

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. IPR2024-00275

U.S. Patent No. 9,072,597

**DECLARATION OF DR. JOHN DELGAUDIO REGARDING
CLAIMS 9, 14, 16, 18, 20, 22-24, 44 AND 46 OF U.S. PATENT NO. 9,072,597**

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I, John DelGaudio, declare as follows:

I. INTRODUCTION

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

2. I have been retained as an expert in this proceeding by counsel for Neurent Medical Inc. and Neurent Medical Ltd. (collectively, “Neurent” or “Petitioners”). I have been asked for my expert conclusions regarding the validity of claims 9, 14, 16, 18, 20, 22-24, 44 and 46 of U.S. Patent No. 9,072,597 (the “’597 patent”) (Exhibit 1001-USP597). For the reasons set forth below, it is my conclusion that claims 9, 14, 16, 18, 20, 22-24, 44 and 46 of the ’597 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 I also serve as the Chief of Rhinology, Sinus, and Skull Base Surgery, a position I have held since 2004.

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

e.g., post nasal drip and chronic cough), nasal polyps, idiopathic intracranial hypertension and skull base defects (repairing defects between the brain and nose/sinuses), and endoscopic orbital surgery.

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

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

have been awarded both the Gerald Gussack Award and the Lester Brown Award by the Georgia Society of Otolaryngology. These are teaching and service awards.

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

10. I have been practicing Otolaryngology and Rhinology since 1995. As part of my practice I have frequently used radiofrequency (RF) energy for the

treatment of nasal conditions such as inferior turbinate hypertrophy and rhinitis, and to treat the tongue and palate for sleep apnea and snoring.

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

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

III. LEGAL PRINCIPLES

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

A. Scope of Opinion

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

B. Anticipation

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

C. Obviousness

16. I understand that a claim is unpatentable if it would have been obvious to a person of ordinary skill in the art at the time the alleged invention was made. I understand that a claim could have been obvious based on the teachings or

suggestions of a single prior art reference or from a combination of two or more prior art references. I understand that an obviousness analysis requires an understanding of the scope and content of the prior art, any differences between the alleged invention and the prior art, and the level of ordinary skill in evaluating the pertinent art.

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

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

19. While it may be helpful to identify a reason for this combination, I understand that there is no rigid requirement of finding an express teaching,

suggestion, or motivation to combine within the references. If a person of ordinary skill in the art can implement a predictable variation, obviousness likely bars its patentability. For the same reason, if a technique has been used to improve one device and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique would have been obvious. I understand that a claim would have been obvious if a person of ordinary skill in the art would have had reason to combine multiple prior art references or add missing features to reproduce the alleged invention recited in the claims.

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

- whether the teachings of the prior art references disclose known concepts combined in familiar ways, which, when combined, would yield predictable results;
- whether a person having ordinary skill in the art could implement a predictable variation, and would see the benefit of doing so;

- whether the claimed elements represent one of a limited number of known design choices, and would have a reasonable expectation of success by those skilled in the art;
- whether a person having ordinary skill would have recognized a reason to combine known elements in the manner described in the claim;
- whether there is some teaching or suggestion in the prior art to make the modification or combination of elements claimed in the patent; and
- whether the alleged invention applies a known technique that had been used to improve a similar device or method in a similar way.

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

22. I further understand that certain factors, commonly referred to as secondary considerations, may support or rebut the obviousness of a claim. I also understand that secondary considerations cannot be used to overcome anticipation. I understand that such secondary considerations include, among other things, commercial success of the patented invention, skepticism of those having ordinary skill in the art at the time of invention, unexpected results of the invention, any long-felt but unsolved need in the art that was satisfied by the

alleged invention, the failure of others to make the alleged invention, praise of the alleged invention by those having ordinary skill in the art, and copying of the alleged invention by others in the field. I understand that there must be a nexus, that is, a connection, between any such secondary considerations and the alleged invention. I also understand that contemporaneous and independent invention by others is a secondary consideration tending to show obviousness.

23. I reserve the right to respond to any allegations that may be put forth by Patent Owner in this proceeding that any secondary considerations tend to rebut the obviousness of any claim of the '271 patent discussed in this declaration.

D. Claim Dependency

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

* * *

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

IV. MATERIALS CONSIDERED

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

V. LEVEL OF ORDINARY SKILL IN THE ART

27. It is my understanding that when considering the claims of the '597 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.

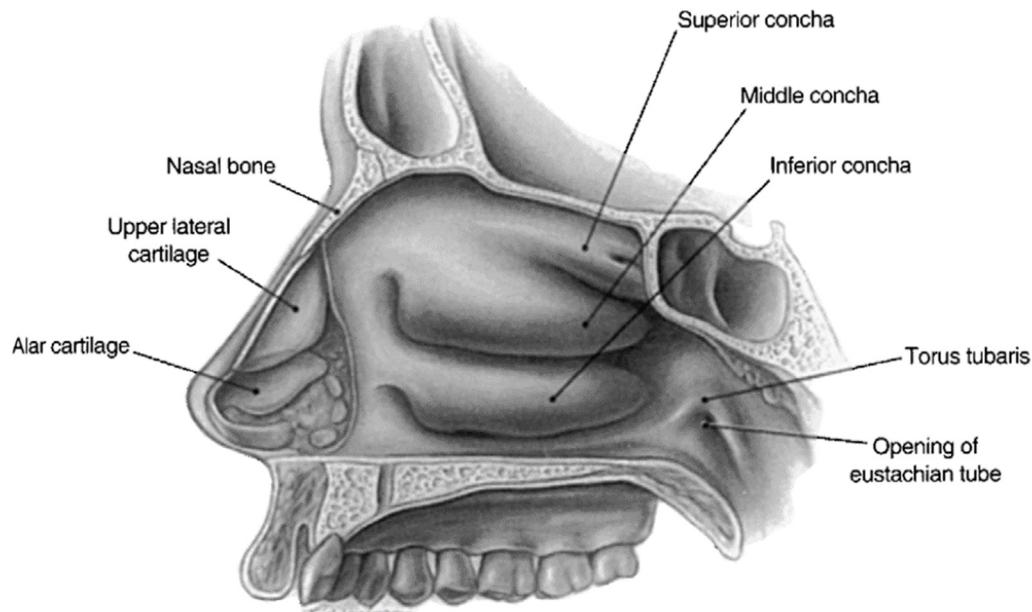
29. Based on these factors as well as my experience and expertise, a person of ordinary skill in the art at all relevant times (2011-2014) would have had (1) a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline and (2) at least three years of experience 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 '597 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.” Ex.1060-Lane, 393. The nasal cavity also “warms inspiratory air through ... flow that maximizes contact with the available mucosal surface area.” *Id.*
- Nasal septum is situated between the left and right side of the nose and partitions the nasal cavity into two sides). *See id.*, 387-388.

¹ Although the caption states “left side,” the figure shows the right side of the nose, which is consistent with other similar figures in the paper being identified in their captions as showing the right side of the nose. *See* Ex.1060-Lane, FIGs. 2 and 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.*, [0004].

31. 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 '597 patent.

B. Using Energy to Treat Medical Conditions

32. 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 '597 patent by as much as a century, include the following:

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

- Ex.1027-Fry (U.S. patent issued in 1964), 1:67-70 (“By focusing an ultrasonic beam upon a portion of the nerve pathway which leads from the eye to the visual cortex, it is possible to reversibly suppress the transmission of nerve impulses along this pathway.”)
- Ex.1046-Olinger (U.S. patent issued in 1976), 3:32-40 (“The invention is particularly useful for inspecting, studying and treating the nervous system and particularly the spinal cord, as, for example, in making radiofrequency lesions in nerve tracts, under direct visual supervision, in patients with intractable pain or spasticity. Now, for the first time, an electrode may be inserted percutaneously into the spinal pathways under direct visual control to make radiofrequency lesions in patients with intractable pain.”)
- Ex.1047-Turner (U.S. patent issued in 1981), 5:55-60 (“As seen in FIG. 1, a broadband electromagnetic radiation (EMR) system or apparatus 10 for irradiation of living tissue or tissue simulating material comprises generally an EMR or microwave generator or source 12 to which is electrically connected, by a transmission means or line 16, EMR irradiating means 14.”)

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

33. 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 '597 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

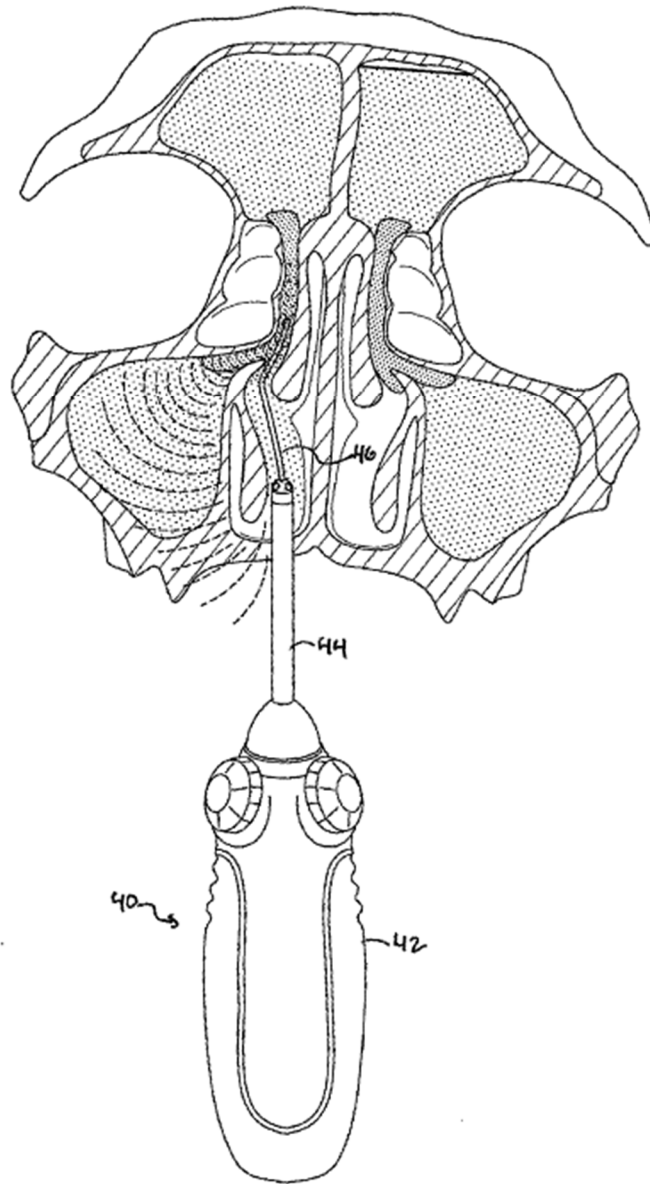
accumulate, and interact, to cause various illnesses and conditions, and to produce undesired symptoms.”), 26:7-8 (“The methods and devices may be used for treating common colds, nasal congestion and allergic rhinitis, as well as sinusitis and other nasal conditions.”); Ex.1056-Liang, 341 (“From October 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, 4:19-28 (“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.

D. Devices for Delivering Energy Within the Nose to Treat Medical Conditions

34. A person of ordinary skill in the art would have been aware of a variety of treatment devices for delivering energy to the upper airways that were known by 2011. At minimum, such energy based treatment devices required the basic elements of (a) a shaft (e.g., a catheter-like structure) for insertion into the patient’s nostril and (b) an energy delivery device at or near the distal end of the shaft that delivers energy to the target tissue. Many configurations and variations of this basic structure of were known. With respect to the shaft, various forms of flexible and/or steerable structures had been disclosed to facilitate precise positioning of the energy delivery device within the nasal passages. *See, e.g.*, Ex.1021-Makower, [0186]; Ex.1013-Baker, Abstract, 16:19-32, 22:10-25. For example, Figure 8C of Baker, reproduced below, illustrates an example of such a shaft having a flexible, steerable structure.



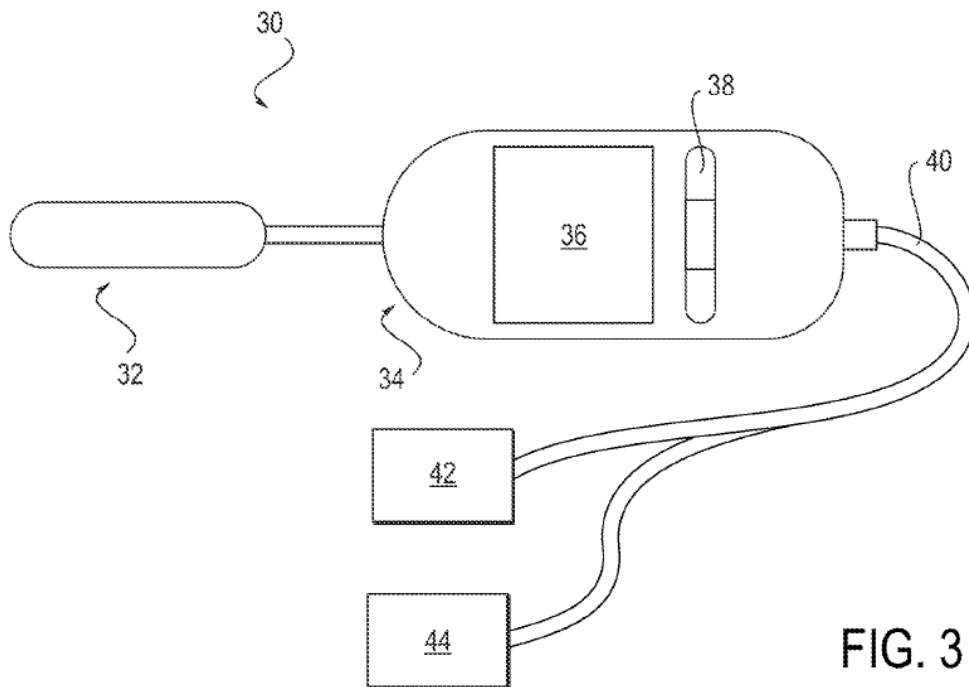
Ex.1013-Baker, FIG.8C. Figure 8C shows that the shaft is bent so as to position energy delivery member 46 within nasal passages proximate to an obstruction (dark gray region). *Id.*, 22:12-25. Once in position, energy delivery member 46 delivers acoustic (e.g., ultrasound) energy to treat the obstruction. *Id.*, 25:5-12.

35. With respect to the energy delivery device, a known configuration was to provide an inflatable chamber (e.g., a balloon) at the distal end of the shaft, which facilitates the delivery of energy by, e.g., securing the energy delivery device in place, delivering fluid to the tissue, cooling the target tissue, or the like. Ex.1010-Edwards-'535, 5:18-34, 6:10-37, FIGs.3A-3B; Ex.1019-Gertner, [0107], [0109], [0111].

VII. OVERVIEW OF THE '597 PATENT

A. Overview of the '597 Patent

36. The '597 patent states in its introductory section, titled “Field of the Invention,” that the patent relates to “treating structures within the nose and upper airway” to “improve airflow.” Ex.1001-USP597, 1:26-32. Figure 3 of the patent is reproduced below.



Ex.1001-USP597, FIG.3. A “treatment device 30” is shown and includes “a treatment element 32...to be placed inside the nasal cavity.” *Id.*, 15:45-49.

37. One embodiment of treatment element 32 is depicted in Figure 4B, reproduced below.

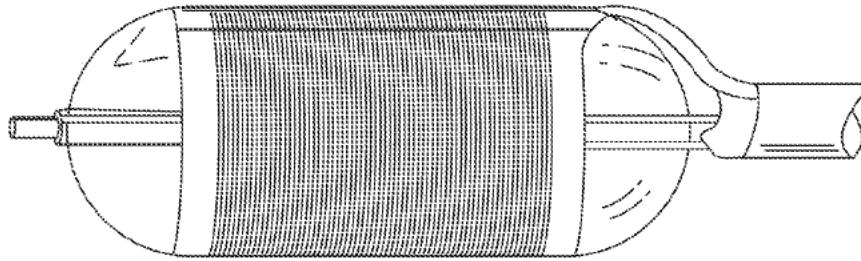


FIG. 4B

Ex.1001-USP597, FIG.4B. The treatment element in Figure 4B includes an inflatable balloon, *id.*, 14:4-10, and other embodiments are described in which the treatment has a flexible shaft, *id.*, 28:66-67. The patent discloses “the treatment element 32 may be a balloon with energy delivery elements positioned at locations where energy transfer is sufficient or optimal to effect change in breathing.” *Id.*, 20:11-14.

38. By applying energy to target tissue within the nose, the '597 patent explains that the treatment device can tighten, shrink, or enlarge the target tissue. *Id.*, 14:64-15:9. The techniques disclosed in the '597 patent do not require, nor does the patent express a preference, that the treatment device deliver any particular form of energy. Rather, the patent states that the energy delivered can

include “[a]ny one or more” of radiofrequency energy, light energy, ultrasound energy, microwave energy, electromechanical energy, mechanical force, cooling, electrical current, “or others.” *Id.*, 14:53-67. Of the challenged claims, dependent claim 18 lists eight different forms of energy that are covered (“ultrasound, microwave, heat, radiofrequency, electrical, light, laser and quantic molecular resonance”), and no other challenged claim limits the form of the energy.

39. The patent also states that delivering the energy based therapy may modify a property of the target tissue without reshaping the tissue. *Id.*, 20:65-21:2 (“deliver[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 in the nasal valve tissue.”). The patent does not elaborate on how this can be achieved.

B. Examination of the ’597 Patent Before the United States Patent and Trademark Office

40. The ’597 patent was filed as a continuation-in-part patent application on June 30, 2014. Ex.1001-USP597, Cover. On December 26, 2014, the examiner issued a non-final office action raising the following rejections and objections:

- Claims 31, 33, and 38-44 (none of which are among the challenged claims) were rejected as being anticipated by U.S. Patent No. 6,416,419;

- Claims 1-4, 9, 18, 25, 27, and 45-47 were rejected for double patenting over the issued claims of the parent application; and
- Claims 5-8, 10-17, 19-24, 26, 28-30, 32, and 34-37 were identified as being allowable but were objected to as being dependent upon a rejected base claim.

Ex.1003-USP597FH, 236-241.

41. In a response filed March 18, 2015, the applicant amended claim 31 (which is not among the challenged claims) to recite subject matter that the examiner had previously deemed allowable, specifically that the claimed “*energy delivery member has a contact surface with a convex shape configured to at least temporarily create a concavity in the at least one tissue.*” *Id.*, 262-63. The applicant also filed a terminal disclaimer to overcome the double patenting rejection. *Id.*, 268. 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.*, 258-67.

42. Subsequently, on April 2, 2015, the examiner issued a notice of allowance, which did not include any statement of the examiner’s reasons for allowance. *Id.*, 276.

43. I understand and have been informed that there may be circumstances where the examination of a parent application provides additional information about the examiner's reasons for allowing the challenged claims. However, in this case, the examiner's apparent basis for allowing the parent application's claims does not apply to the challenged claims. During the examination of the parent application, the examiner issued a non-final office action in which certain claims of the parent application were rejected as being anticipated by Gertner. Ex.1018-USP594FH, 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 (claim language emphasized). 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.

44. 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-USP597FH, 239. 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 24 expressly requires the claimed method to modify tissue “without reshaping the tissue.” Ex.1001-USP597, Claim 24. Moreover, the examiner did not apply Gertner to the challenged claims during the examination history of the ’597 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. The examiner also did not explain why Gertner was not applied to the challenged claims.

45. As I explain in further detail below, the challenged claims are anticipated by Gertner and are also unpatentable over other prior art references (Edwards-’535 and Baker) that were not before the examiner during examination of the ’597 patent.

VIII. OVERVIEW OF THE PRIOR ART REFERENCES

A. Gertner

46. Gertner is directed to systems and methods for “providing therapeutic light [(i.e., energy)] to a target region of tissue within a nasal cavity.” Ex.1019-Gertner, Abstract, [0003] (describing light as a type of “energy”). Figure 4A of Gertner is reproduced below.

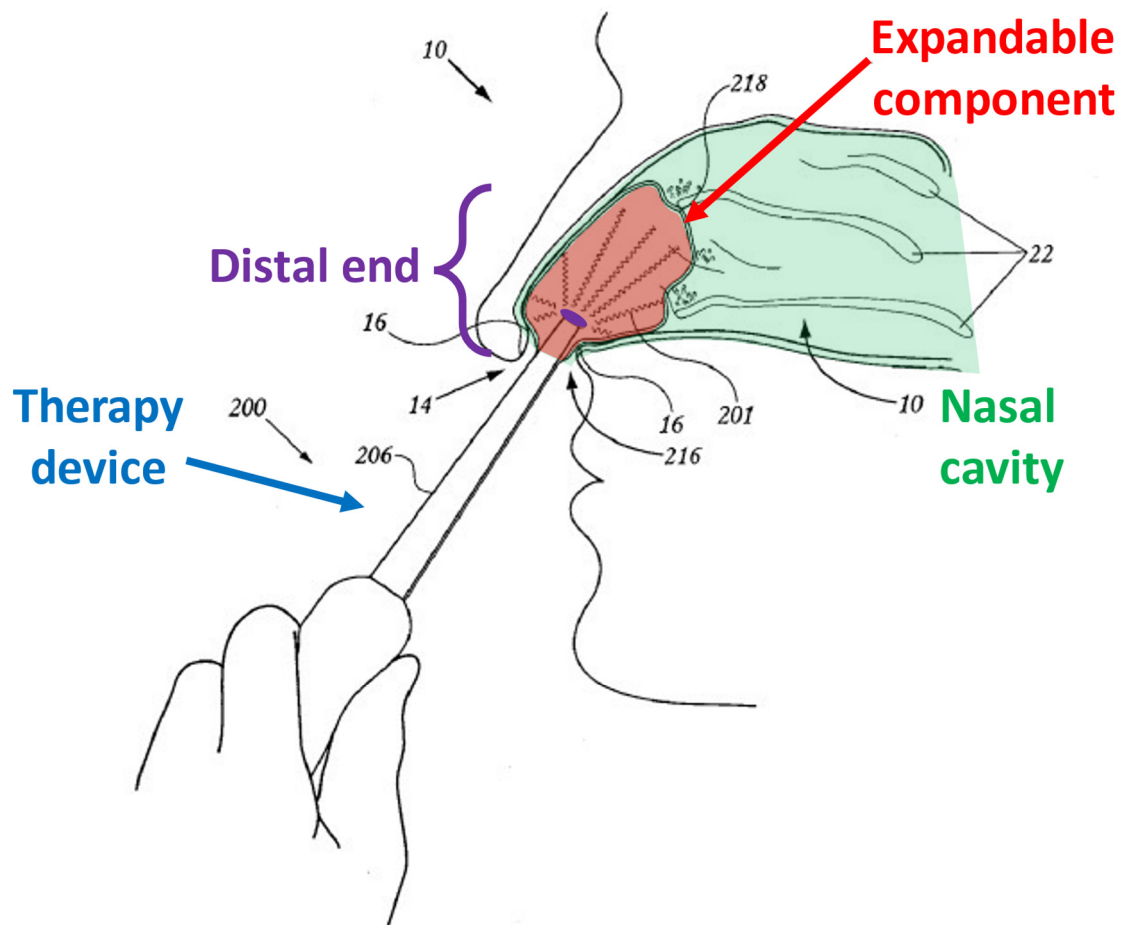
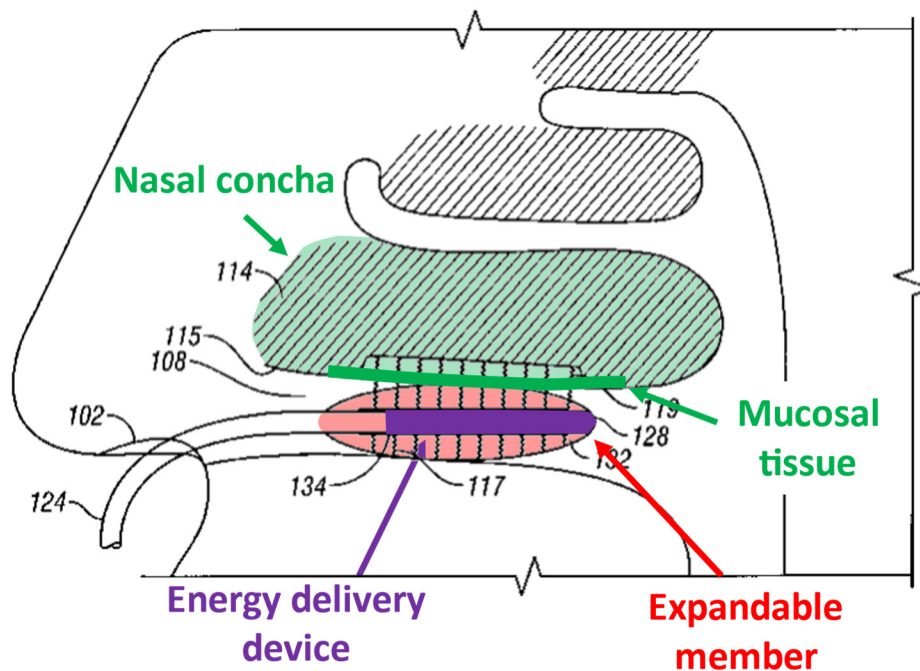


FIG. 4A

Id., FIG.4A. Figure 4A shows a therapy device 200 (blue) having an expandable component 218 (red) at its distal end 216 (purple). *Id.*, [0106]. Light (which Gertner describes as a type of energy) is projected through the walls of the expandable component 218 and into target tissue within the nasal cavity 10 (green). *Id.*, [0107]. A person of ordinary skill in art would have understood the various portions of distal end 216 that are used to deliver light to target tissue – including any light emitter(s), expandable component 218, light transmission media within expandable component 218, and the like – to collectively form a treatment element for delivering light energy to tissue. For example, each of these portions impacts the characteristics of the light that reaches the target tissue, e.g., expandable component 218 affects the uniformity of the light distribution. *Id.* (“In the case where the expandable component 218 is a balloon, the therapeutic light is delivered to the tissue through the wall of the balloon. In one embodiment, the balloon is used to compress the mucous of the nasal cavity and deliver a more relatively uniform distribution of light.”).

B. Edwards-’535

47. 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, 6:66-7:17. Figure 3B of Edwards-’535 is reproduced below.



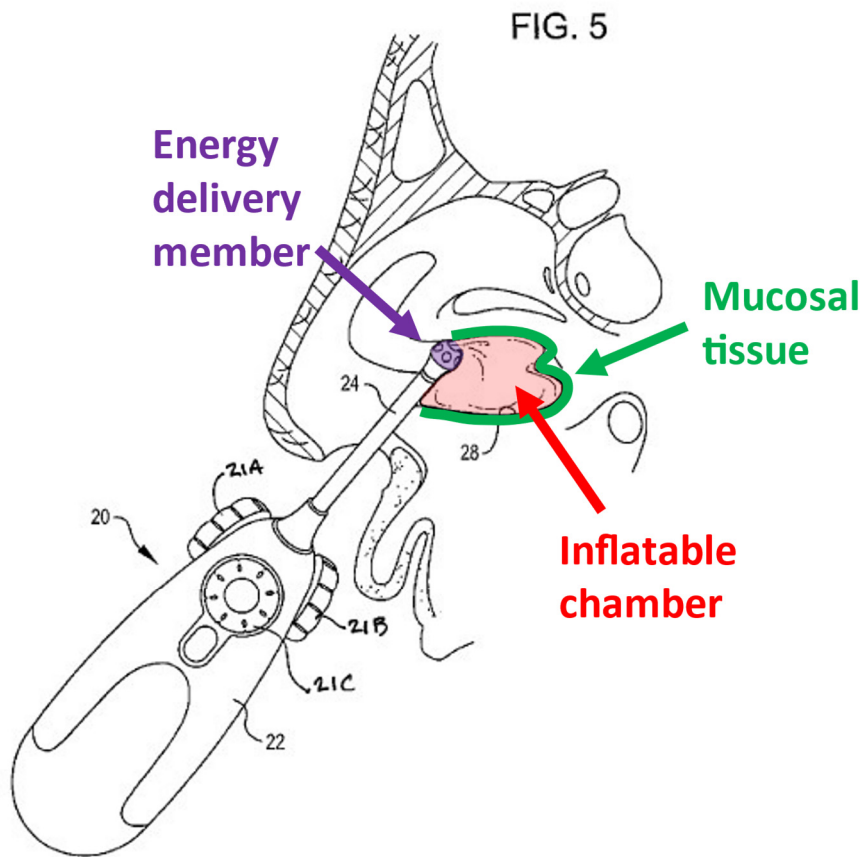
Id., FIG.3B. Figure 3B shows a distal portion 128 of an apparatus 124. The distal portion 128 includes an energy delivery device 134 (purple) positioned within an expandable member 132 (red). *Id.*, 5:18-35, 8:8-33. Energy delivery device 134 can also be positioned “on a surface” of expandable member 132. *Id.*, 8:8-33. After being inserted “though 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. Baker

48. 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.*

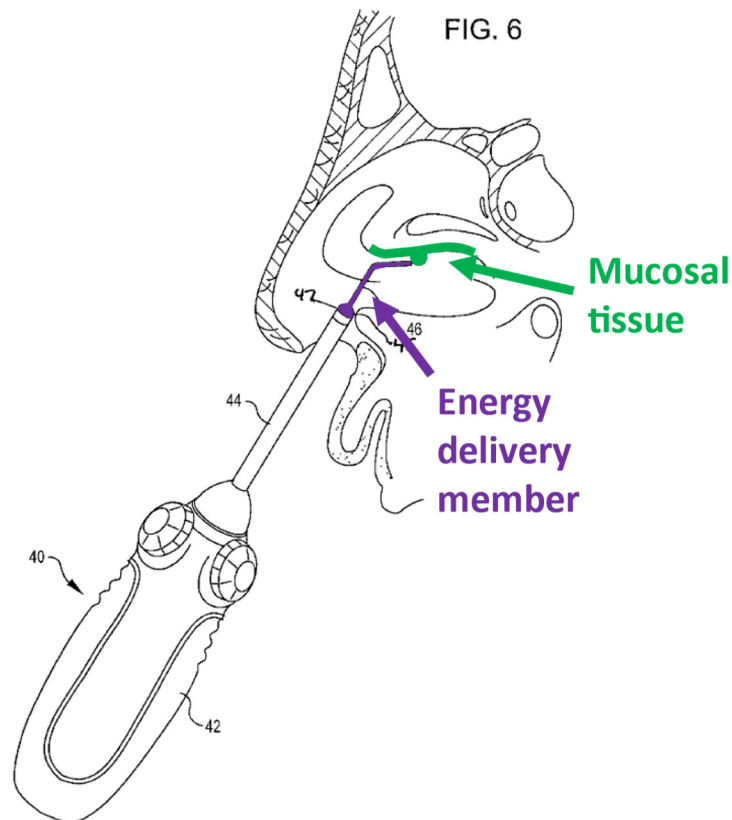
49. Figure 5 of Baker is reproduced below.



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.”).

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



Ex.1013-Baker, 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.

IX. CLAIM CONSTRUCTION

51. 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.

52. 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.

53. 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.

54. 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 THE GROUNDS

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

- Ground I: Claims 9, 14, 18, 20, 22-24, 44, and 46 are anticipated by Gertner under 35 U.S.C. §102.
- Ground II: Claims 9, 14, 18, 20, 22, 23, 44, and 46 are anticipated by Edwards-'535 under 35 U.S.C. §102.
- Ground III: Claim 16 is rendered obvious by Edwards-'535 under 35 U.S.C. §103.
- Ground IV: Claims 9, 14, 16, 19, 20, 22-24, 44, and 46 are anticipated by Baker under 35 U.S.C. §102.
- Ground V: Claim 14 is rendered obvious by Baker under 35 U.S.C. §103.

These grounds demonstrate in detail that claims 9, 14, 16, 18, 20, 22-24, and 46 are unpatentable as anticipated and obvious. A copy of the Challenged Claims are provided as **Appendix C**.

A. Ground I: Challenged Claims 9, 14, 18, 20, 22-24, 44, and 46 Are Anticipated by Gertner

56. As I explain in detail below, Gertner discloses each element of claims 9, 14, 18, 20, 22-24, 44, and 46 and therefore anticipates these claims.

1. Claim 9

a. Element 9[pre]: A method of treating a patient's nasal airway

57. I have been informed and understand that, in general, there are circumstances where the preamble of a claim does not limit the scope of the claim, and there are circumstances where the preamble does limit the scope of the claim.

In any event, even if the preamble of claim 9 is limiting, Gertner discloses the claimed method of treating a patient's nasal airway (e.g., a nasal cavity).

58. For example, Gertner's methods include using an optical therapy device (e.g., therapy device 200) to "provide therapeutic light to a target region of tissue within a nasal cavity." Ex.1019-Gertner, [0103]; *see also id.* [0003] ("The invention relates to devices and methods for delivering radiation to targeted regions of a nasal cavity, which includes the emission and propagation of energy in the form of rays or waves, including light, into the nasal cavity."), [0013]-[0018], FIG.4A. Gertner discloses treating a variety of medical conditions, including rhinitis, using therapeutic light. *Id.*, Abstract, [0007]-[0010], [0042], [0066] ("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."), [0103].

b. Element 9[a]: adjusting a shape of a nasal airway treatment device

59. Gertner's method includes the claimed step of adjusting a shape (e.g., expanding expandable component 218) of a nasal airway treatment device (e.g., therapy device 200).

60. Gertner teaches that light is delivered from a distal end 216 of therapy device 200 to target tissue within nasal cavity 10. Ex.1019-Gertner, [0106],

[0109], FIG.4A. As I explained above with reference to limitation 9[pre], the light is used to treat a nasal airway. Accordingly, a person of ordinary skill in the art would have understood therapy device 200 to be a nasal airway treatment device, as claimed.

61. Figure 4A of Gertner is reproduced below.

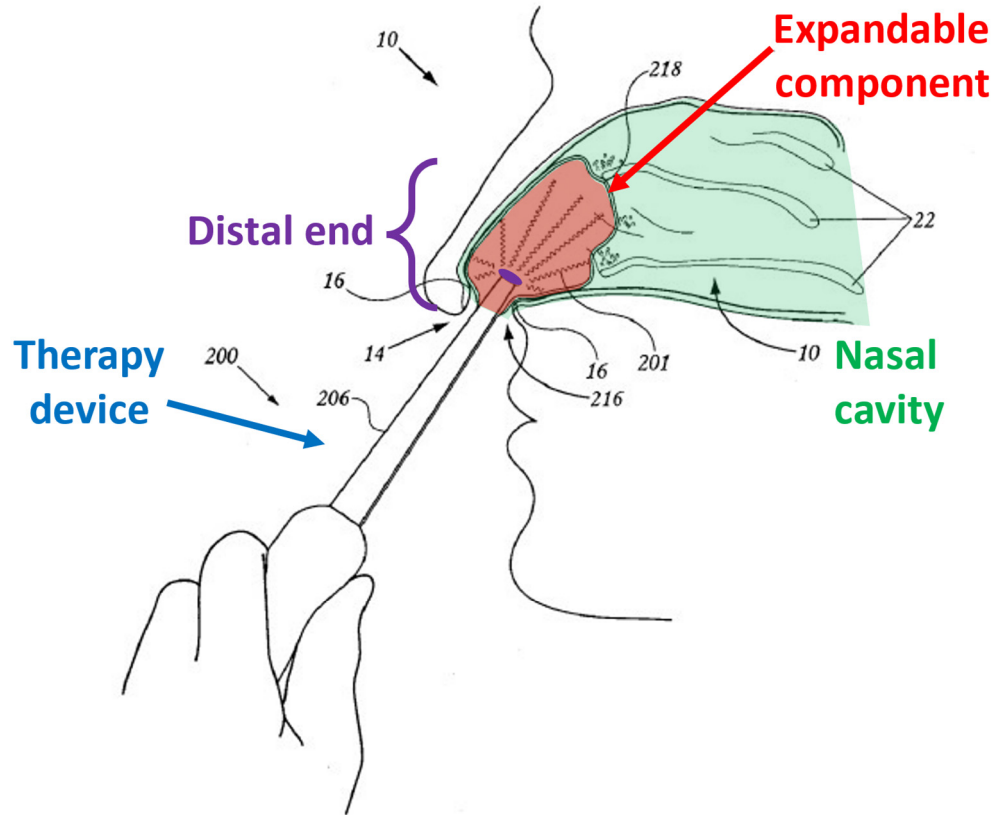


FIG. 4A

Id., FIG.4A. Figure 4A shows that the distal end 216 (purple) of therapy device 200 includes an expandable component 218 (red), which may be, for example, a

silicone balloon filled with water. *Id.*, [0106], [0107], [0111] (“the balloon is placed at the region of the limen nasi and then expanded with a fluid” such that “the balloon conforms to the anterior portion of the nasal cavity,” and “[a] typical silicone balloon filled with water satisfies this requirement.”). One of the purposes of expandable component 218 is to “hold[] the therapy device in place...while the phototherapy is being delivered.” *Id.*, [0103]. Accordingly, one way that a user (e.g., a clinician) adjusts the shape of treatment device 200 is by expanding expandable component 218 at the target location such that light can be delivered to the target tissue. *Id.*, [0103] (“When expended [*sic*: expanded], the expandable component...facilitate[s] positioning of the distal end...Because the expandable component 218 grips the walls of the nasal cavity, the therapy device can pivot and deliver light to various parts of the nasal cavity 10.”), [0107].

62. The '597 patent is explicit that the act of expanding a balloon (as Gertner teaches in connection with therapy device 200) satisfies the step of adjusting the shape of the treatment device. *E.g.*, Ex.1001-USP597, 7:5-8 (“[A]djusting the shape may involve inflating the treatment element to increase a surface area of the treatment element.”). Gertner therefore teaches the claimed step of adjusting a shape of the nasal airway treatment device.

c. Element 9[b]: contacting a treatment element of the treatment device with mucosal tissue in the patient's nasal airway;

63. Gertner's method includes a step of contacting a treatment element (e.g., distal end 216 of therapy device 200, including a light emitter and expandable component 218) of the treatment device (e.g., therapy device 200) with mucosal tissue (e.g., tissue within a nasal cavity 10) in the patient's nasal airway, as claimed.

64. As I explained above with reference to limitations 9[pre] and 9[a], Gertner's therapy device 200 (i.e., the claimed treatment device) emits light via its distal end 216, which also includes an expandable component 218. Specifically, the light is emitted from "within" the expandable component 218. Accordingly, the portions of distal end 216 used to deliver light to target tissue – including any light emitter(s), expandable component 218, light transmission media within expandable component 218, and the like – collectively form a treatment element as claimed. Ex.1019-Gertner, [0103], [0106]-[0107]. For example, each of these portions impacts the characteristics of the light that reaches the target tissue, e.g., expandable component 218 affects the uniformity of the light distribution. *Id.*, [0107] ("In the case where the expandable component 218 is a balloon, the therapeutic light is delivered to the tissue through the wall of the balloon. In one

embodiment, the balloon is used to compress the mucous of the nasal cavity and deliver a more relatively uniform distribution of light.”). Gertner’s disclosure of a treatment element that includes expandable component 218 and one or more therapeutic light emitters is consistent with the ’597 patent’s description of a similar treatment element that includes an inflatable balloon and energy delivery elements. *See* Ex.1001-USP597, 29:12-15 (“the treatment element 32 may be a balloon with energy delivery elements positioned at locations where energy transfer is sufficient or optimal to effect change in breathing.”). For example, Figure 19A of the ’597 patent depicts RF electrodes positioned on an inflatable balloon to transfer sufficient energy to treat tissue, and Figure 4A of Gertner similarly includes light emitting elements within the expandable component 218 that perform the same function.

65. Figure 4A of Gertner is reproduced below.

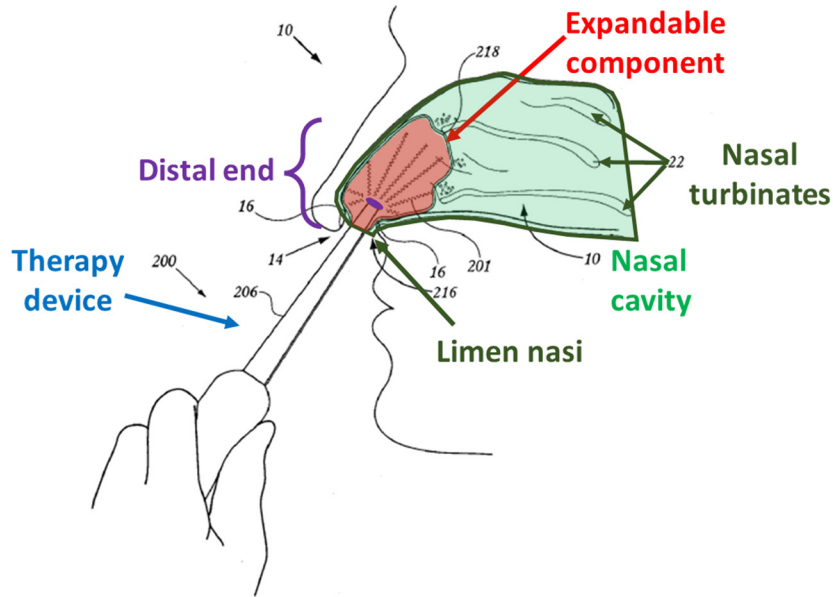


FIG. 4A

Id., FIG.4A. Figure 4A shows that the expandable component 218 (red) is in contact with mucosal tissue that lines the surface of the nasal cavity. Because expandable component 218 is part of a treatment element, as claimed, Gertner therefore teaches that the treatment element contacts mucosal tissue.

66. Gertner identifies various structures within the nasal cavity contacted by expandable component 218, each of which are lined by mucosal tissue. For example, Gertner teaches that expandable component 218 “holds the therapy device in place in a space between a nasal septum and a lateral wall of the nasal cavity,” “grips the walls of the nasal cavity,” and “expand[s] the limen nasi 16 or other portions of the nasal cavity by either an expanding or wedging action.” *Id.*,

[0037], [0103], FIGs.1A, 4A. Figure 4A also shows that expandable component 218 contacts the nasal turbinates, such that “light reaches the turbinates 22.” *Id.*, [0108]; *see also id.*, [0037] (describing turbinates lined with “overlying mucosa”). Accordingly, Gertner teaches that expandable component 218 (i.e., part of the claimed treatment element) contacts mucosal tissue in the patient’s nasal airway (including nasal airway structures such as the limen nasi 16, the nasal cavity, the turbinates 22, and the nasal septum) as claimed.

d. Element 9[c]: delivering an energy based therapy to at least one of the mucosal tissue or an underlying tissue beneath the mucosal tissue, using the treatment element; and

67. Gertner’s method includes a step of delivering an energy based therapy (e.g., therapeutic light) to at least one of the mucosal tissue (e.g., tissue within a nasal cavity 10) or an underlying tissue beneath the mucosal tissue, using the treatment element (e.g., distal end 216), as claimed.

68. As I explained above with reference to limitations 9[b], when “light 201 is emitted” from distal end 216 (i.e., the claimed treatment element), that light is delivered “into the nasal cavity.” Ex.1019-Gertner, [0103]-[0104], [0106]-[0109]. Because light is a type of energy, and its purpose is to treat upper airway conditions such as rhinitis, a person of skill in the art would have understood the

delivery of light via distal end 216 to be an energy based therapy, as claimed. *See supra*, § X.A.1.a. The '597 patent makes clear that light therapy (such as the light therapy of Gertner) is an energy based therapy because it is listed as a possible energy based therapy in Claim 18. Ex.1001-USP597, Clm.18 (“A method as in claim 9, wherein delivering the energy based therapy comprises delivering energy in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light, laser and quantic molecular resonance.”).

69. Figure 4A of Gertner is reproduced below.

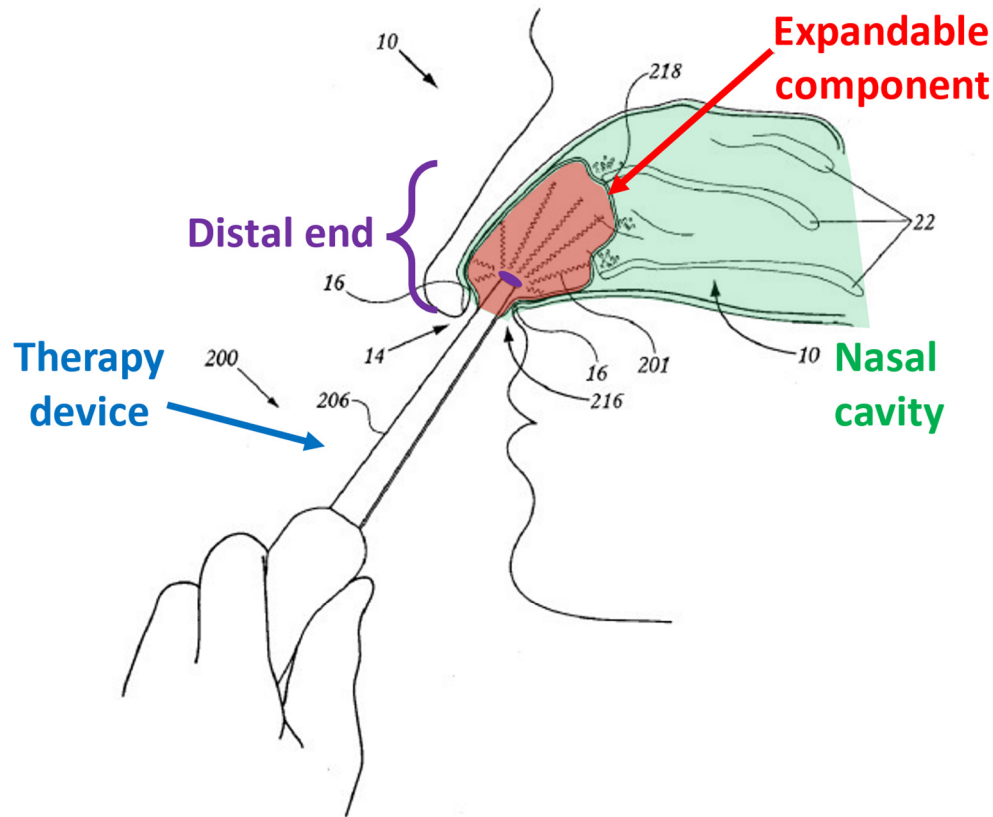


FIG. 4A

Ex.1019-Gertner, FIG.4A. As shown in Figure 4A, and as I explained with reference to limitations 9[b], distal end 216 includes an expandable component 218 (red), which is part of the claimed treatment element. When delivering light therapy, “the therapeutic light is delivered to the tissue through the wall” of expandable component 218 and into the mucosal tissue (e.g., the tissue lining the turbinates, the limen nasi, and/or the nasal septum, *see supra* §X.A.1.c) that is in contact with expandable component 218. Ex.1019-Gertner, [0107], [0109] (“the

therapeutic light emitted from distal end 216 and travels through the expandable component 218.... A distal portion of the expandable component transmits the therapeutic light 201 through the wall of the expandable component and to the tissue of the nasal cavity 10.”); *see also id.*, [0103], [0067], [0106]-[0108], FIG.4A. Accordingly, Gertner teaches the claimed step of delivering an energy based therapy to mucosal tissue using the treatment element (e.g., distal end 216 including expandable component 218 and light emitting and/or light transmitting components within expandable component 218).

e. Element 9[d]: removing the treatment element from the nasal airway.

70. Gertner’s method includes the claimed step of removing the treatment element (e.g., distal end 216) from a patient’s nasal airway (e.g., nasal cavity 10). A person of ordinary skill in the art would have readily understood that Gertner’s method involves removing the treatment element after the treatment is delivered, as it would be impractical for patients to keep the device of Gertner – a large externally operated device which is not intended as an implant – inserted in their nasal passages indefinitely. Consistent with this understanding, Gertner expressly discloses that device 200 (including distal end 216 that includes the claimed

treatment element) is “withdraw[n]...from the nasal cavity.” Ex.1019-Gertner, [0112].

2. Claim 14: A method as in claim 9, wherein adjusting the shape comprises manipulating a secondary component of the treatment element to increase a surface area of the treatment element.

71. Gertner teaches that the step of adjusting the shape, as recited by limitation 9[a], further includes manipulating (e.g., expanding) a secondary component (e.g., expandable component 218) of the treatment element (e.g., distal end 216) to increase a surface area of the treatment element (e.g., expanding the expandable component 218), as recited by claim 14.

72. As I explained above with reference to limitation 9[a], expandable component 218 (i.e., part of the claimed treatment element) is filled with water or otherwise manipulated when placed within the nasal cavity to cause expandable component 218 to expand. Ex.1019-Gertner, [0106], [0107], [0111] (“the balloon is placed at the region of the limen nasi and then expanded with a fluid” such that “the balloon conforms to the anterior portion of the nasal cavity,” and “[a] typical silicone balloon filled with water satisfies this requirement.”). Figure 4A, reproduced below, shows that expanding (i.e., manipulating) expandable component 218 (red) increases its surface area.

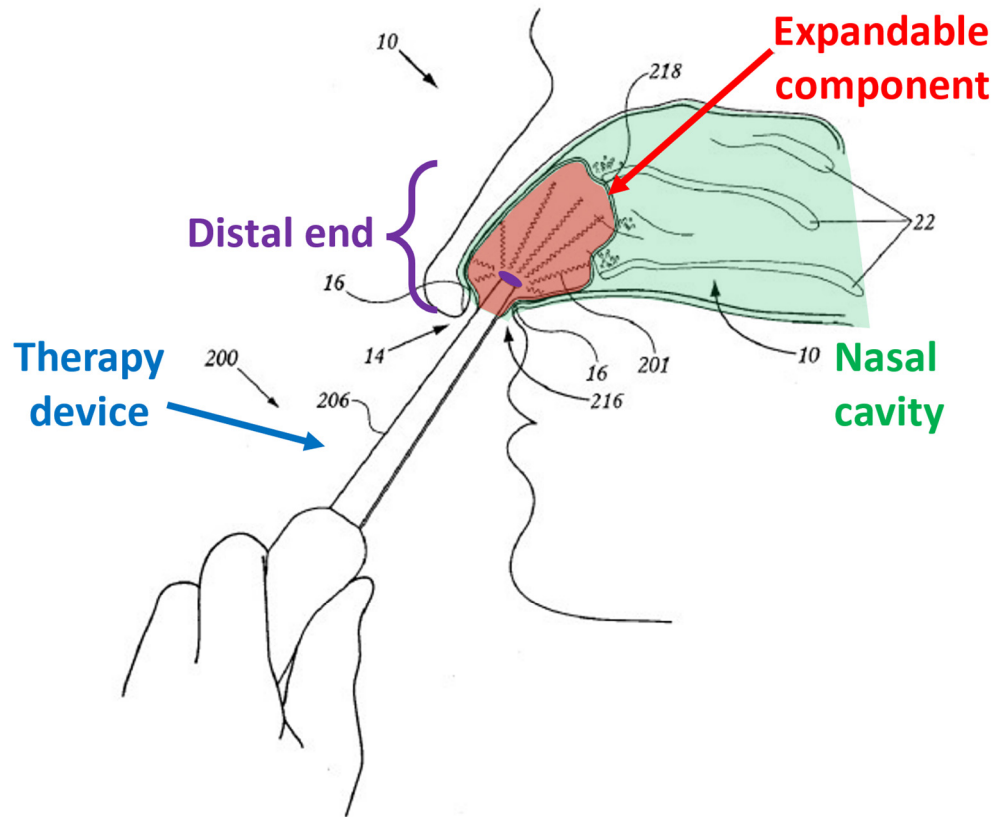


FIG. 4A

Id., FIG.4A; *see also id.*, [0103], [0106]- [0109].

73. A person of ordinary skill in the art would have understood expandable component 218 to be a “secondary component” of the treatment element (e.g., distal end 216), particularly given that the treatment element includes other components (e.g., components used to emit and/or transmit light) that would have been regarded as having a more primary role in the delivery of

light therapy. The functions of expandable component 218, on the other hand, have a secondary role in facilitating the placement and delivery of the light therapy.

- 3. Claim 16: A method as in claim 9, wherein adjusting the shape comprises forming at least one bend in a shaft of the treatment device.**

74. Gertner teaches that the step of adjusting the shape, as recited by limitation 9[a], further includes forming at le

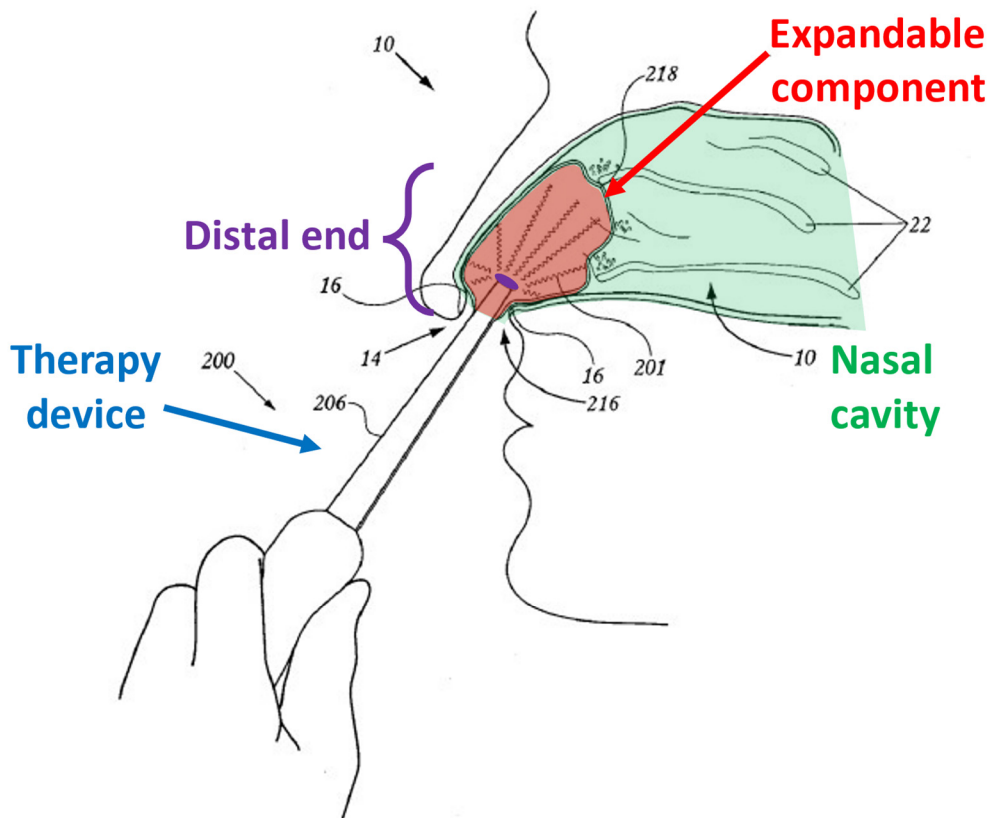


FIG. 4A

Figure 4A shows that therapy device 200 includes an elongate body 206 used to position expandable component 218 at a target site within the nasal passages of a patient. *Id.*, [0106] (“expandable component 218 can be positioned at the distal end 216 of the elongate body 206 such that it extends proximally and distally with respect to the distal end 216”).

76. In connection with a similar embodiment of a therapy device 100 shown in Figure 2A, Gertner teaches that an elongate insertion member 106 (which corresponds to elongate body 206 of therapy device 200) can be made of “flexible materials so that it can bend, or be steered around corners, or conform to the shape of the cavity, as required.” *Id.*, [0077]; *see also id.*, [0072] (“In one embodiment, the insertion member 106 is flexible so that its shape and orientation with respect to the housing or hand piece 102 may be adjusted. A flexible material. Such as rubber, plastic, or metal may be used to construct the insertion member 106, and to provide flexibility thereto. In one embodiment, a goose-neck tube, or spiral wound coil is used to provide a flexible insertion member 106.”). A person of ordinary skill in the art would have understood that Gertner’s description of embodiments in which elongate insertion member 106 (as shown in Figure 2A) is flexible and steerable applies equally to the elongate body 206 shown in Figure 4A. This is particularly true given that Figure 4A depicts a therapy device 200 that has a

modified distal end relative to therapy device 100 in Figure 2A but is otherwise similar with respect to components that are proximal to the distal end, including the elongate body. *Compare id.*, FIG.4 *with id.*, FIG.5. Gertner does not otherwise specify any differences between elongate body 206 in Figure 4A and the elongate insertion member 106 in Figures 2A. *Id.*

77. Furthermore, a person of ordinary skill in the art would have understood that bending elongate body 206 to reach target locations within the nose would have resulted in forming at least one bend in a shaft (e.g., elongate body 206) of the treatment element, as claimed.

4. **Claim 18: A method as in claim 9, wherein delivering the energy based therapy comprises delivering energy in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light, laser and quantic molecular resonance.**

78. Gertner teaches that the step of delivering the energy based therapy, as recited by limitation 9[c], further includes delivering energy in a form selected from the claimed group (e.g., light). For example, as I explained above with reference to limitations 9[p] and 9[c], the distal end 216 of Gertner's treatment device includes a treatment element that delivers energy "in the form of rays or waves, including light, into the nasal cavity." Ex.1019-Gertner, [0003]; *see also id.*, [0103]-[0104], [0106]-[0109].

5. Claim 20: A method as in claim 9, wherein the mucosal tissue is located in a part of the nasal airway other than an internal nasal valve of the airway.

79. Gertner teaches that the mucosal tissue, as recited by limitations 9[b] and 9[c], is located in a part of the nasal airway other than an internal nasal valve of the airway (e.g., limen nasi, nasal turbinates 22, and/or nasal septum). For example, as I explained above with reference to limitations 9[b] and 9[c], Gertner teaches that light therapy is applied to mucosal tissue of the nasal turbinates, posterior to the limen nasi, and/or nasal septum. A person of ordinary skill in the art would have understood from textbook knowledge of nasal anatomy that these structures are not located within an internal nasal valve, particularly given that the nasal valve spans just a small portion of the nose at the front of the nasal cavity that is bounded by the front of the inferior turbinate but does not include the turbinates, the limen nasi, or the nasal septum. As Gertner itself observes, “the nasal valve tissue is limited to the lateral aspect of the nasal vestibule 14.” Ex.1019-Gertner, [0038]; *see also id.* [0103]-[0104] (disclosing delivery of light posterior to the limen nasi but not to the “nasal valve”).

80. For example, Figure 4A of Gertner (reproduced below) depicts the expandable component 218 filling up and contacting surfaces of the nasal cavity

that are not limited to the head of the inferior turbinate where the internal nasal valve is located.

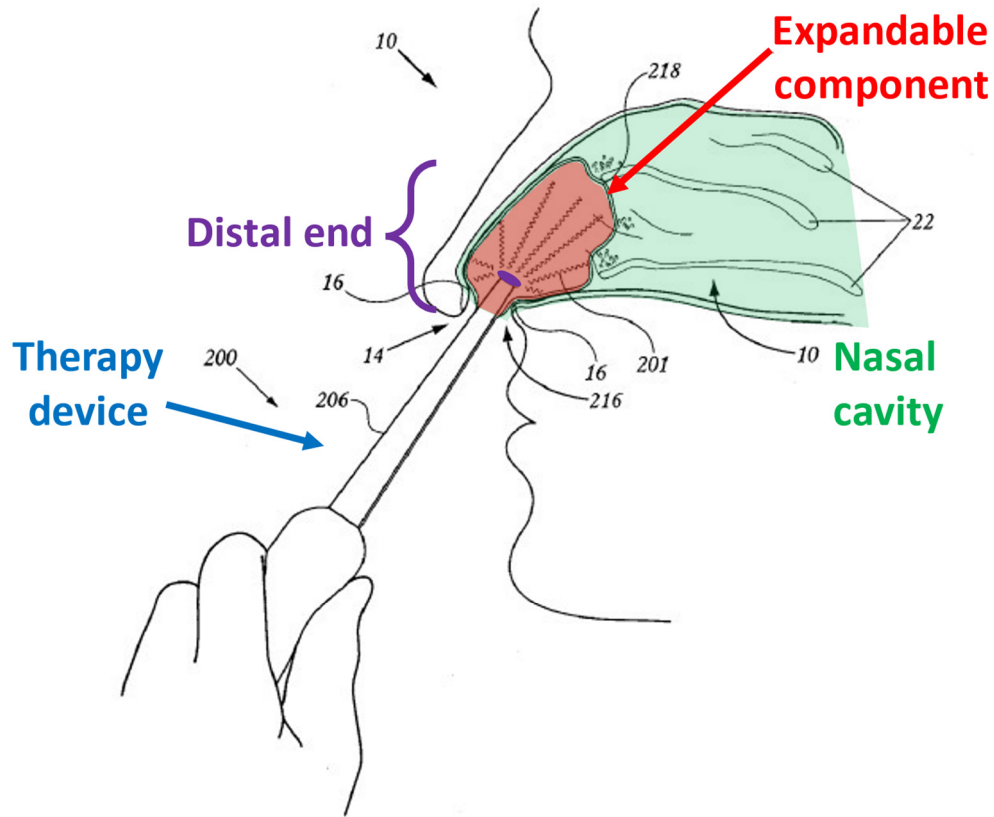


FIG. 4A

Id., FIG.4A; *see also id.*, FIG. 1A.

81. More generally, a person of ordinary skill in the art would have recognized that devices such as Gertner's therapy device 200 are routinely used to deliver treatment to various different areas of the nasal passages where energy based therapy is likely to be effective. For example, given that the same or similar

types of tissue (e.g., mucosa) are present throughout different portions of the nasal passages, treatment methods and devices for the nose would have been generally regarded as being useful to treat multiple anatomical structures, as opposed to being limited in applicability to any one specific structure. *See* Ex.1019-Gertner, [0103] (“the therapy device can pivot and deliver light to various parts of the nasal cavity 10”); Ex.1017-Baker, 17:11-13 (“Energy delivery member 26 may be provided at the tip of the insertion wand and configured for positioning in proximity to and/or contacting blockages within nasal passages, mucous membranes and nasal turbinates, or pathological or undesired tissue.”). The ’597 patent similarly states that its techniques are broadly applicable to treat “the tissue of the nose, including but not limited to skin, muscle, mucosa, submucosa, and cartilage in the area of the nasal valves.” Ex.1001-USP597, 11:6-10.

6. **Claim 22: A method as in claim 20, wherein the wherein [sic] mucosal tissue includes tissue selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum within the nasal valve, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity.**

82. Gertner teaches that the mucosal tissue, as recited by limitations 9[b] and 9[c] and claim 20, includes mucosal tissue of at least one of the nasal septum

within the nasal valve or the nasal septum outside of the nasal valve, as recited by claim 22. For example, as I explained above with reference to limitations 9[b] and 9[c] and claim 20, Gertner teaches that light therapy is applied to mucosal tissue of the nasal septum. Ex.1019-Gertner, [0103] (“An expandable component 218 holds the therapy device in place in a space between a nasal septum and a lateral wall of the nasal cavity while the phototherapy is being delivered posterior to the limen nasi.”). A person of ordinary skill in the art would have understood that the portion of the nasal septum being contacted and treated in Gertner’s method is necessarily located at least one of “within” or “outside of” the nasal valve, as claimed, as those two locations collectively encompass the entire nasal septum. Moreover, as explained above for claim 20, a person of ordinary skill in the art would have understood that devices such as Gertner’s therapy device 200 are routinely used to deliver treatment to various different areas of the nasal passages where energy based therapy is likely to be effective and are not limited in applicability to any specific anatomical structure.

7. Claim 23: A method as in claim 9, further comprising applying force to the mucosal tissue with the treatment

element at least one of before, during or after delivering the energy based therapy to deform the mucosal tissue.

83. Gertner's method includes the claimed step of applying force to the mucosal tissue (e.g., tissue within a nasal cavity 10) with the treatment element (e.g., distal end 216) at least one of before, during or after delivering the energy based therapy (e.g., therapeutic light) to deform the mucosal tissue.

84. As I explained above with reference to limitations 9[a] and 9[b], Gertner's expandable component 218 is inflated by applying water pressure (or that of another fluid). Because expandable component 218 is in contact with mucosal tissue during inflation, the outward-facing fluid pressure also causes the surface of expandable component 218 to apply force to the mucosal tissue, as claimed. In turn, a person of ordinary skill in the art would have understood that the force applied to the mucosal tissue deforms the mucosal tissue, as claimed, particularly given that mucosal tissue and its underlying tissues are soft and malleable such that virtually any amount of force would create at least a temporary deformation. For example, based on my extensive first-hand experience treating patients' nasal passages, the nasal mucosal tissue and its underlying tissues are significantly more malleable than, for example, the tissues lining various parts of the palm of the hand, which themselves deform temporarily under even a slight

amount of pressure. *See also* Ex.1060-Lane, 388 (“The lateral nasal wall presents an irregularly shaped surface characterized by the inferior, middle, and superior turbinates (Fig. 1). Scroll-like in shape and pitted, the conchal bones support the ***soft tissue*** erectile component of the turbinates.”) (emphasis added).

85. Consistent with this understanding, Gertner teaches that expandable component 218 “wedge[s] open” (i.e., deforms) a portion of “the nasal cavity 10,” consistent with how expandable chamber 218 (red) is depicted contacting tissue in a wedged manner in Figure 4A. Ex.1019-Gertner, [0108].

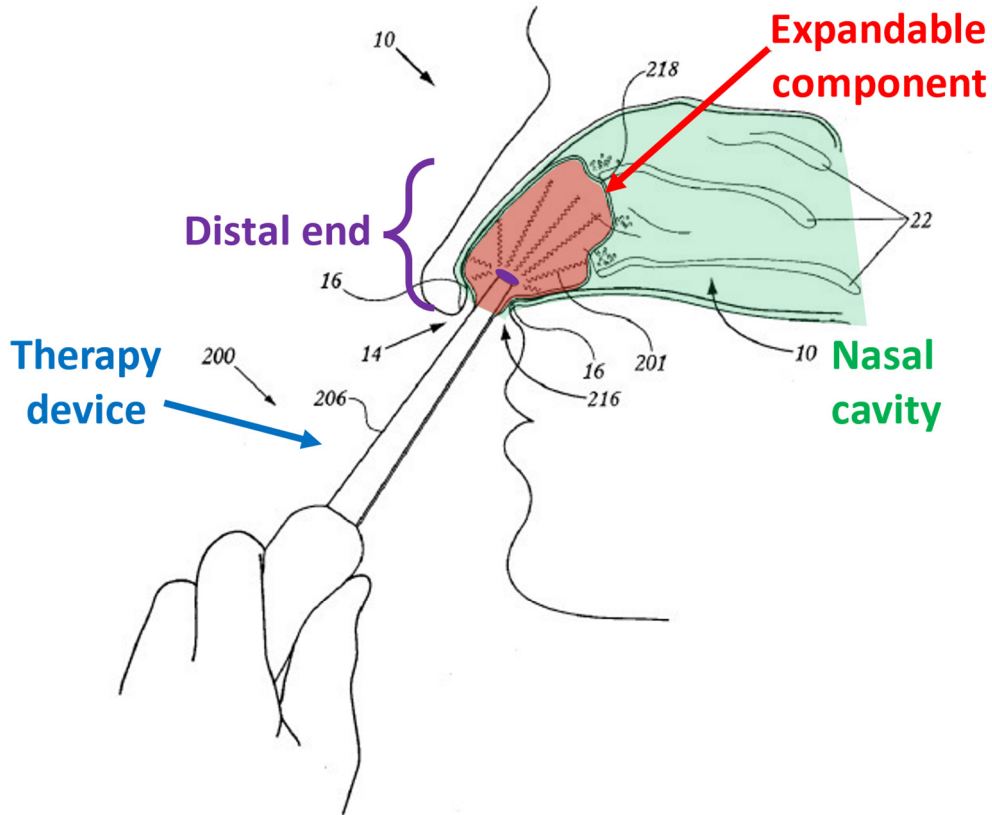


FIG. 4A

Id., FIG.4A.

86. Force is applied to the mucosal tissue in the manner described above before and/or during delivering the energy based therapy as claimed. For example, Gertner teaches that the force is applied during the therapy (i.e., while the light is being emitted) to “deliver a more relatively uniform distribution of light.” *Id.*, [0107]. Gertner also teaches that the force is applied before the therapy as “[t]he expandable component 218 can be filled or expanded prior to placement in the

nose or after insertion into the nasal cavity 10.” *Id.*, [0108]. Namely, if the expandable component 218 is filled before insertion it will apply force to the nasal passages (and the overlying tissues) on the way into the nasal passages before the light energy is being applied to the target tissue. The force is then maintained throughout the treatment to sustain the contact between expandable component 218 and the nasal tissues. *Id.*, [0103], [0106]-[0109].

8. Claim 24: A method as in claim 9, wherein delivering the energy based therapy modifies at least one property of the mucosal tissue or the underlying tissue without reshaping the tissue.

87. Gertner teaches that the step of delivering the energy based therapy (e.g., therapeutic light), as recited by limitation 9[c], modifies at least one property of the mucosal tissue or the underlying tissue (e.g., tissue within a nasal cavity 10) without reshaping the tissue.

88. Gertner explains that there are many clinical benefits to applying light energy to nasal tissues using the disclosed techniques, such as eliminating infections, reducing effects or symptoms of diseases caused by atopy (e.g., rhinitis, asthma), treating psoriasis or vitiligo, minimizing lesions or marks, reducing mucus production (e.g., “dryness”), and “histologic transformation from respiratory epithelium to squamous epithelium.” Ex.1019-Gertner, [0005]-[0011],

[0040], [0157]. A person of ordinary skill in the art would have understood in order to have meaningful clinical effects like those Gertner discloses, the treatment modifies mucosal tissue as claimed. For example, the treatment would have been understood to ablate (remove), disrupt, or otherwise modify mucosal tissue in a manner that reduces excessive mucus production and/or mitigates any of the other symptoms of rhinitis (and other conditions) identified by Gertner.

89. In addition, a person of ordinary skill in the art would have understood that Gertner's application of light energy does not reshape tissue as light therapy is intended to a modify tissue in clinically beneficial ways without having more severe effects, e.g., those associated with reshaping tissue. Consistent with this understanding, Aerin itself acknowledged that Gertner's techniques deliver energy without reshaping tissue when presenting arguments to the Patent Office in an attempt to distinguish Gertner from the claims of the '597 patent's parent application. Ex.1018-USP594FH, 266-268 (Aerin asserting that Gertner contains "no teaching that the therapeutic light changes the shape of nasal tissue.").

9. Claim 44

a. Element 44[pre]: A method of treating a patient's nasal airway

90. The preamble of claim 44 is the same as that of claim 9, and therefore Gertner discloses the preamble for the same reasons that I explained above for limitation 9[pre].

b. Element 44[a]: contacting a treatment element of a treatment device with a first mucosal tissue located in a part of the nasal airway other than an internal nasal valve of the airway

91. Limitation 44[a] is simply a combination of limitation 9[b] and claim 20, and therefore Gertner discloses limitation 44[a] for the same reasons that I explained above for those limitations.

c. Element 44[b]: delivering an energy based therapy to at least one of the first mucosal tissue or an underlying tissue beneath the first mucosal tissue, using the treatment element

92. Limitation 44[b] is the same as limitation 9[c], and therefore Gertner discloses limitation 44[b] for the same reasons that I explained above for limitation 9[c].

d. Element 44[c]: removing the treatment element from the nasal airway.

93. Limitation 44[c] is the same as limitation 9[d], and therefore Gertner discloses limitation 44[c] for the same reasons that I explained above for limitation 9[d].

10. Claim 46: A method as in claim 44, wherein the wherein mucosal tissue includes tissue selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity.

94. Dependent claim 46 recites the same additional limitations as dependent claim 22, and therefore Gertner discloses claim 46 for the same reasons that I explained above for claim 22.

B. Ground II: Challenged Claims 9, 14, 18, 20, 22, 23, 44, and 46 are Anticipated by Edwards-'535

95. As I explain in detail below, Edwards-'535 discloses each element of claims 9, 14, 18, 20, 22, 23, 44, and 46 and therefore anticipates these claims.

1. Claim 9

a. Element 9[pre]: A method of treating a patient's nasal airway

96. 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 9 is limiting,

Edwards-'535 discloses it. Namely, Edwards-'535 teaches the claimed method of treating a patient's nasal airway (e.g., nasal concha).

97. Edwards-'535 discloses techniques that aim to treat nasal conditions and improve air flow through the nasal passages using "a method...for treating airway obstructions." Ex.1010-Edwards-'535, 1:22-50, 1:60-66, 4:19-32, 6:66-7:4, 7:12-25, Clm.1. Figure 3B of Edwards-'535 is reproduced below.

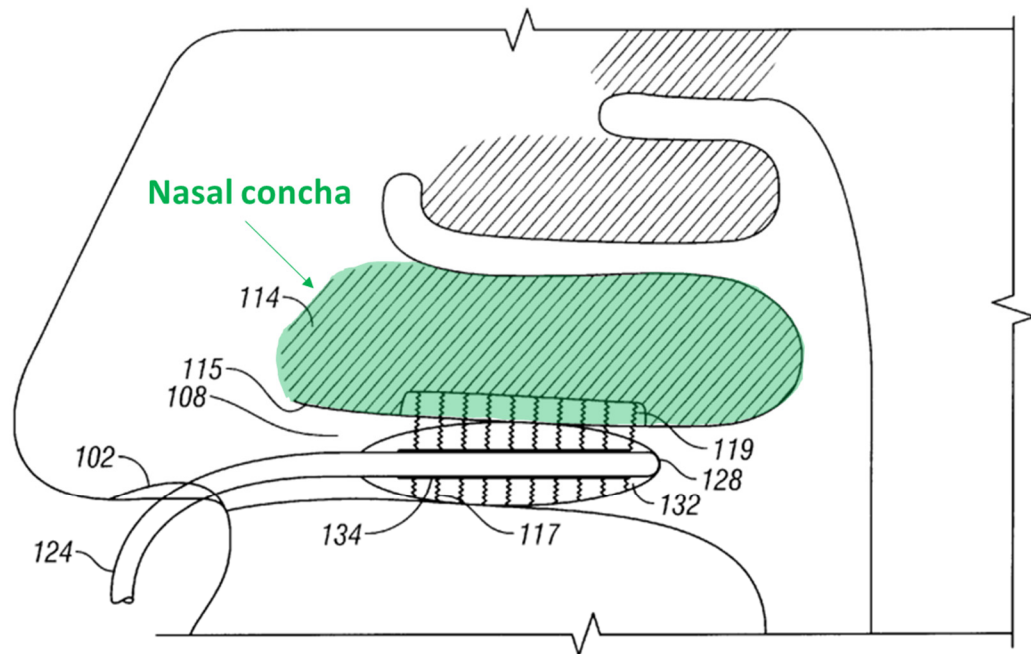


FIG. 3B

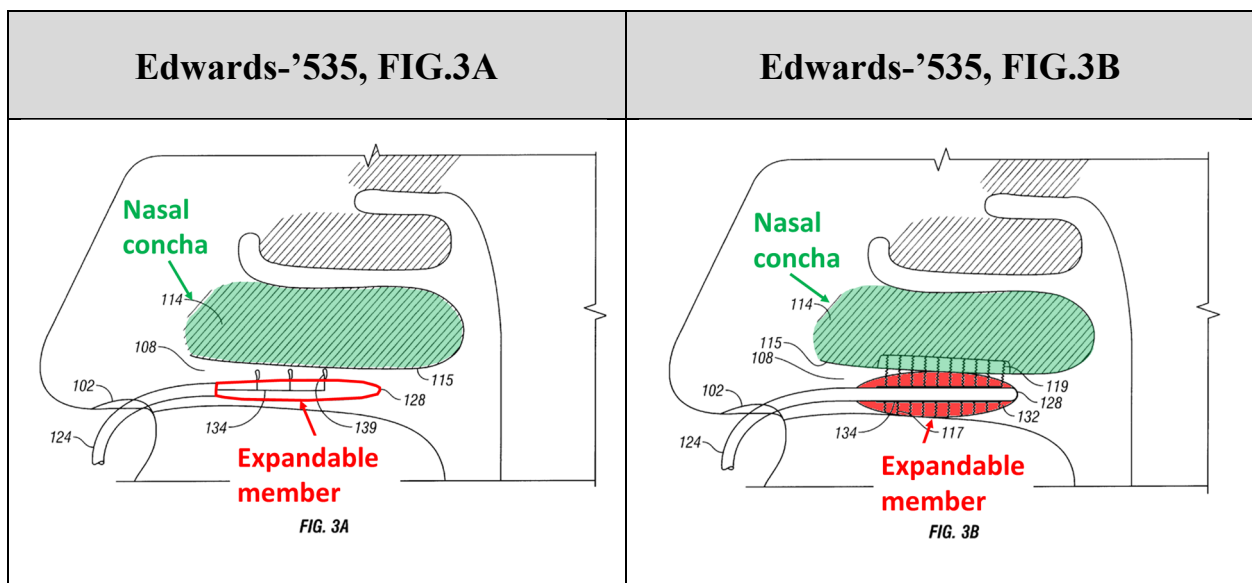
Ex.1010-Edwards-'535, FIG.3B. Figure 3B illustrates how Edwards-'535's method seeks to deliver treatment to the nasal concha (another term for turbinate) (green) by

“ablating at least a portion of a nasal concha (turbinate).” *Id.*, 4:19-32; *see also id.*, Abstract, 1:22-41, 4:63-67, 5:9-15, 6:59-7:4, 7:12-25, Clm.1.

b. Element 9[a]: adjusting a shape of a nasal airway treatment device

98. Edwards-’535’s method includes the claimed step of adjusting a shape (e.g., inflating) of a nasal airway treatment device (e.g., apparatus 124).

99. For example, Edwards-’535 method includes treating the nasal concha (i.e., part of the nasal airway) using “an apparatus 124 having a distal portion 128 with an expandable member 132.” Ex.1010-Edwards-’535, 5:20-26; *see also id.*, 5:27-35 (using expandable member 132 to deliver energy to a “nasal concha 114 to be treated”), 5:51-61, 7:37-53, FIGs.3A-3C. The use of expandable member 132 (red) is illustrated in Figures 3A and 3B below.



Figures 3A and 3B show that “expandable member 132 [(red)] is brought into contact with the surface 115 of the nasal concha 114 [(green)].” *Id.*, 5:27-35.

Once inserted to the nasal passages, expandable member 132 is expanded (i.e., its shape is adjusted, as claimed) by “delivering a medium into the expandable member.” *Id.*, 5:18-35, 5:51-61, FIG.3B. Moreover, as I explained above for the same limitation in Ground I, by using an expandable member Edwards-’535 teaches adjusting the shape of the treatment device in the same manner as one of the corresponding embodiments of the ’597 patent (i.e., using an expandable balloon). *See* Ex.1001-USP597, 17:4-7.

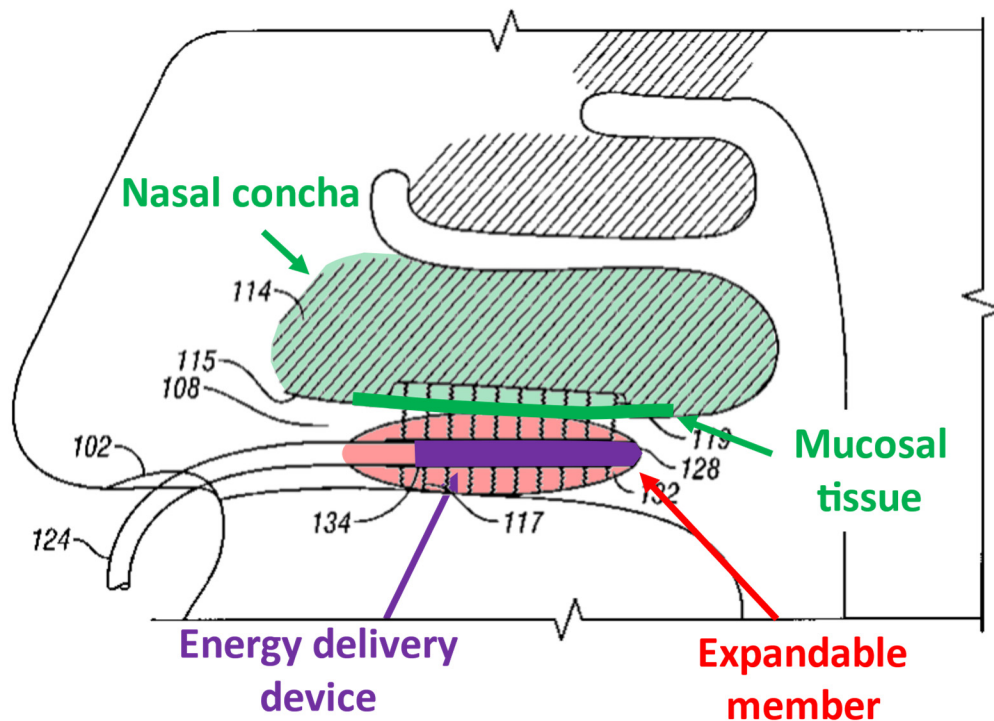
c. Element 9[b]: contacting a treatment element of the treatment device with mucosal tissue in the patient’s nasal airway;

100. Edwards-’535’s method includes the claimed step of contacting a treatment element (e.g., distal portion 128) of the treatment device (e.g., apparatus 124) with mucosal tissue (e.g., nasal concha 114) in the patient’s nasal airway. In fact, this step is performed when carrying out Edwards-’535’s method using any one of multiple device arrangements disclosed by Edwards-’535. For example, as I explain in further detail below, Edwards-’535 satisfies this limitation when using either (a) a device that includes energy delivery device 134 within expandable

chamber 132 and (b) a device that includes energy delivery device 134 on the surface of expandable chamber 132.

101. In either arrangement, distal portion 128 is used as a treatment element, as claimed, given that energy delivery device 134 and expandable member 132 apply “ablative energy” to the nasal concha (turbينات), i.e., the claimed nasal airway, in order to treat the turbinates. Ex.1010-Edwards-’535, 5:18-27, FIGs.3A-4A; *see also* limitation 9[pre].

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



Id., FIG.3B. Figure 3B shows that “the expandable member 132 [(red)] is expanded within the nasal meatus 108 so that the expandable member 132 is brought into contact with the surface 115 of the nasal concha 114 [(green)] to be treated.” *Id.*, 5:27-35; *see also id.*, 4:53-67, 5:46-61, 7:18-25, 8:18-25, Clm.1, FIG.3B. A person of skill in the art would have understood from Edwards-’535’s teachings and textbook knowledge of nasal anatomy that mucosal tissue lines the surface 115 of the nasal concha 114 and is therefore contacted by the treatment element. *Id.*, 7:18-25; *see also* Ex.1021-Makower, [0004] (“The nasal turbinates

...extend inwardly from the lateral walls of the nose and are covered with mucosal tissues”); Ex.1060-Lane, 392.

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

104. Edwards-’535 discloses a variety of ways to position energy delivery device 134 on the surface of expandable member 132, including using “ring electrodes 156 disposed on the surface of the expandable member 132,” *id.*, 8:17-25, FIG.6, and by using known “surface energy delivery devices,” *id.*, 8:30-33. Consistent with this disclosure, Edwards-’535 incorporates by reference another patent, Baker-’788, that discloses examples of a “suitable surface” for expandable member 132. *Id.*, 8:27-30 (incorporating by reference the disclosures of Baker-’788 and describing the teachings as “[a]n example of a suitable surface for disposition on the membrane”). For example, Baker-’788 teaches that the surface can be “implanted with ions” and/or “coated with a material that improves its

conductivity.” Ex.1011-Baker-’788, 7:45-65 (“Conforming member 20 is made of a material that suitably conforms to a surface to be ablated.... Conforming member 20 can be implanted with conductive ions, and conductive surface 24 can be coated with a material that improves its conductivity.”).

d. Element 9[c]: delivering an energy based therapy to at least one of the mucosal tissue or an underlying tissue beneath the mucosal tissue, using the treatment element; and

105. Edwards-’535’s method includes the claimed step of delivering an energy based therapy (e.g., ablative energy) to at least one of the mucosal tissue (e.g., surface 115 of nasal concha 114) or an underlying tissue beneath the mucosal tissue (e.g., tissue within nasal concha 114), using the treatment element (e.g., distal portion 128).

106. As I explained above with reference to limitation 9[b], distal portion 128 (i.e., the claimed treatment element) of Edwards-’535’s device delivers ablative energy with the aim of reducing the size of the nasal concha 114 and thereby treating upper airway conditions. Accordingly, a person of skill in the art would have understood distal portion 128 to deliver an energy based therapy, as claimed.

107. In addition, Edwards-'535 teaches that once “expandable member 132 is brought into contact with the surface 115 of the nasal concha 114 to be treated,” “[s]ufficient [ablative] 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.” Ex.1010-Edwards-'535, 5:27-35. Therefore, given a person of ordinary skill in the art’s textbook knowledge that surface 115 of the nasal concha 114 includes and/or is lined by mucosal tissue, a person of ordinary skill in the art would have recognized that the ablative energy is applied to mucosal tissue, as claimed.

108. Further confirmation that the ablative energy is applied to mucosal tissue, as well as underlying tissue, is seen in Figure 3B, reproduced below.

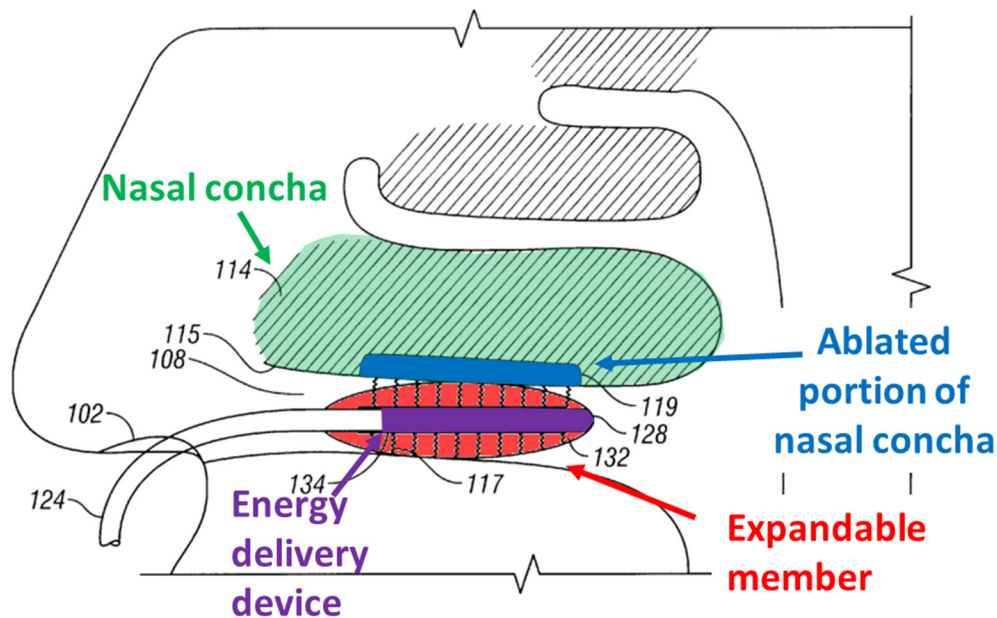


FIG. 3B

Ex.1010-Edwards-'535, FIG.3B. Figure 3B shows that ablative energy is delivered to “at least a portion 119 [(blue)] of the nasal concha 114 [(green)],” where portion 119 corresponds to the surface of nasal concha 114 (which is lined by mucosal tissue) and sub-surface portions of nasal concha 114 (i.e., underlying tissue beneath the mucosal tissue, as claimed). *Id.*, 5:27-35, FIG.3B; *see also id.*, FIG.3D (same).

109. Although not necessary to satisfy limitation 9[c], Edwards-'535 also discloses techniques to facilitate targeting underlying tissue in which “the surface of the nasal concha to be ablated is cooled during the delivery of energy to ablate the nasal concha...to prevent the nasal concha surface from being ablated.” *Id.*, 6:10-22; *see also id.*, 4:53-67; 6:23-37. “As a result, an interior portion of a nasal concha is ablated without ablating the surface of the nasal concha.” *Id.*, 6:14-16; *see also id.*, 6:23-32. This cooling technique is depicted in Figure 4A, reproduced below.

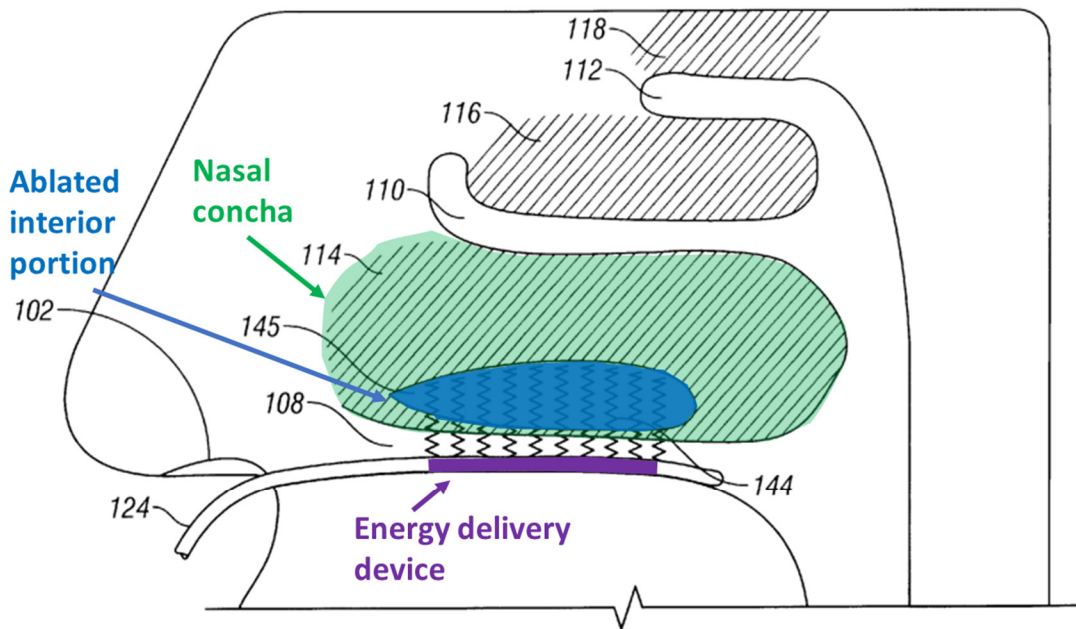


FIG. 4A

Id., FIG.4A. Figure 4A shows that an interior portion (blue) of nasal concha 114 (green) (i.e., underlying tissue beneath the mucosal tissue, as claimed) is ablated whereas the overlying mucosal tissue is preserved. *Id.*, FIG.4A; *see also id.*, FIG.4B-4C, 3:57-65, 6:9-22, 6:66-7:4.

e. Element 9[d]: removing the treatment element from the nasal airway.

110. Edwards-'535's method includes the claimed step of removing the treatment element (e.g., distal portion 128) from a patient's nasal airway. As I explained above for the same limitation in Ground I, a person of ordinary skill in the art would have readily understood that Edwards-'535's method involves

removing the treatment element after the treatment is delivered, as it would be impractical for patients to keep the device of Edwards-'535 – a large externally operated device which is not intended as an implant – inserted in their nasal passages indefinitely.

111. Consistent with this understanding, Edwards-'535 discloses two figures (Figures 4B and 4C) depicting a patient's nasal passages after the procedure. Unlike Figure 4A, which illustrates the device inserted into the patient's nasal airway during the ablation procedure, Figures 4B and 4C demonstrate that the device has been removed from the patient's nasal airway as claimed. Ex.1010-Edwards-'535, 6:66-7:25.

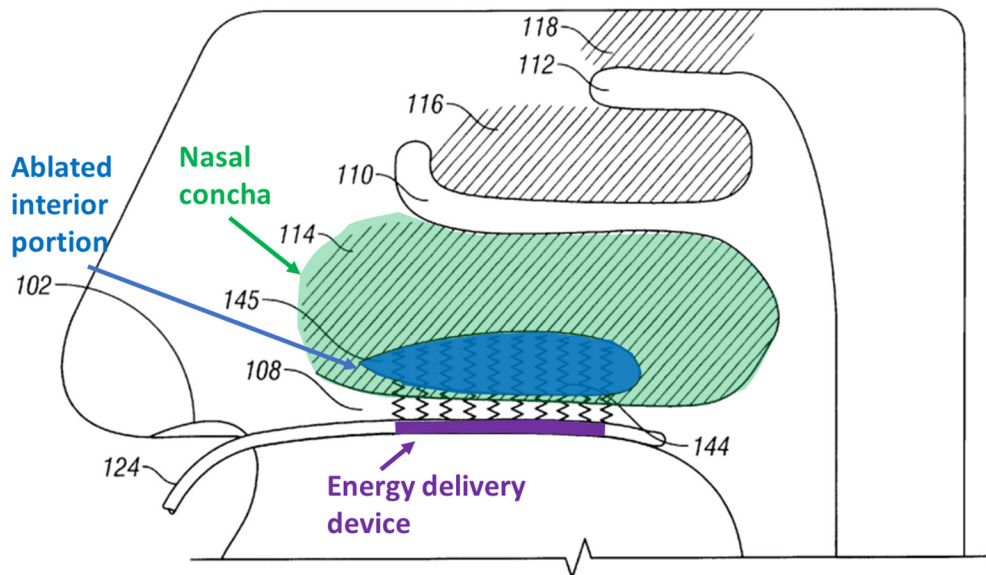


FIG. 4A

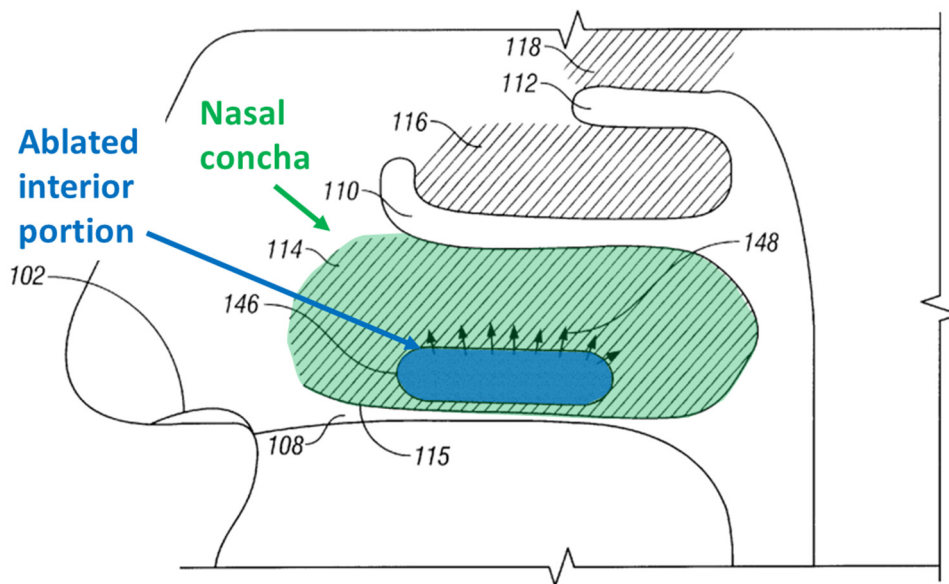


FIG. 4B

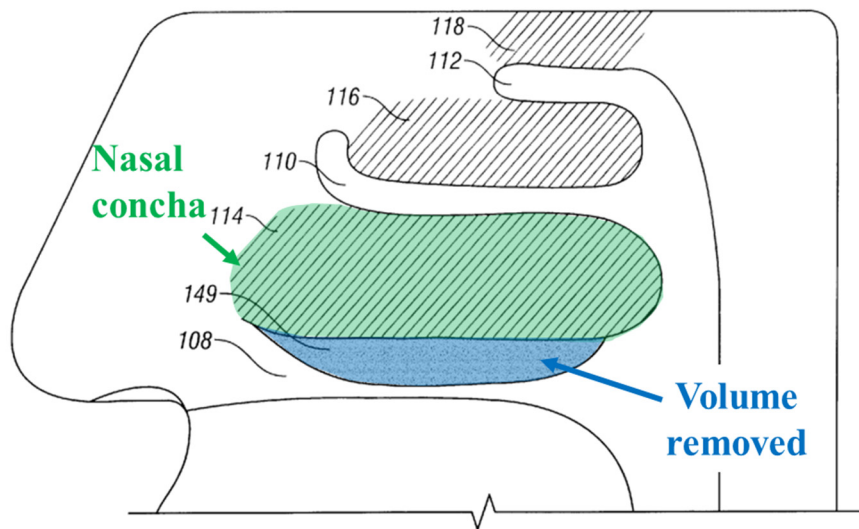


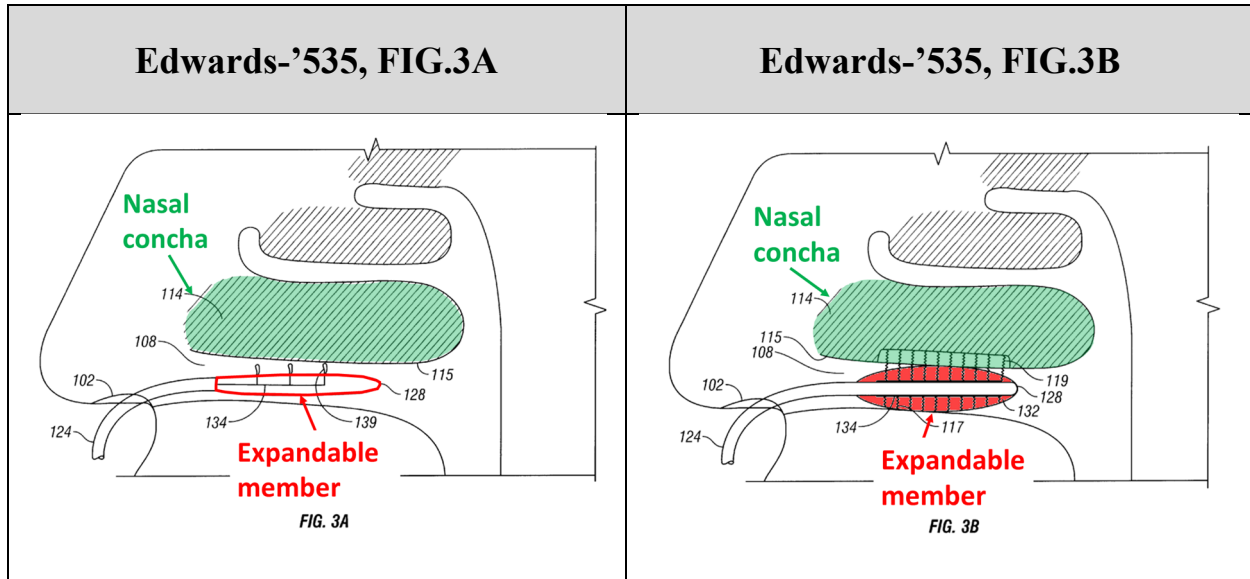
FIG. 4C

Id., FIGs.4A-4C.

2. Claim 14: A method as in claim 9, wherein adjusting the shape comprises manipulating a secondary component of the treatment element to increase a surface area of the treatment element.

112. Edwards-'535 teaches that the step of adjusting the shape, as recited by limitation 9[a], further includes manipulating (e.g., inflating) a secondary component (e.g., expandable member 132) of the treatment element (e.g., distal portion 128) to increase a surface area of the treatment element.

113. As I explained above with reference to limitation 9[a], Edwards-'535 teaches that expandable member 132 is inflated after being inserted into the patient's nasal passages. A person of ordinary skill in the art would have understood that inflating an expandable component, such as expandable member 132, increases its surface area. Namely, the increase in fluid volume within expandable member 132 exerts outward pressure on the surfaces of expandable member 132, and because expandable member 132 is made of a flexible material, the surface responds to the internal pressure by expanding outward and increasing the surface area. This understanding is confirmed by Figures 3A and 3B, reproduced below, which illustrate the expansion of expandable component 218 (red), and in which an increase in the surface area is apparent. *Id.*, 5:51-61, 7:37-54, FIGs.3A-3B; *see also id.*, FIG.3C (showing larger area).



114. Moreover, for similar reasons to those I explained above for this claim in Ground I, a person of ordinary skill in the art would have understood expandable member 132 to be a “secondary component” of the treatment element (e.g., distal portion 128), particularly given that the treatment element includes other components (e.g., energy delivery device 134) that would have been regarded as having a more primary role in the delivery of ablative energy. The functions of expandable member 132, on the other hand, have a secondary role in facilitating the placement and delivery of the ablative energy.

3. **Claim 18: A method as in claim 9, wherein delivering the energy based therapy comprises delivering energy in a form selected from the group consisting of ultrasound,**

**microwave, heat, radiofrequency, electrical, light, laser and
quantic molecular resonance.**

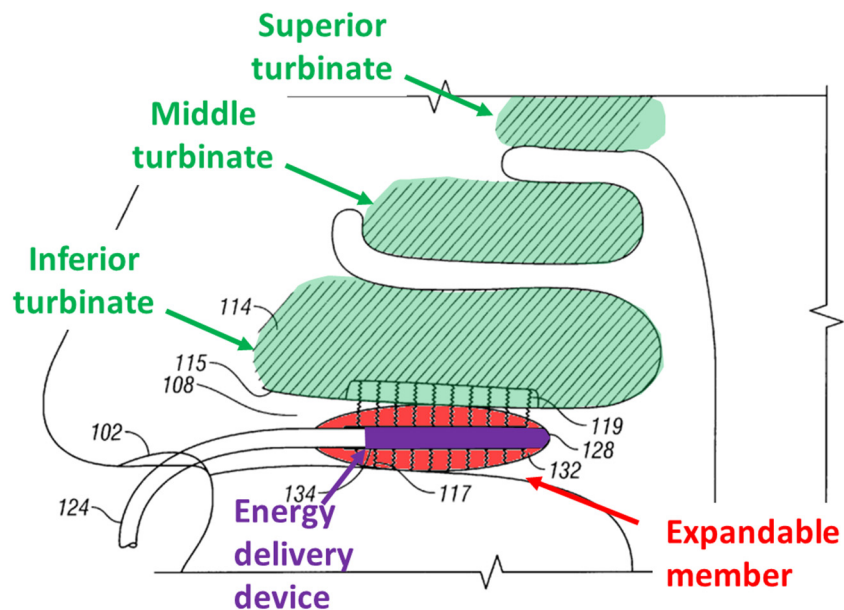
115. Edwards-'535 teaches that the step of delivering the energy based therapy, as recited by limitation 9[c], further includes delivering energy in a form selected from the claimed group (e.g., ultrasound, microwave, radiofrequency, electrical, light, and laser). As I explained above with reference to limitations 9[a]-9[c], Edwards-'535's method delivers energy to ablate tissue. Edwards-'535 further identifies a number of examples of the forms that the energy takes including, in various arrangements, a "diode laser" or "laser fiber" (i.e., light and/or laser, as claimed), "microwave," "ultrasound," and "RF" (i.e., radiofrequency). Ex.1010-Edwards-'535, 5:36-51, 8:47-53, 8:61-9:13, Clm.1.

**4. Claim 20: A method as in claim 9, wherein the mucosal
tissue is located in a part of the nasal airway other than an
internal nasal valve of the airway.**

116. Edwards-'535 teaches that the mucosal tissue, as recited by limitations 9[b] and 9[c], is located in a part of the nasal airway other than an internal nasal valve of the airway, as recited by claim 20. For example, as I explained above with reference to limitations 9[b] and 9[c], Edwards-'535 teaches that light therapy is applied to mucosal tissue of the nasal concha (turbinates). A person of ordinary skill in the art would have understood from textbook knowledge of nasal anatomy that the turbinates are not within an internal nasal valve, particularly given that the

nasal valve spans just a small portion of the nose at the front of the nasal cavity that is bounded by the front of the inferior turbinate but does not include the turbinates.

117. For example, Figure 3B of Edwards-'535 (reproduced below) depicts the expandable member 132 (red) filling up and contacting surfaces of the nasal cavity that are not limited to the head of the inferior turbinate where the internal nasal valve is located.



Ex.1010-Edwards-'535, FIG.3B.

5. **Claim 22:** A method as in claim 20, wherein the wherein [sic] mucosal tissue includes tissue selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum within the nasal valve, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a

septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity.

118. I understand and have been informed that in the parallel district court litigation, the Patent Owner cites to the following annotated diagram as evidence that the Petitioner's accused product allegedly satisfies claim 22.

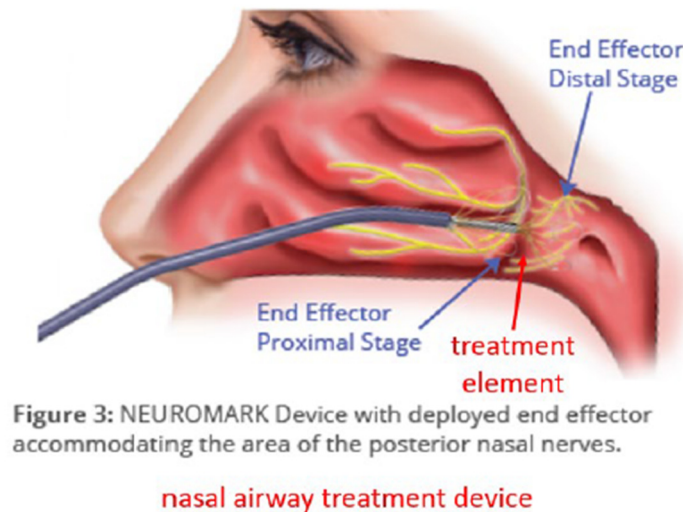
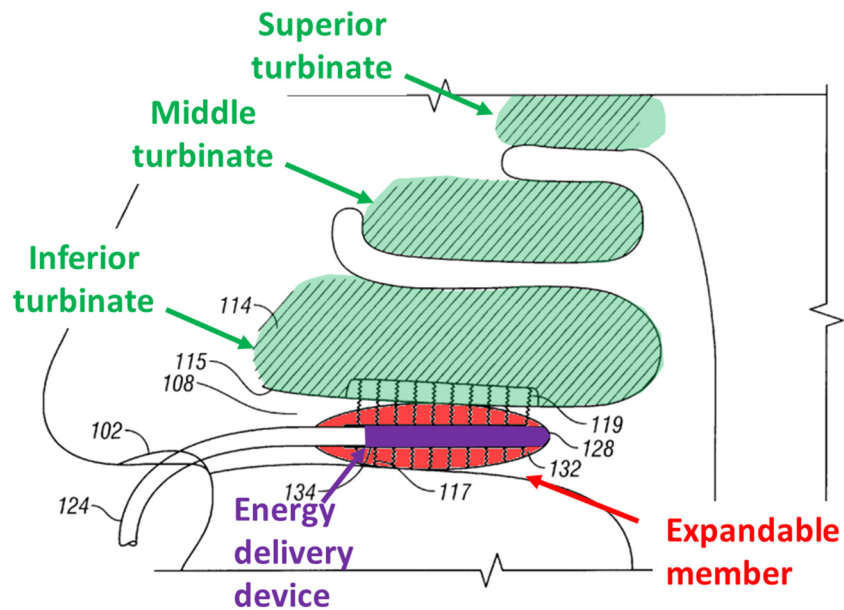


Figure 3: NEUROMARK Device with deployed end effector accommodating the area of the posterior nasal nerves.

Ex.1007, 16 (annotations made by the Patent Owner). In particular, the Patent Owner asserts that the above diagram “shows the end effector contacting mucosal tissue in at least the piriform area and floor of the nasal cavity” and therefore allegedly supports the Patent Owner’s contentions that the accused product infringes claim 22.

119. If the Patent Owner maintains that claim 22 should have the same interpretation in this proceeding as the interpretation it appears to advance in the

parallel litigation, then Edwards-'535 discloses it. Figure 3B of Edwards-'535 is reproduced below.



Ex.1010-Edwards-'535, FIG.3B. Comparing Figure 3B of Edwards-'535 with the diagram that the Patent Owner cites in its infringement allegations, Figure 3B shows distal end 128 (i.e., the claimed treatment element) being in contact with the same or similar parts of the nasal anatomy as the “end effector” in the Patent Owner’s annotated diagram. Accordingly, at least under the Patent Owner’s apparent interpretation of claim 22, Edwards-'535 teaches contacting mucosal tissue in the piriform area and floor of the nasal cavity, as claimed, as these are the structures that the Patent Owner argues are being contacted by the end effector in its annotated diagram of the accused product.

6. Claim 23: A method as in claim 9, further comprising applying force to the mucosal tissue with the treatment element at least one of before, during or after delivering the energy based therapy to deform the mucosal tissue.

120. Edwards-'535's method includes the claimed step of applying force to the mucosal tissue (e.g., tissue lining nasal concha 114) with the treatment element (e.g., distal portion 128) at least one of before, during or after delivering the energy based therapy (e.g., ablative energy) to deform the mucosal tissue.

121. As I explained above with reference to limitations 9[b] and 9[c], Edwards-'535 teaches that the expandable member 132 is inflated sufficiently to "contact...the surface 115 of the nasal concha 114 to be treated." Ex.1010-Edwards-'535, 5:27-35, 5:51-61. Because expandable member 132 is in contact with mucosal tissue (e.g., the tissue lining the surface 115 of nasal concha 114), the pressure used to inflate expandable member 132 also causes the surface of expandable member 132 to apply force to the mucosal tissue, as claimed. In turn, a person of ordinary skill in the art would have understood that the force applied to the mucosal tissue deforms the mucosal tissue, as claimed, particularly given that mucosal tissue and its underlying tissues are soft and malleable such that virtually any amount of force would create at least a temporary deformation.

122. Edwards-'535 teaches that expandable member 132 is inflated before delivering ablative energy and is maintained in its inflated state during delivery of ablative energy. *Id.*, 4:53-67, 5:27-35, 5:46-51, 7:18-25, 8:18-25, Clm.1, FIGs.3A (showing unexpanded expandable member 132 before application of ablative energy), 3B-3D (showing expanded expandable member 132 during application of ablative energy). Accordingly, the expandable member 132 (i.e., treatment element) applies force to the mucosal tissue at least before and during the delivery of ablative energy (i.e., energy based therapy), as claimed.

7. Claim 44

a. Element 44[pre]: A method of treating a patient's nasal airway

123. The preamble of claim 44 is the same as that of claim 9, and therefore Edwards-'535 discloses the preamble for the same reasons that I explained above for limitation 9[pre].

b. Element 44[a]: contacting a treatment element of a treatment device with a first mucosal tissue located in a part of the nasal airway other than an internal nasal valve of the airway

124. Limitation 44[a] is simply a combination of limitation 9[b] and claim 20, and therefore Edwards-'535 discloses limitation 44[a] for the same reasons that I explained above for those limitations.

- c. Element 44[b]: delivering an energy based therapy to at least one of the first mucosal tissue or an underlying tissue beneath the first mucosal tissue, using the treatment element**

125. Limitation 44[b] is the same as limitation 9[c], and therefore Edwards-'535 discloses limitation 44[b] for the same reasons that I explained above for limitation 9[c].

- d. Element 44[c]: removing the treatment element from the nasal airway.**

126. Limitation 44[c] is the same as limitation 9[d], and therefore Edwards-'535 discloses limitation 44[c] for the same reasons that I explained above for limitation 9[d].

- 8. Claim 46: A method as in claim 44, wherein the wherein mucosal tissue includes tissue selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity.**

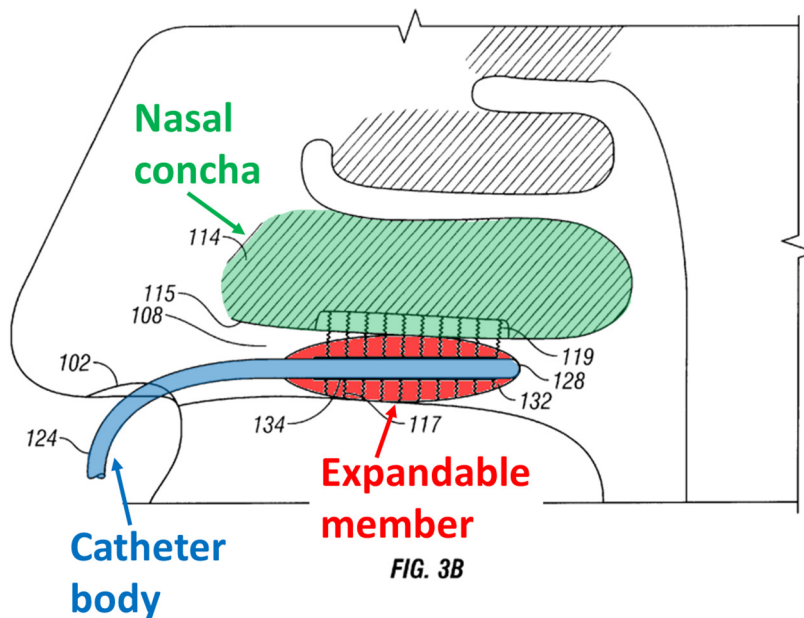
127. Dependent claim 46 recites the same additional limitations as dependent claim 22, and therefore Edwards-'535 discloses claim 46 for the same reasons that I explained above for claim 22.

C. Ground III: Claim 16 Is Obvious Over Edwards-'535

- 1. Claim 16: A method as in claim 9, wherein adjusting the shape comprises forming at least one bend in a shaft of the treatment device.**

128. As I explained above with reference to limitation 9[a], Edwards-'535's method includes the claimed step of adjusting the shape of a treatment device (e.g., apparatus 124). Edwards-'535 further renders obvious that this step includes forming at least one bend in a shaft (e.g., catheter body) of the treatment device (e.g., apparatus 124), as recited by claim 16.

129. Figure 3B of Edwards-'535 is reproduced below.



Ex.1010-Edwards-'535, FIG.3B. Figure 3B shows that apparatus 124 (i.e., the claimed treatment device) includes a catheter (blue) (i.e., the claimed shaft) used to

position expandable member 132 at a target site within the nasal passages of a patient. *Id.*, FIG.3B, 2:63-3:6 (“the apparatus includes a catheter having a distal portion with a dimension configured for positioning the catheter distal portion through a nostril of a patient”). The catheter has a bend along its length, which a person of ordinary skill in the art would have recognized is necessarily formed, often during the medical procedure itself for the purpose of reaching around contours and bends in the patient’s nasal passages.

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

- Ex.1013-Baker, 22:21-35 (“[T]he energy delivery member may comprise a flexible, steerable structure 48.... A distal end of the energy delivery member 46, 48 is preferably navigable to target tissue sites or target blocked sites within cavities, such as nasal passages and blocked ostia, where it can be activated to provide mechanical and cavitation effects that promote recanalization of obstructed passages.”), 23:9-13 (“In some embodiments, a

guidance member, such as a guidewire-type member, may be provided and operated separately from an energy delivery member. In this embodiment, the guidance member may be advanced and positioned at a desired operating site, and the energy delivery member may then be advanced over, along-side or through the guidance member for positioning and activation at the desired operating site.”), FIGs.7-8D;

- Ex.1019-Gertner, [0072] (“In one embodiment, the insertion member 106 is flexible so that its shape and orientation with respect to the housing or hand piece 102 may be adjusted. A flexible material, such as rubber, plastic, or metal may be used to construct the insertion member 106, and to provide flexibility thereto. In one embodiment, a goose-neck tube, or spiral wound coil is used to provide a flexible insertion member 106.”), [0077] (“The insertion member 106 may be made of flexible materials so that it can bend, or be steered around corners, or conform to the shape of the cavity, as required.”);
- Ex.1021-Makower, [0195] (“It is to be further understood that any of the catheters, scopes, elongate working devices or other devices disclosed in this patent application may be rendered steerable or volitionally bendable, unless to do so would make such device inoperative for its intended purpose.

Steerable catheters and scopes are well known in the art and may utilize mechanical steering assemblies (e.g., pull wires, hinges, etc.) or shape memory materials (e.g., nickel titanium alloys, shape memory polymers, etc.) to induce the device to undergo the desired bending or curvature after it has been inserted into the body. Examples of apparatus and construction that may be used to render these devices steerable or volitionally bendable include but are not limited to those described in U.S. Pat. No. 5,507,725 (Savage et al.), U.S. Pat. No. 5,656,030 (Hunjan et al.), U.S. Pat. No. 6,183,464 (Webster), U.S. Pat. No. 5,251,092 (Qin et al.), U.S. Pat. No. 6,500,130 (Kinsella et al.), U.S. Pat. No. 6,571,131 (Nguyen), U.S. Pat. No. 5,415,633 (Lazarus et al.), U.S. Pat. No. 4,998,916 (Hammerslag et al.), U.S. Pat. No. 4,898,577 (Badger et al.), U.S. Pat. No. 4,815,478 (Buchbinder et al.) and published U.S. Patent Applications No. 2003/0181827A1 (Hojeibane et al.) and 2003/0130598A1 (Manning et al.), the entireties [sic] of which are expressly incorporated herein by reference.”).

131. A person of ordinary skill in the art therefore would have been motivated to apply background knowledge of how to use and manipulate catheters to form the bend in Edwards-’535’s catheter shaft, and would have found it obvious to do so. For example, forming a bend in Edwards-’535’s catheter shaft

would have been a matter of using a known technique (i.e., one or more well-known techniques for forming a bend in a catheter shaft) to improve a similar device (Edwards-'535's apparatus 124, which includes a bent catheter shaft) in the same way.

132. Edwards-'535's lack of specificity about the catheter shaft (e.g., the material that the shaft is made of is not specified) further supports that a person of ordinary skill in the art would have recognized that Edwards-'535 is ready for improvement and would have been motivated to turn to background knowledge to implement Edwards-'535's teachings. For example, a person of ordinary skill in the art would have selected a suitable technique for forming the bend in Edwards-'535's catheter shaft as a matter of routine implementation, yielding the predictable result of a catheter having a desired shape for delivering treatment to the nose. A person of ordinary skill in the art also would have had a reasonable expectation of success, as forming a bend in the catheter shaft would have facilitated accurate placement of the distal end of Edwards-'535's catheter shaft at a target location and would have allowed the distal end to reach otherwise hard-to-reach locations of the nose, e.g., posterior surfaces of a nasal turbinate.

D. Ground IV: Claims 9, 14, 16, 18, 20, 22-24, 44, and 46 Are Anticipated by Baker

133. As explained in detail, Baker discloses each element of claims 9, 14, 16, 18, 20, 22-24, 44, and 46 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 also teaches a 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 4, do not include the steerable structure.

1. Claim 9

a. Element 9[pre]: A method of treating a patient's nasal airway

134. As I explained in Grounds I and II, I understand that a preamble does not always limit a claim's scope, but even if the preamble of claim 9 is limiting, Baker discloses it. Namely, Baker teaches the claimed method of treating a

patient's nasal airway (e.g., nasal passages, mucous membranes, and/or nasal turbinates).

i. *Baker's method of using device 20 satisfies limitation 9[pre]*

135. Baker teaches a method in which a device 20, depicted in Figures 3-5, is used to “deliver[] generally high frequency acoustic energy...to tissue sites such as nasal passages.” Ex.1013-Baker, 16:20-22; *see also id.*, 17:24-27, FIGs.3-5.

The clinical goals of the method include “treating common colds, nasal congestion and allergic rhinitis, as well as sinusitis and other nasal conditions.” *Id.*, 26:7-8; *see also id.*, Abstract, 1:11-22, 5:5-12, 16:19-32, Clm.1. Moreover, the method involves treating locations in the nasal airway, e.g., “within nasal passages, mucous membranes and nasal turbinates.” *Id.*, 17:11-16.

ii. *Baker's method of using device 40 also satisfies limitation 9[pre]*

136. Baker's teachings in connection with device 40, depicted in Figures 6-8D, both (a) support that a person of ordinary skill in the art would have understood device 20 to satisfy limitation 9[pre] and (b) satisfy limitation 9[pre] on a standalone basis. Baker teaches that device 40 is used to “deliver[] generally high frequency acoustic energy to nasal passages,” Ex.1013-Baker, 21:22, with the objective of “treating...nasal conditions,” *id.*, 26:7-8. The method is involves

treating locations in the nasal airway including “mucous membranes[,] nasal turbinates[, and] nasal passages.” *Id.*, 22:10-16.

b. Element 9[a]: adjusting a shape of a nasal airway treatment device

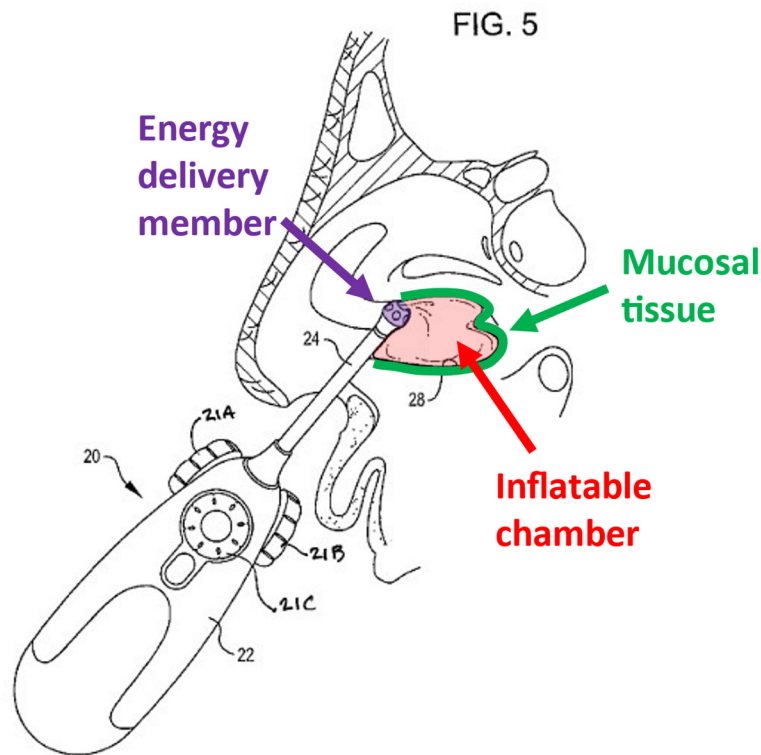
137. Baker’s methods include the claimed step of adjusting a shape (e.g., extending/retracting, bending, and/or enlarging) of a nasal airway treatment device (e.g., device 20 and/or 40).

i. *Baker’s method of using device 20 satisfies limitation 9[a]*

138. Given that Baker describes device 20 as being used “for delivery of high frequency acoustic energy to internal sites, such as nasal passageways,” Ex.1013-Baker, 16:23-24; *see also* limitation 9[pre], a person of ordinary skill in the art would have understood device 20 as a nasal airway treatment device as claimed. At the distal end of an insertion wand 24 of device 20 is an energy delivery member 26 that delivers treatment to target locations within the nasal airway (e.g., tissue that lines nasal passages, mucous membranes, and/or nasal turbinates). *Id.*, 16:19-32, 17:11-21, FIGs.3-5. An “extendible and/or retractable” portion of energy delivery member 26 is included “to provide desired positioning of the energy delivery member in contact with obstructions and/or tissues for delivery of...energy.” *Id.*, 17:11-21. Extending and/or retracting energy delivery

member 26 therefore results in adjusting a shape of the treatment device, as claimed.

139. In the configuration of device 20 depicted in Figure 5, reproduced below, the energy delivery member further includes a “flexible, deformable bladder or inflatable chamber 28” (red).



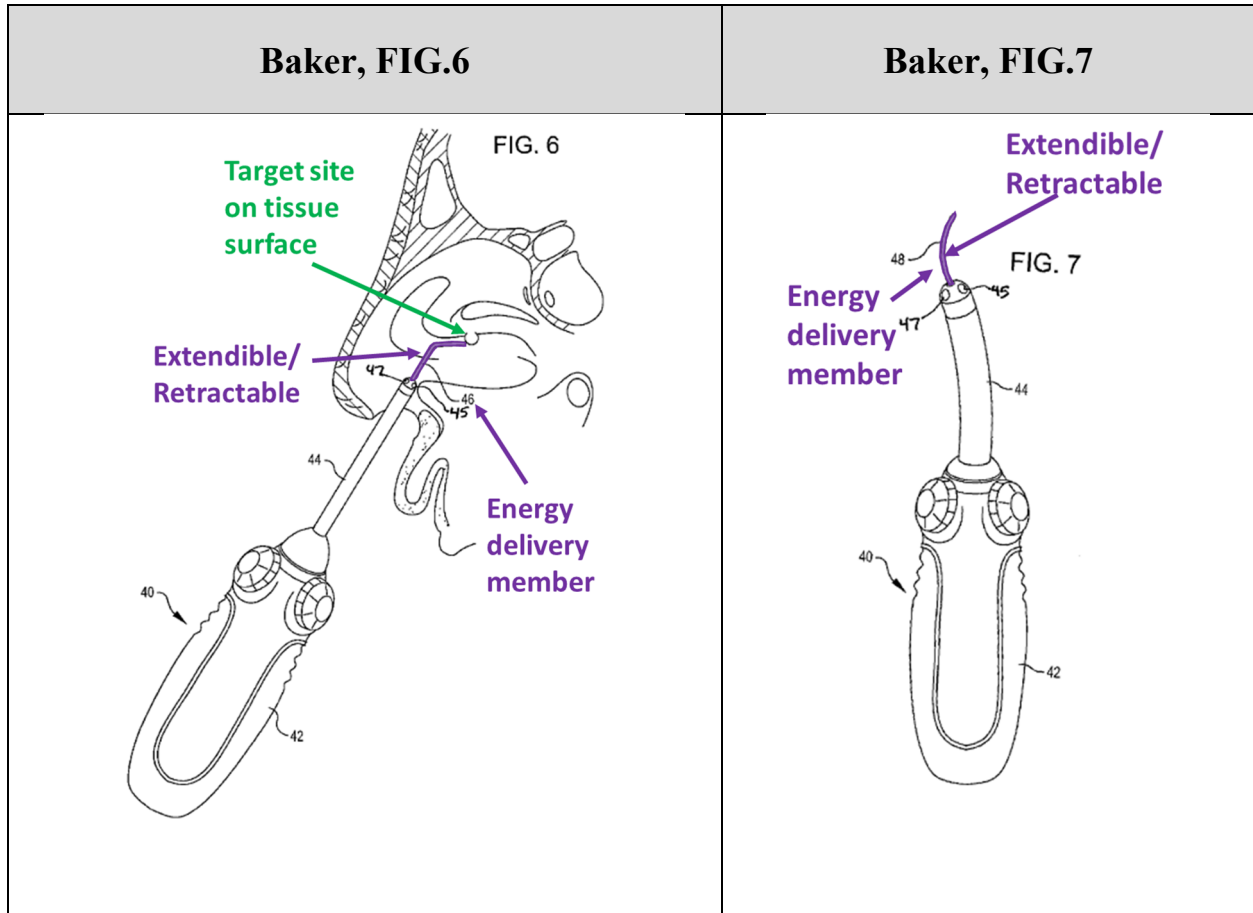
Id., FIG.5. Baker teaches that the inflatable chamber 28 (red) can “be enlarged, at a desired target site, until the walls of the chamber contact a tissue site, or the walls of a cavity or passageway or lumen.” *Id.*, 17:22-32. Accordingly, expanding

inflatable chamber 28 at the target site is another way that Baker's method adjusts the shape of the treatment element, as claimed.

ii. *Baker's method of using device 40 also satisfies limitation 9[a]*

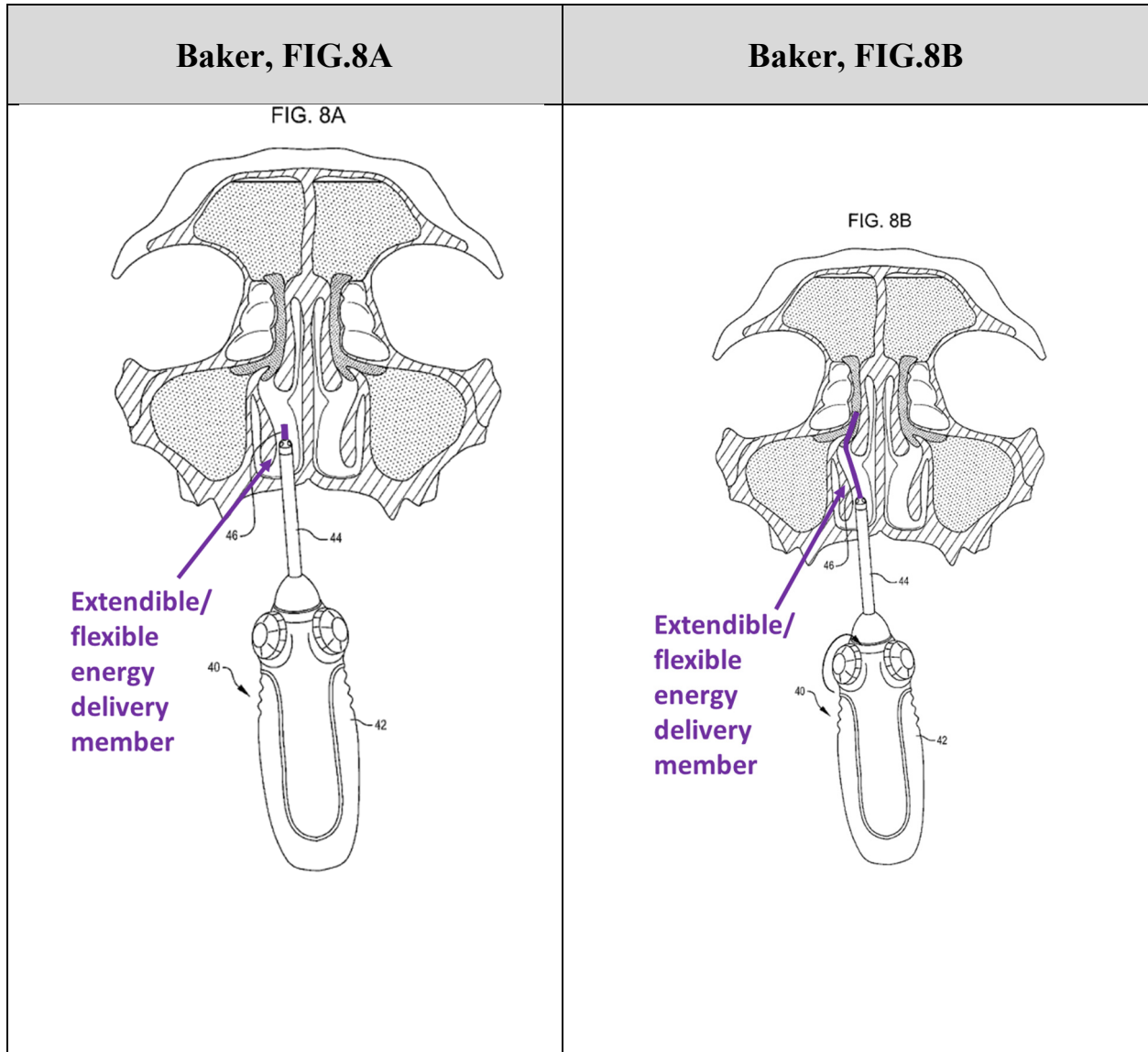
140. Baker's teachings in connection with device 40, depicted in Figures 6-8D, both (a) support that a person of ordinary skill in the art would have understood device 20 to satisfy limitation 9[a] and (b) satisfy limitation 9[a] on a standalone basis.

141. Like device 20, device 40 would have been understood as a nasal airway treatment device, as claimed, given that device 40 is used "for delivery of generally high frequency acoustic energy to nasal passages." Ex.1013-Baker, 21:21-22. As illustrated below in Figures 6 and 7, the basic configuration of device 40 is similar to that of device 20 that I explained above.



For example, Figures 6 and 7 show that device 40 includes an insertion member 44 and energy delivery member 46 (purple), which perform similar functions to the corresponding components of device 20. *Id.*, 21:21-32. An “extendible and/or retractable” portion of energy delivery member 46 is used “to provide desired positioning of the energy delivery member in contact with obstructions and/or tissues for delivery of...energy.” *Id.*, 22:22-25. Extending and/or retracting the energy delivery members 46 therefore results in adjusting a shape of the treatment device, as claimed.

142. In the configuration of device 40 depicted in Figure 7, the energy delivery member further includes “a flexible, steerable structure 48.” *Id.*, 21:21-22:40, FIGs.6-7. Figures 8A and 8B, reproduced below, illustrate the use of flexible steerable structure 48 (purple).



Figures 8A-8B show that steerable structure 48 (purple) is extended and manipulated (e.g., bent) to reach the target region of the nasal passages.

Accordingly, steering steerable structure 48 to the target site is another way that Baker's method adjusts the shape of the treatment element, as claimed.

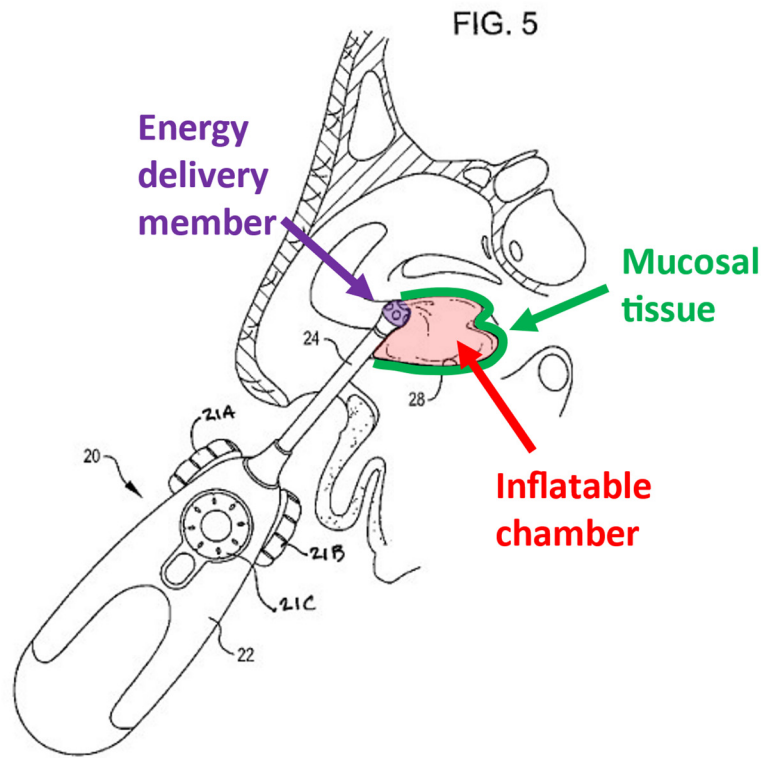
c. Element 9[b]: contacting a treatment element of the treatment device with mucosal tissue in the patient's nasal airway;

143. Baker's method includes the claimed step of contacting a treatment element (e.g., the energy delivery members shown in Figures 4-7) of the treatment device (device 20/40) with mucosal tissue (e.g., tissue lining the nasal passages, mucous membranes, and/or nasal turbinates) in the patient's nasal airway.

i. *Baker's method of using device 20 satisfies limitation 9[b]*

144. Given that the energy delivery member of device 20 delivers high frequency acoustic energy to treat upper airway conditions, Ex.1013-Baker, 17:11-21; *see also id.*, Abstract, 1:11-22, 5:5-12, 16:19-32, 26:7-11, Clm.1, FIGs. 3-5, a person of ordinary skill in the art would have understood the energy delivery member to be a treatment element as claimed. Moreover, when used to treat the nasal passages, the energy delivery member contacts mucosal tissue lining the nasal passages of the upper airway, as Baker teaches that the "energy delivery member...may be extendible and/or retractable...to provide desired positioning of the energy delivery member in contact with...tissues." *Id.*, 17:11-21, FIG.4.

145. In the configuration of device 20 depicted in Figure 5, reproduced below, the energy delivery member further includes a "flexible, deformable bladder or inflatable chamber 28" (red). *Id.*, 17:23.

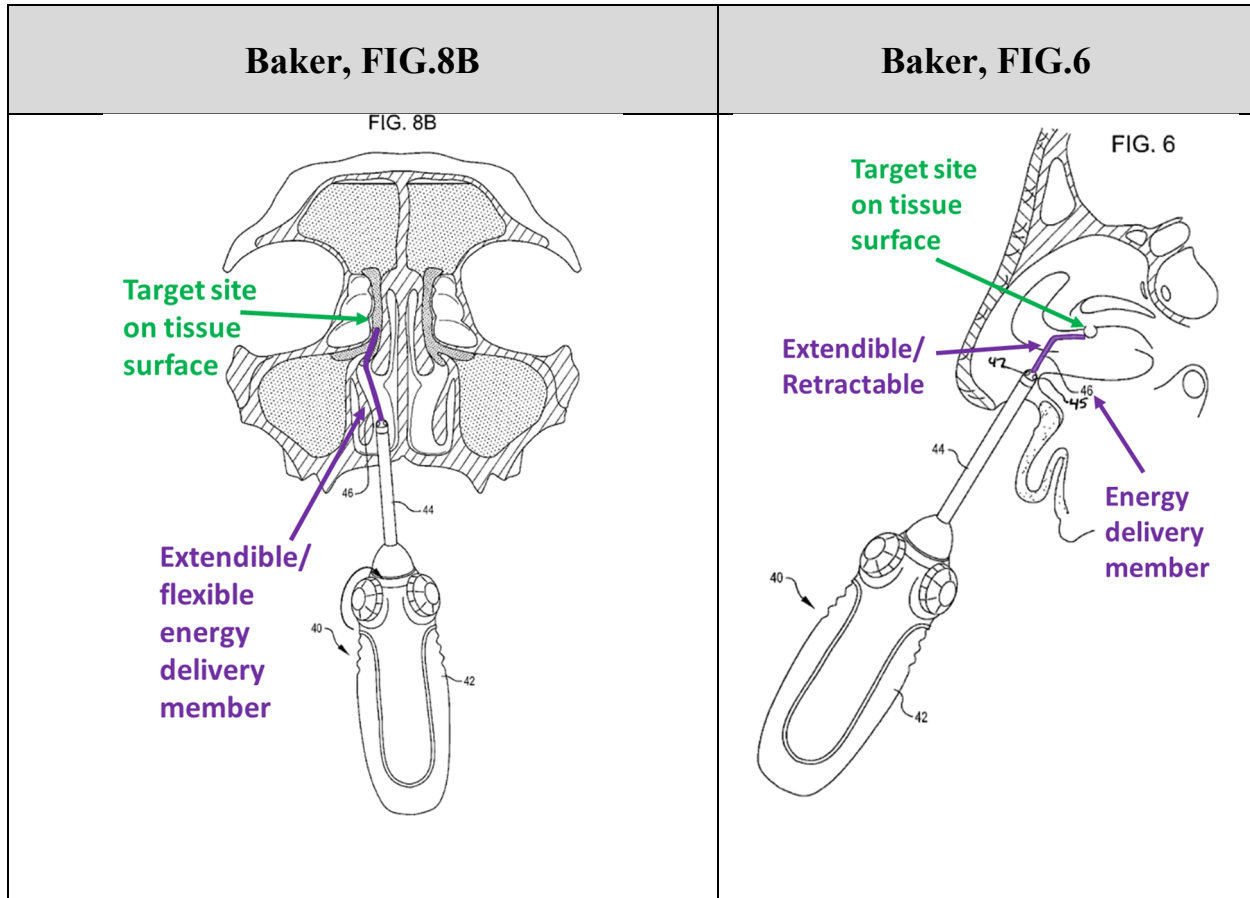


Id., FIG.5. Baker teaches that the inflatable chamber 28 (red) can “be enlarged, at a desired target site, until the walls of the chamber contact a tissue site, or the walls of a cavity or passageway or lumen.” *Id.*, 17:22-32; *see also id.*, 17:33-18:9 (describing similar contact), 20:35-21:10 (same). The target site includes mucosal tissue in the patient’s nasal airway, such as tissue lining the “nasal passages, mucous membranes and nasal turbinates, or pathological or undesired tissue.” *Id.*, 17:11-32. Accordingly, placing inflatable chamber 28 in contact with mucosal tissue is another way that Baker’s method contacts the treatment element with mucosal tissue.

ii. ***Baker's method of using device 40 also satisfies limitation 9[b]***

146. Baker's teachings in connection with device 40, depicted in Figures 6-8D, both (a) support that a person of ordinary skill in the art would have understood device 20 to satisfy limitation 9[b] and (b) satisfy limitation 9[b] on a standalone basis.

147. Like the energy delivery member of device 20, the energy delivery member of device 40 delivers high frequency acoustic energy to treat upper airway conditions, , 21:21-32, such that a person of ordinary skill in the art would have understood the energy delivery member to be a treatment element as claimed. The energy delivery member 46 has a distal end that is "positioned...**contacting** a tissue surface such as mucous membranes and nasal turbinates or polyps,...or accumulations or blockages within cavities such as nasal passages." *Id.*, 22:10-25 (emphasis added); *see also id.*, 7:18-34, 16:33-17:10, 21:21-32, 25:5-15, 25:37-26:6 (describing sterile use covers), FIGs.6-8B. Figures 6 and 8B of Baker, reproduced below, illustrate energy delivery member 46 (purple) in contact with mucosal tissue (green) of the nasal airways.



For example, in its description of Figure 8B, Baker explains that “[e]nergy delivery member 46 [(purple)] may be extended, as shown in Figure 8B, to contacting mucus and/or debris forming an obstruction within nasal passageways.” *Id.*, 25:5-10.

- d. **Element 9[c]: delivering an energy based therapy to at least one of the mucosal tissue or an underlying tissue beneath the mucosal tissue, using the treatment element; and**

148. Baker’s method includes the claimed step of delivering an energy based therapy (e.g., high frequency acoustic energy) to the mucosal tissue (e.g.,

target site on tissue surface, including mucous membranes, nasal turbinates, or pathological undesired tissue) using the treatment element (e.g., the energy delivery members depicted in Figures 4-7).

i. *Baker's method of using device 20 satisfies limitation 9[c]*

149. Baker discloses that the energy delivery member (i.e., the claimed treatment element) of device 20 is used to deliver acoustic energy intended to have therapeutic effects within the nasal passages, e.g., the energy is used to treat, disrupt, and/or remove obstructions or undesired materials. Ex.1013-Baker, 8:10-24, 16:19-32, FIGs.3-5. Accordingly, a person of ordinary skill in the art would have understood the delivery of acoustic energy to be an energy based therapy as claimed.

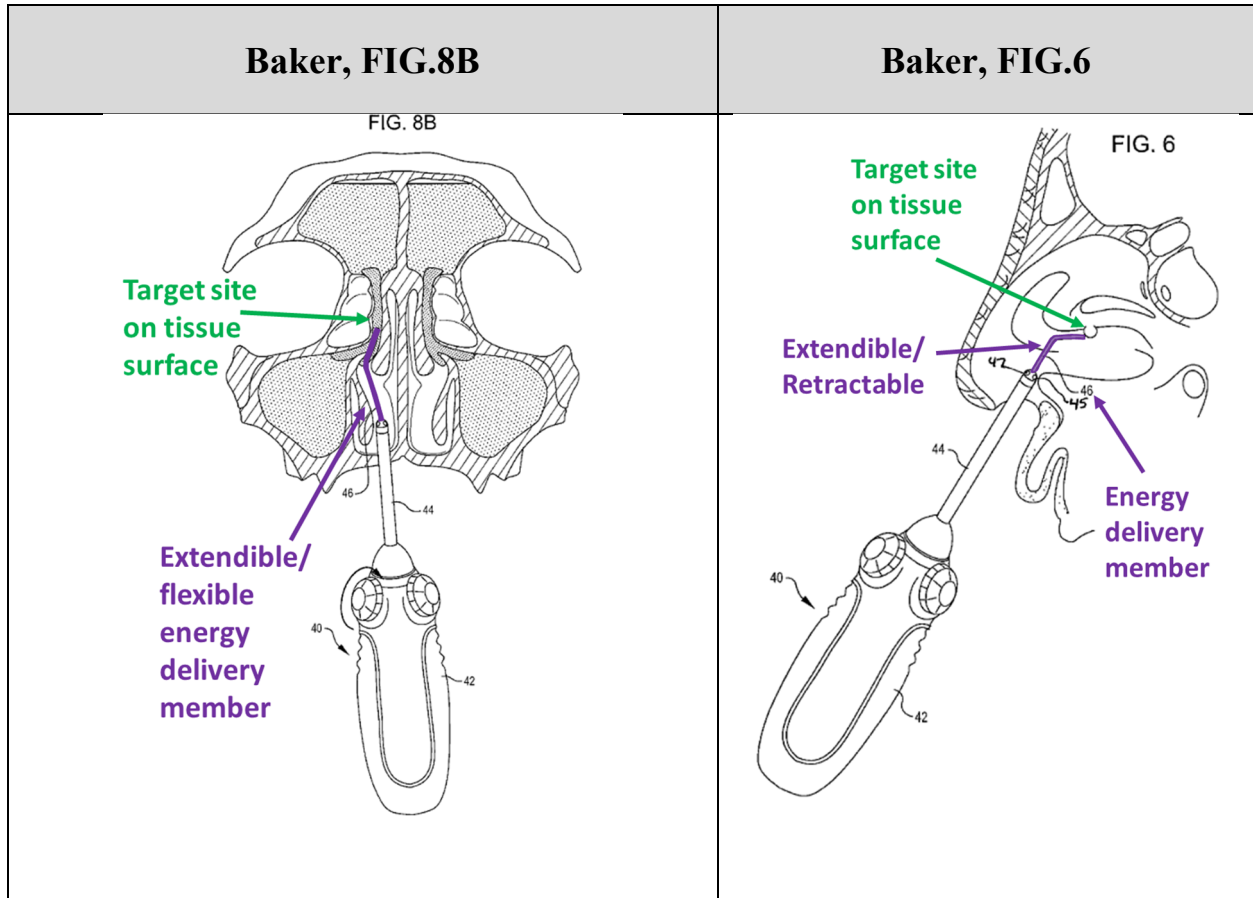
150. For example, the energy based therapy is delivered when a portion of the energy delivery member (e.g., its distal end shown in Figure 4 and/or its inflatable chamber 28 shown in Figure 5) contacts the target tissue (e.g., mucosal tissue lining the nasal passages) and delivers acoustic energy to the tissue. *See, e.g., id.*, 1:11-22, 10:11-25, 17:22-18:9, 19:10-13, 20:17-20, Claims 8, 33, FIGs.3-5. By adjusting the intensity of the acoustic energy, various clinical effects can be achieved, e.g., the intensity can be configured to a level “sufficient to ablate tissue

and/or cellular structures or debris,” or to “a sub-ablation intensity that is sufficient to disrupt tissue and/or cellular structures or debris but not ablate.” *Id.*, 18:35-37.

ii. *Baker’s method of using device 40 also satisfies limitation 9[c]*

151. Baker’s teachings in connection with device 40, depicted in Figures 6-8D, both (a) support that a person of ordinary skill in the art would have understood device 20 to satisfy limitation 9[c] and (b) satisfy limitation 9[c] on a standalone basis.

152. For example, energy delivery member 46 (i.e., the claimed treatment element) applies acoustic energy that treats, disrupts, and/or removes obstructions or undesired materials in a similar manner to the energy delivery member of device 20, and would therefore have been understood as delivering an energy based therapy for the same reasons. , 21:33-22: 29, 23:29-33, 23:39-24:6, 24:22-25, 25:8-20, FIGs.6-8B. Figures 6 and 8B, reproduced below, illustrate the delivery of an energy based therapy (e.g., acoustic energy) to the nasal passages.



As with device 20, Baker teaches that a clinician can adjust the intensity of the acoustic energy to achieve various clinical effects, e.g., the intensity can be configured to a level “sufficient to ablate tissue and/or cellular structures or debris,” or to “a sub-ablation intensity that is sufficient to disrupt tissue and/or cellular structures or debris but not ablate.” *Id.*, 23:29-31.

e. Element 9[d]: removing the treatment element from the nasal airway.

153. Baker's method includes the claimed step of removing the treatment element (e.g., the energy delivery member shown in Figures 4-7) from a patient's nasal airway.

i. *Baker's method of using device 20 satisfies limitation 9[d]*

154. As I explained above for Grounds I and II, a person of ordinary skill in the art would have readily understood that Baker's method involves removing the energy delivery member of device 20 (i.e., the claimed treatment element) after the treatment is delivered, as it would be impractical for patients to keep any portion of Baker's device – a large externally operated device that is not intended as an implant – inserted in their nasal passages indefinitely.

ii. *Baker's method of using device 40 also satisfies limitation 9[d]*

155. A person of ordinary skill in the art would have understood that Baker's method involves removing the energy delivery member of device 40 (i.e., the claimed treatment element) for the same reasons that I provided for device 20.

2. Claim 14: A method as in claim 9, wherein adjusting the shape comprises manipulating a secondary component of

the treatment element to increase a surface area of the treatment element.

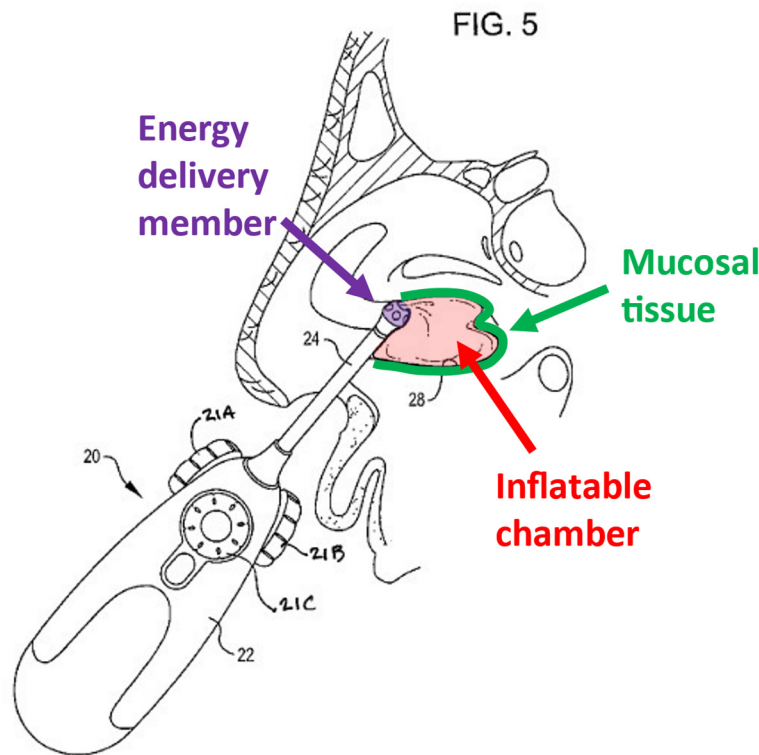
156. Baker teaches that the step of adjusting the shape, as recited by limitation 9[a], further includes manipulating (e.g., inflating and/or extending/retracting) a secondary component (e.g., inflatable chamber 28 and/or the extendible/retractable portion of the energy delivery member) of the treatment element (e.g., the energy delivery member shown in Figures 4-7) to increase a surface area of the treatment element.

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

157. As I explained above with reference to limitation 9[a], energy delivery member 26 is initially positioned within device 20 and is then extended to reach the target tissue. Ex.1013-Baker, 17:11-18:9, 18:15-19. A person of ordinary skill in the art would have understood that manipulating energy delivery member 26 (i.e., the claimed treatment element) in this manner increases its exposed surface area, as claimed. In particular, a person of ordinary skill in the art would have understood that the part of energy delivery member 26 that is being manipulated corresponds to a mechanical support component capable of being extended (e.g., rigid materials). Such mechanical support components would have been understood as secondary components of energy delivery member 26 in comparison

with other components of energy deliver member 26 that have a primary role in the delivery of energy, such as ultrasound transducers.

158. In the configuration of device 20 depicted in Figure 5, reproduced below, the energy delivery member further includes a “flexible, deformable bladder or inflatable chamber 28” (red).



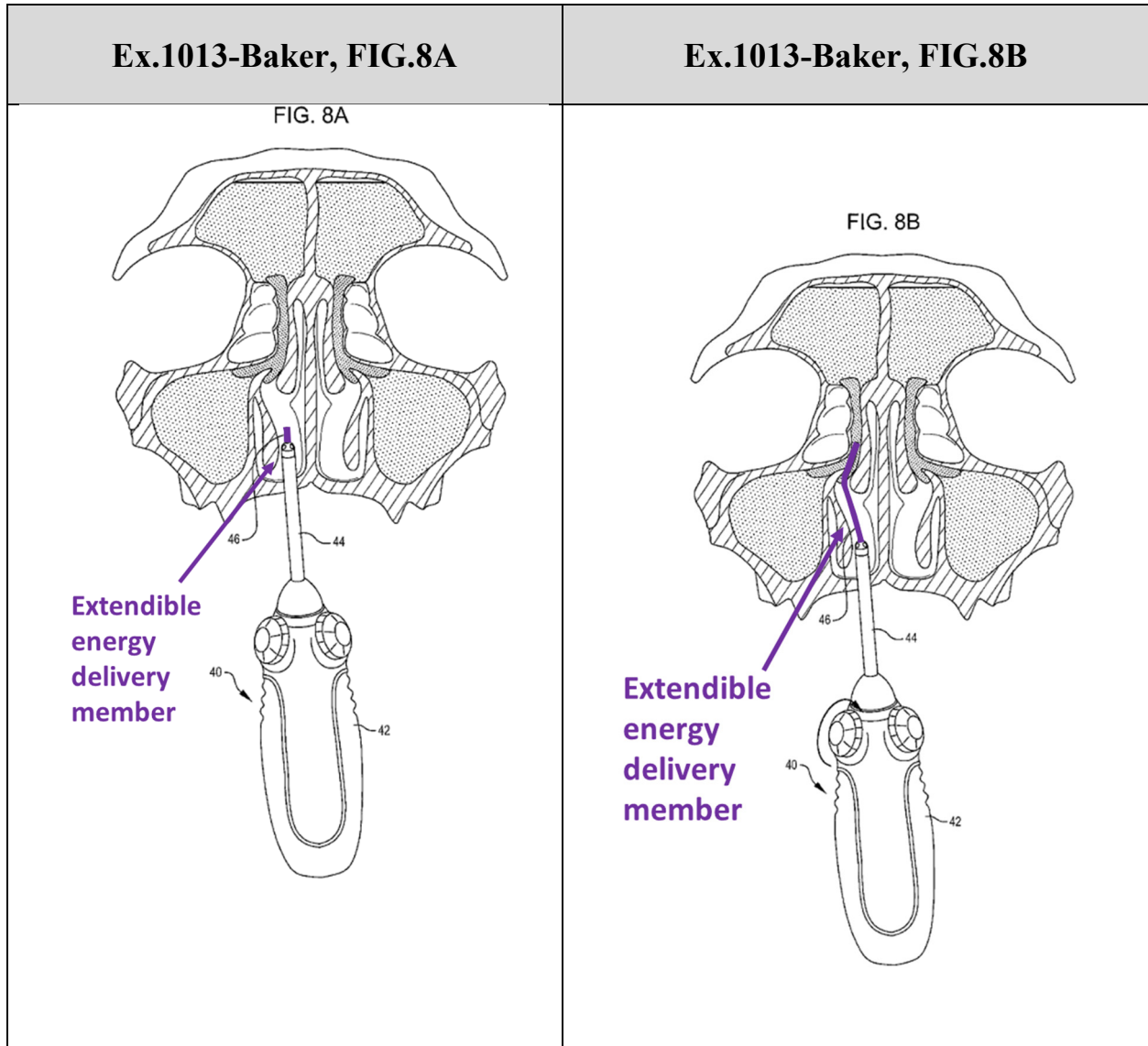
Id., FIG.5. Baker teaches that the inflatable chamber 28 (red) can “be enlarged, at a desired target site, until the walls of the chamber contact a tissue site, or the walls of a cavity or passageway or lumen.” *Id.*, 17:22-32. In this manner, inflating (i.e., manipulating) inflatable chamber 28 (red) increases its surface area. Moreover, for

similar reasons to those I explained above for this claim in Grounds I and II, a person of ordinary skill in the art would have understood inflatable chamber 28 to be a secondary component of the treatment element (e.g., energy delivery member), as claimed, particularly given that the treatment element includes other components (e.g., ultrasound transducer) that would have been regarded as having a more primary role in the delivery of ablative energy. The functions of inflatable chamber 28, on the other hand, have a secondary role in facilitating the placement and delivery of the acoustic energy.

ii. *Baker's method of using device 40 also satisfies claim 14*

159. Baker's teachings in connection with device 40, depicted in Figures 6-8D, both (a) support that a person of ordinary skill in the art would have understood device 20 to satisfy claim 14 and (b) satisfy claim 14 on a standalone basis.

160. Like energy delivery member 26, energy delivery member 46 is extended from within device 40, as shown in Figures 8A and 8B below.



Figures 8A (before extension) and 8B (after extension) show that extending the energy delivery member increases its exposed surface area, as claimed. As I explained above with reference to energy delivery member 26 of device 20, a person of ordinary skill in the art would have understood that the part of energy delivery member 46 being manipulated to achieve the extension corresponds to a

secondary component (e.g., a mechanical support component such as steerable structure 48). *Id.*, 17:11-18:9, 18:15-19, 21:21-22:9, 22:21-40, 23:5-8.

3. Claim 16: A method as in claim 9, wherein adjusting the shape comprises forming at least one bend in a shaft of the treatment device.

161. Baker teaches that the step of adjusting the shape, as recited by limitation 9[a], further includes forming at least one bend in a shaft (e.g., flexible, catheter-like structure of insertion wand/member 24/44 and/or flexible, steerable structure 48) of the treatment device (e.g., device 20/40).

i. *Baker's method of using device 20 satisfies claim 16*

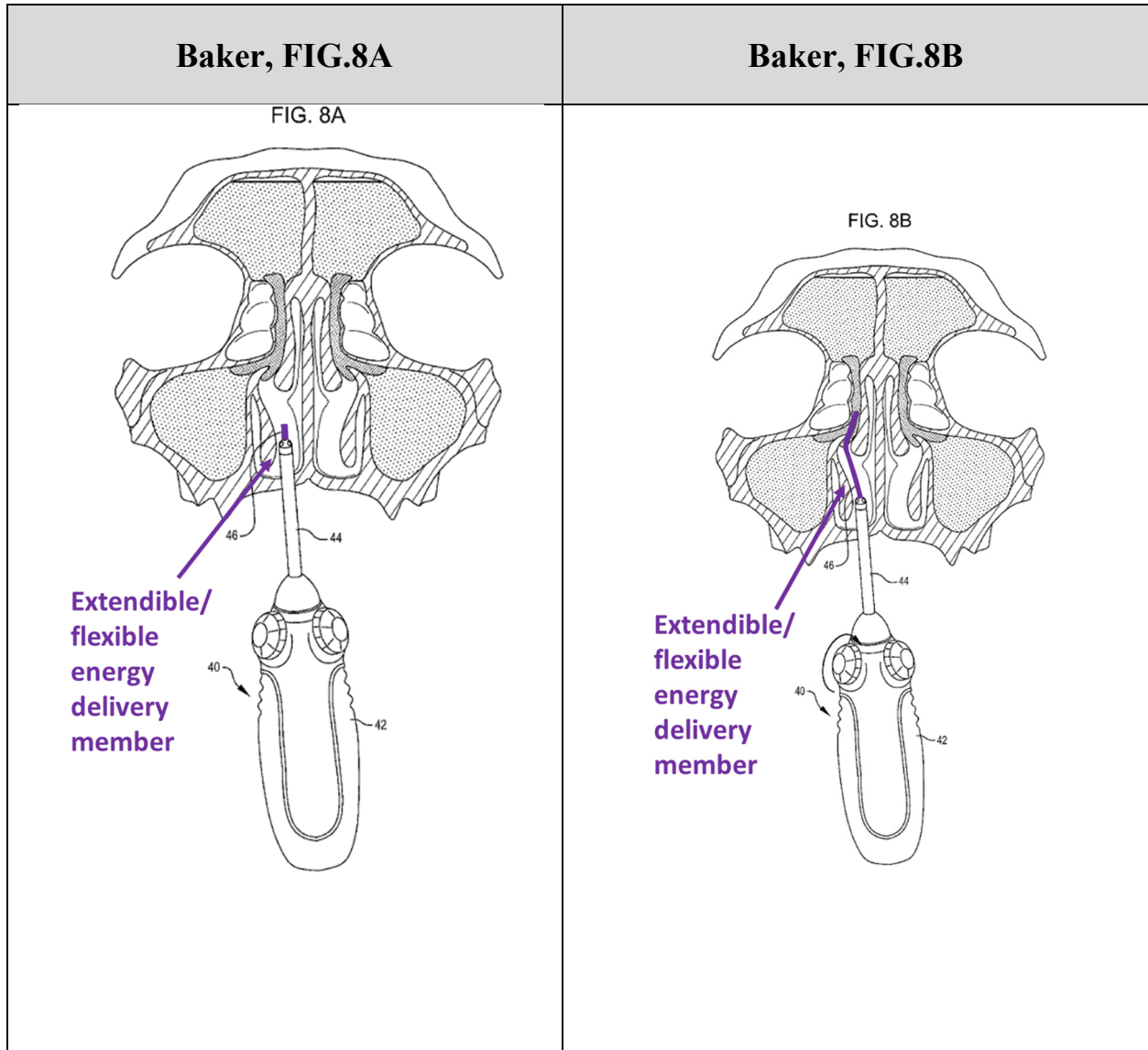
162. Baker's device 20 uses an insertion wand 24 with a "flexible, catheter-like structure" (i.e., the claimed shaft) to advance the energy delivery member through nasal passageways. Ex.1013-Baker, 16:23-28, FIGs.3-5. A person of ordinary skill in the art would have understood that, given the various structures and contours within the nasal passages that vary from patient to patient and side to side within the same patient, there is rarely a straight path between the exterior of the nose (e.g., outside the nostril), and the target location within the nose.

Accordingly, advancing a catheter-like structure of insertion wand 24 through nasal passageways would have been understood to result in forming a bend in the catheter-like structure (i.e., the claimed shaft).

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

163. Baker’s device 40 similarly uses insertion member 44 with a “flexible, catheter-like structure” (i.e., the claimed shaft) and therefore would have been understood to form a bend in the catheter-like structure for the same reasons provided above for device 20. Ex.1013-Baker, 16:23-28, 21:24-27.

164. In the configuration of device 40 depicted in Figure 7, the energy delivery member further includes a “a flexible, steerable structure 48” (i.e., the claimed shaft). *Id.*, 21:21-22:40, FIGs.6-7. Figures 8A and 8B, reproduced below, illustrate the use of flexible steerable structure 48 (purple).



Figures 8A-8B show that steerable structure 48 (purple) is extended and manipulated (e.g., bent) to reach the target region of the nasal passages.

Accordingly, steering steerable structure 48 to the target site is another way that Baker's method adjusts the shape of the treatment element by forming a bend in a shaft of the treatment device, as claimed.

4. **Claim 18: A method as in claim 9, wherein delivering the energy based therapy comprises delivering energy in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light, laser and quantic molecular resonance.**

165. Baker teaches that the step of delivering the energy based therapy, as recited by limitation 9[c], further includes delivering energy in a form selected from the claimed group (e.g., ultrasound), as Baker expressly discloses that both device 20 and device 40 deliver treatment in the form of “ultrasound energy.”

Ex.1013-Baker, 16:19-22, 22:16-22.

5. **Claim 20: A method as in claim 9, wherein the mucosal tissue is located in a part of the nasal airway other than an internal nasal valve of the airway.**

166. Baker teaches that the mucosal tissue, as recited by limitations 9[b] and 9[c], is located in a part of the nasal airway other than an internal nasal valve of the airway, as recited by claim 20. For example, as I explained above with reference to limitations 9[b] and 9[c], Baker teaches that both device 20 and device 40 deliver acoustic energy to mucosal tissue of the turbinates. Ex.1013-Baker, 17:11-21 (device 20), 22:12-16 (device 40). A person of ordinary skill in the art would have understood from textbook knowledge of nasal anatomy that the turbinates are not within an internal nasal valve, particularly given that the nasal

valve spans just a small portion of the nose at the front edge of the nasal cavity away from the turbinates.

6. **Claim 22: A method as in claim 20, wherein the wherein [sic] mucosal tissue includes tissue selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum within the nasal valve, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity.**

- i. *Baker's method of using device 20 satisfies claim 22*

167. As I explained above for claim 22 in Ground II, I understand and have been informed that in the parallel district court litigation, the Patent Owner cites to the following annotated diagram as evidence that the Petitioner's accused product allegedly satisfies claim 22. .

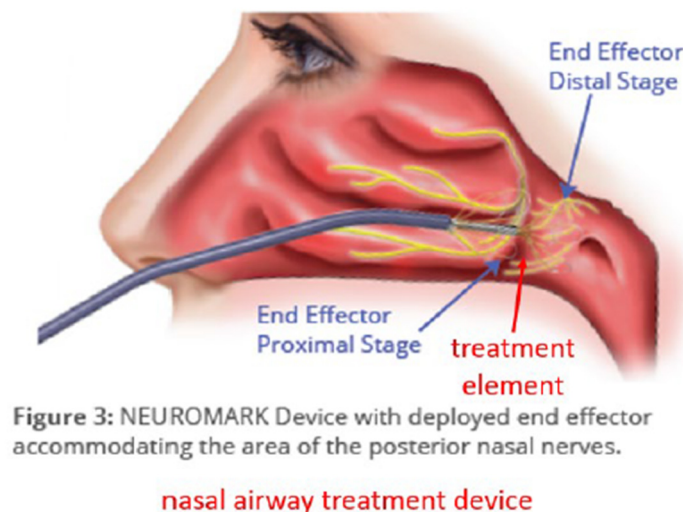
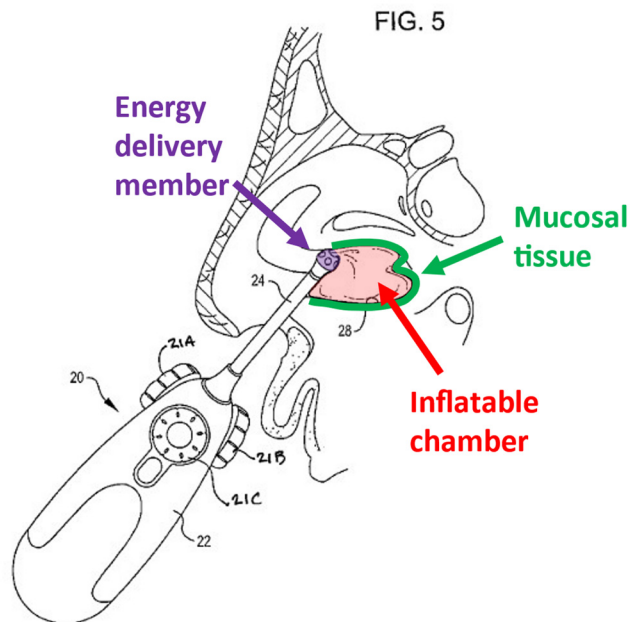


Figure 3: NEUROMARK Device with deployed end effector accommodating the area of the posterior nasal nerves.

Ex.1007, 16 (annotations made by the Patent Owner). In particular, the Patent Owner asserts that the above diagram “shows the end effector contacting mucosal tissue in at least the piriform area and floor of the nasal cavity” and therefore allegedly supports the Patent Owner’s contentions that the accused product infringes claim 22.

168. If the Patent Owner maintains that claim 22 should have the same interpretation in this proceeding as the interpretation it appears to advance in the parallel litigation, then Baker discloses it. Figure 5 of Baker is reproduced below.

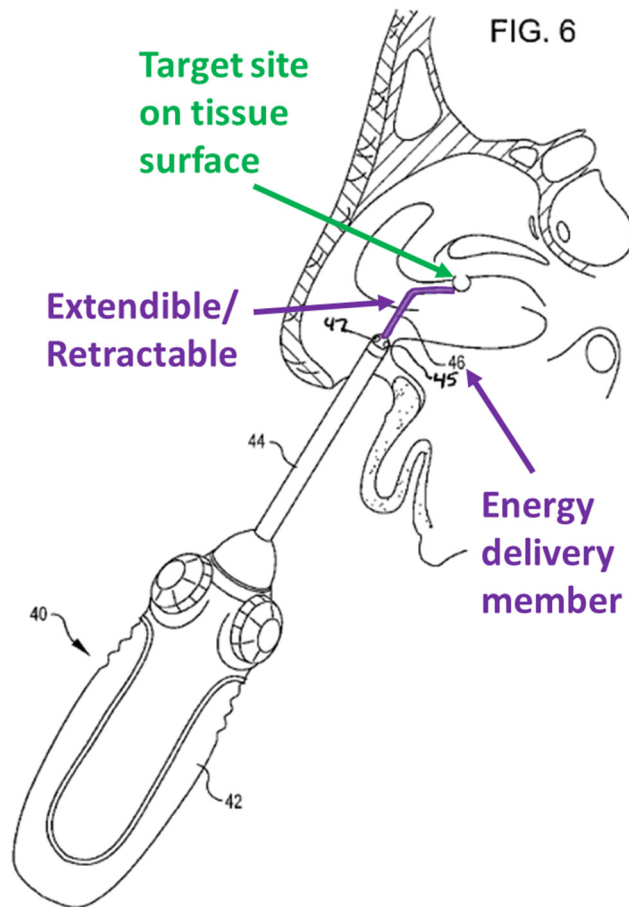


Ex.1013-Baker, FIG.5. Comparing Figure 5 of Baker with the diagram that the Patent Owner cites in its infringement allegations, Figure 5 shows the energy delivery member (i.e., the claimed treatment element), which includes inflatable

chamber 28, being in contact with the same or similar parts of the nasal anatomy as the “end effector” in the Patent Owner’s annotated diagram. Accordingly, at least under the Patent Owner’s apparent interpretation of claim 22, Baker teaches contacting mucosal tissue in the piriform area and floor of the nasal cavity, as claimed, as these are the structures that the Patent Owner argues are being contacted by the end effector in its annotated diagram of the accused product.

ii. *Baker’s method of using device 40 also satisfies claim 22*

169. The above analysis of device 20 applies equally to device 40 given that, as shown in Figure 6 below, Baker depicts device 40 as being in contact with the same or similar parts of the nasal anatomy to Figure 5 above.



Ex.1013-Baker, FIG.6

7. **Claim 23: A method as in claim 9, further comprising applying force to the mucosal tissue with the treatment element at least one of before, during or after delivering the energy based therapy to deform the mucosal tissue.**

170. Baker's method includes the claimed step of applying force to the mucosal tissue (e.g., tissue lining the mucous membranes, nasal turbinates, or pathological undesired tissue) with the treatment element (e.g., the energy delivery

member shown in Figure 4-7) at least one of before, during or after delivering the energy based therapy (e.g., acoustic energy) to deform the mucosal tissue.

i. *Baker's method of using device 20 satisfies claim 23*

171. As I explained above with reference to limitation 9[c], Baker teaches contacting a distal end and/or an inflatable chamber 28 of the energy delivery member (i.e., the claimed treatment element) with a nasal turbinate or other mucosal tissue prior to and during delivery of acoustic energy to the target tissue. Ex.1013-Baker, 16:11-18, 17:11-32. Furthermore, as I explained above for this claim in Grounds I and II, a person of ordinary skill in the art would have understood that the force applied when contacting the mucosal tissue (e.g., the pressure associated with inflating the inflatable chamber 28) deforms the mucosal tissue, as claimed, particularly given that mucosal tissue and its underlying tissues are soft and malleable such that virtually any amount of force would create at least a temporary deformation.

ii. *Baker's method of using device 40 also satisfies claim 23*

172. As I explained above with reference to limitation 9[c], Baker likewise teaches contacting energy delivery member 46 a nasal turbinate or other mucosal tissue prior to and during delivery of acoustic energy to the target tissue, and

therefore teaches that energy delivery member 46 (i.e., the claimed treatment element) applies force to and deforms the mucosal tissue for the same reasons as provided above for device 20.

8. Claim 24: A method as in claim 9, wherein delivering the energy based therapy modifies at least one property of the mucosal tissue or the underlying tissue without reshaping the tissue.

173. Baker teaches that the step of delivering the energy based therapy (e.g., acoustic energy), as recited by limitation 9[c], modifies at least one property of the mucosal tissue (e.g., tissue lining mucous membranes, nasal turbinates, or pathological undesired tissue) without reshaping the tissue.

i. *Baker's method of using device 20 satisfies claim 24*

174. As I explained above with reference to limitation 9[c], Baker's device 20 applies acoustic energy to tissue at a level "sufficient to ablate tissue and/or cellular structures or debris," or "at a sub-ablation intensity that is sufficient to disrupt tissue and/or cellular structures or debris but not ablate." Ex.1013-Baker, 18:35-37. A person of ordinary skill in the art would have understood that ablating or disrupting 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 24, the '597 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-USP597, 20:65-21:2 (“deliver[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 in the nasal valve tissue.”).

175. On the other hand, the ’597 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-USP597, 16:44-48 (“the 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, including the internal and external nasal valves”). Baker’s inflatable chamber is flexible and deformable and is therefore unlike the rigid/inelastic treatment elements that the ’597 patent discloses are used to reshape tissue. Ex.1013-Baker, 17:22-32.

ii. ***Baker's method of using device 40 also satisfies claim 24***

176. As I explained above with reference to limitation 9[c], Baker's of device 40 disrupts or ablates tissue in the same manner as device 20 and therefore modifies a property of the mucosal tissue without reshaping it, as claimed, for the same reasons provided above for device 20. *See* Ex.1013-Baker, 25:5-20, FIGs.8A-8E.

9. **Claim 44**

a. **Element 44[pre]: A method of treating a patient's nasal airway**

177. The preamble of claim 44 is the same as that of claim 9, and therefore Baker discloses the preamble for the same reasons that I explained above for limitation 9[pre].

b. **Element 44[a]: contacting a treatment element of a treatment device with a first mucosal tissue located in a part of the nasal airway other than an internal nasal valve of the airway**

178. Limitation 44[a] is simply a combination of limitation 9[b] and claim 20, and therefore Baker discloses limitation 44[a] for the same reasons that I explained above for those limitations.

c. **Element 44[b]: delivering an energy based therapy to at least one of the first mucosal tissue or an**

**underlying tissue beneath the first mucosal tissue,
using the treatment element**

179. Limitation 44[b] is the same as limitation 9[c], and therefore Baker discloses limitation 44[b] for the same reasons that I explained above for limitation 9[c].

**d. Element 44[c]: removing the treatment element from
the nasal airway.**

180. Limitation 44[c] is the same as limitation 9[d], and therefore Baker discloses limitation 44[c] for the same reasons that I explained above for limitation 9[d].

**10. Claim 46: A method as in claim 44, wherein the wherein
mucosal tissue includes tissue selected from the group
consisting of upper lateral cartilage, lower lateral cartilage,
nasal septum outside of the nasal valve, swell bodies located
on a nasal septum, a septal turbinate, a high deviated nasal
septum, a nasal scroll, a floor of the nasal cavity, a piriform
area, and swell bodies on a floor of the nasal cavity.**

181. Dependent claim 46 recites the same additional limitations as dependent claim 22, and therefore Baker discloses claim 46 for the same reasons that I explained above for claim 22.

E. Ground V: Claim 14 Is Obvious Over Baker

**1. Claim 14: A method as in claim 9, wherein adjusting the
shape comprises manipulating a secondary component of**

the treatment element to increase a surface area of the treatment element.

182. As I explained above with reference to Ground IV, Baker anticipates claim 14. I have also been informed and understand that the Patent Owner has apparently alleged, in parallel litigation, that the claimed step of manipulating a secondary component can encompass “operating a slider” positioned on the handle of the device “to deploy the end effector.” Ex.1007-Complaint-Ex.T, 10-11. To the extent the Patent Owner argues that the same interpretation should apply in this proceeding, Baker satisfies claim 14 under this interpretation. For example, Baker teaches that a handle 22 of device 20 “house[s] control mechanisms, such as mechanical knobs [that] may provide user operable control of...delivery of generally high frequency acoustic energy.” Ex.1013-Baker, 19:24-27, FIGs.4-8B. A person of ordinary skill in the art would have been motivated to apply Baker’s teaching of controls within handle 22 to its disclosures in connection with manipulating (e.g., extending and/or inflating) an energy delivery member (i.e., treatment element), as I previously described, particularly given that Baker instructs a person of ordinary skill in the art to use the control mechanisms for “other operating modalities,” *id.*, 19:25-29, and because a person of ordinary skill in the art would recognize that a control mechanism is needed to extend or inflate

the energy delivery member or portions thereof. Applying Baker's teaching in connection with the controls of handle 22 to the energy delivery member would have resulted in a user manipulating controls (e.g., knobs) within handle 22 (i.e., the claimed secondary component, at least under the Patent Owner's apparent interpretation) to increase the surface area of the treatment element (e.g., by extending a secondary mechanical support component of the energy delivery member and/or by inflating inflatable chamber 28), thereby rendering claim 14 obvious.

XI. AVAILABILITY FOR CROSS-EXAMINATION

183. 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

184. 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

185. 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 10, 2024

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

APPENDIX A

**EMORY UNIVERSITY SCHOOL OF MEDICINE
CURRICULUM VITAE**

10/27/23

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

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

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

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

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

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

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

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

John M. Del Gaudio, M.D.

Attending Physician, Grady Memorial Hospital, July 1995-present

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

c. Administrative appointments:

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

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

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

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

Ambulatory Surgery Committee, The Emory Clinic, 1996-present

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

Otolaryngology Physician Liaison, Charge Capture, 2002

d. Other positions:

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

7. Previous Academic and Professional Appointments:

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

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

8. Previous Administrative and/or Clinical Appointments:

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

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

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

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

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

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

John M. Del Gaudio, M.D.

9. Licensures/Boards:

Georgia – license# 039772, issued April 6, 1995

10. Specialty Boards:

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

11. Education:

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

NBME Part I 6/09/87

NBME Part II 9/28/88

NBME Part III 3/07/90

Certification Date 7/01/90

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

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

12. Postgraduate Training:

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

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

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

13. Military or Government Service:

14. Committee Memberships:

a. National and international:

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

President, American Rhinologic Society, September 2016- September 2017

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

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

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

John M. Del Gaudio, M.D.

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

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

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

ENToday- Literature Review Committee, 2009-2016.

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

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

Scientific Program Committee, American Rhinologic Society, 2007-2010

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

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

Credentials Committee, American Rhinologic Society, December 2002-2007

Scientific Program Committee, American Rhinologic Society, 2004-2006

Education Committee, American Rhinologic Society, 2005-2008

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

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

b. Regional and state:

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

President 2009-2010

President-Elect, 2008-2009

Treasurer- 2007-2008

Secretary, 2006-2007

Metro Atlanta Otolaryngology - Head & Neck Surgery Society

President, 1998-1999

President Elect, 1997-1998

Secretary, 1996-1997

15. Consultantships:

John M. Del Gaudio, M.D.

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

16. Editorships and Editorial Boards:

International Forum of Allergy and Rhinology, 2010-present

17. Manuscript Reviewer:

Ophthalmic Plastic and Reconstructive Surgery 2015

Cephalalgia 2013

International Forum of Allergy and Rhinology, 2010-present

American Journal of Rhinology & Allergy, 2002- present

Otolaryngology Head and Neck Surgery, 2004-present

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

Laryngoscope, 2005-present

Annals of Otolaryngology, Rhinology, Laryngology, 1998-present

Skull Base Surgery, 1999

18. Honors and Awards:

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

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

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

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

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

John M. Del Gaudio, M.D.

Fellow, The Triological Society, 2005

Emory University Woodruff Leadership Academy Class of 2005

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

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

The Alumni Prize, Jefferson Medical College, 1989

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

AOA, 1987

Hobart Amory Hare Medical Honor Society, 1987

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

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

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

Physiology Award, Jefferson Medical College, 1985-1986

19. Society Memberships:

North American Skull Base Society, 2022

American College of Surgeons, Fellow 1998

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

The Triologic Society, Fellow 2005

American Rhinologic Society, Member 1997, Fellow 2002

Georgia Society of Otolaryngology, 1996

Secretary, 2006-2007

Treasurer, 2007-2008

President Elect, 2008-2009

President, 2009-2010

Metro Atlanta Otolaryngology - Head & Neck Surgery Society, 1995

Secretary, 1996-1997

President Elect, 1997-1998

President, 1998-1999

John M. Del Gaudio, M.D.

American Medical Association, 1995

Atlanta Medical Society, 1995

Medical Association of Georgia, 1995

National Board of Medical Examiners, Diplomate 1990

Sigma Xi, The Medical Research Society, 1988

20. Organization of National or International Conferences:

a. Administrative positions:

a. Please refer to Course Director and National Position sections

c. Sessions as chair:

a. Please refer to National and International Presentations

21. Research Focus:

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

22. Patents: None

23. Grant Support:

a. Active Support/Clinical Trials

A 24-Week Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study Evaluating the Efficacy and Safety of Intranasal Administration of 186 and 372 µg of OPN-375 Twice a Day (BID) in Subjects with Chronic Sinusitis With or Without the Presence of Nasal Polyps- Clinical Trial

OptiNose

Co-Investigator (PI Joshua Levy)

2019-

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

Cumberland Pharmaceutical

Co-Investigator

2019-

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

John M. Del Gaudio, M.D.

GlaxoSmithKline
Co-Investigator
2019-

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

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

b. Previous support:

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

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

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

c. Collaborator:

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

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

John M. Del Gaudio, M.D.

Characterization of Human Sinonasal Intercellular Junctional Proteins

American Rhinologic Society

New Investigator Award

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

2010-2011, \$25,000

Intercellular Junctional Proteins in Rhinosinusitis – Inflammatory Mediator Effects

Emory University Research Committee

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

2012, \$30,000

24. Clinical Service Contributions:

25. Formal Teaching:

a. Medical student teaching

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

b. Graduate program

1. Training programs:

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

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

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

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

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

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

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

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

John M. Del Gaudio, M.D.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

John M. Del Gaudio, M.D.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

John M. Del Gaudio, M.D.

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

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

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

2. Residency program:

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

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

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

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

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

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

26. Supervisory Teaching:

a. Ph.D. students directly supervised:

b. Fellows directly supervised:

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

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

c. Residency program

Otolaryngology Residency Program Director, January 2007-July 2015

John M. Del Gaudio, M.D.

Chief of Rhinology and Sinus Surgery 2004-present

d. Other

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

27. Lectureships, Seminar Invitations, and Visiting Professorships:

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

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

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

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

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

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

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

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

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

John M. Del Gaudio, M.D.

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

John M. Del Gaudio, M.D.

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.

John M. Del Gaudio, M.D.

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.

John M. Del Gaudio, M.D.

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

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

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

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

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

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

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

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

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

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

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

John M. Del Gaudio, M.D.

June 13-16, 2016.

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

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

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

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

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

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

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

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

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

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

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

Reunion Annual AOCCCHE. Asociación de Otorrinolaringología y Cirugía de Cabeza, A.C. August 28-30, 2014. Guanajuato, Mexico.

John M. Del Gaudio, M.D.

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.

John M. Del Gaudio, M.D.

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

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

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

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

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

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

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

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

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

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

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

Anatomy and Surgery of the Frontal Recess

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

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

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

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

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

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

Southern States Rhinology Course.

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

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

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

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

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

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

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

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

Diagnosis and Management of Zenker's Diverticulum.

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

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

John M. Del Gaudio, M.D.

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

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

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

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

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

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

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

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

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

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

John M. Del Gaudio, M.D.

16-17, 2004.

- Endoscopic Orbital Decompression and Surgery of the Pterygopalatine and Infratemporal Fossae.
- Endoscopic Resection of Sinonasal Tumors.
- Case Studies on Sinonasal Disease.
- Basic Principles in Endoscopic Sinus Surgery.
- Surgery of the Sphenoid Sinus.

University of Pennsylvania 3rd International Update Course: Otolaryngology Underwater. Cozumel, Mexico. May 21, 2004.

- Skull Base Surgery: Endoscopic or Open. Panel discussion.
- Frontal Recess Anatomic Variations
- Image-Guided Sinus Surgery. Panel discussion.

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

- Reflux and Sinusitis.

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

- Laryngopharyngeal Reflux and Associated Head and Neck Disorders.

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

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

28. National and International Conferences:

American Academy of Otolaryngology- Head and Neck Surgery Annual Meeting. Nashville, TN. October 2, 2023.

- Understanding Central Compartment Atopic Disease. Panel Moderator.

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

- The ABCs of Central Compartment Atopic Disease. Panel Moderator

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

- Olfaction: Practice Guidelines and Management Strategies- Panelist
- Difficult Cases, Panel Moderator

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

- Central Compartment Atopic Disease: What do we know?

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

- The Impact of Covid on Rhinology- Panelist
- New Technologies and Indications for Office Rhinologic Surgery, Panel Moderator

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

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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.

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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

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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

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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.

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

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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.

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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 it's 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.

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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)

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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.

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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:

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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.

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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

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APPENDIX B

Appendix B: Materials Considered

Exhibit	Description
1001	U.S. Patent No. 9,072,597 (“’597 patent”)
1003	File History of U.S. Patent No. 9,072,597
1007	Exhibit T to District Court Amended Complaint
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 infraturbinal 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”)
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”)
1047	U.S. Patent No. 4,271,848 (“Turner”)
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”)
1060	Andrew P. Lane, Nasal anatomy and physiology 12 Facial Plast Surg Clin N Am 387 (2004) (“Lane”)

DelGaudio Declaration: Appendix B (Materials Considered)

APPENDIX C

Appendix C (Challenged Claims)

Ground	35 U.S.C. Section	Claims	References
I	102	9, 14, 16, 18, 20, 22-24, 44, 46	Gertner
II	102	9, 14, 18, 20, 22, 23, 44, 46	Edwards-'535
III	103	16	Edwards-'535
IV	102	9, 14, 16, 18, 20, 22-24, 44, 46	Baker
V	103	14	Baker

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
9[pre]	9. A method of treating a patient's nasal airway, the method comprising:	<p><u>Ground I</u></p> <p><u>Ground II</u></p> <p><u>Ground IV</u></p>
9[a]	adjusting a shape of a nasal airway treatment device;	
9[b]	contacting a treatment element of the treatment device with mucosal tissue in the patient's nasal airway;	
9[c]	delivering an energy based therapy to at least one of the mucosal tissue or an underlying tissue beneath the mucosal tissue, using the treatment element; and	

DelGaudio Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
9[d]	removing the treatment element from the nasal airway.	
14	A method as in claim 9, wherein adjusting the shape comprises manipulating a secondary component of the treatment element to increase a surface area of the treatment element.	<u>Ground I</u> <u>Ground II</u> <u>Ground IV</u> <u>Ground V</u>
16	A method as in claim 9, wherein adjusting the shape comprises forming at least one bend in a shaft of the treatment device.	<u>Ground I</u> <u>Ground III</u> <u>Ground IV</u>
18	A method as in claim 9, wherein delivering the energy based therapy comprises delivering energy in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light, laser and quantic molecular resonance.	<u>Ground I</u> <u>Ground II</u> <u>Ground IV</u>
20	A method as in claim 9, wherein the mucosal tissue is located in a part of the nasal airway other than an internal nasal valve of the airway.	<u>Ground I</u> <u>Ground II</u> <u>Ground IV</u>

DelGaudio Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
22	A method as in claim 20, wherein the wherein mucosal tissue includes tissue selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum within the nasal valve, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity.	<u>Ground I</u> <u>Ground II</u> <u>Ground IV</u>
23	A method as in claim 9, further comprising applying force to the mucosal tissue with the treatment element at least one of before, during or after delivering the energy based therapy to deform the mucosal tissue.	<u>Ground I</u> <u>Ground II</u> <u>Ground IV</u>
24	A method as in claim 9, wherein delivering the energy based therapy modifies at least one property of the mucosal tissue or the underlying tissue without reshaping the tissue.	<u>Ground I</u> <u>Ground IV</u>
44[pre]	A method of treating a patient's nasal airway, the method comprising:	<u>Ground I</u> <u>Ground II</u> <u>Ground IV</u>
44[a]	contacting a treatment element of a treatment device with a first mucosal tissue located in a part of the nasal airway other than an internal nasal valve of the airway;	

DelGaudio Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
44[b]	delivering an energy based therapy to at least one of the first mucosal tissue or an underlying tissue beneath the first mucosal tissue, using the treatment element; and	
44[c]	removing the treatment element from the nasal airway.	
46	A method as in claim 44, wherein the wherein mucosal tissue includes tissue selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity.	<u>Ground I</u> <u>Ground II</u> <u>Ground IV</u>