.

51. The challenged claims are similar to the allowed claims of the parent application, and the examiner identified both sets of claims as being "directed to obvious variations" of each other. Ex.1003-USP194FH, 433-434. However, the challenged claims do not recite the limitation that was added to the parent application's claims to overcome Gertner: "*applying [a] treatment surface to the nasal tissue with sufficient force to alter a shape of the nasal tissue.*" Nor do the

challenged claims recite any similar subject matter; for example, dependent claim 16 expressly requires the claimed method to modify tissue “without changing a shape of the mucosal tissue.” Ex.1001-USP194, Claim 16. Moreover, the examiner did not apply Gertner to the challenged claims during the examination of the ’194 patent even though the challenged claims do not recite the limitations that the applicant had argued rendered Gertner distinguishable from the parent application’s claims. In fact, the challenged claims do not recite any limitations specifically identified as having novelty by either the examiner or the applicant during examination.

52. Moreover, as I explain in further detail below, the challenged claims are unpatentable over prior art references (Baker, Edwards-’535, and Chen) that were not before the examiner during examination of the ’194 patent.

VIII. OVERVIEW OF THE PRIOR ART REFERENCES

A. Baker

53. Baker is directed to systems and methods for using energy based therapy to treat upper airway conditions and their symptoms. Ex.1013-Baker, 26:7-11, 1:25-29. For example, Baker’s techniques “may be used for treating common colds, nasal congestion and allergic rhinitis, as well as sinusitis and other

nasal conditions” and symptoms including “runny nose, nasal congestion and post-nasal drip.” *Id.*

54. Baker discloses using an energy based therapy device similar to the device in the '194 patent, as illustrated in the side-by-side figures below.

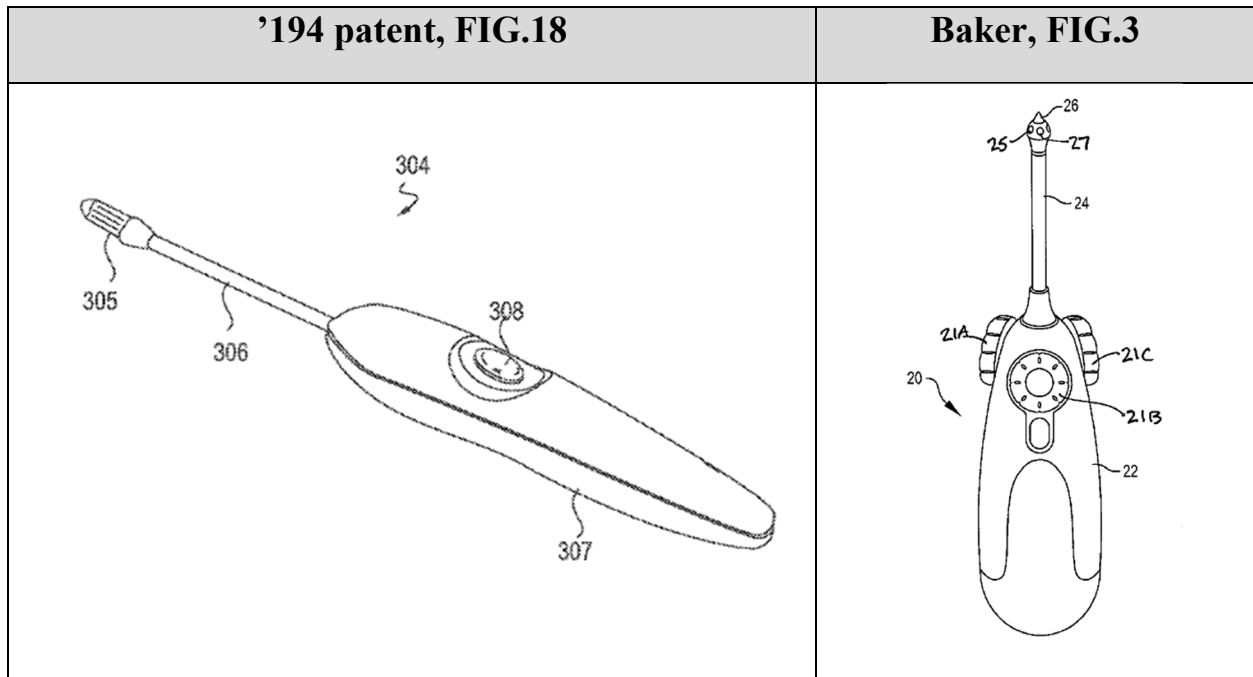
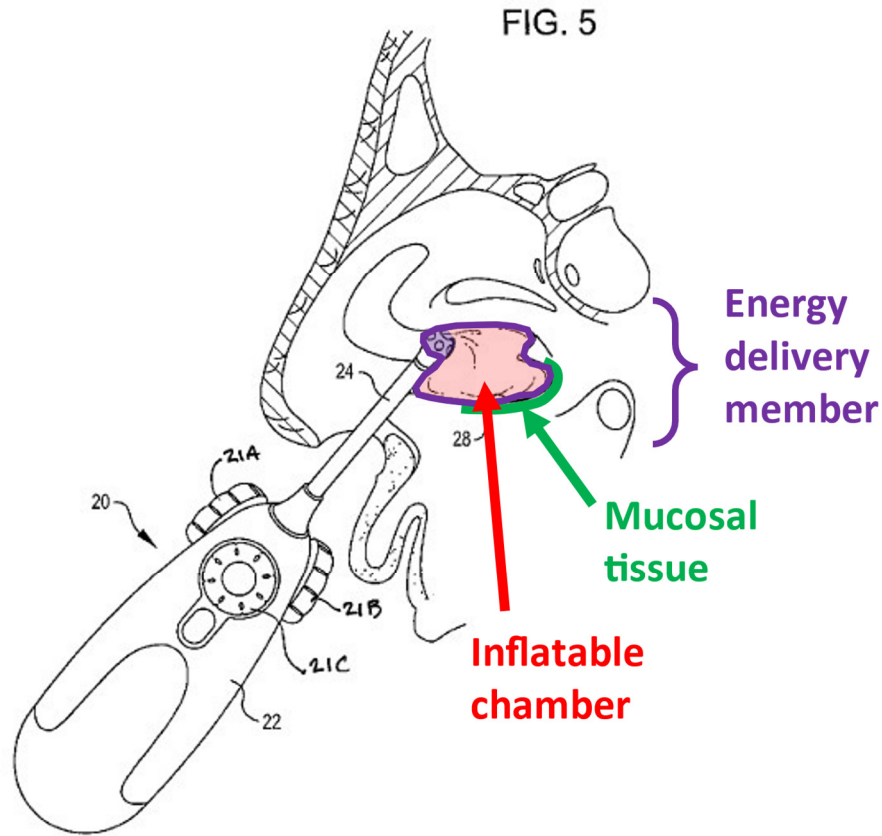


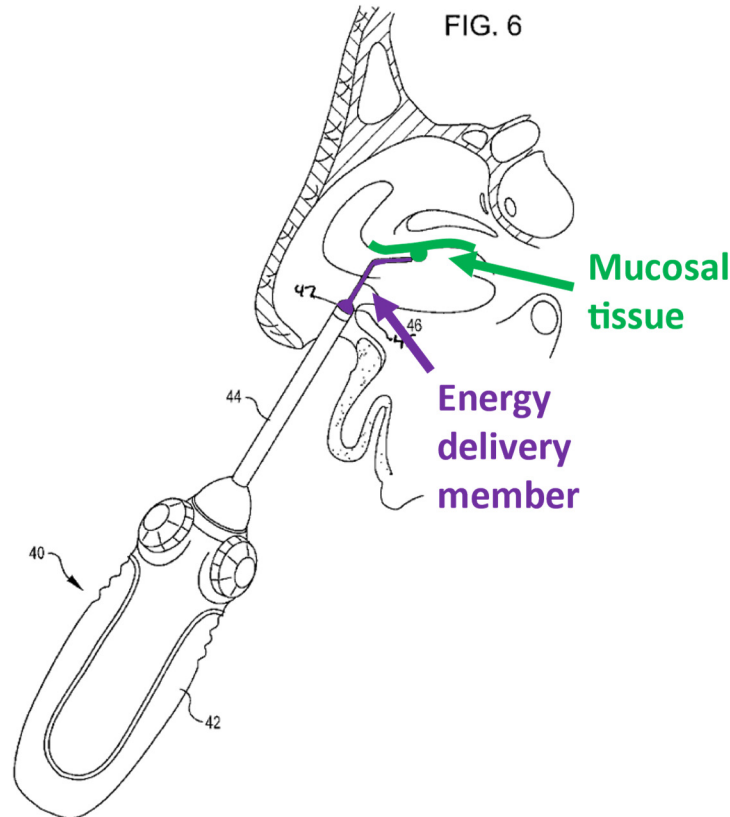
Figure 3 of Baker depicts an energy based therapy device that is inserted into a patient’s nostril and used to “deliver...acoustic energy...directly to tissue surfaces...in nasal passages.” Ex.1013-Baker, 7:18-21; *see also id.*, FIGs.4-7 (depicting further embodiments of Baker’s acoustic energy delivery devices).

55. One embodiment of Baker’s device is depicted in Figure 5, reproduced below.



Id., FIG.5. Figure 5 shows an energy delivery member (purple) having an inflatable chamber (red) at the distal end of a device 20. These components are used to apply ultrasound energy treatment to tissue lining the nasal passages (green). *Id.*, 17:22-36 (“an energy delivery member may comprise a flexible, deformable bladder or inflatable chamber 28 adapted for retaining an acoustically transmissive material.... The bladder or inflatable member(s) ... provides a flexible surface that is expandable and deformable to conform to contours of ... intranasal passages”).

56. Another embodiment of Baker's energy based treatment device is shown in Figure 6 of Baker, reproduced below.

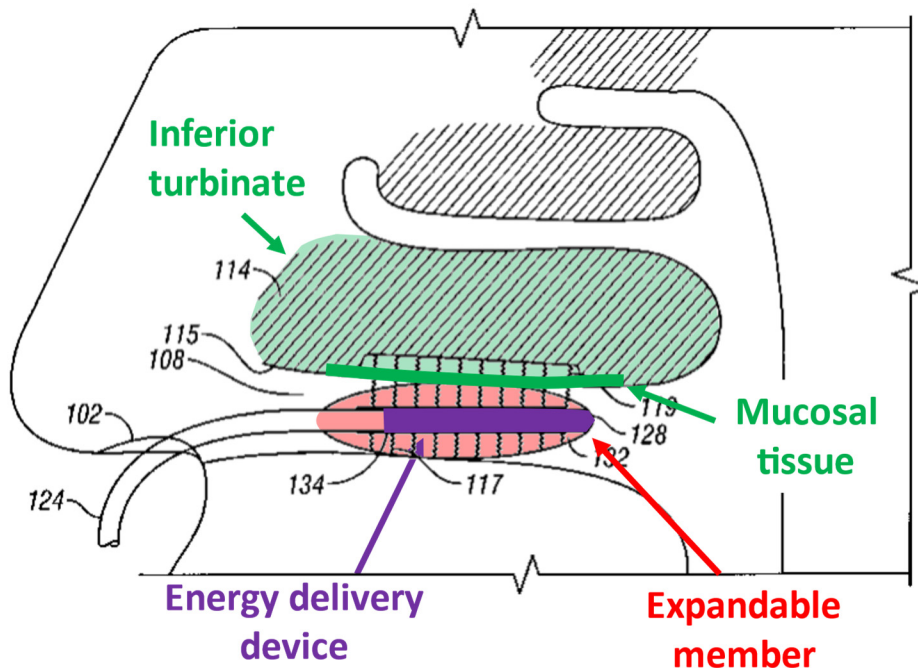


Id., FIG.6. Figure 6 shows an energy delivery member (purple) at the distal end of a device 40. Rather than an inflatable chamber as depicted in Figure 5, Figure 6 shows an energy delivery member 46 (purple) that extends from within insertion member 44 to apply ultrasound energy treatment to the target tissue (green). *Id.*, 22:10-25 (“The energy delivery member may be extendible and/or retractable with respect to handle 42 and/or insertion member 44 to provide desired positioning of

the energy delivery member in contact with obstructions and/or tissues for delivery of high frequency acoustic energy.”). Baker also discloses arrangements of device 40 in which energy delivery member 46 includes a “flexible, steerable” structure 48 that is “navigable to target tissue sites.” *Id.*, 22:21-29, FIG.7.

B. Edwards-’535

57. 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, 5:43-45, 6:66-7:17. Figure 3B of Edwards-’535 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.

C. Chen

58. Chen is a scientific journal article describing a clinical study in which patients with perennial allergic rhinitis were treated by applying RF energy to different areas of the nasal passages. Ex.1017-Chen, Abstract, 239-240 (“From September 2002 to March 2003, 40 patients with PAR [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”). The authors explained that the results of the study were promising and that the treatment was “highly effective” and “easy to perform.” *Id.*, Abstract, 243. For example, the RF energy based treatment was considered a promising technique to “reduce the sensitivity of the nasal mucosa to external stimuli,...reduce the gland secretion, and...alleviate or eliminate symptoms such as

nasal itching, sneezing, nasal congestion, and runny nose in patients, achieving the objective of treating [allergic rhinitis].” *Id.*, 240, 243.

IX. CLAIM CONSTRUCTION

59. I was informed and I understand that, in my analysis, I should give claim terms their ordinary and customary meaning, as understood by a person of skill in the art at the time of the invention. I was informed and I understand that the words of the patent’s claims and the context in which the term is used in the claims 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.

60. 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.

61. In addition to the claims, the specification, the figures, and the prosecution history, I have been instructed that certain “extrinsic evidence” such as scientific or technical references may also help inform the way in which 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.

62. 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

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

- Ground I: Claims 1-3, 12, 14, 16, and 18 are anticipated by Baker under 35 U.S.C. §102.
- Ground II: Claims 1-3, 12, 14, 16, 18, and 19 are anticipated by Baker under 35 U.S.C. §102.
- Ground III: Claims 1-3, 6, 12, 14, 16, 18, and 19 are rendered obvious by Baker, Edwards-'535, and Chen under 35 U.S.C. §103.

These grounds demonstrate in detail that claims 1-3, 6, 12, 14, 16, 18, and 19 are unpatentable as anticipated and obvious. A copy of the challenged claims are provided as **Appendix C**.

A. Ground I: Claims 1-3, 12, 14, 16, and 18 Are Anticipated by Baker

64. As I explain in detail below, Baker discloses each element of claims 1-3, 12, 14, 16, and 18 and therefore anticipates these claims. In fact, Baker teaches multiple embodiments of treatment methods, each of which separately anticipates the challenged claims. For example, Baker teaches a method that carries out the claimed steps (and therefore anticipates the claims) using a device 20. Certain configurations of device 20, such as those depicted in Figure 5, include an expandable balloon at the distal end, and other embodiments, such as those depicted in Figure 4, do not include the balloon. Baker teaches another method that uses a device 40, which also anticipates the claims. Certain configurations of device 40, such as those depicted in Figure 7, include a steerable structure at the distal end, and other embodiments, such as those depicted in Figure 6, do not include the steerable structure. Both the device 20 as shown in Figures 3-5 and device 40 as shown in Figures 6-7 anticipate claims 1-3, 12, 14, 16, and 18.

1. Claim 1

- a. Element 1[pre]: A method for reducing mucus secretion in an upper airway of a patient to treat at**

least one of post nasal drip or chronic cough, the method comprising:

65. 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 1 is limiting, Baker discloses the claimed method for reducing mucus secretion in an upper airway (e.g., nasal passages) of a patient to treat at least one of post nasal drip or chronic cough.

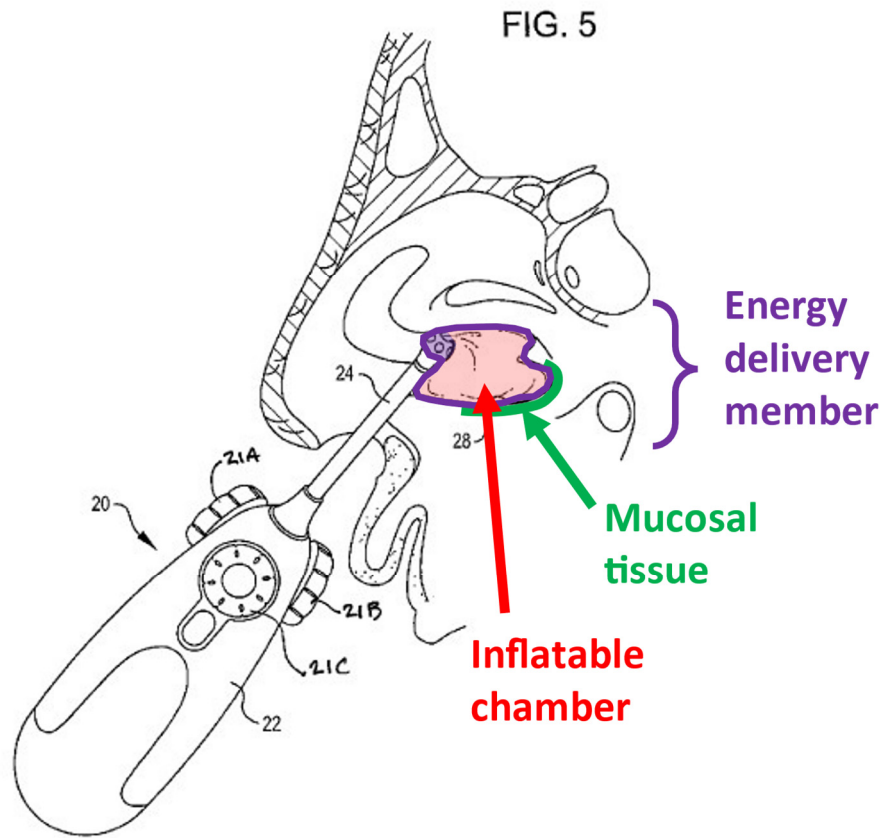
i. *Baker's method of using device 20 satisfies limitation 1[pre]*

66. As I explain in further detail below with reference limitations 1[a]-1[c], Baker teaches a method in which a device 20, as depicted in Figures 3-5, is used to treat conditions such as “common colds, nasal congestion and allergic rhinitis, as well as sinusitis and other nasal conditions.” Ex.1013-Baker, 26:7-11. These conditions are frequently associated with excessive mucous secretion. For example, it was textbook knowledge that allergic rhinitis “is characterized by nasal obstruction, rhinorrhoea [(i.e., runny nose)], sneezing, nasal pruritus [(i.e., itching)] and postnasal drip.” Ex.1037-Chung, 111; *see also* Ex.1013-Baker, 1:25-32 (“Symptoms of rhinitis include runny nose, nasal congestion and post-nasal drip.”). Therefore, a person of ordinary skill in the art would have understood that using

Baker's method to treat allergic rhinitis reduces mucus secretion, as claimed.

Consistent with this understanding, Baker explains that its methods aim to achieve “[e]ffective and long-lasting reduction of mucus...within the nasal passages, sinuses and their drainage systems.” Ex.1013-Baker, 5:5-12.

67. Baker's method of using device 20 reduces mucus secretion in the upper airway of a patient, as claimed. For example, a person of ordinary skill in the art would have understood that allergic rhinitis is a condition that results in excess mucus secretion in the upper airways. Consistent with this understanding, Baker's method is used to apply treatment to “tissue sites such as nasal passages.” *Id.*, 16:19-22. Figure 5, reproduced below, illustrates the application of treatment to the nasal passages (i.e., the claimed upper airways).



Id., FIG.5; *see also id.*, FIG.4. Figure 5 shows device 20 inserted through a patient's nostril and into the upper airway of a patient, where it delivers treatment and ultimately reduces mucus secretion.

68. The objectives of Baker's method of using device 20 include treating at least one of post nasal drip or chronic cough, as claimed. For example, Baker teaches that its method is used for "treating...allergic rhinitis," and further teaches that the symptoms of allergic rhinitis include "post-nasal drip." *Id.*, 26:7-11; 1:25-29 ("Symptoms of rhinitis include...post-nasal drip."). Baker thus teaches that by

using Baker's method to treat allergic rhinitis, one also treats post nasal drip (i.e., a symptom of allergic rhinitis).

69. Furthermore, a person of ordinary skill in the art would have known from textbook knowledge that post nasal drip causes chronic cough. Ex.1037-Chung, 247 (“Multiple studies have demonstrated PNDS [post nasal drip syndrome] to be the most common cause of chronic cough in adults.”). Accordingly, by treating post nasal drip, one also treats chronic cough. *Id.*, 292 (explaining that a known technique for treating cough was to “[t]reat[] the specific underlying cause(s)” including “[a]llergic rhinitis and postnasal drip”).

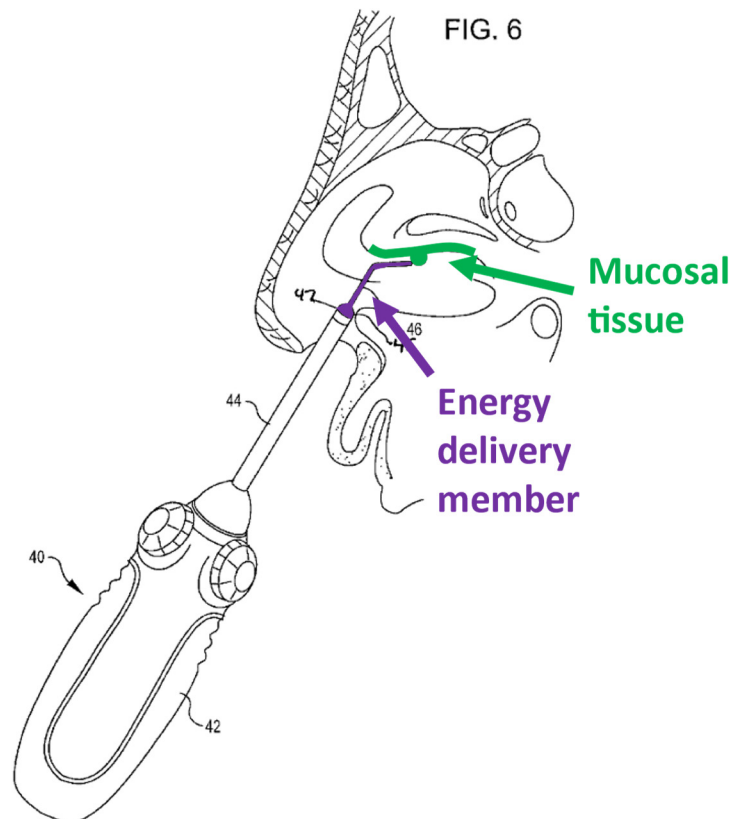
ii. *Baker's method of using device 40 also satisfies limitation 1[pre]*

70. Additionally or alternatively, Baker discloses a method of using a different device 40, depicted in Figures 6-8D, that also reduces mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough, as claimed.

71. Specifically, Baker's method using a device 40 treats the same upper airway conditions as Baker's method of using device 20 that I identified above, including allergic rhinitis. Ex.1013-Baker, 26:7-11. Accordingly, the method of

using device 40 reduces mucus secretion, as claimed, for the same reasons that I provided above for device 20.

72. As I further explained above in connection with device 20, allergic rhinitis creates excess mucus secretion in the upper airway of a patient. Therefore, Baker's method of using device 40 to treat allergic rhinitis reduces mucus secretion in the "nasal passages" (i.e., upper airway), as claimed. *Id.*, 21:21-22. The application of treatment to the nasal passages (i.e., the claimed upper airways) is depicted in Figure 6, reproduced below.



Id., FIG.6; *see also id.*, FIGs.7-8D. Figure 6 shows device 40 inserted through a patient's nostril and into the upper airway of a patient, where it delivers treatment and ultimately reduces mucus secretion.

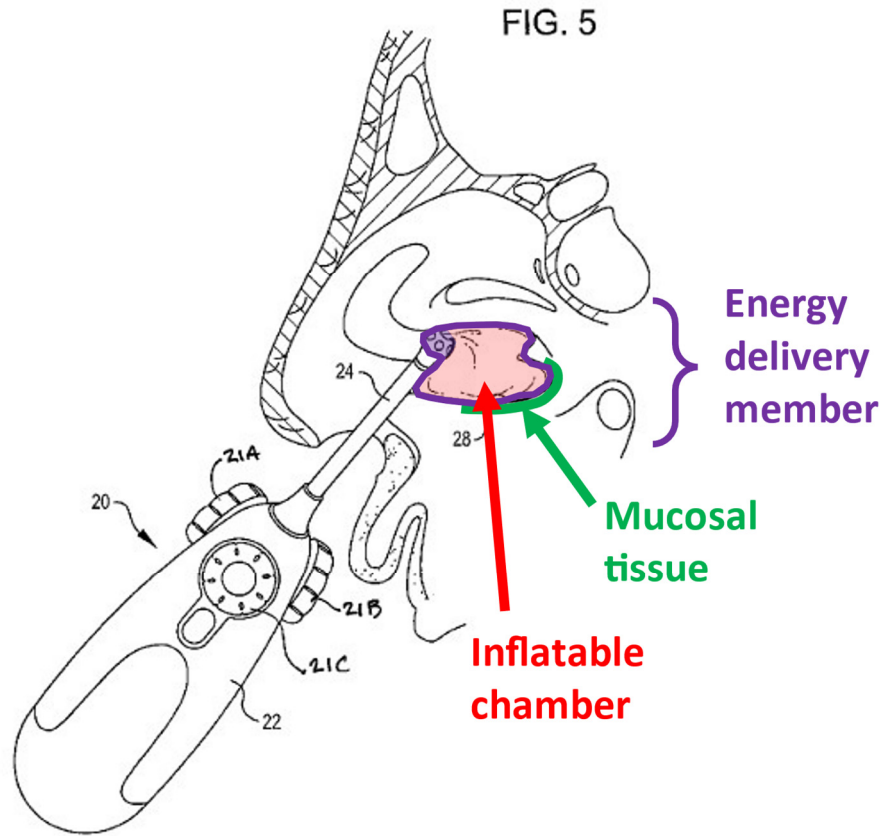
73. Given that Baker's method of using device 40 treats allergic rhinitis, it also treats at least one of post nasal drip or chronic cough, as claimed, for the same reasons that I provided above in connection with device 20.

b. Element 1[a]: advancing a treatment delivery portion of an energy-based treatment device into a nostril of the patient;

74. Baker's methods of using device 20 and device 40 each include the claimed step of advancing a treatment delivery portion (e.g., energy delivery member) of an energy-based treatment device (e.g., device 20 or device 40) into a nostril of the patient.

i. *Baker's method of using device 20 satisfies limitation 1[a]*

75. My analysis of this limitation focuses on Figure 5 of Baker, reproduced below.



Ex.1013-Baker, FIG.5. Figure 5 shows that an insertion wand 24 of device 20 is “insert[ed] through a nostril opening” (i.e., advanced into a nostril of a patient). *Id.*, 16:19-26 (“[I]nsertion wand 24 is configured for insertion through a nostril opening and positioning at least partially within nasal passageways.”). At the distal end of insertion wand 24 is an energy delivery member (purple) with an inflatable chamber 28 (red). *Id.*, 17:22-32 (“[A]n energy delivery member may comprise a flexible, deformable bladder or inflatable chamber 28 adapted for retaining an acoustically transmissive material.”). Given its position at the end of

insertion wand 28, the energy delivery member (including inflatable chamber 28) is likewise advanced into the nostril of the patient, as claimed. *Id.*, 20:35-39 (“[T]he insertion wand and energy delivery member are positioned in a nasal cavity, with the energy delivery member contacting...tissue desired to be treated.”).

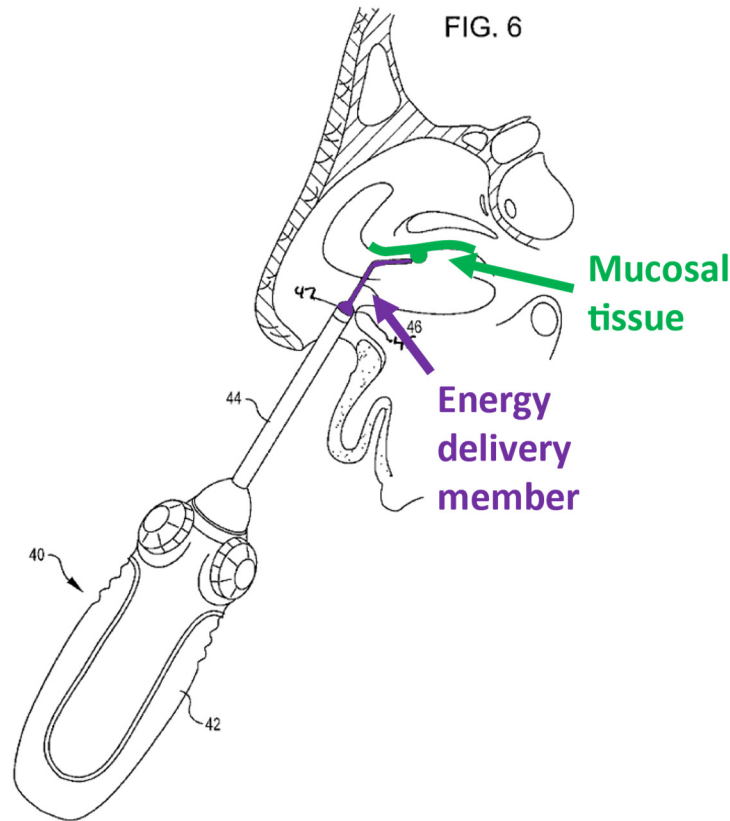
76. The energy delivery member (including inflatable chamber 28) is used to apply acoustic energy, such as ultrasound energy, to tissue surfaces in contact with inflatable chamber 28 and thereby treat the tissue. Ex.1013-Baker, 17:29-32 (“Generally high frequency acoustic energy, e.g. ultrasound energy, may be applied to the tissue surfaces or obstructions in contact with the chamber wall by transmission through the acoustically transmissive material and the wall of the inflatable chamber.”). A person of ordinary skill in the art therefore would have understood the energy delivery member to be a treatment delivery portion of an energy delivery device (e.g., device 20), as claimed.

77. Although the above analysis focuses on Baker’s Figure 5, Baker also depicts an embodiment of device 20 in Figure 4 that does not include inflatable chamber 28 but nevertheless satisfies limitation 1[a] for substantially the same reasons. Namely, Baker teaches that the embodiment in Figure 4 embodiment is likewise used by advancing an energy delivery member 26 into a patient’s nostril

to deliver energy-based treatment. *Id.*, 17:11-21 (“Energy delivery member 26 may be provided at the tip of the insertion wand and configured for...contacting blockages within nasal passages, mucous membranes and nasal turbinates...for delivery of high frequency acoustic energy.”), FIG.4.

ii. *Baker’s method of using device 40 also satisfies limitation 1[a]*

78. Additionally or alternatively, Baker’s method of using device 40 includes the claimed step of advancing a treatment delivery portion of an energy-based treatment device into a nostril of the patient. Figure 6 of Baker is reproduced below.



Ex.1013-Baker, FIG.6; *see also id.*, FIGs.8A-8D. Figure 6 shows an insertion member 44 of device 40 “insert[ed] through a nostril opening” (i.e., advanced into a nostril of a patient). *Id.*, 21:21-25 (“Insertion member 44 is configured for insertion through a nostril opening and positioning at least partially within nasal passageways.”). Extending from the distal end of insertion member 44 is an energy delivery member 46 (purple). *Id.*, 22:10-25 (“The energy delivery member may be extendible and/or retractable with respect to handle 42 and/or insertion member 44”). Given its position at the end of insertion wand 44, energy delivery member 46 is likewise advanced into the nostril of the patient, as claimed. *Id.*

(explaining that energy delivery member 46 “provide[s] desired positioning of the energy delivery member in contact with obstructions and/or tissues for delivery of high frequency acoustic energy.”).

79. Energy delivery member 46 is used to apply acoustic energy, such as ultrasound energy, to tissue surfaces in contact with energy delivery member 46 and thereby treat the tissue. *Id.*, 22:16-21 (“[E]nergy delivery member 46 comprises a generally rigid or semi-rigid wire-like structure capable of conveying, and delivering, high frequency acoustic energy...by contact with tissue or obstructive material along its length and/or at a distal end of the delivery member.”). A person of ordinary skill in the art therefore would have understood energy delivery member 46 to be a treatment delivery portion of an energy delivery device (e.g., device 40), as claimed.

80. Although the above analysis focuses on Baker’s Figure 6, Baker also depicts an embodiment of device 40 in Figure 7 that includes an additional flexible steering structure 48 but nevertheless satisfies limitation 1[a] for substantially the same reasons. Namely, Baker teaches that the embodiment in Figure 7 embodiment is likewise used by advancing an energy delivery member 46 into a patient’s nostril to deliver energy-based treatment. *Id.*, 22:21-29 (“The energy delivery member may be...in contact with obstructions and/or tissues for delivery

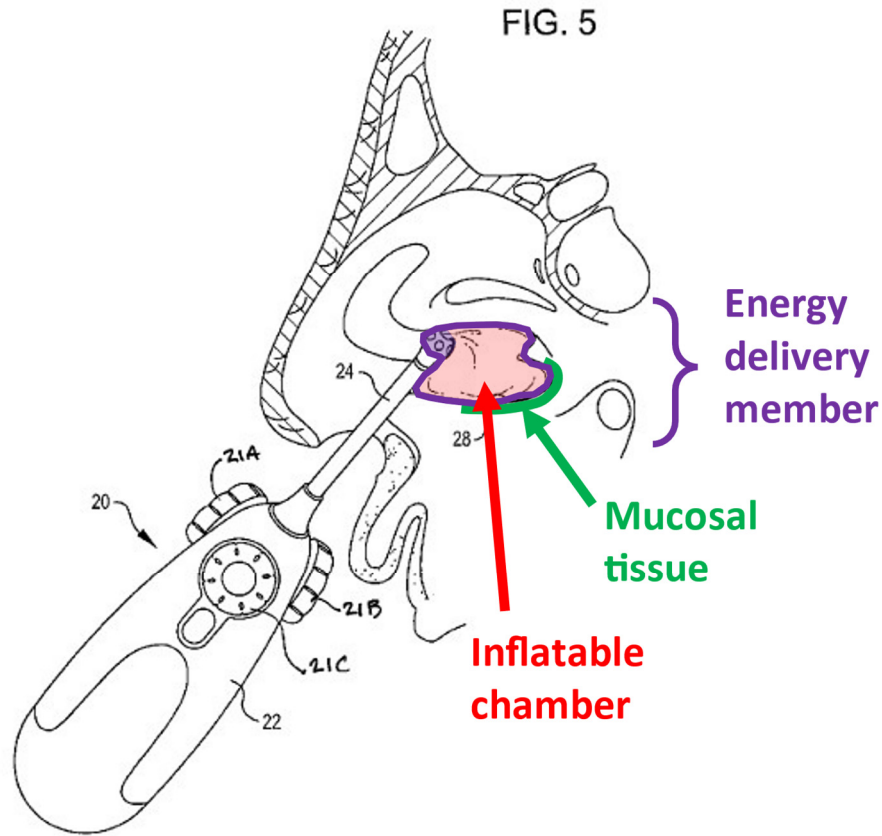
of high frequency acoustic energy. A distal end of the energy delivery member 46, 48 is preferably navigable to target tissue sites or target blocked sites within cavities, such as nasal passages.”), FIG.7.

c. Element 1[b]: contacting mucosal tissue of the upper airway with the treatment delivery portion, without piercing the mucosal tissue; and

81. Baker’s methods of using device 20 and device 40 each include the claimed step of contacting mucosal tissue of the upper airway with the treatment delivery portion (e.g., energy delivery member), without piercing the mucosal tissue.

i. *Baker’s method of using device 20 satisfies limitation 1[b]*

82. My analysis of this limitation focuses on Figure 5 of Baker, reproduced below.



Ex.1013-Baker, FIG.5. Figure 5 shows that the energy delivery member (i.e., the claimed treatment element) “contact[s] a tissue site [(green)]” via its expandable chamber 28 (red). *Id.*, 17:27-32 (“Expandable chamber 28 may be enlarged, at a desired target site, until the walls of the chamber contact a tissue site, or the walls of a cavity or passageway or lumen. Generally high frequency acoustic energy, e.g. ultrasound energy, may be applied to the tissue surfaces or obstructions in contact with the chamber wall by transmission through the acoustically transmissive material and the wall of the inflatable chamber.”). Baker explains,

“[T]he insertion wand and energy delivery member are positioned in a nasal cavity, with the energy delivery member contacting mucus and/or debris forming an obstruction, or tissue desired to be treated.” *Id.*, 20:35-39.

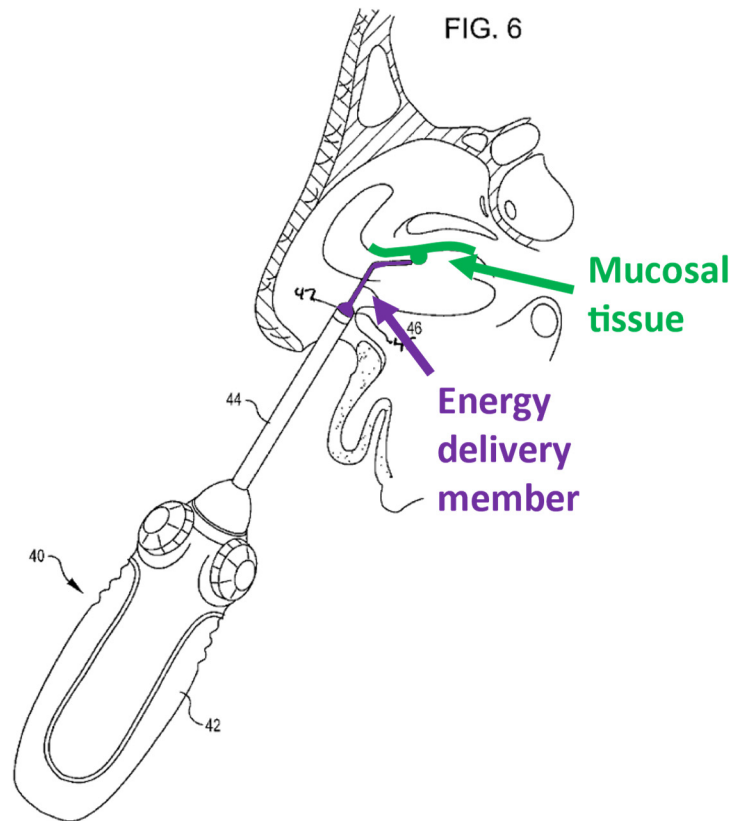
83. As I explained above with reference to limitation 1[pre], the tissue sites contacted using Baker’s method include “tissue sites such as nasal passages.” *Id.*, 16:19-22. A person of ordinary skill in the art would have known from background knowledge of nasal anatomy that the nasal passages are lined with mucosal tissue. 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.”). Therefore, by using the energy delivery member (i.e., the claimed treatment element) to contact tissue sites within the nasal passages, Baker’s method contacts mucosal tissue of the upper airway, as claimed. Ex.1013-Baker, 20:35-39 (“[T]he insertion wand and energy delivery member are positioned in a nasal cavity, with the energy delivery member contacting mucus and/or debris forming an obstruction, or tissue desired to be treated.”).

84. A person of ordinary skill in the art also would have understood that Baker's energy delivery member (i.e., the claimed treatment delivery portion) contacts the mucosal tissue without piercing the mucosal tissue, as claimed. For example, Baker's method delivers energy to tissue "surfaces," which indicates that the method need not pierce tissue to reach the target site. *Id.*, 17:29-32. Consistent with this understanding, Baker describes inflatable chamber 28 as being "flexible" and "deformable" such that it "conform[s] to contours of...intranasal passages" and therefore does not pierce the tissue. *Id.*, 17:22-36. I further note Figure 5 of Baker (reproduced above) shows device 20 contacting but not piercing the mucosal tissue.

85. Although the above analysis focuses on Baker's Figure 5, Baker also depicts an embodiment of device 20 in Figure 4 that does not include inflatable chamber 28 but nevertheless satisfies limitation 1[b] for substantially the same reasons. Namely, Baker teaches that the embodiment in Figure 4 embodiment is likewise used by placing the "energy delivery member in contact with...tissues" without piercing the tissue. *Id.*, 17:11-21; *see also id.*, 18:10-15 ("The energy delivery member...may be flexible or conformable."), FIG.4.

ii. ***Baker's method of using device 40 also satisfies limitation 1[b]***

86. Additionally or alternatively, Baker's method of using device 40 also includes the claimed step of contacting mucosal tissue of the upper airway with the treatment delivery portion without piercing the mucosal tissue. Figure 6 of Baker is reproduced below.



Ex.1013-Baker, FIG.6; *see also id.*, FIGs.8A-8D. Figure 6 shows the energy delivery member 46 (purple) (i.e., the claimed treatment delivery portion)

“contacting a tissue surface [(green)] such as mucous membranes...within cavities

such as nasal passages [(i.e., the claimed mucosal tissue of the upper airways)].”

Id., 22:12-16.

87. A person of ordinary skill in the art would have understood that Baker’s energy delivery member 46 (i.e., the claimed treatment delivery portion) contacts the mucosal tissue without piercing the mucosal tissue, as claimed. For example, when delivering energy, energy delivery member 46 “contact[s] a tissue surface” such that the method need not pierce tissue to reach the target site. *Id.* Consistent with this understanding, Figure 6 of Baker (reproduced above) shows device 40 contacting but not piercing the mucosal tissue.

88. Although the above analysis focuses on Baker’s Figure 6, Baker also depicts an embodiment of device 40 in Figure 7 that includes an additional flexible steering structure 48 but nevertheless satisfies limitation 1[b] for substantially the same reasons. Namely, Baker teaches that the embodiment in Figure 7 embodiment is likewise used by “positioning...the energy delivery member in contact with...tissues” without piercing the tissue. *Id.*, 22:21-25, FIG.7.

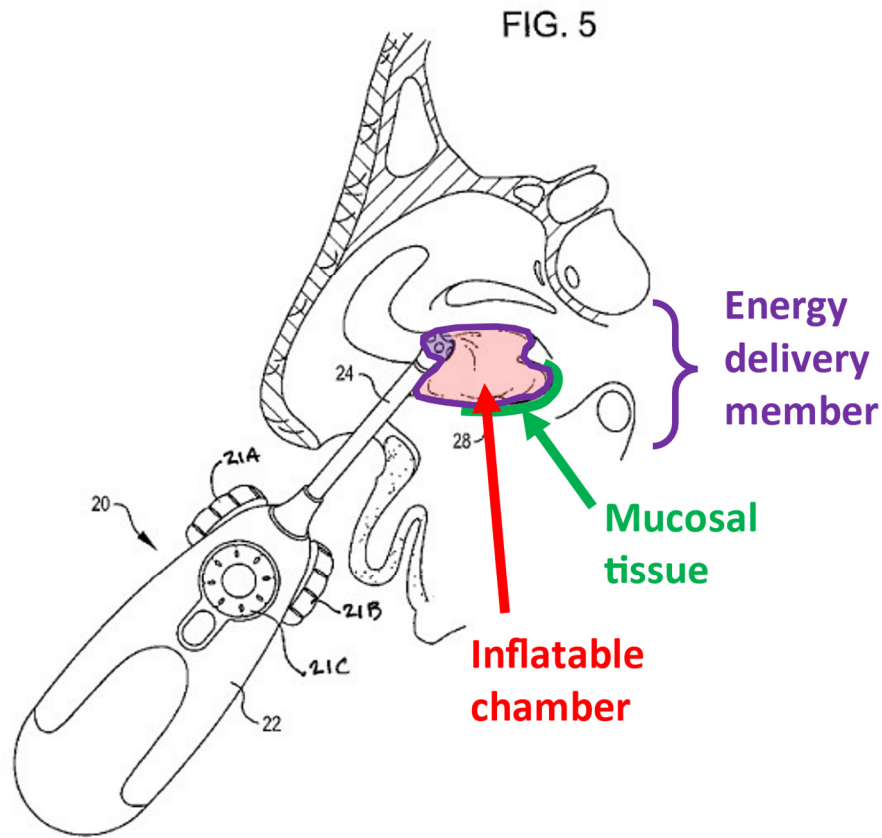
- d. Element 1[c]: delivering a treatment from the treatment delivery portion to at least one tissue selected from the group of the mucosal tissue and another tissue underlying the mucosal tissue to modify a property of the at least one tissue and thus**

**treat at least one of post nasal drip or chronic cough
in the patient.**

89. Baker's methods of using device 20 and device 40 each include the claimed step of delivering a treatment (e.g., energy based therapy) from the treatment delivery portion (e.g., energy delivery member) to at least one tissue selected from the claimed group (e.g., mucosal tissue) to modify a property of (e.g., treat) the at least one tissue and thus treat at least one of post nasal drip or chronic cough in the patient.

**i. *Baker's method of using device 20 satisfies
limitation 1[c]***

90. My analysis of this limitation focuses on Figure 5 of Baker,
reproduced below.



Ex.1013-Baker, FIG.5. Figure 5 shows the energy delivery member (i.e., the claimed treatment delivery portion) “deliver[ing]...ultrasound energy [(i.e., the claimed treatment)] to tissue surfaces.” *Id.*, 18:6-9, 17:22-24, 16:19-23.

91. As I explained above with reference to limitation 1[b], the energy delivery member (i.e., the claimed treatment delivery portion) contacts mucosal tissue. Accordingly, the tissue to which acoustic energy treatment is delivered includes mucosal tissue, as claimed. *Id.*, 17:22-32 (“[H]igh frequency acoustic energy, e.g. ultrasound energy, may be applied to the tissue surfaces...in contact

with the chamber wall by transmission through the acoustically transmissive material and the wall of the inflatable chamber.”), 20:35-39 (“[T]he insertion wand and energy delivery member are positioned in a nasal cavity, with the energy delivery member contacting...tissue desired to be treated.”), 16:19-22.

92. A person of ordinary skill in the art would have understood that the treatment delivered by Baker’s energy delivery member modifies a property of the mucosal tissue, as claimed. For example, one form of modification occurs when the energy delivery member delivers energy at a level “sufficient to ablate tissue,” which removes all or a portion of (and thus modifies) the tissue. *Id.*, 18:35-37. Another form of modification occurs when the energy delivery member delivers energy “at a sub-ablation intensity that is sufficient to disrupt tissue...but not ablate,” which disrupts (and thus modifies) the tissue’s structure or function. *Id.*

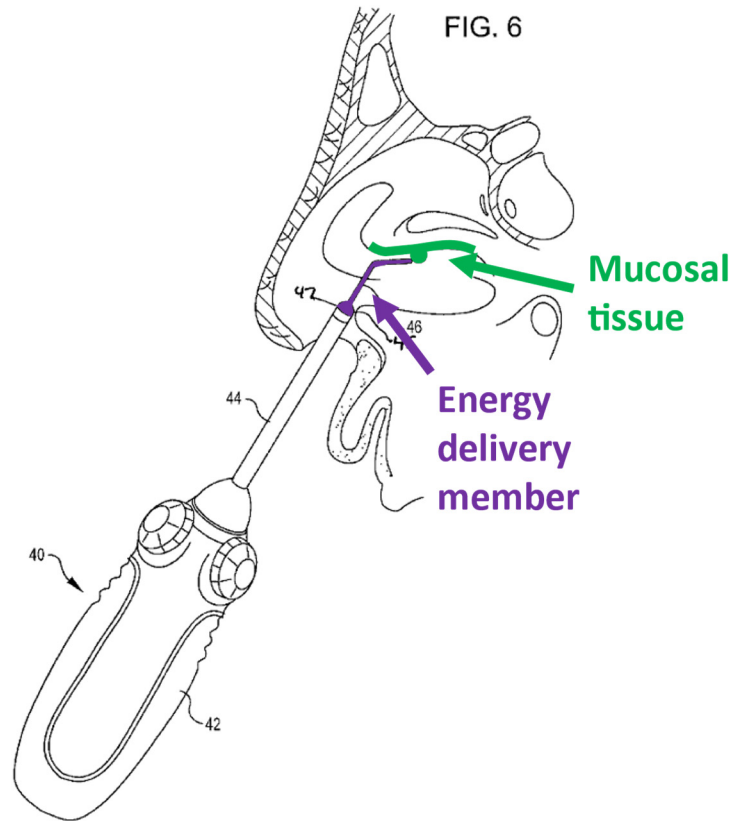
93. Finally, as I explained above with reference to limitation 1[pre], Baker teaches that its method of delivering treatment is used to treat at least one of post nasal drip or chronic cough, as claimed.

94. Although the above analysis focuses on Baker’s Figure 5, Baker also depicts an embodiment of device 20 in Figure 4 that does not include inflatable chamber 28 but nevertheless satisfies limitation 1[c] for substantially the same reasons. Namely, Baker teaches that the embodiment in Figure 4 embodiment is

likewise used to “deliver[] high frequency acoustic energy” to mucosal tissue. *Id.*, 17:11-21 (“Energy delivery member 26 may be provided at the tip of the insertion wand and configured for...contacting blockages within nasal passages, mucous membranes and nasal turbinates...for delivery of high frequency acoustic energy.”), FIG.4.

ii. *Baker’s method of using device 40 also satisfies limitation 1[c]*

95. Baker’s method of using device 40 also includes the claimed step of contacting mucosal tissue of the upper airway with the treatment delivery portion without piercing the mucosal tissue. Figure 6 of Baker is reproduced below.



Ex.1013-Baker, FIG.6; *see also id.*, FIGs.8A-8D. Figure 6 shows energy delivery member 46 (purple) (i.e., the claimed treatment delivery portion) “delivering[] high frequency acoustic energy [(i.e., treatment)]...by contact with tissue [(green)].”

Id., 22:16-21, 21:21-24, 23:5-8.

96. As I explained above with reference to limitation 1[b], energy delivery member 46 (i.e., the claimed treatment delivery portion) contacts mucosal tissue. Accordingly, the tissue to which acoustic energy treatment is delivered includes mucosal tissue, as claimed. *Id.*, 22:10-25 (“Energy delivery member 46 is configured such that a distal end may be...contacting a tissue surface such as

mucous membranes and nasal turbinates [(i.e., mucosal tissue)]...within cavities such as nasal passages. In one embodiment, illustrated in Fig. 6, energy delivery member 46 [is]...capable of conveying, and delivering, high frequency acoustic energy [(i.e., treatment)]...by contact with tissue.”).

97. A person of ordinary skill in the art would have understood that the treatment delivered by Baker’s energy delivery member 46 modifies a property of the mucosal tissue, as claimed. For example, one form of modification occurs when energy delivery member 46 delivers energy at a level “sufficient to ablate tissue,” which removes all or a portion of (and thus modifies) the tissue. *Id.*, 23:29-31. Another form of modification occurs when the energy delivery member delivers energy “at a sub-ablation intensity that is sufficient to disrupt tissue...but not ablate,” which disrupts (and thus modifies) the tissue’s structure or function. *Id.*

98. Finally, as I explained above with reference to limitation 1[pre], Baker teaches that its method of delivering treatment is used to treat at least one of post nasal drip and chronic cough, as claimed.

99. Although the above analysis focuses on Baker’s Figure 6, Baker also depicts an embodiment of device 40 in Figure 7 that includes an additional flexible steering structure 48 but nevertheless satisfies limitation 1[b] for substantially the

same reasons. Namely, Baker teaches that the embodiment in Figure 7 embodiment is likewise used to “deliver[]...high frequency acoustic energy” to mucosal tissue. *Id.*, 22:21-29 (“The energy delivery member may be...in contact with obstructions and/or tissues for delivery of high frequency acoustic energy. 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.”), FIG.7.

2. Claim 2: The method of claim 1, wherein the treatment is delivered without forming an incision in the mucosal tissue and without delivering an implant.

100. Baker teaches that the treatment is delivered (*see* limitation 1[c]) without forming an incision in the mucosal tissue and without delivering an implant, as claimed.

a. Baker’s method of using device 20 satisfies claim 2

101. As I explained above with reference to limitation 1[b], Baker’s method of using device 20 does not pierce mucosal tissue. Accordingly, the method also does not form an incision or deliver an implant given that these processes would require piercing tissue. Consistent with this understanding, Baker distinguishes its methods from other known methods involving the “[p]lacement of stents and other implantable devices in sinus passageways.” Ex.1013-Baker, 4:38-39.

b. Baker's method of using device 40 also satisfies claim 2

102. The same analysis I provided above in connection with device 20 also applies to Baker's method of using device 40 given that device 40 likewise does not pierce mucosal tissue (*see* limitation 1[b]).

3. Claim 3: The method of claim 1, wherein delivering the treatment comprises delivering energy from the delivery treatment portion² in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light and laser energy.

103. Baker teaches that the claimed step of delivering the treatment, as recited by limitation 1[c], further includes delivering energy from the [treatment delivery] portion (e.g., energy delivery member) in a form selected from the claimed group (e.g., ultrasound energy).

a. Baker's method of using device 20 satisfies claim 3

104. As I explained above in connection with limitation 1[c], Baker teaches that the energy delivery member (i.e., the claimed treatment delivery portion) of

² My analysis of claim 3 assumes that the phrase "delivery treatment portion" refers to the "treatment delivery portion" of claim 1.

device 20 “deliver[s]...ultrasound energy to tissue surfaces.” Ex.1013-Baker, 18:6-9, 17:11-21, 16:19-23.

b. Baker’s method of using device 40 also satisfies claim 3

105. The same analysis I provided above in connection with device 20 also applies to Baker’s method of using device 40 given that delivery member 46 (i.e., the claimed treatment delivery portion) likewise “deliver[s]...ultrasound energy” (see limitation 1[c]). Ex.1013-Baker, 22:16-21, 21:21-24, 23:5-8.

4. Claim 12: The method of claim 1, wherein delivering the treatment comprises injuring the at least one tissue.

106. Baker teaches that the claimed step of delivering the treatment, as recited by limitation 1[c], includes injuring the at least one tissue (e.g., mucosal tissue).

a. Baker’s method of using device 20 satisfies claim 12

107. As I explained above with reference to limitation 1[c], Baker teaches that device 20 treats tissue by “ablat[ing] tissue.” Ex.1013-Baker, 18:35-37. A person of ordinary skill in the art would have understood ablation as a type of injury to tissue, as claimed. After ablation, the tissue no longer retains its normal structure or carries out its normal function. Only after undergoing a healing process would the tissue recover from the injury and return to its normal state.

b. Baker's method of using device 40 also satisfies claim 12

108. The same analysis I provided above in connection with device 20 also applies to Baker's method of using device 40 given that device 40 likewise treats tissue by "ablat[ing] tissue." Ex.1013-Baker, 23:29-31.

5. Claim 14: The method of claim 12, wherein the at least one tissues is selected from the group consisting of cilia, goblet cells, nerves, submucosal tissue, muscle, ligaments, cartilage, tendon, and skin.

109. Baker teaches that the at least one tissue (e.g., mucosal tissue, as explained for limitation 1[c] and claim 12) is selected from the claimed group (e.g., cilia and goblet cells).

a. Baker's method of using device 20 satisfies claim 14

110. As I explained above with reference to limitations 1[b]-1[c] and claim 12, device 20 contacts and delivers treatment to the claimed at least one tissue by injuring (e.g., ablating) the at least one tissue. Ex.1013-Baker, 16:19-22 (explaining that treatment is applied to "tissue sites such as nasal passages"), 18:35-37 (explaining that treatment includes "ablat[ing] tissue"), 20:35-39 ("[T]he insertion wand and energy delivery member are positioned in a nasal cavity, with the energy delivery member contacting mucus and/or debris forming an obstruction, or tissue desired to be treated."). Baker further teaches that the at least

one tissue includes “skin surfaces” (i.e., the claimed skin). *Id.*, 5:19-23 (“Methods and systems of the present invention may be applied for the treatment of tissue sites such as skin surfaces ... for the disruption and/or removal of the obstruction(s).”).

b. Baker’s method of using device 40 also satisfies claim 14

111. The same analysis I provided above in connection with device 20 also applies to Baker’s method of using device 40 given that device 40 likewise delivers treatment to (e.g., injures) mucosal tissue. *See* limitations 1[pre], 1[b], 1[c], and claim 12.

6. Claim 16: The method of claim 1, wherein delivering the treatment comprises modifying the at least one tissue in a manner that decreases a volumetric rate of mucus production of the mucosal tissue without changing a shape of the mucosal tissue.

112. Baker teaches that the claimed step of delivering the treatment, as recited by limitation 1[c], includes modifying the at least one tissue in a manner that decreases a volumetric rate of mucus production of the mucosal tissue without changing a shape of the mucosal tissue.

a. Baker’s method of using device 20 satisfies claim 16

113. As I explained above with reference to limitations 1[pre] and 1[c], the energy delivery member of device 20 delivers treatment by modifying the mucosal

tissue (e.g., by ablating or disrupting tissue). Ex.1013-Baker, 18:35-37. The modification of the mucosal tissue is intended to achieve “[e]ffective and long-lasting reduction of mucus...within the nasal passages.” *Id.*, 5:5-12. That is, the tissue is modified in a manner that decreases a volumetric rate of mucus production of the mucosal tissue, as claimed. *See* limitation 1[pre].

114. A person of ordinary skill in the art would have understood that ablating or disrupting tissue in the manner taught by Baker modifies a property of the tissue (e.g., changes or disrupts its function) without changing its shape. For example, in its disclosure supporting claim 16, the ’194 patent discloses embodiments where tissue is modified but not reshaped, and these embodiments use the same process as Baker of disrupting/damaging or ablating tissue without reshaping it. *Compare* Ex.1013-Baker, 18:35-37 (energy delivered by device 20 is “sufficient to disrupt tissue and/or cellular structures” or to “ablate tissue and/or cellular structures) *with* Ex.1001-USP194, 13:14-19 (“[D]eliver[ing] treatment energy to create specific localized tissue damage [(i.e., disrupt tissue and/or cellular structures)] or ablation [(i.e., ablate tissue and/or cellular structures)] stimulat[es] the body’s healing response to create desired conformational or structural changes that reduces the mucus producing ability of the mucus producing cells.”).

115. On the other hand, the '194 patent also discloses embodiments in which tissue is reshaped, and in these embodiments the treatment portion is described as being rigid and inelastic to cause tissue to conform to the shape of the treatment device. Ex.1001-USP194, 11:55-58 (“[T]he treatment element 32 may have a substantially rigid or minimally elastic shape sized and shaped such that it substantially conforms to an ideal shape and size of a patient’s nasal passageway.”). Baker’s inflatable chamber is flexible and deformable and is therefore unlike the rigid/inelastic treatment elements that the '194 patent discloses are used to reshape tissue. Ex.1013-Baker, 17:22-32.

b. Baker’s method of using device 40 also satisfies claim 16

116. The same analysis I provided above in connection with device 20 also applies to Baker’s method of using device 40 given that device 40 likewise modifies mucosal tissue by ablating or disrupting tissue. *See* limitations 1[pre], 1[c].

7. Claim 18: The method of claim 1, wherein delivering the treatment comprises delivering the treatment to at least one turbinate of the upper airway.

117. Baker teaches that the claimed step of delivering the treatment, as recited by limitation 1[c], includes delivering the treatment to at least one turbinate of the upper airway.

a. Baker's method of using device 20 satisfies claim 18

118. As I explained above with reference to limitations 1[b] and 1[c], device 20 is used to treat “tissue sites such as nasal passages,” Ex.1013-Baker, 16:19-22. In Baker's description of the embodiment of device 20 depicted in Figure 4, Baker further explains that “[e]nergy delivery member 26 may be...configured for positioning in proximity to and/or contacting blockages within ... nasal turbinates” (i.e., the claimed at least one turbinate of the upper airway). Ex.1013-Baker, 17:11-13. A person of ordinary skill in the art would have understood that Baker's description of energy delivery member 26 (as shown in Figure 4) contacting nasal turbinates applies equally to the energy delivery member shown in Figure 5. This is particularly true given that Figure 5 depicts the energy delivery member contacting the same or similar portions of the nasal anatomy as shown in Figure 4 and does not otherwise specify the particular structures being contacted. *Id.*, 9:35-10:10; *compare id.*, FIG.4 with *id.*, FIG.5 (each depicting an embodiment of an energy delivery member of device 20 delivering treatment to the same or similar structures within the nose).

b. Baker's method of using device 40 also satisfies claim 18

119. The same analysis I provided above in connection with device 20 also applies to Baker's method of using device 40 given that device 40 likewise delivers

treatment to a “tissue surface such as...nasal turbinates” (i.e., at least one turbinate of the upper airway). Ex. 1013-Baker, 22:12-16.

B. Ground II: Baker Renders Obvious Claims 1-3, 12, 14, 16, 18, and 19

1. Claims 1-3, 12, 14, 16, and 18

120. As I explained above with reference to Ground I, Baker discloses every element of 1-3, 12, 14, 16, and 18. Additionally or alternatively, as I explain in further detail below, certain limitations of claims 1-3, 12, 14, 16, and 18 would have been obvious in view of Baker even if Patent Owner argues that they are not expressly disclosed. Baker therefore renders claims 1-3, 12, 14, 16, and 18 obvious.

a. It would have been obvious to use Baker’s methods “to treat at least one of post nasal drip or chronic cough” as recited by limitations 1[pre] and 1[c]

121. Even assuming Baker did not disclose using its methods to treat post nasal drip or chronic cough as explained in Ground I, it would have been obvious to do so for the following reasons.

i. *Post nasal drip*

122. As I explained above with reference to limitations 1[pre] and 1[c], Baker’s methods of using device 20 and/or device 40 are each used to treat allergic rhinitis and other conditions of the upper airways. Ex.1013-Baker, 26:7-11. It

would have been background knowledge to a person of ordinary skill in the art that post nasal drip is a symptom of allergic rhinitis. Consistent with this understanding, Baker's background section identifies post nasal drip as a symptom of rhinitis. *Id.*, 1:25-29.

123. In view of Baker's teachings in connection with allergic rhinitis and a person of ordinary skill in the art's background knowledge of the symptoms of allergic rhinitis (which include post nasal drip), it would have been obvious to apply Baker's methods to treat post nasal drip. For example, a person of ordinary skill in the art would have been motivated to use a known technique (i.e., Baker's methods for treating allergic rhinitis) to treat a symptom of allergic rhinitis (i.e., post nasal drip) in the same way. A person of ordinary skill in the art also would have understood that treating a symptom's underlying causes would have been reasonably likely to successfully treat or mitigate the target symptom (i.e., post nasal drip). *See* Ex.1037-Chung, 292 (explaining that a known technique for treating upper airway conditions was to "[t]reat[] the specific underlying cause(s)"), 107 ("A number of conditions can cause PNDS [post nasal drip syndrome]. The differential diagnosis includes...perennial allergic rhinitis."); Ex.1049-Konno, 107 (explaining that treating "allergic rhinitis can produce

dramatic relief of hyperreactive nasal symptoms, particularly hyperrhinorrhea [(i.e., a cause of post nasal drip)]”).

ii. *Chronic cough*

124. Although the analysis in the previous section focuses on post nasal drip, it applies equally to chronic cough given that chronic cough was known to be caused by post nasal drip and allergic rhinitis. Ex.1037-Chung, 247 (“Multiple studies have demonstrated PNDS [post nasal drip syndrome] to be the most common cause of chronic cough in adults. PNDS may be the result of various processes, including seasonal and perennial allergic rhinitis, perennial non-allergic rhinitis, vasomotor rhinitis, postinfectious (postviral) rhinitis and chronic bacterial sinusitis.”) (citations omitted). That is, the same background knowledge of allergic rhinitis and its symptoms that would have motivated a person of ordinary skill in the art to apply Baker’s known methods for treating allergic rhinitis to treat one symptom of allergic rhinitis (post nasal drip) would have likewise motivated a person of ordinary skill in the art to treat another symptom of allergic rhinitis (chronic cough, which is also caused by post nasal drip) in the same way. Moreover, as I explained above with reference to post nasal drip, a person of ordinary skill in the art would have understood that treating a symptom’s underlying causes would have been reasonably likely to successfully treat or

mitigate the target symptom (i.e., chronic cough). Ex.1037-Chung, 292 (explaining that a known technique for treating cough was to “[t]reat[] the specific underlying cause(s)” including “[a]llergic rhinitis and postnasal drip”).

b. It would have been obvious to use Baker’s methods to contact and/or deliver treatment to the nasal turbinates as recited by claim 18

125. As I explained above with reference to claim 18, Baker teaches using energy delivery device 26 (depicted in Figure 4) to apply acoustic energy to the turbinates and this teaching would have been understood to apply equally to the energy delivery device depicted in Figure 5. However, even assuming that Baker does not disclose using the energy delivery device depicted in Figure 5 treats the turbinates, doing so would have been obvious. In fact, Baker already states that the other embodiments of energy delivery devices discussed in Ground I (e.g., the embodiments depicted in Figures 4, 6, and 7) are used to treat the turbinates. Ex.1013-Baker, 17:11-13, 22:12-16.

126. For example, in its background section Baker identifies known treatment techniques that achieved successful clinical outcomes by “targeting ultrasound beams on subepithelial layers of nasal mucosa in the nasal turbinates.” *Id.*, 4:13-16 (“Devices targeting ultrasound beams on subepithelial layers of nasal mucosa in the nasal turbinates have been reported to reduce the volume of inferior

turbينات, while increasing the volume of nasal ventilation.”). Accordingly, a person of ordinary skill in the art would have found an express motivation within Baker itself to apply Baker’s method of using device 20 (as shown in Figure 5) to the turbinates. More generally, a person of ordinary skill in the art would have been motivated to use a known technique (i.e., Baker’s method of delivering ultrasound energy to the nasal passages) to treat a particular structure within the nasal passages (i.e., nasal turbinates) in the same way. A person of ordinary skill in the art would have understood that delivering ultrasound energy to nasal turbinates using Baker’s method would have been reasonably likely to improve nasal ventilation, as this was the clinical outcome reported in the prior art study identified in Baker’s background section.

2. Claim 19: The method of claim 18, wherein the at least one turbinate comprises an inferior turbinate, and contacting the mucosal tissue comprises contacting a posterior aspect of the inferior turbinate.

127. The ’194 patent identifies embodiments in which treatment is delivered to the “inferior turbinate” and/or the “posterior aspect of the inferior turbinate,” as claimed, but does not indicate that these locations are preferred locations for treatment or are otherwise clinically significant. Rather, the ’194 patent describes “apply[ing] energy to the posterior aspect of the inferior

turbinate” as merely one example of a structure to which treatment is applied.

Ex.1001-USP194, 23:32-35. The patent otherwise focuses on more general embodiments in which the claimed techniques are used to treat “the tissue of the nose and throat, including but not limited to skin, muscle, mucosa, submucosa and nasal turbinate.” *Id.*, 3:5-10.

128. Baker likewise discloses that its treatment can be applied to tissue of the upper airways including “nasal passages, mucous membranes and nasal turbinates, or pathological or undesired tissue.” Ex.1013-Baker, 17:11-13; *see also id.*, 16:19-23, 22:12-16. Accordingly, a person of ordinary skill in the art would have understood that the claimed “posterior aspect of the inferior turbinate” is simply a specific portion of the “nasal turbinates” disclosed by Baker. Baker’s lack of particularity about which turbinate (or portion of a turbinate) is contacted is consistent with the ’194 patent’s own lack of specificity about the clinical significance of any particular turbinate. A person of ordinary skill in the art therefore would have found it obvious to try contacting the “posterior aspect of the inferior turbinate” given that it is one of a limited number of known turbinates (e.g., inferior, middle, or superior) and aspects of turbinates (e.g., posterior, medial, or anterior). This understanding is consistent with Baker’s choice to leave the

selection of a particular location to the discretion of a person of ordinary skill in the art.

129. Like other anatomical structures of the nasal cavity, the posterior aspect of the inferior turbinate is lined by mucosal tissue and contains other anatomical features (e.g., nerves) that are known to have clinical significance to conditions such as allergic rhinitis. Ex.1017-Chen, 240 (“The use of radiofrequency thermocoagulation of the posterior inferior nasal nerve, anterior ethmoidal nerves, and inferior turbinate under nasal endoscopy for the treatment of PAR [perennial allergic rhinitis] can widely block the source of the parasympathetic nerves in the nasal cavity and reduce the excitability of the parasympathetic nerves, the sensitivity of the nasal mucosa to sensitive areas, and the sensory-parasympathetic reflex.”); Ex.1040-Kong, 214-215 (“The main principle [underlying surgically treatment for allergic rhinitis] is to reduce acetylcholine secretion and substance P release by removing some parasympathetic nerve fibers, the inferior turbinate microganglia, and the parasympathetic plexus, thereby reducing the sensory nerve sensitivity and the vascular permeability, reducing the glandular secretion.”). Therefore, a person of ordinary skill in the art would have understood that contacting and treating the posterior aspect of the inferior turbinate, as claimed, would have been reasonably likely to accomplish the

goals of Baker's treatment (including treating post nasal drip and chronic cough, as explained for limitation 1[pre]) given that the posterior aspect of the inferior turbinate is lined by the mucosal tissue that Baker's methods are intended to contact and treat.

C. Ground III: Baker in view of Edwards-'535 and Chen Renders Obvious Claims 1-3, 6, 12, 14, 16, 18, and 19

130. As I explain in detail below, the teachings of Baker in view of Edwards-'535, and Chen renders each of the challenged claims obvious.

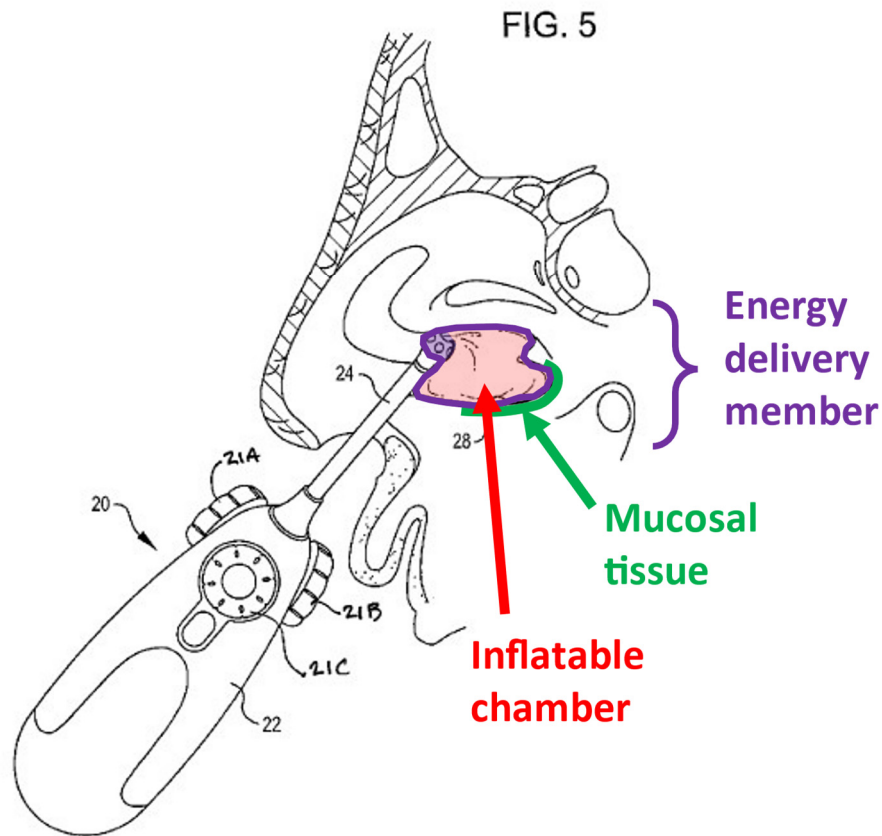
1. Claim 1

a. Element 1[pre]: A method for reducing mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough, the method comprising:

131. As I explained in Ground I, I understand that a preamble does not always limit a claim's scope, but even if the preamble of claim 1 is limiting, Baker in view of Edwards-'535 and Chen renders it obvious. Namely, the combination of Baker, Edwards-'535, Chen renders obvious a method for reducing mucus secretion in an upper airway (e.g., nasal passages) of a patient to treat at least one of post nasal drip or chronic cough.

i. ***Baker's teachings in connection with energy based therapy including RF energy treatments***

132. As I explained above in connection with Grounds I and II, Baker teaches several embodiments of methods for delivering energy based therapy to treat post nasal drip and chronic cough. For the purposes of Ground III, I focus on Baker's method of using device 20 as depicted in Figure 5, reproduced below.



Ex.1013-Baker, FIG.5. Figure 5 shows an arrangement of device 20's energy delivery member (purple) that includes an inflatable chamber 28 (red). *See supra*,

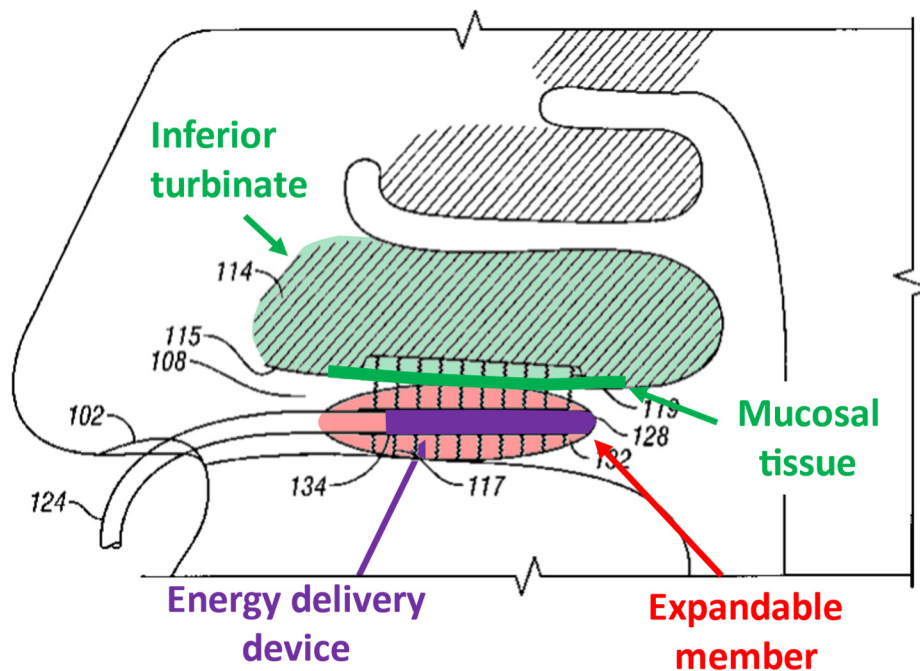
§§ X.A.1.a.i, X.A.1.b.i. The energy delivery member is used to apply “acoustic energy...to tissue sites such as nasal passages.” *Id.*, 16:19-22, 17:22-36.

133. Baker also teaches the possibility of using device 20, as depicted in Figure 5, to deliver acoustic energy “in combination with another treatment modality such as...application of...radio frequency energy.” *Id.*, 5:28-33; *see also id.*, 9:15-18. However, Baker’s disclosure does not otherwise provide details regarding the delivery of treatment using radio frequency (RF) energy.

ii. *Edwards-’535’s teachings in connection with RF energy delivery devices*

134. Edwards-’535 teaches techniques for “treating airway obstructions” using an apparatus 124 that is “introduced through a nostril” of a patient. Ex.1010-Edwards-’535, 1:22-26, 5:18-26. For example, Edwards-’535’s techniques are used to treat obstructions associated with the turbinates. *Id.* With respect to terminology, I note that Edwards-’535 uses the terms “concha” and “turbinates” interchangeably. *Id.*, 4:19-20 (“a nasal concha (turbinate)”), 4:41-43 (“the nasal concha, also referred to as the turbinates”). For purposes of clarity and consistency, I refer to these structures as “turbinates” throughout my analysis.

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



Id., FIG.3B. Figure 3B shows the distal end of apparatus 124 includes an energy delivery device 134 (purple) that is used to apply “RF energy to at least a portion of the nasal [turbينات] being treated.” *Id.*, 5:46-51; *see also id.*, 5:31-35. The RF energy from device 134 “heat[s] at least a portion of the nasal [turbينات (green)] being treated” and thereby “caus[es] the ablation of tissue.” *Id.*, 5:35-38. Figure 3B further shows an expandable member 132 (red) at the distal end of apparatus 124. Edwards-’535’s describes expandable member 132 as having the same attributes as Baker’s inflatable chamber 28 (which I described in the previous section). For example, expandable member 132 “conforms to the surface of the

nasal [turbينات] to be ablated” and does not penetrate mucosal tissue. *Id.*, 5:27-31, 7:33-40.

136. While not depicted in Figure 3B, Edwards-’535 teaches that RF energy delivery device 134 can be located “on a surface 147 of the expandable member.” *Id.*, 8:8-32. 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, 7:44-65 (“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.”).

iii. *Chen's teachings in connection with using RF energy to treat allergic rhinitis and its symptoms*

137. Chen is a scientific journal article describing a clinical study in which patients with perennial allergic rhinitis were treated by applying RF energy to the nasal passages. Ex.1017-Chen, Abstract, 239-240 (“From September 2002 to March 2003, 40 patients with PAR [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”). The authors explained that the results of the study were promising. *Id.*, Abstract, 243 (explaining that the treatment was found to be “highly effective” and “easy to perform” while mitigating the risk of complications). For example, the RF energy based treatment was considered a promising technique to “reduce the sensitivity of the nasal mucosa to external stimuli,...reduce the gland secretion, and...alleviate or eliminate symptoms such as nasal itching, sneezing, nasal congestion, and runny nose in patients, achieving the objective of treating [allergic rhinitis].” *Id.*, 240, 243.

138. In Chen’s study, patients with allergic rhinitis were “treated with radiofrequency thermocoagulation.” *Id.*, 239-40. 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 [turbينات] being treated.”).

139. The tissue targeted using Chen’s RF thermocoagulation technique includes mucosal tissue lining the inferior turbinate and/or nerves within the inferior turbinate (e.g., “posterior inferior nerve,” “cholinergic nerves,” and “parasympathetic nerve plexus”). Ex.1017-Chen, 239-40 (“From September 2002 to March 2003, 40 patients with PAR [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, and comparison was made with another group (control group) of 40 patients with PAR treated with only radiofrequency thermocoagulation of the sphenopalatine nerve³ under nasal endoscopy in order to study the new method to

³ The sphenopalatine nerve or sphenopalatine ganglion (SPG) is also referred to as the pterygopalantine ganglion.

improve the therapeutic effect of PAR. After six months of follow-up, the therapeutic effect was significant.”), 240 (“The treatment for the [posterior inferior nerve] involved placing the [RF energy] probe on the lateral wall of the nasal cavity between the posterior end of the middle and inferior turbinate, making a strip-shaped thermocoagulation from the top to the bottom with a length of about 2.5 cm, a width of 0.5 cm, and a depth up to the bone wall.... Spot-like thermocoagulation was also performed on the anterior and medial mucosa of the inferior turbinate.”), 240 (“In the inferior turbinate, there are cholinergic nerves and parasympathetic nerve plexus.”).

140. A person of ordinary skill in the art would have understood that Chen’s method of delivering RF energy used in the clinical study did not pierce the mucosal tissue of the patients. For example, Chen describes “placing the [RF energy delivery] probe *on* [(not ‘in’ or ‘under’)] the lateral wall of the nasal cavity” *Id.*, 240 (emphasis added). Had Chen used a piercing technique, a person of ordinary skill in the art would have expected Chen to say so given that piercing tissue is a clinically significant part of a medical procedure. Consistent with this understanding, Chen’s description of “a strip-shaped thermocoagulation” in which “local mucosa appear[s] as white patches” suggests that a non-piercing RF energy delivery device was moved over the surface of the mucosal tissue to form strips.

Id. Moreover, other clinical studies carried out in a similar timeframe to Chen – including one (Liang) that was published by the same group that published Chen⁴ – used a non-piercing RF energy delivery device, the SHP-I. Ex.1055-Fang, 876 (“Under nasal endoscopy, the SHP-I five-organ radiofrequency therapy instrument (manufactured by Guangzhou Medical Instrument Factory) was firstly used.”); Ex.1056-Liang, 341 (“the SHP-I type ENT radiofrequency therapy instrument (manufactured by Guangzhou Medical Equipment Factory) was used, with the negative electrode connected to the patient's lower chin...to perform thermal coagulation treatment.”). The SHP-I used a spheroid electrode, not a needle for piercing tissue, such that a person of ordinary skill in the art would have understood the SHP-I to be non-piercing. Ex.1059-Liang-’227, FIG.1 (showing that the SHP-I device uses a ball-shaped (i.e., non-piercing) RF electrode), 3 (“Probe A: treatment head is spherical”). These studies further reinforce that

⁴ Chen and Liang share several common authors and were both published by a research group from the Department of Otolaryngology, the People’s Hospital of Guangxi Autonomous Region in Nanning, China. *Compare* Ex.1013-Chen, 239 (byline and affiliations) *with* Ex.1056-Liang, 341 (byline and affiliations).

Chen's use of non-piercing methods and devices would have been considered unremarkable at the time, unlike a piercing method that one would have expected Chen to state explicitly.

141. More generally, even assuming Chen used devices and methods that pierced mucosal tissue, Chen's promising clinical results would have motivated a person of ordinary skill in the art to carry out Chen's treatment using RF devices that do not penetrate tissue. Chen itself does not state that its methods puncture tissue, nor does it highlight any other specific attributes of the RF energy deliver probe that were necessary or important to achieving the reported clinical results. Accordingly, a person of ordinary skill in the art would have understood Chen's teachings to be compatible with other RF energy delivery methods, including the various non-puncturing methods that were known prior to 2011.

iv. *Motivation to combine the teachings of Baker, Edwards-'535, and Chen*

142. As I explained above, Baker teaches embodiments of its methods in which RF energy is applied to the upper airways. Ex.1013-Baker, 5:28-33; *see also id.*, 9:15-18. Additional details about RF energy based treatments are found in Edwards-'535 and Chen. For example, Edwards-'535 describes devices that deliver RF energy to tissue in the upper airways, and Chen 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 Baker, Edwards-'535, and Chen as follows:

- Baker's device 20 would have been modified to include one or more RF delivery devices, such as those described in Edwards-'535; and
- Baker's method of using device 20 (as modified in view of Edwards-'535) would have been applied to deliver RF energy to specific tissues to treat allergic rhinitis, as taught by Chen.

Below, I explain why a person of ordinary skill in the art would have been motivated to combine Baker, Edwards-'535, and Chen in this manner with a reasonable expectation of success.

143. As an initial matter, a person of ordinary skill in the art would have understood that Baker, Edwards-'535, and Chen are in the same field as the '194 patent and are reasonably pertinent to solving the problems addressed in the '194 patent (e.g., treating tissue in a body cavity) with the same types of solutions (e.g., applying energy to tissue). *See, e.g.*, Ex.1013-Baker, 16:19-22, 17:22-36; Ex.1010-Edwards-'535, Abstract, 5:43-51, 8:47-53, 10:25-31, 10:51-57; Ex.1017-Chen, 239-240.

144. As an initial matter, Baker contemplates improving its methods by adding the capability to apply RF energy (in addition to acoustic energy) to tissue, stating acoustic energy can be delivered “in combination with another treatment modality such as...application of...radio frequency energy.” *Id.*, 5:28-33; *see also id.*, 9:15-18. However, because Baker does not describe details of how to implement such an RF energy treatment, a person of ordinary skill in the art would have been motivated to seek out other teachings, like those Edwards-’535 and Chen, which describe the specifics that are missing from Baker.

145. With respect to modifying Baker’s device 20 to deliver RF energy in view of Edwards-’535, Edwards-’535 lists numerous reasons that applying its teaching in connection with RF energy delivery device 134 would have been advantageous. For example, the advantages of Edwards-’535’s teachings include “eliminat[ing] the need for surgical cutting to remove a portion of a nasal [turbinate] and the risks associated therewith” while allowing medical procedures to be “performed bloodlessly and without the need to penetrate tissue, thereby significantly reducing the risk of infection.” Ex.1010-Edwards-’535, 4:53-60; *see also id.*, 4:66-67 (“This approach should be significantly less painful for the patient than traditional surgical methods”). A person of ordinary skill in the art would have therefore recognized that combining Baker’s teachings in connection with

device 20 with Edwards-'535's teachings of an RF energy delivery device would have improved Baker's method by enabling the delivery of RF energy to nasal tissue with few side effects or risks of complications.

146. With respect to modifying Baker's method of using device 20 (as modified to deliver RF energy according to Edwards-'535's teachings) in view of Chen, Chen supplies ample reasons to treat specified tissues using RF energy. For one, Baker and Chen share the same objective of treating allergic rhinitis, and Chen states (and supports with real-world clinical data) that its approach based on treating specified tissues using RF energy "is highly effective, easy to perform and [has] few complications" and is therefore "a good way to treat" allergic rhinitis. Ex.1017-Chen, Abstract; *see also id.*, 243 ("This method has the advantages of significant therapeutic effect, simple operation, and no side effects, and is worthy of clinical use."). More specifically, Chen includes a detailed analysis to explain why ablating the particular tissues targeted in the study, e.g., nerves within or proximate to the inferior turbinate, results in "alleviat[ing] or eliminat[ing] symptoms such as nasal itching, sneezing, nasal congestion, and runny nose,...[thereby] achieving the objective of treating [allergic rhinitis]." *See id.*, 240, 243 ("The use of radiofrequency thermocoagulation of the posterior inferior nasal nerve, anterior ethmoidal nerves, and inferior turbinate under nasal

endoscopy for the treatment of [allergic rhinitis] can widely ***block the source of the parasympathetic nerves*** in the nasal cavity and reduce the excitability of the parasympathetic nerves, the sensitivity of the nasal mucosa to sensitive areas, and the sensory-parasympathetic reflex. This can disrupt the sneezing reflex arc input pathway, reduce the sensitivity of the nasal mucosa to external stimuli, reduce vascular dilation, reduce the gland secretion, and reduce the swelling of the nasal mucosa, which can thereby ***alleviate or eliminate symptoms*** such as nasal itching, sneezing, nasal congestion, and runny nose in patients, ***achieving the objective of treating [allergic rhinitis].***”) (emphasis added). A person of ordinary skill in the art would have therefore recognized that combining Baker’s teachings in connection with a method for using device 20 (as modified in view of Edwards-’535’s RF energy delivery device) with Chen’s teaching of particular target tissues would have improved Baker’s method by enhancing the ability to treat allergic rhinitis effectively with few side effects or risks of complications.

147. Combining Baker, Edwards-’535, and Chen 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.1013-Baker, 16:19-22 (Baker’s method delivers “acoustic energy...to tissue sites such as nasal passages.”), 26:7-11 (Baker’s method treats “common colds,

nasal congestion and allergic rhinitis, as well as sinusitis and other nasal conditions.”); Ex.1010-Edwards-’535, 5:35-36 (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.1017-Chen, Abstract (Chen discloses a study of patients “treated with nasal posterior-under nerve, ethmoidal nerve and infratubinal radiofrequency [energy] under nasal endoscope.”); *id.* (Chen’s objective is “[t]o study a new method for [treating] perennial allergic rhinitis (PAR).”). Another similarity among Baker, Edwards-’535, and Chen is that they each teach that the applied energy is used to ablate tissue of the upper airways, such as the turbinates. Ex.1013-Baker, 18:35-37 (Baker’s method delivers energy “sufficient to ablate tissue.”), 17:11-13 (“Energy delivery member 26 may be ... configured for positioning in proximity to and/or contacting blockages within nasal passages, mucous membranes, and nasal turbinates, or pathological or undesired tissue.”); 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.1017-Chen, 239-40 ([P]atients were “treated with radiofrequency thermocoagulation,” i.e., a type of ablation, of structures including the “inferior turbinate.”). Given that Baker, Edwards-’535, and Chen 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.

148. A person of ordinary skill in the art would have understood that combining Baker, Edwards-'535, and Chen in the manner described above would have been reasonably likely to improve Baker's method by adding RF energy treatment capabilities. For example, as I explained above, Baker itself expressly contemplates that the addition of RF energy treatment capabilities to its devices and methods. In addition, the combination would have been straightforward and predictable given that the techniques of Edwards-'535 and Chen would have been used to improve Baker's similar method in the same way, for example:

- Edwards-'535's teachings would have been applied to Baker's methods and devices in the same way those teachings are used in Edwards-'535 itself: Edwards-'535 discloses embodiments of RF energy delivery devices arranged on the surface of the inflatable chamber, Ex.1010-Edwards-'535, 8:8-25, and Baker's device 20 has such an inflatable chamber to accommodate Edwards-'535's RF energy delivery devices, Ex.1013-Baker, 17:22-36.

- Similarly, Chen's teachings would have been applied to Baker's methods (as modified in view of Edwards-'535) in the same way those teachings are used in Chen itself: Chen teaches that using RF energy to ablate nerve tissue and/or turbinates is a promising way to treat allergic rhinitis, Ex.1017-Chen, 239-40, and Baker's method (as modified in view of Edwards-'535) delivers RF energy to ablate tissue, Ex.1010-Edwards-'535, 5:36-51.

149. Other clinical studies from the same timeframe as Chen 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 Chen's teaching that RF ablation of nasal tissue is a promising treatment for allergic rhinitis. *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 devices under nasal endoscopy to treat 88 cases of ethmoidal nerve

with allergic rhinitis by thermocoagulation. After 1 year of follow-up, the therapeutic effect was significant.”). In fact, as far back as the 1970s the destruction of nerve tissue within the nose had been identified as a promising way to successfully treat rhinitis. *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). Accordingly, combining Baker, Edwards-’535, and Chen would have yielded the predictable result of Baker’s method being used to deliver RF energy to treat allergic rhinitis, as taught by Edwards-’535 and Chen, 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.

150. The lack of implementation details described in the ’194 patent further supports that a person of ordinary skill in the art would have found obvious and readily implemented the combination of Baker, Edwards-’535, and Chen. For example, the ’194 patent claims the use of an energy based therapy to treat post nasal drip or chronic cough but the disclosure does not explain how such treatment is accomplished. The patent even leaves the form of energy and the effect that the

energy has on the treated tissue to the discretion of a person of ordinary skill in the art. *See* Ex.1001-USP194, 9:55-63 (explaining that the energy based therapy can use many different forms of energy such as “heat, radiofrequency (RF), laser, light, ultrasound (e.g. high intensity focused ultrasound), [etc.]”), 2:48-55 (explaining that the energy based therapy “may have any of a number of different effects on the treated tissue”). Given the range of devices and techniques to treat post nasal drip and chronic cough that the ’194 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 Baker, Edwards-’535, and Chen would successfully reduce mucus production and treat post nasal drip and/or chronic cough.

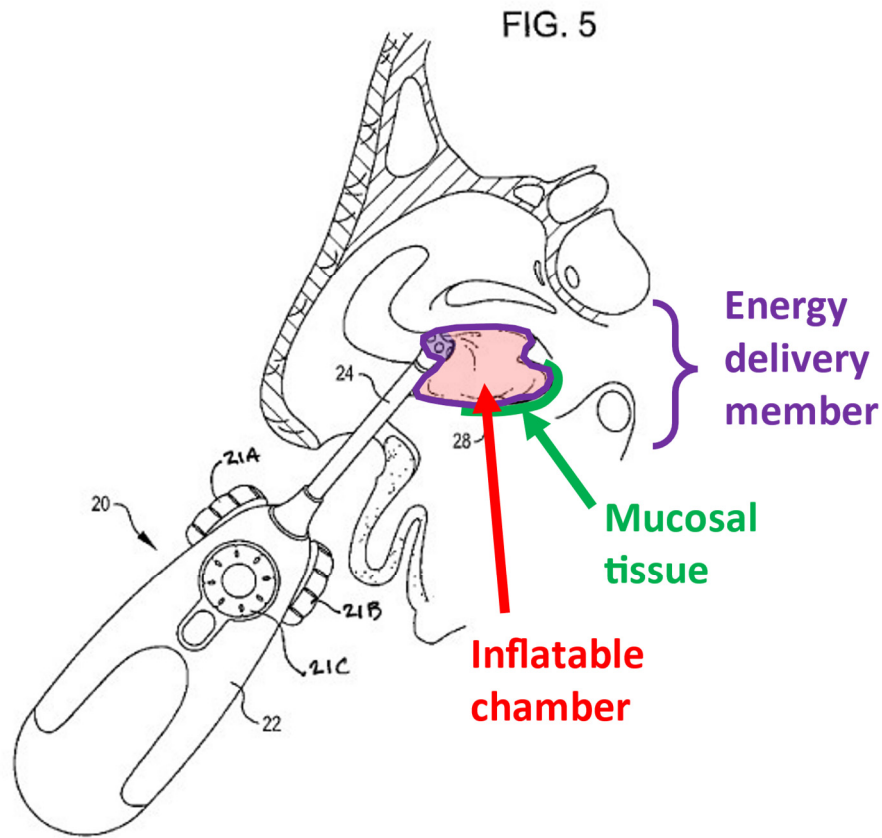
151. Accordingly, a person of ordinary skill in the art would have been motivated to combine the teachings of Baker, Edwards-’535, and Chen and would have done so with a reasonable expectation of success. Moreover, as I explain in further detail below with reference to limitations 1[a]-1[c], the combined teachings would have resulted in a method for reducing mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough. For example, the combined method would have been used to treat allergic rhinitis as taught by Baker and Chen, such that a person of ordinary skill in the art would have

understood, or at least found obvious, that the method also reduces mucus secretion and treats at least one of post nasal drip or chronic cough for the reasons I provided above in connection with Grounds I and II. *See supra*, §§ X.A.1.a.i and X.B.1.

b. Element 1[a]: advancing a treatment delivery portion of an energy-based treatment device into a nostril of the patient;

152. The combined method of Baker, Edwards-'535, and Chen includes the claimed step of advancing a treatment delivery portion (e.g., an RF energy delivery device as taught by Edwards-'535) of an energy-based treatment device (e.g., Baker's device 20 as modified in view of Edwards-'535) into a nostril of the patient.

153. As I explained above in connection with Grounds I and II, Figure 5 of Baker (reproduced below) shows that an insertion wand 24 of device 20 is "insert[ed] through a nostril opening" (i.e., advanced into a nostril of a patient).



Ex.1013-Baker, FIG.5; *see also id.*, 16:19-26 (“[I]nsertion wand 24 is configured for insertion through a nostril opening and positioning at least partially within nasal passageways.”). At the distal end of insertion wand 24 is an energy delivery member (purple) with an inflatable chamber 28 (red). *Id.*, 17:22-32 (“[A]n energy delivery member may comprise a flexible, deformable bladder or inflatable chamber 28 adapted for retaining an acoustically transmissive material.”). Given its position at the end of insertion wand 28, the acoustic energy delivery member (including inflatable chamber 28) is likewise advanced into the nostril of the

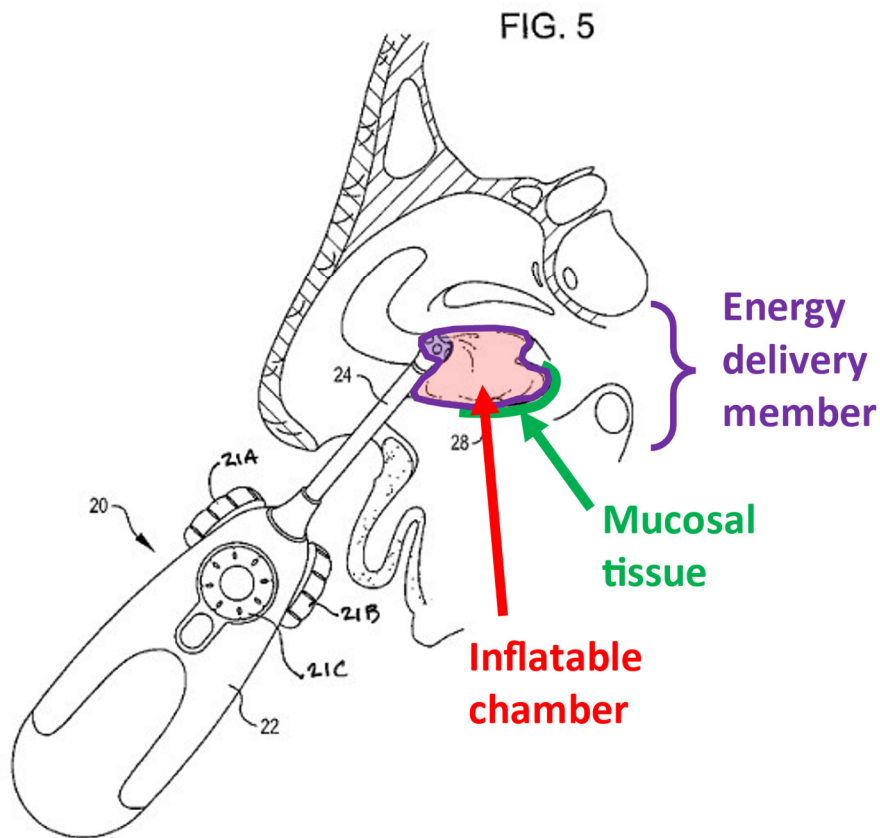
patient, as claimed. *Id.*, 20:35-39 (“[T]he insertion wand and energy delivery member are positioned in a nasal cavity, with the energy delivery member contacting...tissue desired to be treated.”).

154. Moreover, as I explained above for limitation 1[pre], combining the teachings of Baker and Edwards-’535 would have resulted in Baker’s device 20 being modified to include an RF energy delivery device (such as Edwards-’535’s RF energy delivery device 134) on the surface of Baker’s inflatable chamber 28. Ex.1010-Edwards-’535, 8:8-32. Given its position on the surface of inflatable chamber 28, the RF energy delivery device would have likewise been advanced into the nostril of the patient, as claimed.

c. Element 1[b]: contacting mucosal tissue of the upper airway with the treatment delivery portion, without piercing the mucosal tissue; and

155. The combined method of Baker, Edwards-’535, and Chen includes the claimed step of contacting mucosal tissue of the upper airway (e.g., tissue lining the inferior turbinate as taught by Chen) with the treatment delivery portion (e.g., the treatment device of Baker as modified to include an RF energy delivery device, as taught by Edwards-’535), without piercing the mucosal tissue.

156. As I explained above in connection with Grounds I and II, Figure 5 of Baker (reproduced below) shows expandable chamber 28 (red) “contact[ing] a tissue site [(green)].”



Ex.1013-Baker, FIG.5; *see also id.*, 17:27-32 (“Expandable chamber 28 may be enlarged, at a desired target site, until the walls of the chamber contact a tissue site, or the walls of a cavity or passageway or lumen.”).

157. Moreover, as I explained above for limitations 1[pre] and 1[a], combining the teachings of Baker and Edwards-’535 would have resulted in

Baker's device 20 being modified to include an RF energy delivery device (such as Edwards-'535's RF energy delivery device 134) on the surface of Baker's chamber 28, Ex.1010-Edwards-'535, 8:8-32, such that the RF energy delivery device (i.e., the claimed treatment delivery portion) would have likewise contacted mucosal tissue of the upper airway. This arrangement would have been consistent with Edwards-'535's teachings that RF energy delivery device 134 (which is positioned on the surface of an expandable member 132) contacts mucosal tissue lining the surface of nasal turbinate. *Id.*, 5:28-31 (“[E]xpandable member 132 is brought into contact with the surface 115 of the nasal [turbinate] 114 to be treated.”).

158. As I further explained above for limitation 1[pre], combining the teachings of Baker, Edwards-'535, and Chen would have resulted in Baker's method (as modified according to Edwards-'535's teachings) being applied to mucosal tissue lining the inferior turbinate and/or nerves within the inferior turbinate tissues, as these are the tissues Chen targets in its method for treating allergic rhinitis. Ex.1017-Chen, 239-40 (“From September 2002 to March 2003, 40 patients with PAR [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.”), 240 (“The treatment for the [posterior inferior nerve] involved placing the [RF energy]

probe on the lateral wall of the nasal cavity between the posterior end of the middle and inferior turbinate, making a strip-shaped thermocoagulation from the top to the bottom with a length of about 2.5 cm, a width of 0.5 cm, and a depth up to the bone wall.... Spot-like thermocoagulation was also performed on the anterior and medial mucosa of the inferior turbinate.”). Accordingly, a POSITA would have understood that in the combined method, the RF energy delivery device contacts mucosal tissue of the upper airway in at least two instances:

- when treatment is applied directly to mucosal tissue lining the turbinate; *see e.g.* Ex.1017-Chen, 240 (“Spot-like thermocoagulation was also performed on the anterior and medial mucosa of the inferior turbinate.”).
- when treatment is applied to nerves within and/or in proximity to the turbinate; *see, e.g.*, Ex.1017-Chen, 240, (“In the inferior turbinate, there are cholinergic nerves and parasympathetic nerve plexus.”); *id.* (“The treatment for the [posterior inferior nerve] involved placing the [RF energy] probe on the lateral wall of the nasal cavity between the posterior end of the middle and inferior turbinate”).

As I will further explain below with reference to limitation 1[c], a person of ordinary skill in the art would have understood that nerves run underneath mucosal

tissue in the nose. Therefore, the RF energy delivery device contacts the overlying mucosal tissue when delivering treatment to the underlying nerves.

159. Given that the combined method would have delivered treatment using Baker's inflatable chamber 28, the RF energy delivery device (i.e., the claimed treatment delivery portion) on the surface of inflatable chamber 28 would have contacted the mucosal tissue without piercing the mucosal tissue for the same reasons that I provided above in connection with Grounds I and II. *See supra*, §§ X.A.1.c.i. Moreover, Edwards-'535 teaches additional advantages of delivering treatment without piercing mucosal tissue, which would have supplied further motivation not to pierce the mucosal tissue when carrying out the combined method. For example, Edwards-'535 teaches that when mucosal tissue is not pierced, the procedure is "bloodless[]" and has a "significantly reduc[ed] risk of infection." Ex.1010-Edwards-'535, 4:55-60 ("The use of ablative energy eliminates the need for surgical cutting to remove a portion of a nasal concha and the risks associated therewith. As a result, the procedure can be performed bloodlessly and without the need to penetrate tissue, thereby significantly reducing the risk of infection.").

160. Although not necessary to satisfy limitation 1[b], I note that Edwards-'535 discloses an optional cooling technique as an additional measure to ensure

that mucosal tissue is not pierced. This technique involves “cooling the surface of the nasal [turbinate] being ablated” such that “ablation can be performed to remove an internal section of a nasal [turbinate] without damaging the surface of the nasal [turbinate].” Ex.1010-Edwards-’535, 4:60-67, 6:10-37. Edwards-’535 discloses benefits (e.g., the cooling technique would avoid damage to the surface of the turbinate) that would have motivated a person of ordinary skill in the art to apply this technique to the combined method. Moreover, a person of ordinary skill in the art would have had a reasonable expectation of success in applying Edwards-’535’s cooling technique to the combined method. For example, the system of Edwards-’535 in which the cooling technique is used (e.g., a system that delivers RF energy to treat nasal passages) is similar to the combined system of Baker, Edwards-’535, and Chen, such that adapting Edwards-’535’s technique to the combined system would have been straightforward and yielded predictable results.

- d. Element 1[c]: delivering a treatment from the treatment delivery portion to at least one tissue selected from the group of the mucosal tissue and another tissue underlying the mucosal tissue to modify a property of the at least one tissue and thus treat at least one of post nasal drip or chronic cough in the patient.**

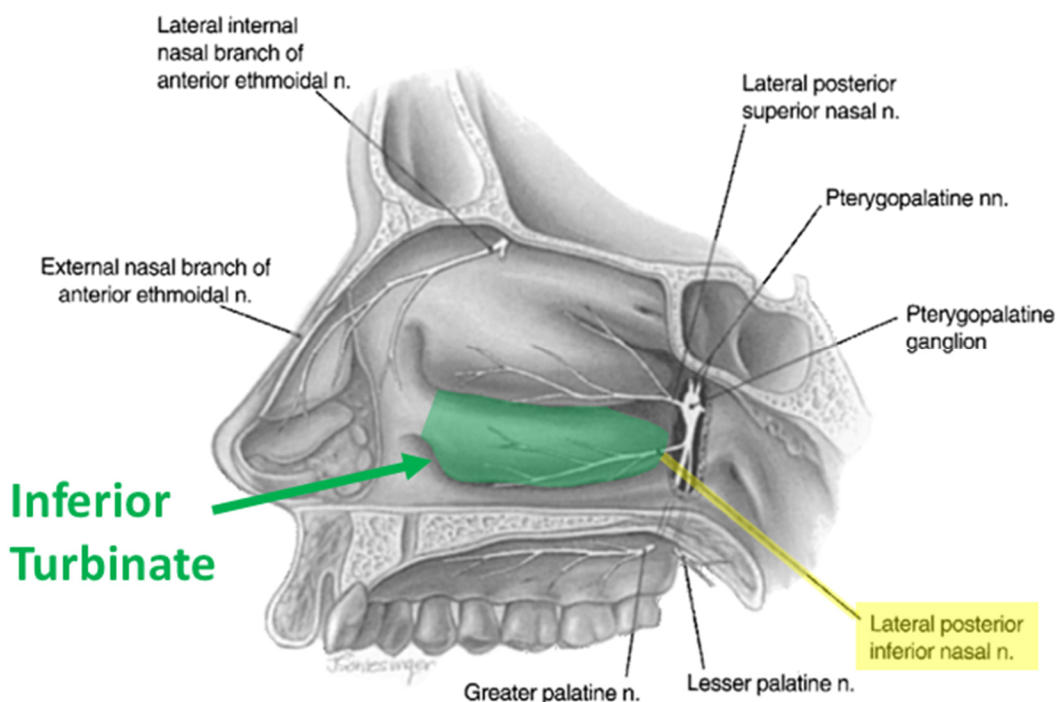
161. The combined method of Baker, Edwards-’535, and Chen includes the claimed step of delivering a treatment (e.g., ablative RF energy) from the treatment

delivery portion (e.g., the treatment device of Baker as modified to include an RF energy delivery device, as taught by Edwards-'535) to at least one tissue selected from the group of the mucosal tissue (e.g., mucosa of the inferior turbinate, as taught by Chen) and another tissue underlying the mucosal tissue (e.g., posterior inferior nasal nerve, as taught by Chen) to modify a property of (e.g., ablate) the at least one tissue and thus treat at least one of post nasal drip or chronic cough in the patient.

162. As I explained above with reference to limitations 1[pre]-1[b], combining the teachings of Baker and Edwards-'535 would have resulted in Baker's device 20 being modified to include an RF energy delivery device (e.g., Edwards-'535's RF energy delivery device 134) that delivers ablative RF energy (i.e., the claimed treatment) to the nasal tissue. Ex.1010-Edwards-'535, 5:30-38 ("Ablative energy 117 is then delivered through the apparatus and the energy delivery device 134 to the nasal [turbinate] 114. 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. According to this method, the ablative energy may be any form of energy capable of causing the ablation of tissue by heating at least a portion of the nasal [turbinate] being treated.").

163. As I further explained above with reference to limitation 1[b], combining the teachings of Baker, Edwards-'535, and Chen would have resulted in Baker's method (as modified in view of Edwards-'535) delivering the ablative RF energy to mucosal tissue lining the inferior turbinate and/or nerves within the inferior turbinate tissues, as these are the tissues Chen targets in its method for treating allergic rhinitis. Ex.1017-Chen, 239-40 ("From September 2002 to March 2003, 40 patients with PAR [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."), 240 ("The treatment for the [posterior inferior nerve] involved placing the [RF energy] probe on the lateral wall of the nasal cavity between the posterior end of the middle and inferior turbinate, making a strip-shaped thermocoagulation from the top to the bottom with a length of about 2.5 cm, a width of 0.5 cm, and a depth up to the bone wall.... Spot-like thermocoagulation was also performed on the anterior and medial mucosa of the inferior turbinate.").

164. 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 underlies 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 understand 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 instances where the combined teachings of Baker, Edwards-’535 and Chen apply RF energy to the nerves within the inferior

turbinate, the RF energy treatment would be delivered to tissue underlying the mucosal tissue, as claimed.

165. 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 modifies a property of the mucosal tissue, as claimed. For example, Edwards-'535 and Chen each disclose 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”); Ex.1017-Chen, 239-40 (“The treatment for the [posterior inferior nasal nerve] involved placing the probe on the lateral wall of the nasal cavity between the posterior end of the middle and inferior turbinate, making a strip-shaped thermocoagulation from the top to the bottom with a length of about 2.5 cm, a width of 0.5 cm, and a depth up to the bone wall.... Repeated thermocoagulation was allowed, with the local mucosa appearing as white patches. Spot-like thermocoagulation was also performed on the anterior and medial mucosa of the inferior turbinate.”).

166. Finally, as I explained above with reference to limitation 1[pre], the combined method of Baker, Edwards-'535, and Chen is used to treat at least one of post nasal drip or chronic cough, as claimed.

2. Claim 2: The method of claim 1, wherein the treatment is delivered without forming an incision in the mucosal tissue and without delivering an implant.

167. As I explained above with reference to limitation 1[b], the combined method of Baker, Edwards-'535, and Chen does not pierce mucosal tissue. Accordingly, the method also does not form an incision or deliver an implant given that these processes would involve piercing tissue. *See supra*, §§ X.A.1.c.1, X.A.2.a, X.C.1.c.

3. Claim 3: The method of claim 1, wherein delivering the treatment comprises delivering energy from the delivery treatment portion in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light and laser energy.

168. As I explained above in connection with limitation 1[c], combining the teachings of Baker, Edwards-'535, and Chen would have resulted in a method that treats tissue by delivering energy from an RF energy delivery device (*i.e.*, the claimed treatment delivery portion) in the form of radiofrequency energy, as recited by claim 3. Ex.1013-Baker, 5:28-33 (discussing treatment using acoustic energy “in combination with another treatment modality such as...application

of...radio frequency energy”), 9:15-18; Ex.1010-Edwards-’535, 5:30-38, 5:43-51 (“[T]he energy is...preferably RF radiation.”); Ex.1017-Chen, Abstract, 239-240 (“From September 2002 to March 2003, 40 patients with PAR [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”).

4. Claim 6: The method of claim 3, wherein the at least one tissue comprises nerve tissue underlying the mucosal tissue, and wherein delivering the energy comprises ablating the nerve tissue.

169. As I explained above with reference to limitation 1[c], combining the teachings of Baker, Edwards-’535, and Chen would have resulted in a method that delivers energy to nerve tissue that underlies the mucosal tissue of the inferior turbinate (i.e., the claimed nerve tissue underlying the mucosal tissue).

170. As I further explained above with reference to limitation 1[c] and claim 3, combining the teachings of Baker, Edwards-’535, and Chen would have resulted in Baker’s device 20 being modified to deliver RF energy that ablates the target nerve tissue, as claimed. Ex.1010-Edwards-’535, 5:30-38 (“Ablative energy 117 is then delivered through the apparatus and the energy delivery device 134 to the nasal [turbinate] 114. 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. According to this method, the ablative energy may be any form of energy capable of causing the ablation of tissue by heating at least a portion of the nasal [turbinate] being treated.”); *see also* Ex.1017-Chen, 239-40 (“From September 2002 to March 2003, 40 patients with PAR [perennial allergic rhinitis] (observation group) were treated with radiofrequency thermocoagulation [(i.e., ablation)] of the posterior inferior nasal nerve anterior ethmoidal nerve, and inferior turbinate.”), 240 (“The treatment for the [posterior inferior nerve] involved placing the [RF energy] probe on the lateral wall of the nasal cavity between the posterior end of the middle and inferior turbinate, making a strip-shaped thermocoagulation from the top to the bottom with a length of about 2.5 cm, a width of 0.5 cm, and a depth up to the bone wall.... Spot-like thermocoagulation was also performed on the anterior and medial mucosa of the inferior turbinate.”), 240 (“In the inferior turbinate, there are cholinergic nerves and parasympathetic nerve plexus.”).

171. Although not necessary to satisfy claim 6, I note that Edwards-’535 discloses an optional cooling technique as an additional measure to facilitate ablating tissue underlying the mucosal tissue. This technique, which I previously described in connection with limitation 1[b], involves “cooling the surface of the

nasal [turbinate] being ablated” such that “ablation can be performed to remove an internal section of a nasal [turbinate] without damaging the surface of the nasal [turbinate].” Ex.1010-Edwards-’535, 4:60-67, 6:10-37. Edwards-’535 discloses benefits (e.g., the cooling technique would avoid damage to the surface of the turbinate) that would have motivated a person of ordinary skill in the art to apply this technique to the combined method. Moreover, a person of ordinary skill in the art would have had a reasonable expectation of success in applying Edwards-’535’s cooling technique to the combined method. For example, the system of Edwards-’535 in which the cooling technique is used (e.g., a system that delivers RF energy to treat nasal passages) is similar to the combined system of Baker, Edwards-’535, and Chen, such that adapting Edwards-’535’s technique to the combined system would have been straightforward and yielded predictable results.

5. Claim 12: The method of claim 1, wherein delivering the treatment comprises injuring the at least one tissue.

172. As I explained above with reference to limitation 1[c], the combined method of Baker, Edwards-’535, and Chen, uses ablative RF energy (i.e., the claimed treatment) to ablate the target tissue. A person of ordinary skill in the art would have understood ablation as a type of injury to tissue, as claimed, given that the tissue no longer retains its normal structure or carries out its normal function.

Only after undergoing a healing process would the tissue recover from the injury and return to its normal state. *See supra*, §§ X.A.4.i.

- 6. Claim 14: The method of claim 12, wherein the at least one tissues is selected from the group consisting of cilia, goblet cells, nerves, submucosal tissue, muscle, ligaments, cartilage, tendon, and skin.**

173. The combination of Baker, Edwards-'535, and Chen renders obvious that the at least one tissue (e.g., mucosal tissue lining the inferior turbinate and/or nerve tissue within the inferior turbinate, as taught by Chen) is selected from the claimed group (e.g., nerves). For example, as I explained above with reference to limitation 1[c], combining the teachings of Baker, Edwards-'535, and Chen would have treated nerves underlying the mucosal tissue of the inferior turbinate (i.e., the claimed nerves). Ex.1017-Chen, 239-40 ("From September 2002 to March 2003, 40 patients with PAR [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."), 240 ("The treatment for the [posterior inferior nerve] involved placing the [RF energy] probe on the lateral wall of the nasal cavity between the posterior end of the middle and inferior turbinate, making a strip-shaped thermocoagulation from the top to the bottom with a length of about 2.5 cm, a width of 0.5 cm, and a depth up to the bone

wall.... Spot-like thermocoagulation was also performed on the anterior and medial mucosa of the inferior turbinate.”), 240 (“In the inferior turbinate, there are cholinergic nerves and parasympathetic nerve plexus.”).

7. Claim 16: The method of claim 1, wherein delivering the treatment comprises modifying the at least one tissue in a manner that decreases a volumetric rate of mucus production of the mucosal tissue without changing a shape of the mucosal tissue.

174. As I explained above with reference to limitations 1[pre] and 1[c], combining the teachings of Baker, Edwards-’535, and Chen would have resulted in delivering ablative RF energy (i.e., the claimed treatment) that ablates (and thereby modifies) tissue in a manner that decreases a volumetric rate of mucus production of the mucosal tissue, as claimed. Ex.1017-Chen, 240 (“The use of radiofrequency thermocoagulation of the posterior inferior nasal nerve, anterior ethmoidal nerves, and inferior turbinate...can...reduce the gland secretion, and...alleviate or eliminate symptoms such as...nasal congestion[] and runny nose”), 243.

175. For similar reasons that I provided in my above analysis of claim 16 for Ground I, a person of ordinary skill in the art would have understood that ablating tissue in accordance with the combined teaching of Baker, Edwards-’535, and Chen modifies a property of the tissue (e.g., changes or disrupts its function) without changing its shape. For example, in its disclosure supporting claim 16, the

'194 patent discloses embodiments where tissue is modified but not reshaped, and these embodiments use the same process as the combined method of ablating tissue without reshaping it. *Compare* Ex.1017-Chen, 240, 243 (“The use of radiofrequency thermocoagulation [(i.e., a type of ablation)] of the posterior inferior nasal nerve, anterior ethmoidal nerves, and inferior turbinate...can...reduce the gland secretion.”) *with* Ex.1001-USP194, 13:14-19 (“[D]eliver[ing] treatment energy to create specific localized tissue damage or ablation[] stimulat[es] the body’s healing response to create desired conformational or structural changes that reduces the mucus producing ability of the mucus producing cells.”).

176. On the other hand, as I explained in Ground I, the '194 patent also discloses embodiments in which tissue is reshaped, and in these embodiments the treatment portion is described as being rigid and inelastic to cause tissue to conform to the shape of the treatment device. Ex.1001-USP194, 11:55-58 (“[T]he treatment element 32 may have a substantially rigid or minimally elastic shape sized and shaped such that it substantially conforms to an ideal shape and size of a patient’s nasal passageway”). Combining the teachings of Baker, Edwards-'535, and Chen would have resulted in using Baker’s inflatable chamber, which is flexible and deformable and is therefore unlike the rigid/inelastic treatment

elements that the '194 patent discloses are used to reshape tissue. Ex.1013-Baker, 17:22-32.

8. Claim 18: The method of claim 1, wherein delivering the treatment comprises delivering the treatment to at least one turbinate of the upper airway.

177. As I explained above with reference to limitations 1[b] and 1[c], combining the teachings of Baker, Edwards-'535, and Chen results in delivering treatment to at least one turbinate (e.g., the inferior turbinate, as taught by Chen) of the upper airway. Ex.1017-Chen, 239-40 ("From September 2002 to March 2003, 40 patients with PAR [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"); *see also* Ex.1010-Edwards-'535, 1:22-23, 5:18-32 ("Ablative energy 117 is then delivered through the apparatus and the energy delivery device 134 to the nasal [turbinate] 114.").

9. Claim 19: The method of claim 18, wherein the at least one turbinate comprises an inferior turbinate, and contacting the mucosal tissue comprises contacting a posterior aspect of the inferior turbinate.

178. As I explained above with reference to limitation 1[c] and claim 18, combining the teachings of Baker, Edwards-'535, Chen would have resulted in delivering treatment to the inferior turbinate, as claimed. Ex.1017-Chen, 239-40

(“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.”); *see also* Ex.1010-Edwards-’535, 1:22-23, 5:18-26, 6:40-42 (“The nasal [turbinate] ablated...is preferably the inferior nasal [turbinate].”).

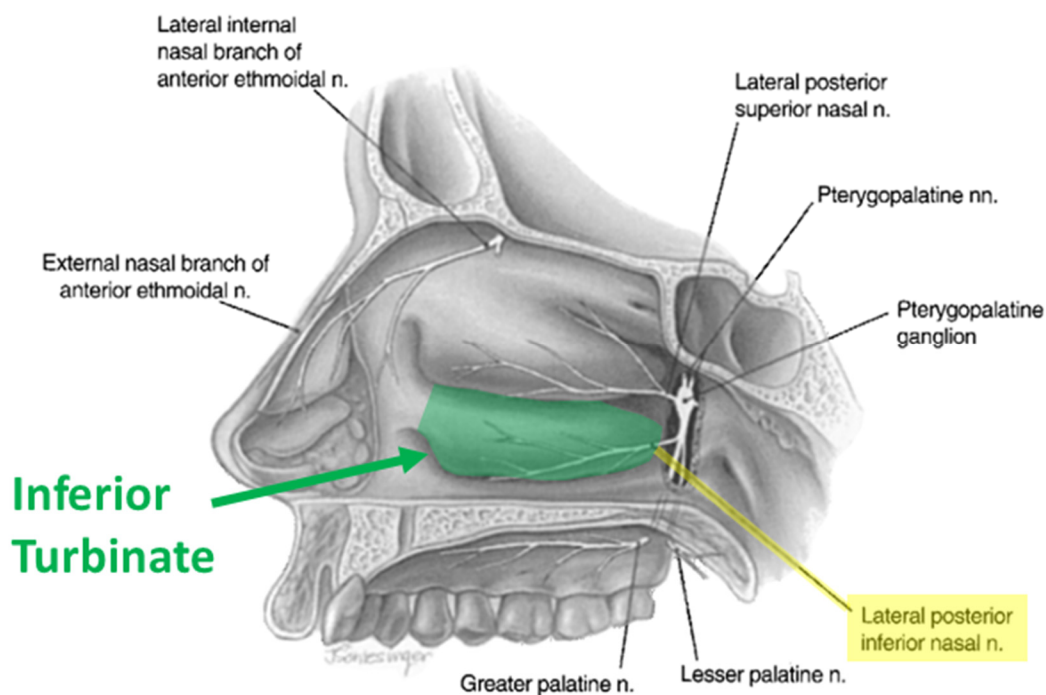
179. As I further explained with reference limitation 1[b], in the combined method of Baker, Edwards-’535, and Chen, the RF energy delivery device contacts mucosal issue given that Chen discloses either targeting mucosal tissue itself or targeting nerve tissue that lies under mucosal tissue – in both instances, the RF energy delivery device contacts the overlying mucosal tissue.

180. Edwards-’535 and Chen each teach that a particular location where mucosal tissue is contacted is the posterior aspect of the inferior turbinate, as claimed. Ex.1010-Edwards-’535, 6:42-47 (“energy may be selectively delivered to the...posterior sections of the inferior nasal [turbinate].”); Ex.1017-Chen, 240 (“The treatment for the [posterior inferior nasal nerve] involved placing the probe on the lateral wall of the nasal cavity between the posterior end of the middle and inferior turbinate, making a strip-shaped thermocoagulation from the top to the bottom with a length of about 2.5 cm, a width of 0.5 cm, and a depth up to the bone wall.”). For example, Chen’s teaching that ablative RF energy is applied between

the posterior ends of the turbinates “from the top to the bottom”, *id.*, would have indicated to a person of ordinary skill in the art that the probe would have contacted the posterior aspects of the turbinates (including the inferior turbinate). Contacting the turbinates would have been particularly likely in the combined method of Baker, Edwards-’535, and Chen given that the RF energy delivery device (as taught by Edwards-’535) would have been positioned on the surface of Baker’s expandable chamber. When expanded, the expandable chamber would have had a large surface area resulting in the energy delivery device contacting structures near the target tissue in addition to the target tissue itself.

181. Furthermore, a person of ordinary skill in the art would have been motivated to try contacting a posterior aspect of the inferior turbinate, as claimed, given the limited number of subdivisions of the inferior turbinate (e.g., anterior, middle, and/or posterior). *See, e.g.*, Ex.1040-Kong, 214 (“the inferior turbinate was divided into two parts, i.e., the anterior and posterior part, or three parts, i.e., the anterior, middle, and posterior part”); Ex.1017-Chen, 240 (“thermocoagulation was also performed on the anterior and medial mucosa of the inferior turbinate”), *id.* (discussing the “posterior end of the ... inferior turbinate”). For example, a person of ordinary skill in the art would have found it reasonably likely that contacting the posterior aspect of the inferior turbinate would have successfully

treated allergic rhinitis given that the mucosal tissue and nerve tissue identified by Chen as a promising target for allergic rhinitis is distributed along the full length of the inferior turbinate. For example, as illustrated below, the posterior inferior nasal nerve branches out and innervates the mucosa lining virtually the entire structure of the inferior turbinate, including its posterior aspect.



Ex.1060-Lane, FIG.4. Accordingly, a person of ordinary skill in the art would have reasonably expected to successfully ablate the intended target nerves (e.g., the posterior inferior nasal nerve identified by Chen) by contacting the posterior aspect of the inferior turbinate.

XI. AVAILABILITY FOR CROSS-EXAMINATION

182. 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

183. 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

184. 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 11, 2024

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

APPENDIX A

10/27/23

- 124 -

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

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

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

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:

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 Otology, 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

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

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

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

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

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 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

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

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.

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
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.
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.
- 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. Ocotober 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. 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 Rinología 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.

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.

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.

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.

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 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.

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.
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
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

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.
- 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.
- Intemational 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.
- 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.

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.
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)

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.

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:

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.

Schertzer J, Edwards TS, DelGaudio JM. Olfactory Cleft Polyps: REAH or Glandular Hyperplasia. *Current Otorhinolaryngology Reports*. July 2023. DOI 10.1007/s40136-023-00477-y.

Rubel K, Lubner R, Lopez A, Li P, Wu J, Wise S, DelGaudio J, Chandra R, Chowdhury N, Turner J. Inflammatory Characteristics of Central Compartment Atopic Disease. *Int Forum Allergy Rhinol*. 2023 Jun 11. doi: 10.1002/alr.23207. Online ahead of print. PMID: 37302116

Wise SK, Damask C, Roland LT, Ebert C, Levy JM, Lin S, Luong A, Rodriguez K, Sedaghat AR, Toskala E, Villwock J, Abdullah B, Akdis C, Alt JA, Ansotegui MD, IJ, Azar A, Baroody F, Benninger MS, Bernstein J, Brook C, Campbell R, Casale T, Chaaban M, Chew FT, Chambliss J, Cianferoni A, Custovic A, Mahoney Davis E, DelGaudio JM, Ellis AK, Flanagan C, Fokkens WJ, Franzese C, Greenhawt M, Gill A, Halderman A, Hohlfield JM, Incorvaia CM, Joe SA, Joshi S, Kuruvilla ME, Kim J, Klein AM, Krouse HJ, Kuan EC, Lang D, Larenas-Linnemann D, Laury AM, Lechner M, Lee SE, Lee VS, Loftus P, Marcus S, Marzouk H, Mattos J, McCoul E, Melen E, Mims JW, Mullol J, Nayak JV, Oppenheimer J, Orlandi RR, Phillips K, Platt M, Ramanathan M, Raymond M, Rhee CS, Reitsma S, Ryan M. International consensus statement on allergy and rhinology: Allergic rhinitis – 2023. *Int Forum Allergy Rhinol*. 2023;13:293–859. PMID: 36878860

Liu , Power Y, Schartinger V, et al. The Role of Somatostatin Receptor 2 (SSTR2) in Sinonasal Cancers. *Current Otolaryngology Reports*.

Ramonell RP, Brown M, Woodruff MC, Levy J, Wise S, DelGaudio J, Duan M, Saney CL, Kyu S, Cashman³ KS, Hom J, Fucile CF, Rosenberg AF, Tipton CM, Sanz I, Gibson G, Lee FE. Single cell analysis of human nasal mucosal IgE antibody secreting cells reveals newly minted phenotype. *Mucosal Immunity*. 2023 Jun;16(3):287-301. PMID: 36931600

Porto E, Revuelta Barbero JM, Sun H, DelGaudio JM, Henriquez OA, Barrow E, Zada G, Solares A, Garzon Muvdi T, Pradilla G. A Cost-effective and Reproducible Cadaveric Training Model for Internal Carotid Artery Injury Management during Endoscopic

Endonasal Surgery: the Submersible Peristaltic Pump. *World Neurosurg.* 2023 Mar;171:e355-e362. doi: 10.1016/j.wneu.2022.12.014. Epub 2022 Dec 10. PMID: 36513301

Velasquez N, DelGaudio JM. The Role of the Otolaryngologist in the Evaluation and Management of "Sinus Headache". *Otolaryngol Clin N Am* 55;(2022):501–518. PMID: 35680204

Edwards TS, DelGaudio JM, Levy JM, Wise SK. A prospective analysis of systemic and local aeroallergen sensitivity in Central Compartment Atopic Disease. *Otolaryngol- Head Neck Surg.* Article first published online: March 1, 2022. <https://doi.org/10.1177/01945998221082554>. PMID: 35230893

Burnham AJ, Magliocca K, Pettitt-Schieber B, Edwards T, Marcus S, DelGaudio, J, Wise SK, Levy J, Roland L. Intermediate invasive fungal sinusitis, a distinct entity from acute fulminant and chronic invasive fungal sinusitis. *Annals Otol, Rhinol, Laryngol.* 2021 Oct 25;34894211052854. doi: 10.1177/00034894211052854. Epub ahead of print. PMID: 34694144.

Roland LT, Wise SK, Wang H, Mehta C, DelGaudio JM, Levy JM. Influence of Omalizumab on Treatment Costs for Chronic Rhinosinusitis with Nasal Polyps and Asthma: An Insurance Claims Analysis. *Int Forum Allergy Rhinol.* 2022;12(3):310-312.

Shrestha K, Inthavong K, Shang Y, DelGaudio JM, Wise SK, Edwards TS, Bradshaw K, Wong E, Smith M, Singh N. Inhalation and deposition of spherical and pollen particles after middle turbinate resection in a human nasal cavity. *Respir Physiol Neurobiol.* 2021 Dec;294:103769. doi: 10.1016/j.resp.2021.103769. Epub 2021 Aug 2. PMID: 34352383

Steehler AJ, Vuncannon J, Wise SK, DelGaudio JM. Central Compartment AtopicDisease: Outcomes Compared to Other Subtypes of Chronic Rhinosinusitis with Nasal Polyps. *Int Forum Allergy Rhinol.* 2021;11(11):1549-56. PMID: 34076353.

Corrado A, Ramonell RP, Woodruff MC, Tipton C, Wise S, Levy J, DelGaudio J, Kuruvilla ME, Magliocca KR, Tomar D, Garimalla S, Scharer CD, Boss JM, Wu H, Gumber S, Fucile C, Gibson G, Rosenberg A, Sanz I, Lee FE, et al. Extrafollicular IgD+ B cells Generate IgE Antibody Secreting Cells in the Nasal Mucosa. *Mucosal Immunity.* 2021. 14 (5) 1144-1159. PMID: 34050324

Buchowicz B, Chen BS, Bidot S, Bruce BB, Newman NJ, Saindane AM, Levy JM, Biousse V for the CSF-Leak Study Group. Post-operative risk of raised intracranial pressure after spontaneous skull base cerebrospinal fluid leak repair. *J Neuro-Ophthalmol.* Accepted July 2020.

Orlandi R, et al. International Consensus Statement on Rhinology and Allergy: Rhinosinusitis. *Int Forum Allergy Rhinol.* 2021;11(3):211-739. PMID: 33236525

Soriano R, Solares CA, Pradilla G, DelGaudio JM. Endoscopic Study of the Distribution of Olfactory Filaments: A cadaveric study. *Am J Rhinol Allergy.* 2021;35(2):226-233. PMID: 32762251

DelGaudio JM. Central Compartment Atopic Disease: the Missing Link in the Allergy and CRSwNP Saga. *Int Forum Allergy Rhinol*. 2020;10 (10):1191-92.

Bidot S, Levy JM, Saindane AM, Narayana KM, Datillo M, DelGaudio JM, Mattox DE, Oyesiku NM, Peragallo JH, Solares CA, Vivas EX, Wise SK, Newman NJ, Biousse V. Spontaneous Skull Base Cerebrospinal Fluid Leaks and Their Relationship to Idiopathic Intracranial Hypertension. *Am J Rhinol Allergy*. 2021;35(1): 36-43. PMID: 32551921

Roland LT, Marcus S, Wise SK, Levy JM, DelGaudio JM. CT Findings Can Help Identify Different Chronic Rhinosinusitis with Nasal Polyp Phenotypes. *Amer J Rhinol and Allergy*. 2020;34(5):679–685. PMID: 32375489

Schertzer JS, Levy JM, Wise SK, Magliocca K, DelGaudio JM. Is Respiratory Epithelial Adenomatoid Hamartoma Related to Central Compartment Atopic Disease? *Amer J Rhinol Allergy*. 2020;34(5): 610–617.

Yan CY, Rathor A, Krook K, Ma Y, Rotella MR, Dodd MD RL, Hwang PH, Nayak JV, Oyesiku NM, DelGaudio JM, Levy JL, Wise J, Wise SK, Patel ZM. Effect of Omega-3 Supplementation in Patients with Smell Dysfunction following Endoscopic Sellar Tumor Resection. *Neurosurgery*. doi:10.1093/neuros/nyz559.

Helman SN, DelGaudio JM, Barrow E, Edwards T, Levy JM, Wise SK. The Role of Allergic Rhinitis in Chronic Rhinosinusitis. *Immunology and Allergy Clinics N America*. 2020;40:201–214.

Studer M, Roland L, Ochsner M, Cox D, DelGaudio JM, Wise SK, Levy J. Aspirin-exacerbated Respiratory Disease with Allergic Fungal Sinusitis: a Case Series of Overlapping Endotypes. *Amer J Rhinol Allergy*. 2020;(3):422-427.

Eckhoff A, Cox D, Luk L, Maidman S, DelGaudio JM. Unilateral versus Bilateral Sinonasal Disease: Considerations in Differential Diagnosis and Diagnostic Workup. *Laryngoscope*. 2020;130:E116–E121. PMID: 31219616.

Marcus S, Schertzer J, Roland LT, Wise SK, Levy JM, DelGaudio JM. Central Compartment Atopic Disease: Prevalence of Allergy and Asthma Compared to Other Chronic Rhinosinusitis with Nasal Polyp Subtypes. *Int Forum Allergy Rhinol*. 2020;10(2):183-189. PMID: 31600866

Ikeda AK, Luk LJ, Patel ZM, Oyesiku NM, Solares CA, DelGaudio JM, Levy JM, Wise SK. Follow-up Management of Patients After Transsphenoidal Approach for Resection of Pituitary Adenomas. *Am J Allergy Rhinol*. 2020;34:150-155.

Roland L, Nagy C, Wang H, Moore R, Cahill K, Laidlaw T, Wise S, DelGaudio J, Levy JM. Treatment Practices for Aspirin-Exacerbated Respiratory Disease: Analysis of a National Insurance Claims Database. *Int Forum Allergy Rhinol*. 2020;10(2):190-193.

Stunkel L, Saindane A, DelGaudio J, et al. Neuro-Imaging Evidence for Reversible Collapsibility of the Distal Transverse Sinuses in Spontaneous CSF Leak. *Neurology*. 2020

Roland LT, Wang H, Mehta CC, Cahill KN, Laidlaw TMD, DelGaudio JM, Wise SK, Levy JM. Longitudinal Progression of Aspirin Exacerbated Respiratory Disease: Analysis of a National Insurance Claims Database. *Int Forum Allergy Rhinol*. 2019;9(12):1420-1423.

DelGaudio JM, Levy JM, Wise SK. Central Compartment Involvement in Aspirin Exacerbated Respiratory Disease: The Role of Allergy and Previous Sinus Surgery. *Int Forum Allergy Rhinol*. 2019; 9:1017-1022.

Luk LJ, Ikeda A, Wise SK, DelGaudio JM. Middle Turbinate Friendly Technique for Cribiform Cerebrospinal Fluid Leak Repair. *Otolaryngol Head Neck Surg*. 2019;161(3):522-528. PMID: 31039072.

Marcus S, Roland LT, DelGaudio JM, Wise SK. Chronic Rhinosinusitis: Does Allergy Play a Role? *Med Sci*. 2019; 7(2): 57-64.

Marcus S, Roland L, DelGaudio JM, Wise SK. The Relationship Between Allergy and Chronic Rhinosinusitis. *Laryngoscope Investigative Otolaryngology*. *Laryngoscope Investig Otolaryngol*. 2019; 4(1): 13–17. PMID: 30828613

Lee JT, DelGaudio J, Orlandi RR. Practice Patterns in Office-Based Rhinology: Survey of the American Rhinologic Society. *Amer J Rhinol Allergy*. 2019;33(1):26-35.

Corrado A, Battle M, Wise S, Lee F Eun-Hyung, Guidot D, DelGaudio J, Molina S, Levy J. The Endocannabinoid Receptor CB2R is Significantly Expressed in Aspirin Exacerbated Respiratory Disease: A Pilot Study. *Int Forum Allerg Rhinol*. 2018; 8(10):1184-1189.

Luk LJ, DelGaudio JM. *Laryngopharyngeal Reflux in CRS: Evidence-Based Practice*. *Otolaryngology Clinics*. Luke Rudmik, MD. Elsevier. 2018; 25-35. ISBN: 9780323544603.

Hamizan AH, Loftus PA, Alvarado R, Ho J, Sansoni E, DelGaudio JM, Harvey RJ. Allergic phenotype of chronic rhinosinusitis based on radiologic pattern of disease. *Laryngoscope* 2018; 128 (9):2015-2021.

Ikeda AK, Belcher RH, DelGaudio JM. Remodeling of the paradoxical middle turbinate. Preserving function while gaining access. *Amer J Rhinol Allergy*. 2018; Vol. 32(2): 98–100.

deGabory L, Sowerby LJ, DelGaudio JM. Al-Hussaini A, Hopkins C, Serrano E. International Surey and Consensus (ICON) on Ambulatory Surgery in Rhinology. *European Annals Otorhino Head Neck Diseases*. 2018 (Feb);135(1):S49-S53.

Sarah K. Wise, Sandra Y. Lin, Elina Toskala, Richard R. Orlandi, Cezmi A. Akdis, Jeremiah A. Alt, Antoine Azar, Fuad M. Barody, Claus Bachert, G. Walter Canonica, Thomas Chacko, Cemal Cingi, Giorgio Ciprandi, Jacquelynne Corey, Linda S. Cox, Peter Socrates Creticos, Adnan Custovic, Cecelia Damask, Adam DeConde, John M.

DelGaudio, Charles S. Ebert, Jean Anderson Eloy, Carrie E. Flanagan, Wytske J. Fokkens, Christine Franzese, Jan Gosepath, Ashleigh Halderman, Robert G. Hamilton, Hans Jürgen Hoffman, Jens M. Hohlfeld, Steven M. Houser, Peter H. Hwang, Cristoforo Incorvaia, Deborah Jarvis, Ayesha N. Khalid, Maritta Kilpeläinen, Todd. T. Kingdom, Helene Krouse, Desiree Larenas-Linnemann, Adrienne M. Laury, Stella E. Lee, Joshua M. Levy, Amber U. Luong, Bradley F. Marple, Edward D. McCoul, K. Christopher McMains, Erik Melén, James W. Mims, Gianna Moscato, Joaquim Mullol, Harold S. Nelson, Monica Patadia, Ruby Pawankar, Oliver Pfaar, Michael P. Platt, William Reisacher, Carmen Rondón, Luke Rudmik, Matthew Ryan, Joaquin Sastre, Rodney J. Schlosser, Russell A. Settipane, Hemant P. Sharma, Aziz Sheikh, Timothy L. Smith, Pongsakorn Tantilipikorn, Jody R. Tversky, Maria C. Veling, De Yun Wang, Marit Westman, Magnus Wickman and Mark Zacharek. International Consensus Statement on Allergy and Rhinology: Allergic Rhinitis. *Int Forum Allergy Rhinology*. 2018;8(2): 108–352. PMID: 29438602.

Piccirillo JF, Payne SC, Rosenfeld RM, Baroody FM, Batra PS, DelGaudio JM, Edelstein DR, Lane AP, Luong AU, Manes RP, McCoul ED, Platt MP, Reh DD, Corrigan MD. Clinical Consensus Statement: Balloon Dilation of the Sinuses. *Otolaryngol Head Neck Surg*. 2018; 158(2):203-214. PMID: 29389303.

Morrison DA, Wise SK, Chowdhury N, DelGaudio JM, Levy JM. Intranasal Tissue Necrosis Associated with Opioid Abuse: Case Report and Systematic Review. *Laryngoscope*. 2018;128(8): 1767-1771. PMID: 29280484

DelGaudio JM, Loftus PA, Hamizan A, Harvey RJ, Wise SK. Central Compartment Atopic Disease. *Amer J Rhinol Allergy*. 2017;31(4):228-234. PMID: 28716173

Patel ZM, Wise SK, DelGaudio JM. Randomized Controlled Trial demonstrating Cost-Effective Method of Olfactory Training in Clinical Practice: Essential Oils at Uncontrolled Concentration. *Laryngoscope Investigative Otolaryngology*. 2017; 2;2(2):53-56.

Daraei P, Gross JH, DelGaudio JM. “Sinus Headache” in Chronic Rhinosinusitis (CRS): An Analysis of Otolaryngology Initiated Treatment Efficacy of Migraine in the CRS patient. *Journal of Sinusitis and Migraine*. 2017;1; 1:1-5.

Luk LJ, DelGaudio JM. Topical Drug Therapies for Chronic Rhinosinusitis. *Otolaryngol Clinics of North America*. 2017 (June);50(3):533-544.

Kumar M, Oh M, Leader B, Rotella M, Stillman L, DelGaudio JM, Wise SK. Perceived Compliance and Barriers to Care in Sublingual Immunotherapy. *Int Forum Allerg Rhinol*. 2017; 7(5):525-529.

Chen VH, Grossniklaus HE, DelGaudio JM, Kim HJ. A concomitant case of orbital granuloma faciale and eosinophilic angiocentric fibrosis. *Ophth Plastic Reconst Surg*. 2017;33(2): e47-e49. PMID: 27281484

Loftus P, Wise SK, Baugnon K, DelGaudio JM. Excavating Meningoencephaloceles: a Newly Diagnosed Entity. *Amer J Rhinol Allerg*. 2017;31(2):127-134.

Leason SR, Barham HP, Oakley G, MD; Rimmer J, Christensen JM, DelGaudio JM, Sacks R, Harvey RJ. The Association of Gastroesophageal Reflux with Chronic Rhinosinuitis: A Systematic Review and Meta-Analysis. *Rhinology*. 2017; 53:3-16. PMID: 28214353.

Arash Shahangian, Zachary Soler, Andrew Baker, Sarah Wise, Shruthi K Rerreddy, Zara M Patel, Nelson M Oyesiku, John M. DelGaudio, Constantinos G. Hadjipanayis, Bradford A. Woodworth, Kristen O. Riley, John Lee, Michael D. Cusimano, Satish Govindaraj, Alkis Psaltis, Peter John Wormald, Stephen Santoreneos, Raj Sindwani, Samuel Trosman, Janalee K. Stokken, Troy D. Woodard, Pablo F. Recinos, W. Alexander Vandergrift, Caitlin Boling, Rodney J. Schlosser Successful Repair Of Intraoperative Cerebrospinal Fluid Leaks Improves Outcomes In Endoscopic Skull Base Surgery. *Int Forum Allergy Rhinol*. 2017;7(1):80-86.

Cox D, Ashby S, Mace J, DelGaudio JM, Smith TL, Orlandi RR, Alt JA. The Pain-Depression Dyad and the Association with Sleep Dysfunction in Chronic Rhinosinuitis. *Int Forum Allerg Rhinol*. 2017;7(1):56-63. PMID: 27552637

Loftus PM, Wise SK, Aiken A, Nieto D, DelGaudio JM. Intranasal Volume Increases with Age: Computed Tomography Volumetric Analysis in Adults. *Laryngoscope*. 2016; 126:2212-15. PMID: 27261245

Karnezis T, Baker A, Soler Z, Woodworth B, Riley K, Wise S, Rerreddy S, Patel Z, Oyesiky N, DelGaudio J, Hadjipanayis C, Lee J, Cusimano M, Govindaraj S, Psaltis A, Santoreneos S, Sindwani R, Trosman S, Stokken J, Woodard T, Recinos P, Vandergrift W, Schlosser R. Factors Impacting Cerebrospinal Fluid Leak Rates in Endoscopic Sellar Surgery. *Int Forum Allergy Rhinol*. 2016;6(11):1117-1125.

Luk LJ, DelGaudio JM, Wise SK. Advancements in Skull Base Reconstruction. *Curr Otorhinolaryngol Rep*. 2016; 4:286-294.

DelGaudio JM, Panella N. Presbynasalis. *Int Forum Allerg Rhinol*. 2016; 6 (10):1083–1087. PMID: 27279549

Ryan TP, Specht J, Smith S, DelGaudio JM. Patient Centered Care: Does the Press Ganey Correlate to Online Health Grades in a Major Academic Otolaryngology Department? *Otolaryngol Head Neck Surg*. 2016 155: 411-415.

Abugideiri M, Patel KR, Switchenko JM, Magliocca KR, Buchwald ZS, DelGaudio JM, Lawson DH, Danish H, Beitler JJ, Khan MK. Adjuvant Radiation Therapy Improved Local Control for Primary Mucosal Melanoma of the Head and Neck. 2016;96(2), Supplement, E384-385.

Johnston N, Ondrey F, Rosen R, Hurley BP, Gould J, Allen J, DelGaudio J, Altman, K. Airway Reflux. *Ann NY Acad Sci*. 2016 :1–9.

Leader B, Rotella M, Stillman L, DelGaudio JM, Patel ZP, Sarah K. Wise MD, Immunotherapy Compliance: Comparison Of Subcutaneous Versus Sublingual Immunotherapy. *Int Forum Allerg Rhinol*. 2016;6(5):460-464.

Lipin R, Deshpande A, Wise SK, DelGaudio JM, Patel ZM. Rhinosinusitis And Obstructive Sleep Apnea: No Association Between Cpap Reservoir Bacterial Colonization and Sinus Culture Results. *Sinusitis*. 2016; 1:44-48.

Orlandi R, Kingdom T, Hwang P, et al. International Consensus Statement of Rhinosinusitis. *Int Forum Allergy Rhinol*. 2016;6(S1):S22-S209.

Boling CC, Karnezis TT, Baker AB, Lawrence LA, Soler ZM, Vandergrift WA, Wise SK, DelGaudio JM, Patel ZM, Rereddy SK, Lee JM, Khan MN, Govindaraj S, Chun C, Sakiko O, Psaltis AJ, Wormald PJ, Trosman S, Stokken J, Woodard T, Sindwani, R, , Schlosser RJ. Multi-institutional study of risk factors for perioperative morbidity following transnasal endoscopic pituitary adenoma surgery. *Int Forum Allergy Rhinol*. 2016;6(1):101-107.

Patel ZM, DelGaudio JM. Olfaction Following Endoscopic Skull Base Surgery. *Current Opinions in Otolaryngol Head Neck Surg*. 2016 Feb;24(1):70-4. PMID: 26679777

Patel ZM, DelGaudio JM, Wise SK. Higher body mass index is associated with subjective olfactory dysfunction. *Behavioral Neurology*. Volume 2015 (2015), Article ID 675635

Dao AM, Rereddy S, Wise SK, DelGaudio JM, Patel ZM. Management of Non-Invasive Rhinosinusitis in the Immunosuppressed Patient Population. *Laryngoscope*. 2015 Aug;125(8):1767-71

DelGaudio JM. The Superior Turbinate Straddling Sphenoidotomy. *Int Forum Allergy Rhinol*. 2015; 5:445–447. PMID: 25558810

Flanagan CE, Wise SK, DelGaudio JM, Patel ZM. Association of Decreased Rate of Influenza Vaccination with Increased Subjective Olfactory Dysfunction. *JAMA Otolaryngol Head Neck Surg*. 2015 Mar;141(3):225-8. PMID: 25590362.

Ochsner MC, DelGaudio JM. The place of the osteoplastic flap in the endoscopic era: Indications and pitfalls. *Laryngoscope* 2015; 125:801-806. PMID: 25417859.

DelGaudio JM, Baugnon KM, Wise SK, Patel ZM, Aiken A, Hudgins PA. MR Cisternogram with Intrathecal Gadolinium (MRCgGd) with delayed imaging for difficult to diagnose CSF leaks of anterior skull base. *Int Forum Allergy Rhinol* 2015. 5(4):333-338. PMID: 25561376.

DelGaudio JM, Ochsner M. Office Surgery for Paranasal Sinus Recirculation. *Int Forum Allergy Rhinol* 2015. 5(4):326-328.

Barrow EM, DelGaudio JM. In-Office Drainage of Sinus Mucocoeles: An Alternative to OR Drainage. *Laryngoscope*. 2015 May;125(5):1043-7. PMID: 25418415.

Venkatesan NN, Mattox DE, DelGaudio JM. Cerebrospinal Fluid Leaks after Septoplasty. *ENT Journal*. *Ear Nose Throat J* 2014 Dec; 93(12): E43-6.

Daraei P, DelGaudio JM. Inferior Meatus Endoscopy and Directed Treatment for Epiphora: Long Term Follow-Up and Treatment Paradigm. *JAMA Otolaryngol Head and Neck Surg*. 2014 Aug;140(8):736-41. PMID: 25418415

White L, Rotella M, DelGaudio JM. Polypoid Changes of the Middle Turbinate as an Indicator of Atopic Disease. *Int Forum Allergy Rhinol* 2014;4(5):376-80. PMID: 24449408

Patel ZM, Setzen M, Poetker DM, DelGaudio JM. Evaluation and Management of "Sinus Headache" in the Otolaryngology Practice. *Otolaryngol Clin North Am* 2014 Apr;47(2):269-287. PMID: 24680494

Berg E, Bunge F, DelGaudio JM. Results of Multi-level Treatment of Moderate and Severe Obstructive Sleep Apnea Utilizing Bone-Anchored Pharyngeal Suspension Sutures. *ENT Journal*. 2013;92(8): E1-5. PMID: 23975494

Patel ZM, Setzen M, Sclafani AP, DelGaudio JM. Concurrent Functional Endoscopic Sinus Surgery and Septorhinoplasty: Using Evidence to make Clinical Decisions. *International Forum Allerg Rhinol*. 2013; 3:488-92. PMID: 23293086

Laury A, Oyesiku N, Hadjipanayis C, DelGaudio J, Wise S. Incidental Sinonasal Findings Identified During Preoperative Evaluation for Endoscopic Transsphenoidal Approaches. *Amer J Rhinol Allergy*. 2013;37(3):202-5. PMID: 23710956

Patel ZM, Kennedy DW, Setzen M, Poetker DM, DelGaudio JM. "Sinus Headache"; rhinogenic headache or migraine? An Evidence-Based Guide to Diagnosis and Treatment of Sinus Headache. *Int Forum Allergy Rhinol*. 2013; 3:221-230. PMID: 23129234

White LJ, Hapner ER, Klein AM, DelGaudio JM, Hanfelt JJ, Jinnah HA, Johns MM 3rd. Coprevalence of Anxiety and Depression with Spasmodic Dysphonia: a Case Control Study. *J Voice*. 2012;26(5):667.e1-6.

Henriquez OA, Wolfenden L, Stecenko A, DelGaudio JM, Wise SK. Endoscopic Sinus Surgery in the Adult Cystic Fibrosis Patient: Effect on Lung Function, Intravenous Antibiotic Use, and Hospitalization. *Arch Otolaryngol Head Neck Surg*. Dec 2012;138(12):1167-70.

Lupa M, DelGaudio JM. Evidence-Based Practice: Reflux in Sinusitis. *Otolaryngol Clinics N Amer*. 2012;45(5):983-92.

Prickett K, Wise S, DelGaudio J. Cost Analysis of Office-based and Operating Room Procedures in Rhinology. *International Forum Allerg Rhinol* 2012 May;2(3):207-11.

Villari C, Wojno T, DelGaudio J. Case report of orbital violation with placement of ethmoid drug-eluting stent. *Int Forum Allergy Rhinol*. 2012 Jan-Feb;2(1):89-92.

White LJ, Klein AM, Hapner ER, DelGaudio JM, Hanfelt JJ, Jinnah HA, Johns MM 3rd. Co-Prevalence of Tremor with Spasmodic Dysphonia: A Case-Control Study. *Laryngoscope*. 2011;121(8):1752-5.

Shah R, Schniederjan M, DelGaudio JM, Ioachimescu AG. Visual vignette. Ectopic ACTH-secreting pituitary adenoma. *Endocr Pract* 2011;17(6):966.

Muller S, Eljack S, DelGaudio JM. Clinical Pathologic Conference Case 1: Wegener's Granulomatosis. *Head Neck Pathol* 2011; 5:268-72.

Prickett KK, Wise SK, DelGaudio JM. Choice of Graft Material and Post-operative Healing in Endoscopic Repair of CSF Leak. *Arch Otol Head Neck Surg* 2011;137(5):457-61.

Baddour HM Jr, Mattox DE, DelGaudio JM. Case study: clear rhinorrhea. *J Med Assoc Ga.* 2011;100(1):24.

Colby CC, DelGaudio JM. Stylohyoid Complex Syndrome: A New Diagnostic Classification. *Arch Otolaryngol Head Neck Surg.* 2011; 137:248-52.

Rogers GA, Wise SK, Nusrat A, DelGaudio JM, Parkos CA. Epithelial Tight Junction Alterations in Nasal Polyposis. *Int Forum Allergy Rhinol* 2011;1(1):50-54.

Sillings CN, Weathers D, DelGaudio JM. Thyroid –like Papillary Adenocarcinoma of the Nasopharynx: a Case Report in a 19-year-old male. *Oral Surg, Oral Med, Oral Path, Oral Radiology, and Endontology* 2010;110(3): e25-8.

DelGaudio JM, Ingley A. Treatment of pneumocephalus after endoscopic sinus and microscopic skull base surgery. *Am J Otolaryngol.* 2010;31(4):226-230.

Laury AM, DelGaudio JM. Aspergillus Infections in the Head and Neck. *Current Infectious Disease Reports.* 2010;12(3):217-224.

Venkatesan NN, Johns MM, Hapner ER, DelGaudio JM. Abductor Paralysis after Botox Injection for Adductor Spasmodic Dysphonia. *Laryngoscope.* 2010; 120:1177-80.

Otto KJ, DelGaudio JM. Operative Findings in the Frontal Recess at Time of Revision Surgery. *Am J Otolaryngol.* 2010; 31:175-180.

DelGaudio JM, Sobol SE, Evans SH, Parikh SL. Intracranial complications of Sinusitis: What is the Role of Endoscopic Sinus Surgery in the Acute Setting? *American Journal of Otolaryngology- Head Neck Med Surg.* 2010;31(1):25-28.

Braden M, Johns MM, Klein A, DelGaudio J, Gilman M, Hapner. Assessing the effectiveness of botulinum toxin injections for Adductor Spasmodic Dysphonia: Clinician and patient perception. *J Voice.* 2010 Mar;24(2):242-9.

Wise SK, Rogers GA, Ghegan MD, Harvey RJ, DelGaudio JM, Schlosser RJ. Radiologic Staging System for Allergic Fungal Rhinosinusitis (AFRS). *Otolaryngol Head Neck Surg* 2009; 140:735-40.

Zuckerman J, Wise SK, Rogers GA, Senior BA, Schlosser RJ, DelGaudio JM. The Utility of Cadaver Dissection in Endoscopic Sinus Surgery Training Courses. *Am J Rhinol Allergy* 2009; 23:218-24.

Rogers GA, Murchison AP, Wojno TH, DelGaudio JM. Inferior Meatus Endoscopy and Directed Treatment for Epiphora: Early Experience with a Novel Approach. *Otolaryngol Head Neck Surg* 2009; 140:579-84.

Huang BY, Lloyd KM, DelGaudio JM, Jablonowski E, Hudgins PA. Failed Endoscopic Sinus Surgery: Spectrum of CT Imaging Findings in the Frontal Recess. *Radiographics* 2009; 29:177-95.

Golub JS, Johns MM, Lim JH, DelGaudio JM, Klein AM. Comparison of an Oropharyngeal pH Probe and a Standard Dual pH Probe for Diagnosis of Laryngopharyngeal Reflux. *Annals Otol Rhinol Laryngol* 2009; 118:1-5.

DelGaudio JM, Clemson LA. An Early Detection Protocol for Invasive Fungal Sinusitis in Neutropenic Patients Successfully Reduces Extent of Disease at Presentation and Long-Term Morbidity. *Laryngoscope* 2009; 119:180-83.

Zuckerman J, Lee WY, DelGaudio JM, Moore CE, Nava P, Nusrat A, Parkos C. Pathophysiology of Nasal Polyposis: The Role of Desmosomal Junctions. *Amer J Rhinol* 2008; 22:589-97.

Klein AM, Stong BC, Wise JC, DelGaudio JM, Hapner ER, Johns III MM. Vocal Outcome Measures After Simultaneous Bilateral Posterior Cricoid Muscle Injections with Botulinum Toxin Injections for Abductor Spasmodic Dysphonia. *Otolaryngol Head Neck Surg* 2008; 139(3):421-23.

Kari E, DelGaudio JM. Empiric Treatment of Sinus Headache as Migraine: The Diagnostic Utility of Triptans. *Laryngoscope* 2008; 118(12):2235-39.

Rogers GA, DelGaudio JM. Inferior meatus dacryolith: an easily managed cause of epiphora. *Arch Otolaryngol* 2008; 134:1110-11.

Lloyd KM, DelGaudio JM, Hudgins PA. Imaging of skull base cerebrospinal fluid leaks in adults. *Radiology* 2008; 248:725-36.

DelGaudio JM, Mathison CC, Hudgins PH. Preoperative disease severity at sites of subsequent skull base defects after endoscopic sinus surgery. *Amer J Rhinol* 2008; 22:321-24.

La Fata V, McLean N, Wise SK, DelGaudio JM, Hudgins PA. CSF leaks: correlation of high -resolution CT and multiplanar reformations with intraoperative endoscopic findings. *Am J Neuroradiol* 2008; 29: 536-41.

Zuckerman J, DelGaudio JM. Identification of Cerebrospinal Fluid Leaks with Preoperative High Resolution CT and Intraoperative Image Guidance May Preclude the Need for Routine Use of Intraoperative Fluorescein and Lumbar Drainage for Endoscopic Repair. *Amer J Rhinol* 2008; 22:151-54.

Ingle A, Parikh S, DelGaudio JM. Cranial nerve palsies and orbital presentations and sequelae are hallmarks of invasive fungal sinusitis caused by *Mucor* in contrast to *Aspergillus*. *Amer J Rhinol* 2008; 22:155-58.

Das S, Maeso PA, Figueroa R, Senior BA, DelGaudio J, Sillers MJ, Schlosser RJ, Kountakis SE. The use of portable intraoperative computed tomography scanning for real-time image guidance: a pilot cadaver study. *Amer J Rhinol* 2008; 22:166-69.

DelGaudio JM, Naseri I, Wise JC. Proximal pharyngeal reflux correlates with increasing severity of lingual tonsil. *Otolaryngol Head Neck Surg* 2008; 138:473-78.

DelGaudio JM, Wojno T. Nasolacrimal duct orifice cysts in adults: a previously unrecognized, easily treatable cause of epiphora. *Laryngoscope* 2007;117(10):1830-33.

Wise SK, Wojno TH, DelGaudio JM. Silent Sinus Syndrome: Lack of Orbital Findings in Early Presentation. *Am J Rhinol* 2007; 21:489-494.

Golub JS, Parikh SL, Bernardino CR, DelGaudio JM, Inverted Papilloma of the Nasolacrimal System Invading the Orbit. *Ophth Plast Recon Surg* 2007; 23:151-153.

McLean JN, DelGaudio JM. Endoscopic Resection of a Giant Esophageal Fibrovascular Polyp: Case report and review of the literature. *Amer J Otolaryngol* 2007; 28:115-117.

Otto K, DelGaudio JM. Invasive Fungal Sinusitis: What is the Appropriate Follow-up? *Amer J Rhinol* 2006; 20:582-85.

DelGaudio JM, Wise SK. Topical Steroid drops for the treatment of Sinus Ostia Stenosis. *Amer J Rhinol* 2006; 20:563-67.

Wise SK, Wise JC, DelGaudio JM. Gastroesophageal Reflux and Laryngopharyngeal Reflux in Patients with Sleep Disordered Breathing. *Otolaryngol Head Neck Surg* 2006; 135:253-57.

Wise SK, Wise JC, DelGaudio JM. Association of Nasopharyngeal and Laryngopharyngeal Reflux with PostNasal Drip Symptomatology in Patients with and Without Chronic Rhinosinusitis. *Am J Rhinol* 2006; 20:283-89.

DelGaudio JM, Hudgins PA, Venkatraman G, Beningfield A. Multiplanar Computed Tomographic Analysis of Frontal Recess Cells: Effect on frontal isthmus dimensions and frontal sinusitis. *Arch Otolaryngol Head Neck Surg* 2005; 131:230-235.

Wise SK, Kingdom TK, McKean L, DelGaudio JM, Venkatraman G. Presence of Fungus in Sinus Cultures of Cystic Fibrosis Patients. *Amer J Rhinol* 2005; 19:47-51.

DelGaudio JM, Wise SK, Wise J. Correlation of Degree of Frontal Sinus Disease to the Presence of Frontal Headache. *Amer J Rhinol* 2005; 19:167-173.

Evans S, DelGaudio JM. Pharyngeal Perforation and Pseudodiverticulum After Anterior Cervical Spine Plating. *Arch Oto Head Neck Surg* 2005; 131:523-525.

DelGaudio JM. Direct Nasopharyngeal Reflux of Gastric Acid is a Contributing Factor in Refractory Chronic Rhinosinusitis. *Laryngoscope* 2005; 115:946-957.

Wise SK, DelGaudio JM. Computer-Aided Surgery of the Paranasal Sinuses and Skull Base. *Expert Rev.of Med Devices* 2005;2(4):395-408.

- Stong B, DelGaudio JM, Hapner ER, Johns M. Safety of Simultaneous Bilateral Botulinum Toxin Injections for Abductor Spasmodic Dysphonia. *Arch Oto Head Neck Surg* 2005; 131:793-795.
- Wise SK, Wise J, DelGaudio JM. Evaluation of Postoperative Pain Following Sinonasal Surgery. *Amer J Rhinol* 2005; 19:471-77.
- An YH, Venkatraman G, DelGaudio JM. Isolated Inflammatory Sphenoid Sinus Disease- a Revisitation of CT Indications Based Upon Presenting Findings. *Amer J Rhinol* 2005; 19:627-632.
- DelGaudio JM, Muller S. Diagnosis and Treatment of a Supraglottic Laryngeal Paraganglioma: Report of a Case. *Head & Neck*. 2004; 26(1): 94-98.
- Parikh S, Venkatraman G, DelGaudio JM. Invasive Fungal Sinusitis: A 15-Year Review from a Single Institution. *Amer J Rhinol*. 2004; 18:75-81.
- DelGaudio JM, Martinez EJ. Endoscopic Sinus Surgery in Patients with Chronic Hepatic Failure Waiting Liver Transplant. *Amer J Rhinol*.2004;18:253-258.
- Wise SK, Venkatraman G, Wise JC, DelGaudio JM. Ethnic and Gender Differences in Bone Erosion in Allergic Fungal Sinusitis. *Amer J Rhinol* 2004; 18:397-404.
- Kingdom TK, DelGaudio JM. Endoscopic management of lesions of the sphenoid sinus, orbital apex, and clivus. *Am J Otolaryngol*. 2003; 24(5): 317-22.
- DelGaudio JM. Endoscopic transnasal approach to the pterygopalatine fossa. *Arch Otolaryngol Head Neck Surg*. 2003; 129:441-446.
- DelGaudio JM, Waring JP. Empiric esomeprazole in the treatment of laryngopharyngeal reflux. *Laryngoscope*. 2003; 113(4):598-601.
- DelGaudio JM, Swain R, Kingdom TT, Hudgins. Computed tomography findings in invasive fungal sinusitis. *Arch Otolaryngol Head Neck Surg*. 2003; 129:236-40.
- DelGaudio JM. Steroid inhaler laryngitis: a result of inhaled fluticasone therapy. *Arch Otolaryngol Head Neck Surg*. 2002; 128(6):677-81.
- Albritton FD, Kingdom TT, DelGaudio JM. Malleable registration mask for image-guided surgery. *Amer J Rhinology*. 2001; 15(4):219-224.
- Dillard DG, Muller S, Cohen C, Bloch D, DelGaudio JM, Gal AA. High tumor grade in salivary gland mucoepidermoid carcinomas and loss of expression of transforming growth factor beta receptor type II. *Arch Otolaryngol Head Neck Surg*. 2001; 127(6):683-686.
- Dillard DG, Venkatraman G, Cohen C, DelGaudio J, Gal AA, Mattox DE. Immunolocalization of erythropoietin and erythropoietin receptor in vestibular schwannoma. *Acta Otolaryngol*. 2001; 121:149-152.
- Swain RE, Kingdom TT, DelGaudio JM, Muller S, Grist WJ. Meningiomas of the

paranasal sinuses. *Amer J Rhinology*. 2001; 15(1):27-30.

Penner CR, Muller S, DelGaudio JM. Clinicopathologic conference: diffuse parotid swelling. *Oral Surg Oral Med Oral Pathol*. 2001; 91(1):8-11.

Dillard DG, Cohen C, Muller S, DelGaudio JM, Reichman O, Parrish B, Rackley D, Gal AA. Immunolocalization of activated transforming growth factor B1 in juvenile nasopharyngeal angiofibroma. *Arch Otolaryngol Head Neck Surg* 2000; 126(6):723-25.

DelGaudio JM, Dillard D, Albritton F, Hudgins P, Wallace V, Lewis M. CT guided needle biopsy of head and neck lesions. *Arch Otolaryngol Head Neck Surg*. 2000; 126(3):366-370.

Wo JM, Grist WJ, Gussack GS, DelGaudio JM, Waring JP. Empiric trial of high dose omeprazole in patients with posterior laryngitis: a prospective study. *Amer J Gastroenterology*. 1997; 92(12):2160-65.

DelGaudio JM, Sciote JJ. Changes in myosin expression in denervated laryngeal muscle. *Annals of Otol, Rhinol, Laryngol*. 1997;106(12):1076-81.

DelGaudio JM, Garetz SL, Bradford CR, Stenson KM. Hemangiopericytoma of the oral cavity. *Otolaryngol Head Neck Surg*. 1996; 114 (2):339-340.

DelGaudio JM, Sciote JJ, Carroll WR, Esclamado RM. Atypical myosin heavy chain in rat laryngeal muscle. *Annals Otol Rhinol Laryngol*. 1995; 104:237-245.

DelGaudio JM, Myers MW, Telian SA. Angiolymphoid hyperplasia with eosinophilia involving the external auditory canal. *Otolaryngol Head Neck Surg*. 1994; 111:669-673.

DelGaudio JM, Fleming DJ, Esclamado RM, Carroll WR, Bradford CR. Hemilaryngectomy for glottic carcinoma after radiation therapy failure. *Arch Otolaryngol Head Neck Surg*. 1994; 120:959-963.

Clevens RA, Esclamado RM, DelGaudio JM, Myers MW: Amyloidoma of the neck: case report and review of the literature. *Head & Neck*. 1994; 16:191-195.

b. Manuscripts submitted:

Smith-Davidson P, Altartoor K, Kabongo MM, Claussen H, Arthur RA, Johnson HR, DelGaudio JM, Wise SK, Solares CA, Barrow EM, Magliocca KR, Koval M, Levy JM. Prostaglandin E Receptor 2 (EP2) Dysregulation in Allergic Fungal Rhinosinusitis Nasal Polyp Epithelium. *Laryngoscope*.

Spielman DB, Warfield-McAlpine P, Singh N, Wise S, Inthavong K, DelGaudio JM. A computational fluid dynamics study supporting asymmetric involvement in CCAD. *Laryngoscope*.

Eder AE, Avila SA, Malenke J, DelGaudio JM, Wojno T. Intraosseous Hemangioma of the Orbit: A case report involving pre-operative embolization with reconstruction using a custom 3D printed porous polyethylene implant. *Ophthalmology Plastic Reconstr Surgery*.

c. Review articles:

Laury A, DelGaudio JM. Aspergillus Infections in the Head and Neck. *Current infectious Disease Reports* 2010;12(3):217-24.

d. Symposium contributions:

e. Book chapters:

Carroll WR, DelGaudio JM: Review of Neuromuscular Reinnervation in Head and Neck Reconstruction. In: *Otolaryngology, Head and Neck Surgery*, 2nd edition, Update 1. Cummings C, Krause CJ et al. (eds). Mosby Yearbook Publishing, Philadelphia, 1995, 101-111.

DelGaudio JM. Oral Cavity and Oropharynx. *The Anatomic Basis of Tumor Surgery*. Wood WC, Skandalakis JE (eds). Quality Medical Publishing, Inc., St. Louis, 1999, 1-57.

Jacobs IN, Rabkin D, DelGaudio JM, Skandalakis JE. Pharynx. In: *Surgical Anatomy: The Embryologic and Anatomic Basis for Modern Surgery*. Skandalakis JE, Colburn GL, Weidman TA, Foster RS, Kingsnorth AN, Skandalakis LJ (eds). Paschalidis Medical Publishing, Athens, Greece, 2004, 611- 646.

Jacobs IN, DelGaudio JM, Colborn GL, Weidman TA, Skandalakis JE. Larynx. In: *Surgical Anatomy: The Embryologic and Anatomic Basis for Modern Surgery*. Skandalakis JE, Colburn GL, Weidman TA, Foster RS, Kingsnorth AN, Skandalakis LJ (eds). Paschalidis Medical Publishing, Athens, Greece, 2004, 229- 262.

DelGaudio JM. Tonsillectomy and Adenoidectomy. In: *Medical Management of the Surgical Patient*, 4th Edition. Lubin MF, Smith RB, Dodson TH, Spell NO, Walker HK (eds). Cambridge University Press, New York, 2006, 753-4.

DelGaudio JM. Uvulopalatopharyngoplasty. In: *Medical Management of the Surgical Patient*. 4th Edition. Lubin MF, Smith RB, Dodson TH, Spell NO, Walker HK (eds). Cambridge University Press, New York, 2006, 755-6.

Naseri I, DelGaudio JM. Predictors of Failure of Primary Sinus Surgery. In: *Revision Sinus Surgery*. Kountakis S, Jacobs J, Gosepath J (eds). Springer Press, Berlin, 2008, 19-23.

Zuckerman JD, DelGaudio JM. Endoscopic Tumor Resection and Cerebrospinal Fluid Leak Repair. In: *Skull Base Techniques and Concepts*. Moore CE, Olson JJ (eds). Plural Publishing. NY, NY, 2010, 65-70.

DelGaudio JM, Chen AY. Oral Cavity and Oropharynx. In: *The Anatomic Basis of Tumor Surgery*. 2nd edition. Wood WC, Skandalakis JE (eds). Springer-Verlag. Berlin, Germany.

2010,1-54.

Baugnon KL, DelGaudio JM, Hudgins PA. Functional Endoscopic Sinus Surgery, Postoperative Findings and Complications. In: Head and Neck Imaging. 5th edition. Som PM, Curtin HD (eds). Elsevier, Mosby. St. Louis. 2011, 411-437.

Wise SK, Orlandi RR, DelGaudio JM. Sinonasal Anatomy and Embryology. In: Rhinology: Diseases of the Nose, Sinuses, and Skull Base. Kennedy D, Hwang P (eds). Thieme Publishing. 2012.

Wise SK, DelGaudio JM. Managing Intraoperative Complications in Endoscopic Sinus Surgery. In: Endoscopic Sinus Surgery: Optimizing Outcomes and Avoiding Failures. Scholsser and Harvey (Eds). Plural Publishing. 2012. Chapter 13.

Hoddeson EK, Wise SK, DelGaudio JM. History of Nasal Endoscopy. In: Office-Based Rhinology. Patel ZM, Wise SK, DelGaudio JM (eds). Plural Publishing. San Diego, CA. 2013,1-4.

Wise SK, Villari C, DelGaudio JM. Endoscopic Anatomy for Office-Based Rhinology Procedures. In: Office-Based Rhinology. Patel ZM, Wise SK, DelGaudio JM (eds). Plural Publishing. San Diego, CA. 2013,5-13.

Duggal P, DelGaudio JM. Office-Based Inferior Turbinate Reduction. In: Office-Based Rhinology. Patel ZM, Wise SK, DelGaudio JM (eds). Plural Publishing. San Diego, CA. 2013, 77-88.

Henriquez O, DelGaudio JM. Office-Based Nasal Polypectomy. In: Office-Based Rhinology. Patel ZM, Wise SK, DelGaudio JM (eds). Plural Publishing. San Diego, CA. 2013, 101-108.

Laury A, DelGaudio JM. Office-Based Management of Mucocoeles. In: Office-Based Rhinology. Patel ZM, Wise SK, DelGaudio JM (eds). Plural Publishing. San Diego, CA. 2013, 109-116.

Kim HJ, DelGaudio JM. Office-Based Evaluation and Treatment of Epiphora. In: Office-Based Rhinology. Patel ZM, Wise SK, DelGaudio JM (eds). Plural Publishing San Diego, CA. 2013, 137-144.

Lupa M, DelGaudio JM. Benign Sinonasal Neoplasms. In: Encyclopedia of Otolaryngology- Head and Neck Surgery. Kountakis S (ed). [Springer Verlag, Berlin, Heidelberg, New York](#). 2013, 309-316.

Laury A, DelGaudio JM. Reflux Disease and LPR. In: Encyclopedia of Otolaryngology- Head and Neck Surgery. Kountakis S (ed). [Springer Verlag, Berlin, Heidelberg, New York](#), 2013, 2266-2271.

Flanagan C, Baugnon KL, DelGaudio JM. Radiographic Diagnosis of Chronic Rhinosinusitis. In: Practical Medical and Surgical Management of Chronic Rhinosinusitis. Batra P, Han J. (Eds). Springer. [New York](#) 2015. 43-72.

Laury A, DelGaudio JM. Reflux and Sinusitis. In: Sataloff's Textbook of Otolaryngology.

Duggal P, DelGaudio JM. Office-Based Treatment and Management of the Frontal Sinus. In: *The Frontal Sinus 2nd Edition*. Kountakis S, Senior B, Draf W (Eds), Springer Verlag, Berlin, Heidelberg, New York, 2016. 285-300.

Levy JM, DelGaudio JM. Controversial Topics in Current Practice- Office-Based Frontal Sinus Procedures. In: *Frontal Sinus Procedures*. Georgalas C, Sama A (Eds). Thieme.

Levy JM, DelGaudio JM. Acute Sinusitis. In: *Crush Otolaryngology Boards*. Mohamad Chaaban, Ed. Nova Science Publishers, Inc. 2019. 335- 340.

Lal D, Aoun RJM, DelGaudio JM, Patel NP. External Techniques in Frontal Sinus Surgery. In: *Frontal Sinus Surgery. A Systematic Approach*. Lal D, Hwang PH (Eds). Springer. 2019. 143-178.

Thamboo A, DelGaudio JM, Patel ZM. Management of Frontal Headaches. In: *Frontal Sinus Surgery. A Systematic Approach*. Lal D, Hwang PH (Eds). Springer. 2019. 355-366.

Helman SH, Edwards TS, DelGaudio JM, Wise SK. Allergic Rhinitis and Chronic Rhinosinusitis. In: *The Unified Airway: Rhinologic Disease and Respiratory Disorders*. Gudis D, Schlosser RJ (eds).

DelGaudio JM, Vuncannon JR, Barrow EM. Skull Base Injury and Intracranial Complication from Office Sinus Surgery. In: *Lessons Learned from Rhinologic Procedure Complications*. Chandra R, Welch K. (eds). Springer. 2021. 101-108.

Arnold M, DelGaudio JM. Debates and Controversies in Frontal Sinus Surgery. In: *Atlas of Frontal Sinus Surgery*. Lobo DR, Artiles JV, Ospina JA (eds). Springer, Cham. October 2022. 311-16.

Spielman DB, DelGaudio JM. Endoscopic Sinus Surgery in the Office. In: *Office-Based Surgery in Otolaryngology*. Sindwani R (ed). Elsevier.

f. Books edited and written:

Office-Based Rhinology. Patel ZM, Wise SK, DelGaudio JM (eds). Plural Publishing. San Diego, CA. 2013.

g. Book reviews:

h. Manuals, videos, computer programs, and other teaching aids:

DelGaudio JM. GERD, refractory sinusitis, and postnasal drip. Audio-Digest Otolaryngology June 21, 2007; Volume 40: Issue 12.

Scope It Out. Podcast of Int Forum Allerg Rhinol. Central Compartment Involvement in Aspirin Exacerbated Respiratory Disease: the Role of Allergy and Previous Sinus Surgery. July 2019.

i. Other publications:

Sciote JJ, DelGaudio JM. Muscle fiber types in rat laryngeal muscle. (Abstract) J Mus Res Cell Motility. 1994; 15:191.

DelGaudio JM. Nasopharyngitis is a Clinical Sign of Laryngopharyngeal Reflux. Response to Letter to the Editor. Amer J Rhinol 2007;21:135.

DelGaudio JM, Colby CC. Stylohyoid Complex Syndrome: Is 1 More Classification Needed? Reply. (Letter) Arch Otolaryngol Head Neck Surg 2011;143:952.

Fried MP, Marple BF, Altman KW, Delgaudio JM, Krouse JH, Postma GN
Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery **147**(2 suppl):P24 Aug 2012

Shah R, Schniederjan M, DelGaudio JM, Ioachimescu AG. Southern Regional Meeting, New Orleans, LA, 17 Feb 2011 - 19 Feb 2011. Journal of Investigative Medicine. Lippincott Williams & Wilkins. 59: 415-415. 01 Feb 2011

Patel ZM, DelGaudio JM. Rhinology Perspectives: The Question of Middle Turbinate Resection Versus Preservation in Endoscopic Sinus Surgery. American Rhinologic Society Nose News. Feb 2014.

Patel ZM, DelGaudio JM. Rhinology Perspectives: Evaluation and Management of "Sinus Headache". American Rhinologic Society Nose News. June 2015.

Stunkel L, Saindane A, DelGaudio J, Newman NJ, Biousse V. Neuro-Imaging Evidence for Reversible Collapsibility of the Distal Transverse Sinuses in Spontaneous CSF Leak. Neurology. April 14, 2020; 94 (15 Supplement).

APPENDIX B

Appendix B: Materials Considered

Exhibit	Description
1001	U.S. Patent No. 9,415,194 (“’194 patent”)
1003	File History of U.S. Patent No. 9,415,194
1010	U.S. Patent No. 6,517,535 (“Edwards-’535”)
1011	U.S. Patent No. 5,575,788 (“Baker”)
1013	WO 2010/077980 (“Baker-’980”)
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”)
1018	File History of U.S. Patent No. 8,936,594
1019	U.S. Patent App. No. 2007/0219600 (“Gertner”)
1021	U.S. Patent App. No. 2005/0240147 (“Makower”)
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, 32:3 India J. Otolaryngology 80 (September 1980) (“Arora”)
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”)
1046	U.S. Patent No. 3,941,121 (“Olinger”)

Dr. DelGaudio Declaration: Appendix B (Materials Considered)

Exhibit	Description
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”)
1049	Konno, “Historical, pathophysiological, and therapeutic aspects of Vidian neurectomy” (“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”)
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”)
1066	U.S. Patent App. No. 2004/0230188 (“Cioanta”)

APPENDIX C

Appendix C (Challenged Claims)

Ground	35 U.S.C. Section	Claims	References
I	102	1-3, 12, 14, 16, 18	Baker
II	103	1-3, 12, 14, 16, 18, 19	Baker
III	103	1-3, 6, 12, 14, 16, 18, 19	Baker + Edwards-'535 + Chen

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
1[pre]	1. A method for reducing mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough, the method comprising:	<u>Ground I</u> <u>Ground II</u> <u>Ground III</u>
1[a]	advancing a treatment delivery portion of an energy-based treatment device into a nostril of the patient;	
1[b]	contacting mucosal tissue of the upper airway with the treatment delivery portion, without piercing the mucosal tissue; and	
1[c]	delivering a treatment from the treatment delivery portion to at least one tissue selected from the group of the mucosal tissue and another tissue underlying the mucosal tissue to modify a property of the at least one tissue and thus treat at least one of post nasal drip or chronic cough in the patient.	

Dr. DelGaudio Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
2	The method of claim 1, wherein the treatment is delivered without forming an incision in the mucosal tissue and without delivering an implant.	<u>Ground I</u> <u>Ground II</u> <u>Ground III</u>
3	The method of claim 1, wherein delivering the treatment comprises delivering energy from the delivery treatment portion in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light and laser energy.	<u>Ground I</u> <u>Ground II</u> <u>Ground III</u>
6	The method of claim 3, wherein the at least one tissue comprises nerve tissue underlying the mucosal tissue, and wherein delivering the energy comprises ablating the nerve tissue.	<u>Ground III</u>
12	The method of claim 1, wherein delivering the treatment comprises injuring the at least one tissue.	<u>Ground I</u> <u>Ground II</u> <u>Ground III</u>
14	The method of claim 12, wherein the at least one tissues is selected from the group consisting of cilia, goblet cells, nerves,	<u>Ground I</u> <u>Ground II</u>

Dr. DelGaudio Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
	submucosal tissue, muscle, ligaments, cartilage, tendon, and skin.	<u>Ground III</u>
16	The method of claim 1, wherein delivering the treatment comprises modifying the at least one tissue in a manner that decreases a volumetric rate of mucus production of the mucosal tissue without changing a shape of the mucosal tissue.	<u>Ground I</u> <u>Ground II</u> <u>Ground III</u>
18	The method of claim 1, wherein delivering the treatment comprises delivering the treatment to at least one turbinate of the upper airway.	<u>Ground I</u> <u>Ground II</u> <u>Ground III</u>
19	The method of claim 18, wherein the at least one turbinate comprises an inferior turbinate, and contacting the mucosal tissue comprises contacting a posterior aspect of the inferior turbinate.	<u>Ground II</u> <u>Ground III</u>