UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AERIN MEDICAL INC.
Petitioner

v.

NEURENT MEDICAL LTD.
Patent Owner.

U.S. Patent No. 12,096,974

Case No.: IPR2025-01127

DECLARATION OF DR. DANIEL VAN DER WEIDE UNDER 37 C.F.R. § 1.68 IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW

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I, Dr. Daniel van der Weide, do hereby declare as follows:

I. INTRODUCTION

1. I make this declaration based upon my own personal knowledge and, if called upon to testify, will testify competently to the matters stated herein.

2. I have been asked by Petitioner to provide my expert opinion in connection with the *Inter Partes* Review of U.S. Patent No. 12,096,974 ("the '974 patent") to Townley concerning whether the '974 patent is unpatentable over certain prior art. This declaration is a statement of my opinions on issues relating to the patentability of claims 1–20 (the "Challenged Claims") of the '974 patent. As I explain more fully below, it is my opinion that all of the Challenged Claims would have been obvious to a person of ordinary skill in the art at the time of the alleged invention.

3. I am being compensated for my work in this matter at my standard hourly rate. I am also being reimbursed for reasonable and customary expenses associated with my work and testimony in this investigation. My compensation is not contingent on the outcome of this matter or the specifics of my testimony.

4. I have reviewed and considered the following documents in connection with my analysis of the '974 patent:

Exhibit	Description
1001	U.S. Patent No. 12,096,974 ("the '974 patent")
1002	File history of U.S. Patent No. 12,096,974

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Exhibit	Description
1004	U.S. Patent Appl. Pub. No. 2016/0331459 ("Townley")
1005	U.S. Patent Appl. Pub. No. 2015/0202003 ("Wolf-003")
1006	U.S. Patent Appl. Pub. No. 2019/0282290 ("Wolf-290")
1007	U.S. Patent Appl. Pub. No. 2020/0129223 ("Angeles")
1008	U.S. Patent No. 11,883,091
1009	File history of U.S. Patent No. 11,883,091
1010	U.S. Patent No. 11,998,262 ("the '262 patent")
1011	File history of U.S. Patent No. 11,998,262
1012	U.S. Patent No. 12,089,889 ("the '889 patent")
1013	File history of U.S. Patent No. 12,089,889
1014	U.S. Patent No. 12,096,973 ("the '973 patent")
1015	File history of U.S. Patent No. 12,096,973
1016	RESERVED
1017	RESERVED
1018	Andrew Lane, *Nasal anatomy and physiology*, Facial Plast. Surg. Clin. N. Am. 12:387-395 (2004)
1019	U.S. Patent Appl. Pub. No. 2011/0021971
1020	U.S. Patent Appl. Pub. No. 2014/0096772
1021	Brook, Itzhak. "*Sinusitis: From Microbiology To Management*" 2006
1022	*Curriculum Vitae* of Dr. Daniel van der Weide
1024	U.S. Patent No. 6,517,535

5. In forming the opinions expressed below, I have considered:

a) the documents listed above;

b) the relevant legal standards, including the standards for anticipation, obviousness, person of ordinary skill in the art, and

any additional authoritative documents as cited in the body of this declaration; and

c) my own knowledge and experience based upon my work in the electrical engineering and medical device fields.

6. Unless otherwise noted, all emphasis in any quoted material has been added.

II. QUALIFICATIONS AND PROFESSIONAL EXPERIENCE

7. My complete qualifications and professional experience are described in my *Curriculum Vitae*, a copy of which can be found in Exhibit 1022. The following is a brief summary of my relevant qualifications and professional experience.

8. I obtained a Ph.D. in Electrical Engineering in 1993 from Stanford University. I also received a Bachelor of Science in Electrical Engineering from the University of Iowa in 1988.

9. I am Grainger Institute of Engineering Professor at the University of Wisconsin-Madison. I was appointed a Full Professor in the Electrical and Computer Engineering Department of the University of Wisconsin-Madison in 2004. I have also received courtesy appointments in the Radiology, Biomedical Engineering, and Materials Science Departments at the University of Wisconsin-Madison. I previously served as an Associate Professor in the University of

Wisconsin-Madison's Electrical and Computer Engineering Department from 1999 to 2004. Before that, I also served as both an Associate Professor and an Assistant Professor in the Electrical and Computer Engineering Department of the University of Delaware from 1995-1999. And from 1993 to 1995 I was a Post-Doctoral Researcher in the group of Klaus von Klitzing (Nobel Prize winner) at the Max Planck Institut für Festkörperforschung in Stuttgart, Germany.

10. I have extensive professional experience. I am the Founder and President of vdW Design, LLC, which specializes in design and consulting services for electrical measurements at high frequencies. I also have professional experience with medical devices. For example, I have been Co-Founder, Board Member and Advisor for NeuWave Medical, Inc., which develops and sells microwave-based systems for percutaneous tissue ablation. I have been Co-Founder, Board Member and Advisor for Elucent Medical, Inc., which develops and sells wireless surgical navigation systems. In addition, I am the Founder and President of NFI, LLC, which develops devices relating to near-field imaging for skin and other cancers. I have also been involved with numerous other professional companies, starting companies in the areas of ultrawideband antennas, coherent lightwave signal analyzers and handwriting recognition devices; and working for companies in microwave devices, cellular telephones, dye laser systems, and automatic testing equipment.

11. I have also received extensive recognition for my work. I received the

Vilas Associate Award, the Alexander Von Humboldt Fellowship, and the PECASE Award from the National Science Foundation. I also received the Young Investigator Program Award from the Office of Naval Research. The DARPA ULTRA Program also awarded me with the Innovation/Technical Achievement Award. I also received the University Research Award from the Ford Motor Company. Additionally, I received the Dean's Merit Increase and the Provost's Special Merit Increase from the University of Delaware. I was also a Fellow at both the National Science Foundation and the University of Delaware.

12. I have performed extensive research, receiving over forty research grants. I have also supervised numerous post-doctoral researchers and doctoral candidates and graduates. Through my academic placements, I have extensive teaching experience, including in courses such as Applied Communication Systems, Advanced Communications Circuit Designs, Electromagnetic Wave Transmission, and many others.

13. My work has also led to over 110 journal publications, numerous book sections, over one 160 conference presentations, and over 80 patents in the United States and abroad.

III. LEGAL STANDARDS

14. I am not an attorney. In preparing and expressing my opinions and considering the subject matter of the '974 patent, I am relying on certain basic legal

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principles that counsel have explained to me. These principles are discussed below.

15. I understand that prior art to the '974 patent includes patents and printed publications in the relevant art that predate the proper priority date of the alleged invention recited in the '974 patent.

A. Anticipation

16. I have been informed by counsel that a claimed invention is anticipated under 35 U.S.C. § 102 if all limitations of the claim are disclosed, expressly or inherently, by a single prior art reference.

B. Obviousness

17. I have been informed by counsel that a claimed invention is unpatentable for being obvious under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. I have also been informed by counsel that the obviousness analysis takes into account factual inquiries including the level of ordinary skill in the art, the scope and content of the prior art, and the differences between the prior art and the claimed subject matter.

18. I have been informed by counsel that the Supreme Court has recognized several rationales for combining references or modifying a reference to show obviousness of claimed subject matter. Some of these rationales include the

following: (a) combining prior art elements according to known methods to yield predictable results; (b) simple substitution of one known element for another to obtain predictable results; (c) use of a known technique to improve a similar device (method, or product) in the same way; (d) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (e) choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and (f) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

19. I have been informed by counsel that, for an obviousness combination relying on multiple teachings, that there should have been a 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, and that there should have been a reasonable expectation of success in combining those teachings. I understand from counsel that a motivation to combine may be provided by, for instance, from the prior art teachings themselves and/or knowledge of a person or ordinary skill in the art.

20. I further understand that certain factors may support or rebut the obviousness of a claim. 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—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.

21. I am not aware of any allegations by the named inventor of the ’974 patent or any assignee of the ’974 patent that any secondary considerations are relevant to the obviousness analysis of any Challenged Claim of the ’974 patent.

C. Person of Ordinary Skill in the Art (POSITA)

22. I understand that my assessment of the claims of the ’974 patent must be undertaken from the perspective of what would have been known or understood by a person having ordinary skill in the art, reading the ’974 patent on its earliest effective filing date (priority date) in light of the specification and file history of the ’974 patent. I will refer to such a person as a “POSITA.”

23. I understand that my analysis and opinions expressed in this declaration must be rendered based on the perspective of a POSITA as of the priority date of the ’974 patent. I also understand that a POSITA is a hypothetical person who is presumed to know the relevant art as of the earliest effective filing date of the alleged

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invention claimed in the ’974 patent.

24. I further understand that in determining the level of ordinary skill in the art, I am to consider factors, including:

- the educational level and experience of active workers in the field,
- the type of problems encountered in the art or field of invention,
- the nature of prior art solutions to those problems,
- sophistication of the technology, and
- the rapidity with which innovations are made.

25. I have been instructed to assume a person of ordinary skill in the art is not a specific real individual, but rather a hypothetical individual having the qualities reflected by the factors discussed above.

IV. OVERVIEW OF THE ’974 PATENT

A. Priority Chain

26. The ’974 patent was filed on April 26, 2024, and purports to claim priority to (a) U.S. patent application no. 18,411,476, filed January 12, 2024, now U.S. Patent No. 11,998,262 (“the ’262 patent), (b) U.S. patent application no. 17/225,560, filed April 8, 2021, now U.S. Patent No. 11,883,091 (“the ’091 patent”), and (c) U.S. provisional patent application no. 63/007,584, filed April 9, 2020. (Ex-1001, Cover.) For my analysis, I apply an effective filing date of April 9, 2020, without conceding the ’974 patent is entitled to claim priority to such a date.

B. General Background

27. The ’974 patent is titled “Systems and Methods for Improving Sleep With Therapeutic Nasal Treatment,” and relates to “improving sleep by treating at least one of rhinitis, congestion, and/or rhinorrhea to thereby reduce or eliminate symptoms associated therewith, including, but not limited to, nasal congestion, coughing, sneezing, and nasal or throat irritation and itching.” (Ex-1001 at Abstract.) The ’974 patent discloses a “neuromodulation device 102” as shown in Figure 2 below:

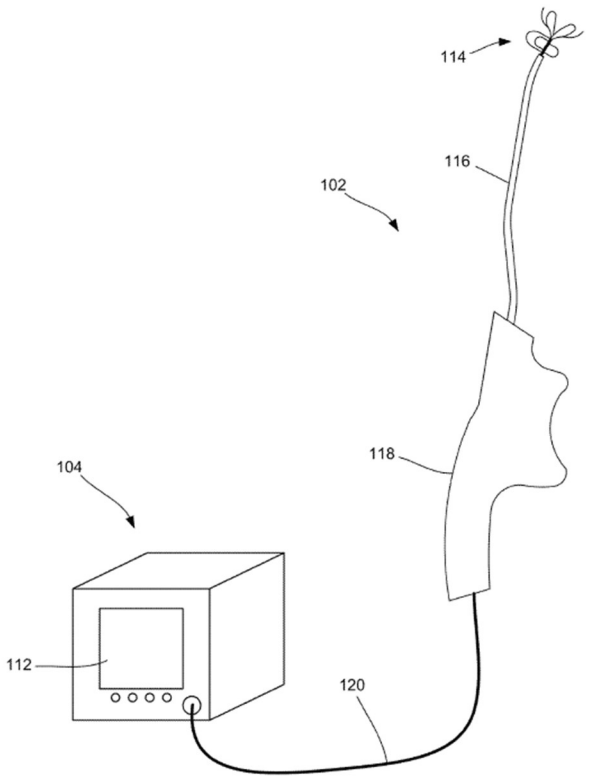

FIG. 2

(*Id*. at FIG. 2.)

28. As shown, the "neuromodulation device 102" includes a "multi-segment end effector 114, a shaft 116 operably associated with the end effector 114 and a handle 118." (*Id*. at 12:26-28.) "The end effector 114 is configured to be advanced into the nasal cavity of a patient 12 and positioned at a location associated with one or more target sites to undergo therapeutic neuromodulation treatment." (*Id*. at 12:26-32.)

29. Figure 5c (below) illustrates an enlarged, top view of a multi-segment end effector. (*Id.* at 7:22-23.) "The first and second segments 122, 124, specifically struts 130, 132, and 134 include one or more energy delivery elements, such as a plurality of electrodes 136." (*Id.* at 19:19-21.) "The electrodes 136 can apply bipolar or multi-polar radiofrequency (RF) energy to the target site to therapeutically modulate postganglionic parasympathetic nerves that innervate the nasal mucosa proximate to the target site." (*Id.* at 19:27-31.)

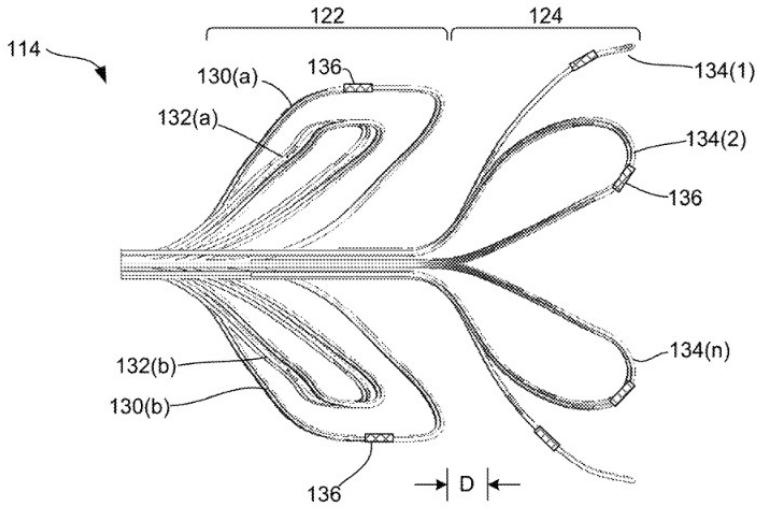

FIG. 5C

30. Figure 12 of the ’974 patent, reproduced below, illustrates device 102 deployed in a nasal passage:

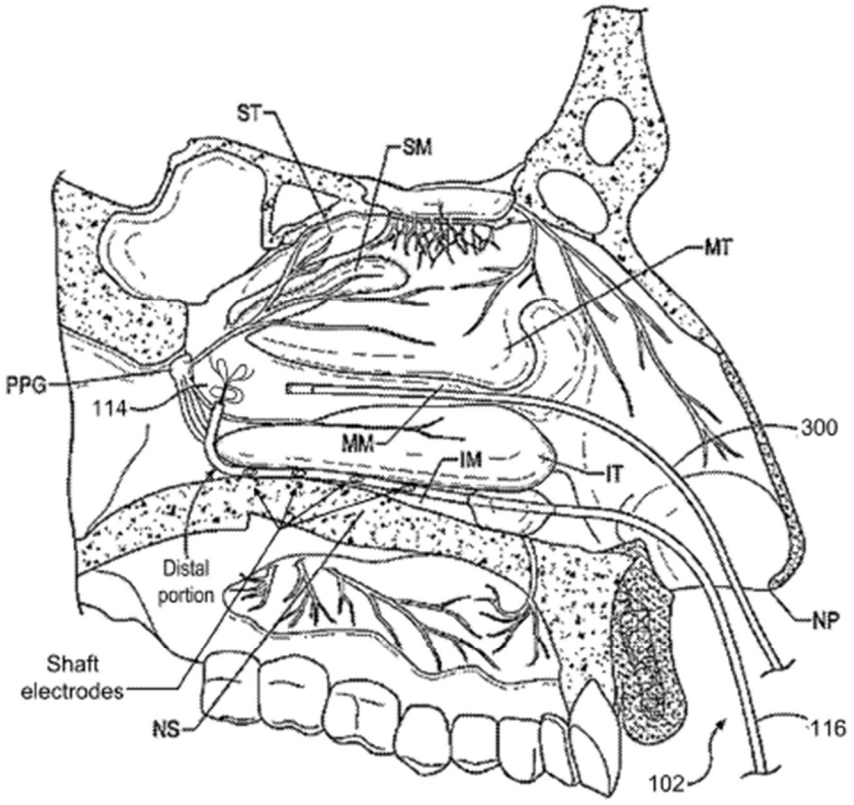

FIG. 12

(*Id*. at FIG. 12.)

31. According to the ’974 patent, Figure 12 illustrates “one approach for delivering an end effector 114 [to] a target site within a nasal region.” (*Id*. at 27:60-62.) The “distal portion of the shaft 116” extends into the nasal passage and “around the posterior portion of the inferior turbinate (IT) where the end effector 114 is

deployed at a treatment site." (*Id*. at 27:63:28:1.) The '974 patent discloses that, "[o]nce positioned at the target site, the therapeutic modulation may be applied via the one or more electrodes 136 and/or other features of the end effector 114 to precise, localized regions of tissue to induce one or more desired therapeutic neuromodulating effects to disrupt parasympathetic motor sensory function." (*Id*. at 29:7-12.)

C. The '974 patent's claims

32. The '974 patent has twenty claims of which claim 1 is the only independent claim.

33. Claim 1 relates to a methods for "treating at least one of rhinitis, congestion, and rhinorrhea within a sino-nasal cavity of a patient," by "advancing a multi-electrode end effector into the sino-nasal cavity of the patient," and "delivering energy, via the first and second electrodes, to one or more target sites within a sino-nasal cavity of the patient to disrupt multiple neural signals to mucus producing and/or mucosal engorgement elements, thereby reducing production of mucus and/or mucosal engorgement within a nose of the patient and reducing or eliminating one or more symptoms associated with at least one of rhinitis, congestion, and rhinorrhea to improve nasal breathability of the patient." (Ex-1001 at claim 1.)

34. Claim 1 requires a specific device arrangement, including of the first and second electrodes of the multi-electrode end effector:

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> "wherein the multi-electrode end effector is operably associated with a shaft of a treatment device and configured for delivering energy to one or more target sites within the sino-nasal cavity of the patient, wherein the multi-electrode end effector comprises a first electrode that is spaced apart from a second electrode along a length of the multi-electrode end effector, wherein each of the first and second electrodes comprise an active state and an inactive state and comprise a respective location on the multi-electrode end effector, wherein at least one portion of the multi-electrode end effector comprises a diameter that is larger than a diameter of the shaft, and wherein: the first electrode is exposed from a surface of the multi-electrode end effector and is positioned at a discrete portion thereon, the first electrode extending in a first outward direction relative to a longitudinal axis of the shaft to interact with anatomy at a first location within the nasal cavity; and the second electrode is exposed from the surface of the multi-electrode end effector and is positioned at a discrete portion thereon, the second electrode extending in a second outward direction relative to a longitudinal axis of the shaft to interact with anatomy at a second location within the nasal cavity; …"

(*Id.*)

However, as shown herein, such methods of treatment were known as were the claimed multi-electrode end effector devices.

D. Prosecution history of the '974, '262 and '091 patents

35. I have reviewed the prosecution history of the '974 patent, which is included as Exhibit 1002. From my review, I understand that the U.S. Patent Office

did not reject the claims based on any prior art. Instead, the claims were rejected for obviousness-type double patenting. (Ex-1002 at 76-82.) After a terminal disclaimer was filed, an allowance was issued. (Ex-1002 at 15-22 (Notice of Allowance), 61-66 (response with terminal disclaimer).) In the reasons for allowance, the Examiner repeated the claim language of claim 1 of the '974 patent and then stated:

> "The most pertinent piece of prior art, Townley (U.S. Patent No. 11,998,262), no longer constitutes as prior art in view of the terminal [disclaimer] filed 07/15/2024. Therefore, it is the Examiner's position that the claimed invention is in condition for allowance." (*Id.,* 21.)

36. I have also reviewed the prosecution history of the '262 patent. From my review, I understand that the U.S. Patent Office Examiner did not issue any rejections against the claims. Instead, a first action allowance was issued. (Ex-1011 at 26-34.) In the Reasons for Allowance, the Examiner repeated the claim language of claim 1 of the '262 patent and then stated:

> "*Specifically, the prior art does not teach the structural limitations* 'wherein each of the first and second electrodes comprises an active state and an inactive state and comprises a respective location on the multi-electrode end effector, wherein: the first electrode is exposed from a surface of the multi-electrode end effector and is positioned at a separate and discrete portion thereon, the first electrode extending in a first outward direction relative to a longitudinal axis of the shaft to interact with anatomy at a first location within the nasal cavity; and the second electrode is exposed from a surface of the multi-electrode end

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> effector and is positioned at a separate and discrete portion thereon, the second electrode extending in a second outward direction relative to a longitudinal axis of the shaft to interact with anatomy at a second location within the nasal cavity;' *that is seen in parent patent (11,883,091)*, and it would not have been obvious to one of ordinary skill in the art to modify known probe structures to arrive at the claimed structural limitations of the multi-electrode end effector."

(Ex-1011 at 32-33.)

37. I have also reviewed the prosecution history of the '091 patent, a predecessor application to the '974 patent. There, the Examiner initially rejected the claims based on Townley (Ex-1004), but then later allowed the claims after substantial amendments were made. (Ex-1009 at 129-150 (first office action), 117-125 (response to first office action), 14-21 (Notice of Allowance).) Here, the Examiner allowed the claims of the '091 patent because:

> "[T]he prior art does not describe 'a second set of flexible support elements that each comprises an array of electrodes positioned at separate and discrete portions thereon and extend in a second outward direction relative to the longitudinal axis and substantially opposite the first outward direction and are positioned within a second half of the first segment and cooperatively form an inwardly extending second concave shape opposing the first concave shape when the first segment is in the expanded deployed configuration' as detailed in the instant application."

(Ex-1009 at 20.)

38. The ’974 patent claims fail to include many of these requirements including:

- “flexible support elements;” and
- “a second array of electrodes that (a) extend “substantially opposite the first outward direction,” (b) “are positioned within a second half of the first segment and cooperatively form an inwardly extending second concave shape opposing the first concave shape when the first segment is in the expanded deployed configuration.”

Indeed, had the Examiner properly evaluated how the ’974 patent’s claims were broadened relative to the ’091 patent, the Examiner would have realized that the Townley reference (and other prior art) read on the ’974 patent’s claims.

V. TECHNOLOGY BACKGROUND

39. Below I provide a brief overview of nasal anatomy, rhinosinusitis, and the use of radiofrequency (RF) electrodes to treat target tissues and nerves in the nose, all of which were well-known to a POSITA prior to the ’974 patent. I also provide a brief discussion of the prior art references I discuss in the Grounds.

A. Nasal Anatomy and Rhinosinusitus Were Well Understood

40. Well before the ’974 patent, the nasal anatomy was well known. Pertinent anatomical features of the nose are shown in Lane (Ex-1018) and reproduced below.

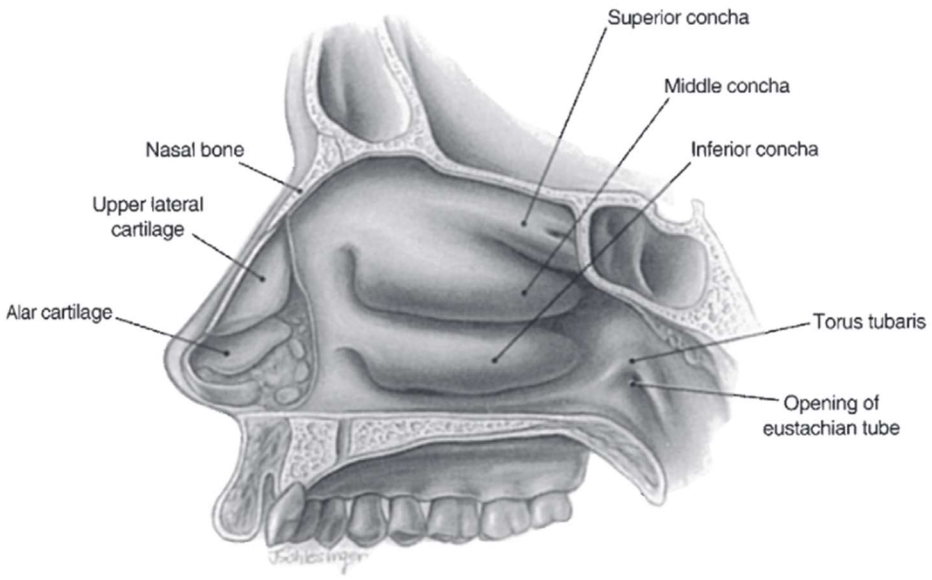

Fig. 1. Lateral nasal wall anatomy. Left side of the nose with nasal septum removed. (*From* O'Neal RM, Beil Jr RJ, Schlesinger J. Surgical anatomy of the nose. Otolaryngol Clin N Am 1999;32(1):175 [Fig. 29]; with permission.)

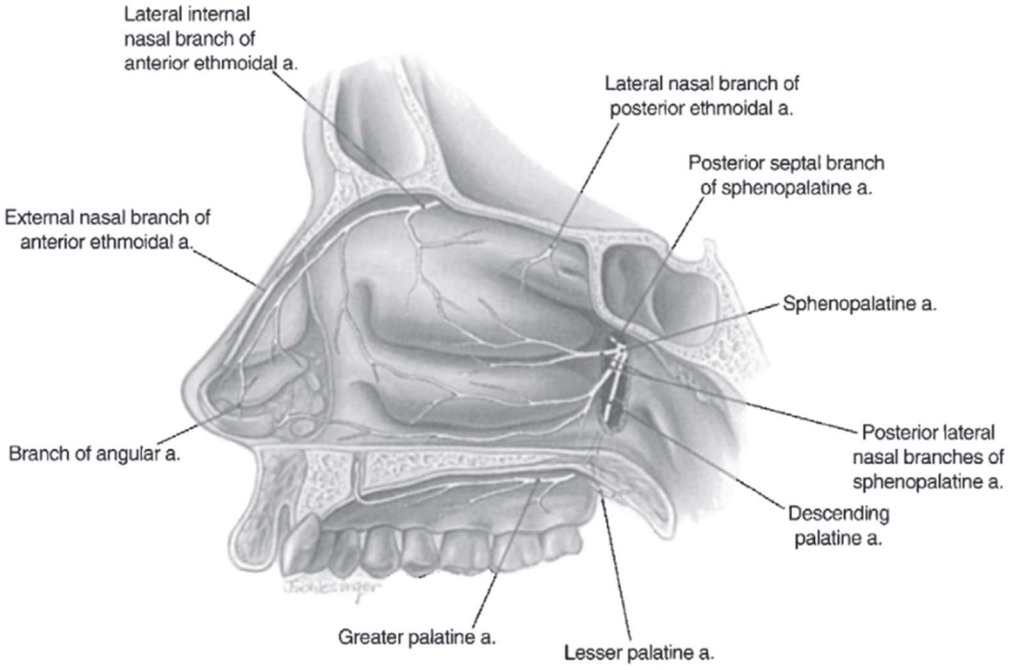

Fig. 2. Right lateral wall of the nose showing arterial blood supply. (*From* Otolaryngol Clin N Am 1999;177 [Fig. 32]; with permission.)

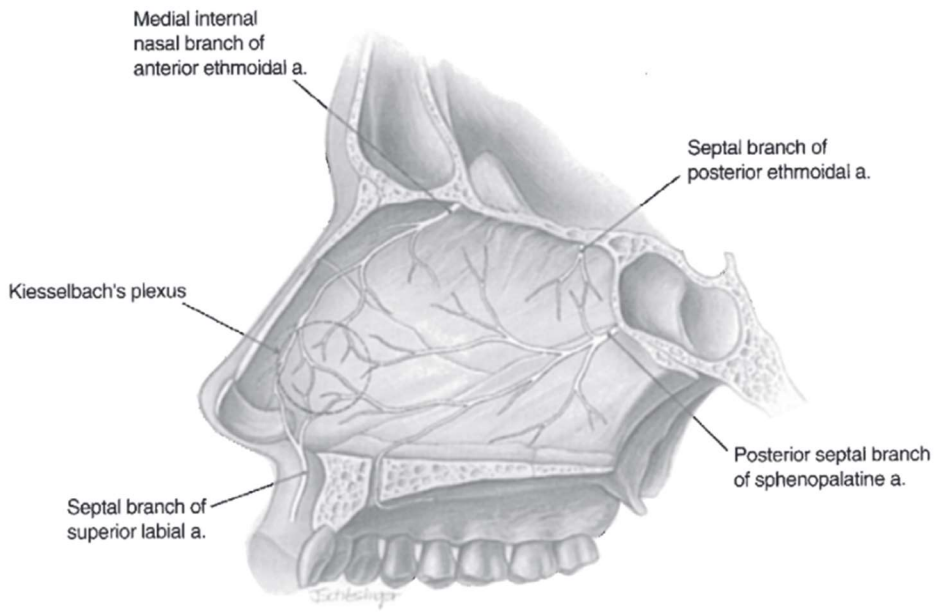

Fig. 3. Left side of the nasal septum showing arterial blood supply. Circle demonstrates Kesselbach's plexus. (*From* Otolaryngol Clin N Am 1999;177 [Fig. 33]; with permission.)

(Ex-1018-Lane at FIGS. 1-3.)

As Lane explains:

"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. The projection of each concha into the nasal cavity creates a space beneath the turbinate called a meatus. The inferior meatus lies between the inferior turbinate and the floor of the nose. Contained within this space is the orifice of the nasolacrimal duct. Between the inferior and middle turbinate lies the middle meatus, a region critical to the function of the anterior paranasal sinuses. The frontal, maxillary, and ethmoid sinuses all have their outflow through this area either directly or by means of the ethmoidal infundibulum."

(Ex-1018-Lane at 388.)[1]

41. Townley also illustrates and describes the anatomy of the nasal cavity. (Ex-1004-Townley at FIGS. 1A-1C, [0033]-[0041].)

42. Diagnosing and treating symptoms and conditions associated with rhinosinusitis (including rhinitis, congestion and/or rhinorrhea) was also well known. As the year 2006 book *Sinusitis* explains:

> "Sinusitis refers to an inflammatory process localized within one or more of the paranasal sinuses, whereas ***rhinitis*** *is an inflammatory process within the nasal cavity*. Since it is unusual for sinusitis to be present without a concurrent rhinitis, *rhinosinusitis may be a more appropriate descriptor for this clinical disease process*. *Rhinosinusitis has recently been defined as 'a group of disorders characterized by inflammation of the mucosa of the nose and paranasal sinuses*'. This definition has two important features: the understanding that rhinosinusitis is a group of disorders with a number of different potential etiologies, and that the hallmark is inflammation, whether that inflammation is caused by an infection or some other inflammatory

[1] The term "concha" and "turbinate" are synonymous as it relates to the inferior, middle, and superior turbinates. (Ex-1001 at 16:63-67 ("The posterior nasal nerves are branches of the maxillary nerve that innervate the nasal cavity via a number of smaller medial and lateral branches extending through the mucosa of the superior and middle turbinates ST, MT (i.e., *nasal conchae*) and to the nasal septum.").)

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> process. … *Chronic rhinosinusitis (CRS)* may be associated with a number of different disorders or pathogenic mechanisms."

(Ex-1021 at 40.)

> "The most common symptoms of rhinosinusitis include **nasal congestion**, **purulent rhinorrhea**, facial pressure or pain, and anosmia or hyposmia." (*Id.* at 39.) "The symptoms of **nasal congestion**/ obstruction, facial pressure/pain, **nasal purulence or rhinorrhea**, and anosmia/hyposmia are considered major symptoms. The presence of two major symptoms is sufficient for the diagnosis of rhinosinusitis."

(*Id.* at 44.)

43. Townley includes a generally similar description of rhinosinusitis:

> "Rhinosinusitis is characterized as an inflammation of the mucous membrane of the nose and refers to a *group of conditions*, including allergic rhinitis, non-allergic rhinitis, *chronic rhinitis*, chronic sinusitis, and medical resistant rhinitis. *Symptoms of rhinosinusitis include nasal blockage, obstruction,* ***congestion, nasal discharge (e.g., rhinorrhea and/or posterior nasal drip****), facial pain, facial pressure, and/or reduction or loss of smell*. … Depending on the duration and type of systems, rhinosinusitis can fall within four subtypes: acute rhinosinusitis, recurrent rhinosinusitis, chronic rhinosinusitis with nasal polyposis (i.e., soft, non-cancerous growths on the lining of the nasal passages or sinuses), and chronic rhinosinusitis without nasal polyposis. Acute rhinosinusitis refers to symptoms lasting for less than twelve weeks, whereas chronic rhinosinusitis (with and without nasal polyposis) refers to symptoms lasting longer than twelve weeks.

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> Recurrent rhinosinusitis refers to four or more episodes of acute rhinosinusitis within a twelve-month period, with resolution of symptoms between each episode."

(Ex-1004-Townley at [0003].)

B. Radiofrequency Treatment of Target Tissue In The Nasal Cavity To Address Symptoms and Conditions of Rhinosinusitus Was Well Known

44. Prior to the '974 patent, the literature was replete with methods, systems and apparatus for addressing symptoms and conditions of rhinosinusitis, including by removing obstructions or blockages within the nasal cavity and/or by targeting tissues and/or nerves that cause excess mucus production. One common manner of doing so was by applying radiofrequency energy to target tissue(s) and/or nerves.

45. For example, Wolf-003 describes "systems, devices and methods for treating structures within the upper airway to reduce and/or prevent overproduction and/or flow of mucus to alleviate the discomfort of post nasal drip symptoms." (Ex-1005-Wolf-003 at [0003].) Wolf-003's "treatment device[s] may apply energy of form selected from a group consisting of ultrasound, microwave, heat, *radiofrequency*, electrical, light, cryogenic and laser." (*Id.* at [0014].) "In embodiments using energy delivery, a handle may be provided comprising a button or other input control to activate one or more electrodes. Electrodes may comprise one or more monopolar needles, one or more monopolar plates, or *one or more bipolar electrode pairs* (which may also comprise one or more needles or plates).

These electrodes may be located in various locations, for example, inside the nasal passageway, inside the throat or external to both nose and throat. For example, when using [] bipolar electrode pairs, a first electrode surface may be positioned internal to the nose and a second electrode surface may be positioned external to the nose, so that the two electrode surface are positioned on opposite sides of the nasal tissue. In certain implementations, electrodes may be surface acting, transdermal or subdermal (e.g., by access via an incision) or a combination thereof." (*Id.* at [0016].) "In certain implementations, the method may further comprise delivering radiofrequency (RF) energy to the one or more electrodes to locally heat the tissue to be treated, wherein delivering RF energy while altering the properties of the tissue causes less mucus production in the treatment area." (*Id.* at [0022].)

46. Similarly, Wolf-290 describes "devices, systems and methods for treating nasal airways." (Ex-1006-Wolf-290 at [0009].) The devices may "be used to deliver energy to nasal airway tissues, for example to help reshape the tissues *and/or to ablate goblet cells, nerve fibers or other tissue,* ***to reduce rhinitis***." (*Id.*) "In some embodiments, *delivering the energy involves delivering sufficient energy to damage nerve fibers underlying the nasal mucosa*. In some embodiments, delivering the energy to damage the nerve fibers involves ablating at least one targeted nerve. For example, the targeted nerve may be the sphenopalatine ganglion and/or a branch of the sphenopalatine ganglion. According to various alternative

embodiments, any suitable type of energy may be delivered by the energy delivery member, such as but not limited to *radiofrequency*, ultrasound, microwave, heat, electrical, light and laser energy." (*Id.* at [0012].)

47. Townley also describes "devices, systems, and methods for therapeutically modulating nerves in or associated with a nasal region of a patient. In particular, various embodiments of the present technology are related to therapeutic neuromodulation systems and methods for the treating rhinitis and other indications." (Ex-1004-Townley at [0002].) Townley's devices may "include[] at least one energy delivery element 214 configured to provide therapeutic neuromodulation to the target site. In certain embodiments, for example, the energy delivery element 214 can include one or more electrodes configured *to apply electromagnetic neuromodulation energy (e.g., RF energy) to target sites*." (*Id.* at [0043]; *see also id.* at [0030] (Townley's "devices are configured to provide an accurate and localized non-invasive application of energy to disrupt the parasympathetic motor sensory function in the nasal region"), [0032] (defining "therapeutic modulation" of nerves and "therapeutic neuromodulation" refer "to the partial or complete incapacitation or other effective disruption of neural activity, including partial or complete *ablation* of nerves"), [0038] (explaining that "modulating the parasympathetic pathways that innervate the mucosa [is] expected to reduce or eliminate the hyper activation of the submucosal glands and

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engorgement of vessels that cause symptoms associated with rhinosinusitis and other indications), [0055] (explaining that "therapeutic modulation may be applied via the energy delivery element 214 … to precise, localized regions of tissue to induce one or more desired therapeutic neuromodulating effects to disrupt parasympathetic motor sensory function" including by "selectively target[ing] postganglionic parasympathetic fibers that innervate the nasal mucosa at a target or treatment site proximate to or at their entrance into the nasal region" and that "the therapeutic neuromodulating effects may include partial or complete denervation via thermal ablation and/or non-ablative thermal alteration or damage (e.g., via sustained heating and/or resistive heating), [0058] (explaining "modulating at least a portion of the parasympathetic nerves is expected to slow or potentially block conduction of autonomic neural signals to the nasal mucosa to produce a prolonged or permanent reduction in nasal parasympathetic activity" which "is expected to reduce or eliminate activation or hyperactivation of the submucosal glands and venous engorgement and, thereby, reduce or eliminate the symptoms of rhinosinusitis.").)

VI. PRIOR ART OVERVIEW

48. Below I provide a non-limiting overview of the prior art I apply in the invalidity grounds stated herein. This overview is for background purposes and is not to be taken as an exhaustive list of the teachings of the prior art. I include additional details regarding the prior art in the Grounds below.

A. Townley (Ex-1004)

49. Townley is U.S. Patent App. Pub. No. 2016/0331459, published November 17, 2016. I understand Townley is prior art to the '974 patent at least because it published more than a year before the earliest possible effective filing date of the '974 patent. Notably, the first named inventor (David Townley) is the same inventor of the '974 patent.

50. Townley is analogous art to the '974 patent as it discloses minimally invasive systems, devices and methods for treating conditions associated with rhinosinusitis. (Ex-1001 at 1:19-24, 8:28-10:7; Ex-1004-Townley at Abstract, [0002]-[0003], [0058].)

51. Townley is directed to "therapeutic neuromodulation systems and methods for the treating rhinitis and other indications." (Ex-1004-Townley at [0002].)

52. In Townley, "the terms '*therapeutic modulation*' of nerves and '*therapeutic neuromodulation*' refer to the partial or complete incapacitation or other effective ***disruption of neural activity****, including partial or complete* ***ablation*** *of nerves*. Therapeutic neuromodulation, for example, can include partially or completely inhibiting, reducing, and/or blocking neural communication along neural fibers." (*Id.* at [0032].)

53. Townley's system includes a therapeutic neuromodulation device 202

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comprising a shaft 208 and a therapeutic assembly 212 at the distal portion of the shaft. (*Id*. at [0042].) "The therapeutic assembly 212 can include at least one energy delivery element 214 configured to therapeutically modulate the postganglionic parasympathetic nerves." (*Id*.)

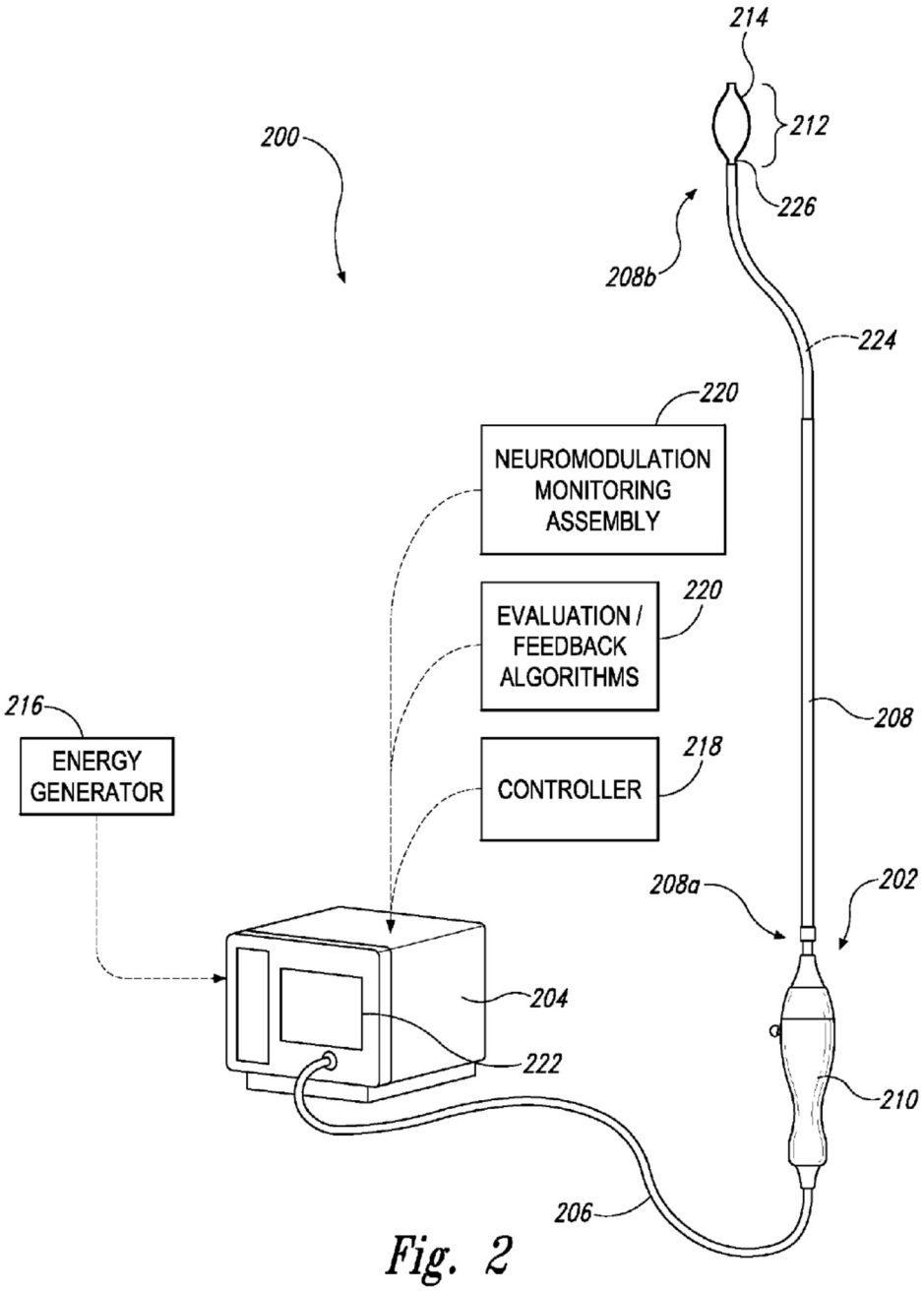

Fig. 2

(*Id*. at FIG. 2.)

54. "Once positioned at the target site, the therapeutic modulation may be applied via the energy delivery element 214 and/or other features of the therapeutic assembly 212 to precise, localized regions of tissue to induce one or more desired therapeutic neuromodulating effects to disrupt parasympathetic motor sensory function." (*Id.* at [0055].) "[M]odulating the parasympathetic pathways that innervate the mucosa are expected to reduce or eliminate the hyper activation of the submucosal glands and engorgement of vessels that cause symptoms associated with rhinosinusitis and other indications." (*Id*. at [0038].)

B. Wolf-003 (Ex-1005)

55. Wolf-003 is U.S. Patent App. Pub. No. 2015/0202003, published July 23, 2015. I understand Wolf-003 is prior art to the '974 patent at least because it published before the earliest possible effective filing date of the '974 patent.

56. Wolf-003 is analogous art to the '974 patent as it discloses minimally invasive systems, devices and methods for treating conditions associated with rhinosinusitis. (Ex-1001 at 1:19-24, 8:28-10:7; Ex-1005-Wolf-003 at Abstract, [0003], [0011]-[0012], [0023], [0067].)

57. Wolf-003 is directed to "systems, devices and methods for treating structures within the upper airway to reduce and/or prevent overproduction and/or flow of mucus to alleviate the discomfort of post nasal drip symptoms." (Ex-1005-

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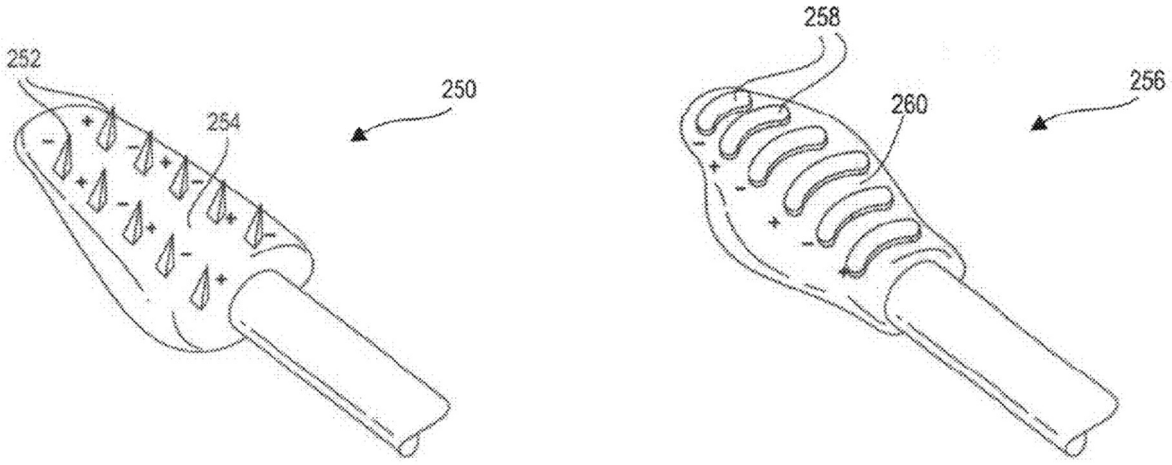
Wolf-003 at [0003].) Wolf-003's method comprises "advancing a treatment delivery portion of an energy-based treatment device into a nostril of the patient; contacting mucosal tissue of the upper airway with the treatment delivery portion, without piercing the mucosal tissue; and delivering a treatment from the treatment delivery portion to the mucosal tissue and/or another tissue underlying the mucosal tissue to modify a property the tissue and thus treat at least one of post nasal drip or chronic cough in the patient." (*Id*. at [0023].)

58. As shown below, the treatment delivery portion of Wolf-003's treatment device may comprise a plurality of radiofrequency electrodes:



(*Id*. at FIGS. 13-14; *see also id*. at [0021]-[0022], [0025], [0029]-[0031], [0126]-[0127], [0148].)

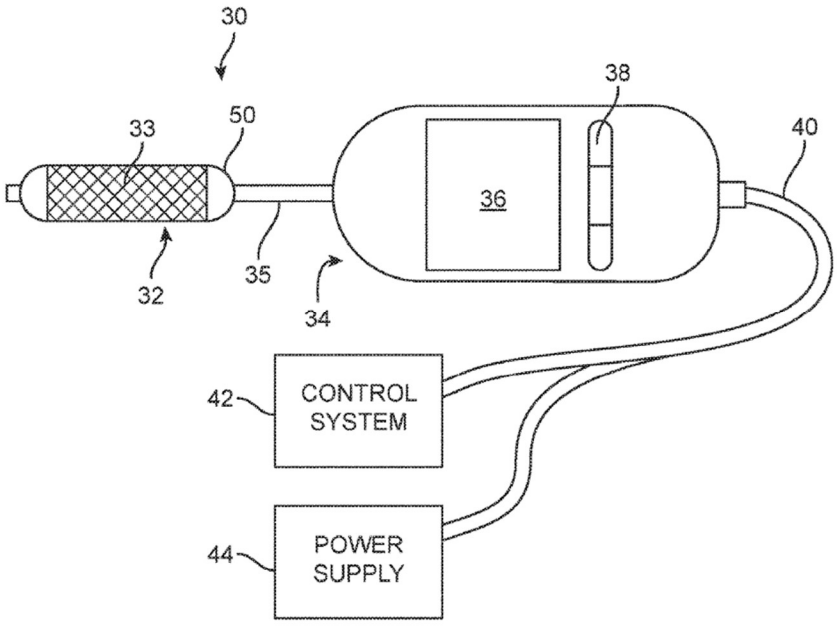
C. Wolf-290 (Ex-1006)

59. Wolf-290 is U.S. Patent App. Pub. No. 2019/0282290, published September 19, 2019. I understand Wolf-290 is prior art to the '974 patent at least

because it published before the earliest possible effective filing date of the '974 patent.

60. Wolf-290 is analogous art to the '974 patent as it discloses minimally invasive systems, devices and methods for treating conditions associated with rhinosinusitis. (Ex-1001 at 1:19-24, 8:28-10:7; Ex-1006-Wolf-290 at [0009], [0042]-[0043].)

61. Wolf-290 is directed to "medical devices, systems and methods for treating structures in the human airway, to facilitate breathing, reduce chronic runny nose or address any of a number of other airway conditions." (Ex-1006-Wolf-290 at [0002].) Wolf-290's method "comprises positioning a treatment element within the nasal airway adjacent to nasal tissue to be treated," "pressing a surface of the treatment element against the nasal tissue to be treated," and "delivering radiofrequency (RF) energy to the one or more electrodes to locally heat the nasal tissue." (*Id*. at [0027].) Wolf-290 discloses that the treatment element may comprise one or more electrodes, such as one or more pairs of bipolar radiofrequency electrodes. (*Id*. at [0011], [0020], [0023], [0027], [0092], claims 1, 6, and 13.)



(*Id*. at FIG. 3.)

62. Wolf-290 discloses that its systems and methods may be used to treat rhinitis, congestion, runny nose, snoring, and sleep disordered breathing. (*Id*. at [0002], [0008]-[0009], [0042]-[0043], [0053], [0076], claims 12 and 19; *see also id*. at [0050], [0078].) Wolf-290 further discloses that its systems and methods "improve breathing." (*Id*. at [0009]; *see also id*. at [0002], [0042]-[0043], [0050], [0074]-[0075].)

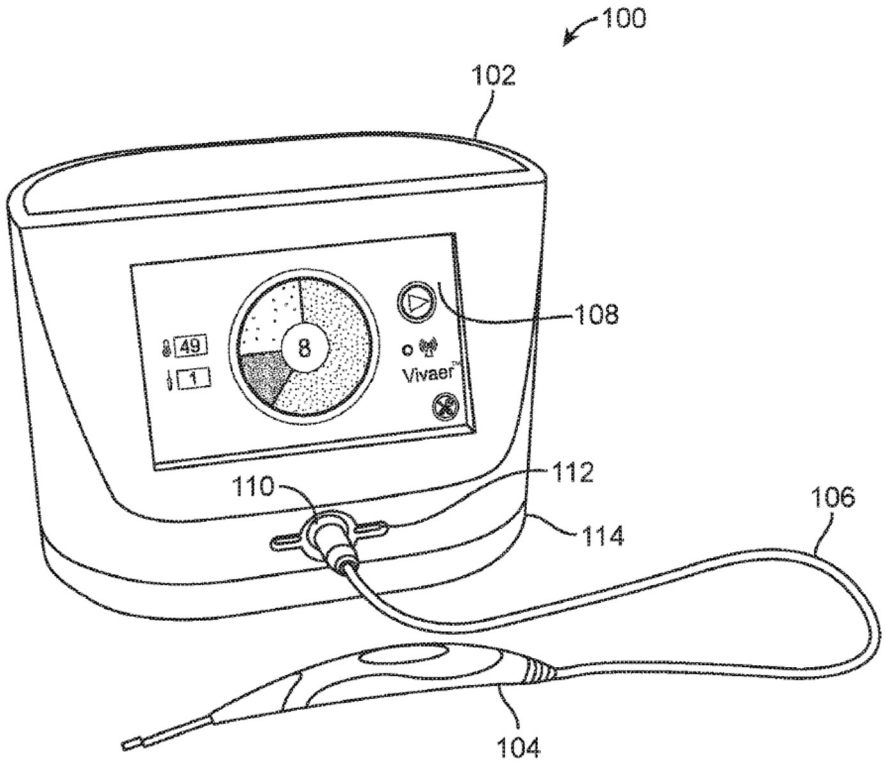
D. Angeles (Ex-1007)

63. Angeles is U.S. Patent App. Pub. No. 2020/0129223, filed October 30, 2019. I understand Angeles is prior art to the '974 patent at least because it was filed before the earliest possible effective filing date of the '974 patent.

64. Angeles is analogous art to the '974 patent as it discloses minimally

invasive systems, devices and methods for treating conditions associated with rhinosinusitis. (Ex-1001 at 1:19-24, 8:28-10:7; Ex-1007-Angeles at [0003], [0035], [0040].)

65. Angeles is directed to "an electrosurgery system console and user interface." (Ex-1007-Angeles at [0002].) The counsel may include "a housing, an energy generator in the housing, a computer processor in the housing, … [and] a touchscreen display on the housing." (*Id*. at Abstract.) The energy generator may be "a radiofrequency (RF) generator, configured to deliver monopolar and/or bipolar RF energy to the energy delivery treatment device." (*Id*. at [0007].)



(*Id*. at FIG. 1.)

66. Angeles' console may include "an improved user interface" which

"allows a physician user to monitor and alter treatment parameters for a particular treatment stylus, applicator, catheter or the like." (*Id*. at [0005].) For example, the physician may set a treatment time and a maximum temperature. (*Id*. at [0049].)

67. Angeles further discloses "a method for performing an energy delivery therapy on nasal airway tissue in a patient" comprising "activating a console attached to an energy delivery stylus; advancing a distal end of the energy delivery stylus into a nostril of the patient; delivering energy from the energy delivery stylus to treat the nasal airway tissue; and watching a display on a display screen of the console." (*Id*. at [0011].) The stylus may be a radiofrequency stylus, such as one provided by Aerin Medical Inc. (*Id*. at [0003], [0012], [0040].)

VII. LEVEL OF ORDINARY SKILL IN THE ART

68. Based on my review and analysis of the '974 patent, the prior art cited herein, and the ordinary skill factors described previously, a POSITA in the field of the '974 patent at the assumed earliest effective filing date (April 9, 2020) would have had at least a bachelor's degree in biomedical engineering, mechanical engineering, electrical engineering, or a related field, plus two or three years of industry experience, or research experience, relating to medical devices that apply energy to tissue. Additional education may serve as a substitute for a lack of experience and vice versa.

VIII. CLAIM CONSTRUCTION

69. It is my understanding that in order to properly evaluate the ’974 patent, the terms of the claims must first be interpreted. It is my understanding that for the purposes of this *inter partes* review, the claims are to be construed under the so-called *Phillips* standard, under which claim terms are given their ordinary and customary meaning as would have been understood by a POSITA in light of the specification and prosecution history, unless the inventor has set forth a special meaning for a term. For the purposes of this declaration, it is my opinion that none of the claim terms requires a specific construction, and all will be given their plain and ordinary meaning.

IX. CLAIMS 1-20 ARE UNPATENTABLE

70. I have been asked to provide my opinion as to whether the Challenged Claims of the ’974 patent would have been anticipated or obvious in view of the prior art. The discussion below provides a detailed analysis of how the prior art references identified below teach the limitations of the Challenged Claims of the ’974 patent.

71. As part of my analysis, I have considered the scope and content of the prior art and any differences between the alleged invention and the prior art. I describe in detail below the scope and content of the prior art, as well as any differences between the alleged invention and the prior art, on an

element-by-element basis for each Challenged Claims of the ’974 patent.

72. As described in detail below, the alleged invention of the Challenged Claims would have been obvious in view of the teachings of the identified prior art references as well as the knowledge of a POSITA.

Grounds	Claim(s)	Basis
#1	1-20	Rendered obvious by Townley (Ex-1004)
#2	1-4 and 8-12	Rendered obvious by Wolf-003 (Ex-1005) alone or in view of Wolf-290 (Ex-1006)
#3	8-20	The Ground 2 art in view of Angeles (Ex-1006)

A. Ground 1: Claims 1-20 are obvious in view of Townley

1. Summary of Ground 1

73. Ground 1 relies on Townley, which is a 2016 publication by the same named inventor as the ’974 patent. As shown below, Townley discloses, teaches or suggests all limitations of claims 1-20 of the ’974 patent.

74. As shown below, Townley expressly discloses nearly all limitations of claim 1, except (arguably) that its treatments improve a patient’s nasal breathability. However, Townley’s focus is on therapeutic modulation of “the parasympathetic pathways that innervate the mucosa are expected to reduce or eliminate the hyper activation of the submucosal glands and engorgement of vessels that cause symptoms associated with rhinosinusitis and other indications.” (Ex-1004-Townley at [0042]). It would have been obvious to a POSITA that patient’s receiving Townley’s treatments would have improved nasal breathability because such

treatments indisputably treat conditions and symptoms of rhinosinusitis, i.e., treat rhinitis, congestion and/or rhinorrhea (runny nose). Thus, Townley teaches claim 1. Townley also discloses, teaches, or suggests claims 2-20, likewise rendering those claims obvious.

2. Challenged Claims

[Claim 1, 1-PRE] A method for treating at least one of rhinitis, congestion, and rhinorrhea within a sino-nasal cavity of a patient, the method comprising:

75. Townley discloses the preamble.

76. Townley discloses that its technology, including its system (200), is for treating "one of rhinitis, congestion, and rhinorrhea:"

> "The present technology relates generally to devices, systems, and methods for therapeutically modulating nerves in or associated with a nasal region of a patient. *In particular, various embodiments of the present technology are related to therapeutic neuromodulation systems and* ***methods for the treating rhinitis and other indications***."

(Ex-1004-Townley at [0002].)

> "Sufficiently modulating at least a portion of the parasympathetic nerves is expected to slow or potentially block conduction of autonomic neural signals to the nasal mucosa to produce a prolonged or permanent reduction in nasal parasympathetic activity. *This is expected to reduce or eliminate activation or hyperactivation of the submucosal glands and venous engorgement and,* ***thereby, reduce or eliminate the symptoms of rhinosinusitis***. Further, because the system 200 applies therapeutic neuromodulation to the multitude of branches of the

> posterior nasal nerves rather than a single large branch of the posterior nasal nerve branch entering the nasal cavity at the SPF, the system 200 provides a more complete disruption of the parasympathetic neural pathway that affects the nasal mucosa and results in rhinosinusitis. *Accordingly, the system 200 is expected to have enhanced therapeutic effects* ***for the treatment of rhinosinusitis*** *and reduced re-innervation of the treated mucosa*."

(*Id.* at [0058]; *see also id.* at [0030], [0038].)

77. As for the term "sino-nasal cavity," I note that this term is not defined in the '974 patent, but it appears to mean a sinus cavity and/or a nasal cavity. The claims of the '974 patent confirm that the "sino-nasal cavity" at least includes a nasal cavity. As shown below, claims 1-2 of the '974 patent recites "the nasal cavity" instead of "the sino-nasal cavity," indicating the sino-nasal cavity includes the nasal cavity:

> 1. A method for treating at least one of rhinitis, congestion, and rhinorrhea within *a sino-nasal cavity* of a patient, the method comprising: advancing a multi-electrode end effector into ***the*** *sino-nasal cavity* of the patient… the first electrode extending in a first outward direction relative to a longitudinal axis of the shaft to interact with anatomy at a first location within ***the*** *nasal cavity*; and the second electrode is exposed from a surface of the multi-electrode end effector and is positioned at a discrete portion thereon, the second electrode extending in a second outward direction relative to a longitudinal axis

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> of the shaft to interact with anatomy at a second location within ***the*** *nasal cavity*…."
>
> 2. The method of claim 1, wherein the one or more target sites comprises an inferior turbinate within ***the*** *nasal cavity* and the tissue comprises submucosal tissue associated with the inferior turbinate.

(Ex-1001 at 59:7-32, 59:44-49.)

78. Townley's technology, including its system (200), are used "within the sino-nasal cavity."

> "FIG. 2 is a partially schematic view of a therapeutic neuromodulation system 200 ("system 200") *for therapeutically modulating nerves in a nasal region* in accordance with an embodiment of the present technology. The system 200 includes a therapeutic neuromodulation catheter or device 202, a console 204, and a cable 206 extending therebetween. The therapeutic neuromodulation device 202 includes a shaft 208 having a proximal portion 208a, a distal portion 208b, a handle 210 at a proximal portion 208a of the shaft 208, and a therapeutic assembly or element 212 at the distal portion 208b of the shaft 208. *The shaft 208 is configured to locate the distal portion 208b intraluminally at a treatment or target site within a nasal region proximate to postganglionic parasympathetic nerves that innervate the nasal mucosa*. The target site may be a region, volume, or area in which the target nerves are located and may differ in size and shape depending upon the anatomy of the patient. For example, the target site may be a 3 cm area inferior to the SPF. In other embodiments, *the target site may*

> *be larger, smaller, and/or located elsewhere* ***in the nasal cavity*** *to target the desired neural fibers*.

(Ex-1004-Townley at [0041]*; see also id.* at [0051], [0065], [0072], [0118], [0128], [0133], [0136]-[0137] (disclosing applying treatment in the nasal cavity).)

79. Thus, Townley discloses limitation [1-PRE].

[1a-1] advancing a multi-electrode end effector into the sino-nasal cavity of the patient,

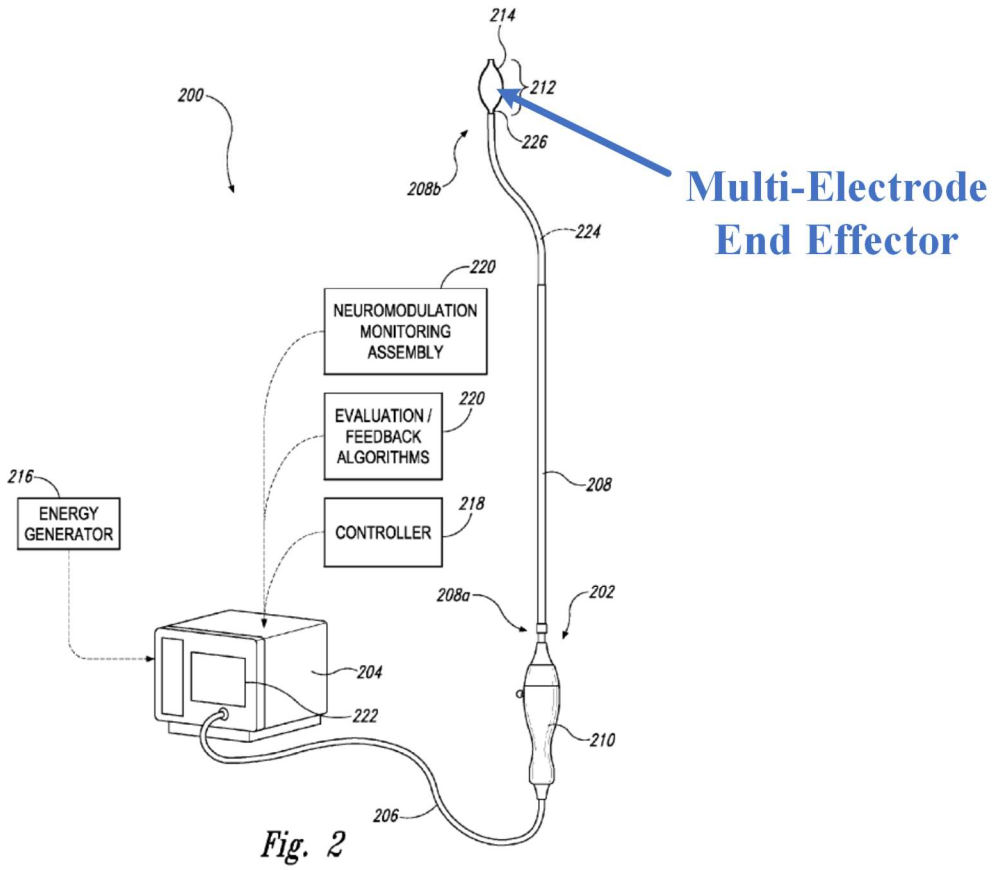
80. Townley discloses limitation [1a-1].

81. First, I note that the '974 patent states that "the terms 'end effector' and 'therapeutic assembly' may be used interchangeably." (Ex-1001 at 12:32-34.)

82. Accordingly, Townley's multiple electrode therapeutic assemblies (described below) disclose the claimed "multi-electrode end effector," or "MEEE" for short.

83. Townley discloses several multiple-electrode therapeutic assemblies, *i.e*., "MEEEs." As explained previously, Townley discloses a therapeutic neuromodulation system 200 including a therapeutic neuromodulation catheter/device 202 having a therapeutic assembly 212. (Ex-1004-Townley at [0042].) Townley discloses that its "the therapeutic assembly 212 includes at least one energy delivery element 214 configured to provide therapeutic neuromodulation to the target site." (*Id*. at [0042]-[0043].) "[T]he energy delivery element 214 can include *one or more electrodes* configured to apply electromagnetic

neuromodulation energy (e.g., RF energy) to target sites." (*Id*. at [0043].) Thus, Townley discloses therapeutic assembles (end effectors) having multiple electrodes, *i.e*., the claimed multi-electrode end effector.



(*Id*. at FIG. 2.)[2]

84. Townley discloses additional multi-electrode therapeutic assemblies in Figures 4, 5A-G, 8-9, and 11A-D. (*Id*. at FIGS. 4, 5A-G, 8-9, and 11A-D, [0066], [0075], [0105].)

[2] Annotations and emphasis added herein unless otherwise indicated.

85. Townley's multi-electrode end effectors are advanced into a patient's nasal cavity in order to treat target sites within the nasal cavity." (*Id*. at [0042] (explaining use of the "system 200…for therapeutically modulating nerves in a nasal region," that "the shaft 208 is configured to locate the distal portion 208b intraluminally at a treatment or target site within a nasal region proximate to postganglionic parasympathetic nerves that innervate the nasal mucosa," and that "the target site may be larger, smaller, and/or located elsewhere in the *nasal cavity* to target the desired neural fibers); *see also id.* at FIGS. 3A-E.)

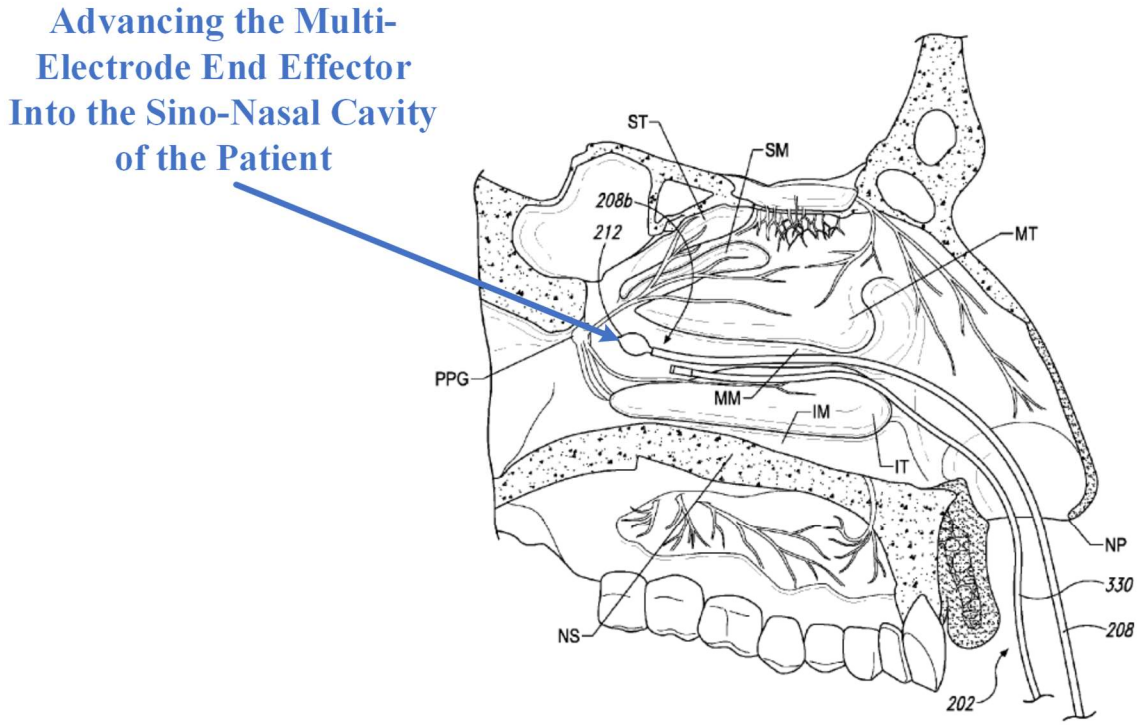


Fig. 3B

(*Id*. at FIG. 3B.)

86. Thus, Townley discloses limitation [1a-1].

[1a-2] wherein the multi-electrode end effector is operably associated with a shaft of a treatment device and configured for delivering energy to one or more target sites within the sino-nasal cavity of the patient,

87. Townley discloses limitation [1a-2].

88. Townley discloses and illustrates that its multi-electrode end effectors are operably associated with a "shaft" of a treatment device, such as shaft 208 of therapeutic neuromodulation device 202, for positioning the therapeutic assembly at a target site.

> "FIG. 2 is a partially schematic view of a therapeutic neuromodulation system 200 ("system 200") for therapeutically modulating nerves in a nasal region in accordance with an embodiment of the present technology. The system 200 includes a therapeutic neuromodulation catheter or device 202, a console 204, and a cable 206 extending therebetween. *The therapeutic neuromodulation device 202 includes a shaft 208 having a proximal portion 208a, a distal portion 208b, a handle 210 at a proximal portion 208a of the shaft 208, and a therapeutic assembly or element 212 at the distal portion 208b of the shaft 208. The shaft 208 is configured to locate the distal portion 208b intraluminally at a treatment or target site within a nasal region proximate to postganglionic parasympathetic nerves that innervate the nasal mucosa*."

(Ex-1004-Townley at [0042].)

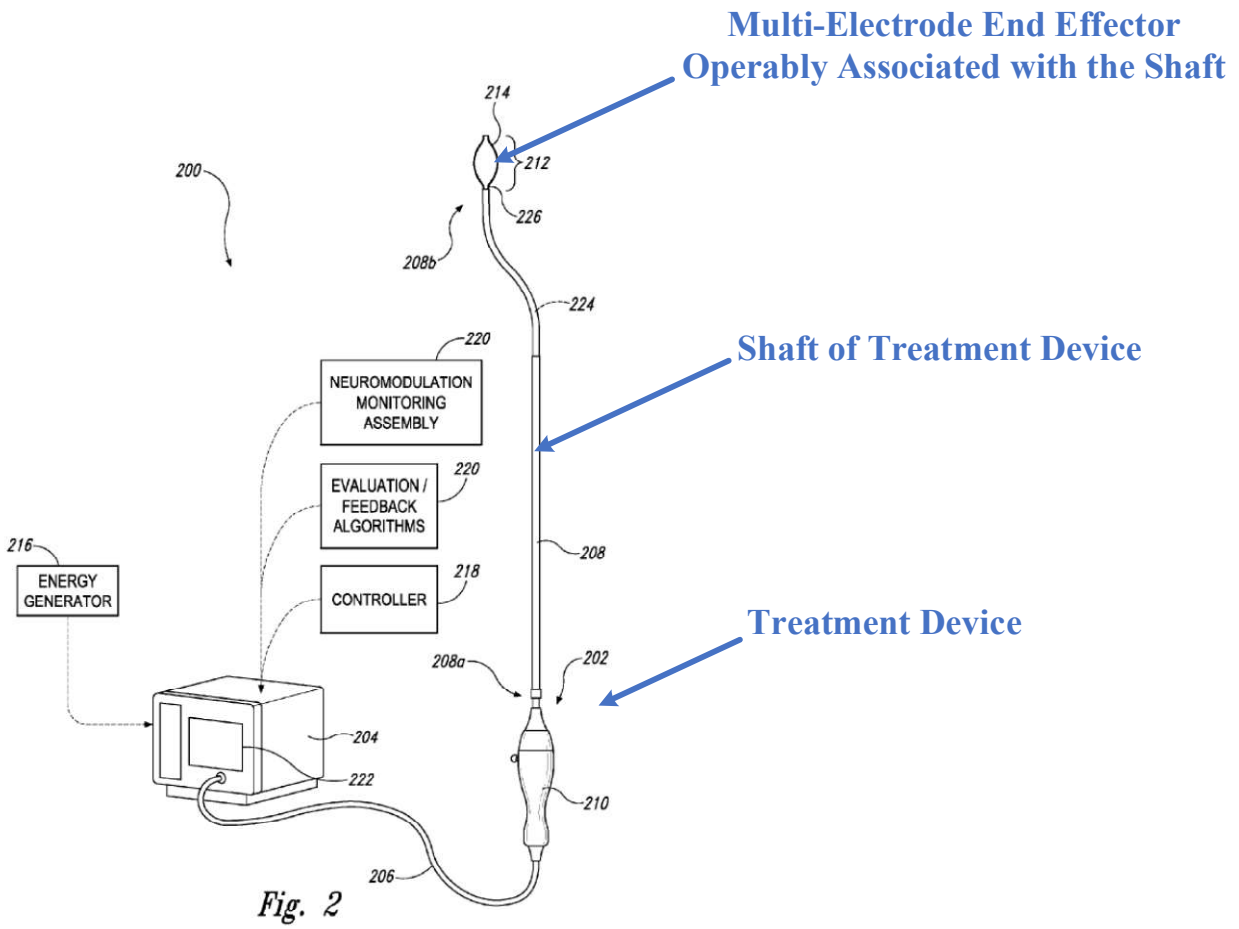


Fig. 2

(*Id*. at FIG. 2; *see also id.* at FIGS. 3A-E, 4, 5A-G, 8-9, and 11A-D, Abstract, [0051], [0061], [0066], [0105], claims 1, 26, 41, and 103.)

89. Townley discloses that its multi-electrode end effectors are configured to deliver energy, such as radiofrequency energy, to one or more target sites within the patient's nasal cavity:

> "As shown in FIG. 2, the therapeutic assembly 212 includes *at least one energy delivery element 214 configured to provide therapeutic neuromodulation to the target site*. In certain embodiments, for example, the energy delivery element 214 can include *one or more*

electrodes configured to apply electromagnetic neuromodulation energy (e.g., RF energy) ***to target sites***."

(*Id.* at [0043]; *see also id*. at [0041]-[0042], [0045], [0051], [0066], [0075], [0109], claims 2, 10, 41-42.)

90. Thus, Townley discloses limitation [1a-2].

[1a-3] wherein the multi-electrode end effector comprises a first electrode that is spaced apart from a second electrode along a length of the multi-electrode end effector, wherein each of the first and second electrodes comprise an active state and an inactive state and comprise a respective location on the multi-electrode end effector,

91. Townley discloses limitation [1a-3].

92. Townley discloses several multi-electrode end effectors that satisfy the electrode arrangement requirements of [1a-3]. The multi-electrode end effectors of Figures 4, 5A-G, 8-9, and 11A-D, for example, comprise first and second electrodes that are spaced apart from each other along a length of the multi-electrode end effector, and are positioned at respective locations on the multi-electrode end effector:

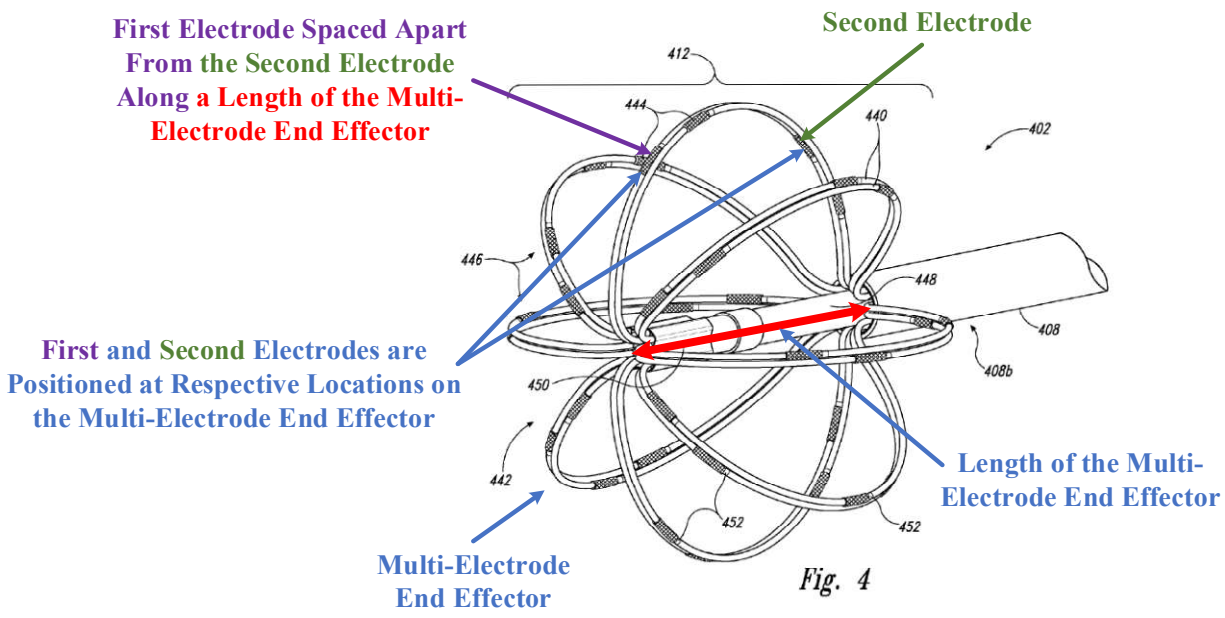


Fig. 4

(Ex-1004-Townley at FIG. 4.)

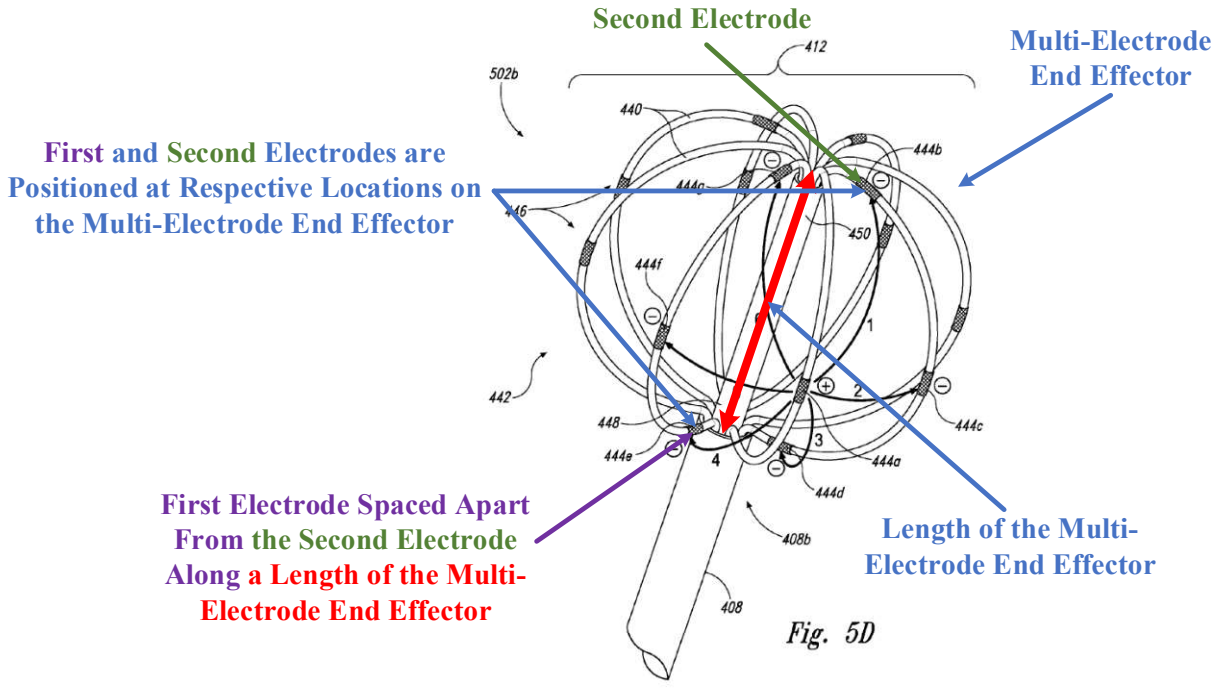


Fig. 5D

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

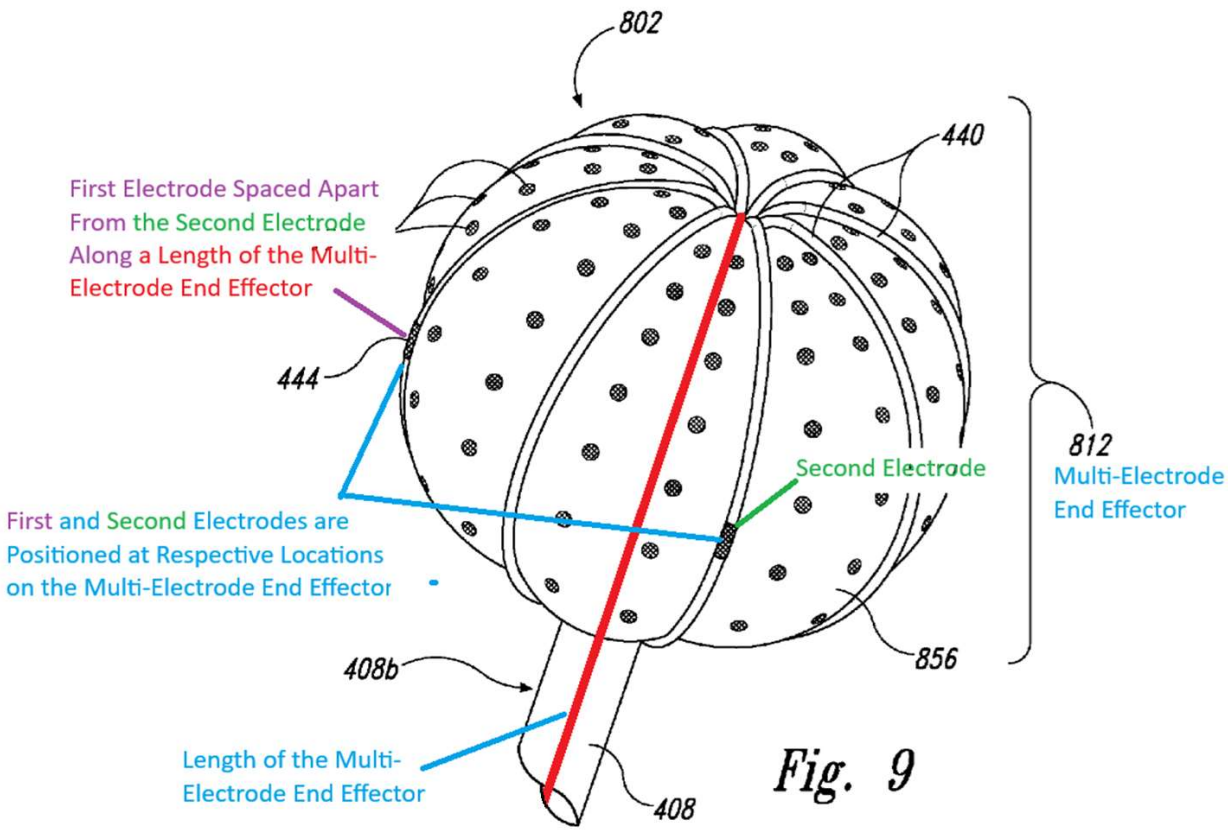


Fig. 9

(*Id.* at FIG. 9; *see also id.* at [0099] ("device 802 can include various features generally similar to the features of the therapeutic neuromodulation devices 402 and 502a-d described above with reference to FIGS. 4-5G;" "one or more electrodes 444 disposed on one or more of the struts 440").)

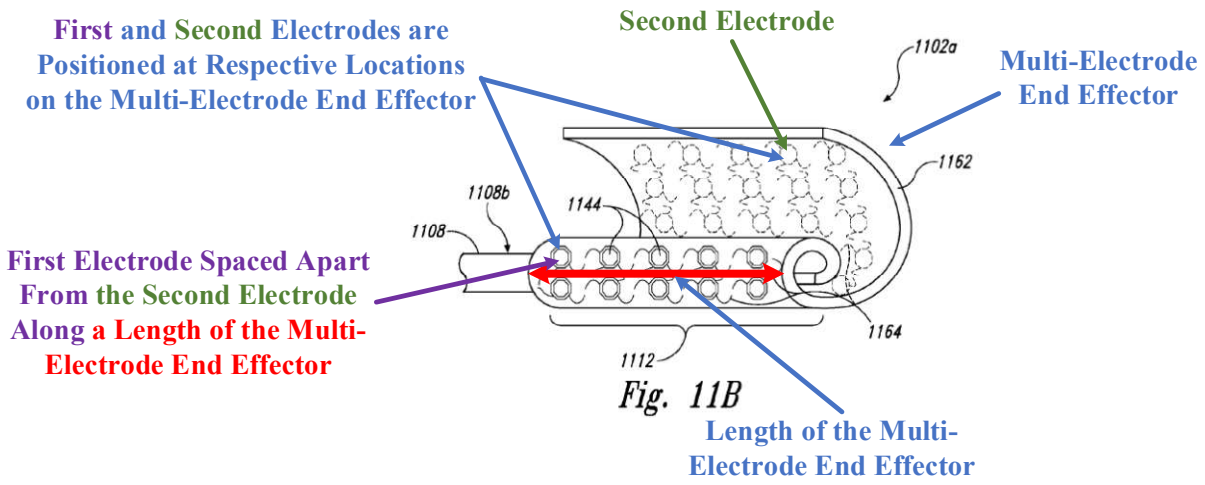


Fig. 11B

(*Id*. at FIG. 11B; *see also id.* at [0066]-[0073] (explaining electrode arrangements and functionality).)

93. Townley discloses that each of the first and second electrodes comprises an active state and an inactive state.

> "In certain embodiments, each electrode 444 can be operated independently of the other electrodes 444. *For example, each electrode can be individually activated* and the polarity and amplitude of each electrode can be selected by an operator or a control algorithm (e.g., executed by the controller 218 of FIG. 2). *Various embodiments of such independently controlled electrodes 444 are described in further detail below with reference to FIGS. 5A-5G. The selective independent control of the electrodes 444 allows the therapeutic assembly 412 to deliver RF energy to highly customized regions. For example, a select portion of the electrodes 444 can be activated to target neural fibers in a specific region while the other electrodes 444 remain inactive*. In certain embodiments, for example, electrodes 444 may be activated across the portion of the basket 442 that is adjacent to tissue at the target

> site, and the electrodes 444 that are not proximate to the target tissue can remain inactive to avoid applying energy to non-target tissue. Such configurations facilitate selective therapeutic modulation of nerves on the lateral nasal wall within one nostril without applying energy to structures in other portions of the nasal cavity."

(*Id*. at [0072]; *see also id*. at [0073], [0075]-[0079], [0082]-[0083], [0091].)

94. Thus, Townley discloses limitation [1a-3].

[1a-4] wherein at least one portion of the multi-electrode end effector comprises a diameter that is larger than a diameter of the shaft, and wherein:

95. Townley discloses limitation [1a-4].

96. As one example, Townley discloses that the basket 442 (*at least one portion*) of its multi-electrode end effector (412) forms a generally spherical structure:

> "In the embodiment illustrated in FIG. 4, ***the basket 442*** includes eight branches 446 spaced radially apart from each other ***to form at least a generally spherical structure***, and each of the branches 446 includes two struts 440 positioned adjacent to each other. In other embodiments, however, the basket 442 can include fewer than eight branches 446 (e.g., two, three, four, five, six, or seven branches) or more than eight branches 446. In further embodiments, each branch 446 of the basket 442 can include a single strut 440, more than two struts 440, and/or the number of struts 440 per branch can vary. In still further embodiments, the branches 446 and struts 440 can form baskets or frames having other suitable shapes for placing the electrodes 444 in contact with tissue at

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the target site. For example, when in the expanded state, the struts 440 can form an ovoid shape, a hemispherical shape, a cylindrical structure, a pyramid structure, and/or other suitable shapes."

(Ex-1004-Townley at [0067].)

97. As illustrated below, the basket 442 "comprises a diameter that is larger than a diameter of the shaft" 408:

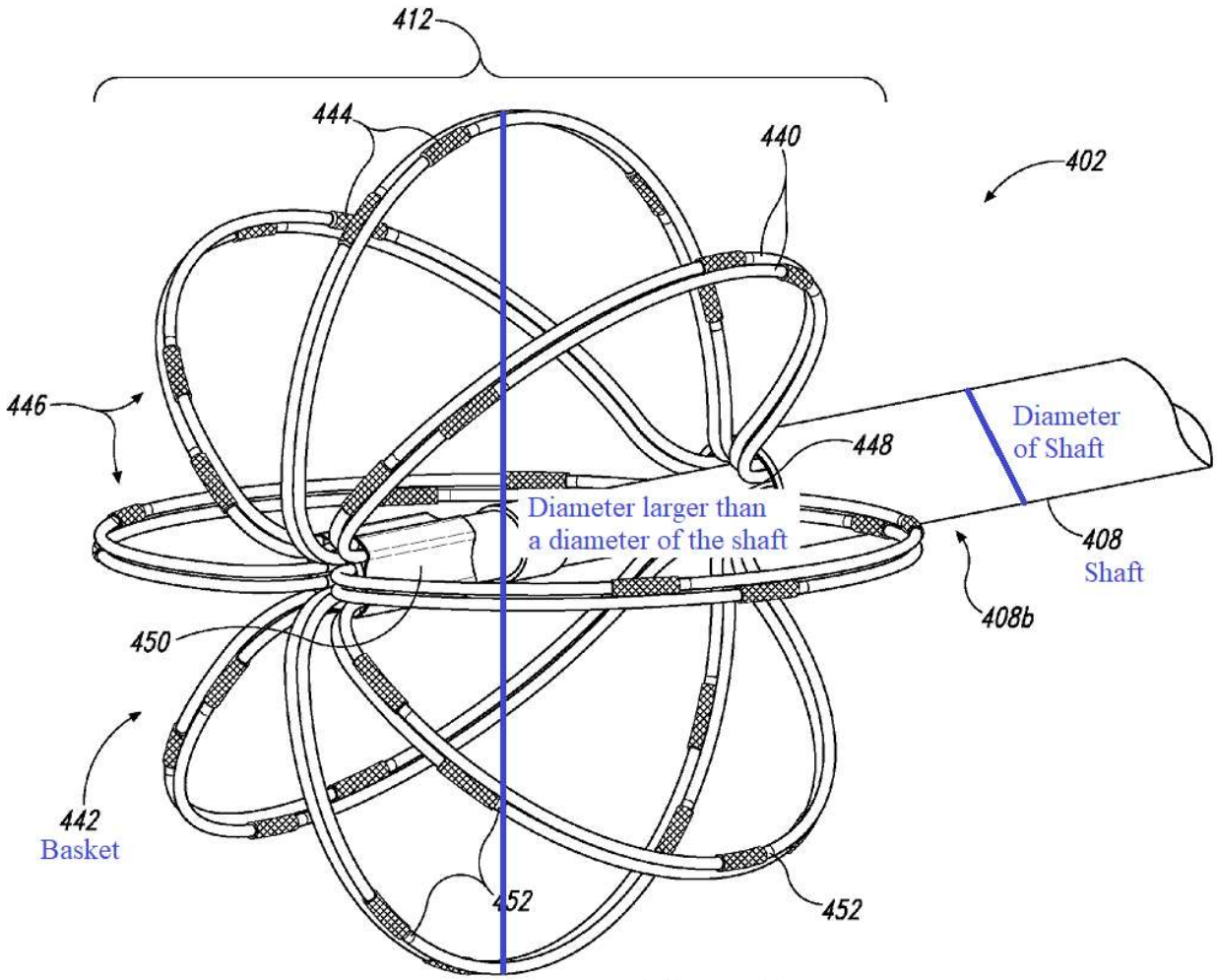

Fig. 4

(Ex-1004-Townley at FIG. 4.) The multi-electrode end effectors of Figures 5A-G

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include generally similar baskets 442 as that of Figure 4 and thus also disclose "a portion of the multi-electrode end effector comprises a diameter that is larger than a diameter of the shaft."

98. As another example, Figure 9 illustrates a multi-electrode end effector (812) having an expandable member (856) (*at least one portion*) with a diameter larger than that of the shaft (408):

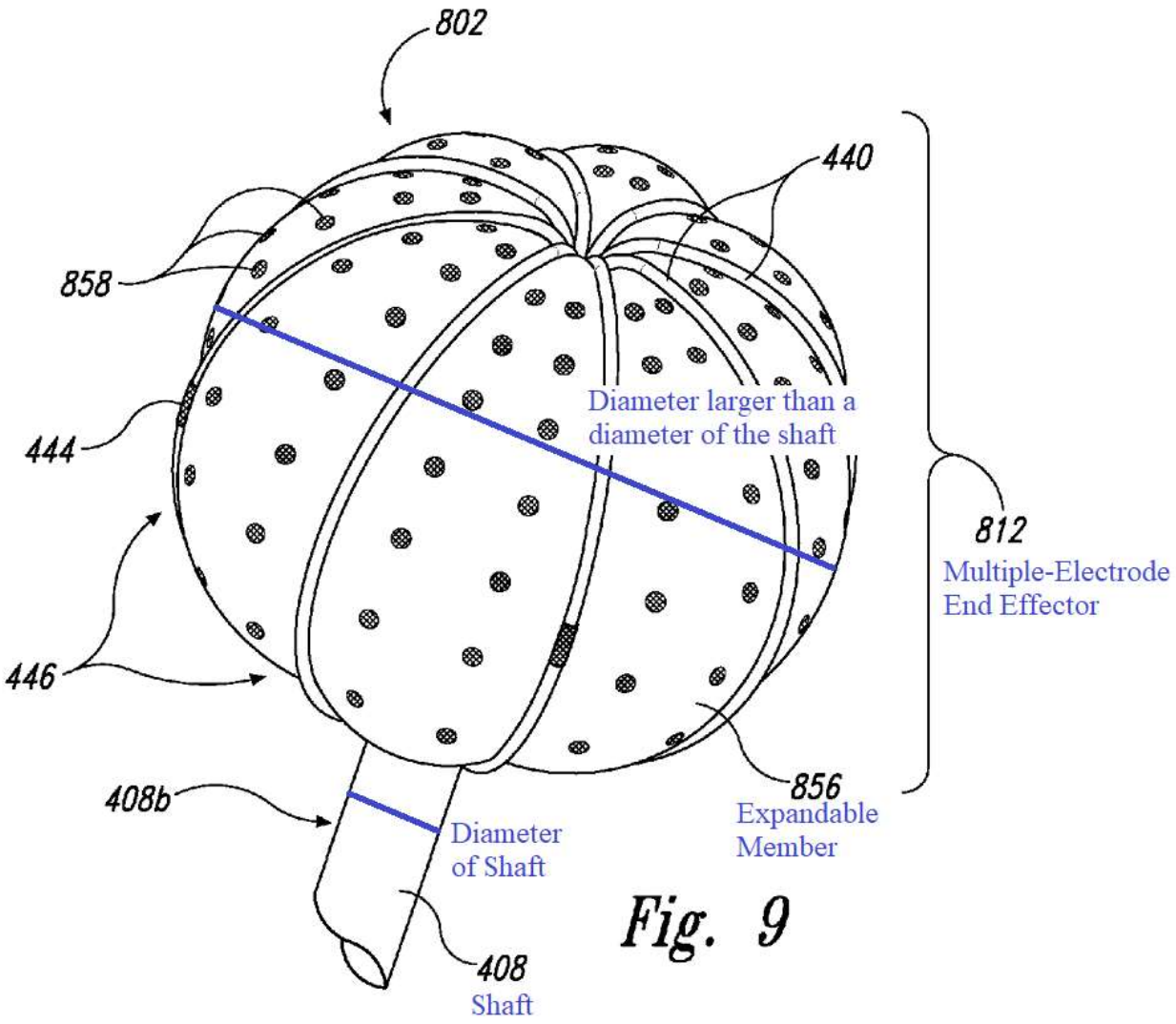

Fig. 9

(*Id*., FIG. 9, [0099].)

99. Figures 11A-D also illustrate multi-electrode therapeutic assemblies (1112) having elements (1162) with diameters larger than a diameter of the shaft:

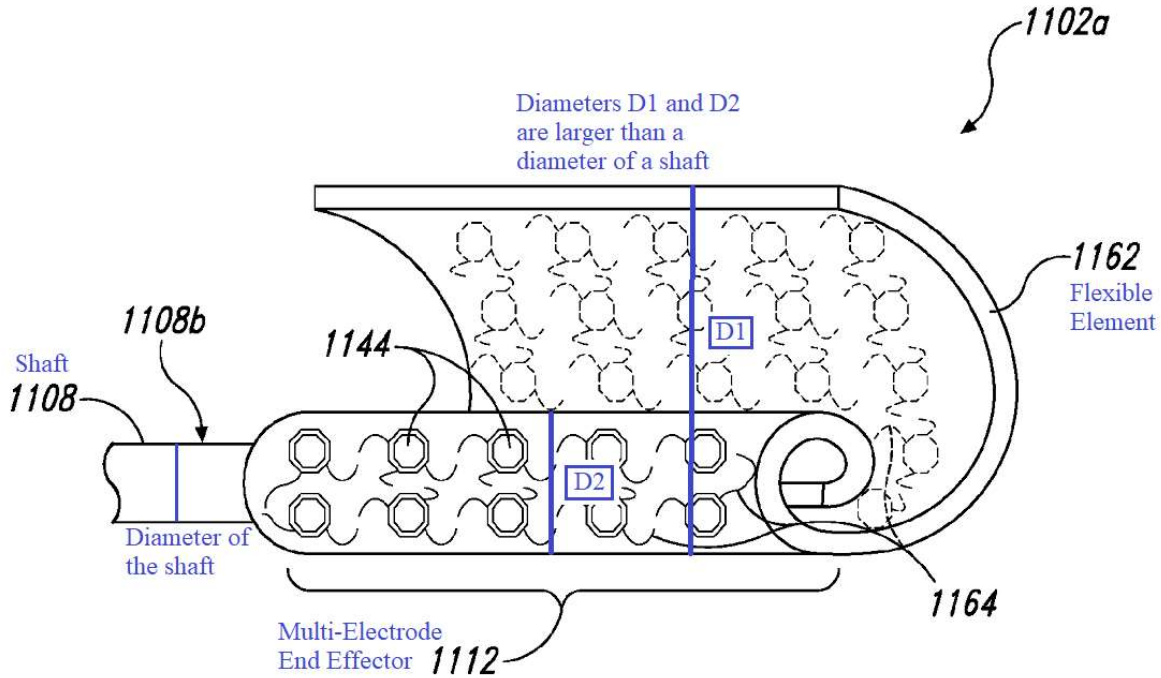

Fig. 11B

(*Id.*, FIG. 11B, [0105]-[0106].)

100. Thus, Townley discloses limitation [1a-4].

[1b] the first electrode is exposed from a surface of the multi-electrode end effector and is positioned at a discrete portion thereon, the first electrode extending in a first outward direction relative to a longitudinal axis of the shaft to interact with anatomy at a first location within the nasal cavity; and

101. Townley discloses limitation [1b].

102. Townley discloses several multi-electrode end effectors having a first electrode that meets the requirements of [1b]. The multi-electrode end effectors of Figures 4, 5A-G, 8-9, and 11A-D, for instance, comprise a first electrode that: (i) is

exposed from the surface of the multi-electrode end effector; (ii) is positioned at a discrete portion thereon; and (iii) extends in a first outward direction relative to a longitudinal axis of the shaft:

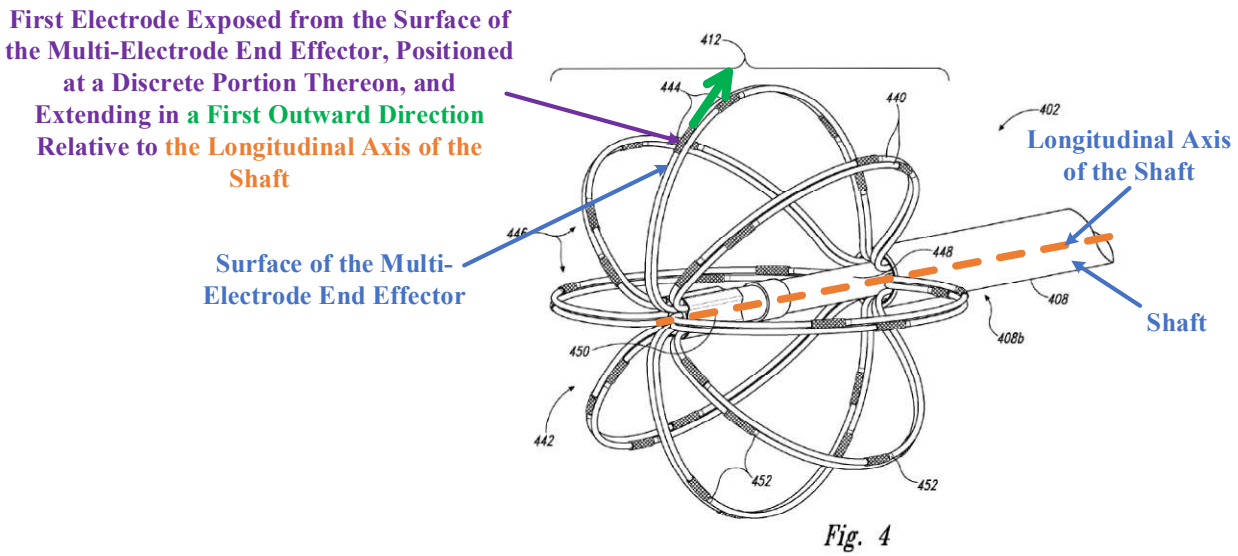

Fig. 4

(Ex-1004-Townley at FIG. 4; *see also id*. at [0071] ("At least one electrode 444 is disposed on individual struts 440.").)

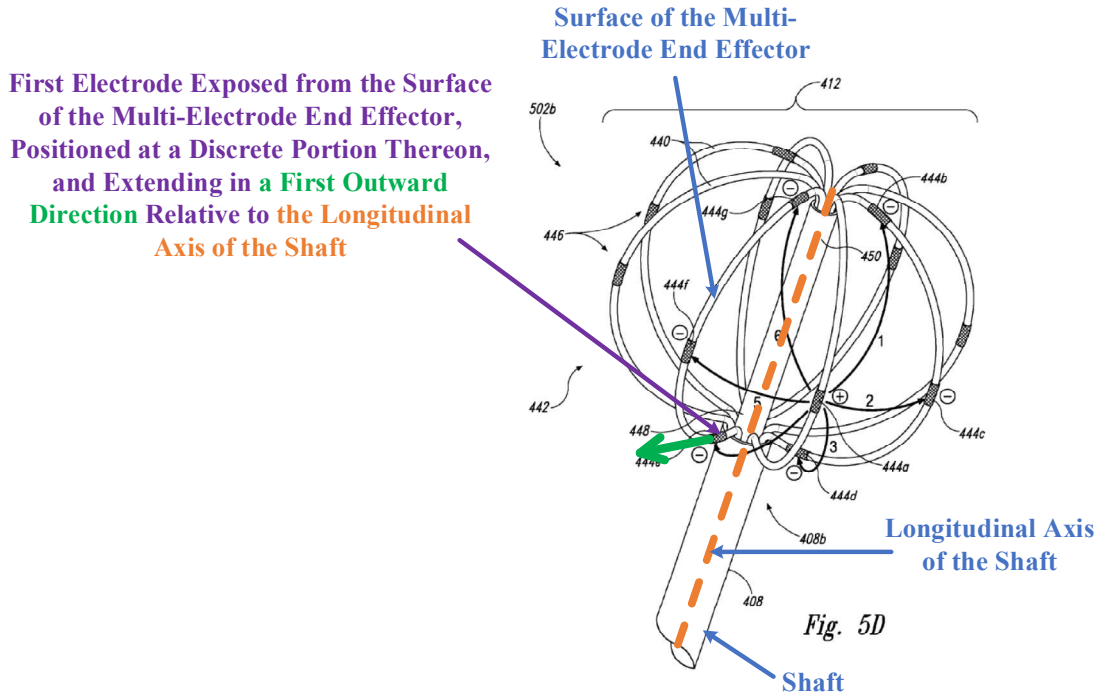

Fig. 5D

(*Id*. at FIG. 5D; *see also id*. at [0075] ("a plurality of electrodes 444 disposed on one or more of the struts 440.").)

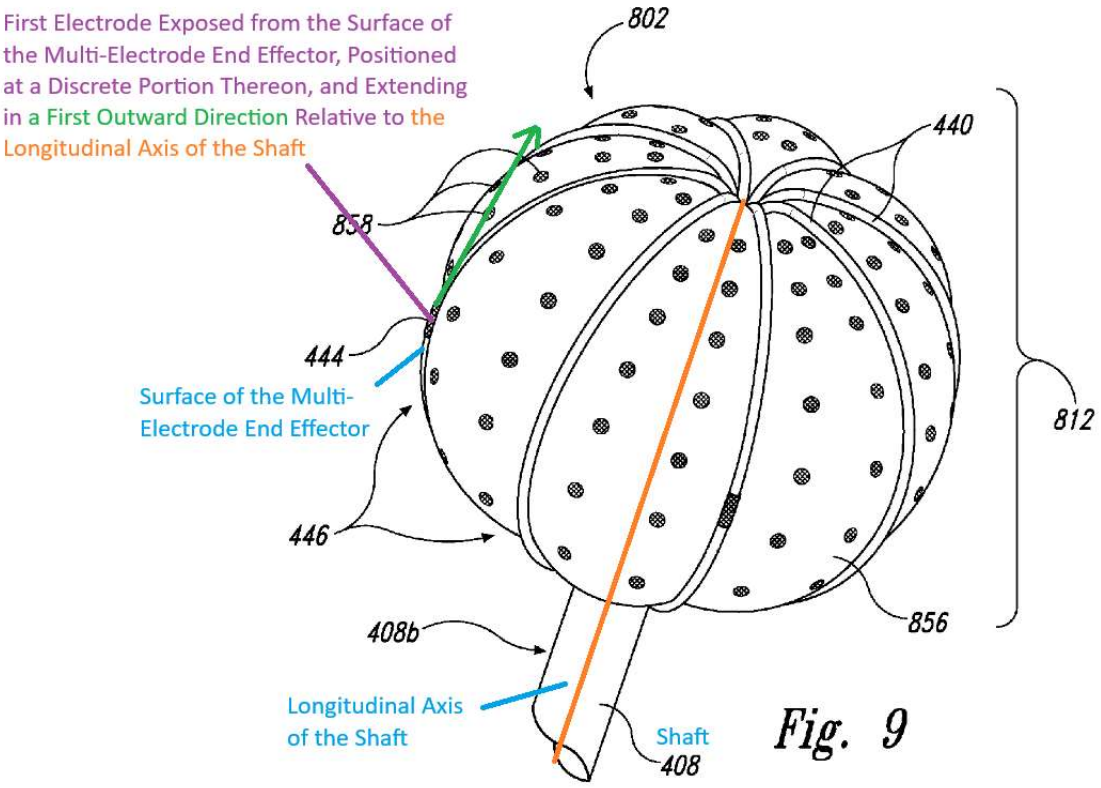

Fig. 9

(*Id.* at FIG. 9; *see also id.* at [0099] ("one or more electrodes 444 disposed on one or more of the struts 440").)

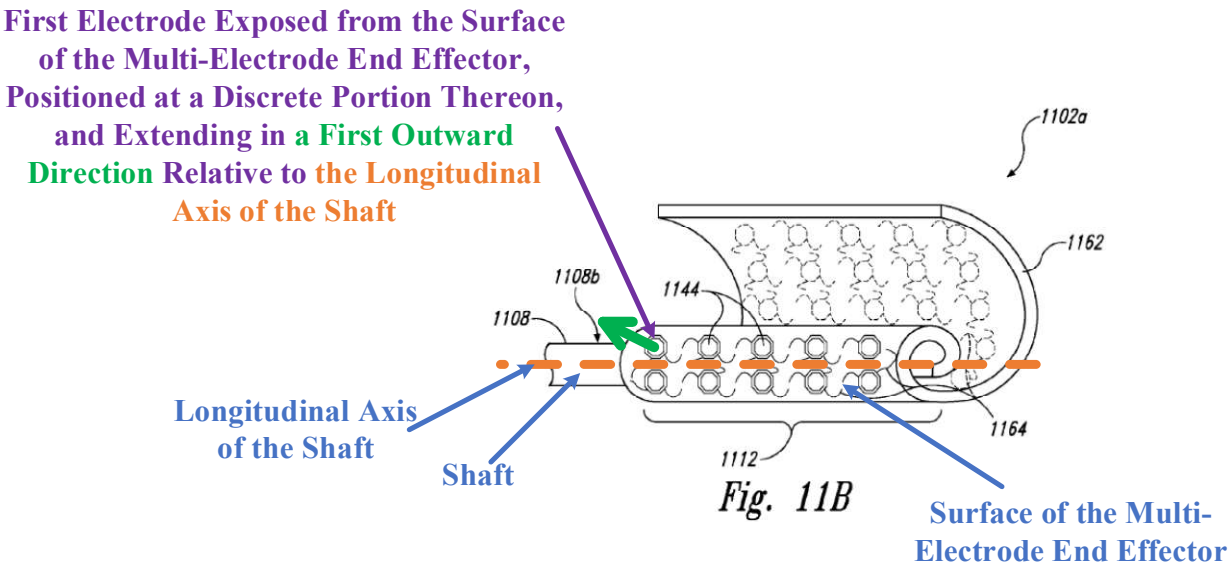

Fig. 11B

(*Id.* at FIG. 11D; *see also id.* at [0109] ("The electrodes 1144 may be surface mounted on the flexible membrane 1162").)

103. Townley's electrodes, including the first electrodes, are configured to contact / interact with anatomy at various locations within the nasal cavity:

> "*Accordingly, embodiments of the present technology are configured* ***to therapeutically modulate nerves at precise and focused treatment sites*** *corresponding to the sites* of rami extending through fissures, accessory foramina, and microforamina throughout the palatine bone (e.g., target region T shown in FIG. 1B). In certain embodiments, the targeted nerves are postganglionic parasympathetic nerves that go on to innervate the nasal mucosa."

(*Id.* at [0041].)

> "In certain embodiments, the system 200 can determine *the locations of the nerves, accessory foramen, and/or microforamina* before therapy *such that the therapeutic neuromodulation can be applied to precise regions including parasympathetic neural fibers*. For example, the system 200 may identify a target site that has a length and/or width of about 3 mm inferior to the SPF, and the therapeutic assembly 212 can apply therapeutic neuromodulation to the identified target site via one or more applications of therapeutic neuromodulation. In other embodiments, the target site may be smaller or larger (e.g., a 3 cm-long target region) based on the detected locations of neural fibers and foramena. This neural and anatomical mapping allows the system 200 to accurately detect and therapeutically modulate the postganglionic parasympathetic neural fibers that innervate the mucosa at the numerous neural entrance points into the nasal cavity. Further, because there are not any clear anatomical markers denoting the location of the SPF, accessory foramen, and microforamina, *the neural mapping allows the operator to identify and therapeutically modulate nerves that would otherwise be unidentifiable without intricate dissection of the mucosa*. In addition, anatomical mapping can also allow the operator to identify certain structures that the operator may wish to avoid during therapeutic neural modulation (e.g., certain arteries)."

(*Id.* at [0057].)

> "FIG. 4 is an isometric view of a distal portion of a therapeutic neuromodulation device 402 configured in accordance with an embodiment of the present technology. The therapeutic neuromodulation device 402 can be used in conjunction with the system

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200 described above with respect to FIGS. 2-3E. As shown in FIG. 4, the therapeutic neuromodulation device 402 can include a shaft 408 having a proximal portion (not shown) and a distal portion 408b, and a therapeutic assembly 412 at the distal portion 408b of the shaft 408. The therapeutic assembly 412 is transformable between a low-profile delivery state to facilitate intraluminal delivery of the therapeutic assembly 412 to a treatment site within the nasal region and an expanded state (shown in FIG. 4). The therapeutic assembly 412 includes a plurality of struts 440 that are spaced apart from each other to form a frame or basket 442 when the therapeutic assembly 412 is in the expanded state. *The struts 440 can carry one or more energy delivery elements, such as a plurality of electrodes 444. In the expanded state, the struts 440* ***can position at least two of the electrodes 444 against tissue at a target site*** *within the nasal region (e.g., proximate to the palatine bone inferior to the SPF)*. The electrodes 444 can apply bipolar or multi-polar radiofrequency (RF) energy to the target site to therapeutically modulate postganglionic parasympathetic nerves that innervate the nasal mucosa proximate to the target site. In various embodiments, the electrodes 444 can be configured to apply pulsed RF energy with a desired duty cycle (e.g., 1 second on/0.5 seconds off) to regulate the temperature increase in the target tissue."

(*Id.* at [0066].)

"The electrodes 444 can be electrically coupled to an RF generator (e.g., the generator 216 of FIG. 2) via wires (not shown) that extend from the electrodes 444, through the shaft 408, and to the RF generator. When each of the electrodes 444 is independently controlled, each

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> electrode 444 couples to a corresponding wire that extends through the shaft 408. In other embodiments, multiple electrodes 444 can be controlled together and, therefore, multiple electrodes 444 can be electrically coupled to the same wire extending through the shaft 408. The RF generator and/or components operably coupled (e.g., a control module) thereto can include custom algorithms to control the activation of the electrodes 444. *For example, the RF generator can deliver RF power at about 200-300 W to the electrodes 444, and do so while activating the electrodes 444 in a predetermined pattern selected based on the position of the therapeutic element 412 relative to the treatment site and/or the identified locations of the target nerves*. In other embodiments, the RF generator delivers power at lower levels (e.g., less than 15 W, 15-50 W, 50-150 W, etc.) and/or higher power levels."

(*Id.* at [0073]; *see also id.* at [0079] ("This path of least resistance is dictated by the natural anatomy of the treatment site *in contact with* the electrodes 444."); *id*. at [0055], [0067], [0070], [0096], [0106]-[0107].)

104. Thus, Townley discloses limitation [1b].

[1c] the second electrode is exposed from the surface of the multi-electrode end effector and is positioned at a discrete portion thereon, the second electrode extending in a second outward direction relative to a longitudinal axis of the shaft to interact with anatomy at a second location within the nasal cavity; and

105. Townley discloses limitation [1c] for many of the same reasons provided above relative to limitation [1b].

106. The multi-electrode end effectors of Figures 4, 5A-G, 8-9, and 11A-D, for instance, comprise a second electrode that: (i) is exposed from the surface of the

multi-electrode end effector; (ii) is positioned at a discrete portion thereon; and (iii) extends in a second outward direction relative to a longitudinal axis of the shaft:

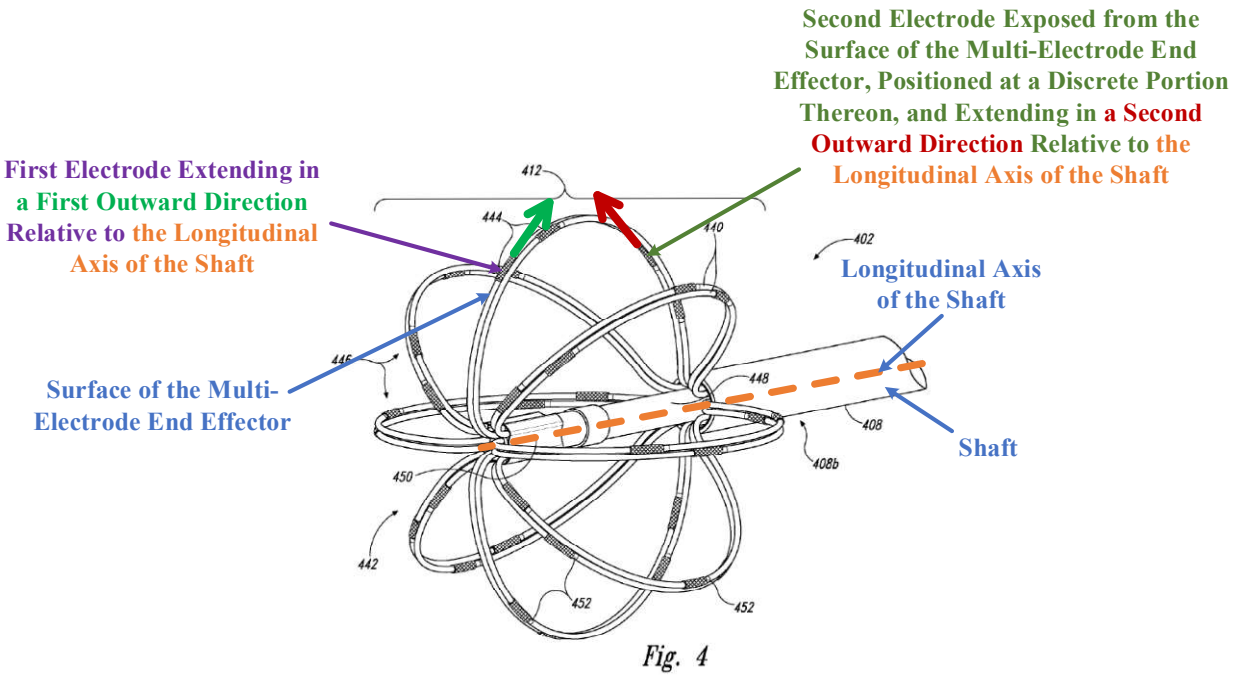

Fig. 4

(Ex-1004-Townley at FIG. 4; *see also id*. at [0071].)

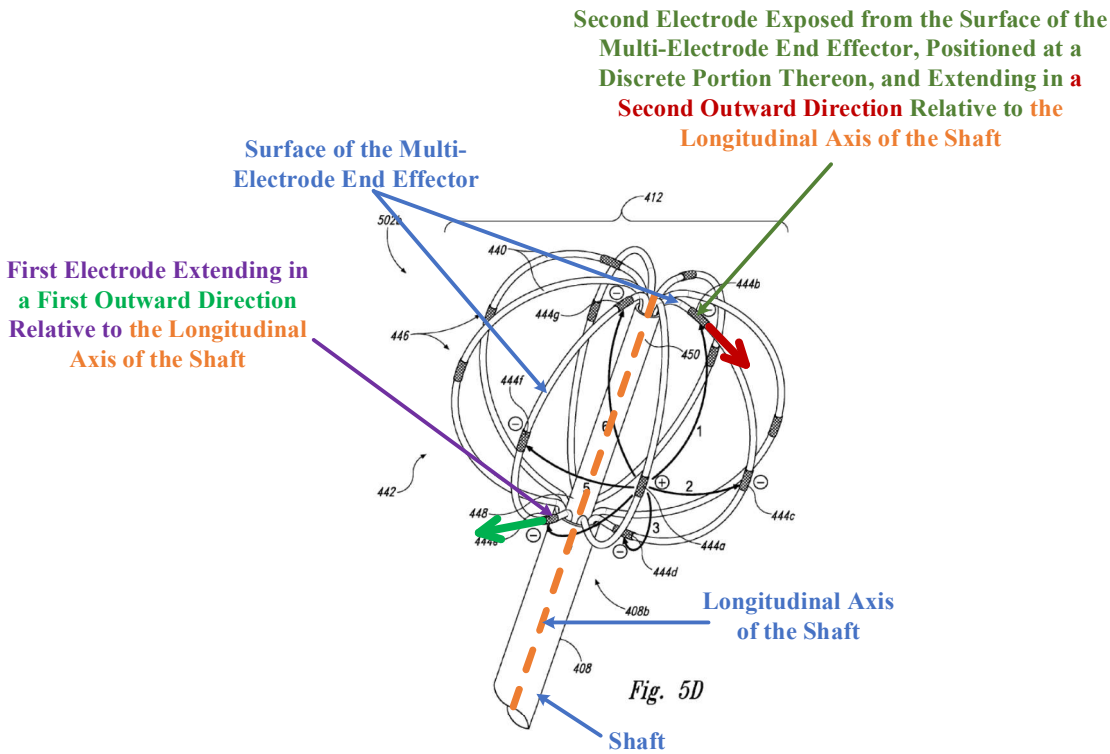

Fig. 5D

(*Id*. at FIG. 5D; *see also id*. at [0075].)

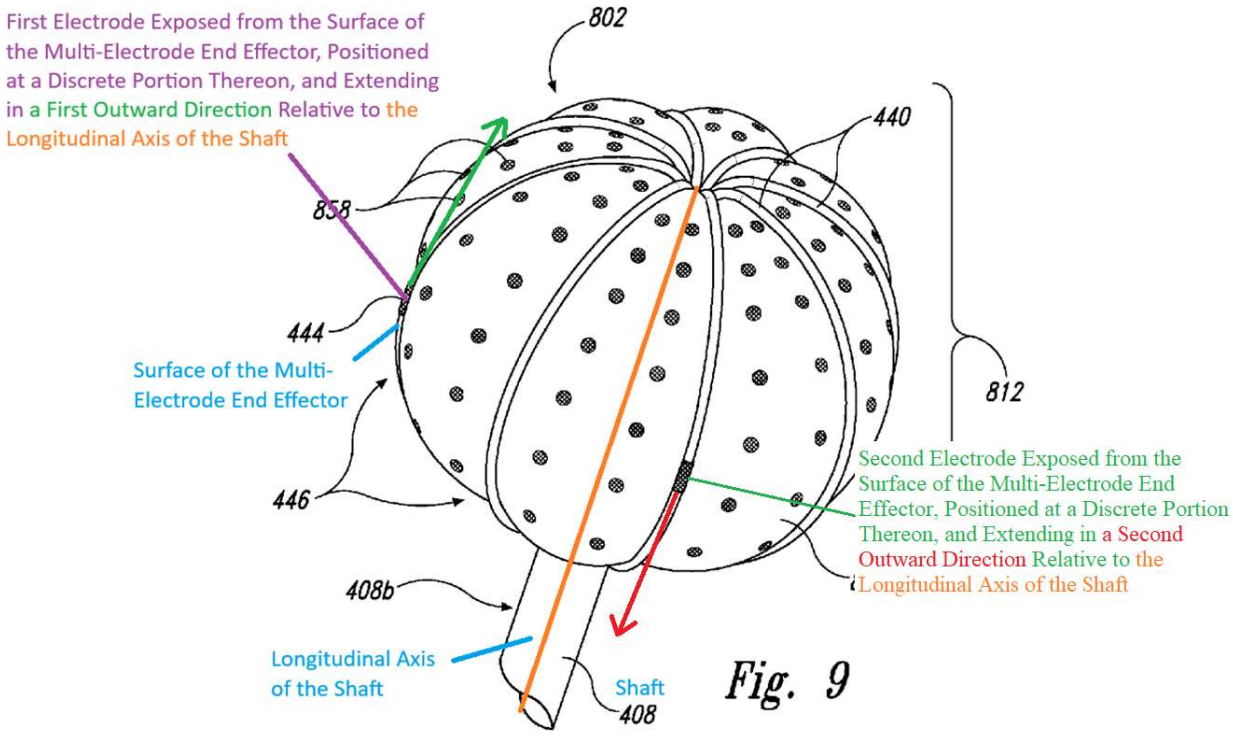

Fig. 9

(*Id.* at FIG. 9; *see also id*. at [0099].)

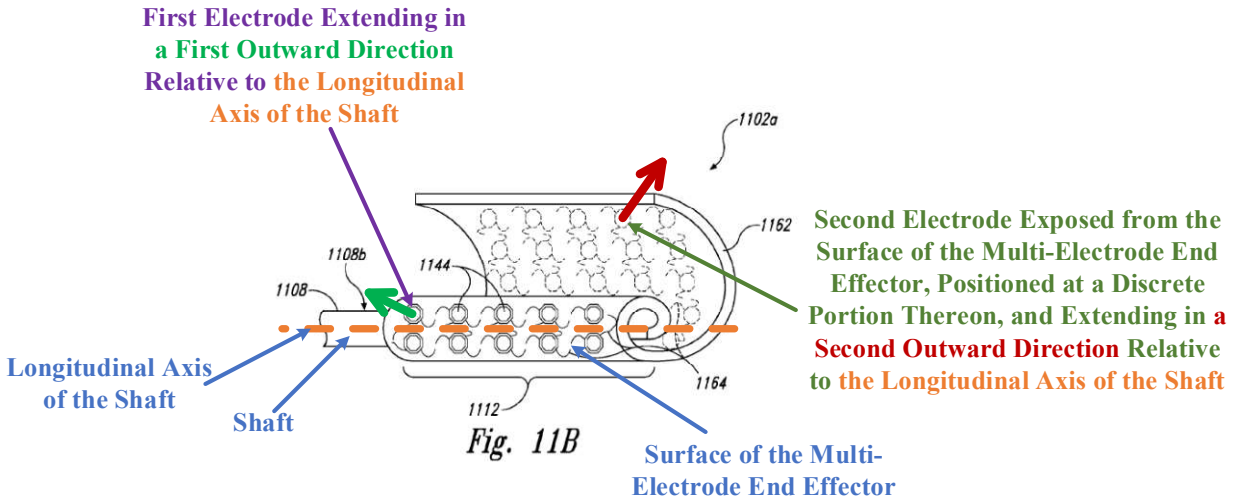

Fig. 11B

(*Id*. at FIG. 11D; *see also id*. at [0109].)

107. The annotations I have provided above and elsewhere in my Declaration are merely a few examples of the many different ways in which Townley's electrode arrangements disclose first and second electrodes per the requirements of the claims, including the requirements that the first and second electrodes extend outwardly in first and second directions, respectively, relative to the longitudinal axis of the shaft.

108. Townley discloses that its multi-electrode end effectors include struts 440 or a flexible membrane 1162 that "conform" to the "irregular anatomy of the nasal space (e.g., turbinates, sinus, and/or other para-nasal)" to enhance the contact between the electrodes and the tissue at the target site. (*Id.* at [0070], [0106]-[0107], claim 94.) A POSITA would have understood that the many electrodes of Townley's multi-electrode end effectors extend in different directions to conform to the "irregular anatomy of the nasal space."

109. Additionally, as explained above relative to limitation [1b], Townley's second electrodes are each configured to contact / interact with nasal anatomy at a second location within the nasal cavity. (*Id.* at [0041], [0057], [0066], [0073]; *see also id.* at [0079] ("This path of least resistance is dictated by the natural anatomy of the treatment site in contact with the electrodes 444."); *id*. at [0055], [0067], [0070], [0096], [0106]-[0107].)

110. Thus, Townley discloses limitation [1c].

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[1d-1] delivering energy, via the first and second electrodes, to one or more target sites within a sino-nasal cavity of the patient

111. Townley discloses limitation [1d-1].

112. Townley states:

> "As used herein, the terms '*therapeutic modulation*' of nerves and '*therapeutic neuromodulation*' refer to the partial or complete incapacitation or *other effective* ***disruption*** *of neural activity*, including partial or complete ablation of nerves. Therapeutic neuromodulation, for example, can include partially or completely inhibiting, reducing, and/or blocking neural communication along neural fibers."

(Ex-1004-Townley at [0032].)

113. Townley discloses that the first and second electrodes of its multi-electrode end effectors deliver energy to one or more target sites within a patient's sino-nasal cavity to achieve such therapeutic modulation:

> "As shown in FIG. 2, the therapeutic assembly 212 includes *at least one energy delivery element 214 configured* ***to provide therapeutic neuromodulation to the target site****. In certain embodiments, for example, the energy delivery element 214 can include one or more electrodes configured* ***to apply electromagnetic neuromodulation energy (e.g., RF energy) to target sites***."

(*Id*. at [0043]; *see also id.* at [0041]-[0042], [0055], [0066], [0072], [0075]-[0080], [0083], [0086]-[0087], claims 10, 12-13, 26, 42, 45, 90, and 98.)

114. Thus, Townley discloses limitation [1d-1].

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[1d-2] to disrupt multiple neural signals to mucus producing and/or mucosal engorgement elements, thereby reducing production of mucus and/or mucosal engorgement within a nose of the patient and reducing or eliminating one or more symptoms associated with at least one of rhinitis, congestion, and rhinorrhea to improve nasal breathability of the patient.

115. Townley teaches and suggests limitation [1d-2].

116. As noted above, Townley's definition of "'therapeutic neuromodulation' refer[s] to the *partial or complete incapacitation or other effective* ***disruption of neural activity***, including partial or complete ablation of nerves. Therapeutic neuromodulation, for example, can include partially or completely inhibiting, reducing, and/or blocking neural communication along neural fibers." Thus, when Townley's assemblies therapeutically neuromodulate nerves, such assemblies are "disrupting neural activity."

117. Townley also discloses that the step of delivering energy to the target tissue(s) "is expected to slow or potentially block conduction of autonomic neural signals to [*i.e.*, disrupt multiple neural signals to] the nasal mucosa [*i.e.*, mucus producing elements] to produce a prolonged or permanent reduction in nasal parasympathetic activity," thus reducing production of mucus and mucosal engorgement within the patient's nose. (Ex-1004-Townley at [0038], [0058]; *id*. at [0030], [0032], [0049], [0055], [0089], [0096], [0141]-[0142].)

118. As explained above relating to limitation [1d-1], Townley discloses that its electrodes deliver energy to provide therapeutic neuromodulation to target sites.

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Further, such therapeutic neuromodulation may be applied to any location in the nasal cavity, including locations responsible for mucus production, thereby "reducing or eliminating one or more symptoms associated with at least one of rhinitis, congestion, and rhinorrhea":

> "The shaft 208 is configured to locate the distal portion 208b intraluminally at a treatment or target site *within a nasal region* ***proximate to*** *postganglionic parasympathetic nerves that innervate the nasal mucosa*. The target site may be a region, volume, or area in which the target nerves are located and may differ in size and shape depending upon the anatomy of the patient. For example, the target site may be a 3 cm area inferior to the SPF. In other embodiments, the target site may be larger, smaller, and/or located elsewhere in the nasal cavity to target the desired neural fibers. The therapeutic assembly 212 can include at least one energy delivery element 214 *configured to therapeutically modulate the postganglionic parasympathetic nerves*. In certain embodiments, for example, the therapeutic assembly 212 *can therapeutically modulate the postganglionic parasympathetic nerves branching from the pterygopalatine ganglion and innervating the nasal region and nasal mucosa, such as parasympathetic nerves* (e.g., the posterior nasal nerves) traversing the SPF, accessory foramen, and microforamina of a palatine bone."

(*Id.* at [0042].)

> "The respiratory portion of the nasal cavity mucosa is composed of a type of ciliated pseudostratified columnar epithelium with a basement membrane. Nasal secretions (e.g., mucus) are secreted by goblet cells,

submucosal glands, and transudate from plasma. Nasal seromucous glands and blood vessels are highly regulated by parasympathetic innervation deriving from the vidian and other nerves. Parasympathetic (cholinergic) stimulation through acetylcholine and vasoactive intestinal peptide generally results in mucus production. Accordingly, the parasympathetic innervation of the mucosa is primarily responsible submucosal gland activation/hyper activation, venous engorgement (e.g., congestion), and increased blood flow to the blood vessels lining the nose. *Accordingly, severing or modulating the parasympathetic pathways that innervate the mucosa are expected to reduce or eliminate the hyper activation of the submucosal glands and engorgement of vessels that cause symptoms associated with rhinosinusitis and other indications*."

(*Id*. at [0038].)

"*Sufficiently modulating at least a portion of the parasympathetic nerves is expected to slow or potentially block conduction of autonomic neural signals to the nasal mucosa to produce a prolonged or permanent reduction in nasal parasympathetic activity. This is expected to reduce or eliminate activation or hyperactivation of the submucosal glands and venous engorgement* ***and, thereby, reduce or eliminate the symptoms of rhinosinusitis***. Further, because the system 200 applies therapeutic neuromodulation to the multitude of branches of the posterior nasal nerves rather than a single large branch of the posterior nasal nerve branch entering the nasal cavity at the SPF, the system 200 provides a more complete disruption of the parasympathetic neural pathway that affects the nasal mucosa and results in

> rhinosinusitis. Accordingly, the system 200 is expected to have enhanced therapeutic effects for the treatment of rhinosinusitis and reduced re-innervation of the treated mucosa."

(*Id.* at [0058]; *see also id.* at [0002]-[0003], [0030], [0032], [0049], [0055], [0089], [0096], [0142].)

119. Townley does not expressly disclose that its therapeutic modulation treatments "would improve nasal breathability of a patient." However, a POSITA would have found it obvious that nasal breathability would have been improved because treating rhinitis, congestion, and rhinorrhea was known to improve breathability by reducing mucus secretion and/or removing nasal blockage(s) and/or obstruction(s). (*Id.* at [0003] ("Symptoms of rhinosinusitis include nasal blockage, obstruction, congestion"); Ex-1024 at Abstract, 4:18-32, 7:18-22 (explaining reducing the size of obstructions (e.g., the size of turbinates) improves breathing).) A POSITA would have recognized it is easier to breathe through one's nose after improper blockage(s)/obstruction(s) are removed and when mucus secretion is reduced.

120. Thus, Townley teaches and suggests limitation [1d-2].

121. As shown above, Townley discloses, teaches or suggests all limitations of claim 1. Accordingly, claim 1 is obvious based on Townley.

[Claim 2] The method of claim 1, wherein the one or more target sites comprises an inferior turbinate within the nasal cavity and the tissue comprises submucosal tissue associated with the inferior turbinate.

122. Claim 2 refers to "the tissue," yet no prior tissues were discussed in claim 1. Thus, I find claim 2 ambiguous.

123. Assuming "the tissue" of claim 2 was meant to refer to a "target" tissue, Townley teaches claim 2.

124. FIG. 3A of Townley shows the deployment of Townley's multi-electrode end effector device (212) within the nasal cavity, proximal the inferior turbinate (IT):

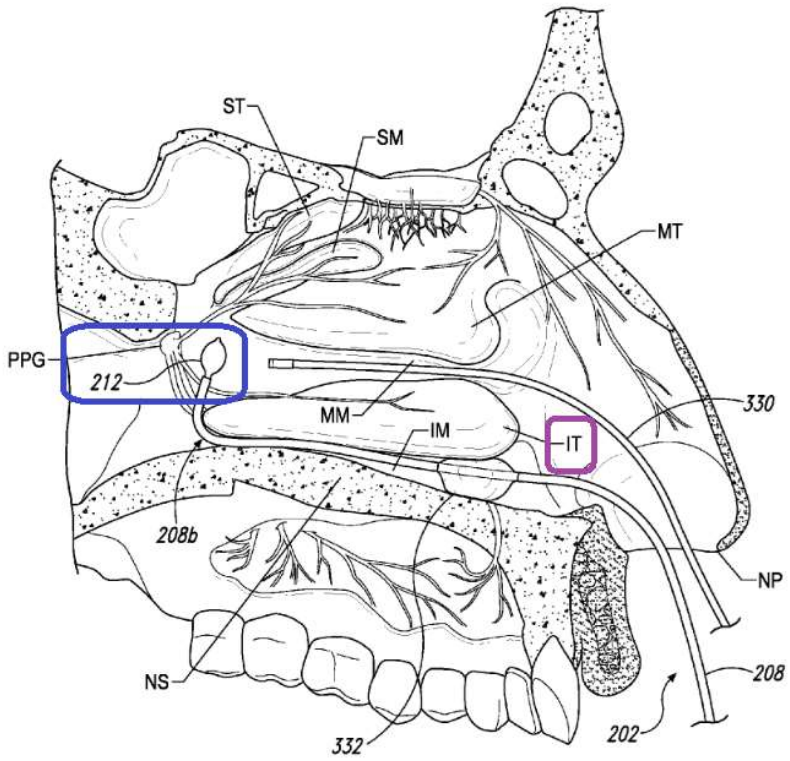

Fig. 3A

(Ex-1004-Townley at FIG. 3A)

As Townley explains:

> "As shown in FIG. 3A, in various embodiments the distal portion 208b of the shaft 208 extends into the nasal passage NP, through the inferior meatus IM *between the inferior turbinate IT* and the nasal sill NS, and *around the posterior portion of the inferior turbinate IT where the therapeutic assembly 212 is deployed at a treatment site*. As shown in FIG. 3A, the treatment site can be located proximate to the access point or points of postganglionic parasympathetic nerves (e.g., branches of the posterior nasal nerve and/or other parasympathetic neural fibers that innervate the nasal mucosa) into the nasal cavity.."

(*Id*. at [0060].)

125. Townley further explains that its multi-electrode end effectors may be used to deliver energy to, or proximal to, the turbinates, including the inferior turbinate:

> "In addition, the expanded basket 442 can press against surrounding anatomical structures *proximate to the target site (e.g., **the turbinates**, **the palatine bone***, etc.) and the individual struts 440 can at least partially conform to the shape of the adjacent anatomical structures to anchor the therapeutic element 412 at the treatment site during energy delivery. In addition, the expansion and conformability of the struts 440 can facilitate placing the electrodes 444 in contact with the surrounding tissue at the target site."

(*Id.* at [0070].)

> "As shown in FIG. 10B, for example, the device 1002 *can apply energy* ***across the top and bottom portions of the inferior turbinate****, where a high density of microforamina reside*."

(*Id.* at [0104].)

126. Townley further explains that the target tissues may be those associated with the submucosa, and that nerves and tissue may undergo therapeutic modulation:

> "The respiratory portion of the nasal cavity mucosa is composed of a type of ciliated pseudostratified columnar epithelium with a basement membrane. *Nasal secretions (e.g., mucus) are secreted* by goblet cells, *submucosal glands*, and transudate from plasma. Nasal seromucous glands and blood vessels are highly regulated by parasympathetic innervation deriving from the vidian and other nerves. Parasympathetic (cholinergic) stimulation through acetylcholine and vasoactive intestinal peptide generally results in mucus production. Accordingly, *the parasympathetic innervation of the mucosa is primarily responsible submucosal gland activation/hyper activation*, venous engorgement (e.g., congestion), and increased blood flow to the blood vessels lining the nose. *Accordingly*, severing or *modulating the parasympathetic pathways that innervate the mucosa* are expected to reduce or eliminate the hyper activation of the submucosal glands and engorgement of vessels that cause symptoms associated with rhinosinusitis and other indications."

(*Id.* at [0038].) Further, Figure 1B shows such nerves innervating the inferior turbinate and Townley recommends treating nerves in the ***target region "T"*** of FIG.

1B:

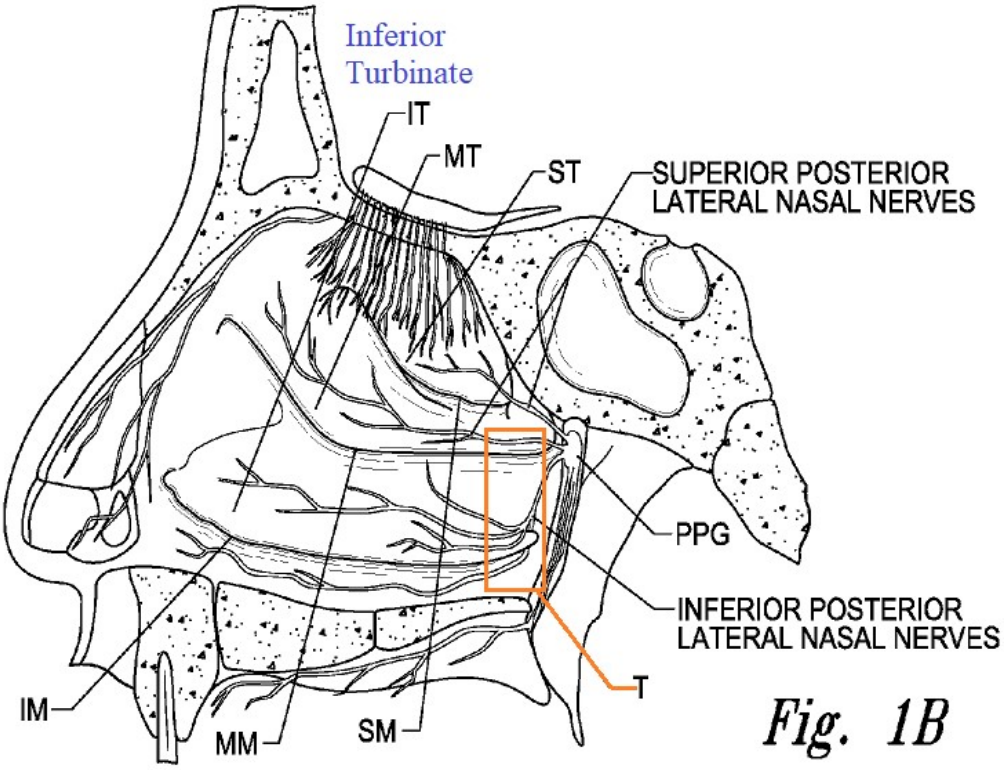

Fig. 1B

(*Id.* at FIG. 1B)

> "Accordingly, embodiments of the present technology are configured to therapeutically modulate nerves at precise and focused treatment sites corresponding to the sites of rami extending through fissures, accessory foramina, and microforamina ***throughout the palatine bone*** (e.g., ***target region T shown in FIG. 1B***)."

(*Id.* at [0041].) As shown in Figure 1B, the target nerves include the inferior

posterior nerves of the inferior turbinate. Moreover, Townley illustrates and describes the target nerves being proximal to the inferior turbinate:

> "Recent microanatomic dissection of the pterygopalatine fossa (PPF) have further evidenced the highly variable anatomy of the region surrounding the SPF, showing that ***a multiplicity of efferent rami that project from the pterygopalatine ganglion*** ("PPG"; FIG. 1) to innervate the orbit and nasal mucosa via numerous groups of small nerve fascicles, rather than an individual postganglionic autonomic nerves (e.g., the posterior nasal nerve). Studies have shown that at least 87% of humans have microforamina and micro rami in the palatine bone. FIG. 1C, for example, is a front view of a left palatine bone illustrating geometry of microforamina and micro rami in a left palatine bone. ***In FIG. 1C, the solid regions represent nerves traversing directly through the palatine bone, and the open circles represent nerves that were associated with distinct microforamina***. Indeed, FIG. 1C illustrates that a medial portion of the palatine bone can include at least 25 accessory posterolateral nerves."

(*Id.* at [0037].)

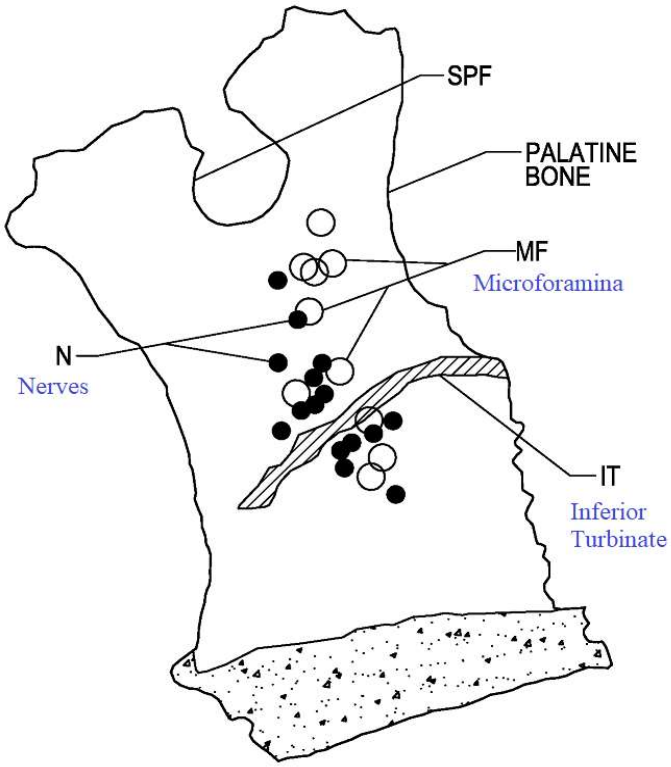

Fig. 1C

Townley further teaches modulating the nerves "branching from the pterygopalatine ganglion and innervating the nasal region and nasal mucosa, such as parasympathetic nerves (e.g., the posterior nasal nerves) traversing the SPF, accessory foramen, and microforamina of a palatine bone." (*Id.* at [0042].)

127. Thus, Townley teaches claim 2.

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[Claim 3] The method of claim 1, wherein the multi-electrode end effector comprises at least one temperature sensor arranged relative to first and second electrode.

[Claim 4] The method of claim 3, wherein the at least one temperature sensor is configured to sense temperature of tissue at the one or more target sites.

128. Townley discloses claims 3-4.

129. Townley discloses:

"As shown in FIG. 4, ***the therapeutic assembly 412*** can further include ***one or more temperature sensors 452*** disposed on the struts 440 and/or other portions of the therapeutic assembly 412 and ***configured to detect the temperature adjacent to the temperature sensor 452***. The temperature sensors 452 can be electrically coupled to a console (e.g., the console 204 of FIG. 2) via wires (not shown) that extend through the shaft 408***. In various embodiments, the temperature sensors 452 can be positioned proximate to the electrodes 444 to detect the temperature at the interface between tissue at the target site and the electrodes 444. In other embodiments, the temperature sensors 452 can penetrate the tissue at the target site (e.g., a penetrating thermocouple) to detect the temperature at a depth within the tissue***." The temperature measurements can provide the operator or the system with feedback regarding the effect of the therapeutic neuromodulation on the tissue. For example, in certain embodiments the operator may wish to prevent or reduce damage to the tissue at the treatment site (e.g., the nasal mucosa), and therefore the temperature sensors 452 can be used to determine if the tissue temperature reaches a predetermined threshold for irreversible tissue damage. Once the threshold is reached,

> the application of therapeutic neuromodulation energy can be terminated to allow the tissue to remain intact. In certain embodiments, the energy delivery can automatically terminate based on an evaluation/feedback algorithm (e.g., the evaluation/feedback algorithm 220 of FIG. 2) stored on a console (e.g., the console 204 of FIG. 2) operably coupled to the temperature sensors 452.

(*Id.* at [0074]; *see also id.* at [0044], [0046]-[0047], [0095], [0111], FIG. 7, claims 29, 39, 80.)

130. Thus, Townley discloses claims 3-4.

[Claim 5] The method of claim 1, [5a] wherein the multi-electrode end effector comprises at least four electrodes, wherein the at least four electrodes are oriented at an angle less than 90 degrees relative to the shaft for the delivery of radiofrequency (RF) energy,

131. Townley discloses limitation [5a].

132. Townley discloses that its electrodes are configured to deliver RF energy.

> "As shown in FIG. 2, the therapeutic assembly 212 includes at least one energy delivery element 214 configured to provide therapeutic neuromodulation to the target site. In certain embodiments, for example, the energy delivery element 214 can include one or more ***electrodes*** *configured to apply electromagnetic neuromodulation energy (e.g.,* ***RF energy****) to target sites*."

(Ex-1004-Townley at [0043]; *see also id.* at [0066], [0072]-[0073], [0111].)

133. As shown below, the multi-electrode end effectors of Figures 4, 5A-G,

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and 11A-D comprise at least eight electrodes, wherein the at least eight electrodes[3] are oriented at an angle less than 90 degrees relative to the shaft.

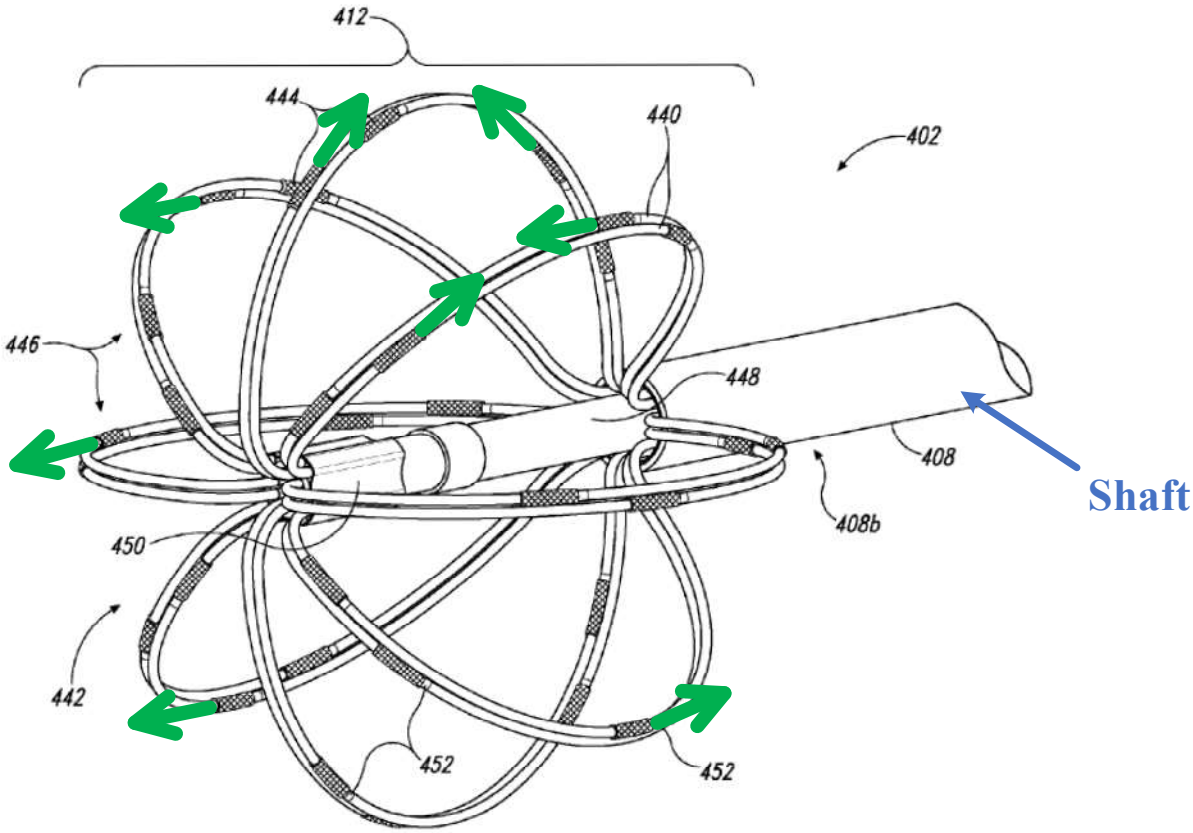

Fig. 4

(Ex-1004-Townley at FIG. 4.)

134. As the green arrows demonstrate, the at least eight electrodes 444 are

[3] Eight electrodes are illustrated because later claims 6-7 require "at least six" and "at least eight" electrodes, respectively.

oriented at angles less than 90 degrees relative to the shaft 408.[4]

135. The electrode arrangements of Figures 5A-G, 8-9, and 11A-D also disclose limitation [5a]. Below is an example (Figure 5D) showing how such electrode arrangements meet the requirements of limitation [5a], *i.e.*, at least eight electrodes 444 oriented at an angle less than 90-degrees relative to the shaft 408:

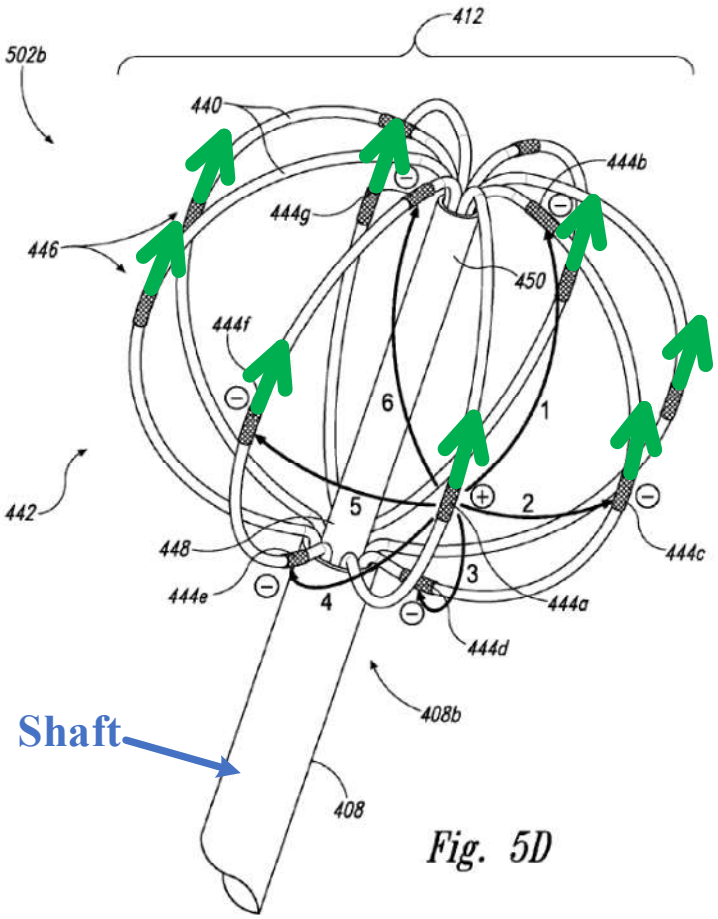

Fig. 5D

(Ex-1004-Townley at FIG. 5D.)

[4] The illustration provided here is only one example of the many different manners of illustrating the at least eight electrodes of Figure 4.

136. The electrodes 444 of Figure 9 may have the same or similar arrangements to those of Figures 4 and 5A-G. (Ex-1004-Townley at [0099].) Thus, Figure 9 teaches limitation [5a] for the same reasons as Figures 4 and 5A-G of Townley.

137. The electrodes of Figures 11A-D also teach the requirements of limitation [5a]. For example, more than eight electrodes (1144) of Figure 11B are illustrated as being located on the flexible membrane (1162), and the membrane and electrodes "conform to the irregular anatomy of the nasal space (e.g., turbinates, sinus, and/or other para-nasal) to enhance the contact area between the flexible membrane 1162 (*and the electrodes 1144 disposed thereon*) with ***the non-planar*** anatomy."

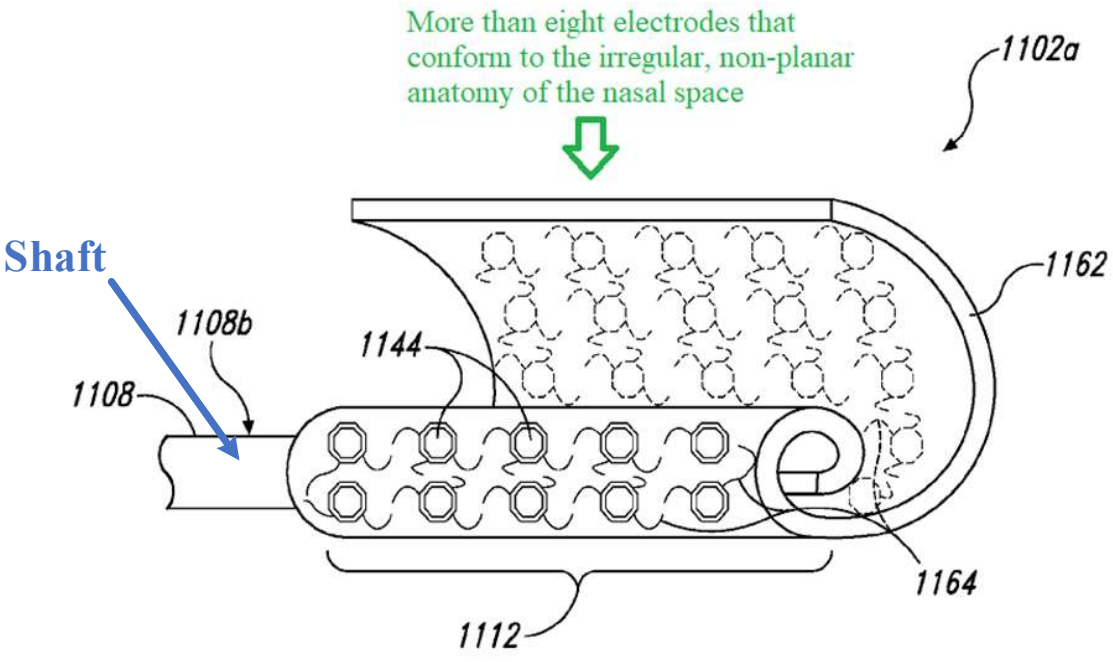

Fig. 11B

(*Id.* at FIG. 11B; *see also id*. at [0106].)[5] A POSITA would have found it obvious that at least eight of the electrodes of Figure 11B would be oriented at an angle less than 90 degrees relative to the shaft when conforming to the irregular, non-planar anatomy of the nasal space.

138. Thus, Townley discloses limitation [5a].

[5b] wherein the shaft is a substantially rigid shaft with a hollow cavity, wherein the shaft comprises an outer sheath and hypotube,

139. Townley discloses "the shaft is a substantially rigid shaft."

> "In other embodiments, the articulating ***shaft 208 can be made from a substantially rigid material*** (e.g., a metal material) and include rigid links at the distal portion 208b of the shaft 208 that resist deflection, yet allow for a small bend radius (e.g., a 5 mm bend radius, a 4 mm bend radius, a 3 mm bend radius or less). In further embodiments, the steerable shaft 208 may be a laser-cut tube made from a metal and/or other suitable material. The laser-cut tube can include one or more pull wires operated by the clinician to allow the clinician to deflect the distal portion 208b of the shaft 208 to navigate the tortuous nasal anatomy to the target site."

(Ex-1004-Townley at [0051].)

140. Townley also discloses that the "shaft comprises an outer sheath," a

[5] The use of Figures 4, 5D, 9, and 11B are exemplary, and are just some of the many examples in which the devices of Townley meet the requirements of limitation [5a].

"hypotube," and "a hollow cavity." As shown in Figure 4 (below), the shaft 408 includes an ***outer sheath*** having a ***hollow cavity*** to allow for components such as ***internal support member 448*** that supports "the distal end portions of the struts 440 to form the desired basket shape." (Ex-1004-Townley at [0068].)

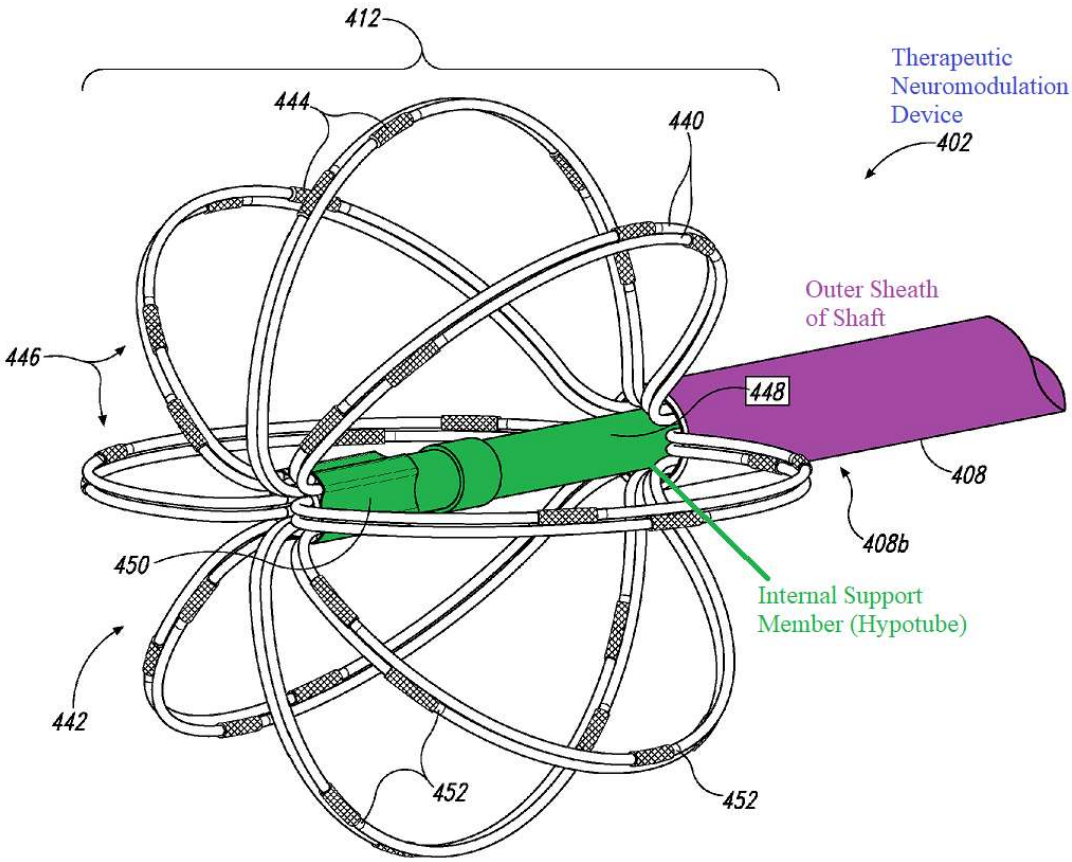

Fig. 4

(*Id*., FIG. 4.)

141. As shown above, Townley's shaft comprises an ***internal support member 448 (a hypotube)*** that extends distally from a distal portion 408*b* of the ***outer sheath*** of the shaft. (*Id.* at [0068].)

> "***[T]he support member 448*** *can include an* ***internal channel*** *(not shown)* through which electrical connectors (e.g., wires) coupled to the electrodes 444 and/or other electrical features of the therapeutic element 412 can run."

(*Id*.)

142. Townley further discloses that is support member 448 is moveable relative to the outer sheath and is expandable from a low profile configuration (pre-deployment) to an expanded state:

> "The therapeutic assembly 412 is transformable between *a low-profile delivery state to facilitate intraluminal delivery of the therapeutic assembly 412* to a treatment site within the nasal region and an expanded state (shown in FIG. 4). The therapeutic assembly 412 includes a plurality of struts 440 that are spaced apart from each other to form a frame or basket 442 when the therapeutic assembly 412 is *in the expanded state*."

(Ex-1004-Townley at [0066].)

> "The basket 442 can transform *from the low-profile delivery state to the expanded state (FIG. 4) by manipulating a handle* (e.g., the handle 210 of FIG. 2) and/or other feature at the proximal portion of the shaft 408 and operably coupled to the basket 442. For example, to move the basket 442 from the expanded state to the delivery state, *an operator can push the support member 448 distally to bring the struts 440 inward toward the support member 448*. An introducer or guide sheath (not shown) can be positioned over the low-profile therapeutic assembly

> 412 to facilitate intraluminal delivery or removal of the therapeutic assembly 412 from or to the target site. In other embodiments, the therapeutic assembly 412 is transformed between the delivery state and the expanded state using other suitable means.

(*Id.* at [0069].)

143. Townley's description of its "internal support member 448" aligns with the '974 patent's description of a "hypotube," *i.e.*, a moveable tube within an outer sheath of a shaft that is assembled over components to protect them, and which allows for deployment and retraction of such components:

> "The shaft 116 includes an outer sheath 138, surrounding a hypotube 140, which is further assembled over electrode wires 129 which surround an inner lumen 142."

(Ex-1001 at 22:4-6.)

> "The hypotube 140 is assembled over the electrode wires starting within the handle 118 and travelling to the proximal end of the end effector 114. The hypotube 140 generally acts *to protect the wires during delivery* and is malleable to enable flexibility without kinking to thereby improve trackability. The hypotube 140 provides stiffness and enables torquability of the device 102 to ensure accurate placement of the end effector 114. The hypotube 140 also provides a low friction exterior surface which enables low forces *when the outer sheath 138 moves relative to the hypotube 140 during deployment and retraction or constraint*."

(*Id.* at 22:25-32.)

144. Thus, Townley discloses limitation [5b].

[5c] wherein the first electrode and second electrode is operably coupled to a console unit via wires disposed in the hollow cavity of the substantially rigid shaft, and wherein RF energy is delivered from the first and second electrodes to tissue at the one or more target sites and is controlled via the console unit operably associated with the treatment device and multi-electrode end effector.

145. Townley discloses and illustrates a console unit (204) that is operably associated with the treatment device (202) and the multi-electrode end effector (212) of Figure 2:

> "The therapeutic neuromodulation device 202 can be operatively coupled to the console 204 via a wired connection (e.g., via the cable 206) and/or a wireless connection. The console 204 can be configured to control, monitor, supply, and/or otherwise support operation of the therapeutic neuromodulation device 202. The console 204 can further be configured to generate a selected form and/or magnitude of energy for delivery to tissue or nerves at the target site via the therapeutic assembly 212, and therefore the console 204 may have different configurations depending on the treatment modality of the therapeutic neuromodulation device 202."

(*Id.* at [0045].)

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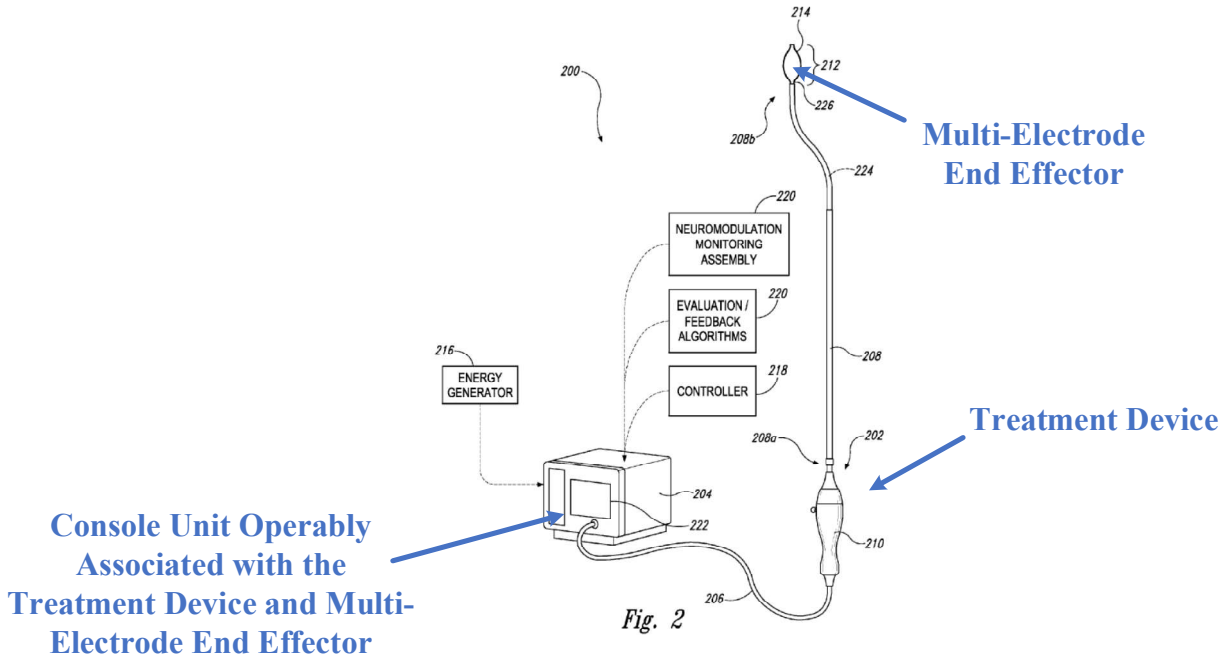

(*Id*. at FIG. 2; *see also id.* at [0042], [0046], [0048], [0074], [0110].)

146. Townley discloses that the console 204 may be used with any of Townley's therapeutic assemblies, including those illustrated in Figures 4, 5A-G, 8-9, and 11A-D. (*Id.* at [0066], [0074]-[0075], [0099], [0105], [0110]-[0111].)

147. The console unit 204 includes an energy generator 216, *e.g.*, an RF energy generator. (*Id.* at [0045] ("the console 204 can include an ***energy generator 216*** configured to ***generate RF energy*** (e.g., monopolar, bipolar, or multi-polar RF energy)…").)

148. Townley discloses that the first and second electrodes of its multi-electrode end effectors are operably coupled to the console via wires disposed in the hollow cavity of the substantially rigid shaft.

> "The electrodes 444 can be electrically coupled to an RF generator (e.g., the generator 216 of FIG. 2) via wires (not shown) that extend from the electrodes 444, through the shaft 408, and to the RF generator."

(Ex-1004-Townley at [0073]; *see also id.* at FIGS. 2 and 14, [0044], [0048], [0068], [0074].)

149. Townley discloses that RF energy is delivered from the first and second electrodes of the multi-electrode end effectors to tissue at the target site(s) and is controlled via the console operably associated with the treatment device and the multi-electrode end effector.

> "As further shown in FIG. 2, the system 200 can further include a controller 218 communicatively coupled to the therapeutic neuromodulation device 202. In the illustrated embodiment, *the* ***controller 218*** *is housed in the* ***console 204***."

(*Id.* at [0046].)

> "*In certain embodiments,* ***each electrode 444 can be operated independently of the other electrodes 444****. For example, each electrode can be individually activated and the polarity and amplitude of each electrode can be selected by an operator or a control algorithm (e.g.,* ***executed by the controller 218*** *of FIG. 2)*. Various embodiments of such independently controlled electrodes 444 are described in further detail below with reference to FIGS. 5A-5G. The selective independent control of the electrodes 444 allows the therapeutic assembly 412 to deliver RF energy to highly customized regions. For example, a select

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> portion of the electrodes 444 can be activated to target neural fibers in a specific region while the other electrodes 444 remain inactive. In certain embodiments, for example, electrodes 444 may be activated across the portion of the basket 442 that is adjacent to tissue at the target site, and the electrodes 444 that are not proximate to the target tissue can remain inactive to avoid applying energy to non-target tissue. Such configurations facilitate selective therapeutic modulation of nerves on the lateral nasal wall within one nostril without applying energy to structures in other portions of the nasal cavity."

(*Id.* at [0074]; *see also id.* at FIG. 2, [0042]-[0043], [0045]-[0046], [0048], [0066], [0074], [0110].)

150. Thus, Townley discloses limitation [5c].

151. Accordingly, Townley discloses Claim 5.

[Claim 6] The method of claim 5, wherein the multi-electrode end effector comprises at least six electrodes, and wherein the at least six electrodes are oriented at an angle less than 90 degrees relative to the shaft for the delivery of RF energy.

[Claim 7] The method of claim 5, wherein the multi-electrode end effector comprises at least eight electrodes, and wherein the at least eight electrodes are oriented at an angle less than 90 degrees relative to the shaft for the delivery of RF energy.

152. Townley discloses claims 6-7.

153. As explained above relative to claim 5, Townley discloses multi-electrode end effectors that have at least six (Claim 6) and at least eight (Claim 7) "electrodes oriented at an angle less than 90 degrees relative to the shaft for the

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delivery of RF energy."

154. Thus, Townley discloses Claims 6-7.

[Claim 8] The method of claim 1, wherein radiofrequency (RF) energy is delivered from the first and second electrodes to tissue at the one or more target sites and is controlled via a console unit operably associated with the treatment device and multi-electrode end effector.

155. Townley discloses claim 8.

156. Townley discloses that its multi-electrode end effectors may apply radiofrequency ("RF") energy from the first and second electrodes to tissue at the target site(s).

> "As shown in FIG. 2, the therapeutic assembly 212 includes at least one energy delivery element 214 configured to provide therapeutic neuromodulation to the target site. In certain embodiments, for example, the energy delivery element 214 can include one or more electrodes configured *to apply electromagnetic neuromodulation energy (e.g., RF energy) to target sites*."

(Ex-1004-Townley at [0043].)

> "The struts 440 can carry one or more energy delivery elements, such as a plurality of electrodes 444. In the expanded state, the struts 440 can position at least two of the electrodes 444 against tissue at a target site within the nasal region (e.g., proximate to the palatine bone inferior to the SPF). *The electrodes 444 can apply bipolar or multi-polar radiofrequency (RF) energy to the target site* to therapeutically modulate postganglionic parasympathetic nerves that innervate the nasal mucosa proximate to the target site. In various embodiments, the

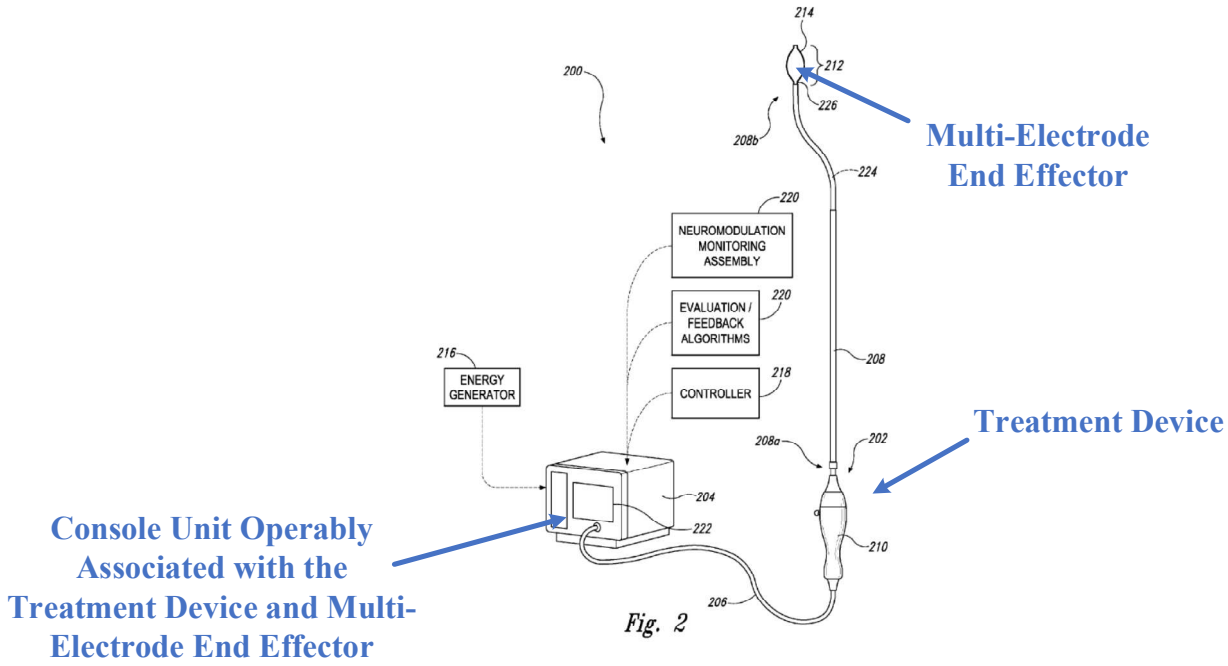
> electrodes 444 can be configured to apply pulsed RF energy with a desired duty cycle (e.g., 1 second on/0.5 seconds off) to regulate the temperature increase in the target tissue."

(*Id.* at [0066]; *see also id*. at [0055], [0072]-[0073], [0075], [0078], [0080], [0083], [0085]-[0086], claims 2, 10, 12-13, 15-16, 26, and 42.)

157. Townley discloses and illustrates a console unit (204) that is operably associated with the treatment device (202) and the multi-electrode end effector (212) of Figure 2:

> "The therapeutic neuromodulation device 202 can be operatively coupled to the console 204 via a wired connection (e.g., via the cable 206) and/or a wireless connection. The console 204 can be configured to control, monitor, supply, and/or otherwise support operation of the therapeutic neuromodulation device 202. The console 204 can further be configured to generate a selected form and/or magnitude of energy for delivery to tissue or nerves at the target site via the therapeutic assembly 212, and therefore the console 204 may have different configurations depending on the treatment modality of the therapeutic neuromodulation device 202."

(*Id.* at [0045].)



(*Id*. at FIG. 2; *see also id.* at [0042], [0046], [0048], [0074], [0110].)

158. Townley discloses that the console 204 may be used with any of Townley's therapeutic assemblies, including those illustrated in Figures 4, 5A-G, 8-9, and 11A-D. (*Id.* at [0066], [0074]-[0075], [0105], [0110]-[0111].)

159. Thus, Townley discloses claim 8.

[Claim 9] The method of claim 8, wherein the console unit is operably coupled to an energy generator configured to generate RF energy to be delivered by the first and second electrodes.

[Claim 10] The method of claim 9, wherein the RF energy comprises at least bipolar RF energy.

160. Townley discloses claims 9-10.

161. Townley discloses and illustrates console 204 as operably coupled to an energy generator 216 configured to generate RF energy to be delivered by the

first and second electrodes, which RF energy may be bipolar RF energy:

> "The console 204 can further be configured to generate a selected form and/or magnitude of energy for delivery to tissue or nerves at the target site via the therapeutic assembly 212, and therefore the console 204 may have different configurations depending on the treatment modality of the therapeutic neuromodulation device 202. For example, when therapeutic neuromodulation device 202 is configured for electrode-based, heat-element-based, and/or transducer-based treatment, the console 204 *can include an* ***energy generator 216*** *configured to generate RF energy (e.g., monopolar,* ***bipolar****, or multi-polar RF energy)*…."

(Ex-1004-Townley at [0045].)

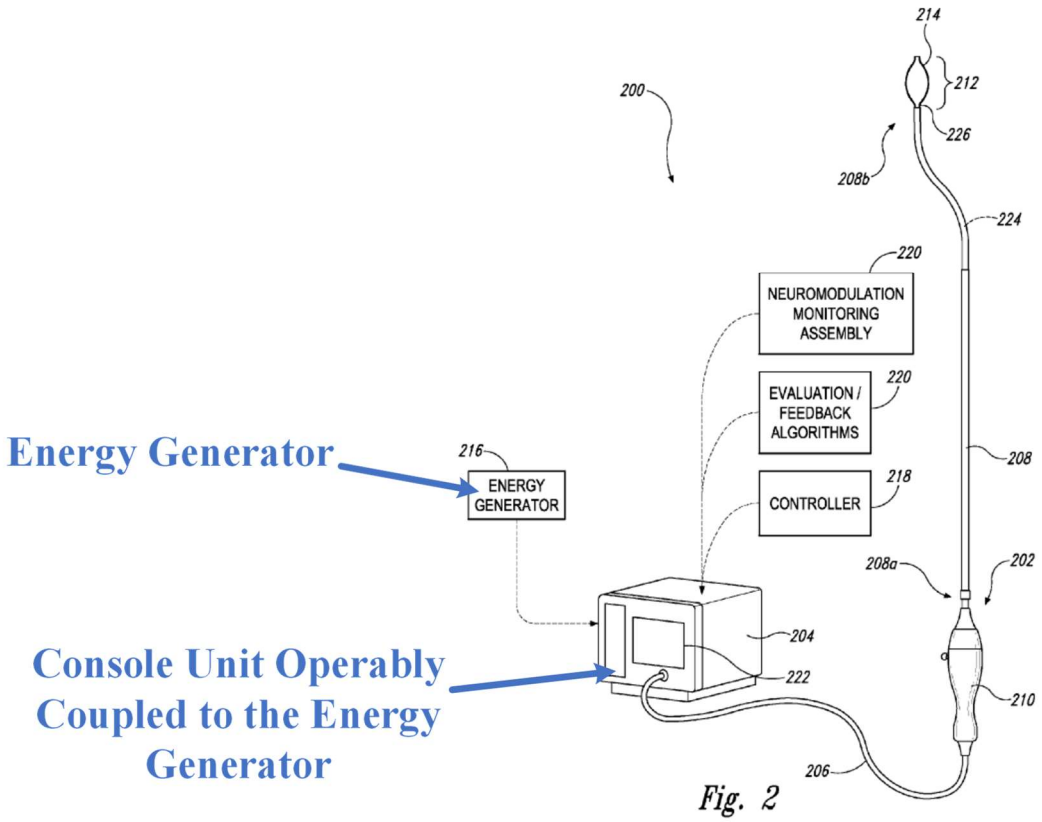


Fig. 2

(*Id*. at FIG. 2; *see also id.* at [0066], [0073], [0075], [0083], [0103], [0109], [0115]; claims 39-40.)

162. Thus, Townley discloses claims 9-10.

[Claim 11] The method of claim 8, [11a] wherein the console unit is configured to receive feedback from at least one temperature sensor arranged relative to the first and second electrodes and configured to sense temperature at an interface between tissue and the first and second electrodes,

163. Townley discloses limitation [11a].

164. Townley discloses that is console unit 204 is configured to receive feedback from temperature sensors 452 arranged relative to the first and second electrodes and configured to sense temperature at an interface between tissue and the first and second electrodes:

> " As shown in FIG. 4, the therapeutic assembly 412 can further include one or more temperature sensors 452 disposed on the struts 440 and/or other portions of the therapeutic assembly 412 and configured to detect the temperature adjacent to the temperature sensor 452. The temperature sensors 452 can be electrically coupled to a console (e.g., the console 204 of FIG. 2) via wires (not shown) that extend through the shaft 408. In various embodiments, *the temperature sensors 452 can be positioned proximate to the electrodes 444 to detect the temperature at the interface between tissue at the target site and the electrodes 444*. In other embodiments, the temperature sensors 452 can penetrate the tissue at the target site (e.g., a penetrating thermocouple) to detect the temperature at a depth within the tissue. *The temperature measurements can provide the operator or the system with feedback regarding the*

effect of the therapeutic neuromodulation on the tissue. For example, in certain embodiments the operator may wish to prevent or reduce damage to the tissue at the treatment site (e.g., the nasal mucosa), and therefore *the temperature sensors 452 can be used to determine if the tissue temperature reaches a predetermined threshold for irreversible tissue damage*. Once the threshold is reached, the application of therapeutic neuromodulation energy can be terminated to allow the tissue to remain intact. In certain embodiments, *the energy delivery can automatically terminate based on an evaluation/feedback algorithm (e.g., the evaluation/feedback algorithm 220 of FIG. 2) stored on a console (e.g., the console 204 of FIG. 2) operably coupled to the temperature sensors 452*."

(Ex-1004-Townley at [0074].)

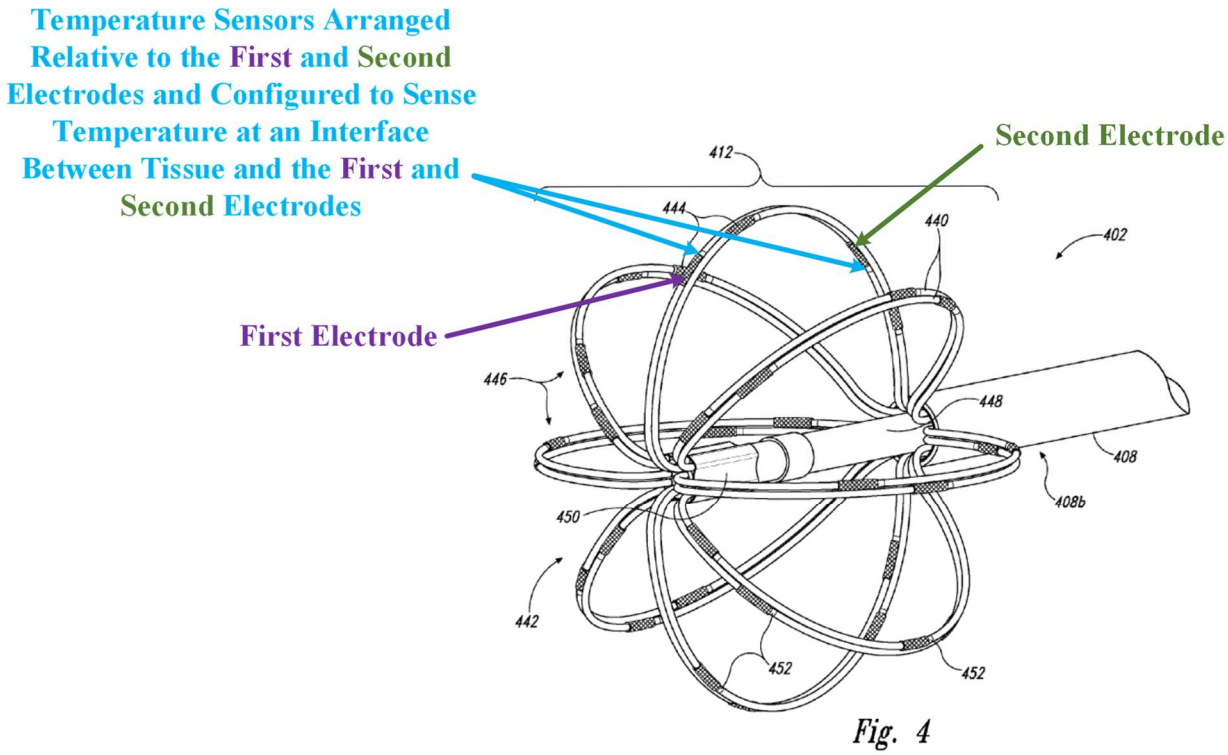


Fig. 4

(*Id*. at FIG. 4; *see also id.* at [0044], [0047]-[0048], [0111], [0114], claims 29 and 39.)

165. Thus, Townley discloses limitation [11a].

[11b] wherein the console unit is configured to control energy output from the first and second electrodes based, at least in part, on the feedback in order to maintain a predetermined temperature of tissue at the one or more target sites.

166. Townley teaches and suggests limitation [11b].

167. Townley discloses that is console unit 204 is configured to control energy output from the first and second electrodes based, at least in part, on the feedback from the temperature sensors 452:

> "Further, the console 204 can be configured *to provide feedback to an operator before, **during**, and/or after a treatment procedure* via evaluation/feedback algorithms 220. For example, the evaluation/feedback algorithms 220 can be configured *to provide information associated with the temperature of the tissue at the treatment site*, the location of nerves at the treatment site, and/or the effect of the therapeutic neuromodulation on the nerves at the treatment site. In certain embodiments, the evaluation/feedback algorithm 220 can include features to confirm efficacy of the treatment and/or enhance the desired performance of the system 200. For example, *the evaluation/feedback algorithm 220, in conjunction with the controller 218, can be configured to monitor temperature at the treatment site during therapy and automatically shut off the energy delivery when the temperature reaches a predetermined maximum (e.g., when applying RF energy)* or predetermined minimum (e.g., when applying

> cryotherapy). In other embodiments, the evaluation/feedback algorithm 220, in conjunction with the controller 218, can be configured *to automatically terminate treatment after a predetermined maximum time, a predetermined maximum impedance rise of the targeted tissue (i.e., in comparison to a baseline impedance measurement)*, a predetermined maximum impedance of the targeted tissue), and/or other threshold values for biomarkers associated with autonomic function. This and other information associated with the operation of the system 200 can be communicated to the operator via a display 222 (e.g., a monitor or touchscreen) on the console 204 and/or a separate display (not shown) communicatively coupled to the console 204."

(*Id.* at [0047]; *see also id.* at [0045]-[0046], [0074], [0111], [0114], claim 80.)

168. Townley also discloses maintaining a predetermined "target temperature" of tissue at the one or more target sites:

> "Once positioned at the target site, *the therapeutic modulation may be applied via the energy delivery element 214 and/or other features of the therapeutic assembly 212 to precise, localized regions of tissue to induce one or more desired therapeutic neuromodulating effects to disrupt parasympathetic motor sensory function*. … The therapeutic neuromodulating effects are generally a function of, at least in part, power, time, and contact between the energy delivery elements and the adjacent tissue. For example, in certain embodiments therapeutic neuromodulation of autonomic neural fibers are produced by applying RF energy at a power of about 2-20 W (e.g., 5 W, 7 W, 10 W, etc.) for a time period of about 1-20 sections (e.g., 5-10 seconds, 8-10 seconds,

> 10-12 seconds, etc.). The therapeutic neuromodulating effects may include partial or complete denervation via thermal ablation and/or non-ablative thermal alteration or damage (e.g., via sustained heating and/or resistive heating). *Desired thermal heating effects may include raising the temperature of target neural fibers* ***above a desired threshold*** *to achieve non-ablative thermal alteration, or above a higher temperature to achieve ablative thermal alteration*. For example, *the* ***target*** *temperature* may be above body temperature (e.g., approximately 37° C.) but less than about 90° C. (e.g., 70-75° C.) for non-ablative thermal alteration, or the target temperature may be about 100° C. or higher (e.g., 110° C., 120° C., etc.) for the ablative thermal alteration. Desired non-thermal neuromodulation effects may include altering the electrical signals transmitted in a nerve."

(*Id.* at [0055]; *see also id*. at [0047], [0074], [0111], claim 80.)

169. A POSITA would have also found it obvious to maintain the predetermined target temperature based on temperature feedback to ensure that each treatment produces the desired neuromodulation and heating effects, and without inappropriately damaging tissue, as Townley expressly recognizes.

170. For instance, Figure 7 of Townley (below) is "a graph illustrating threshold levels of electrical conductivity of nasal tissue with respect to temperature." (*Id.* at [0017].)

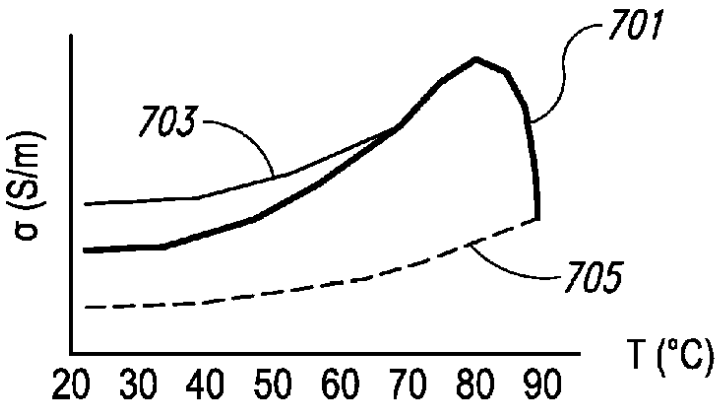


Fig. 7

(*Id*. at FIG. 7.)

171. As Townley explains in relation to Figure 7, the "second curve 703 shows that *the electrical conductivity of the tissue* ***permanently*** *increases significantly* (i.e., impedance decreases) *after the tissue has been exposed to temperatures of 70° C, as it may during therapeutic neuromodulation*." (*Id*. at [0095].)

172. To avoid inappropriately damaging tissue, Townley teaches to "stop neuromodulation when the temperature reaches about 70° C. (e.g., 70-80° C.) *to* ***avoid structural*** *changes or damage to the mucosa,* ***but still providing*** *what is expected to be* ***therapeutically effective neuromodulation***." (*Id.*)

173. Thus, Townley teaches and suggests limitation [11b].

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[Claim 12] The method of claim 11, wherein the console unit is configured to receive one or more temperature readings from the at least one temperature sensor and process the readings to determine a level of RF energy to be delivered by the first and second electrodes that is sufficient to maintain a temperature of tissue at the one or more target sites below a predetermined threshold.

174. Townley discloses claim 12.

175. As discussed above with respect to claim 11, Townley's console unit 204 is configured to receive temperature readings from the temperature sensors 452. (Ex-1004-Townley at [0047], [0074], [0111], [0114].)

176. Townley's console unit 204 also includes an evaluation/feedback algorithm 220. (*Id.* at [0047].) This "evaluation/feedback algorithm 220, in conjunction with the controller 218, can be configured to monitor temperature at the treatment site during therapy." (*Id.*) Townley further teaches ensuring sufficient energy is applied to achieve predetermined target temperatures:

> Desired thermal heating effects may include raising the temperature of target neural fibers *above a desired threshold* to achieve non-ablative thermal alteration, *or above a higher temperature* to achieve ablative thermal alteration. For example, *the target temperature* may be above body temperature (e.g., approximately 37° C.) but less than about 90° C. (e.g., 70-75° C.) for non-ablative thermal alteration, or *the target temperature may be about 100° C.* or higher (e.g., 110° C., 120° C., etc.) for the ablative thermal alteration. Desired non-thermal neuromodulation effects may include altering the electrical signals transmitted in a nerve."

(*Id.* at [0055].)

177. Townley further discloses that the console unit may be programmed to "automatically shut off the energy delivery *when the temperature reaches a predetermined maximum* (e.g., when applying RF energy)…." (*Id*. at [0047]; *see also id.* at [0074], [0111].)

178. Thus, Townley teaches claim 12.

[Claim 13] The method of claim 12, [13a] wherein the console unit is configured to monitor temperature of tissue at the one or more target sites during delivery of RF energy thereto based on temperature readings from the at least one temperature sensor

179. Townley discloses limitation [13a].

180. As explained previously, Townley's console unit 204 is configured to monitor temperature of tissue at the target site(s) during delivery of RF energy based on temperature readings from the temperature sensors 452. (Ex-1004-Townley at [0047]; *id*. at [0045], [0074], [0111], [0114].)

181. Thus, Townley discloses limitation [13a].

[13b] and further monitor an elapsed time during delivery of RF energy to tissue at the one or more target sites.

182. Townley discloses, teaches, and suggests limitation [13b].

183. Townley discloses:

> "The console 204 can be configured to control, *monitor*, supply, and/*or otherwise support operation of the therapeutic neuromodulation device 202*."

(Ex-1004-Townley at [0045].)

184. Townley's console unit 204 is also "configured to automatically terminate treatment after a predetermined maximum time." (*Id*. at [0047]; *see also id*. at [0055], claim 81.) In order to determine whether "a predetermined maximum time" was achieved, a POSITA would have understood Townley's console unit 204 to monitor the elapsed time during treatment, including during delivery of RF energy.

185. Thus, Townley discloses, teaches, and suggests limitation [13b].

[Claim 14] The method of claim 12, wherein the console unit is configured to provide, via a display, feedback information to an operator during a given treatment application, wherein said feedback information comprises at least an elapsed time during delivery of RF energy to tissue at the one or more target sites.

186. Townley teaches and suggests claim 14.

187. Townley discloses that its console unit 204 comprises a display 222 configured to provide feedback information to an operator during treatment, including information associated with a "predetermined maximum time." (Ex-1004-Townley at [0047] ("In other embodiments, the evaluation/feedback algorithm 220, in conjunction with the controller 218, can be configured *to automatically terminate treatment after a predetermined maximum time*….*This and other information* associated with the operation of the system 200 *can be communicated to the operator via a display 222* (e.g., a monitor or touchscreen) on the console 204 and/or a

separate display (not shown) communicatively coupled to the console 204."), [0048] ("This information can then be communicated to the operator via a high resolution spatial grid (e.g., on the display 222) and/or other type of display.").) A "predetermined maximum time" reads on "an elapsed time during delivery of RF energy to tissue at" the target site(s) because Townley teaches that the display would show that the "predetermined maximum time" has been reached—the predetermined maximum time includes the total elapsed time.

188. A POSITA also would have found it obvious to display the elapsed time during delivery of RF energy to inform the operator as to how much time remains in a given treatment, thus dissuading the operator from deactivating the treatment device before treatment is completed.

189. Thus, Townley teaches and suggests claim 14.

[Claim 15] The method of claim 14, wherein the display is a touchscreen monitor.

190. Townley discloses claim 15.

191. Townley discloses that its display 222 may be a "touchscreen" (*i.e.*, a touchscreen monitor). (Ex-1004-Townley at [0047] ("This and other information associated with the operation of the system 200 can be communicated to the operator via a display 222 (e.g., a monitor *or touchscreen*) on the console 204 and/or a separate display (not shown) communicatively coupled to the console 204.").)

192. Thus, Townley discloses claim 15.

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[Claim 16] The method of claim 12, wherein the console unit comprises a hardware processor coupled to non-transitory, computer-readable memory containing instructions executable by the processor to cause the console unit to automatically control and adjust RF energy output from the first and second electrodes based, at least in part, on a predetermined elapsed time period and a predetermined threshold maximum temperature during delivery of RF energy to ensure that application of said RF energy results in the desired effect of reduced engorgement of the tissue at the target site for a given treatment application.

193. Townley teaches and suggests claim 16.

194. Townley discloses that its console unit 204 comprises a controller 218 "configured to execute an automated control algorithm" and/or execute "a computer-readable medium carrying instructions," and a POSITA would have known such "automated control algorithms" and "computer-readable medium carrying instructions are commonly executed using a "hardware processor," such as a conventional computer processor. (Ex-1004-Townley at [0046].) Accordingly, a POSITA would have found it obvious that Townley's controller includes "a hardware processor."

195. Townley's controller 218 is coupled to a "non-transitory" memory including a "computer-readable medium" (*i.e.*, a non-transitory, computer-readable memory) that contains "instructions" that are executable by the controller 218. (Ex-1004-Townley at FIG. 2, [0046]-[0047], claims 32-33 and 39-40.) When executed by the controller 218, the instructions "cause[] the therapeutic assembly 202 to perform certain functions (e.g., apply energy in a specific manner, detect impedance,

detect temperature, detect nerve locations or anatomical structures, etc.)." (*Id*. at [0046].)

196. Townley's automated control algorithm causes console unit 204 to "automatically" adjust and terminate (*i.e.*, automatically control and adjust) energy RF energy output from the first and second electrodes. (*Id*. at [0047], [0074], [0111].) Townley teaches that automatically terminating the RF energy output may be based on a predetermined maximum time (*i.e.*, a predetermined elapsed time period) and a predetermined maximum temperature (*i.e.*, a predetermined threshold maximum temperature). (*Id*.) A POSITA would have found it obvious to include an automated control algorithm in Townley's controller-executable instructions because the automated control algorithm causes the therapeutic assembly 202 to "apply energy in a specific manner." (*Id.* at [0046]).)

197. Townley further discloses ensuring that application of RF energy results in the desired effect for a given treatment, including reduced engorgement of the tissue at the target site.

> "Accordingly, severing or *modulating the parasympathetic pathways that innervate the mucosa are expected to reduce or eliminate* the hyper activation of the submucosal glands and *engorgement of vessels* that cause symptoms associated with rhinosinusitis and other indications."

(Ex-1004-Townley at [0038].)

> "[T]he evaluation/feedback algorithms 220 can be configured to provide information associated with the temperature of the tissue at the treatment site, the location of nerves at the treatment site, and/or the effect of the therapeutic neuromodulation on the nerves at the treatment site. In certain embodiments, *the evaluation/feedback algorithm 220 can include features to* ***confirm efficacy*** *of the treatment* and/or enhance the desired performance of the system 200. For example, the evaluation/feedback algorithm 220, in conjunction with the controller 218, can be configured to monitor temperature at the treatment site during therapy and automatically shut off the energy delivery when the temperature reaches a predetermined maximum (e.g., when applying RF energy) or predetermined minimum (e.g., when applying cryotherapy)."

(*Id.* at [0047]; *see also id*. at [0049], [0055], [0058], [0074], [0089], [0096], [0101], [0111], [0141]-[0142].)

198. Thus, Townley teaches claim 16.

[Claim 17] The method of claim 16, wherein the predetermined threshold maximum temperature is less than 90° C.

[Claim 18] The method of claim 16, wherein the predetermined threshold maximum temperature is greater than 37° C and less than 90° C.

199. Townley discloses claims 17-18.

200. Townley discloses that the predetermined threshold maximum temperature is "above body temperature (e.g., approximately 37° C.) but less than about 90° C. (e.g., 70-75° C.)." (Ex-1004-Townley at [0055]; *id*. at [0095].)

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201. Thus, Townley discloses claims 17-18.

[Claim 19] The method of claim 16, the predetermined elapsed time period is from about 1 second to about 20 seconds.

[Claim 20] The method of claim 19, wherein the predetermined elapsed time period is from about 10 seconds to about 12 seconds.

202. Townley discloses claims 19-20.

203. Townley discloses that the predetermined elapsed time period is between "1-20 [seconds] (e.g., 5-10 seconds, 8-10 seconds, 10-12 seconds, etc.)." (Ex-1004-Townley at [0055].)

204. Thus, Townley discloses claims 19-20.

B. Ground 2: Claims 1-4 and 8-12 are obvious based on Wolf-003 alone or in view of Wolf-290.

1. Summary of Ground 2

205. Ground 2 relies on Wolf-003 alone or in combination with Wolf-290, with Wolf-290 being used to show it was obvious to treat rhinosinusitis using the methods, systems, and apparatus described by Wolf-003, and with a reasonable expectation of successfully doing so.

2. Scope, Content and Motivation to Combine the Ground 2 Art

206. As I show below, Wolf-003 expressly discloses all limitations of claim 1, except Wolf-003 does not expressly state that its systems, devices, and methods treat rhinitis, congestion, or rhinorrhea, or that improved nasal breathability would

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be realized.

207. However, Wolf-003 does disclose that its systems, devices, and methods treat "structures within the upper airway to reduce and/or prevent overproduction and/or flow of mucus to alleviate the discomfort of post nasal drip symptoms," including "post nasal drip syndrome (PNDS) or upper airway cough syndrome (UACS)," such as by "delivering energy to mucosal tissue and/or a tissue underlying mucosal tissue in the upper airway" to "decrease the absolute number and/or the mucus producing ability of mucus producing cells and/or mucus glands, such as by inactivating, retarding and/or replacing the cells." (Ex-1005-Wolf-003 at [0002], [0004], [0011].) As the '974 patent admits, such energy treatments would be expected to treat conditions or symptoms of rhinosinusitis, including rhinitis, congestion, and rhinorrhea:

> "One aspect of the invention provides a method for improving a patient's sleep *by treating at least one of rhinitis, congestion, and rhinorrhea within a sino-nasal cavity of the patient*. The method includes delivering energy to one or more target sites within a sino-nasal cavity of the patient to disrupt multiple neural signals to, and/or result in local hypoxia of, mucus producing and/or mucosal engorgement elements, *thereby reducing production of mucus* and/or mucosal engorgement within a nose of the patient and *reducing or eliminate one or more symptoms associated with at least one of rhinitis, congestion, and rhinorrhea to improve nasal breathability of the patient*. The one or more symptoms associated with at least one of

> rhinitis, congestion, and rhinorrhea are selected from the group consisting of nasal congestion, coughing, sneezing, and nasal or throat irritation and itching."

(Ex-1001 at 5:37-52.)

208. As shown, the '974 patent ties reduced production of mucus to the reduction or elimination of "one or more symptoms associated with at least one of rhinitis, congestion, and rhinorrhea to improve nasal breathability of the patient," including symptoms such as "nasal congestion, coughing, sneezing, and nasal or throat irritation and itching." (Ex-1001 at 5:53-6:14 (tying ablative energy treatment of tissues and/or nerves associated with excess mucus production to treatment of rhinitis, congestion, or rhinorrhea).) Accordingly, Wolf-003 alone teaches and suggests that its systems, devices, and methods may be used to treat "at least one of rhinitis, congestion, and rhinorrhea."

209. Wolf-290 confirms that it was obvious to use Wolf-003's systems, devices, and methods to treat rhinitis, congestion, and rhinorrhea. Specifically, Wolf-290 discloses that, when energy, such as ablative energy, is delivered to nasal airway tissues to ablate nerve fibers and/or goblet cells, one is reducing or treating rhinitis:

> "Embodiments of the present application are directed to devices, systems and methods for treating nasal airways. … These or alternative embodiments may alternatively or additionally be used *to deliver*

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> *energy to nasal airway tissues, for example to help reshape the tissues and/or to* ***ablate goblet cells, nerve fibers*** *or other tissue,* ***to reduce rhinitis***."

(Ex-1006-Wolf-290 at [0009].)

> "Although many of the embodiments and aspects described herein are directed toward modifying tissue in some way to affect airflow through a nasal valve, alternative embodiments, or in some cases the same embodiments, may be used to address other airway conditions or issues. For example, in one embodiment, *the device and method may be used* ***to ablate one or more nerve fibers*** *in the airway* ***to reduce mucus hypersecretion and thus help treat rhinitis***. The same or other embodiments may be used *to ablate goblet cells for the same purpose*.

(*Id.* at [0053].)

210. Further, a POSITA would have known that using Wolf-003's systems, devices, and methods to treat conditions beyond PNDS and UCNS would have desirably yielded several clinical and commercial benefits, including: (i) providing patients with a more comprehensive treatment and reducing the need for multiple interventions; (ii) allowing device manufacturers to target a larger patient population, thus increasing revenue potential; and (iii) reducing the cost and time needed to develop a new device by leveraging an existing device for new uses.

211. Accordingly, to the extent not already obvious to do so based on Wolf-0003 alone, a POSITA would have been motivated to treat, and would have found it obvious to treat, rhinitis, congestion, or rhinorrhea using the systems, devices, and

methods of Wolf-003.

212. A POSITA also would have had a reasonable expectation of success in treating rhinitis, congestion, or rhinorrhea using the systems, devices, and methods of Wolf-003. The systems, devices, and methods of Wolf-003 are already configured to treat various locations in the nasal cavity with ablative energy, including mucosal tissue associated the turbinates (e.g., the inferior turbinate):

> "In some embodiments, delivering the treatment comprises *injuring the at least one tissue*. In some embodiments, delivering the treatment comprises injuring goblet cells that are part of the mucosal tissue. In some embodiments, *the at least one tissues is selected from the group consisting of cilia, goblet cells,* ***nerves****, submucosal tissue*, muscle, ligaments, cartilage, tendon, and skin. In some embodiments, delivering the treatment comprises simultaneously mechanically altering the mucosal tissue and delivering energy to the at least one tissue. In some embodiments, delivering the treatment comprises *modifying the at least one tissue in a manner that decreases a volumetric rate of mucus production of the mucosal tissue without changing a shape of the mucosal tissue*. In some embodiments, delivering the treatment comprises delivering a cauterizing agent to tissue to be treated. In some embodiments, delivering the treatment comprises *delivering the treatment to at least one turbinate* of the upper airway. In some embodiments, *the at least one turbinate comprises an inferior turbinate*, and contacting the mucosal tissue comprises contacting a posterior aspect of the inferior turbinate."

(Ex-1005-Wolf-003 at [0027].)

213. Such mucosal tissues were known to have nerve fibers and goblet cells responsible for mucus production:

> "Posteroinferior nasal branches give sensation to the mucosa of the turbinates and lateral nasal wall."

(Ex-1018-Lane at 390.)

> "At the limen vestibuli, the epithelium begins to change over to *a pseudostratified respiratory epithelium* characterized by five cell types: basal cells, *goblet cells*, ciliated columnar cells, nonciliated columnar cells, and small granule cells. *In high-airflow regions of the nasal cavity, such as the heads of the turbinates*, there may be islands of squamous epithelium amid *the respiratory epithelium*."

(*Id.* at 392*; see also id.* at FIGS. 4-5 (showing nerve supply of the nose).)

214. Accordingly, no changes to Wolf-003's systems, devices, and methods would have been required to treat rhinitis, congestion, or rhinorrhea.

215. Further, as I explained above in Ground 1, it was known that treating rhinitis, congestion, or rhinorrhea would have been expected to improve nasal breathability. (Ex-1001 at 1:49-60; Ex-1004-Townley at [0003]; Ex-1024 at Abstract, 4:18-32, 7:18-22.)

216. Thus, it was obvious to treat rhinitis, congestion, or rhinorrhea using the systems, devices, and methods of Wolf-003, and with a reasonable expectation of improving a patient's nasal breathability.

3. The Challenged Claims

[Claim 1, 1-PRE] A method for treating at least one of rhinitis, congestion, and rhinorrhea within a sino-nasal cavity of a patient, the method comprising:

217. Irrespective of whether the preamble is limiting, Wolf-003 alone and in combination with Wolf-290 teaches it.

218. Wolf-003 discloses methods of treating tissue to reduce or prevent overproduction of mucus secretion in the nose:

> "This application relates generally to the field of medical devices and treatments. More specifically, the application relates to systems, devices and *methods* for treating structures within the upper airway *to reduce and/or prevent overproduction and/or flow of mucus* to alleviate the discomfort of post nasal drip symptoms."

(Ex-1005-Wolf-003 at [0003].)

> "Certain implementations of the systems and methods disclosed herein address the above mentioned needs by delivering a therapy in an upper airway to treat [post nasal drip syndrome] PNDS and/or [upper airway cough syndrome] UACS."

(*Id.* at [0011].)

219. To achieve its reduced mucus production, Wolf-003 discloses applying "energy to mucosal tissue and/or a tissue underlying mucosal tissue in the upper airway", which may "decrease the absolute number and/or the mucus producing ability of mucus producing cells and/or mucus glands, such as by inactivating, retarding and/or replacing the cells." (*Id.*) The location of the energy delivery may

be "inside the nasal cavity, nasal passage, nasal airway and/or throat to deliver the desired treatment." (*Id.* at [0089].)

220. As I explained above, it was obvious to treat symptoms of rhinitis, congestion, and rhinorrhea with the energy delivery methods described by Wolf-003. (Ex-1001 at 5:53-6:11.) Accordingly, Wolf-003 alone teaches and suggests to a POSITA that its systems, methods, and devices may be used to treat rhinitis, congestion, and rhinorrhea "within a sino-nasal cavity of a patient."

221. As I also explained above, Wolf-290 confirms that Wolf-003's systems, devices, and methods may be used to treat rhinitis, congestion, and rhinorrhea and it would have been obvious to do so. As explained previously, Wolf-290 discloses that when energy, such as ablative energy, is delivered to nasal airway tissues to ablate nerve fibers and/or goblet cells, one is reducing or treating rhinitis. (Ex-1006-Wolf-290 at [0009], [0053].) As I also explained previously, a POSITA would have been motivated, and would have found it obvious, to treat rhinitis, congestion, and rhinorrhea using the systems, devices and methods of Wolf-003. As I also explained previously, a POSITA would have had a reasonable expectation of success because the systems, devices, and methods of Wolf-003 are already configured to treat locations in the nasal cavity with ablative energy, including mucosal tissue associated the turbinates (*e.g.*, the inferior turbinate), which mucosal tissues were known to have nerve fibers and goblet cells responsible for mucus production. (Ex-

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1005-Wolf-003 at [0027]; Ex-1018-Lane at 390, 392; FIGS. 4-5.)

222. Accordingly, Wolf-003 in view of Wolf-290 also teaches and suggests that Wolf-003's systems, devices, and methods may be used to treat rhinitis, congestion, and rhinorrhea "within a sino-nasal cavity of a patient."

223. Thus, Wolf-003 alone or in view of Wolf-290 teaches limitation [1-PRE].

[1a-1] advancing a multi-electrode end effector into the sino-nasal cavity of the patient

224. Wolf-003 discloses limitation [1a-1].

225. As explained previously, the '974 patent states that "the terms 'end effector' and 'therapeutic assembly' may be used interchangeably." (Ex-1001 at 12:32-34.)

226. Wolf-003 discloses several therapeutic assemblies having multiple electrodes. For instance, device 30 of Figure 6 is described as one embodiment of a mucus reduction treatment device. (Ex-1005-Wolf-003 at [0039], [0089].) Wolf-003 discloses that "device 30 comprises a treatment element 32 which may be configured to be placed inside the nasal cavity, nasal passage, nasal airway and/or throat to deliver the desired treatment." (*Id*. at [0089].) Wolf-003 further discloses that treatment element 32 may have multiple electrodes. (*Id*. at [0021] ("The treatment element comprises one or more electrodes, such as described above in further detail below."), [0099] ("RF electrodes"); *see also id*. at [0016], [0022],

[0029], [0097], [0117].)

227. Additional disclosures regarding device 30 and treatment element 32 are provided in subsequent figures and text, including in relation to Figures 19A-B. (*Id*. at [0145] ("Embodiments of treatment devices incorporating treatment elements such as the electrodes described above are illustrated in FIGS. 17-19B. The designs described in these embodiments may be used in various devices, for example the device 30, described above.").) As to the device illustrated in Figures 19A-B, Wolf-003 discloses a treatment portion 350 comprising eight radiofrequency electrodes 352. (*Id*. at FIG. 9B, [0148], [0150]-[0151], [0153], [0156], [0165].) Wolf-003 discloses additional multi-electrode treatment elements/portions in Figures 13-14, 25, 26A-F, and 27. (*Id*. at FIGS. 13-14, 25, 26A-F, and 27, [0126]-[0127], [0174]-[0179].)

228. A POSITA would have understood that Wolf-003's multi-electrode treatment elements/portions, including treatment portion 350, disclose multi-electrode therapeutic assemblies (*i.e.*, multi-electrode end effectors) because they are assemblies of components, including multiple electrodes, that deliver a therapeutic treatment to a patient. (Ex-1005-Wolf-003 at [0011], [0088], [0099], [0151], [0157], [0164]-[0165].)

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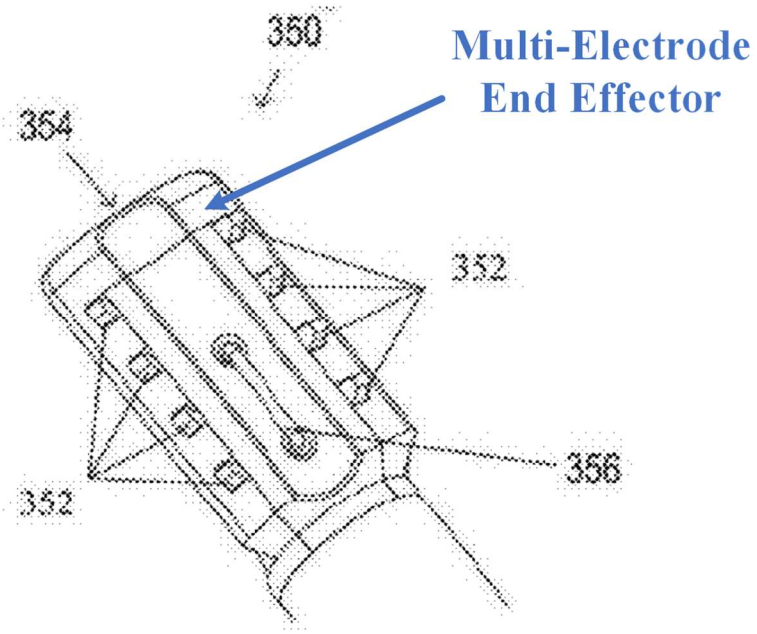

(Ex-1005-Wolf-003 at FIG. 19B.)

229. Wolf-003 further discloses advancing its multi-electrode therapeutic assemblies (*i.e.*, multi-electrode end effectors), including the multi-electrode therapeutic assembly of Figures 19A-B, into the nasal cavity[6] of the patient. (Ex-1005-Wolf-003 at FIG. 20, [0089] ("The device 30 comprises a treatment element 32 which may be configured to be placed inside the nasal cavity"), [0160] ("Advancing a portion of the device to a treatment site 504 may follow the preparation of the device 502."); *see also id*. at Abstract, [0013], [0021], [0023], [0030], [0157], [0164], [0176], claims 1 and 26.)

[6] As I explained previously in Ground 1, claim 1, the nasal cavity is part of the sino-nasal cavity.

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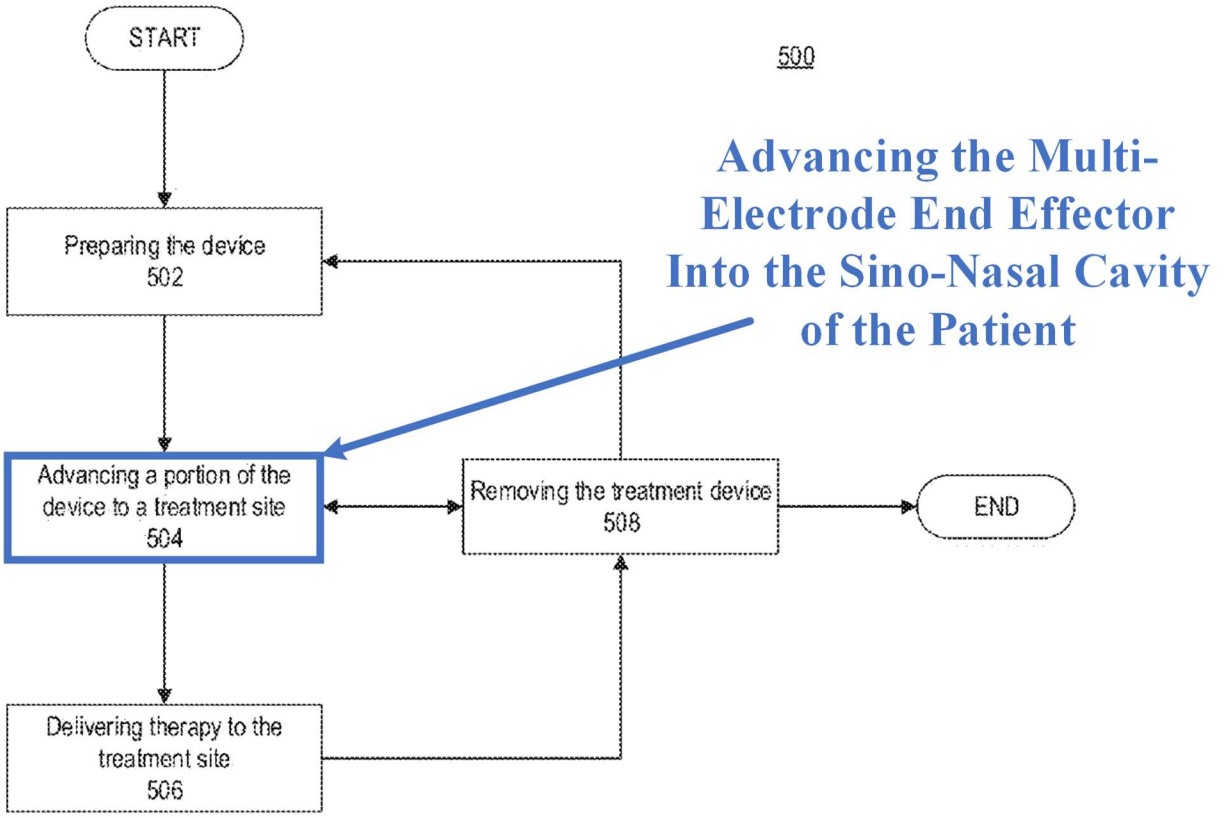


(*Id*. at FIG. 20.)

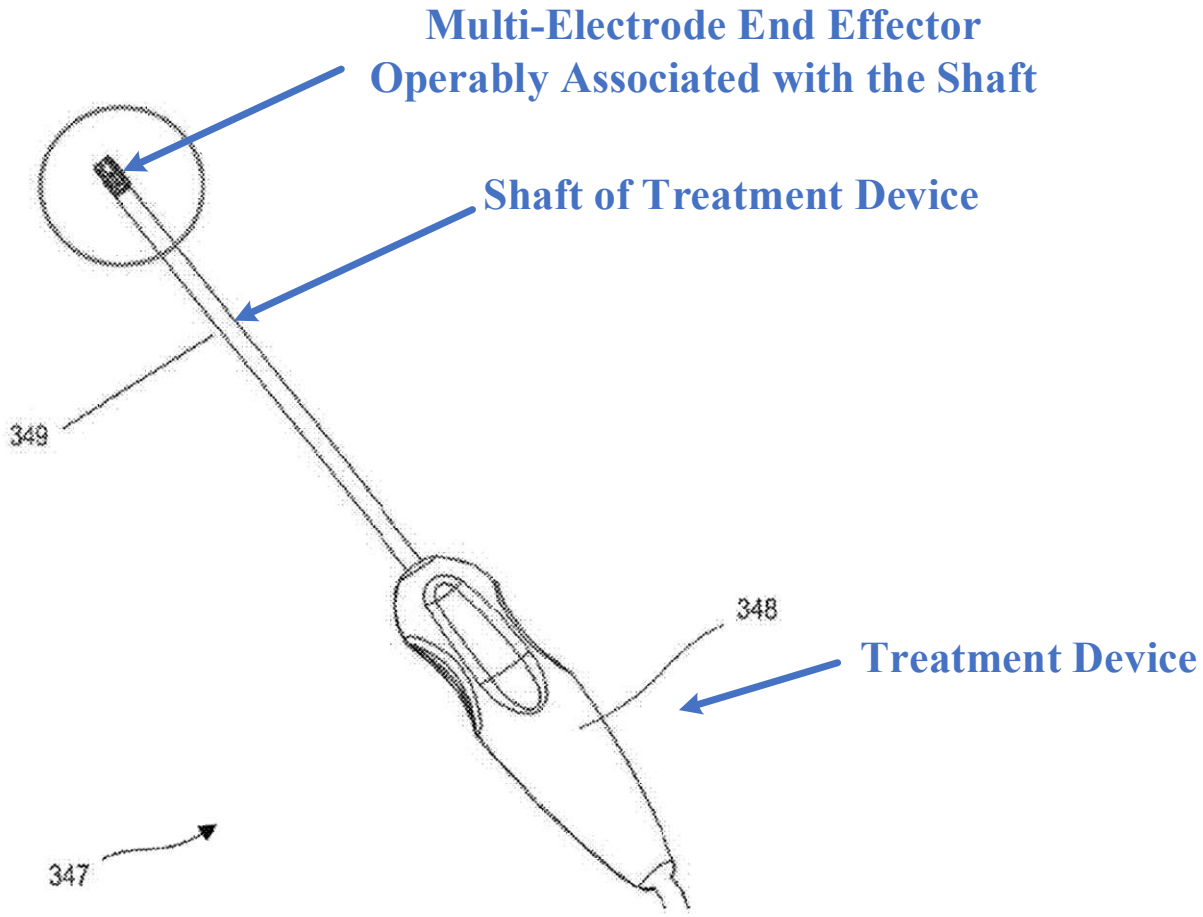
230. Thus, Wolf-003 discloses limitation [1a-1].

[1a-2] wherein the multi-electrode end effector is operably associated with a shaft of a treatment device and configured for delivering energy to one or more target sites within the sino-nasal cavity of the patient,

231. Wolf-003 discloses limitation [1a-2].

232. Wolf-003 discloses that its multi-electrode end effectors (*e.g.*, the multi-electrode end effector 350 of Figures 19A-B) are operably associated with a "shaft" of a treatment device (*e.g.*, shaft 349 of treatment device 347) for advancing the multi-electrode end effector into the patient's nasal cavity and placing it in contact with the tissue to be treated. (Ex-1005-Wolf-003 at FIG. 19A, [0148] ("the

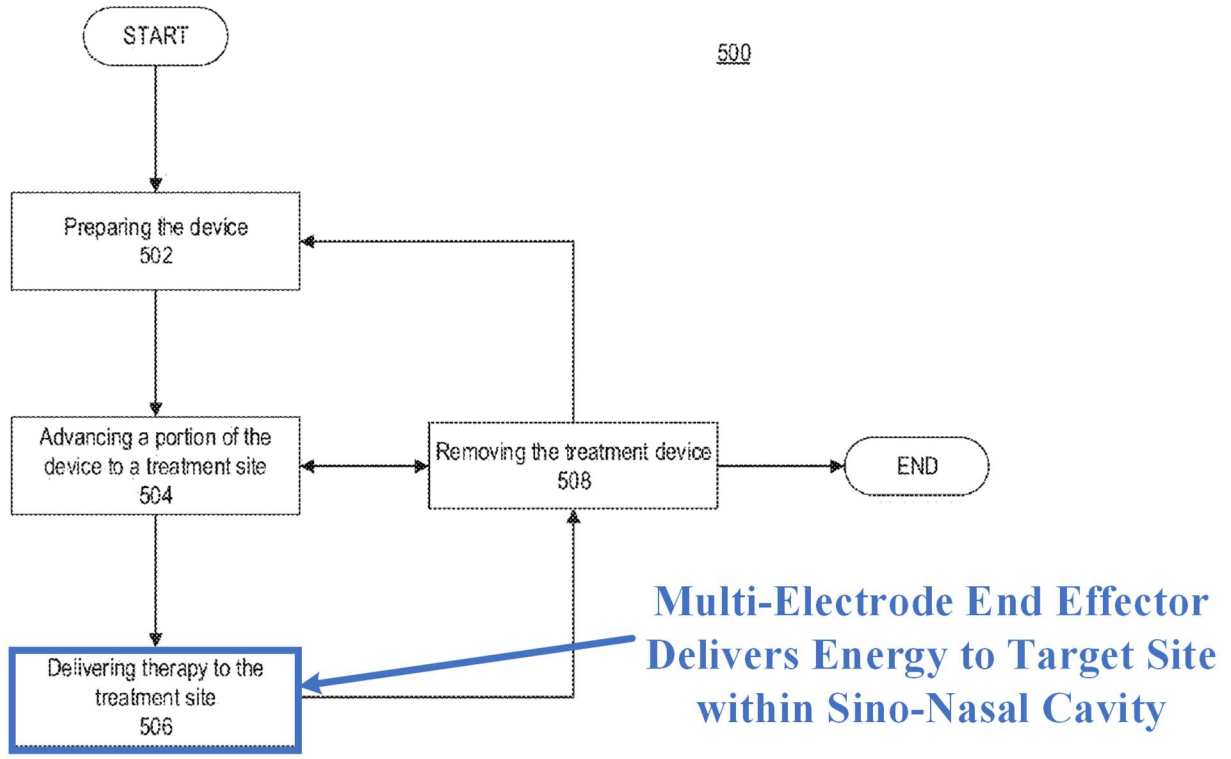
device 347 may include … a shaft 349"), [0150] ("The adjustability of the shaft 349 may enable a clinician to re-shape the shaft 349 to improve the ability of the device 347 to navigate nasal or other anatomy. The adjustability may also enable the electrodes 352 to be positioned to contact tissues to be treated."); *see also id*. at FIGS. 13-14, 25, 26A-F, and 27, [0013], [0028], [0030], [0158], [0168], [0172], [0176], claims 20 and 26.)



(*Id*. at FIG. 19A.)

233. Wolf-003 further discloses that its multi-electrode end effectors, including the multi-electrode end effector 350 of Figures 19A-B, are configured to

deliver energy (*e.g.*, radiofrequency energy) to one or more target sites within the patient's nasal cavity. (*Id*. at FIG. 20, [0089], [0151]-[0152], [0157], [0164]-[0165]; *see also id*. at Abstract, [0013], [0024], [0028], [0092], [0096]-[0097], [0099]-[0101], [0167], [0176], claims 1 and 26.)



(*Id*. at FIG. 20.)

234. Thus, Wolf-003 discloses limitation [1a-2].

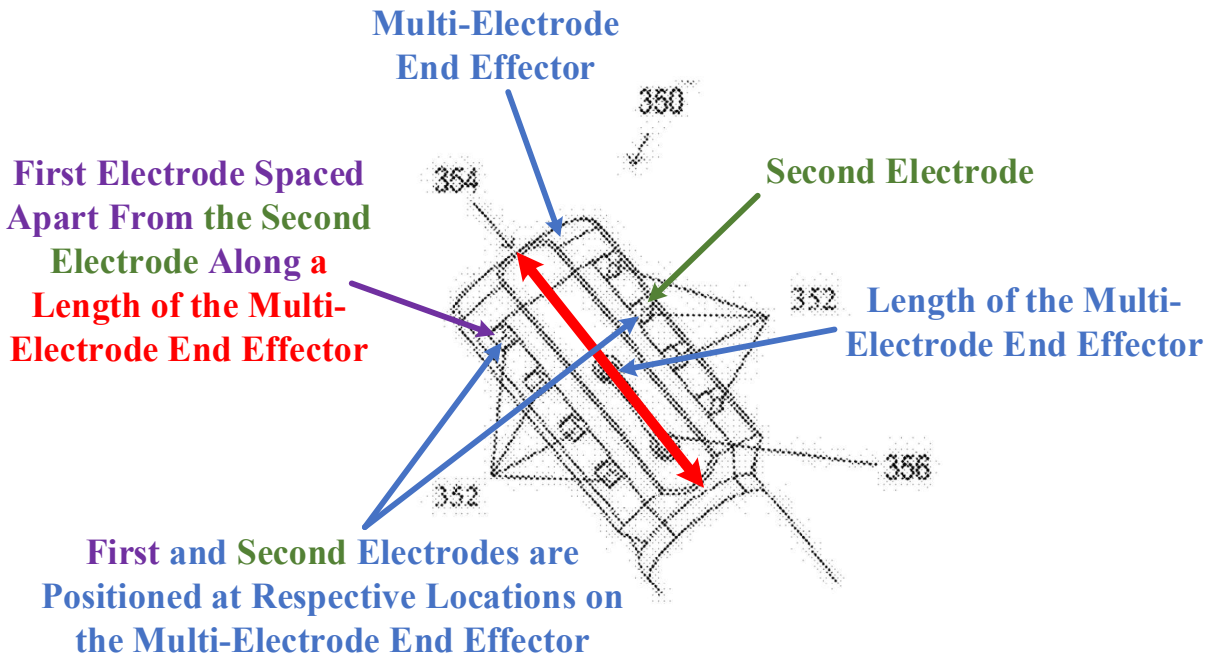
[1a-3] wherein the multi-electrode end effector comprises a first electrode that is spaced apart from a second electrode along a length of the multi-electrode end effector, wherein each of the first and second electrodes comprise an active state and an inactive state and comprise a respective location on the multi-electrode end effector,,

235. Wolf-003 discloses limitation [1a-3].

236. Wolf-003 discloses that its multi-electrode end effectors satisfy the

requirements of limitation [1a-3].

237. For example, as shown below, the multi-electrode end effector 350 of Figures 19A-B comprises first and second electrodes 352 that are spaced apart from each other along a length of the multi-electrode end effector, and are positioned at respective locations on the multi-electrode end effector:



(Ex-1005-Wolf-003 at FIG. 19B; *see also id*. at [0151], [0153].)[7]

238. Additionally, Wolf-003 discloses that each of the first and second electrodes comprises an active state and an inactive state:

[7] *See also id*. at FIGS. 13-14, 19A-B, 26A-F, and 27, [0028], [0126]-[0127], [0151], [0178]-[0179] (additional relevant electrode disclosures).)

> "In embodiments using energy delivery, a handle may be provided comprising a button or other input control *to activate one or more electrodes*."

(*Id.* at [0016].)

> "In other embodiments, RF electrodes may be positioned adjacent to and in contact with a targeted tissue region. The RF electrodes may then be activated at some frequency and power level therapeutically effective duration. In some embodiments, the depth of treatment may be controlled by controlling a spacing between electrodes."

(*Id.* at [0099].)

> "While the tissue is in this configuration, *the clinician may activate **one or more pairs of electrodes 352** to deliver therapy to the treatment site*. In certain implementations, delivering therapy to the treatment site 506 may include delivering radiofrequency energy from a first electrode on the treatment portion 350 across the trough 354 of the treatment portion 350 to a second electrode on the treatment portion 350, to treat at least one tissue selected from the group of the mucosal tissue and another tissue underlying the mucosal tissue to modify a property of the at least one tissue and thus treat at least one of post nasal drip or chronic cough in the patient."

(*Id.* at [0162]; *see also id.* at [0165], [0168] [0172]-[0173].)

239. Wolf-003 further discloses that the first and second electrodes may be activated individually/separately to achieve the desired treatment:

> "Alternatively, the treatment element 32 may be configured to deliver energy at only selective locations on the outer surface of the treatment element 32 in order to treat selected regions of upper airway tissues. In such embodiments, *the treatment element 32 may be configured so that energy being delivered to selected regions of the treatment element 32 can be individually controlled*. In some embodiments, portions of the treatment element 32 are inert and do not deliver energy to the tissue. In further alternative embodiments, the treatment element 32 may be configured with energy-delivery (or removal) elements distributed over an entire outer surface of the treatment element 32. *The control system 42 may be configured to engage such distributed elements individually or in selected groups so as to treat only targeted areas of the upper airway passageway*."

(*Id*. at [0096].)

> "In some embodiments of treatment devices comprising *an array or multiple pairs of electrodes, each pair of electrodes (bipolar)* or each electrode (monopolar) *may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately*. For example, in some embodiments, needles or needle pairs may be individually controlled to produce an optimal treatment effect. *For another example, in some embodiments, separate electrodes (e.g. those of FIGS. 12B and 12C) may be individually controlled to produce an optimal treatment effect*."

(*Id.* at [0128].)

> "This creates a situation in which the treatment energy flowing through each pair of electrodes is not repeatable due to the electrodes-tissue

> contact being user dependent. To ensure a greater degree of control and accuracy over the treatment energy through *each electrode, each pair of electrodes may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately*. Each electrode pair may also be paired up with its own thermocouple."

(*Id*. at [0134].)

Other electrode arrangements of Wolf-003 also meet the requirements of limitation [1a-3]. (Ex-1005-Wolf-003 at FIGS. 13-14, 26A-F, and 27.)

240. Thus, Wolf-003 discloses limitation [1a-3].

[1a-4] wherein at least one portion of the multi-electrode end effector comprises a diameter that is larger than a diameter of the shaft, and wherein:

241. Wolf-003 teaches limitation [1a-4]

242. Figure 13 include a multi-electrode end effector (treatment element 350) having a ***diameter (D)*** that is larger than a diameter of the shaft.

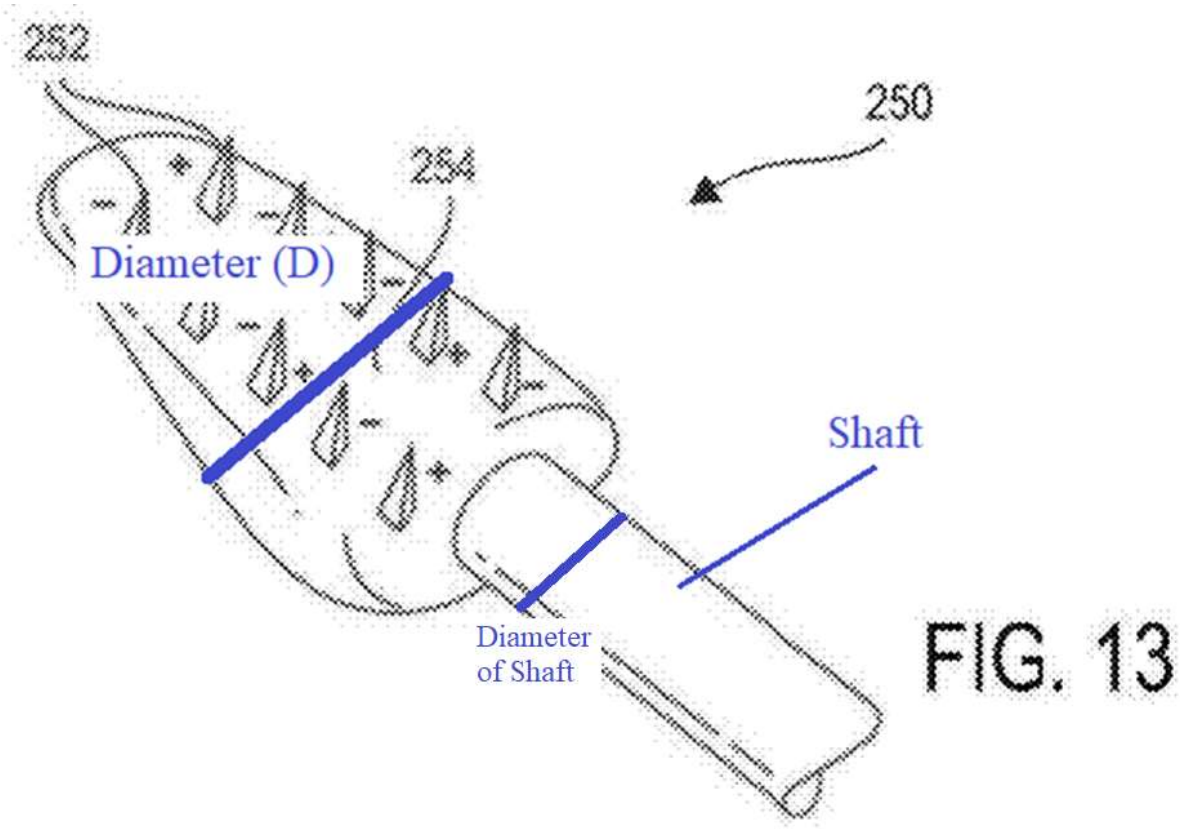


FIG. 13

(Ex-1005-Wolf-003 at FIG. 13.)

243. As illustrated and described, the embodiment of Figure 13 includes ten needle electrodes:

> "FIG. 13 is a perspective view of an electrode arrangement of a *treatment element 250* according to one embodiment. *An array of electrodes comprising* one, two, or many pairs of bipolar *needles 252 may be located on the treatment element 250* and be configured to be placed into contact with the mucus producing cells.

(*Id.* at [0126].)

244. Wolf-003 discloses that, like Figure 13, the embodiment of Figure 19 may include needle electrodes:

> "In certain implementations, one or more electrodes 352 may be designed to avoid puncturing tissue (e.g. by having blunt, rounded, or otherwise atraumatic tips). In certain other implementations, ***one or more electrodes 352 may be designed to puncture tissue***."

(*Id.* at [0153].)

245. Further, the embodiment of FIG. 19B includes only eight electrodes on its treatment element 354:

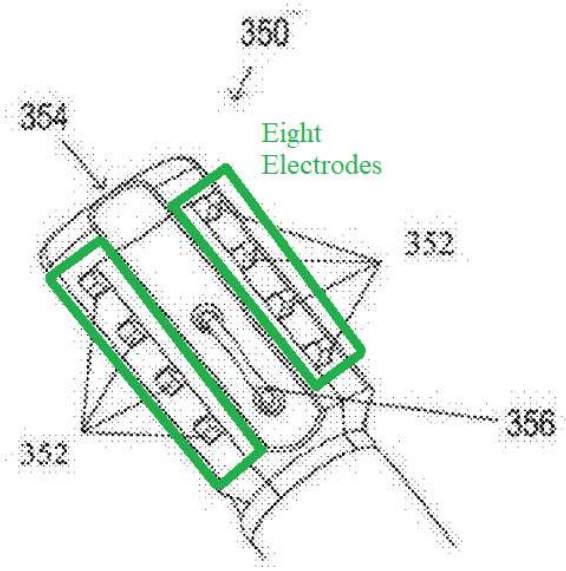


FIG. 19B

246. FIG. 19B does not specifically show whether the diameter of the treatment element 350 is larger than the shaft of that embodiment.

247. However, a POSITA would have found it obvious that the diameter of treatment element 354 would be "larger than a diameter of the shaft," such as when treatment element 354 included needle electrodes and/or more than eight electrodes,

as specifically taught and described by Wolf-003 in relation to Figure 13.

248. Accordingly, Wolf-003 discloses and teaches that its treatment element 350 "comprises a diameter that is larger than a diameter of the shaft." (Ex-1003-Weide, ¶248.)

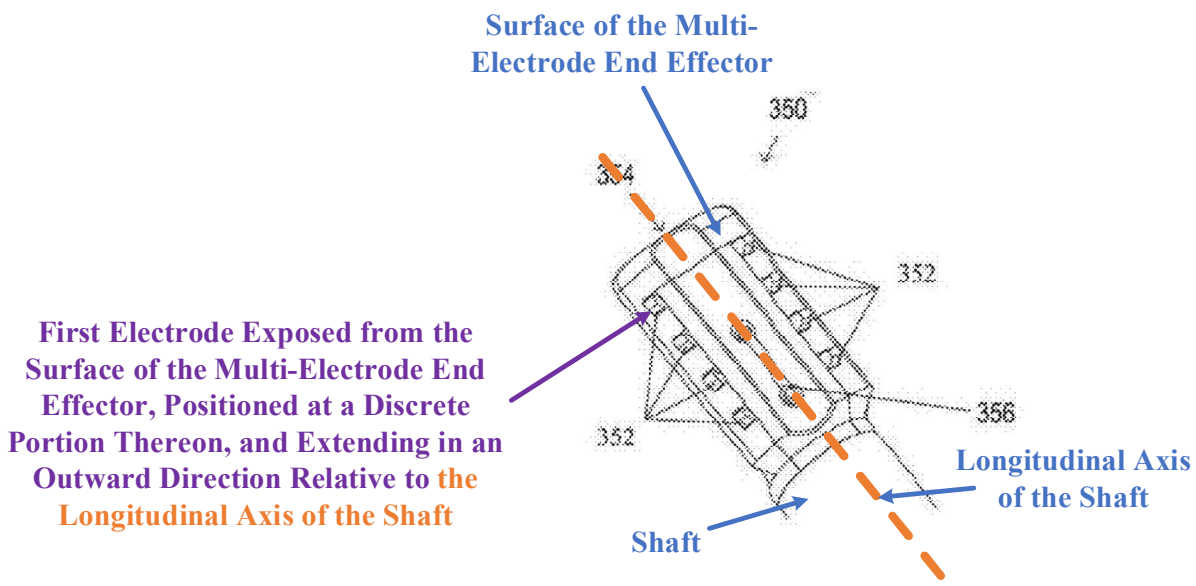
249. Thus, Wolf-003 teaches limitation [1a-4].

[1b] the first electrode is exposed from a surface of the multi-electrode end effector and is positioned at a discrete portion thereon, the first electrode extending in a first outward direction relative to a longitudinal axis of the shaft to interact with anatomy at a first location within the nasal cavity; and

250. Wolf-003 discloses limitation [1b].

251. Wolf-003 discloses that its multi-electrode end effectors comprise a first electrode that: (i) is exposed from a surface of the multi-electrode end effector; (ii) is positioned at a discrete portion thereon; and (iii) extends in a first outward direction relative to a longitudinal axis of the shaft. (Ex-1005-Wolf-003 at FIGS. 13-14, 19A-B, 26A-F, and 27.)

252. For example, as shown below, the multi-electrode end effector 350 of Figures 19A-B comprises a first electrode 352 that: (i) is exposed from the surface of the multi-electrode end effector 350; (ii) is positioned at a discrete portion thereon; and (iii) extends in a first outward direction relative to a longitudinal axis of the shaft 349:



(*Id*. at FIG. 19B.)

Wolf-003 further explains that:

> "The electrodes 352 may be recessed from, flush with, and/or ***protrude from*** the treatment portion 350. The electrodes 352 ***may extend substantially perpendicularly*** from the treatment portion 350 ***and/or may extend at a non-perpendicular angle***. The rows of electrodes 352 may, but need not, extend parallel to each other."

(*Id*. at [0153]; *see also id*. at [0029] ("the electrodes … protrude from the treatment surface"), [0151] ("The electrodes 352 … [are] raised off of the treatment surface").)

253. Additionally, Wolf-003 discloses that the first electrode is configured to contact (*i.e.*, interact with) nasal anatomy (*e.g.*, a nasal turbinate) at a first location within the nasal cavity. (*Id*. at [0089] ("a treatment element 32 which may be configured to be placed inside the nasal cavity"), [0150] ("enable the electrodes 352 to be positioned to contact tissues to be treated."), [0151] ("The treatment portion

350 has tissue contact surface … which is the surface of the treatment portion 350 that includes the multiple features for addressing and treating tissue, such as mucosal tissue."); *see also id*. at FIG. 21B, Abstract, [0022], [0027], [0095], [0126]-[0128], [0153]-[0154], [0160], [0163]-[0165], [0169], [0174], [0176].)

254. Other electrode arrangements of Wolf-003 also meet the requirements of limitation [1b]. (Ex-1005-Wolf-003 at FIGS. 13-14, 26A-F, and 27.)

255. Thus, Wolf-003 discloses limitation [1b].

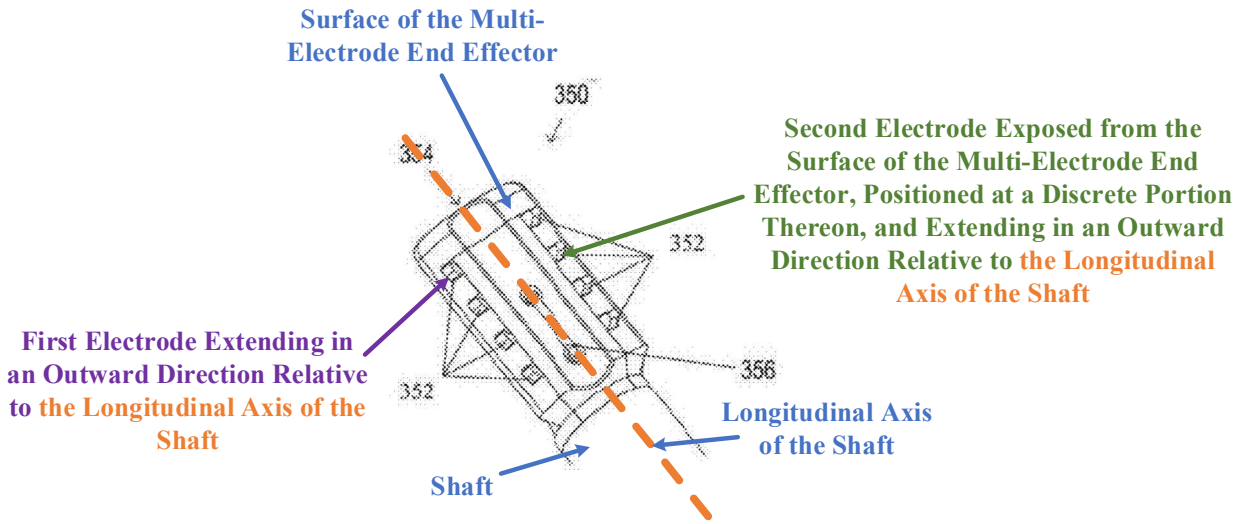
[1c] the second electrode is exposed from the surface of the multi-electrode end effector and is positioned at a discrete portion thereon, the second electrode extending in a second outward direction relative to a longitudinal axis of the shaft to interact with anatomy at a second location within the nasal cavity; and

256. Limitation [1c] is generally the same as limitation [1b] except a second electrode is recited.

257. Wolf-003 discloses that its multi-electrode end effectors comprise a second electrode that: (i) is exposed from a surface of the multi-electrode end effector; (ii) is positioned at a discrete portion thereon; and (iii) extends in a second outward direction relative to a longitudinal axis of the shaft. (Ex-1005-Wolf-003 at FIGS. 13-14, 19A-B, 26A-F, and 27.)

258. For example, as shown below, the multi-electrode end effector 350 of Figures 19A-B comprises a second electrode 352 that: (i) is exposed from the surface of the multi-electrode end effector 350; (ii) is positioned at a discrete portion thereon; and (iii) extends in an outward direction relative to a longitudinal axis of the shaft

349:



(*Id*. at FIG. 19B.)

Additionally, Wolf-003 discloses:

"The electrodes 352 may *extend substantially perpendicularly* from the treatment portion 350 ***and/or*** *may extend at a non-perpendicular angle*. *The rows of electrodes 352* ***may, but need not, extend parallel*** *to each other*."

(*Id*. at [0153]; *see also id*. at [0029], [0151].)

259. Wolf-003 thus teaches that the second electrode 352 may extend in any direction, including a second outward direction relative to a longitudinal axis of the shaft.

260. Additionally, Wolf-003 discloses that the second electrode is configured to contact (*i.e.*, interact with) nasal anatomy (*e.g.*, a nasal turbinate) at a second location within the nasal cavity. (*Id*. at [0089] ("a treatment element 32

which may be configured to be placed inside the nasal cavity"), [0150] ("enable the electrodes 352 to be positioned to contact tissues to be treated."), [0151] ("The treatment portion 350 has tissue contact surface … which is the surface of the treatment portion 350 that includes the multiple features for addressing and treating tissue, such as mucosal tissue."); *see also id*. at FIGS. 19B and 21B, Abstract, [0022], [0027], [0095], [0126]-[0128], [0153]-[0154], [0160], [0163]-[0165], [0169], [0174], [0176].)

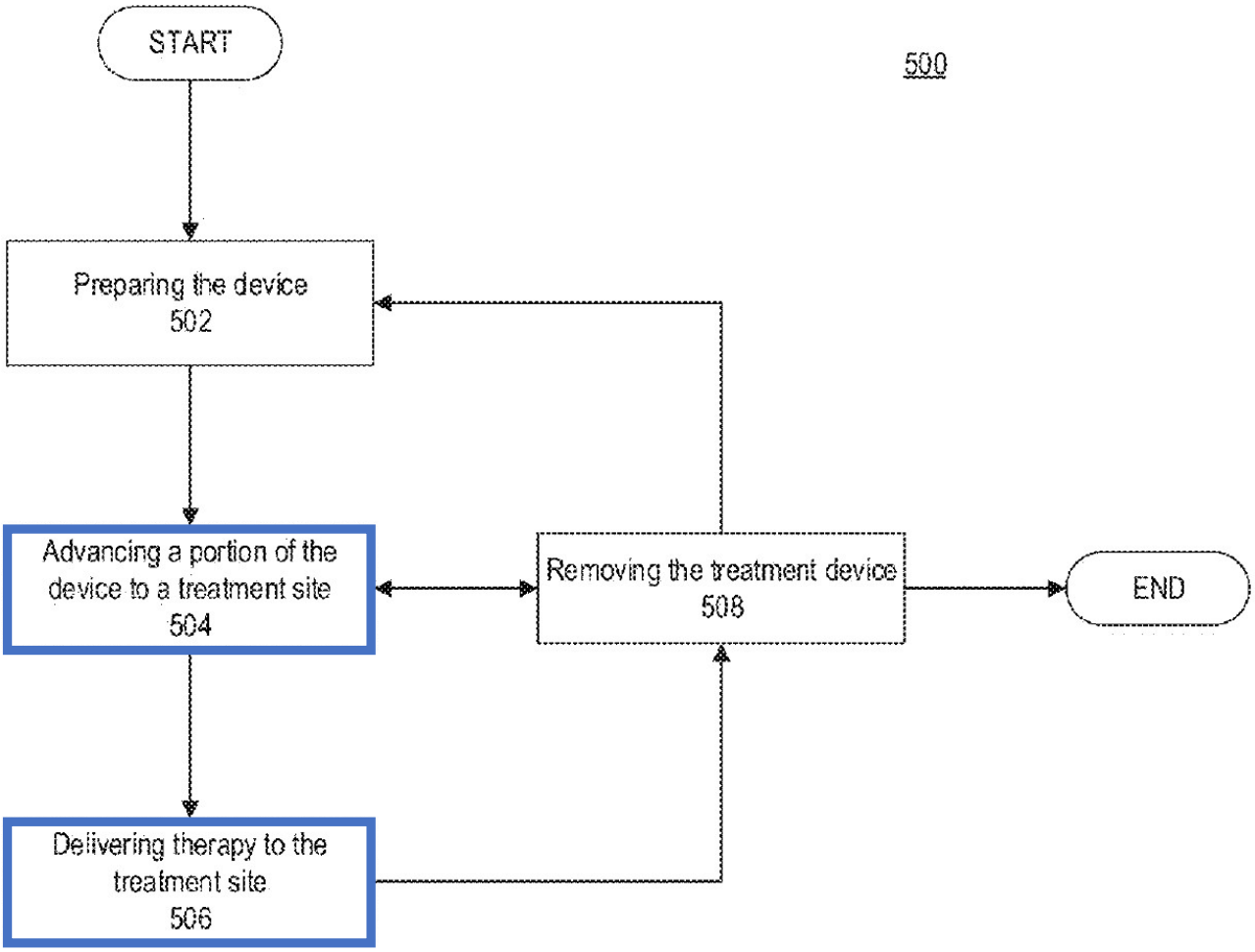
261. Other electrode arrangements of Wolf-003 also meet the requirements of limitation [1c]. (Ex-1005-Wolf-003 at FIGS. 13-14, 26A-F, and 27.)

262. Thus, Wolf-003 discloses limitation [1c].

[1d-1] delivering energy, via the first and second electrodes, to one or more target sites within a sino-nasal cavity of the patient

263. Wolf-003 discloses limitation [1d-1].

264. Figure 20 of Wolf-003 (below) is a flow diagram of an example method of use of various devices, and including the device of FIGS. 19A-B. (Ex-1005-Wolf-003 at [0054], [0157].) Once the device is prepared (502), a portion of the device is advanced to a treatment site (504) and therapy is delivered (506). Further, energy delivery may be repeated as necessary (loop of arrows for steps 504, 506, and 508). (*Id.* at [0167].)



(*Id*. at FIG. 20.)

As Wolf-003 explains:

"In certain implementations, *delivering therapy to the treatment site 506 may include delivering radiofrequency energy from a first electrode* on the treatment portion 350 across the trough 354 of the treatment portion 350 *to a second electrode* on the treatment portion 350, *to treat at least one tissue* selected from the group of the mucosal tissue and another tissue underlying the mucosal tissue *to modify a property of the at least one tissue and thus treat at least one of post nasal drip or chronic cough in the patient*."

(*Id.* at [0165].)

265. Thus, Wolf-003 discloses limitation [1d-1].

[1d-2] to disrupt multiple neural signals to mucus producing and/or mucosal engorgement elements, thereby reducing production of mucus and/or mucosal engorgement within a nose of the patient and reducing or eliminating one or more symptoms associated with at least one of rhinitis, congestion, and rhinorrhea to improve nasal breathability of the patient.

266. Wolf-003 alone and in combination with Wolf-290 teaches and suggests limitation [1d-2].

267. Preliminarily, I note that ablating nerves associated with mucosal tissue is a manner of "disrupting multiple neural signals to the mucus producing and/or mucosal engorgement elements within the nose." (Ex-1001 at 5:53-65, 29:36-67.)

268. Wolf-003 discloses that the step of delivering energy to the target tissue(s) may involve injuring, ablating,[8] or otherwise deactivating the nerves that control the behavior of mucus producing cells or tissue. (Ex-1005-Wolf-003 at [0011], [0025], [0027], [0088], claims 6, 12, and 14; *id*. at [0167] (disclosing that energy may be applied to multiple treatment sites).) A POSITA would have known that injuring, ablating, or otherwise deactivating such nerves permanently or temporarily prevents the neural signals carried by the nerves from reaching the

[8] Ablation destroys target tissue. (Ex-1001 at 56:52-61 (disclosing that ablation leads to "necrosis").)

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mucus producing cells/tissue (*i.e.*, the mucus producing elements) controlled by the nerves. A POSITA would have thus understood that injuring, ablating, or otherwise deactivating such nerves disrupts multiple neural signals to mucus producing elements.

269. Wolf-003 further discloses that that the step of delivering energy to the target tissue(s) may involve ablating mucosal tissue.[9] (Ex-1005-Wolf-003 at [0101] ("the treatment element 32 and control system 42 may be configured to deliver treatment energy to create specific localized tissue damage or ablation"); *id*. at Abstract, [0011], [0023], [0027], [0032], [0165], claims 1 and 26 (disclosing that energy may be applied to mucosal tissue).)

270. Additionally, Wolf-003 discloses that the step of delivering energy to the target tissue(s) reduces production of mucus within the patient's nose. (Ex-1005-Wolf-003 at [0066] ("Various embodiments may be used to reduce movement of mucus, reduce amount of mucus produced, reduce frequency of mucus production, change the mucus viscosity/consistency, and/or change the path of mucus flow."), [0101] ("the treatment element 32 and control system 42 may be configured to deliver treatment energy to create specific localized tissue damage or ablation,

[9] Wolf-003 discloses that mucosal tissue is mucus producing tissue. (Ex-1005-Wolf-003 at [0005].)

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stimulating the body's healing response to create desired conformational or structural changes that reduces the mucus producing ability of the mucus producing cells."); *see also id*. at Abstract, [0003], [0012], [0020], [0023], [0028], [0030], [0039], [0068], [0079], [0089], [0117], [0165], claims 1, 20, and 26.)

271. While Wolf-003 does not expressly disclose that the step of delivering energy to the target tissue(s) reduces or eliminates symptoms of rhinitis, congestion, or rhinorrhea to improve nasal breathability of the patient, Wolf-003 discloses that delivering energy to the target tissue(s) reduces or eliminates PNDS, UACS, and excess mucus production. (Ex-1005-Wolf-003 at Abstract, [0003], [0012]-[0013], [0023], [0028], [0030], [0066]-[0069], [0165], claims 1, 20, and 26.) A POSITA would have known that PND, chronic cough, and excess mucus production are symptoms of rhinitis, nasal congestion, and rhinorrhea. (Ex-1001 at Abstract, 1:16-21, 1:35-38, 4:59-63, 5:44-48, 8:28-31, 9:57-61 (disclosing that PND and coughing are symptoms of rhinitis, congestion, and rhinorrhea).) A POSITA also would have recognized that reducing or eliminating PNDS, UACS, and excess mucus production would reasonably be expected to improve the patient's nasal breathability, as each of these symptoms impacts a patient's ability to breathe through his or her nose.

272. Thus, Wolf-003 alone teaches or suggests limitation [1d-2].

273. Additionally, limitation [1d-2] would have been obvious in view of Wolf-290. Wolf-290 discloses the application of energy, including ablative energy,

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to nasal airway tissues, including nerve fibers and/or goblet cells. Wolf-290 further discloses that such methods treat rhinitis. (Ex-1006-Wolf-290 at [0009], [0053].)

274. Thus, Wolf-003 in combination with Wolf-290 also teaches and suggests limitation [1d-2].

275. As shown above, Wolf-003 alone or in view of Wolf-290 discloses, teaches, or suggests all limitations of claim 1.

[Claim 2] The method of claim 1, wherein the one or more target sites comprises an inferior turbinate within the nasal cavity and the tissue comprises submucosal tissue associated with the inferior turbinate.

276. As I explained in Ground 1, claim 2 refers to "the tissue," yet no "tissue" is recited in claim 1. Thus, I find claim 2 ambiguous. Nonetheless, assuming "the tissue" of claim 2 was meant to refer to a "target" tissue, Wolf-003 discloses of claim 2.

277. Specifically, Wolf-003 discloses treating the inferior turbinate within the nasal cavity, including submucosal tissue associated with the inferior turbinate. (Ex-1005-Wolf-003 at [0164] ("For example, in certain implementations, a clinician may use the device to apply energy to the posterior aspect of the inferior turbinate."); *id*. at [0087] ("In some embodiments, energy may be delivered into the submucosal tissue to cause a conformational change and/or a change in the physical properties and/or type of the submucosal tissue."); *see also id*. at [0011]-[0012], [0020], [0027], [0032], [0066], [0088], [0169], FIG. 21B, claims 14, 18-19, and 29-30.)

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278. Accordingly, Wolf-003 discloses claim 2.

[Claim 3] The method of claim 1, wherein the multi-electrode end effector comprises at least one temperature sensor arranged relative to first and second electrode.

[Claim 4] The method of claim 3, wherein the at least one temperature sensor is configured to sense temperature of tissue at the one or more target sites.

279. Wolf-003 discloses claims 3-4.

280. Wolf-003 discloses that its multi-electrode end effector comprises temperature sensor(s) (*e.g.*, thermocouple 356) arranged relative to the first and second electrodes and configured to sense temperature of tissue at the one or more target sites. (Ex-1005-Wolf-003 at FIG. 19B, [0018] ("A thermocouple or other sensor may be provided to measure a temperature near the tissue"), [0031] ("measuring a temperature of the mucosal tissue using the thermocouple"), [0155] ("The thermocouple 356 may be one or more sensors configured to gather one or more temperature readings of tissue during operation of the device 347."); *see also id*. at [0138]-[0139], [0141], [0143], [0151], [0188], [0190].)

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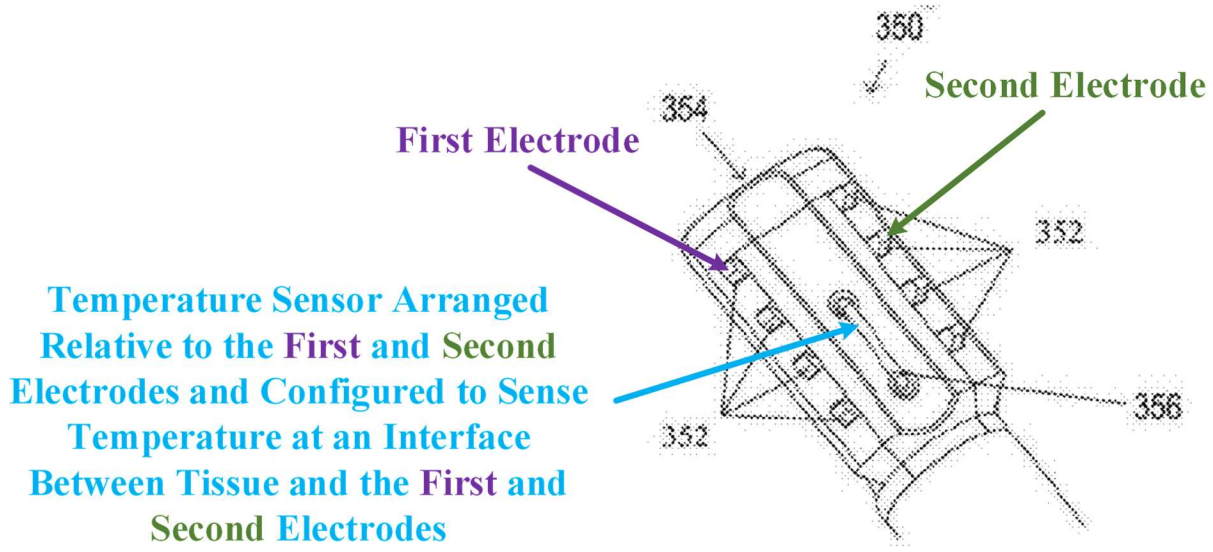

(*Id*. at FIG. 19B.)

281. Thus, Wolf-003 discloses claims 3-4.

[Claim 8] The method of claim 1, wherein radiofrequency (RF) energy is delivered from the first and second electrodes to tissue at the one or more target sites and is controlled via a console unit operably associated with the treatment device and multi-electrode end effector.

282. Wolf-003 discloses claim 8.

283. Wolf-003 discloses delivering RF energy from the first and second electrodes to tissue at the one or more target sites. For instance, Wolf-003 discloses:

> "In certain implementations, the method may further comprise *delivering radiofrequency (RF) energy to the one or more electrodes to locally heat the tissue to be treated*, wherein delivering RF energy while altering the properties of the tissue causes less mucus production in the treatment area."

(Ex-1005-Wolf-003 at [0022].)

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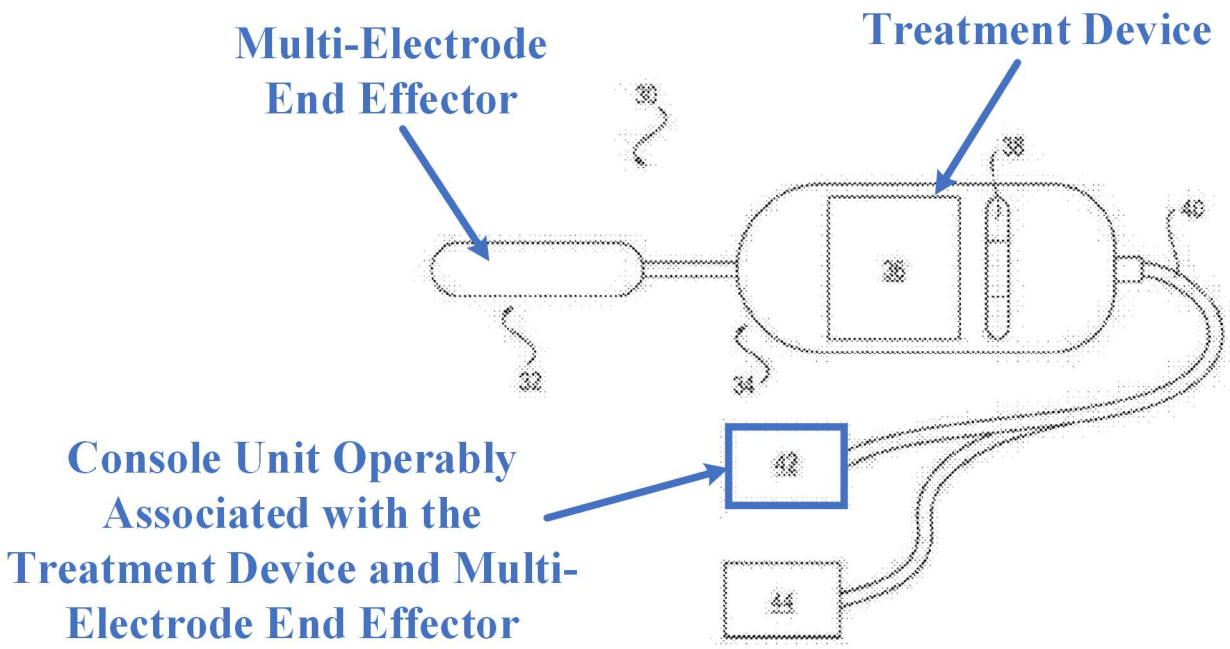
> "In other embodiments, RF electrodes may be positioned adjacent to and in contact with a targeted tissue region. The RF electrodes may then be activated at some frequency and power level therapeutically effective duration. In some embodiments, the depth of treatment may be controlled by controlling a spacing between electrodes. In alternative embodiments, RF electrodes may include needles which may puncture a nasal or upper airway tissue to a desired depth (as shown for example in FIG. 10 and in other embodiments below)."

(*Id.* at [0099]; *see also id.* at [0014], [0017], [0024]-[0025], [0082], [0093], [0096]-[0097], [0117], [0148], [0152], claims 3-4 and 26.)

284. With respect to the claimed "console unit," the '974 patent discloses that "[t]he console 104 is configured to provide various functions for the neuromodulation device 102, which may include, but is not limited to, controlling, monitoring, supplying, and/or otherwise supporting operation of the neuromodulation device 102." (Ex-1001 at 13:8-12.) The electronic control system of Wolf-003 discloses such a "console unit." (Ex-1005-Wolf-003 at [0092].)

285. Wolf-003 discloses an electronic control system 42 "configured to control the timing, location, intensity and/or other properties and characteristics of energy or other treatment applied to targeted regions of a nasal passageway." (Ex-1005-Wolf-003 at [0092]; *see also id*. at [0017] ("The device may also comprise a control system configured to control the characteristics of the energy applied to the tissue."), [0019].)

286. The control system 42 is operably associated with the treatment device 30 and the multi-electrode end effector 32:



(*Id*. at FIG. 6.)

287. "[T]he control system 42 may be located in an external device which may be configured to communicate with electronics within the handle section 34." (*Id*. at [0092].) The control system 42 may also have "any number of sensors, such as thermocouples, electric resistance or impedance sensors, ultrasound transducers, or any other sensors configured to detect treatment variables or other control parameters." (*Id*. at [0092].)

288. The control system 42 "may be configured to deliver treatment energy to create specific localized tissue damage or ablation, stimulating the body's healing response to create desired conformational or structural changes that reduces the

mucus producing ability of the mucus producing cells." (*Id*. at [0101].) Further, the "the treatment element 32 and control system 42 may be configured to deliver treatment energy … to a selected tissue depth in order to target treatment at specific tissues." (*Id.* at [0100].)

289. Further, the control system 42 may engage the electrodes "individually or in selected groups so as to treat only targeted areas of the upper airway passageway." (*Id.* at [0096].)

290. Additional disclosures include:

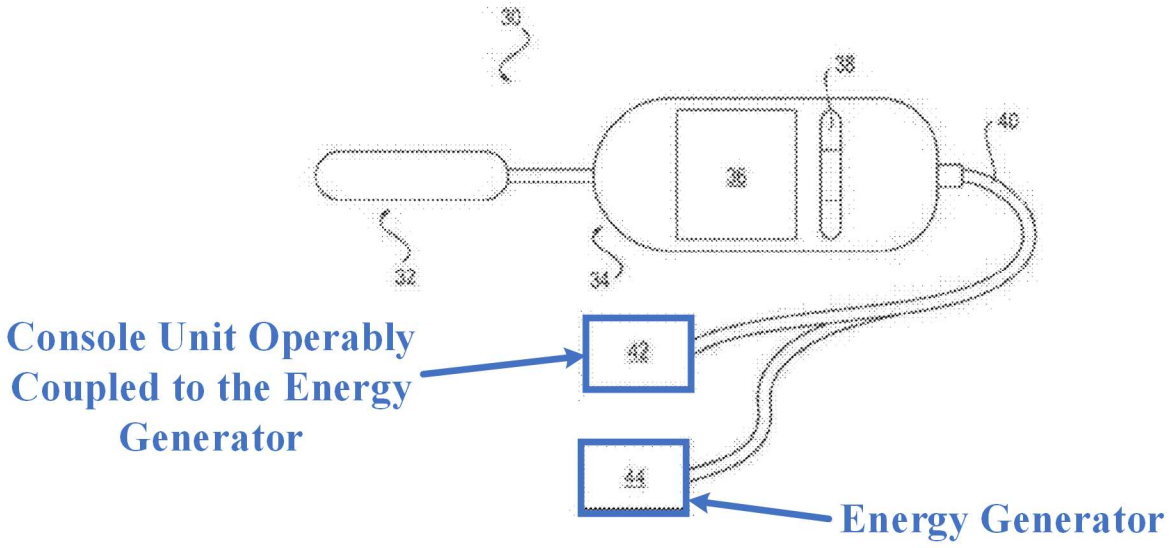
- [0019] ("a control system for controlling the … treatment device"),
- [0092] ("control system 42 … may be configured to communicate with electronics within the handle section 34."),
- [0094] ("control system 42 may be configured to engaged [the electrodes of the multi-electrode end effector]"),
- [0100] ("the treatment element 32 and control system 42 may be configured to deliver treatment energy"), [0101] (same),
- [0156] ("electrodes 352 … may be connected with a device control system").)

291. Thus, Wolf-003 discloses claim 8.

[Claim 9] The method of claim 8, wherein the console unit is operably coupled to an energy generator configured to generate RF energy to be delivered by the first and second electrodes.

292. Wolf-003 discloses claim 9.

293. Wolf-003 discloses a control system 42 operably coupled to the power supply 44 (*i.e.*, the energy generator).[10] (Ex-1005-Wolf-003 at FIG. 6, [0019] ("a control system for controlling the energy source"); *see also id*. at [0017], [0092], [0156].)



(*Id*. at FIG. 6.)

294. Wolf-003 discloses the external power supply 44 is "configured to deliver power to the handle section 34 and/or the treatment element 32 by a cable or

[10] Wolf-003 also refers to the power supply 44 as an "energy source" or a "remote generator." (*Id*. at [0017], [0019], [0156], [0158], [0168], [0170], [0172].)

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other suitable connection." (Ex-1005-Wolf-003 at [0093].) "[T]he power supply 44 may include a battery or other electrical energy storage or energy generation device," or "may be configured to draw electrical power from a standard wall outlet." (*Id.*)

295. Wolf-003 discloses that the power supply 44 is configured to generate RF energy to be delivered by the multi-electrode end effector's electrodes. (*Id.* ("In some embodiments, a power supply 44 may also include a system configured for driving a specific energy delivery technology in the treatment element 32. For example, the power supply 44 may be configured *to deliver a radio frequency alternating current signal to an RF energy delivery element*."); *see also id*. at [0014], [0022], [0024]-[0025], [0082], [0096]-[0097], [0099], [0117], [0148], [0152], [0188], claims 3-4 and 26.)

296. Accordingly, Wolf-003 discloses claim 9.

[Claim 10] The method of claim 9, wherein the RF energy comprises at least bipolar RF energy.

297. Wolf-003 discloses of claim 10.

298. Wolf-003 discloses the RF energy comprises at least bipolar RF energy. (Ex-1005-Wolf-003 at [0052] ("FIG. 19A is a perspective view of a device for applying energy to the upper airway tissues *using a bipolar electrode* according to one embodiment."), [0148] ("FIG. 19A is a perspective view of a device 347 for applying energy to the upper airway tissues *using a bipolar electrode* according to one embodiment. … In certain implementations, the device 347 may include …

radiofrequency electrodes 352 (such as bi-polar electrodes)"), [0168] ("a device 310 for applying energy to the upper airway tissues using bipolar electrodes"); *see also id*. at [0016], [0119]-[0122], [0125]-[0128].)

299. Accordingly, Wolf-003 discloses claim 10.

[Claim 11] The method of claim 8, [11a] wherein the console unit is configured to receive feedback from at least one temperature sensor arranged relative to the first and second electrodes and configured to sense temperature at an interface between tissue and the first and second electrodes

300. Wolf-003 discloses limitation [11a].

301. Wolf-003 discloses that the control system 42 (*i.e.*, the console unit) is configured to receive feedback from one or more temperature sensors, such as thermocouple 356. (Ex-1005-Wolf-003 at [0092] ("A control system may include a closed-loop control system having any number of sensors, such as thermocouples, electric resistance or impedance sensors, ultrasound transducers, or any other sensors configured to detect treatment variables or other control parameters."), [0148] ("the device 347 may include … a thermocouple 356."), [0156] ("The electrodes 352 and the thermocouple 356 may be connected with a device control system"), [0188] ("the sensor(s) may provide feedback"); *see also id*. at [0029], [0128], [0134]-[0139], [0155], [0190].)

302. Wolf-003 further discloses that the temperature sensor(s) is/are arranged relative to the first and second electrodes such that it/they sense the temperature of the tissue treated by those electrodes (*i.e.*, are configured to sense

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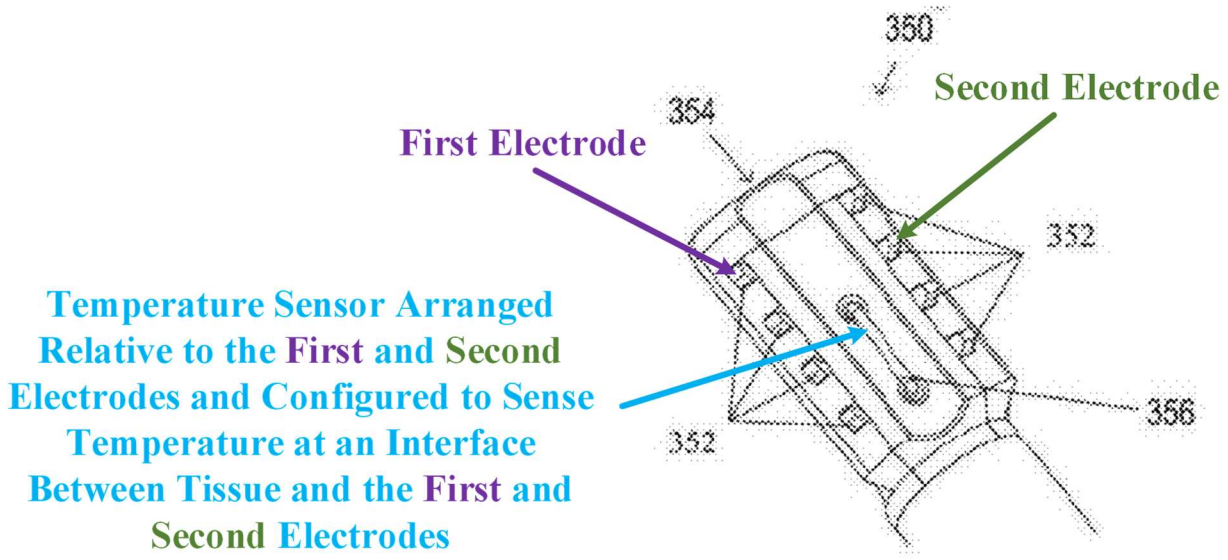
temperature at an interface between tissue and the first and second electrodes). (*Id*. at FIG. 19B, [0018] ("A thermocouple or other sensor may be provided to measure a temperature near the tissue"), [0031] ("measuring a temperature of the mucosal tissue using the thermocouple"), [0155] ("The thermocouple 356 may be one or more sensors configured to gather one or more temperature readings of tissue during operation of the device 347."); *see also id*. at [0138]-[0139], [0141], [0143], [0151], [0188], [0190].)



(*Id*. at FIG. 19B.)

303. Indeed, because ablation involves the heating of target tissue, and because improper ablation can potentially lead to improper damaging of tissue, a POSITA would have wanted temperature sensors in contact with and arranged as close as possible to the target tissue so as to effectively measure tissue temperature to properly ablate tissue while avoiding unnecessary injury.

304. Thus, Wolf-003 discloses limitation [11a].

[11b] wherein the console unit is configured to control energy output from the first and second electrodes based, at least in part, on the feedback in order to maintain a predetermined temperature of tissue at the one or more target sites.

305. Wolf-003 discloses limitation [11b].

306. Wolf-003 discloses that the "control system may include *a closed-loop control system having any number of sensors, such as thermocouples*, electric resistance or impedance sensors, ultrasound transducers, or any other sensors configured to detect treatment variables or other control parameters." (Ex-1005-Wolf-003 at [0092].)

307. Wolf-003 discloses that the control system controls the amount of power delivered to the electrodes based on temperature measurements:

> "In some embodiments, delivering and measuring steps comprise delivering a first amount of the radiofrequency energy from the first electrode to the second electrode; *measuring a temperature of the mucosal tissue using the thermocouple*; and delivering a second amount of the radiofrequency energy from the first electrode to the second electrode, *wherein the second amount of radiofrequency energy is based at least in part on the measured temperature*."

(*Id*. at [0031].)

As one example:

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> "if a particular tissue temperature threshold is reached, a sensor (or sensors) may send a signal to a power generator to shut down *or decrease power delivered to a treatment device*."

(*Id*. at [0188].)

308. A POSITA would have recognized that a closed-loop control system that includes sensors to measure temperature and uses those temperature measurements to decrease power delivered to a treatment device discloses, teaches and suggests a "console unit [] configured to control energy output from [] electrodes based, at least in part, on the [temperature sensor] feedback."

309. Wolf-003 further discloses using the feedback from the one or more temperature sensors to maintain a predetermined temperature of tissue at the one or more target sites. (Ex-1005-Wolf-003 at [0135] ("*to reach or maintain **set** temperature*"), [0136] ("The thermocouple 362 act[s] as a feedback-control to ensure that proper temperature is maintained at the site of surgery."), [0137] ("The thermocouple 362 may act as a feedback control to ensure that proper temperature is maintained at the site of treatment."), [0139] ("In certain implementations, the temperature input signals sensed from neighboring thermocouples 372 *a* and 372 *b* … act as a feedback-control to ensure that proper temperature is maintained at the treatment site. … The temperature reading may act as a feedback control to ensure that proper temperature is maintained at the treatment site.").)

310. Thus, Wolf-003 discloses limitation [11b].

[Claim 12] The method of claim 11, wherein the console unit is configured to receive one or more temperature readings from the at least one temperature sensor and process the readings to determine a level of RF energy to be delivered by the first and second electrodes that is sufficient to maintain a temperature of tissue at the one or more target sites below a predetermined threshold.

311. Wolf-003 teaches and suggests claim 12.

312. Wolf-003 teaches that the control system 42 (*i.e.*, the console unit) is configured to receive temperature readings from the one or more temperature sensors (*e.g.*, thermocouple 356).

> "The electrodes 352 and ***the thermocouple 356 may be connected with a device control system*** connected integrated with or attached to the device 347. For example, the device 347 may comprise a generator or a means for connecting to a remote generator. This connection may be established through wires extending the length of the shaft 349 to a connection within a handle of the device 347."

(Ex-1005-Wolf-003 at [0156]; *see also id.* at [0029], [0031], [0092], [0128], [0134]-[0139], [0148], [0156], [0188], [0190].)

313. Wolf-003 further teaches that the control system 42 (*i.e.*, the console unit) adjusts the level of RF energy delivered by the first and second electrodes based on the received temperature readings from the one or more temperature sensors. (*Id*. at [0031] ("measuring a temperature of the mucosal tissue using the thermocouple; and delivering a second amount of the radiofrequency energy from the first electrode

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to the second electrode, wherein the second amount of radiofrequency energy is based at least in part on the measured temperature."), [0092] ("an electronic control system 42 configured to control the timing, location, intensity and/or other properties and characteristics of energy or other treatment applied to targeted regions of a nasal passageway."), [0136] ("A pair of electrodes 363, 364 may have its own individual subsystem 360 of controlled RF output channel 361 and thermocouple 362 to allow for independent adjustments. The thermocouple 362 act as a feedback-control to ensure that proper temperature is maintained at the site of surgery."); *see also id*. at [0025], [0030], [0099], [0137], [0139], [0188], claims 7-8 and 28.)

314. Wolf-003 does not expressly disclose that its control system 42 "processes" temperature readings to "determine" the level of RF energy delivered. However, a POSITA would have found it obvious that Wolf-003's control system was processing temperature readings to determine a level of RF energy delivered because (a) Wolf-003 discloses an *electronic* control system, and (b) Wolf-003 discloses applying a second amount of energy based on a prior temperature measurement. (Ex-1005-Wolf-003 at [0031] ("*measuring a temperature* of the mucosal tissue using the thermocouple; and *delivering a second amount* of the radiofrequency energy from the first electrode to the second electrode, *wherein the second amount of radiofrequency energy* ***is based*** *at least in part* ***on the measured temperature***").) Indeed, it has been commonplace to process temperature

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measurements and make appropriate adjustments to ensure proper delivery of RF energy to tissue for many decades. (Ex-1024 at 9:45-11:45, FIGS. 5-6.) Moreover, Wolf-003's control system 42 could not adjust the level of RF energy delivered based on received temperature readings, as disclosed, without first processing the received temperature readings and determining the new level of RF energy to be delivered.

315. Wolf-003 further teaches that the level of RF energy delivered by the electrodes is sufficient to maintain a temperature of tissue at the one or more target sites below a predetermined threshold. (Ex-1005-Wolf-003 at [0135] ("in order to reach or *maintain **set** temperature*"); *see also id*. at [0136]-[0137], [0139].)

316. Accordingly, Wolf-003 teaches and suggests claim 12.

C. Ground 3: Claims 8-20 are obvious based on the Ground 2 art further in view of Angeles.

1. Summary of Ground 3

317. Ground 3 relies on the Ground 2 art plus Angeles.

318. As shown above, the Ground 2 art discloses, teaches, or suggests claims 1-4 and 8-12.

319. Claims 8-20 of the '974 patent relate to trivial, uninventive aspects relating to consoles and control of energy delivery, which are disclosed, taught, or suggested by Angeles.

320. As shown below, it was obvious to use the console of Angeles with

Wolf-003's methods, systems and apparatus to control energy delivery and provide feedback to the operator.

2. Reasons to Combine the Ground 2 Art with Angeles

321. As explained in Ground 2, Wolf-003 discloses an electronic control system 42 that is "configured to control the timing, location, intensity and/or other properties and characteristics of energy or other treatment applied to targeted regions of a nasal passageway." (Ex-1005-Wolf-003 at [0092]; *see also id*. at [0017], [0019], [0100]-[0101].) Wolf-003 discloses that the "control system 42 may be located in an external device which may be configured to communicate with electronics within the handle section 34." (*Id*. at [0092].) However, Wolf-003 does not provide specific implementation details for how to implement its control system 42 as an external device. (*See, e.g., id*. at FIG. 6 (depicting control system 42 as a box).) Angeles does.

322. In the same field of endeavor, Angeles discloses a "console for an electrosurgical device" that includes "a housing, an energy generator in the housing, a computer processor in the housing, … [and] a touchscreen display on the housing." (Ex-1007-Angeles at Abstract; *see also id*. at [0002], [0006].) The energy generator may be "a radiofrequency (RF) generator, configured to deliver monopolar and/or bipolar RF energy to the energy delivery treatment device." (*Id*. at [0007].) The console may also include "an improved user interface" which "allows a physician

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user to monitor and alter treatment parameters for a particular treatment stylus, applicator, catheter or the like." (*Id*. at [0005].)

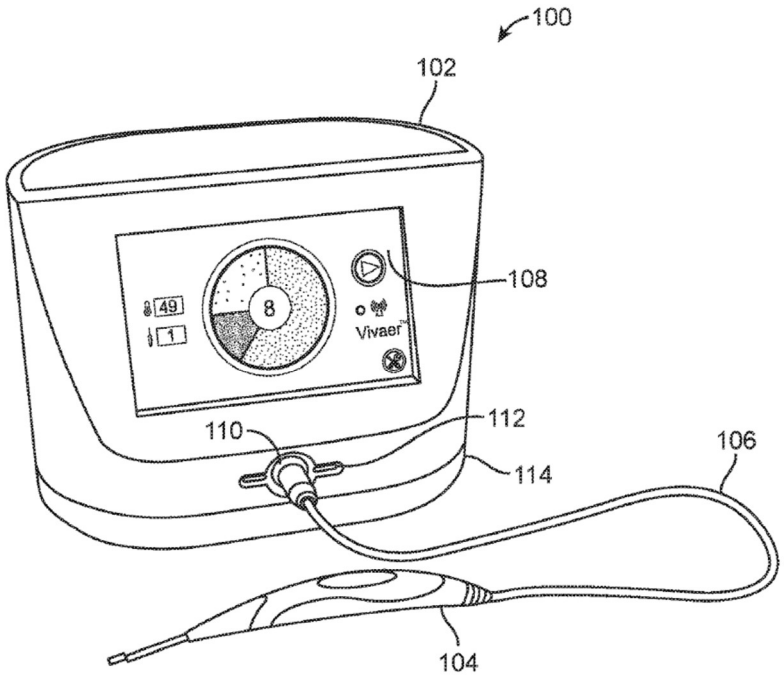

FIG. 1

(*Id*. at FIG. 1.)

323. A POSITA would have been motivated to, and would have found it obvious to, apply Angeles' console teachings to Wolf-003. Angeles discloses that its console may be used with a wide variety of devices for delivering energy to tissue in the nasal airway, including devices developed by Aerin Medical Inc.[11] (Ex-1007-

[11] Wolf-003 and Angeles share an inventor (*i.e.*, Andrew Frazier) and have the same applicant/assignee (*i.e.*, Aerin Medical Inc.). (Ex-1005-Wolf-003 at [71]-[73]; Ex-1007-Angeles at [71]-[72].)

Angeles at [0003], [0040].) This would include Wolf-003's device. (Ex-1005-Wolf-003 at [71], [73].) Thus, a POSITA would have recognized that Angeles' console would have been a suitable choice for implementing the control system of Wolf-003.

324. Moreover, a POSITA would have found Angeles' console to be a *highly desirable* choice for several reasons. A POSITA would have appreciated that Angeles' console desirably integrates device control and energy generation functionalities into a single "box," thus reducing the amount of space occupied.

325. Angeles' console also provides "an improved user interface" that beneficially "allows [the] physician user to monitor and alter treatment parameters for a particular treatment stylus, applicator, catheter or the like." (Ex-1007-Angeles at [0005]).)

326. Additionally, Angeles' console has a touchscreen display that allows the physician to interact with the console. (Ex-1007-Angeles at [0006], [0028].) A POSITA would have recognized that touchscreen displays are highly desirable as they simplify user interactions with the system and decrease the need for additional hardware, such as buttons, knobs, etc.

327. Moreover, Angeles' console beneficially allows the physician to set various treatment conditions, such as power, temperature, treatment time, and/or cool down time. (Ex-1007-Angeles at [0006], [0013], [0049]). A POSITA would have found such functionality highly desirable as it allows the physician to

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customize treatments for patients.

328. A POSITA would have had a reasonable expectation of success in combining Angeles' console teaching with Wolf-003. As noted above, Angeles discloses that its console may be used with devices developed by Aerin Medical Inc., which would include Wolf-003's device. (Ex-1007-Angeles at [0003], [0040].) Implementing Angeles' console teachings with Wolf-003 would have been routine to a POSITA, merely requiring conventional hardware and software to provide energy delivery and control, a user interface, and related functionality taught by the combination of Angeles and Wolf-003.

3. The Challenged Claims

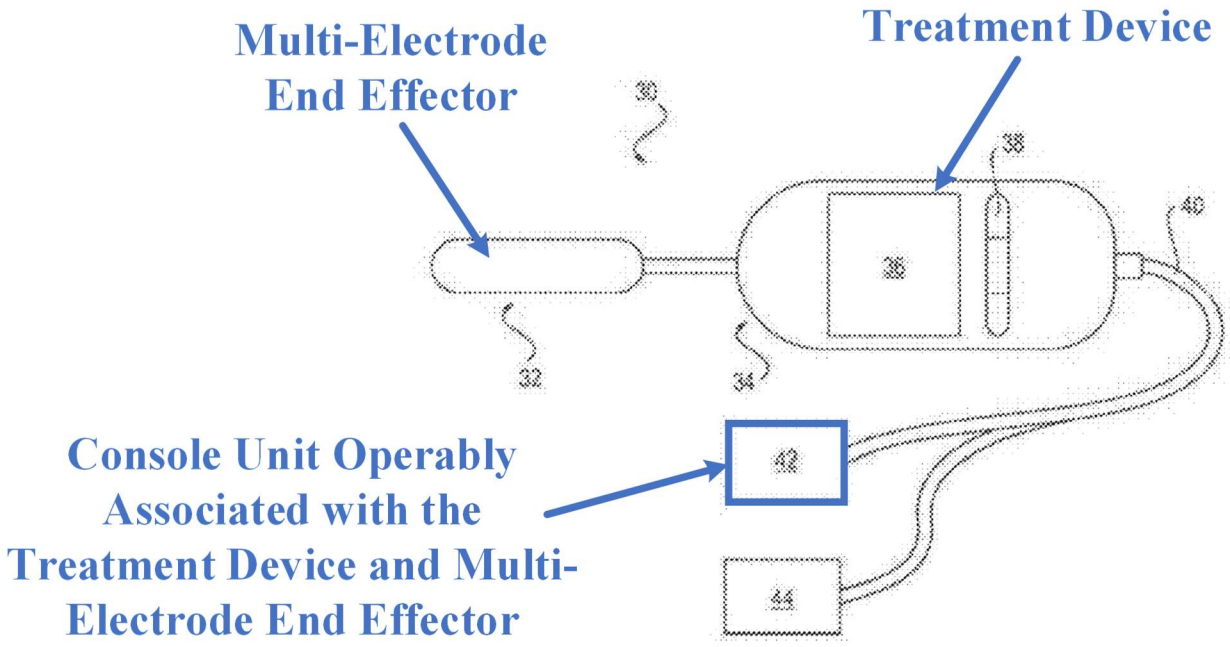
[Claim 8] The method of claim 1, wherein radiofrequency (RF) energy is delivered from the first and second electrodes to tissue at the one or more target sites and is controlled via a console unit operably associated with the treatment device and multi-electrode end effector.

329. Wolf-003 in view of Angeles teaches claim 8.

330. Wolf-003 discloses "wherein radiofrequency (RF) energy is delivered from the first and second electrodes to tissue at the one or more target sites." (Ex-1005-Wolf-003 at [0022] ("the method may further comprise delivering radiofrequency (RF) energy to the one or more electrodes to locally heat the tissue to be treated"), [0099] ("RF electrodes may be positioned adjacent to and in contact with a targeted tissue region. The RF electrodes may then be activated at some frequency and power level therapeutically effective duration."), [0117] ("These

electrodes may, for example, deliver RF energy"), [0148] ("radiofrequency electrodes 352"); *see also id.* at [0014], [0017], [0024]-[0025], [0082], [0093], [0096]-[0097], [0152], claims 3-4 and 26.)

331. Wolf-003 in view of Angeles discloses that such RF energy "is controlled via a console unit operably associated with the treatment device and multi-electrode end effector. Wolf-003 discloses "a console unit operably associated with the treatment device and multi-electrode end effector:"



(*Id.*, FIG. 6 (showing control system 42 operably associated with the treatment device and multi-electrode end effector 32).) Angeles also discloses a "a console unit operably associated with the treatment device and multi-electrode end effector:"

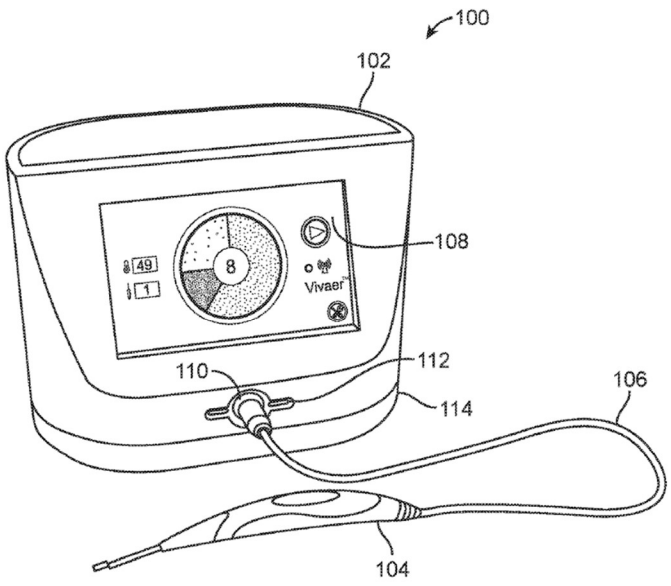


FIG. 1

(Ex-1007-Angeles at FIG. 1 (showing console 102 operably associated with RF delivery stylus 104).) Angeles further discloses that its "console" may be a "controller:"

> "The word 'console,' in this disclosure, is meant to encompass the terms 'generator,' 'box,' 'controller,' and any other commonly used terms to describe an electrosurgical system console or generator."

(*Id.* at [0028].) Angeles further explains that the console controls the delivery of RF energy to a patient. (*Id.* at [0043]-[0045]; *see also id.* [0005], [0007], [0012], [0047]-[0050], [0054].)

332. Thus, Wolf-003 in view of Angeles teaches claim 8.

[Claim 9] The method of claim 8, wherein the console unit is operably coupled to an energy generator configured to generate RF energy to be delivered by the first and second electrodes.

333. Wolf-003 in view of Angeles teaches claim 9.

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334. Angeles discloses that its console (*i.e.*, console unit) is operably coupled to an "energy generator" integrated in the console. (Ex-1007-Angeles at Abstract, [0005]-[0007], [0028], claims 1-2.) Angeles discloses that its energy generator is configured to generate RF energy to be delivered by an energy delivery treatment device. (*Id.*) In the combination of Wolf-003 and Angeles, RF energy generated by Angeles' energy generator would be delivered by the first and second electrodes of Wolf-003's multi-electrode end effector.

335. Thus, Wolf-003 in view of Angeles teaches claim 9.

[Claim 10] The method of claim 9, wherein the RF energy comprises at least bipolar RF energy.

336. Angeles discloses claim 10.

337. Angeles discloses that its energy generator is configured to generate "bipolar RF energy." (Ex-1007-Angeles at [0007], claim 2.)

338. Thus, Angeles discloses of claim 10.

[Claim 11] The method of claim 8, [11a] wherein the console unit is configured to receive feedback from at least one temperature sensor arranged relative to the first and second electrodes and configured to sense temperature at an interface between tissue and the first and second electrodes, [11b] wherein the console unit is configured to control energy output from the first and second electrodes based, at least in part, on the feedback in order to maintain a predetermined temperature of tissue at the one or more target sites.

339. Wolf-003 in combination with Angeles teaches claim 11.

340. As explained in Ground 2, Wolf-003 discloses claim 11, wherein Wolf-003's control system 42 is configured to receive feedback from at least one

temperature sensor arranged relative to the first and second electrodes and configured to sense temperature at an interface between tissue and the first and second electrodes, wherein the control system 42 is configured to control energy output from the first and second electrodes based, at least in part, on the feedback in order to maintain a predetermined temperature of tissue at the one or more target sites. (Ex-1005-Wolf-003 at FIG. 19B, [0018], [0031], [0092], [0135]-[0136], [0139], [0148], [0155]-[0156], [0188].)

341. A POSITA would have been motivated to retain this same helpful functionality in the combination of Wolf-003 and Angeles, with the Angeles console unit (a) receiving feedback from Wolf-003's temperature sensors and (b) controlling energy output from Wolf-003's electrodes based, at least in part, on the feedback in order to maintain a predetermined temperature of tissue at the one or more target sites. Indeed, such functionality is expressly contemplated and desired by the combination of Wolf-003 and Angeles. (Ex-1007-Angeles at [0050] ("During treatment, *the **actual** RF power 617 and **temperature reading** 609 are also shown*."), [0028] ("The word "console," in this disclosure, is meant to encompass the terms "generator," "box," "*controller*," and any other commonly used terms to describe an electrosurgical system console or generator."), [0036] ("Under normal operating conditions, *the **user** can select* either default treatment settings or *manual treatment settings*."), [0047] ("Additionally, *the default (or **custom**) settings of the console 102*

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may have any suitable ranges and combinations for the various parameters of the console 102. For example, one timing default setting may have a total treatment time of 30 seconds, an RF ON time of 18 seconds, and a cooling time of 12 seconds. This is but one example, however, and any number of other time settings may alternatively be used. Total treatment time may be in minutes, for example, and each segment of the treatment may be measured in seconds and/or minutes. *A default temperature may also be set for RF delivery, for example 60 degrees Celsius as the maximum temperature. Again, any suitable default settings may be set in various embodiments*.), [0048] ("the physician or other user can choose to access a custom treatment screen 630 … In the embodiment shown, the custom treatment screen 630 includes *a graphical* ***treatment progress*** *display 600*… The custom treatment screen 630 also includes … *a set RF ON time window 607, a set temperature window 608, an actual temperature indicator 609* … and *a temperature icon 620*."), [0049] ("Through the custom treatment screen 630, ***the user can adjust*** *the power (power window 618),* ***temperature*** *(temperature window 608), treatment time (RF on time window 607) and/or cool down time (cooling time window 606)*, by touching any one of the set windows and then touching the up button 616 and/or the down button 610 *to adjust a given value*. To set power, for example, the user may touch the power window 618 and *then adjust the temperature* by pressing the up button 616 or the down button 610. *The console 102 may be configured to only allow adjustments*

within ranges. For example, the power on the console 102 may be selected at 3 W, 4 W or 5 W[. I]n one embodiment[,] *Maximum stylus **temperature may be selected** in a range of 50 degrees Celsius to 70 degrees Celsius*[. I]n one embodiment[,] RF energy delivery time (RF ON time) may be selected for between 6 seconds and 18 seconds, in 2-second increments, and cooling time may be selected for between 0 seconds and 12, in 3-second increments, in one embodiment. *Any other suitable ranges and combinations of ranges may be used, in alternative embodiments, and those provided here are merely examples*.").)

342. Thus, Wolf-003 in combination with Angeles teaches claim 11.

[Claim 12] The method of claim 11, wherein the console unit is configured to receive one or more temperature readings from the at least one temperature sensor and process the readings to determine a level of RF energy to be delivered by the first and second electrodes that is sufficient to maintain a temperature of tissue at the one or more target sites below a predetermined threshold.

343. Angeles teaches claim 12.

344. As explained above relative to claim 11, in the combination of Wolf-003 and Angeles, Angeles's console is configured to receive temperature readings from Wolf-003's temperature sensor(s).

345. Angeles discloses that its console unit is configured to maintain a temperature of tissue at a target site below a predetermined threshold. (Ex-1007-Angeles at [0047] ("A default temperature may also be set for RF delivery, for example 60 degrees Celsius as the maximum temperature."), [0049] ("Maximum

stylus temperature may be selected in a range of 50 degrees Celsius to 70 degrees Celsius in one embodiment.").)

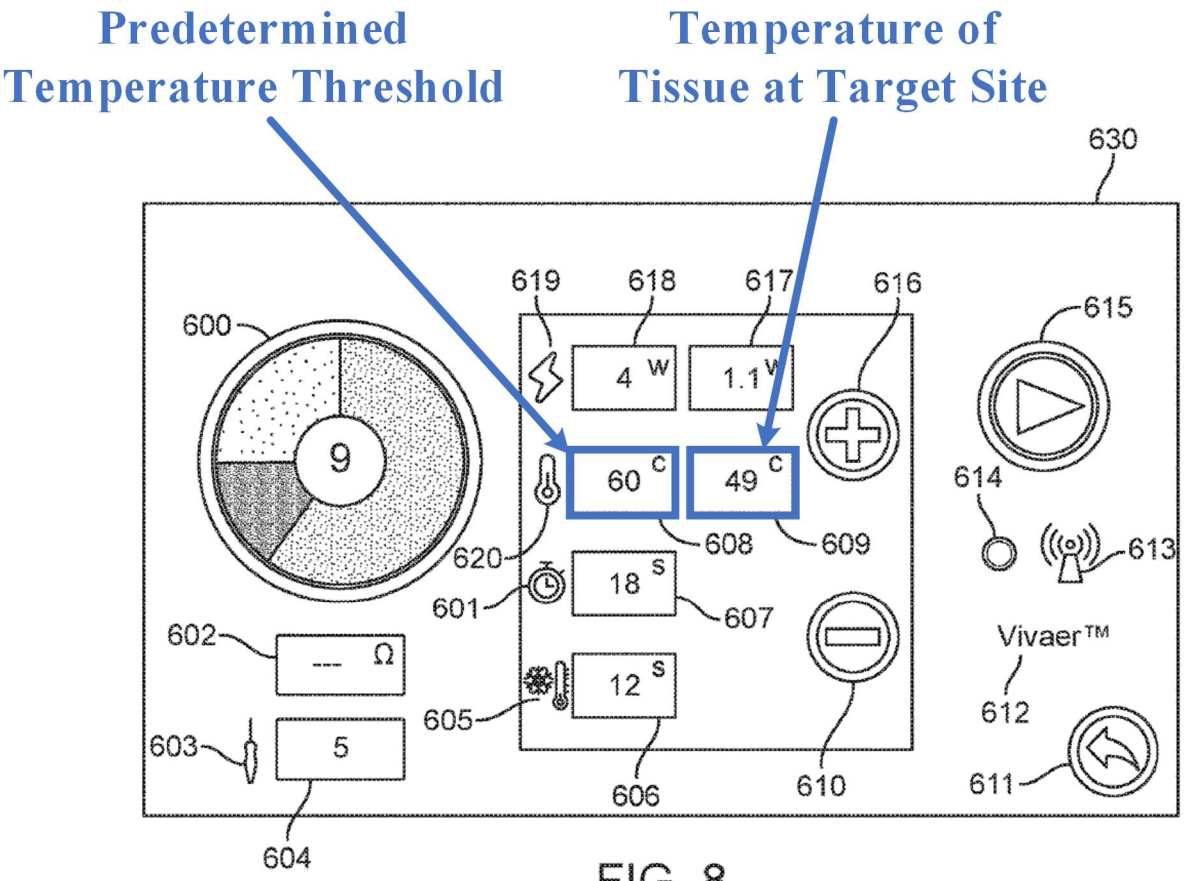

FIG. 8

(*Id*. at FIG. 8.)

346. Angeles' console unit includes a "computer processor" that would be used to process sensed temperature readings of the Wolf-003 device to determine a level of RF energy to be delivered by the RF electrodes of the Wolf-003 device. (Ex-1007-Angeles at Abstract, [0006], [0028], [0036], claim 1.)

347. Thus, Angeles teaches 12.

[Claim 13] The method of claim 12, [13a] wherein the console unit is configured to monitor temperature of tissue at the one or more target sites during delivery of RF energy thereto based on temperature readings from the at least one temperature sensor

348. Angeles teaches limitation [13a].

349. As explained in claim 11, in the combination of Wolf-003 and Angeles, Angeles's console is configured to receive temperature readings from Wolf-003's temperature sensor(s).

350. Angeles discloses that its console unit is configured to monitor temperature of tissue at a target site during delivery of RF energy thereto based on temperature sensor readings. (Ex-1007-Angeles at [0004] ("the generator may also *send and/or receive signals* to and from the applicator (for example, treatment algorithms, *tissue temperature measurements*, etc.)"), [0042] ("Other indicators that the treatment is in progress include the temperature indicator 501, showing a temperature of 60 degrees Celsius"), [0043] ("The stylus *temperature indicator 501 shows the actual temperature* of the distal, treatment end of the stylus 104."), [0050] ("During treatment, *the actual* RF power 617 and *temperature* reading 609 are also shown."); *see also id*. at [0007], [0013], [0037], [0039], [0045], [0048], claims 5 and 13.)

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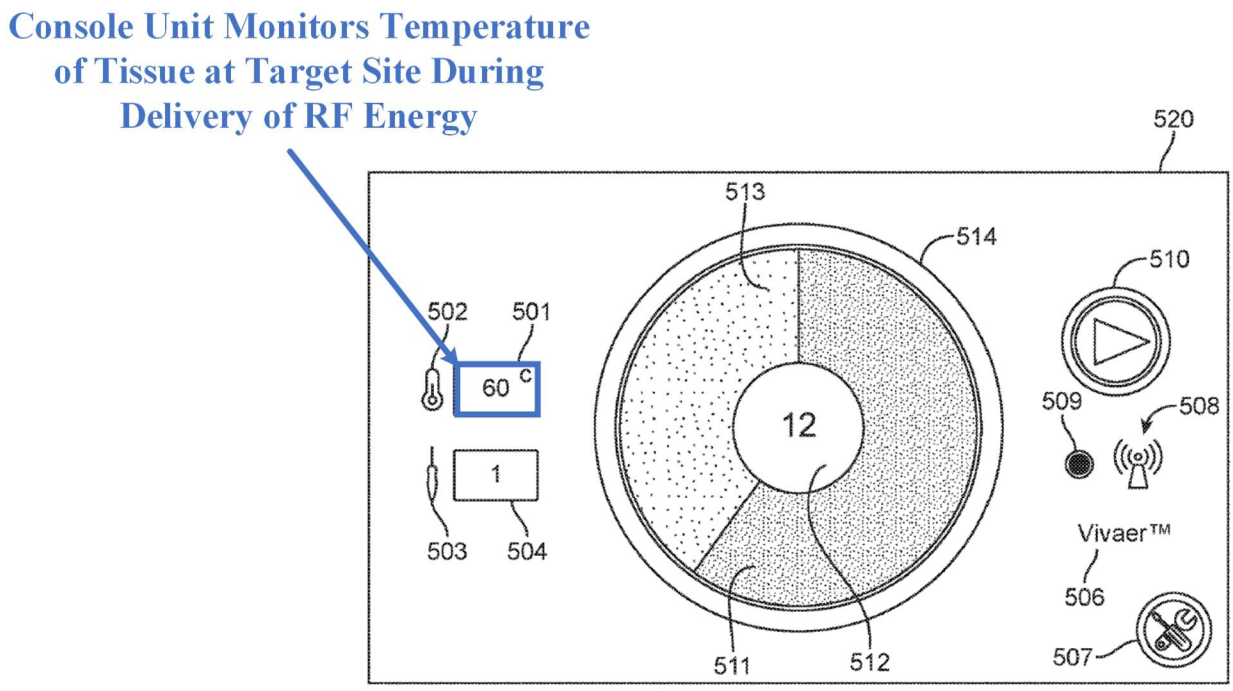

FIG. 6

(*Id*. at FIG. 6.)

351. Thus, Wolf-003 in combination with Angeles teaches limitation [13a].

[13b] and further monitor an elapsed time during delivery of RF energy to tissue at the one or more target sites.

352. Angeles teaches limitation [13b].

353. Angeles discloses that its console unit is configured to monitor an elapsed time during delivery of RF energy to tissue at a target site. For instance, Figure 7 of Angeles (below) shows illustrates a "Total Treatment Timer 512," which currently shows "that 12 seconds remain in the treatment—in other words, 18 seconds of the 30-second total time have elapsed.," with the "darker RF energy delivery time portion 511, designating the elapsed 18 seconds of RF energy delivery

time." (Ex-1007-Angeles at [0041].)

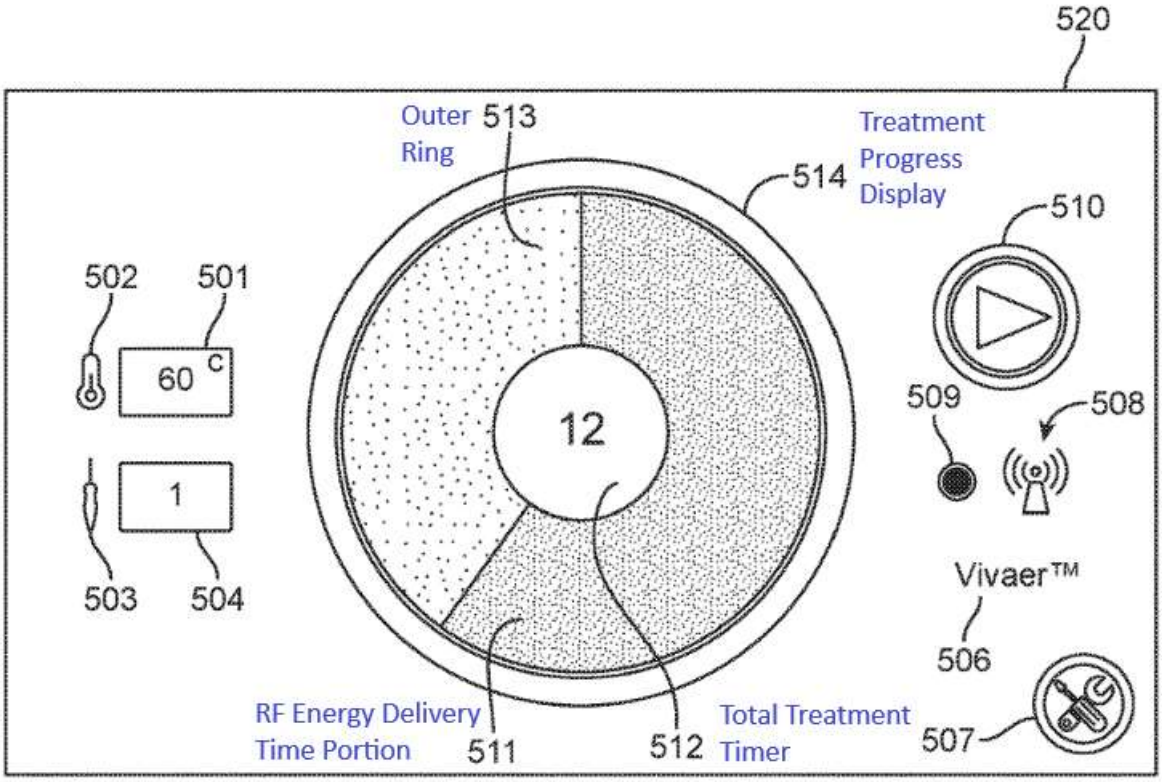

FIG. 6

(*Id.* at FIG. 6; *see also id.* at [0007] ("the outer ring changes colors in a clockwise direction *to indicate* ***elapsed time*** *of the energy delivery procedure*."), [0010], [0038], [0044]-[0045], claim 3.)

354. To display an elapsed time of RF energy delivery (as per above), a POSITA would have known that Angeles' console would "monitor an elapsed time during delivery of RF energy to tissue at the one or more target sites."

355. Thus, Angeles teaches claim 13.

[Claim 14] The method of claim 12, wherein the console unit is configured to provide, via a display, feedback information to an operator during a given treatment application, wherein said feedback information comprises at least an elapsed time during delivery of RF energy to tissue at the one or more target sites.

356. Angeles teaches claim 14.

357. As explained above relative to claim 13, Angeles' console unit includes the below display, which displays feedback information such as "an elapsed time during delivery of RF energy to tissue at the one or more target sites":

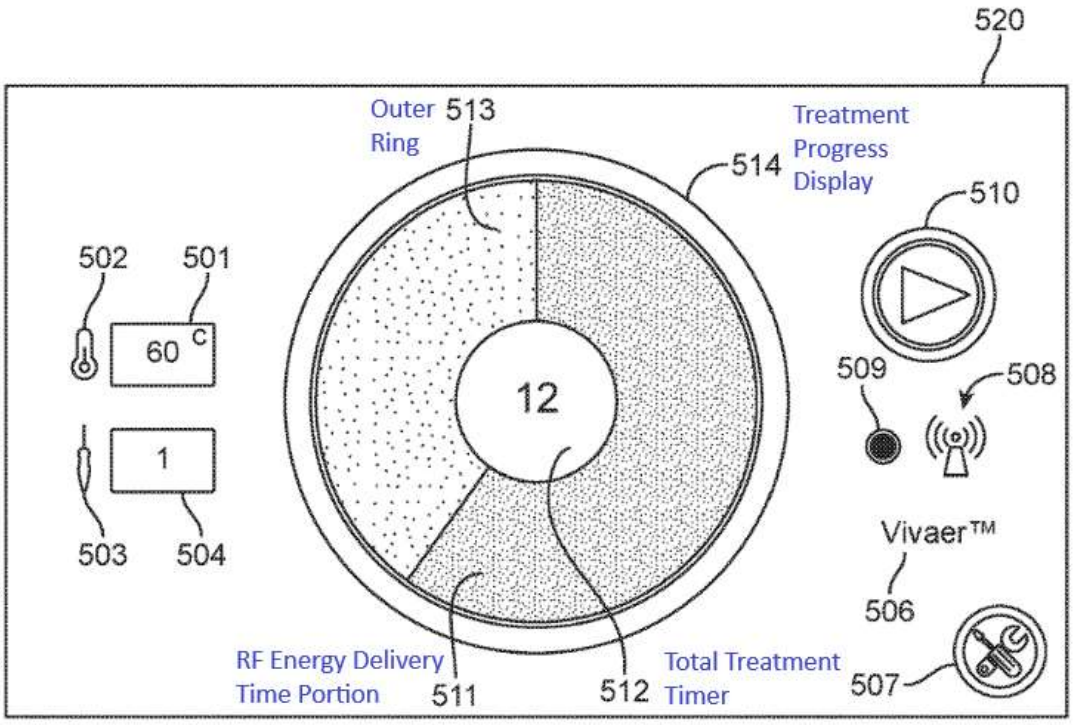

FIG. 6

(Ex-1007-Angeles at FIG. 6.)

358. As Angeles explains:

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> "The total treatment timer 512 of the graphical treatment progress display 514 *shows that 12 seconds remain in the treatment—in other words, 18 seconds of the 30-second total time have elapsed. The outer ring 513 now includes a darker RF energy delivery time portion 511, designating the elapsed 18 seconds of RF energy delivery time*. The lighter remaining portion of the ring 513 indicates the 12-second portion of the total treatment time that is still remaining. As the RF energy delivery stage of the treatment begins and progresses, the darker RF energy delivery time portion 511 sweeps clockwise around the outer ring 513, thus taking up more and more of the outer ring 513. In other words, the RF energy deliver indicator 511 starts at zero, at the twelve o'clock position on the ring 513, and moves around the ring in a clockwise direction. In this embodiment, treatment time (during which RF energy is delivered) is 18 seconds, and cool down time (during which RF energy is turned off) is 12 seconds. In alternative embodiments, any suitable alternative treatment times and cool down times may be used."

(Ex-1007-Angeles at [0041]; *see also id.* at [0006]-[0007], [0010], [0021], [0028], [0038], claims 1 and 3.)

359. Thus, Angeles discloses claim 14.

[Claim 15] The method of claim 14, wherein the display is a touchscreen monitor.

360. Angeles discloses claim 15.

361. Angeles discloses that its console unit has a "touchscreen display" (*i.e.*, a touchscreen monitor). (Ex-1007-Angeles at Abstract, [0006], [0010], [0028],

claim 1.)

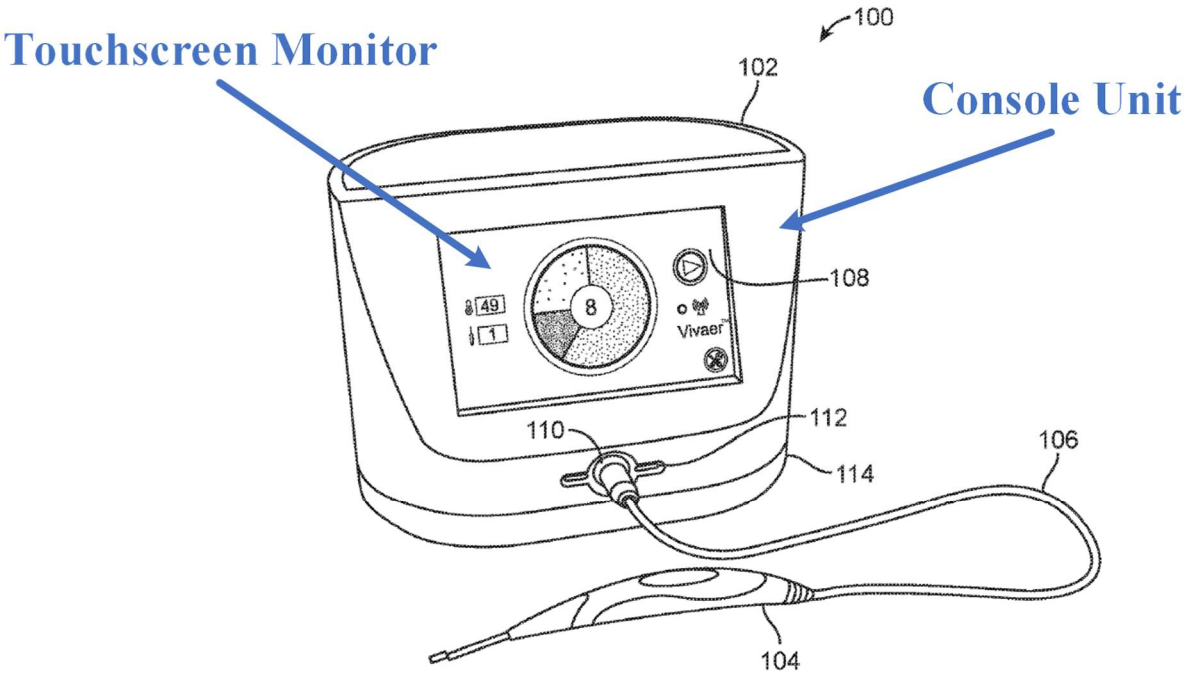

FIG. 1

(*Id*. at FIG. 1.)

362. Thus, Angeles discloses claim 15.

[Claim 16] The method of claim 12, wherein the console unit comprises a hardware processor coupled to non-transitory, computer-readable memory containing instructions executable by the processor to cause the console unit to automatically control and adjust RF energy output from the first and second electrodes based, at least in part, on a predetermined elapsed time period and a predetermined threshold maximum temperature during delivery of RF energy to ensure that application of said RF energy results in the desired effect of reduced engorgement of the tissue at the target site for a given treatment application.

363. Wolf-003 in view of Angeles teaches claim 16.

364. Angeles discloses that its console unit comprises a "computer processor" (*i.e.*, a hardware processor) and a "non-transitory computer readable

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medium" (*i.e.*, a non-transitory, computer-readable memory) "in the computer processor" (*i.e.*, coupled to the hardware processor). (Ex-1007-Angeles at Abstract, [0006], [0028], claim 1.) Angeles also discloses that its non-transitory, computer-readable memory contains "computer-executable programming instructions" (*i.e.*, instructions executable by the processor). (*Id*.)

365. In view of Wolf-003 and Angeles, a POSITA would also have found it obvious that the instructions executable by Angeles' processor cause the Angeles' console unit to automatically control and adjust RF energy output from the first and second electrodes for each treatment application based, at least in part, on the predetermined elapsed time period and the predetermined threshold maximum temperature during delivery of RF energy to ensure that application of said RF energy results in desired therapeutic effects.

366. Specifically, Wolf-003 in combination with Angeles discloses that the console unit automatically controls and adjusts RF energy output from the first and second electrodes based, at least in part, on the predetermined threshold maximum temperature. (Ex-1005-Wolf-003 at [0031] ("measuring a temperature of the mucosal tissue using the thermocouple; and delivering a second amount of the radiofrequency energy from the first electrode to the second electrode, wherein the second amount of radiofrequency energy is based at least in part on the measured temperature."), [0188] ("if a particular tissue temperature threshold is reached, a

sensor (or sensors) may send a signal to a power generator to shut down or decrease power delivered to a treatment device."); Ex-1007-Angeles at [0047], [0049] (disclosing setting a predetermined threshold maximum temperature on the console unit).) According to Wolf-003, when the predetermined threshold maximum temperature is reached, the RF energy output is automatically decreased or turned off. (Ex-1005-Wolf-003 at [0188].)

367. Angeles further discloses that the console unit automatically controls and adjusts RF energy output for each treatment application based, at least in part, on the predetermined elapsed time. (Ex-1007-Angeles at [0041] ("In this embodiment, treatment time (during which RF energy is delivered) is 18 seconds, and cool down time (during which RF energy is turned off) is 12 seconds."), [0044] ("At a given amount of time into the procedure, the console 102 stops delivering RF energy to the stylus 104, and a cool down phase begins."); *see also id*. at [0010]-[0011], [0045], [0047]-[0049], [0054].) When the predetermined elapsed time is reached, the RF energy output is automatically turned off. (*Id*.)

368. A POSITA would have understood that Angeles' processor-executable instructions in the non-transitory computer readable memory cause Angeles' console unit to perform the function of automatically controlling and adjusting the RF energy output. Angeles discloses that its "instructions" control the console unit's "active display," which controls setting the predetermined elapsed time period and the

predetermined threshold maximum temperature, setting and adjusting the power (*i.e.*, the RF energy output), and turning the RF energy on and off. (Ex-1007-Angeles at Abstract, [0006], [0008], [0013], [0037], [0041], [0043], [0048]-[0049], claims 1, 7, and 14.) A POSITA would have likewise expected and understood that Angeles' "instructions" control adjusting the RF energy output based on the predetermined elapsed time period and threshold maximum temperature (*e.g.*, turning the RF energy off when the predetermined elapsed time period or threshold maximum temperature is reached). Indeed, electronic devices with a processor, such as Angeles' console unit, regularly require processor-executable instructions in memory to function.

369. As explained above relative to Ground 2, claim 1, Wolf-003 discloses methods of treating tissue to reduce or prevent overproduction of mucus secretion in the nasal cavity, nasal passage, and nasal airway by applying energy to mucosal tissue and/or a tissue underlying mucosal tissue, which may decrease the absolute number and/or the mucus producing ability of mucus producing cells and/or mucus glands, such as by inactivating, retarding and/or replacing the cells. (Ex-1005-Wolf-003 at [0003], [0011], [0089].) While Wolf-003 does not expressly disclose that the desired therapeutic result is reduced engorgement of the tissue at the target site, Wolf-290 discloses this. (Ex-1006-Wolf-290 at [0076] ("energy may be directed at the mucosa, to shrink the tissue or reduce swelling of the mucosa"); *see also id*. at

[0043], [0057], [0077], [0104], [0113].) As explained in Ground 2, a POSITA would have been motivated and would have found it obvious in view of Wolf-290's teachings to use Wolf-003's systems and methods to reduce mucosal engorgement to treat rhinitis, congestion, and/or rhinorrhea (runny nose) with a reasonable expectation of success.

370. Thus, Wolf-003 in view of Wolf-290 and Angeles teaches claim 16.

[Claim 17] The method of claim 16, wherein the predetermined threshold maximum temperature is less than 90ºC.

[Claim 18] The method of claim 16, wherein the predetermined threshold maximum temperature is greater than 37° C and less than 90° C.

371. Angeles discloses claims 17-18.

372. Angeles discloses that the predetermined threshold maximum temperature "may be selected in a range of 50 degrees Celsius to 70 degrees Celsius," "for example 60 degrees Celsius." (Ex-1007-Angeles at [0047], [0049].) These disclosures lie within the claimed ranges of "less than 90ºC" and "greater than 37° C and less than 90° C."

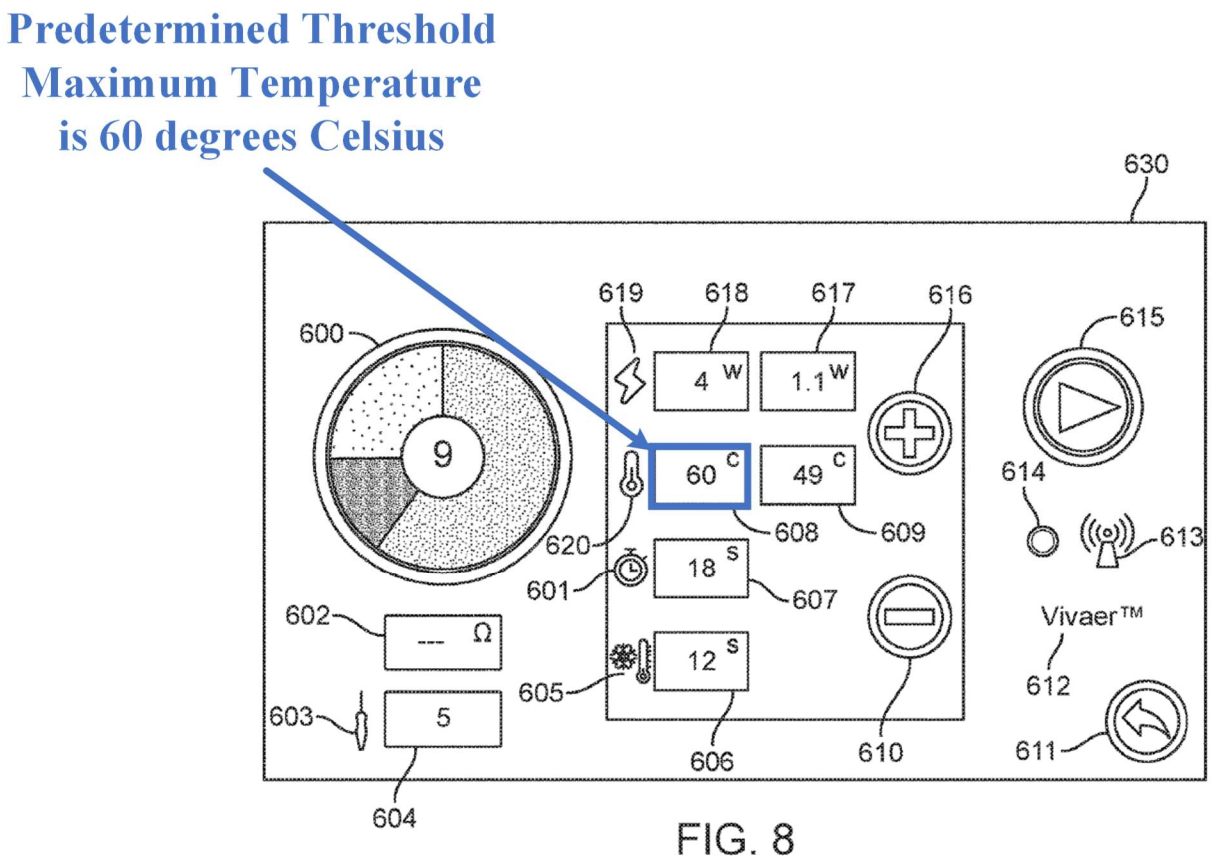

FIG. 8

(Ex-1007-Angeles at FIG. 8.)

373. Thus, Angeles discloses claims 17-18.

[Claim 19] The method of claim 16, the predetermined elapsed time period is from about 1 second to about 20 seconds.

[Claim 20] The method of claim 19, wherein the predetermined elapsed time period is from about 10 seconds to about 12 seconds.

374. Angeles discloses, teaches or suggest claims 19-20.

375. Angeles discloses that the predetermined elapsed time period for RF energy delivery "may be selected for between 6 seconds and 18 seconds, *in 2-second increments*." (Ex-1007-Angeles at [0049].) Thus, Angeles expressly contemplates

the following predetermined RF energy delivery times: 6 seconds, 8 seconds, 10 seconds, 12 seconds, 14 seconds, 16 seconds, and 18 seconds.

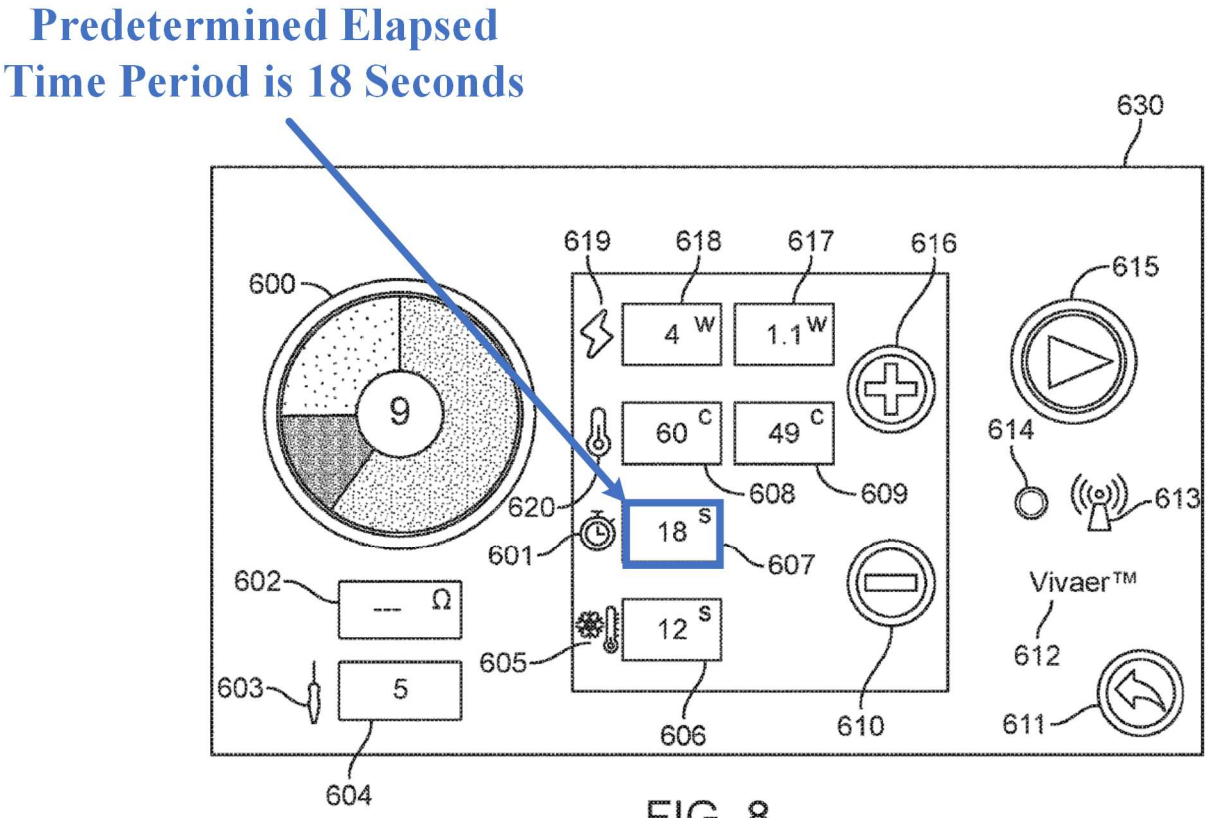

FIG. 8

(Ex-1007-Angeles at FIG. 8.)

376. Claim 19 is taught by Angeles because all of the predetermined times of 6, 8, 10, 12, 14, 16, and 18 seconds fall within the claimed range.

377. Claim 20 is taught by Angeles because the predetermined times of 10 and 12 seconds fall within the claimed range.

378. Thus, claims 19-20 are taught by Angeles.

X. CONCLUSION

379. This declaration and my opinions herein are made to the best of my knowledge and understanding, and based on the material available to me, at the time of signing this declaration. I declare that all statements made herein on 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 or Title 18 of the United States Code.

Date: June 27, 2025

Daniel van der Weide