**UNITED STATES PATENT AND TRADEMARK OFFICE**

**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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AERIN MEDICAL INC.
Petitioner

v.

NEURENT MEDICAL LTD.
Patent Owner.

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U.S. Patent No. 12,096,973

Case No.: IPR2025-01126

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# 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. 12,096,973 ("the '973 patent") to Townley concerning whether the '973 patent is unpatentable over certain prior art. This declaration is a statement of my opinions on issues relating to the patentability of claims 1–30 (the "Challenged Claims") of the '973 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 '973 patent:



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| Exhibit | Description |
|---|---|
| 1001 | U.S. Patent No. 12,096,973 ("the '973 patent") |
| 1002 | File history of U.S. Patent No. 12,096,973 |
| 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 | RESERVED |
| 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 | RESERVED |
| 1015 | RESERVED |
| 1016 | U.S. Patent No. 12,096,974 ("the '974 patent") |
| 1017 | File history of U.S. Patent No. 12,096,974 |
| 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 ’973 patent, I am relying on certain basic legal principles that counsel have explained to me. These principles are discussed below.

**15.** I understand that prior art to the ’973 patent includes patents and printed publications in the relevant art that predate the proper priority date of the alleged invention recited in the ’973 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 ’973 patent or any assignee of the ’973 patent that any secondary considerations are relevant to the obviousness analysis of any Challenged Claim of the ’973 patent.

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

**22.** I understand that my assessment of the claims of the ’973 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 ’973 patent on its earliest effective filing date (priority date) in light of the specification and file history of the ’973 patent. I will refer to such a person as a “POSITA.”


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**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 ’973 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 invention claimed in the ’973 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 ’973 PATENT

### A. Priority Chain

**26.** The ’973 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.


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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 '973 patent is entitled to claim priority to such a date.

### B. General Background

**27.** The '973 patent is titled "Systems and Methods for Therapeutic Nasal Treatment Using Handheld Device," 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 '973 patent discloses a "neuromodulation device 102" as shown in Figure 2 below:

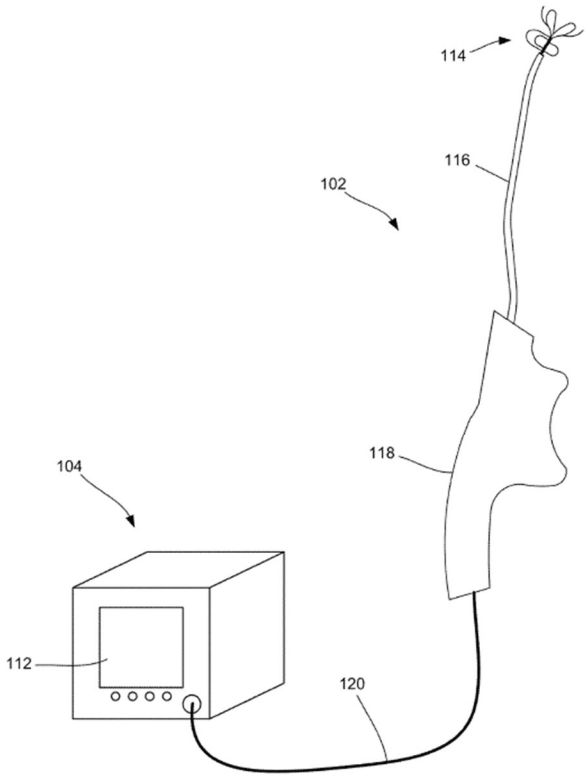


**FIG. 2**

(*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 12:25-28.) "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 12:28-32.)

**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.)

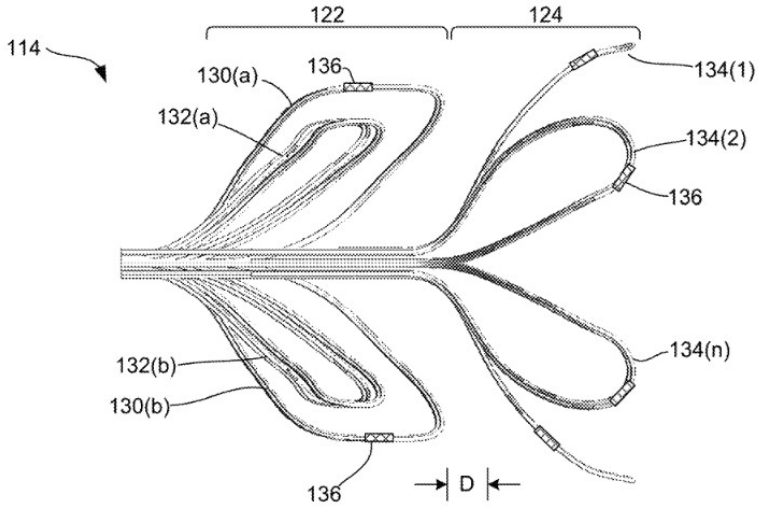


FIG. 5C

**30.** Figure 12 of the '973 patent, reproduced below, illustrates device 102 deployed in a nasal passage:

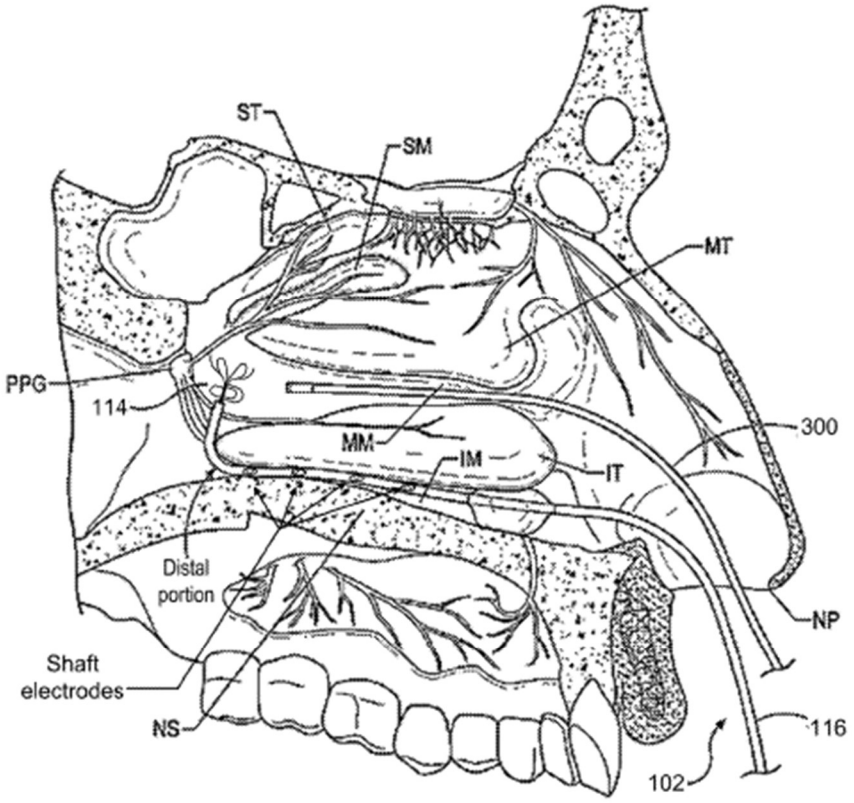


**FIG. 12**

(*Id*. at FIG. 12.)

**31.** According to the ’973 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 ’973 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 '973 patent's claims

**32.** The '973 patent has thirty claims, of which claims 1 and 16 are the independent claims.

**33.** Claims 1 and 16 are essentially identical and relate to 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 claims 1, 16.)

**34.** Claims 1 and 16 require 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 comprises a plurality of electrodes, wherein the plurality of electrodes comprises at least [six / eight] electrodes extend beyond surface of the shaft and are oriented at an angle less than 90 degrees relative to the shaft for the delivery of RF energy, wherein the at least [six / eight] electrodes comprise a first electrode spaced apart from a second electrode along a length of the multi-electrode end effector, 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, 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 '973, '262 and '091 patents

**35.** I have reviewed the prosecution history of the '973 patent, which is included as Exhibit 1002. 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-1002 at 15-22.) In the Reasons for Allowance, the Examiner repeated the claim language of claim 1 of the '973 patent and then stated:

> "The most pertinent piece of prior art, U.S. Patent No. 11,998,262 no longer constitutes as prior art given the terminal disclaimer filed 07/11/2024." (*Id.* at 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 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 '973 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 '973 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 '973 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 '973 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 '973 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 '973 patent, the nasal anatomy was well known. Pertinent anatomical features of the nose are shown in Lane (Ex-1018) and reproduced below.

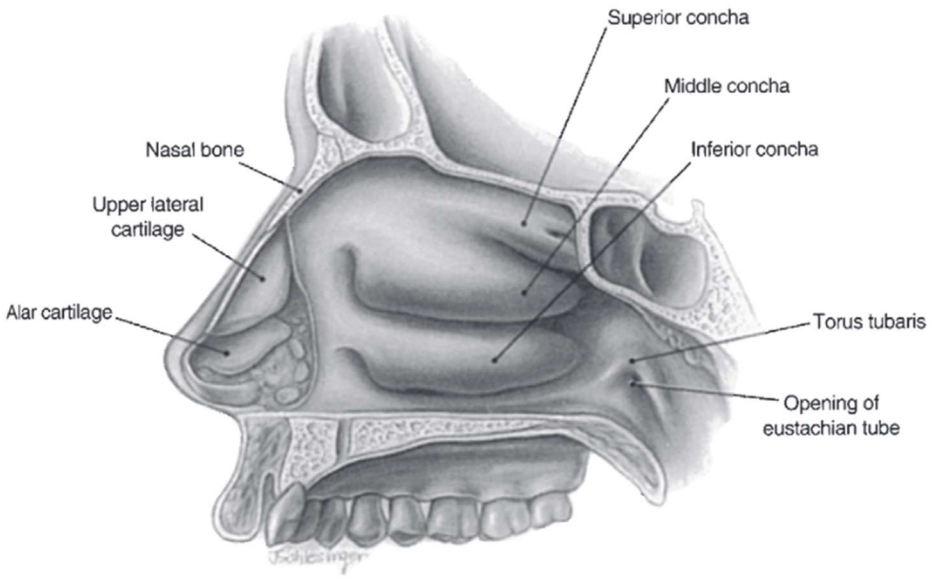


Fig. 1. Lateral nasal wall anatomy. Left side of the nose with nasal septum removed. (*From* O'Neal RM, Beil Jr RJ, Schlesinger J. Surgical anatomy of the nose. Otolaryngol Clin N Am 1999;32(1):175 [Fig. 29]; with permission.)

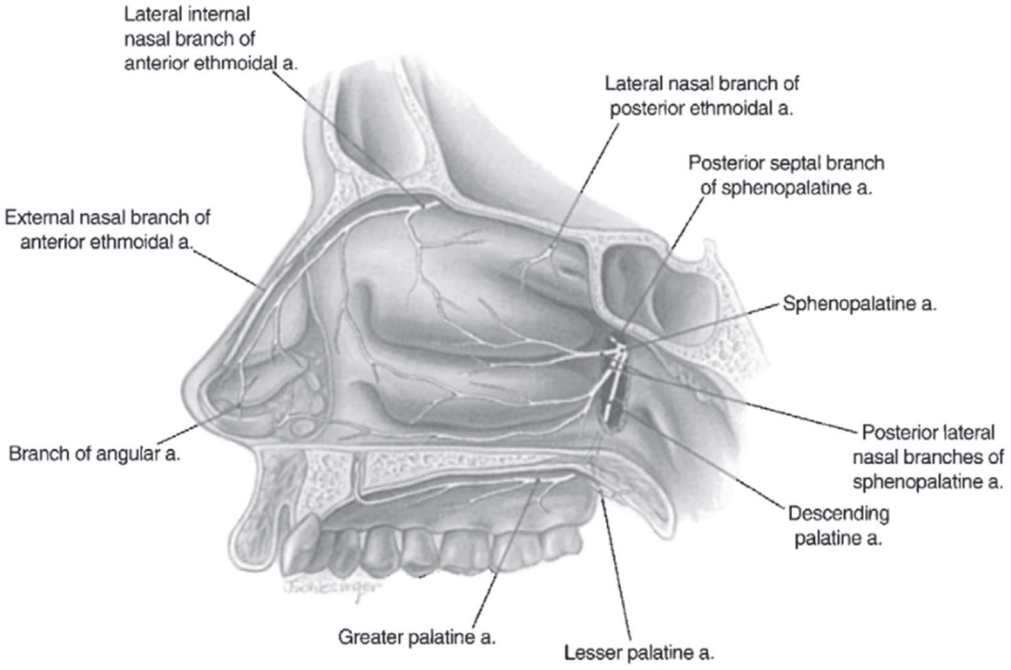


Fig. 2. Right lateral wall of the nose showing arterial blood supply. (*From* Otolaryngol Clin N Am 1999;177 [Fig. 32]; with permission.)

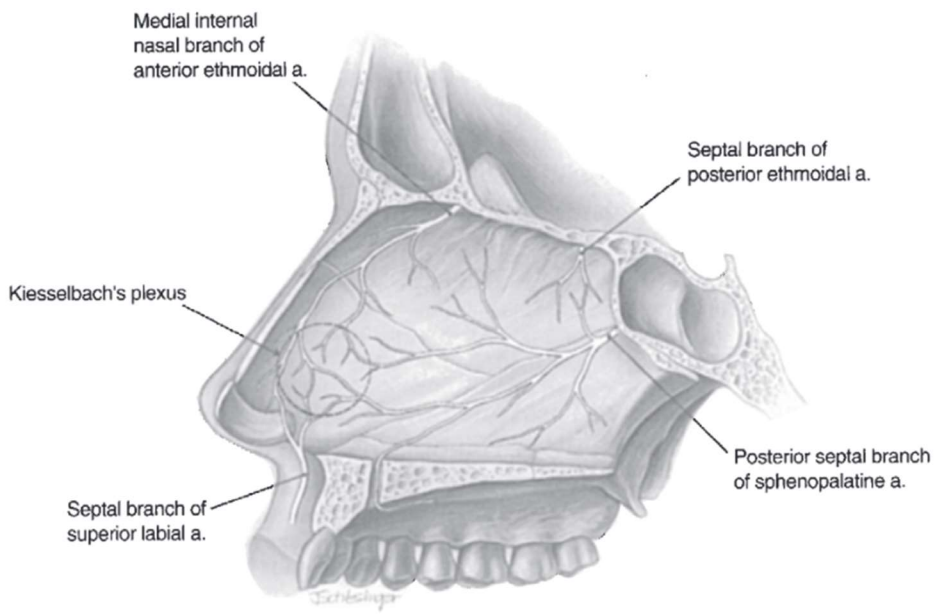


Fig. 3. Left side of the nasal septum showing arterial blood supply. Circle demonstrates Kesselbach's plexus. (*From* Otolaryngol Clin N Am 1999;177 [Fig. 33]; with permission.)

(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.").)

> 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 '973 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


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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 '973 patent at least because it published more than a year before the earliest possible effective filing date of the '973 patent. Notably, the first named inventor (David Townley) is the same inventor of the '973 patent.

**50.** Townley is analogous art to the '973 patent as it discloses minimally invasive systems, devices and methods for treating conditions associated with rhinosinusitis. (Ex-1001 at 1:19-24, 8:28-10:6; 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*.)

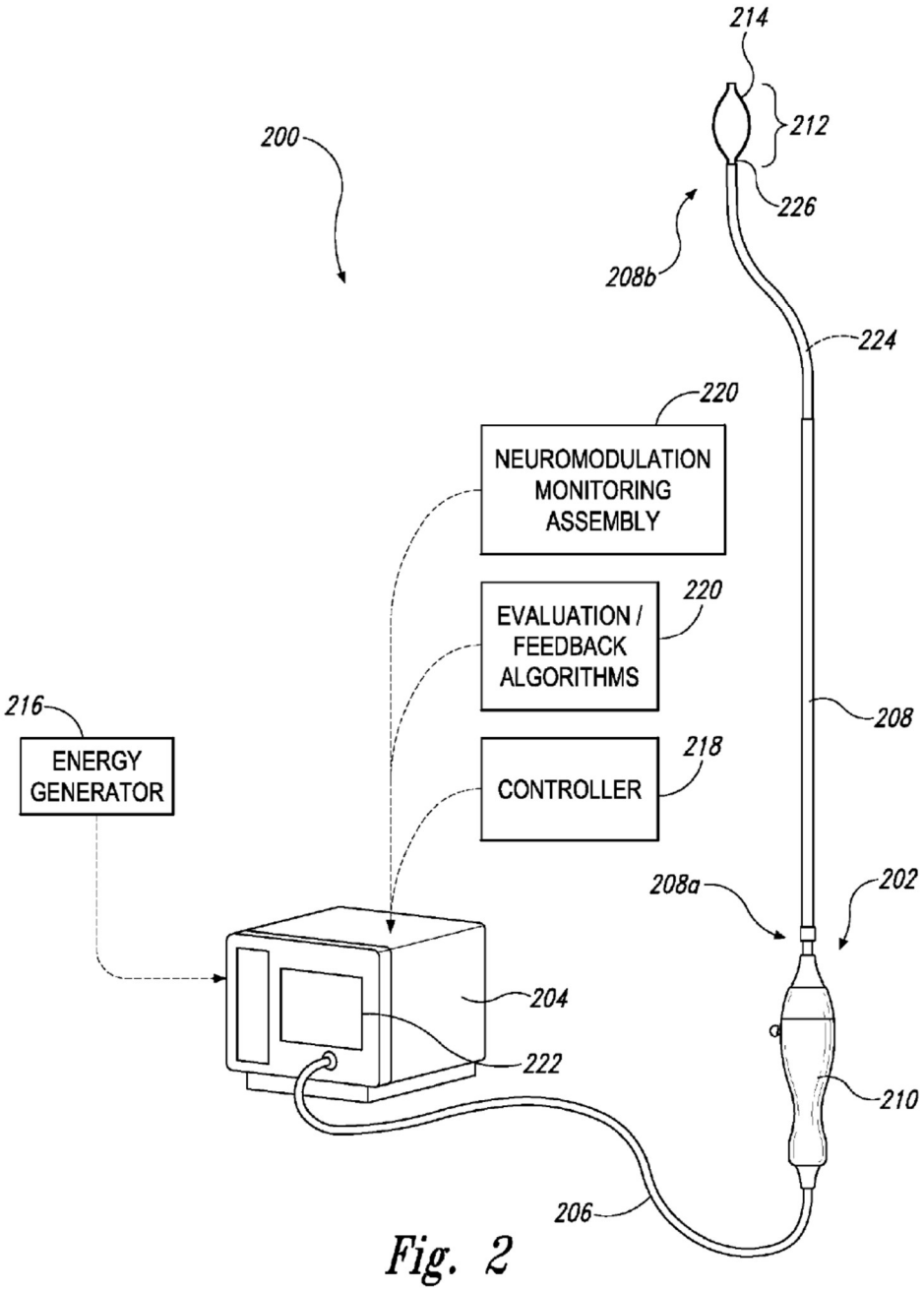


*Fig. 2*

(*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 '973 patent at least because it published before the earliest possible effective filing date of the '973 patent.

**56.** Wolf-003 is analogous art to the '973 patent as it discloses minimally invasive systems, devices and methods for treating conditions associated with rhinosinusitis. (Ex-1001 at 1:19-24, 8:28-10:6; 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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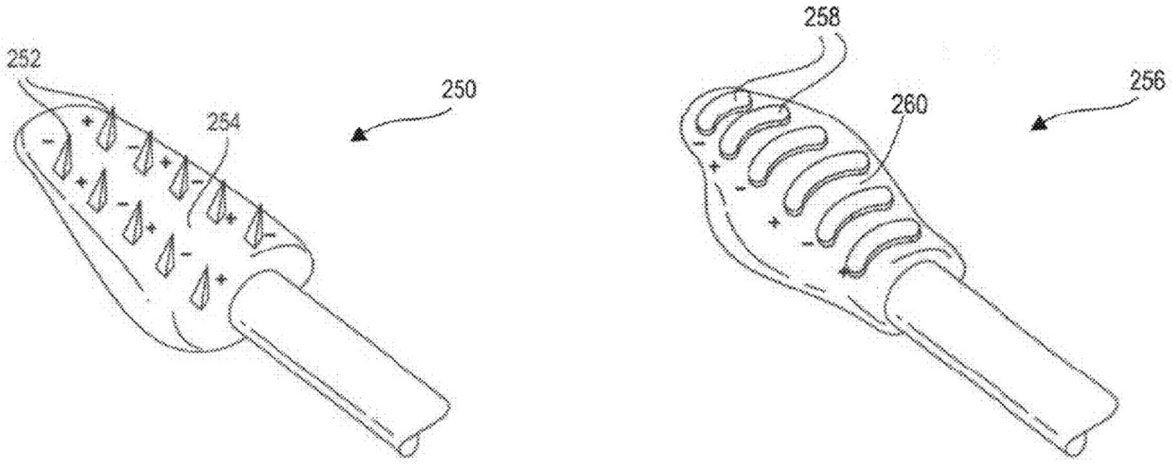
Wolf-003 at [0003].) Wolf-003's method comprises "advancing a treatment delivery portion of an energy-based treatment device into a nostril of the patient; contacting mucosal tissue of the upper airway with the treatment delivery portion, without piercing the mucosal tissue; and delivering a treatment 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].)

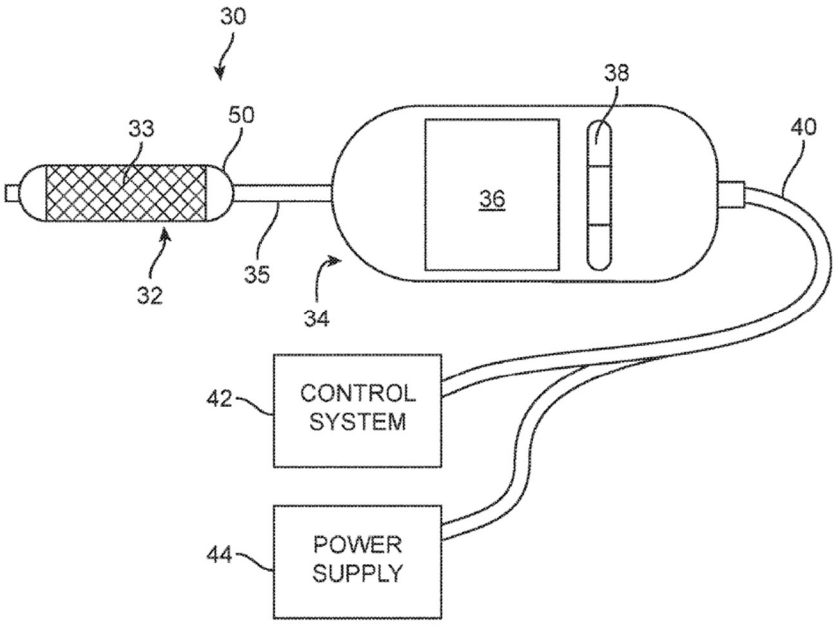
### C. Wolf-290 (Ex-1006)

**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 '973 patent at least

because it published before the earliest possible effective filing date of the '973 patent.

**60.** Wolf-290 is analogous art to the '973 patent as it discloses minimally invasive systems, devices and methods for treating conditions associated with rhinosinusitis. (Ex-1001 at 1:19-24, 8:28-10:6; 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].)

## VII. LEVEL OF ORDINARY SKILL IN THE ART

**63.** Based on my review and analysis of the '973 patent, the prior art cited herein, and the ordinary skill factors described previously, a POSITA in the field of the '973 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

**64.** It is my understanding that in order to properly evaluate the ’973 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 1-30 ARE UNPATENTABLE

**65.** I have been asked to provide my opinion as to whether the Challenged Claims of the ’973 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 ’973 patent.

**66.** 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 '973 patent.

**67.** 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 | 1-30 | Rendered obvious by Townley (Ex-1004) |
| #2 | 1-2 and 16-17 | Rendered obvious by Wolf-003 (Ex-1005) alone or in view of Wolf-290 (Ex-1006) |

**68.** The '973 patent contains 30 claims, of which Claims 1 and 16 are independent. (Ex-1001 at 59:6-62:51.) The only pertinent difference between Claims 1 and 16 is that Claim 1 requires at least ***six*** electrodes, whereas Claim 16 requires at least ***eight*** electrodes. (*Id.* at 59:15-16, 60:63-64.) Dependent Claims 17-30 mirror dependent Claims 2-15. (*Id.* at 59:48-60:53, 61:29-62:51.) Thus, I address both claim sets together across the Grounds.

### A. Ground 1: Claims 1-30 are obvious in view of Townley

#### 1. Summary of Ground 1

**69.** Ground 1 relies on Townley, which is a 2016 publication by the same

named inventor as the ’973 patent. As shown below, Townley discloses, teaches or suggests all limitations of claims 1-30 of the ’973 patent.

**70.** As shown below, Townley expressly discloses nearly all limitations of claims 1 and 16, 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 patients 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 claims 1 and 16. Townley also discloses, teaches, or suggests claims 2-15 and 17-30, 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:**

**[Claim 16, 16-PRE] A method for treating at least one of rhinitis, congestion, and rhinorrhea within a sino-nasal cavity of a patient, the method comprising:**

**71.** Townley discloses the preambles of Claims 1 and 16.

**72.** 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].)

**73.** As for the term "sino-nasal cavity," I note that this term is not defined in the '973 patent, but it appears to mean a sinus cavity and/or a nasal cavity. The

claims of the '973 patent confirm that the "sino-nasal cavity" at least includes a nasal cavity. As shown below, for example, claim 1 of the '973 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 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*…."

(Ex-1001 at claim 1; *see also id*. at claim 16 (same).)

**74.** 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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> 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).)

**75.** Thus, Townley discloses [1-PRE] and [16-PRE].

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

**[16a-1] advancing a multi-electrode end effector into the sino-nasal cavity of the patient**

**76.** Townley discloses limitations [1a-1] and [16a-1].

**77.** First, I note that the '973 patent states that "the terms 'end effector' and 'therapeutic assembly' may be used interchangeably." (Ex-1001 at 12:32-34.)

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


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for short.

**79.** 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.

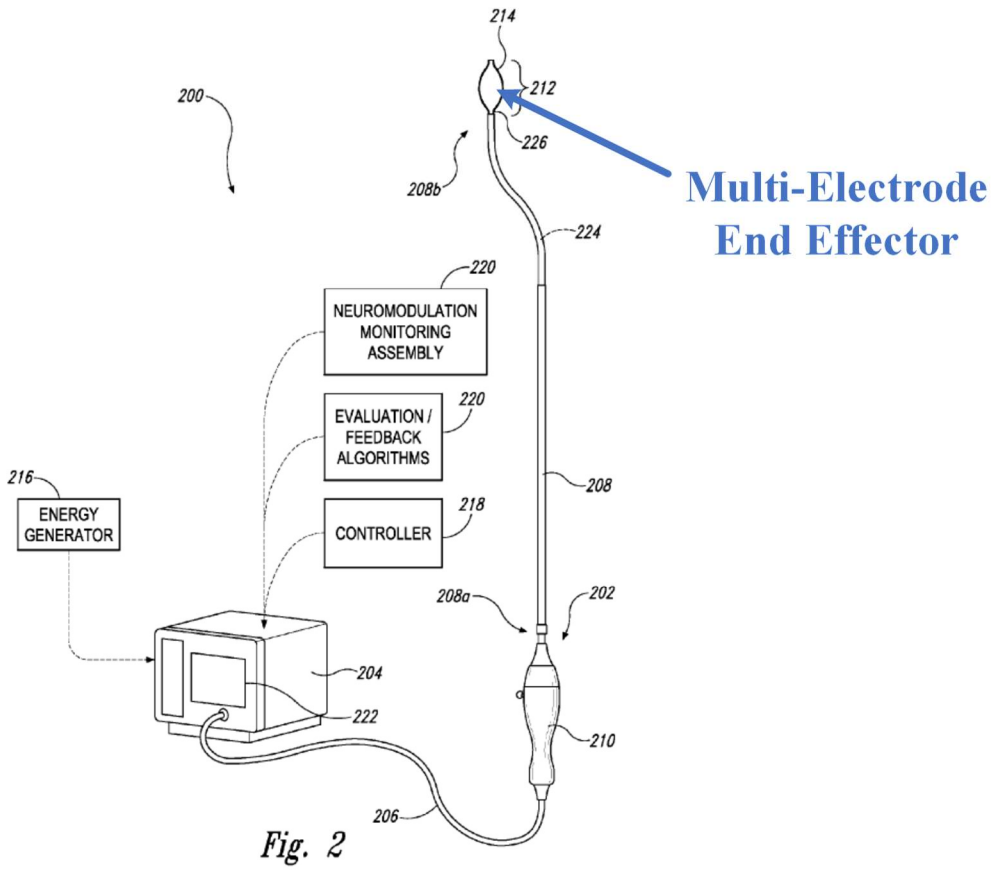


*Fig. 2*

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

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

**81.** 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

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

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.)

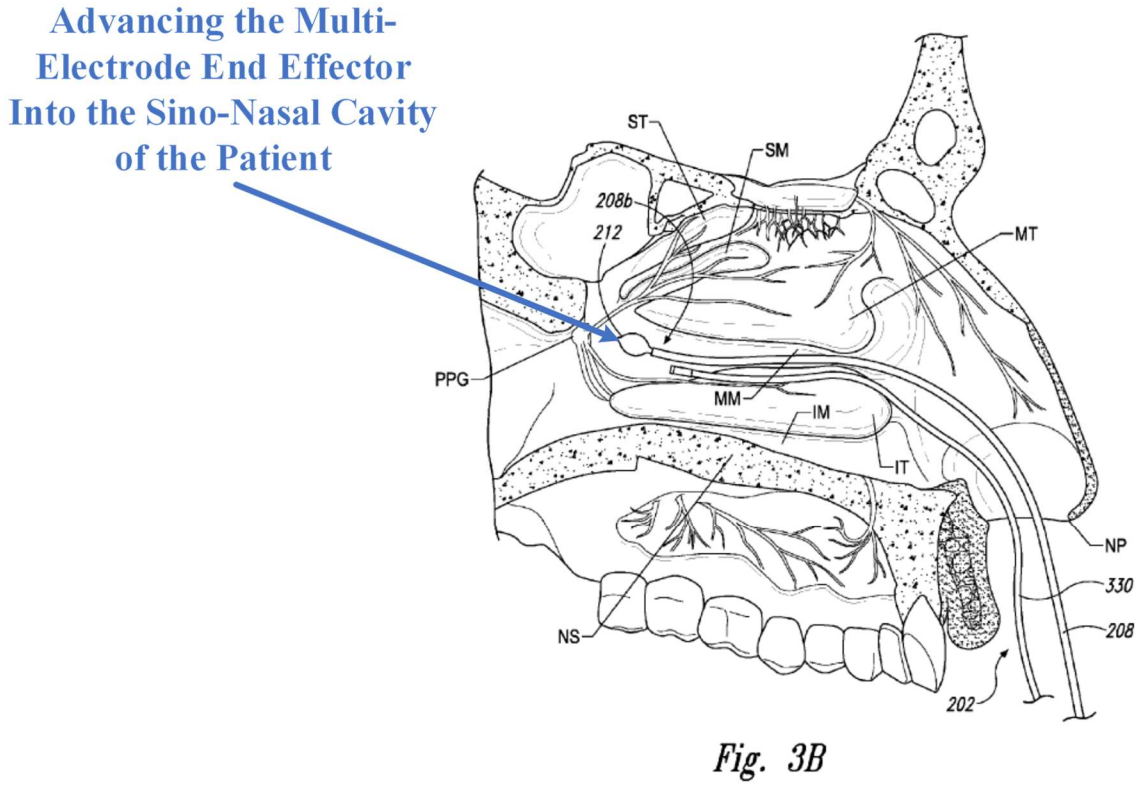


*Fig. 3B*

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

**82.** Thus, Townley discloses limitations [1a-1] and [16a-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**

**[16a-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**

**83.** Townley discloses limitations [1a-2] and [16a-2].

**84.** 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].)



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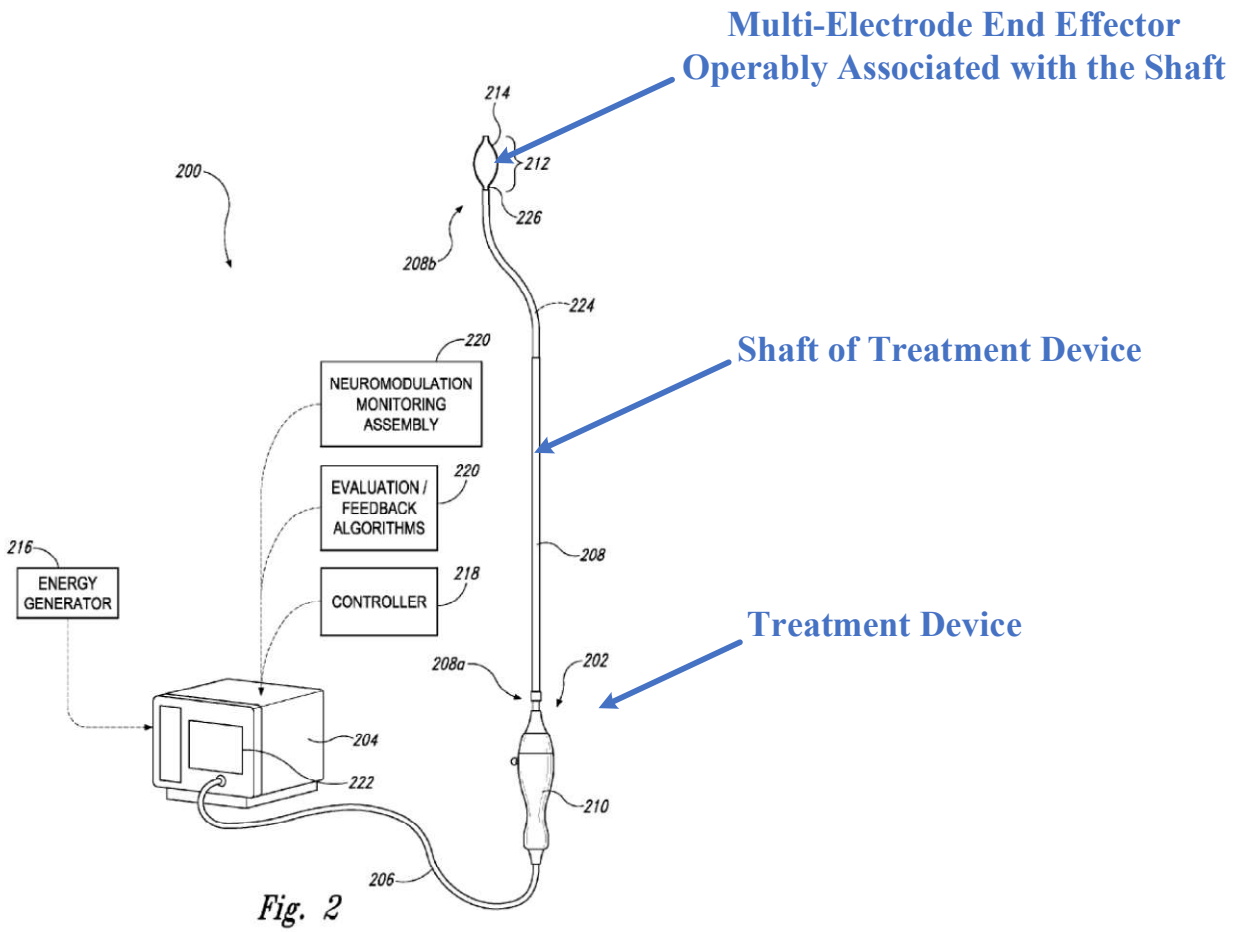


(*Id*. at FIG. 2; *see also id.* at FIGS. 3A-E, 4, 5A-G, and 11A-D, Abstract, [0051], [0061], [0066], [0105], claims 1, 26, 41, and 103.)

**85.** 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.)

**86.** Thus, Townley discloses limitations [1a-2] and [16a-2].

**[1a-3] wherein the multi-electrode end effector comprises a plurality of electrodes, wherein the plurality of electrodes comprises at least six electrodes extend beyond surface of the shaft and are oriented at an angle less than 90 degrees relative to the shaft for the delivery of RF energy**

**[16a-3] wherein the multi-electrode end effector comprising a plurality of electrodes, wherein the plurality of electrodes comprises at least eight electrodes extend beyond surface of the shaft and are oriented at an angle less than 90 degrees relative to the shaft for the delivery of RF energy**

**87.** Townley discloses limitations [1a-3] and [16a-3].

**88.** Townley discloses that its electrodes are configured to deliver RF energy. (Ex-1004-Townley, [0043], [0066], [0072]-[0073], [0111].)

**89.** The multi-electrode end effectors of Figures 4, 5A-G, and 11A-D comprise at least eight electrodes, wherein the at least eight electrodes[3] extend beyond the surface of the shaft and are oriented at an angle less than 90 degrees relative to the shaft.

[3] Eight electrodes are illustrated because Claims 1 and 16 require "at least six" and "at least eight" electrodes, respectively.


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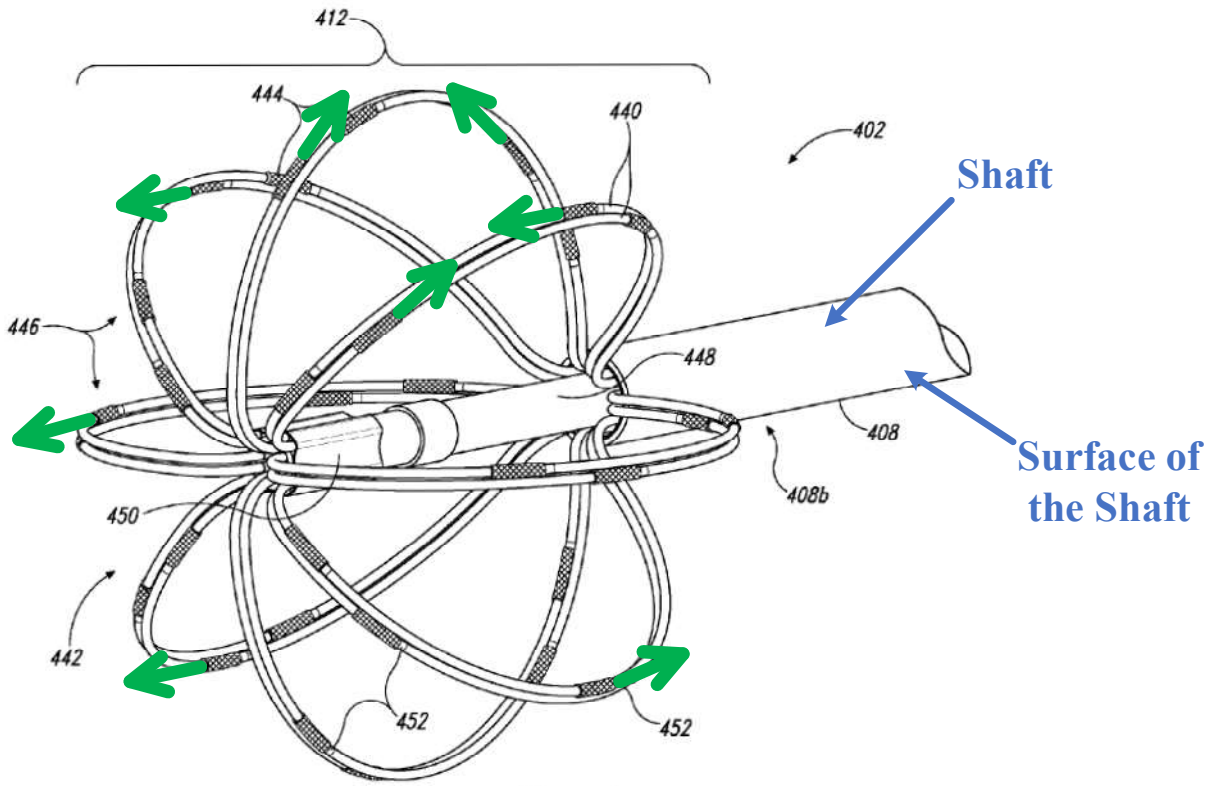


*Fig. 4*

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

**90.** As the green arrows demonstrate, the at least eight electrodes 444 extend beyond the surface of the shaft 408 and are oriented at angles less than 90 degrees relative to the shaft 408.[4]

**91.** The electrodes arrangements of Figures 5A-G also disclose limitations

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


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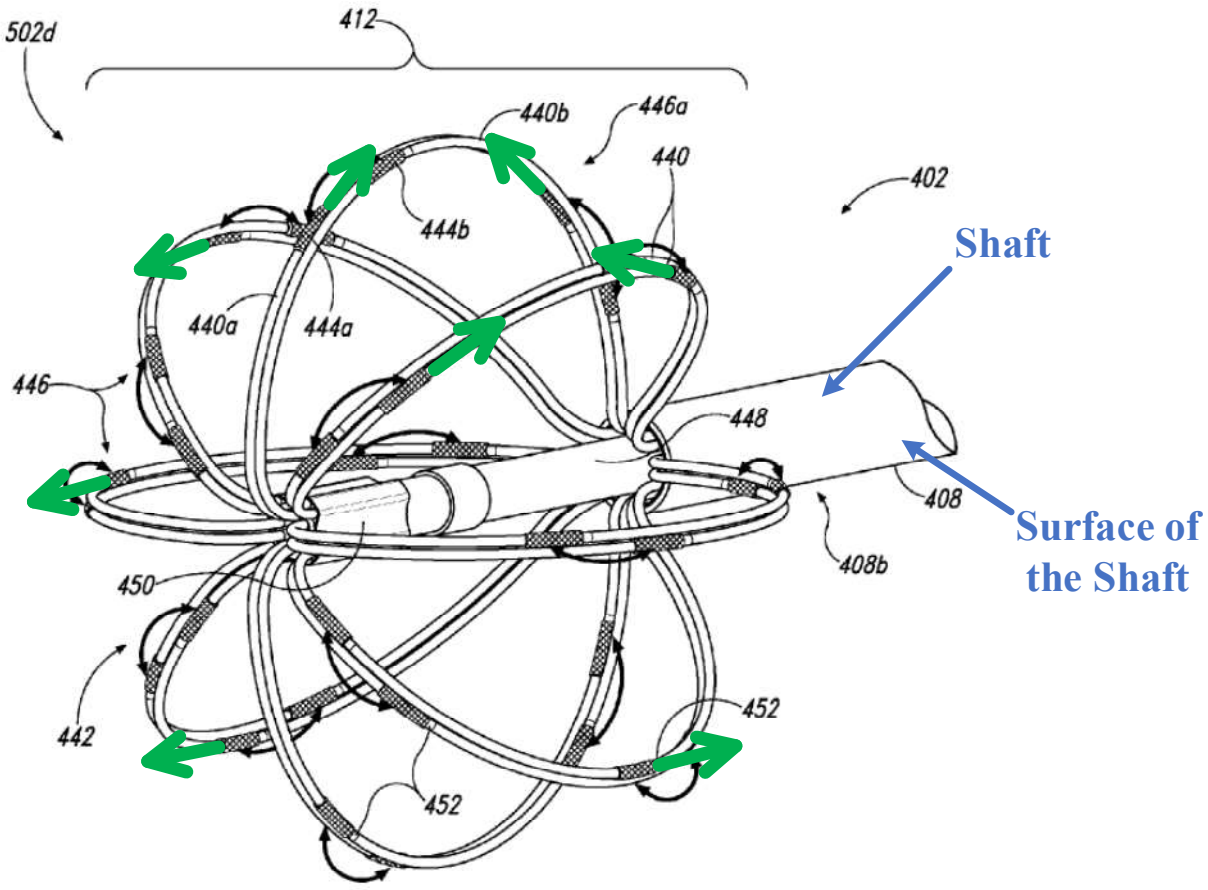
[1a-3] and [16a-3]. Below is an example (Figure 5F) showing how such electrode arrangements meet the requirements of limitations [1a-3] and [16a-3], i.e., at least eight electrodes 444 that extend beyond the surface of the shaft 408 and are oriented at an angle less than 90-degrees relative to the shaft 408:




(Ex-1004-Townley at FIG. 5F; *see also id*. at [0075] ("a plurality of electrodes 444

disposed on one or more of the struts 440.").)[5]

**92.** The electrodes of Figures 11A-D also teach the requirements of limitations [1a-3] and [16a-3]. For example, Figure 11B illustrates at least eight electrodes (1144). (Ex-1004-Townley at FIG. 11B.) Townley discloses that the at least eight electrodes (1144) are disposed on the flexible membrane (1162), and that 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." (*Id*. at [0106].)

[5] Again, the use of Figure 5F is exemplary, and is just one of many examples in which the devices of Townley meet the "less than 90 degree" requirement of limitations [1a-3] and [16a-3].

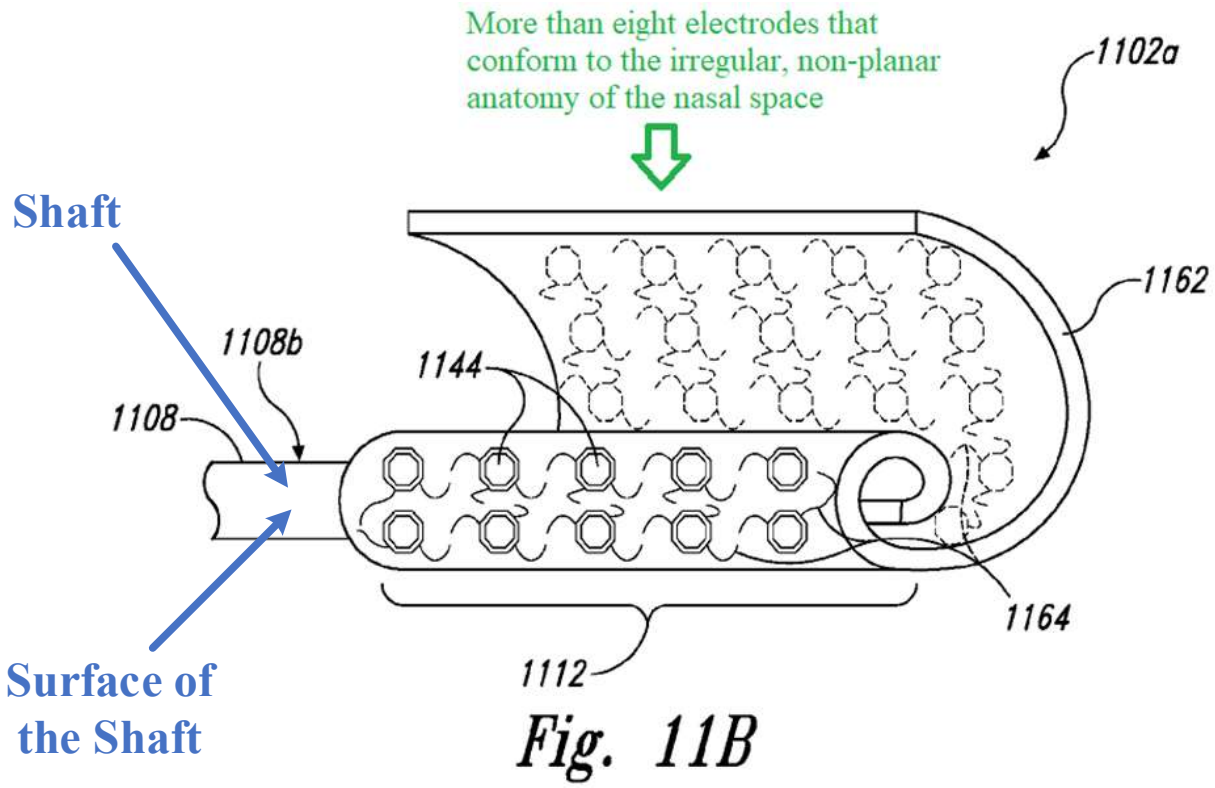



*Fig. 11B*

(*Id*. at FIG. 11B.)

**93.** A POSITA would have known or reasonably expected the at least eight electrodes of Figure 11B to be oriented at an angle less than 90 degrees relative to the shaft to conform to the irregular, non-planar anatomy of the nasal space.

**94.** Thus, Townley discloses limitations [1a-3] and [16a-3].

**[1a-4] wherein the at least six electrodes comprise a first electrode spaced apart from a second electrode along a length of the multi-electrode end effector, 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, and wherein:**

**[16a-4] wherein the at least eight electrodes comprise a first electrode 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, and wherein:**

**95.** Townley discloses limitations [1a-4] and [16a-4].

**96.** Townley discloses several multi-electrode end effectors having electrodes that satisfy the requirements of limitations [1a-4] and [16a-4]. The at least eight electrodes of the multi-electrode end effectors of Figures 4, 5A-G, 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:

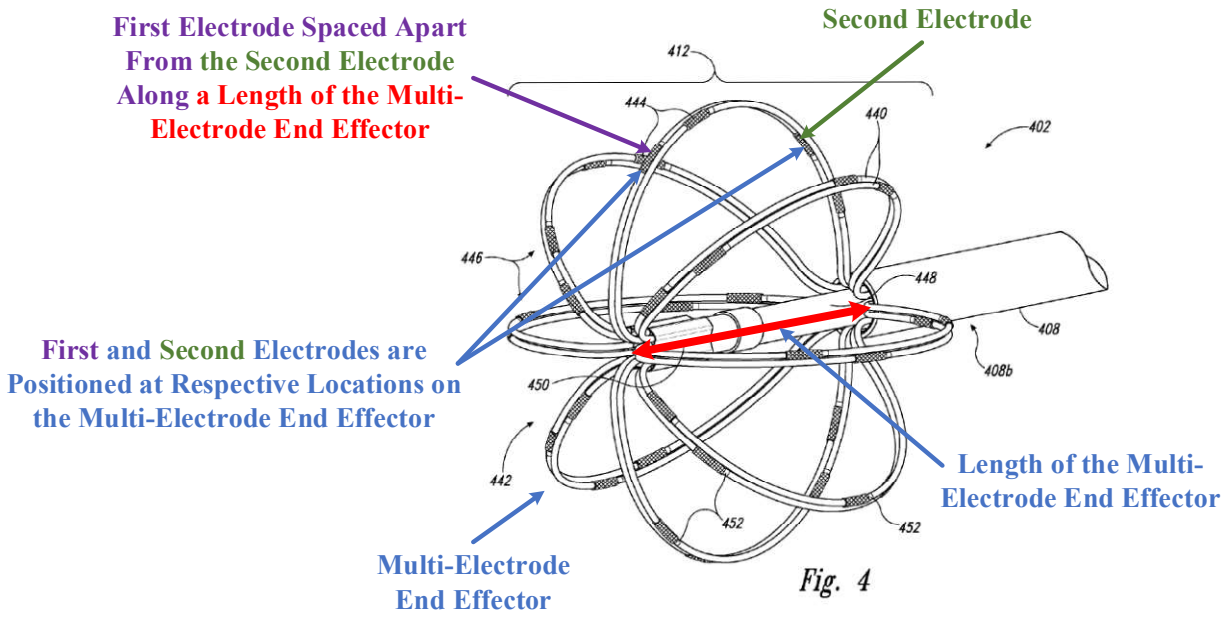
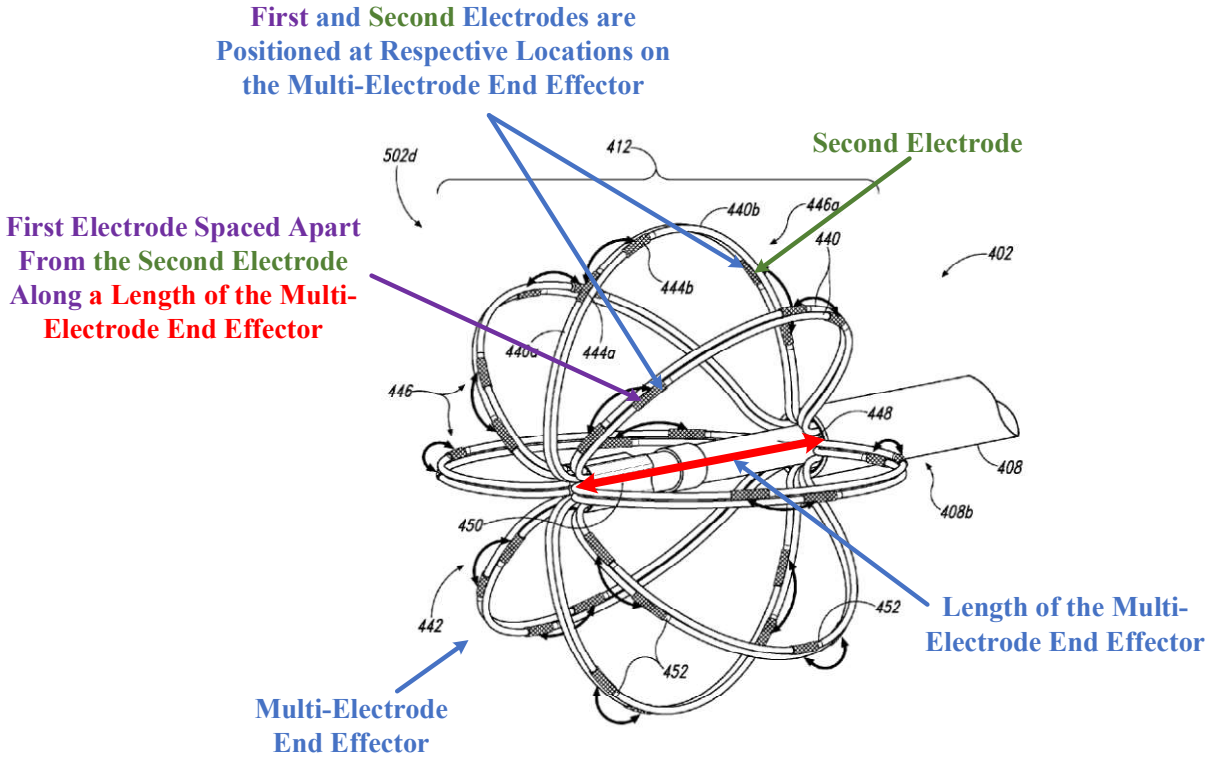



*Fig. 4*

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




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

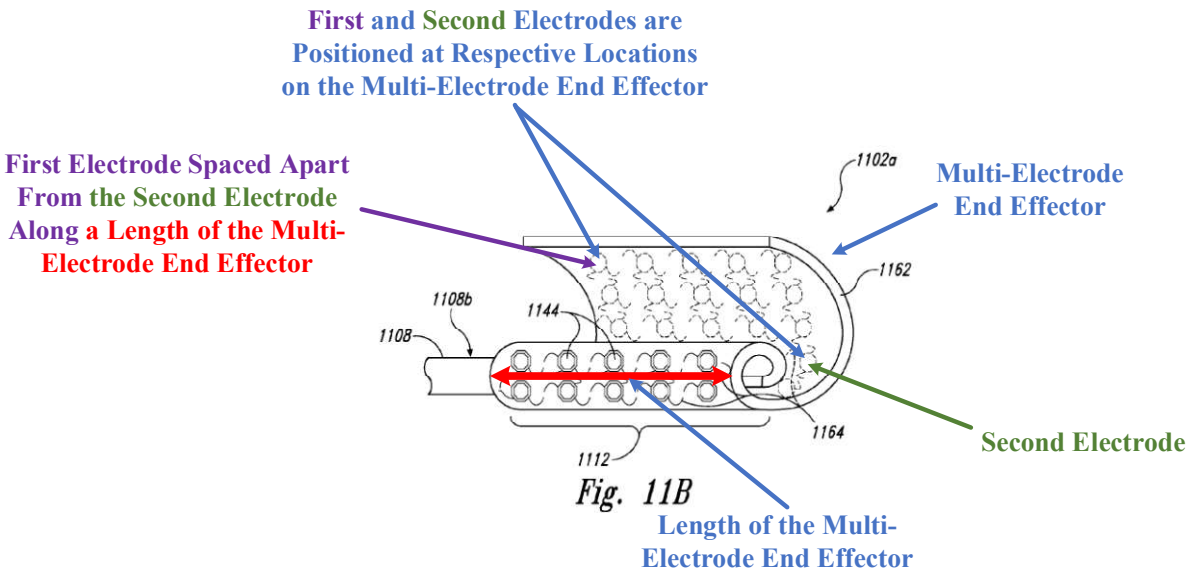



*Fig. 11B*

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

**97.** 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].)

**98.** Thus, Townley discloses limitations [1a-4] and [16a-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**

**[16b] 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**

**99.** Townley discloses limitations [1b] and [16b]

**100.** Townley discloses several multi-electrode end effectors having a first electrode that meets the requirements of limitations [1b] and [16b]. The multi-electrode end effectors of Figures 4, 5A-G, 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: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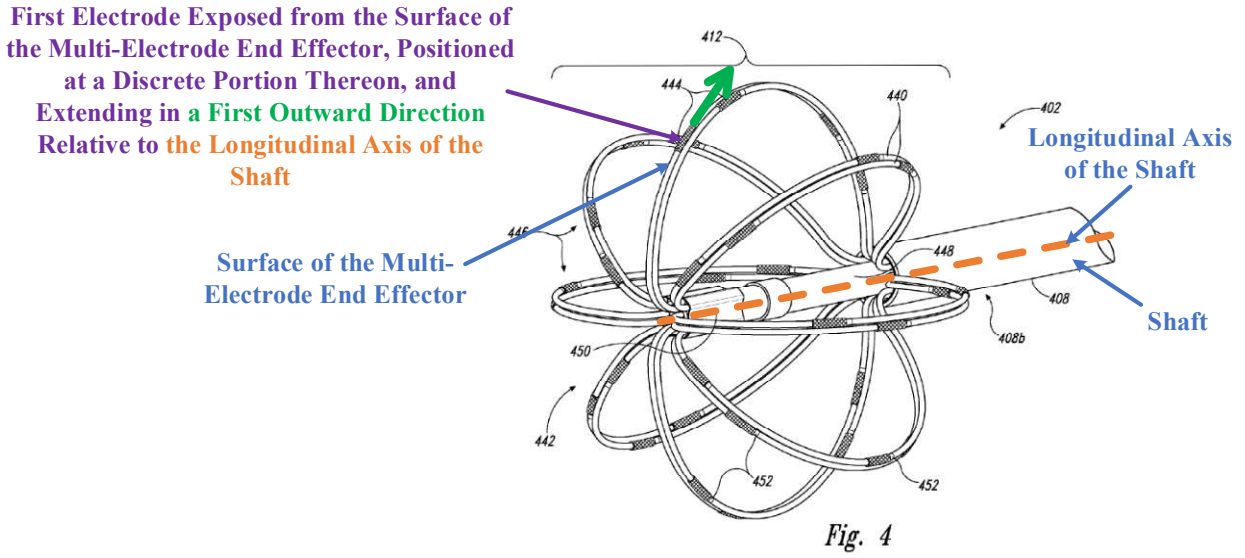
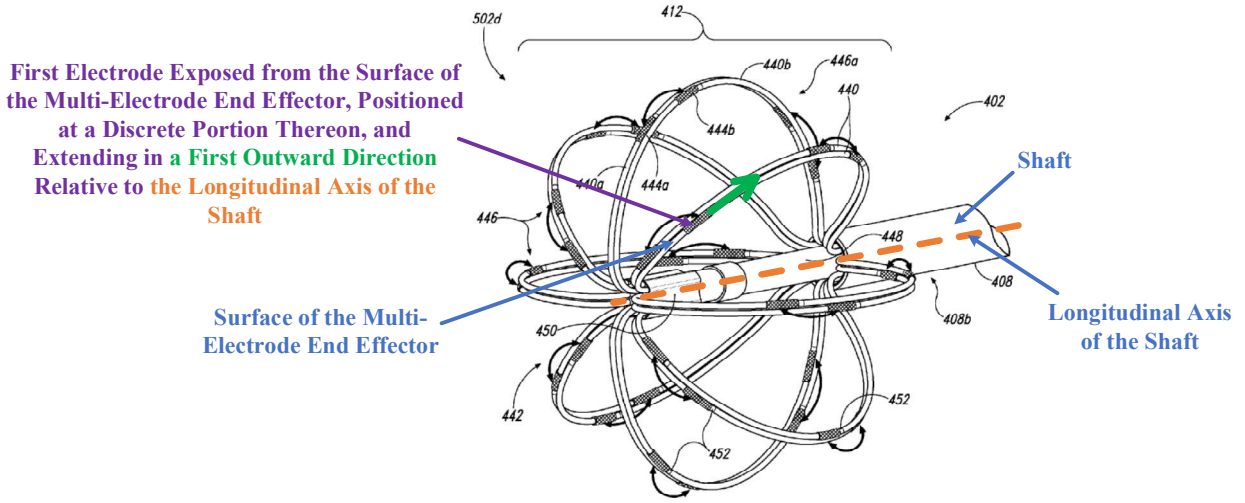



*Fig. 4*

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




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

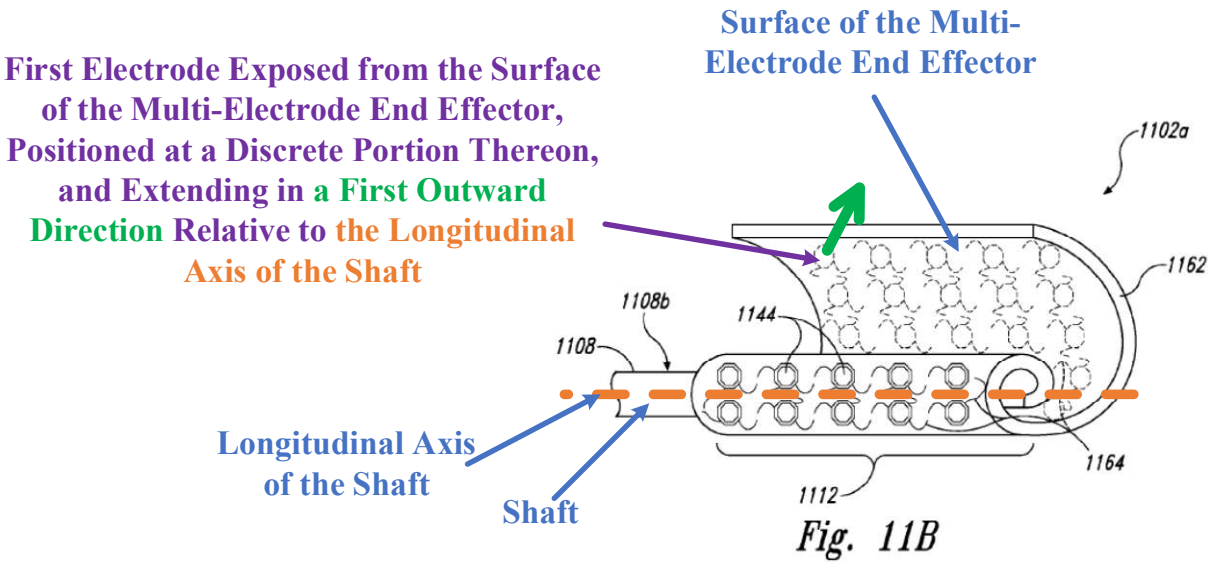


*Fig. 11B*

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

**101.** 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 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 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].)

**102.** Thus, Townley discloses limitations [1b] and [16b].

**[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**

**[16c] 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**

**103.** Townley discloses limitations [1c] and [16c] for many of the same reasons provided above relative to limitations [1b] and [16b].

**104.** The multi-electrode end effectors of Figures 4, 5A-G, and 11A-D, for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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:

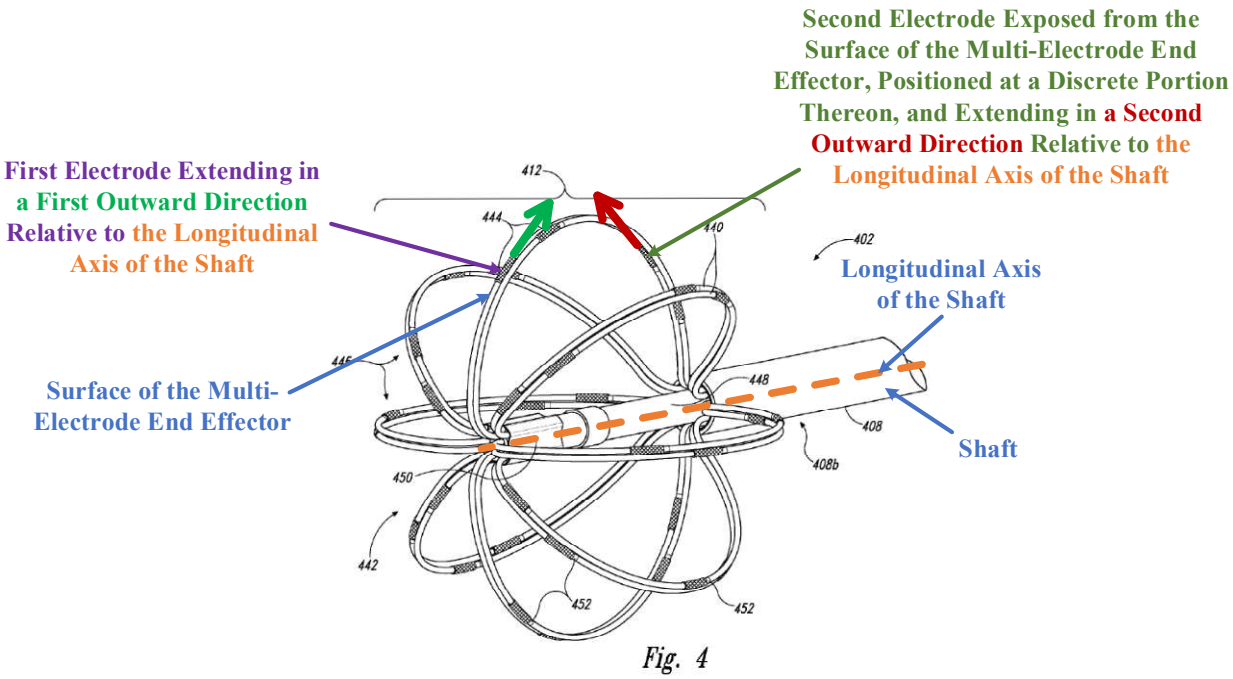
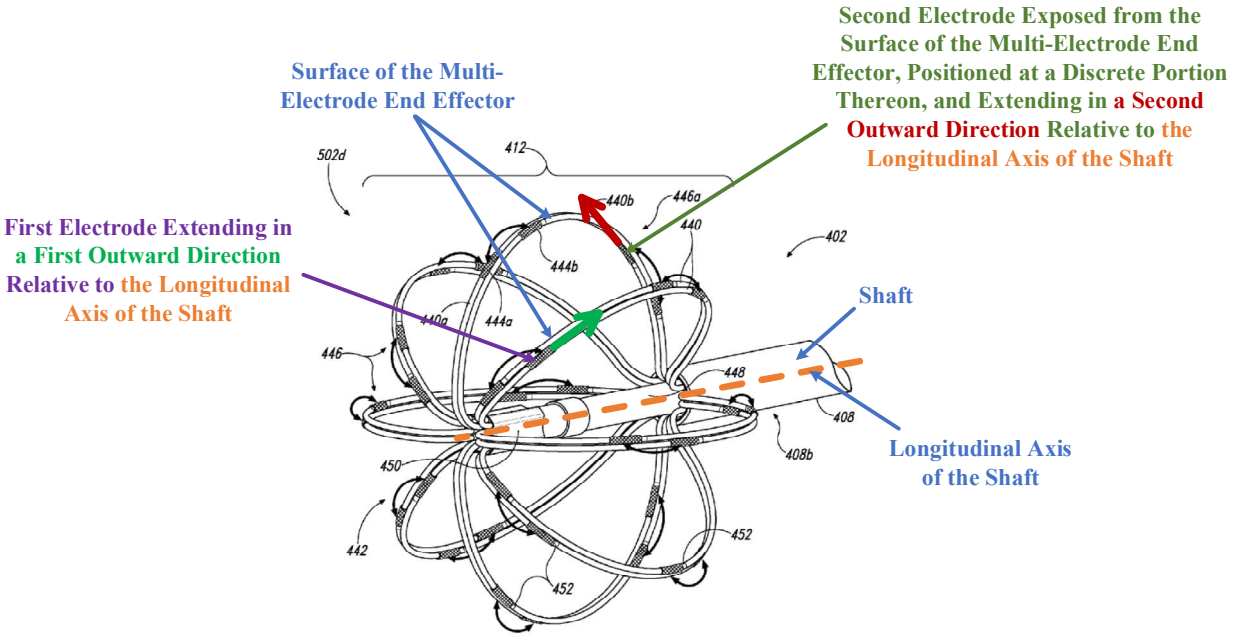



*Fig. 4*

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




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

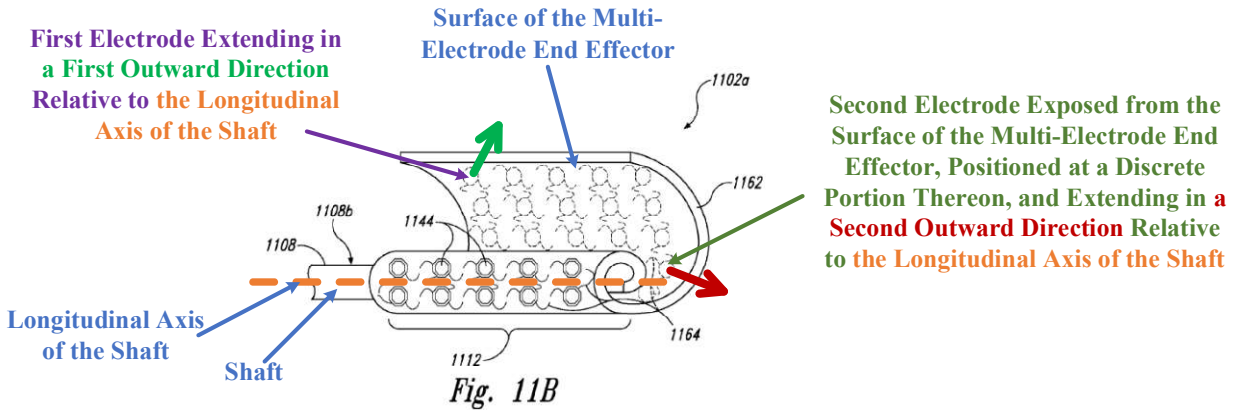



*Fig. 11B*

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

**105.** 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.

**106.** 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.,* [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.

**107.** Additionally, as explained above relative to limitations [1b] and [16b], 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].)

**108.** Thus, Townley discloses limitations [1c] and [16c].

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

**[16d-1] delivering energy, via the first and second electrodes, to one or more target sites within a sino-nasal cavity of the patient**

**109.** Townley discloses limitations [1d-1] and [16d-1].



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**110.** 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].)

**111.** 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.)

**112.** Thus, Townley discloses limitations [1d-1] and [16d-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.**

**[16d-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.**

**113.** Townley teaches and suggests limitations [1d-2] and [16d-2].

**114.** 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."

**115.** 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


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[0030], [0032], [0049], [0055], [0089], [0096], [0141]-[0142].)

**116.** As explained above relating to limitations [1d-1] and [16d-1], Townley discloses that its electrodes deliver energy to provide therapeutic neuromodulation to target sites. 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."


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(*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].)

**117.** 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.

**118.** Thus, Townley teaches and suggests limitations [1d-2] and [16d-2].

**119.** As shown above, Townley discloses, teaches or suggests all limitations

of Claims 1 and 16. Accordingly, Claims 1 and 16 are 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.**

**[Claim 17] The method of claim 16, 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.**

**120.** Claims 2 and 17 refer to "the tissue," yet no prior tissues were discussed in Claims 1 or 16. Thus, I find Claims 2 and 17 ambiguous.

**121.** Assuming "the tissue" of Claims 2 and 17 was meant to refer to a "target" tissue, Townley teaches Claims 2 and 17.

**122.** 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):

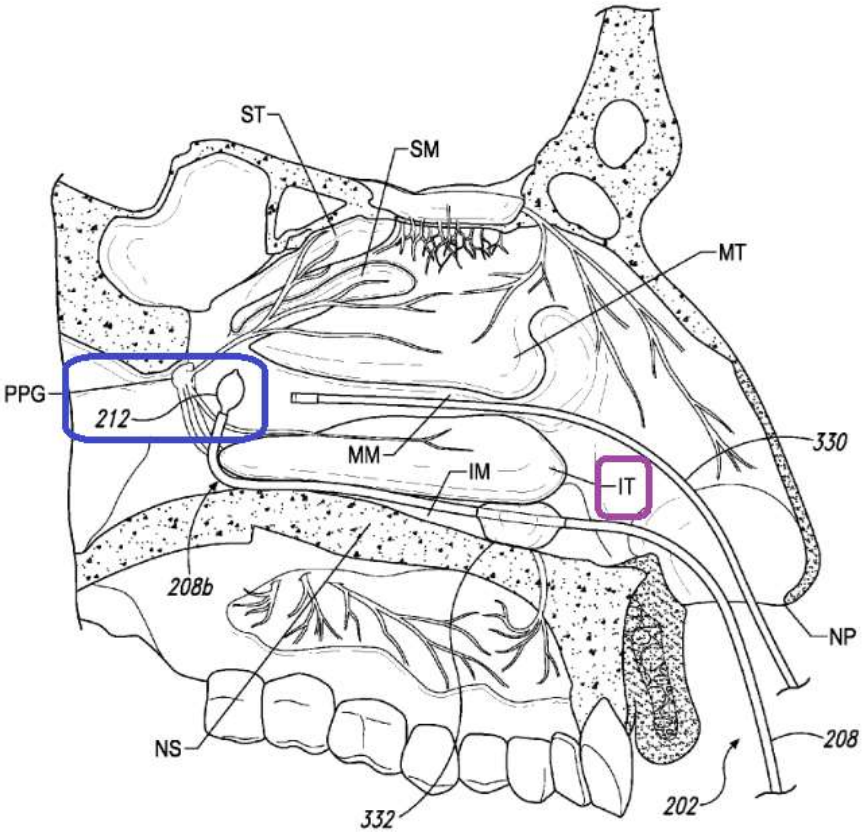


*Fig. 3A*

(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].)

**123.** 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].)

**124.** 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].)

**125.** Further, Figure 1B shows such nerves innervating the inferior turbinate and Townley recommends treating nerves in the ***target region "T"*** of FIG. 1B:

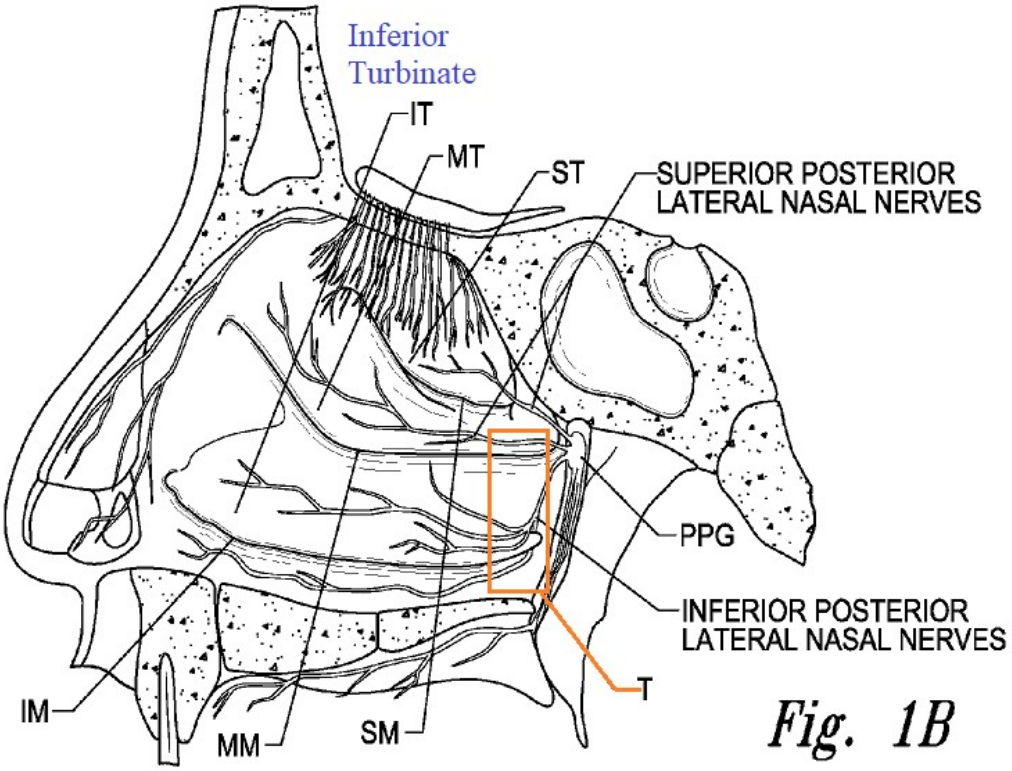


*Fig. 1B*

(*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.

**126.** 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].)

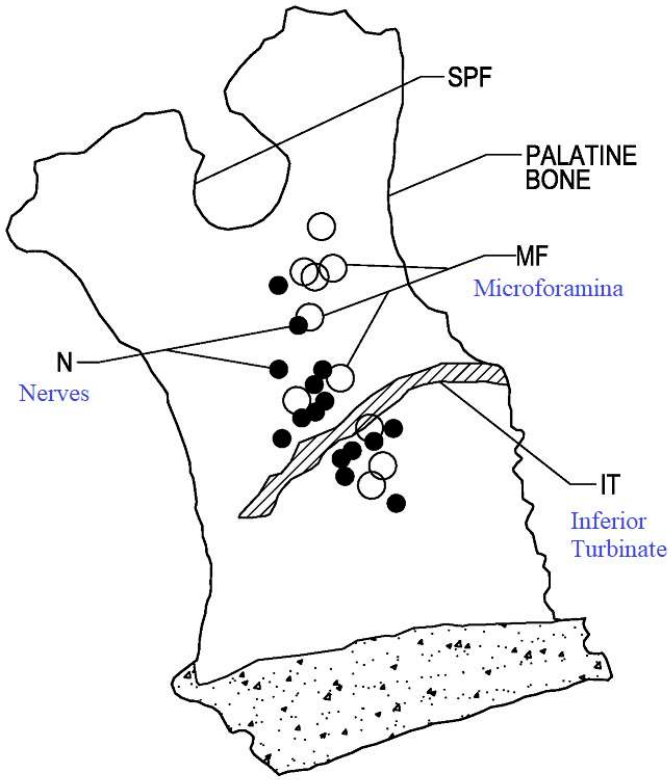


*Fig. 1C*

**127.** 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].)

**128.** Thus, Townley teaches Claims 2 and 17.

**[Claim 3] The method of claim 1, [3a] 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,**

**[Claim 18] The method of claim 16, [18a] 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,**

**129.** Townley discloses limitations [3a] and [18a].

**130.** 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


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> 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.)

**131.** 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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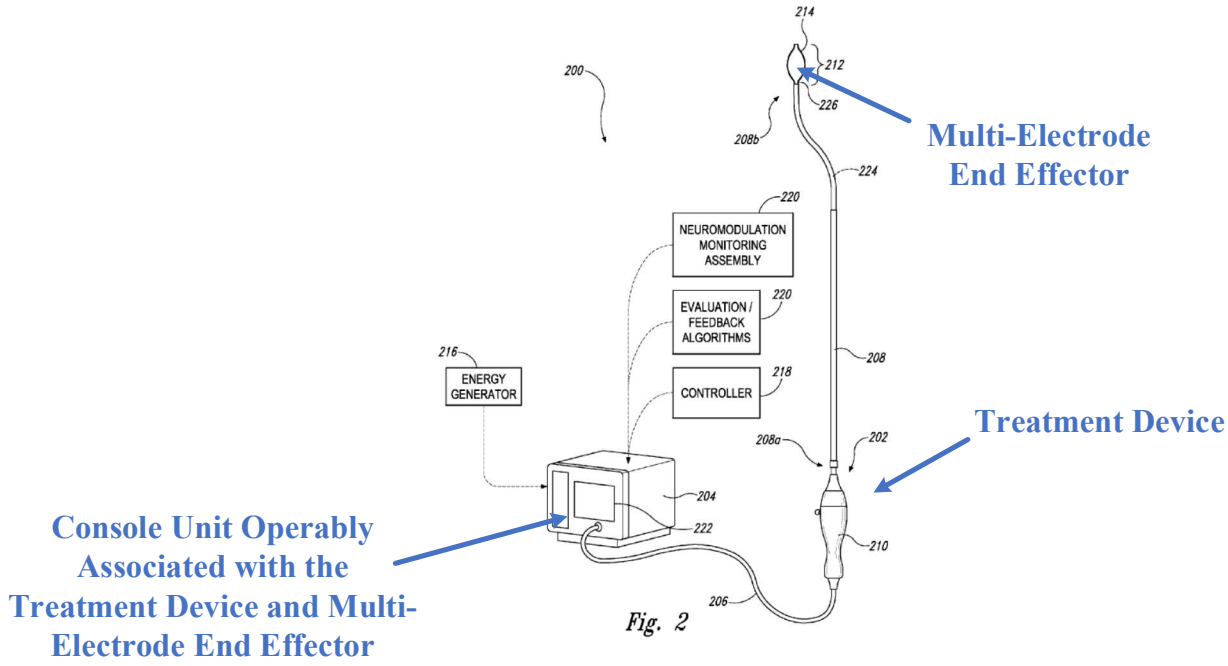


*Fig. 2*

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

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

**133.** Thus, Townley discloses limitations [3a] and [18a].

**[3b] wherein the shaft is a substantially rigid shaft with a hollow cavity, wherein the shaft comprises an outer sheath and hypotube, and wherein the first electrode and second electrode is operably coupled to the console unit via wires disposed in the hollow cavity of the substantially rigid shaft.**

**[18b] wherein the shaft is a substantially rigid shaft with a hollow cavity, wherein the shaft comprises an outer sheath and hypotube, and wherein the first electrode and second electrode is operably coupled to the console unit via wires disposed in the hollow cavity of the substantially rigid shaft.**

**134.** 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].)

**135.** Townley also discloses that the "shaft comprises an outer sheath," a "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].)

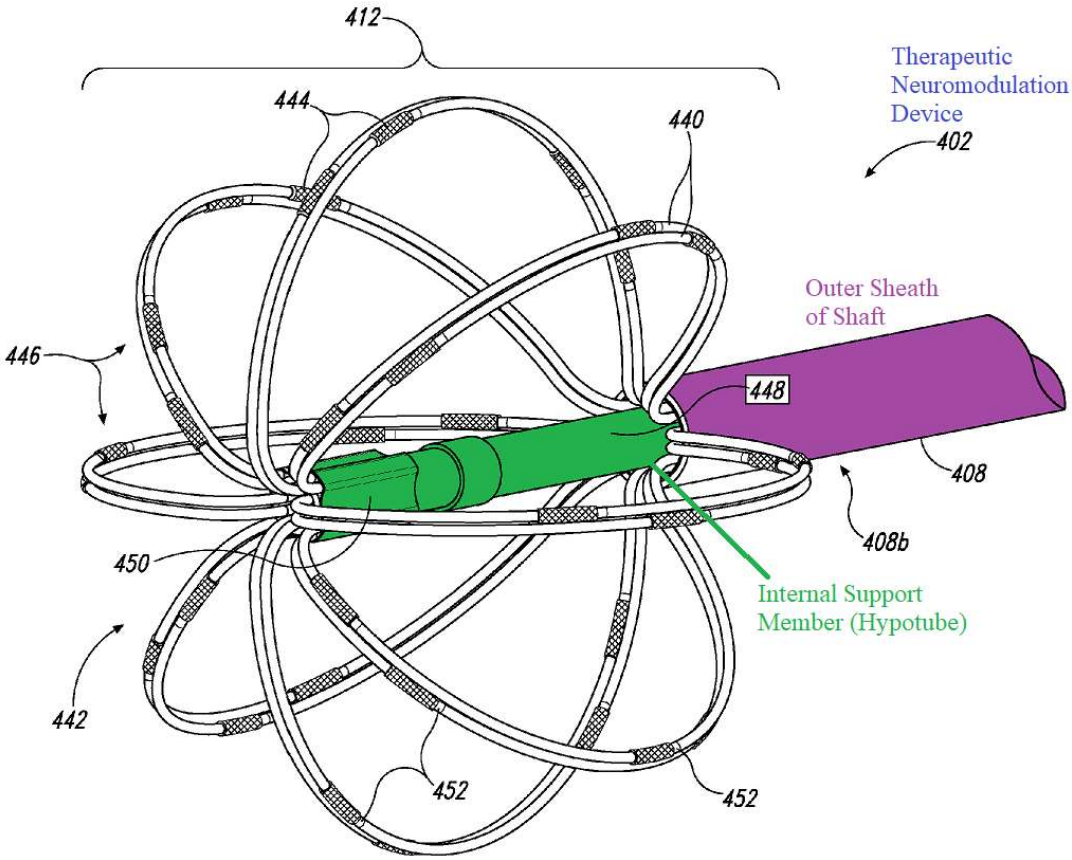


*Fig. 4*

(*Id*. at FIG. 4.)

**136.** 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*.)

**137.** 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].)

**138.** Townley's description of its "internal support member 448" aligns with

the ’973 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.)

**139.** Townley further 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].)

**140.** Thus, Townley discloses limitations [3b] and [18b].

**141.** Accordingly, Townley discloses Claims 3 and 18.

**[Claim 4] The method of claim 3, 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 5] The method of claim 4, wherein the RF energy comprises at least bipolar RF energy.**

**[Claim 19] The method of claim 18, 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 20] The method of claim 19, wherein the RF energy comprises at least bipolar RF energy.**

**142.** Townley discloses Claims 4-5 and 19-20.

**143.** 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


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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].)

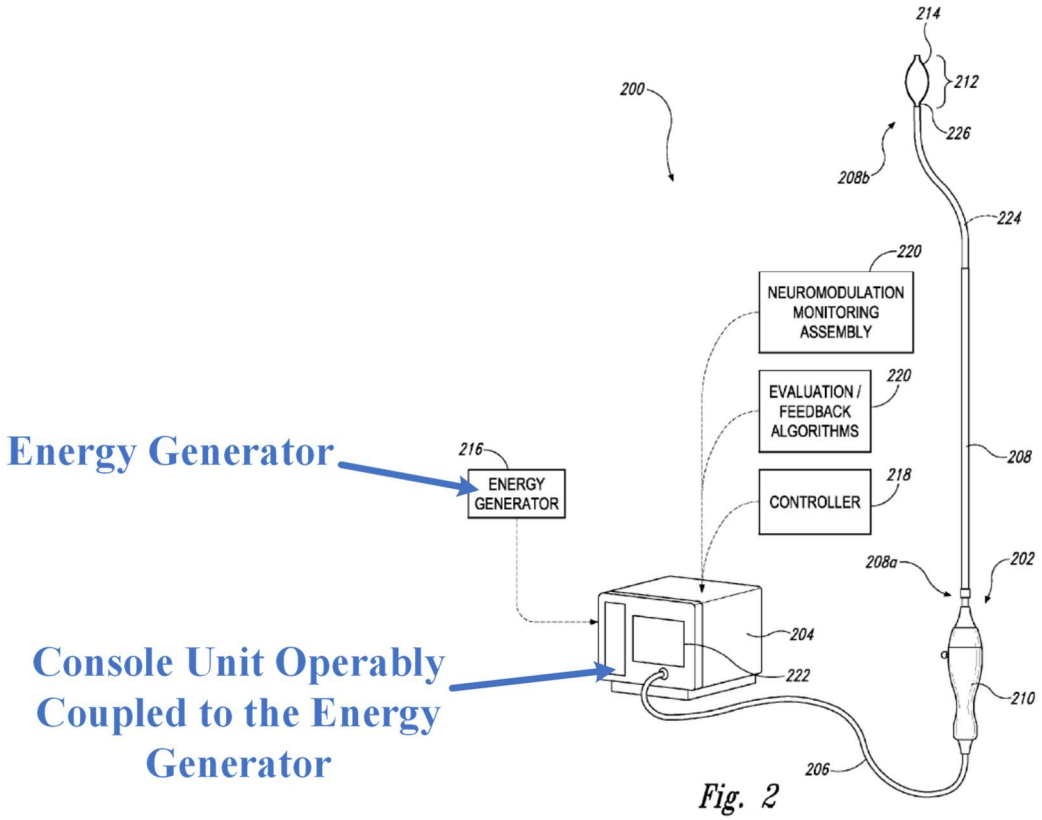


*Fig. 2*

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

**144.** Thus, Townley discloses Claims 4-5 and 19-20.

**[Claim 6] The method of claim 3, [6a] 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**

**[Claim 21] The method of claim 18, [21a] 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**

**145.** Townley discloses limitations [6a] and [21a].

**146.** 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*


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*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].)

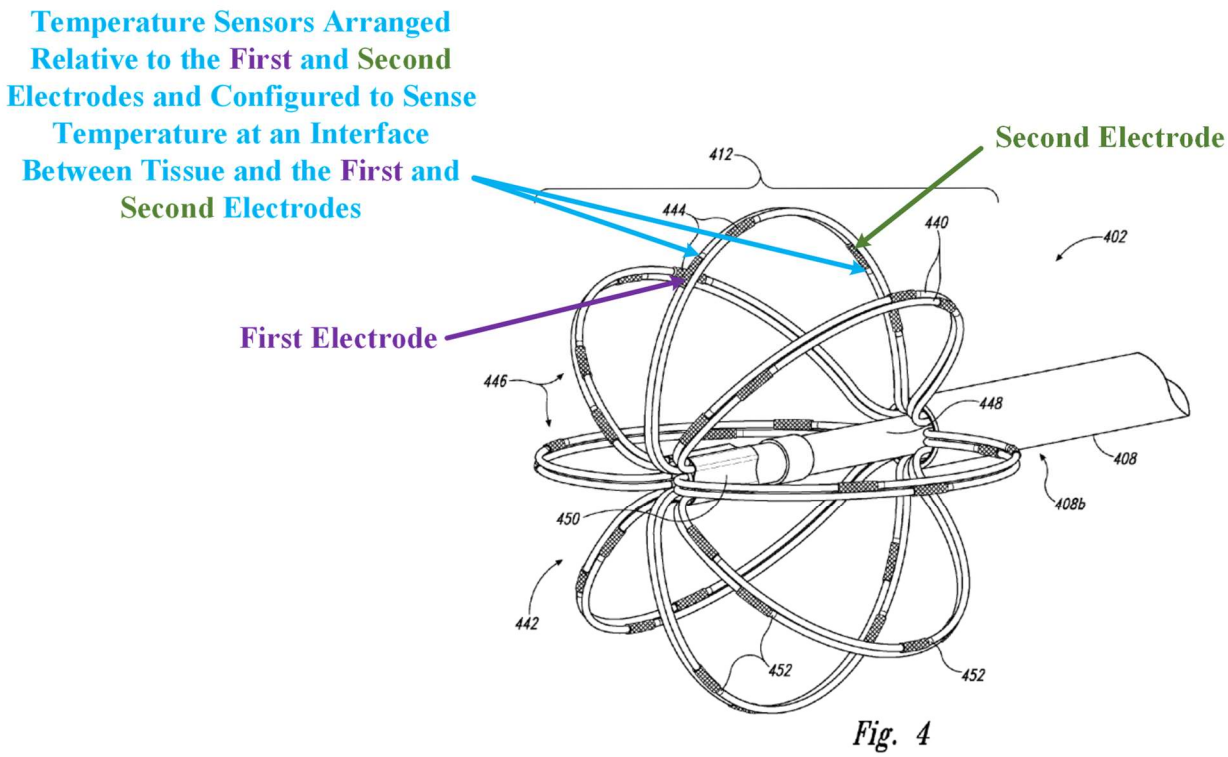


*Fig. 4*

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

**147.** Thus, Townley discloses limitations [6a] and [21a].

**[6b] 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.**

**[21b] 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.**

**148.** Townley teaches and suggests limitations [6b] and [21b].

**149.** 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*


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> *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.)

**150.** 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.)

**151.** 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.

**152.** 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].)

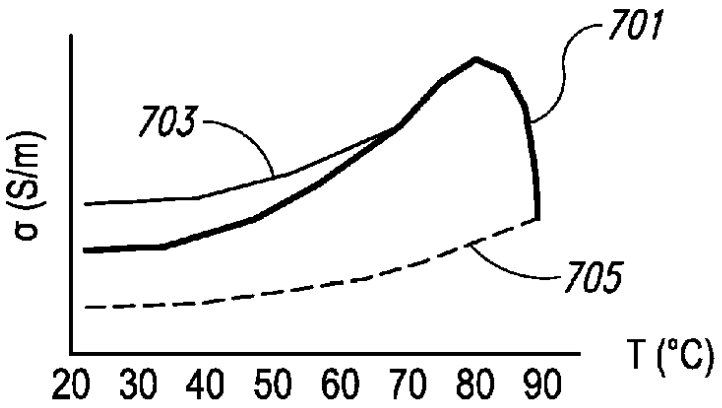


*Fig. 7*

(*Id*. at FIG. 7.)

**153.** 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].)

**154.** 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.*)

**155.** Thus, Townley teaches and suggests limitations [6b] and [21b].

**156.** Accordingly, Townley teaches and suggests Claims 6 and 21.

**[Claim 7] The method of claim 6, 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.**

**[Claim 22] The method of claim 21, 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.**

**157.** Townley discloses Claims 7 and 22.

**158.** As discussed above with respect to Claims 6 and 21, Townley's console unit 204 is configured to receive temperature readings from the temperature sensors 452. (Ex-1004-Townley at [0047], [0074], [0111], [0114].)

**159.** 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°


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> 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].)

**160.** 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].)

**161.** Thus, Townley teaches Claims 7 and 22.

**[Claim 8] The method of claim 7, [8a] 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**

**[Claim 23] The method of claim 22, [23a] 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**

**162.** Townley discloses limitations [8a] and [23a].

**163.** 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].)


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**164.** Thus, Townley discloses limitations [8a] and [23a].

**[8b] and further monitor an elapsed time during delivery of RF energy to tissue at the one or more target sites.**

**[23b] and further monitor an elapsed time during delivery of RF energy to tissue at the one or more target sites.**

**165.** Townley discloses, teaches, and suggests limitations [8b] and [23b].

**166.** 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].)

**167.** 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.

**168.** Thus, Townley discloses, teaches, and suggests limitations [8b] and [23b].

**169.** Accordingly, Townley discloses, teaches, and suggests Claims 8 and 23.


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**[Claim 9] The method of claim 7, 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.**

**[Claim 24] The method of claim 22, 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.**

**170.** Townley teaches and suggests Claims 9 and 24.

**171.** 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


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show that the "predetermined maximum time" has been reached—the predetermined maximum time includes the total elapsed time.

**172.** 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.

**173.** Thus, Townley teaches and suggests Claims 9 and 24.

**[Claim 10] The method of claim 9, wherein the display is a touchscreen monitor.**

**[Claim 25] The method of claim 24, wherein the display is a touchscreen monitor.**

**174.** Townley discloses Claims 10 and 25.

**175.** 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.").)

**176.** Thus, Townley discloses Claims 10 and 25.

**[Claim 11] The method of claim 7, 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.**

**[Claim 26] The method of claim 22, 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.**

**177.** Townley teaches and suggests Claims 11 and 26.

**178.** 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."

**179.** 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].)

**180.** 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]).)

**181.** 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].)

**182.** Thus, Townley teaches Claims 11 and 26.

**[Claim 12] The method of claim 11, wherein the predetermined threshold maximum temperature is less than 90° C.**

**[Claim 13] The method of claim 11, wherein the predetermined threshold maximum temperature is greater than 37° C and less than 90° C.**

**[Claim 27] The method of claim 26, wherein the predetermined threshold maximum temperature is less than 90° C.**

**[Claim 28] The method of claim 26, wherein the predetermined threshold maximum temperature is greater than 37° C and less than 90° C.**

**183.** Townley discloses Claims 12-13 and 27-28.

**184.** 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].)

**185.** Thus, Townley discloses Claims 12-13 and 27-28.

**[Claim 14] The method of claim 11, the predetermined elapsed time period is from about 1 second to about 20 seconds.**

**[Claim 15] The method of claim 14, wherein the predetermined elapsed time period is from about 10 seconds to about 12 seconds.**

**[Claim 29] The method of claim 26, the predetermined elapsed time period is from about 1 second to about 20 seconds.**

**[Claim 30] The method of claim 29, wherein the predetermined elapsed time period is from about 10 seconds to about 12 seconds.**

**186.** Townley discloses Claims 14-15 and 29-30.

**187.** 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].)

**188.** Thus, Townley discloses Claims 14-15 and 29-30.

## B. Ground 2: Claims 1-2 and 16-17 are obvious based on Wolf-003 alone or in view of Wolf-290.

### 1. Summary of Ground 2

**189.** 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

**190.** As I show below, Wolf-003 expressly discloses all limitations of Claims 1 and 16, except Wolf-003 does not expressly state that its systems, devices and methods treat rhinitis, congestion, or rhinorrhea, or that improved nasal breathability would be realized.

**191.** 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 '973 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.)

**192.** As shown, the '973 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


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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."

**193.** 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 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***


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> ***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].)

**194.** 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.

**195.** 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.

**196.** 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].)

**197.** 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).)

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

**199.** 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.)

**200.** 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:**

**[Claim 16, 16-PRE] A method for treating at least one of rhinitis, congestion, and rhinorrhea within a sino-nasal cavity of a patient, the method comprising:**

**201.** Irrespective of whether the preambles are limiting, Wolf-003 alone and in combination with Wolf-290 teaches [1-PRE] and [16-PRE].

**202.** 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].)

**203.** 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].)

**204.** 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,


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congestion, and rhinorrhea "within a sino-nasal cavity of a patient."

**205.** 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-1005-Wolf-003 at [0027]; Ex-1018-Lane at 390, 392; FIGS. 4-5.)

**206.** 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."

**207.** Thus, Wolf-003 alone or in view of Wolf-290 teaches [1-PRE] and [16-PRE].

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

**[16a-1] advancing a multi-electrode end effector into the sino-nasal cavity of the patient**

**208.** Wolf-003 discloses limitations [1a-1] and [16a-1].

**209.** As explained previously, the '973 patent states that "the terms 'end effector' and 'therapeutic assembly' may be used interchangeably." (Ex-1001 at 12:32-34.)

**210.** 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].)

**211.** 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


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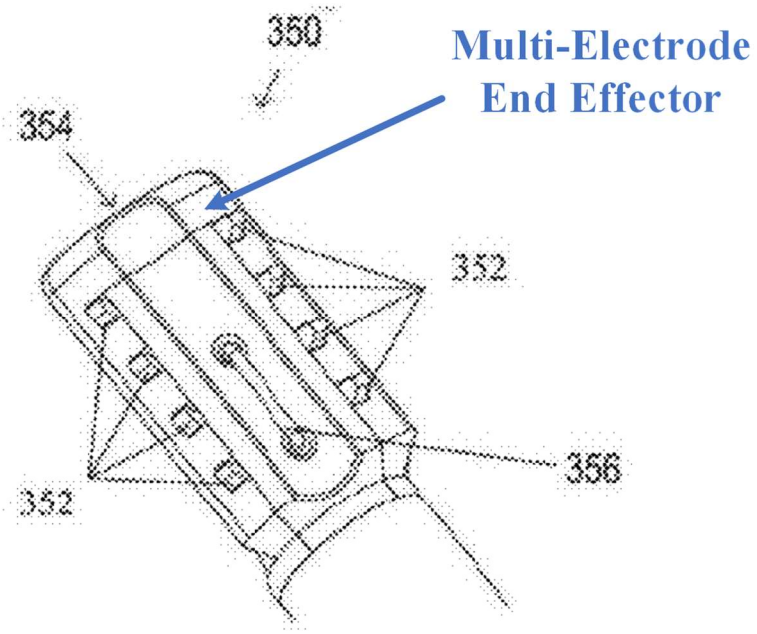
such as the electrodes described above are illustrated in FIGS. 17-19B. The designs described in these embodiments may be used in various devices, for example the device 30, described above.").) As to the device illustrated in Figures 19A-B, Wolf-003 discloses a treatment portion 350 comprising eight 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].)

**212.** 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].)




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

**213.** 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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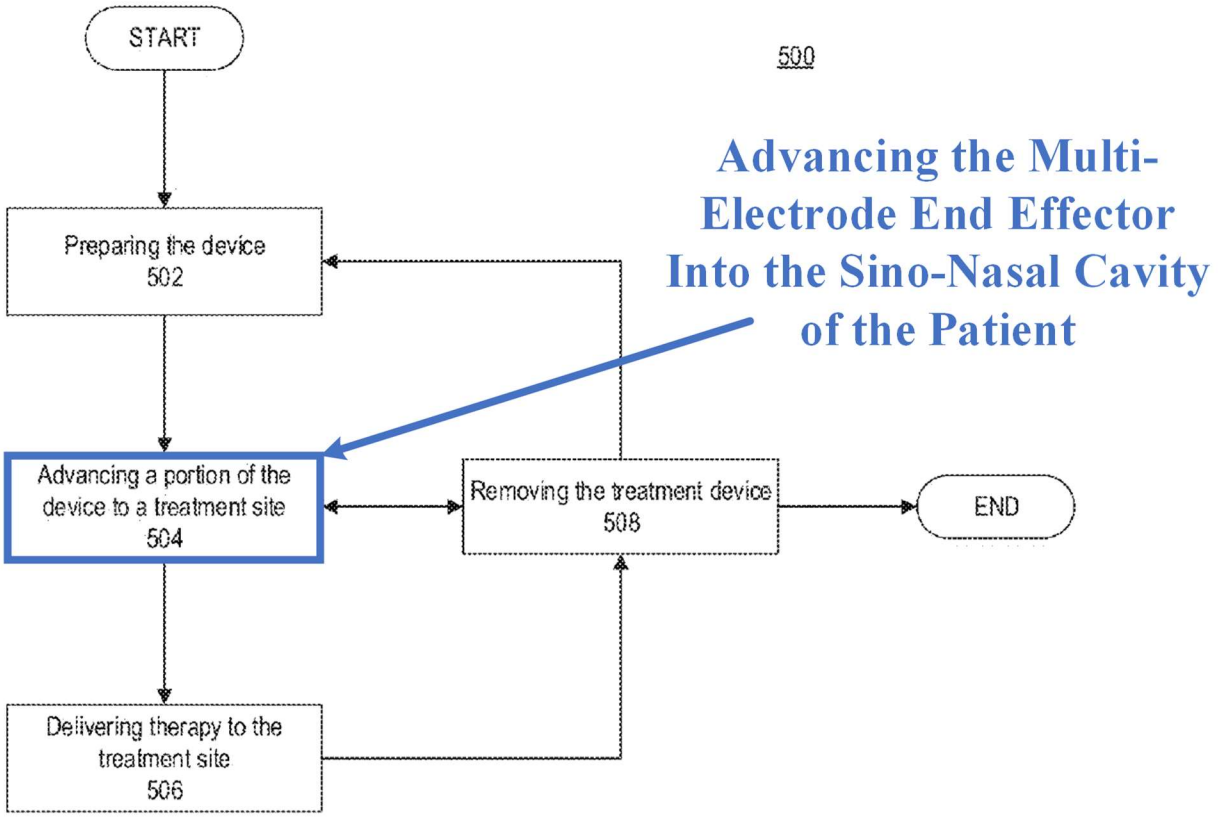



(*Id*. at FIG. 20.)

**214.** Thus, Wolf-003 discloses limitations [1a-1] and [16a-1].

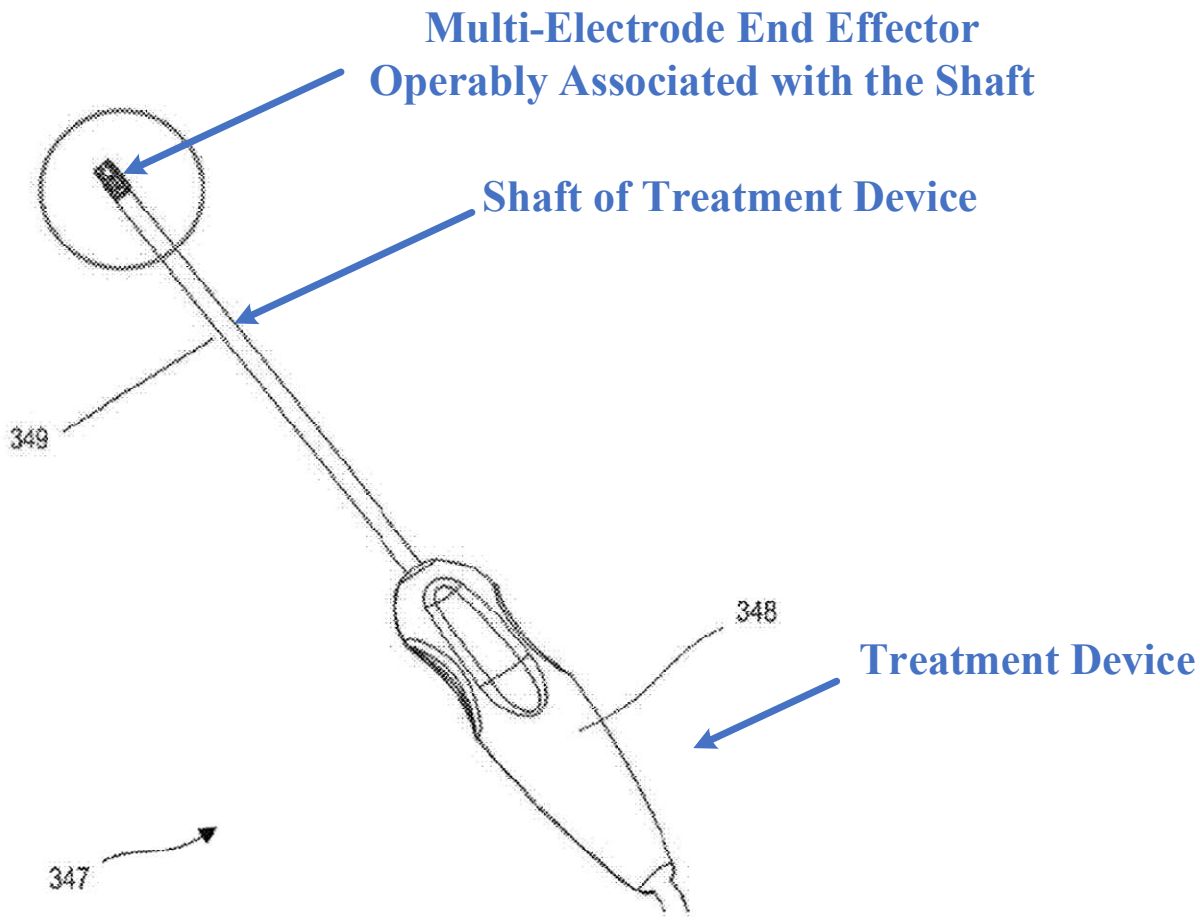
**[1a-2] wherein the multi-electrode end effector is operably associated with a shaft of a treatment device and configured for delivering energy to one or more target sites within the sino-nasal cavity of the patient**

**[16a-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**

**215.** Wolf-003 discloses limitations [1a-2] and [16a-2].

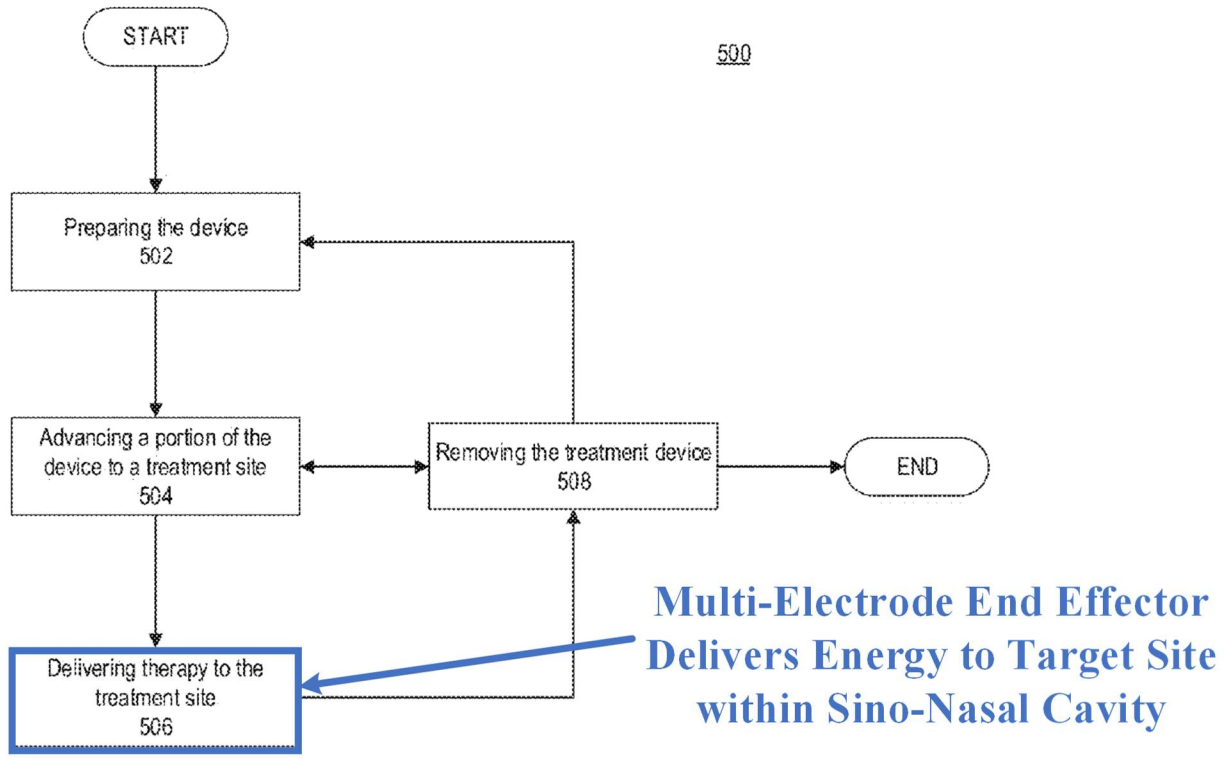
**216.** Wolf-003 discloses that its multi-electrode end effectors (*e.g.*, the multi-electrode end effector 350 of Figures 19A-B) are operably associated with a "shaft" of a treatment device (*e.g.*, shaft 349 of treatment device 347) for advancing

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.)

**217.** 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.)

**218.** Thus, Wolf-003 discloses limitations [1a-2] and [16a-2].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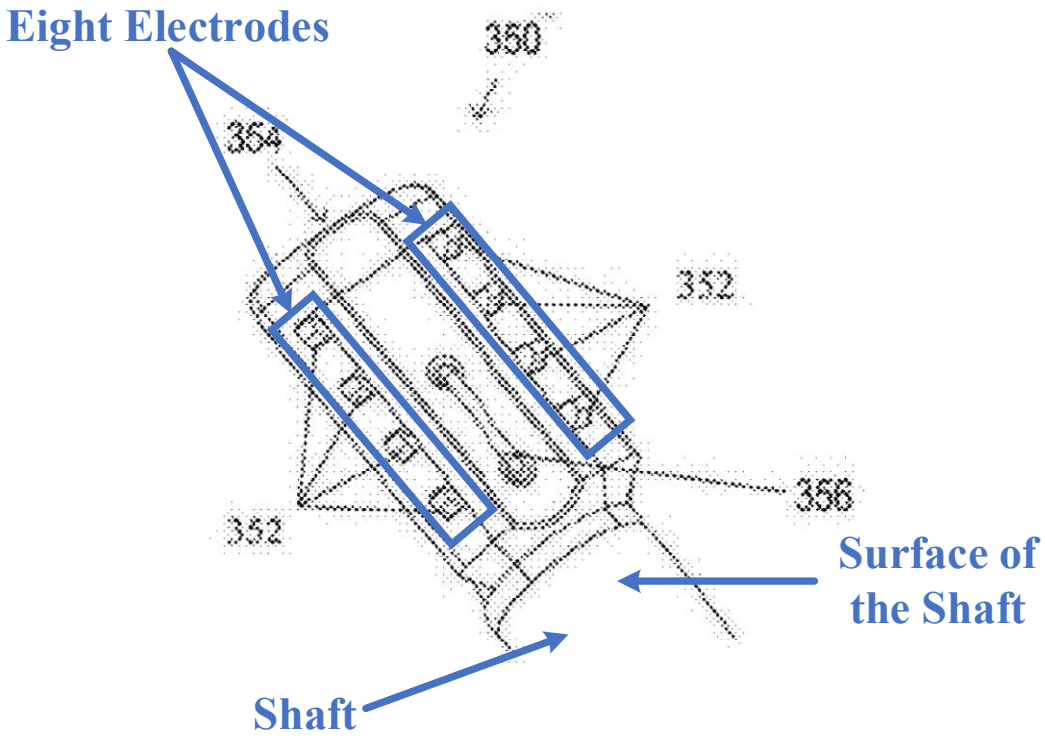
**[1a-3] wherein the multi-electrode end effector comprises a plurality of electrodes, wherein the plurality of electrodes comprises at least six electrodes extend beyond surface of the shaft and are oriented at an angle less than 90 degrees relative to the shaft for the delivery of RF energy**

**[16a-3] wherein the multi-electrode end effector comprising a plurality of electrodes, wherein the plurality of electrodes comprises at least eight electrodes extend beyond surface of the shaft and are oriented at an angle less than 90 degrees relative to the shaft for the delivery of RF energy**

**219.** Wolf-003 discloses limitations [1a-3] and [16a-3].

**220.** Wolf-003's multi-electrode end effectors have electrodes meeting the requirements of limitations [1a-3] and [16a-3]. For example, as shown below, the multi-electrode end effector of Figures 19A-B comprises eight electrodes, wherein the eight electrodes extend beyond the surface of the shaft and are oriented at an angle less than 90 degrees relative to the shaft:




(Ex-1005-Wolf-003 at FIG. 19B; *see also id*. at [0153] ("The electrodes 352 may be recessed from, flush with, and/or ***protrude from*** the treatment portion 350.").)

**221.** As shown above, the eight electrodes 352 extend beyond the surface of the shaft and are oriented at an angle less than 90 degrees relative to the shaft.

**222.** Wolf-003 further 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].)

**223.** As shown above, Wolf-003 teaches that its electrodes 352 may be

oriented in any direction, including at a "non-perpendicular" angle. A "non-perpendicular" angle includes an angle less than 90 degrees relative to the shaft.

**224.** Wolf-003 further discloses that its electrodes are configured to deliver RF energy. (*Id*. 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"); *see also id.* at [0014], [0017], [0024]-[0025], [0082], [0093], [0096]-[0097], [0099], [0117], [0148], [0152], claims 3-4 and 26.)

**225.** Other electrode arrangements of Wolf-003 also meet the requirements of limitations [1a-3] and [16a-3]. (Ex-1005-Wolf-003 at FIGS. 13-14, 26A-F, and 27.)

**226.** Thus, Wolf-003 discloses limitations [1a-3] and [16a-3].

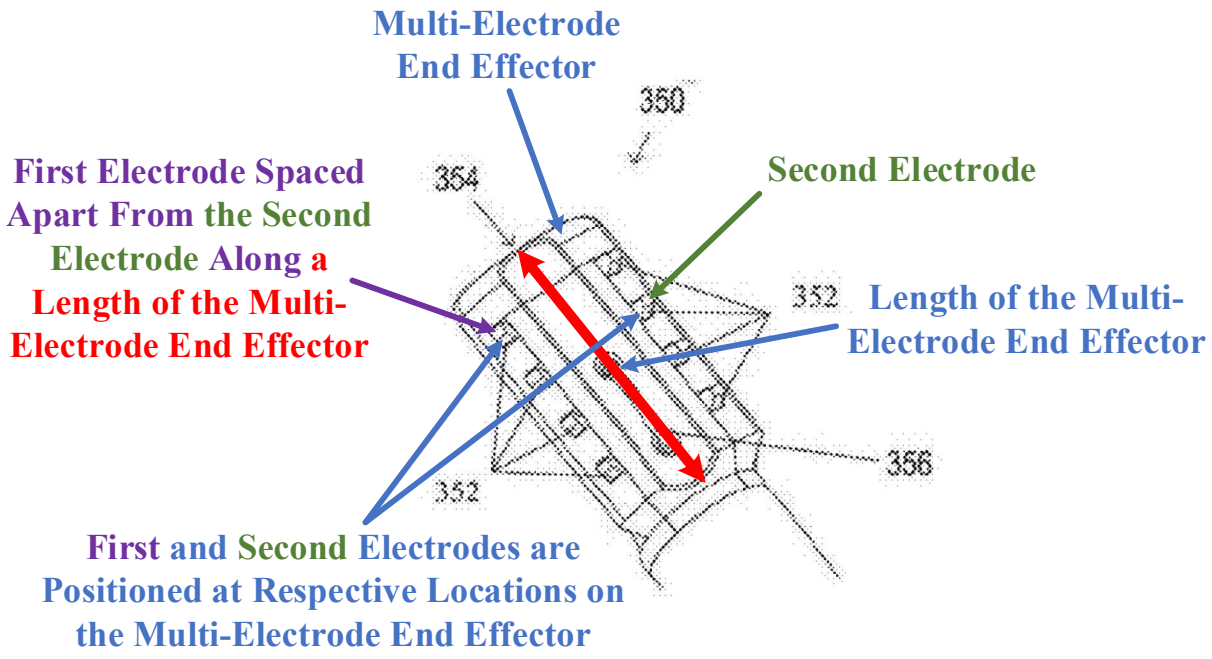
**[1a-4] wherein the at least six electrodes comprise a first electrode spaced apart from a second electrode along a length of the multi-electrode end effector, wherein each of the first and second electrodes comprises an active state and an inactive state and comprises a respective location on the multi-electrode end effector, and wherein:**

**[16a-4] wherein the at least eight electrodes comprise a first electrode 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, and wherein:**

**227.** Wolf-003 discloses limitations [1a-4] and [16a-4].

**228.** Wolf-003 discloses that its multi-electrode end effectors have electrodes that satisfy the requirements of limitations [1a-4] and [16a-4].

**229.** For example, as shown below, the at least eight electrodes of the multi-electrode end effector 350 of Figures 19A-B comprise 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]

**230.** 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).)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> "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].)

**231.** 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].)

**232.** Other electrode arrangements of Wolf-003 also meet the requirements of limitations [1a-4] and [16a-4]. (Ex-1005-Wolf-003 at FIGS. 13-14, 26A-F, and 27.)

**233.** Thus, Wolf-003 discloses limitations [1a-4] and [16a-4].

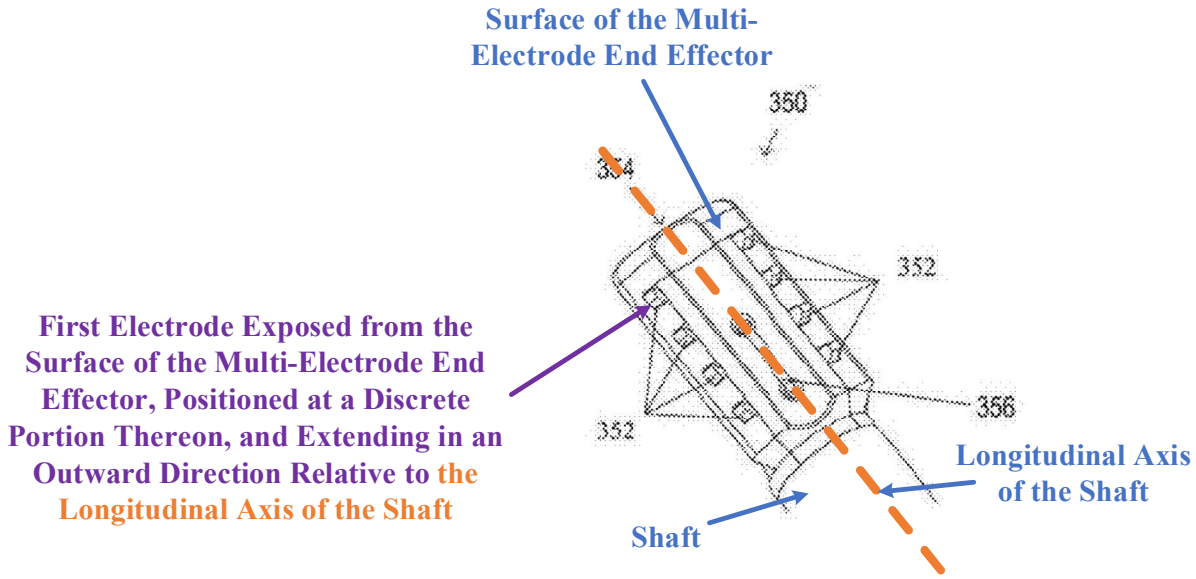
**[1b] the first electrode is exposed from a surface of the multi-electrode end effector and is positioned at a discrete portion thereon, the first electrode extending in a first outward direction relative to a longitudinal axis of the shaft to interact with anatomy at a first location within the nasal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

**[16c] 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**

**234.** Wolf-003 discloses limitations [1b] and [16b].

**235.** 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.)

**236.** 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").)

**237.** 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].)

**238.** Other electrode arrangements of Wolf-003 also meet the requirements of limitations [1b] and [16b]. (Ex-1005-Wolf-003 at FIGS. 13-14, 26A-F, and 27.)

**239.** Thus, Wolf-003 discloses limitations [1b] and [16b].

**[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**

**[16c] 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**

**240.** Limitations [1c] and [16c] are generally the same as limitations [1b] and [16b], respectively, except a second electrode is recited.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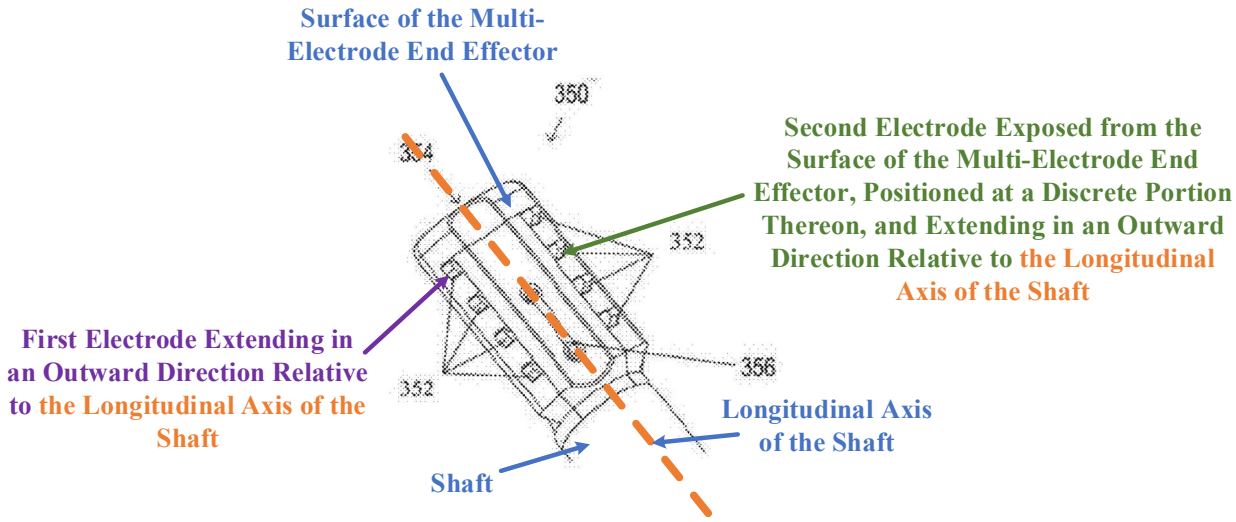
**241.** Wolf-003 discloses that its multi-electrode end effectors comprise a second electrode that: (i) is exposed from a surface of the multi-electrode end effector; (ii) is positioned at a discrete portion thereon; and (iii) extends in a second outward direction relative to a longitudinal axis of the shaft. (Ex-1005-Wolf-003 at FIGS. 13-14, 19A-B, 26A-F, and 27.)

**242.** 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].)

**243.** 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.

**244.** 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].)

**245.** Other electrode arrangements of Wolf-003 also meet the requirements of limitations [1c] and [16c]. (Ex-1005-Wolf-003 at FIGS. 13-14, 26A-F, and 27.)

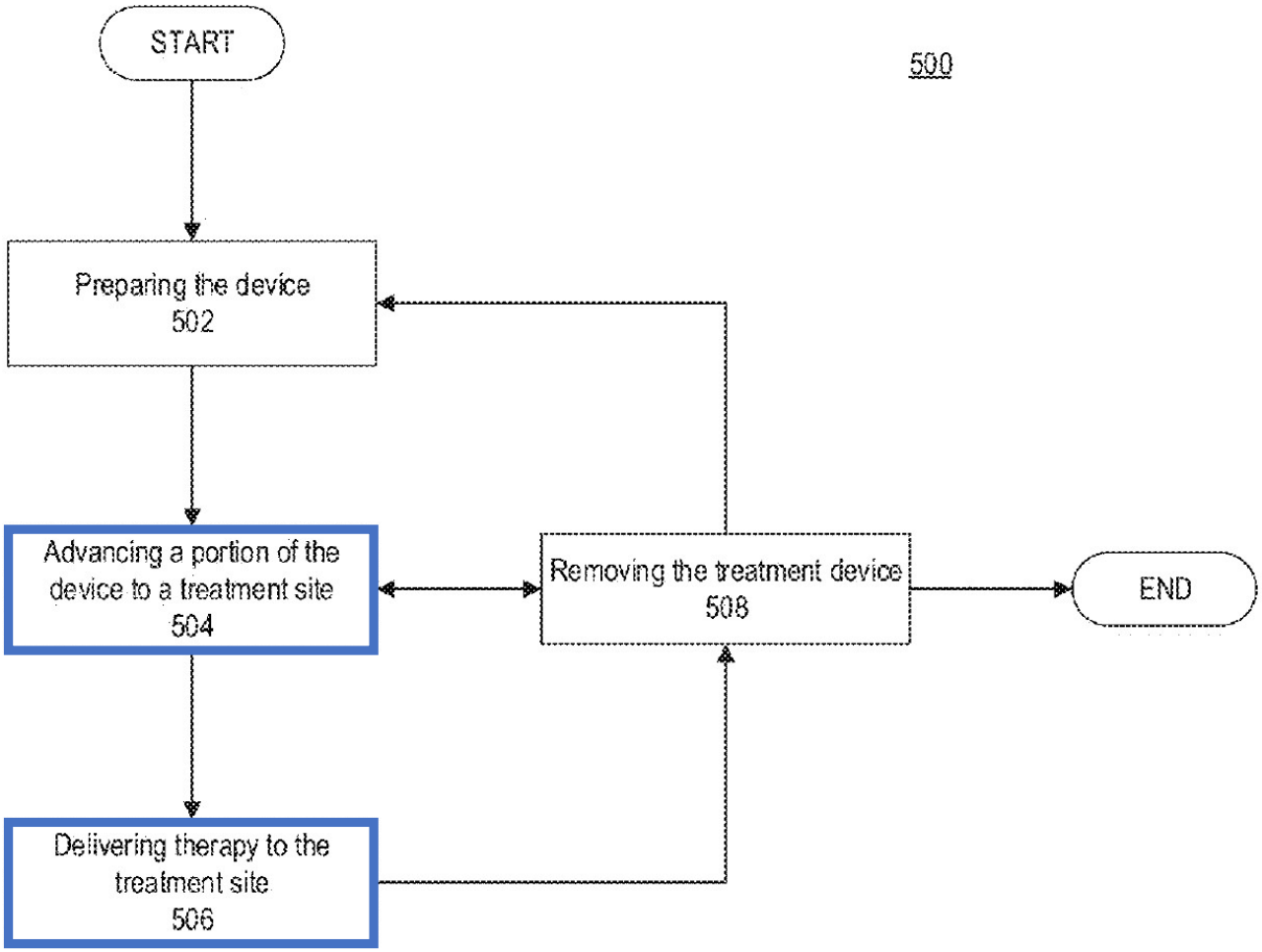
**246.** Thus, Wolf-003 discloses limitations [1c] and [16c].

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

**[16d-1] delivering energy, via the first and second electrodes, to one or more target sites within a sino-nasal cavity of the patient**

**247.** Wolf-003 discloses limitations [1d-1] and [16d-1].

**248.** Figure 20 of Wolf-003 (below) is a flow diagram of an example method of use of various devices, 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].)

**249.** Thus, Wolf-003 discloses limitations [1d-1] and [16d-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.**

**[16d-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.**

**250.** Wolf-003 alone and in combination with Wolf-290 teaches and suggests limitations [1d-2] and [16d-2].

**251.** 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.)

**252.** 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

[8] Ablation destroys target tissue. (Ex-1001 at 56:56-65 (disclosing that ablation leads to "necrosis").)

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 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.

**253.** 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).)

**254.** 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,

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

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, 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.)

**255.** 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, 1:19-24, 1:37-41, 4:65-67, 5:48-52, 8:32-35, 9:60-64 (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.

**256.** Thus, Wolf-003 alone teaches or suggests limitations [1d-2] and [16d-2].

**257.** Additionally, limitations [1d-2] and [16d-2] would have been obvious in view of Wolf-290. Wolf-290 discloses the application of energy, including ablative energy, 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].)

**258.** Thus, Wolf-003 in combination with Wolf-290 also teaches and suggests limitations [1d-2] and [16d-2].

**259.** As shown above, Wolf-003 alone or in view of Wolf-290 discloses, teaches, or suggests all limitations of Claims 1 and 16.

**[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.**

**[Claim 17] The method of claim 16, 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.**

**260.** As I explained in Ground 1, Claims 2 and 17 refer to "the tissue," yet no "tissue" is recited in Claims 1 or 16. Thus, I find Claims 2 and 17 ambiguous. Nonetheless, assuming "the tissue" of Claims 2 and 17 was meant to refer to a "target" tissue, Wolf-003 discloses Claims 2 and 17.

**261.** 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.)

**262.** Accordingly, Wolf-003 discloses Claims 2 and 17.

## X. CONCLUSION

**263.** 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 25, 2025

Daniel van der Weide