UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AERIN MEDICAL INC.
Petitioner

v.

NEURENT MEDICAL LTD.
Patent Owner.

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

Case No.: IPR2025-01126

PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1-30 OF U.S. PATENT 12,096,973 UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. §§ 42.100 ET SEQ.

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CLAIMS LISTING

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

[1d-1] delivering energy, via the first and second electrodes, to one or more target sites within a sino-nasal cavity of the patient
[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.
[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 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,
[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.
[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 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,
[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.
[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 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
[8b] and further monitor an elapsed time during delivery of RF energy to tissue at the one or more target sites.
[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 10] The method of claim 9, wherein the display is a touchscreen monitor.
[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 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 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 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:
[16a-1] advancing a multi-electrode end effector into 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,
[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,
[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:
[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; and
[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; and
[16d-1] delivering energy, via the first and second electrodes, to one or more target sites within a sino-nasal cavity 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.
[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.
[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,
[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.
[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.
[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,
[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.
[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.
[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
[23b] and further monitor 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.
[Claim 25] The method of claim 24, wherein the display is a touchscreen monitor.
[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.
[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.
[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.

I. INTRODUCTION

Aerin Medical Inc. ("Aerin" or "Petitioner") hereby seeks *inter partes* review and cancellation of claims 1-30 ("the Challenged Claims") of U.S. Patent No. 12,096,973 ("the '973 patent").

II. MANDATORY NOTICES UNDER 37 C.F.R. §42.8

A. Real Party-in-Interest Under 37 C.F.R. §42.8(b)(1)

The real party-in-interest is Aerin Medical Inc.

B. Related Matters Under 37 C.F.R. §42.8(b)(2)

The following pending federal district court litigation may affect or be affected by a decision in this proceeding:

- *Aerin Medical Inc. et al. v. Neurent Medical Inc. et al.*, Case No. 23-cv-756 (D. Del.) ("the Litigation").

Petitioner further notes that it has filed, or intends to file, *inter partes* reviews against the following additional patents owned by Neurent Medical Ltd. ("Neurent" or "Patent Owner"), which patents are also the subject of the Litigation:

- IPR2025-01124 challenging U.S. Patent No. 11,998,262;
- IPR2025-01125 challenging U.S. Patent No. 12,089,889; and
- IPR2025-01127 challenging U.S. Patent No. 12,096,974.

The undersigned is unaware of any other judicial or administrative matter that would affect, or be affected by, a decision in this proceeding. However, Petitioner notes that several of its patents are the subject of pending *inter partes* review

proceedings filed by Patent Owner (Neurent Medical Ltd.), which matters are listed below. As of the filing of this Petition, final written decisions had not yet issued in those proceedings.

AIA Review #	U.S. Patent No.
IPR2024-00277	11,241,271
IPR2024-00278	11,033,318
IPR2024-00279	10,610,675
IPR2024-00280	10,894,011
IPR2024-00282	11,766,286
IPR2024-00669	11,679,077

C. Lead and Back-up Counsel Under 37 C.F.R. §42.8(b)(3) and Service Information under 37 C.F.R. §42.8(b)(4)

Petitioner designates the following lead and backup counsel:

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Service on Petitioner may be made by mail or hand delivery to: Greenberg Traurig, LLP, 1144 15th St., Suite 3300, Denver, CO 80202. Petitioner consents to and prefers electronic service by emailing AerinMed-IPRs@gtlaw.com and counsel of record (shown above).

III. CERTIFICATION OF WORD COUNT UNDER 37 C.F.R. §42.24(d)

Petitioner certifies that the word count in this Petition is 9,546 words, as counted by the word-processing program (Microsoft Word for Microsoft 365) used to generate this Petition, where such word count excludes the claims listing, table of contents, mandatory notices, certificate of service, appendix of exhibits, and this certificate of word count. This Petition is in compliance with the 14,000 word limit set forth in 37 C.F.R. §42.24(a)(1)(i).

IV. STIPULATION

Aerin hereby stipulates that if the PTAB institutes trial in this IPR (2025-01126), Aerin agrees not to pursue any grounds raised in this petition, or any grounds Aerin could have reasonably raised in this petition, in the Litigation or any parallel

proceeding. *Sotera Wireless, Inc. v. Masimo Corp.*, Case IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020). For the sake of clarity and to avoid any doubt, if the PTAB declines to institute IPR2025-01126, Aerin reserves the right to assert any grounds of invalidity in the Litigation against the '973 patent.

V. GROUNDS FOR STANDING UNDER 37 C.F.R. §42.104

Petitioner certifies that the '973 patent is available for IPR and Petitioner is not barred/estopped from requesting cancellation of the Challenged Claims per the below Grounds:

Ground	'973 Patent Claims	Basis
Ground 1	1-30	Obvious in view of Townley (Ex-1004)
Ground 2	1-2 and 16-17	Obvious in view of Wolf-003 (Ex-1005) alone or in view of Wolf-290 (Ex-1006)

Because the '973 patent is an AIA patent granted September 24, 2024, the '973 patent was not IPR eligible until June 25, 2025. *See* 35 U.S.C. § 311(c)(1) ("A petition for inter partes review shall be filed after … the date that is 9 months after the grant of a patent…").

VI. OVERVIEW OF THE '973 PATENT

A. The '973 Patent and the Challenged Claims

The '973 patent 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, Abstract.) The '973 patent discloses and illustrates a "neuromodulation device 102":

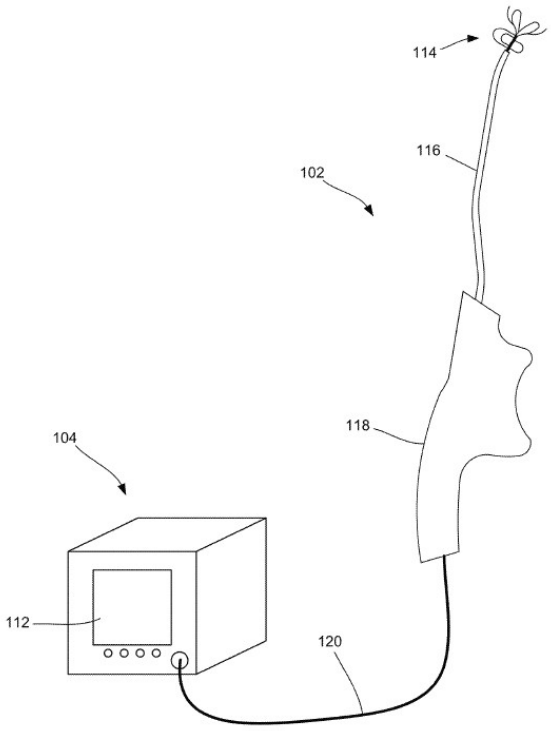


FIG. 2

(*Id*., FIG. 2.)

The neuromodulation device includes "a retractable and expandable multi-segment end effector 114, a shaft 116 operably associated with the end effector 114

and a handle 118." (*Id.,* 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.,* 12:28-32.) "Once 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.,* 29:7-12.)

B. Priority Date

The alleged priority date of the '973 patent is April 9, 2020. (Ex-1001, [60].) Petitioner applies this date without conceding the '973 patent is so entitled.

C. Prosecution History

The '973 patent is an expedited (Track One) continuation application of U.S. Patent Nos. 11,883,091 ("the '091 patent") and 11,998,262 ("the '262 patent"). (Ex-1001, [63]; Ex-1002, 163.) Prosecution of the '973 patent was minimal. A first action allowance was issued approximately three months after the '973 patent was filed. (Ex-1002, 15.) The Notice of Allowance states "the prior art does not teach" the body of claim 1, reproduced *verbatim*. (*Id.,* 20-21.) The Notice of Allowance further states that the "most pertinent piece of prior art, [the '262 patent] no longer constitutes as prior art given the [filed] terminal disclaimer…." (*Id.,* 21.)

The Notice of Allowance shows the Examiner did not meaningfully consider the prior art. Had the Examiner meaningfully considered the prior art, including how the claims of the '973 patent had been broadened relative to the claims of the '091 patent, the '973 patent would not have been allowed.

Specifically, the '091 patent was allowed in view of ***numerous*** limitations that are ***not*** present in the '973 patent. (Ex-1009, 20 (explaining allowance due to, *inter alia*, "flexible support elements," and a second array of electrodes that (a) extend "substantially opposite the first outward direction," and (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."); Ex-1003-Weide, ¶¶37-38.) The '973 patent also changed, *inter alia*, the language "multi-***segment*** end effector" (as per the '091 patent) to "multi-***electrode*** end effector." (*Compare* Ex-1008, claim 1 *to* Ex-1001, claim 1.)

Neurent's purpose in filing a Track One (expedited) application seeking broader claims was (apparently) to allow Neurent to file a patent infringement counterclaim in the Litigation relative to Aerin's highly successful RhinAer® device, even though the RhinAer® device had been sold, and was in public use, prior to the '973 patent. (Ex-1023, 6-11.) The broadened claims, however, read on multiple prior art devices, including the inventor's own device he described in 2016

(Ex-1004-Townley), and the devices described by Aerin in patents and publications that predate the '973 patent (Exs. 1005-1006).

D. Person of Ordinary Skill in the Art ("POSITA")

A POSITA 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. (Ex-1003-Weide, ¶63.)

E. Claim Construction

Petitioner does not believe any specific constructions are required at this time, and, therefore, applies the plain and ordinary meanings ("plain meanings") to the Challenged Claims. Petitioner reserves the right to propose specific constructions if appropriate/necessary during these proceedings. However, Petitioner's application of the prior art herein does not indicate Petitioner agrees the '973 patent is compliant with 35 U.S.C. § 112. The '973 patent's claims may lack written description support and/or be indefinite, among other things.

VII. OVERVIEW OF THE PRIOR ART

A. Technical Background

Prior to the '973 patent, the anatomy of the nose was well known. (Ex-1003-Weide, ¶¶40-41; Ex-1018-Lane, FIGS. 1-3, p.388; Ex-1004-Townley, [0033]-[0041], FIGS. 1A-1C.) Further, by at least 2006, diagnosing and treating

rhinosinusitis was also well known. (Ex-1003-Weide, ¶¶42-43.) Rhinosinusitis includes conditions such as chronic rhinitis, and its symptoms include nasal blockage, obstruction, congestion, nasal discharge (*e.g.*, rhinorrhea and/or posterior nasal drip). (*Id.*; Ex-1004-Townley, [0003].) Severe rhinosinusitis can lead to exacerbation of coexisting asthma, *sleep disturbances*, and impairment of daily activities. (Ex-1004-Townley, [0004].) Thus, treating rhinosinusitis was known to improve sleep. (*Id.*; Ex-1006-Wolf-290, [0043]; Ex-1019, [0004]; Ex-1020, [0003]; Ex-1024, 1:29-41.)

It was further known that rhinosinusitis can be treated by delivering energy to remove obstructions or blockages within the nasal cavity and/or by targeting tissues and/or nerves that cause excess mucus production. (Ex-1003-Weide, ¶¶44-47; Ex-1005-Wolf-003, [0003], [0014], [0016], [0022]; Ex-1006-Wolf-290, [0009], [0012]; Ex-1004-Townley, [0002], [0030], [0032], [0038], [0043], [0055], [0058].) Indeed, prior to 2020, the art was replete with disclosures of selective application of radiofrequency energy within the nose to treat various conditions, such as chronic rhinitis and congestion, including a 2016 disclosure by the inventor (David Townley) and various pre-2020 disclosures by Aerin.

B. Townley (Ex-1004-Townley)

Townley is US2016/0331459, is the inventor's own prior work, and is §102(a)(1) prior art. Townley discloses therapeutic assemblies designed to treat

symptoms associated with rhinosinusitis. (Ex-1004-Townley, [0058].) The therapeutic assemblies may include multiple radiofrequency electrodes to accomplish the treatment. (*Id.,* [0066].)

Townley is analogous to the '973 patent as it discloses minimally invasive systems, devices and methods for treating conditions associated with rhinosinusitis. (Ex-1003-Weide, ¶50.)

C. Wolf-003 (Ex-1005-Wolf-003)

Wolf-003 is US2015/0202003 owned by Aerin and is §102(a)(1) prior art.

Wolf-003 discloses energy-based treatment devices for use in a nostril of a patient. (Ex-1005-Wolf-003, [0023].) Wolf-003's device may comprise a plurality of radiofrequency electrodes. (*Id.,* FIGS. 13-14, [0148].)

Wolf-003 is analogous to the '973 patent as it discloses minimally invasive systems, devices and methods for treating conditions associated with rhinosinusitis. (Ex-1003-Weide, ¶56.)

D. Wolf-290 (Ex-1006-Wolf-290)

Wolf-290 is US2019/0282290 owned by Aerin and is §102(a)(1) prior art.

Wolf-290 discloses systems and methods used to treat "any of a large number of airway-related conditions, such as chronic rhinitis, snoring, sleep disordered breathing, perceived nasal congestion and poor quality of life, by treating structures within the nose that form the passageways for airflow." (Ex-1006-Wolf-290,

[0043].) Wolf-290's treatments may "improve breathing." (*Id.,* [0009]; Ex-1003-Weide, ¶62.)

Wolf-290 is analogous to the '973 patent as it discloses minimally invasive systems, devices and methods for treating conditions associated with rhinosinusitis. (Ex-1003-Weide, ¶60.)

VIII. SPECIFIC GROUNDS FOR PETITION

The '973 patent contains 30 claims, of which Claims 1 and 16 are independent. (Ex-1001, 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.*, 59:15-16, 60:63-64.) Dependent claims 17-30 mirror dependent claims 2-15. (*Id.*, 59:48-60:53, 61:29-62:51.) Thus, Petitioner addresses both claim sets together across Grounds 1 and 2.

A. GROUND 1: Townley Renders Obvious Claims 1-30.

1. Scope and Content

Ground 1 relies on Townley, which is the inventor's own prior work. As shown below, Townley expressly discloses nearly all limitations of Claims 1 and 16. Townley discloses that 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, [0042].) Although

Townley does not specifically state that treating rhinosinusitis conditions or symptoms (*e.g.*, rhinitis, congestion, and/or rhinorrhea) improves a patient's nasal breathability, a POSITA would have found it obvious that Townley's treatments, which indisputably treat conditions and symptoms of rhinosinusitis, would improve a patient's nasal breathability. (Ex-1003-Weide, ¶70.) Accordingly, Townley renders obvious Claims 1 and 16. Townley also discloses, teaches, or suggests Claims 2-15 and 17-30, likewise rendering those claims obvious.

2. The Challenged Claims

[Claims 1 and 16, 1-PRE and 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

Townley discloses the preambles of Claims 1 and 16 irrespective of whether they are limiting.

Townley discloses methods of treating rhinitis, congestion, and/or rhinorrhea (hereinafter "RCR") within a patient's sino-nasal cavity. (Ex-1003-Weide, ¶¶72, 74; Ex-1004-Townley, [0002], [0041], [0058].)[1]

Thus, Townley discloses limitations [1-PRE] and [16-PRE]. (Ex-1003-Weide, ¶75.)

[1] Claims 1-2 and 16-17 recite "the nasal cavity" in places, which confirms "the sino-nasal cavity" includes the nasal cavity. (Ex-1003-Weide, ¶73.)

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

The '973 patent states that "the terms 'end effector' and 'therapeutic assembly' may be used interchangeably." (Ex-1001, 12:32-34.) Townley's multi-electrode therapeutic assemblies (described below) disclose the claimed multi-electrode end effector ("MEEE"). (Ex-1003-Weide, ¶¶77-78.)

Townley discloses many multiple-electrode therapeutic assemblies, *i.e.*, MEEEs. (Ex-1003-Weide, ¶79.) For example, Townley discloses a therapeutic neuromodulation system 200 including a therapeutic neuromodulation catheter/device 202 having a therapeutic assembly 212. (Ex-1004-Townley, FIG. 2, [0042].) "[T]he therapeutic assembly 212 includes at least one energy delivery element 214 configured to provide therapeutic neuromodulation to the target site." (*Id.,* [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.,* [0043].) Target sites may include one or more locations within the nasal cavity, such as "proximate to postganglionic parasympathetic nerves that innervate the nasal mucosa." (*Id.,* [0042].) Townley discloses additional MEEEs in Figures 4, 5A-G, and 11A-D. (Ex-1003-Weide, ¶80.)

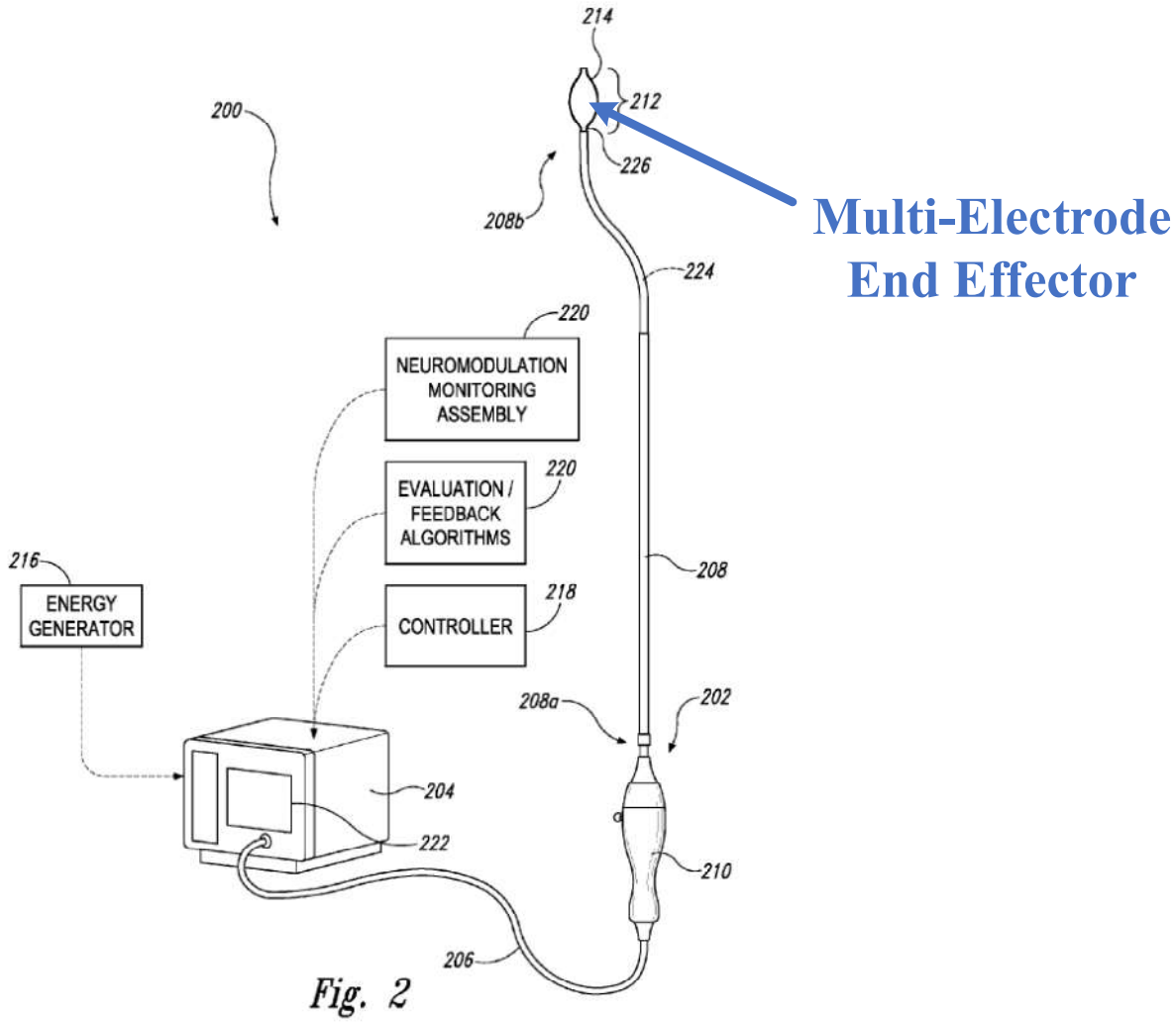


Fig. 2

(Ex-1004-Townley, FIG. 2.)[2]

Townley's MEEEs are advanced into the patient's nasal cavity. (Ex-1004-Townley, [0042], FIGS. 3A-E; Ex-1003-Weide, ¶81.)

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

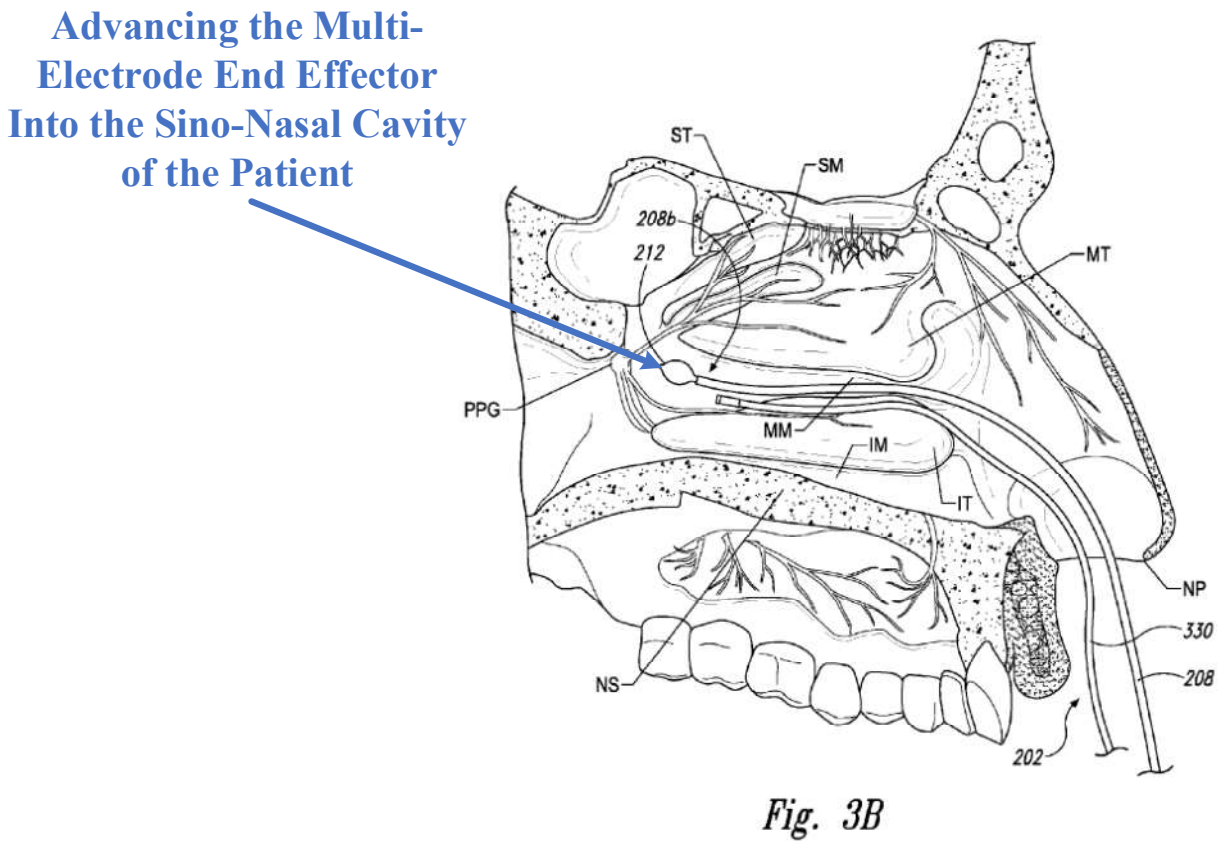


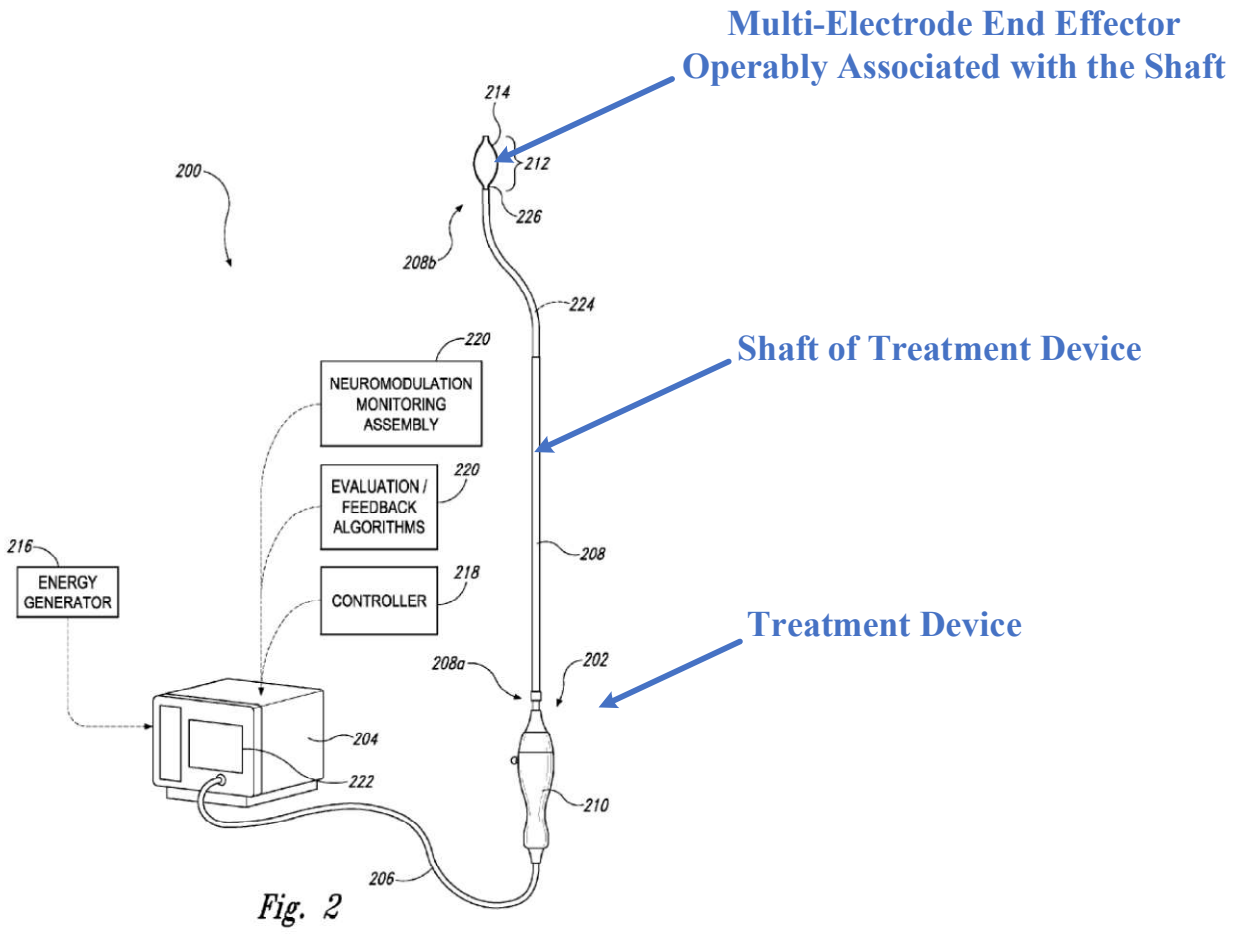
Fig. 3B

(Ex-1004-Townley, FIG. 3B.)

Thus, Townley discloses limitations [1a-1] and [16a-1]. (Ex-1003-Weide, ¶82.)

[1a-2 and 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

Townley's MEEEs are operably associated with a "shaft" of a treatment device (*e.g.*, shaft 208 of therapeutic neuromodulation device 202) for positioning the therapeutic assembly at a target site. (Ex-1003-Weide, ¶84; Ex-1004-Townley, FIGS. 3A-E, 4, 5A-G, and 11A-C, [0042].)



(Ex-1004-Townley, FIG. 2.)

Townley's MEEEs are configured to deliver energy to one or more target sites within the patient's nasal cavity. (Ex-1003-Weide, ¶85; Ex-1004-Townley, [0043].)

Thus, Townley discloses limitations [1a-2] and [16a-2]. (Ex-1003-Weide, ¶86.)

[1a-3 and 16a-3] 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

Townley discloses that its electrodes are configured to deliver RF energy. (Ex-1004-Townley, [0043], [0066], [0072]-[0073], [0111]; Ex-1003-Weide, ¶88.) Further, the MEEEs 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. (Ex-1003-Weide, ¶89.)

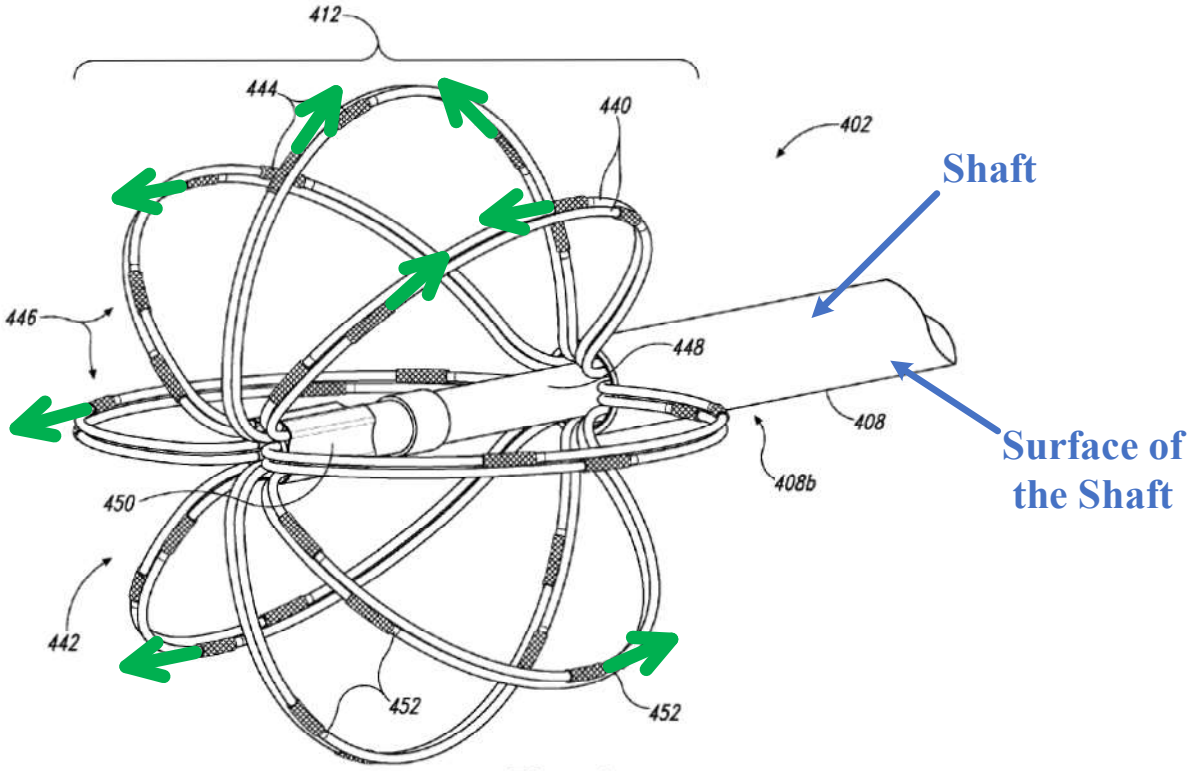


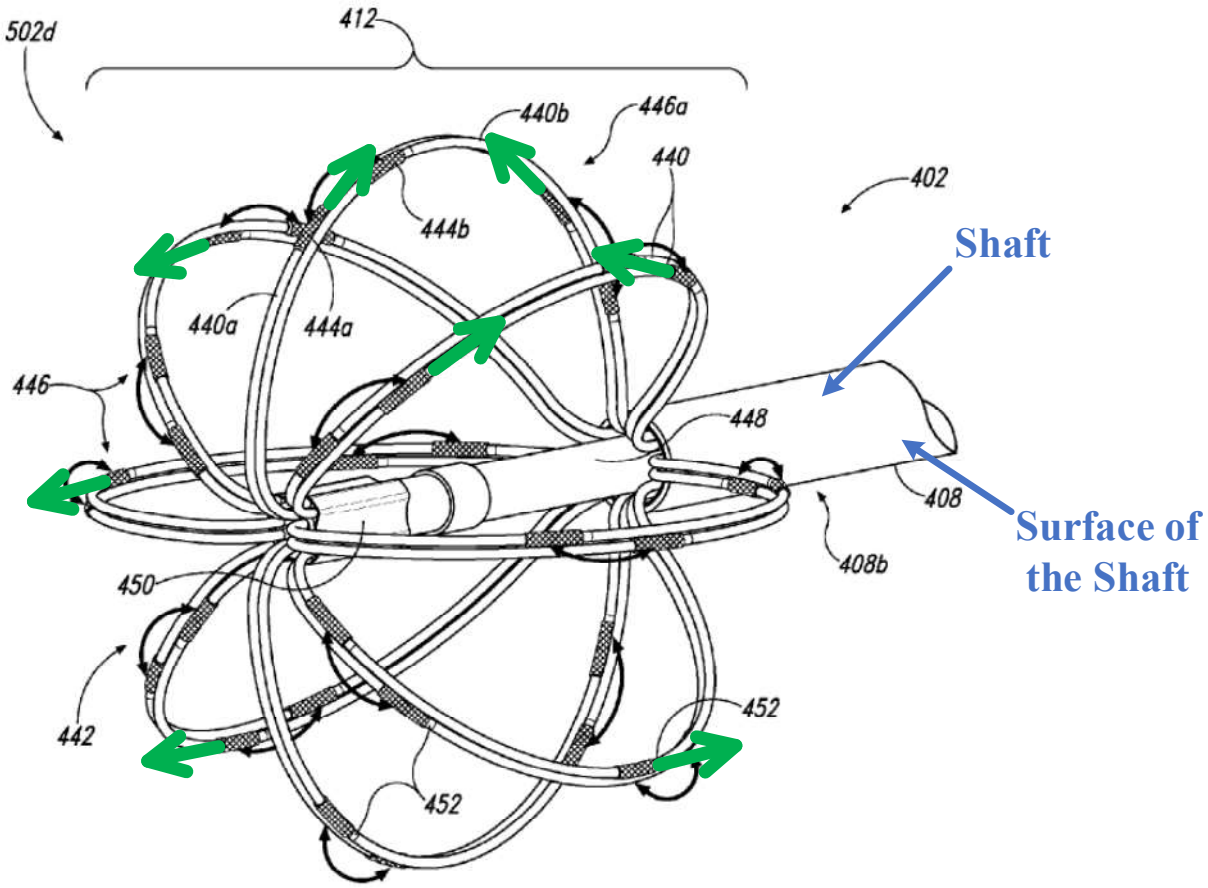
Fig. 4

[3] Petitioner demonstrates Townley's use of "at least eight" electrodes, as recited in Claim 16, because such demonstration also applies to the "at least six" electrodes recited in Claim 1.

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

As shown by the green arrows above (which illustrates only one example of many different manners of selecting the at least eight electrodes of Figure 4), 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. (Ex-1003-Weide, ¶90.)

The electrode arrangements of Figures 5A-G also disclose limitations [1a-3] and [16a-3]. (Ex-1003-Weide, ¶91.) As one example, Petitioner annotates Figure 5F below:



(Ex-1004-Townley, FIG. 5F (showing at least eight electrodes 444 oriented at an angle less than 90-degrees relative to the shaft 408); *id*., [0075] ("a plurality of electrodes 444 disposed on one or more of the struts 440."); Ex-1003-Weide, ¶91.)

The electrodes arrangements of Figures 11A-D also disclose limitations [1a-3] and [16a-3]. (Ex-1003-Weide, ¶92.) For example, Figure 11B illustrates at least eight electrodes (1144). (Ex-1004-Townley, 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*., [0106].)

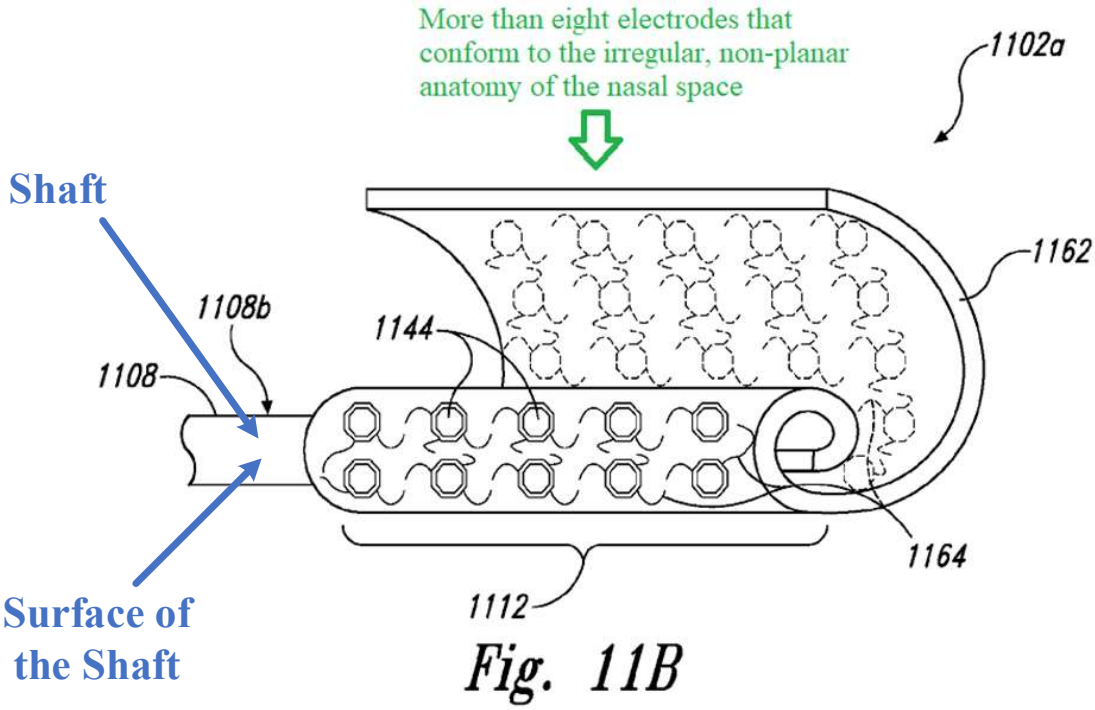


Fig. 11B

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

It would have been obvious that the at least eight electrodes (1144) of Figure 11B would be non-perpendicular (*i.e*., oriented at an angle less than 90 degrees) relative to the shaft (1108) to confirm to the non-planar anatomy of the nasal space. (Ex-1003-Weide, ¶93.)

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

[1a-4 and 16a-4] 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

Townley's MEEEs have electrodes meeting the requirements of limitations [1a-4] and [16a-4]. (Ex-1003-Weide, ¶96.) For example, as shown below, the at least eight electrodes of the MEEEs of Figures 4, 5A-G, and 11A-D comprise first and second electrodes that are spaced apart from each other along a length of the MEEE and are positioned at respective locations on the MEEE:

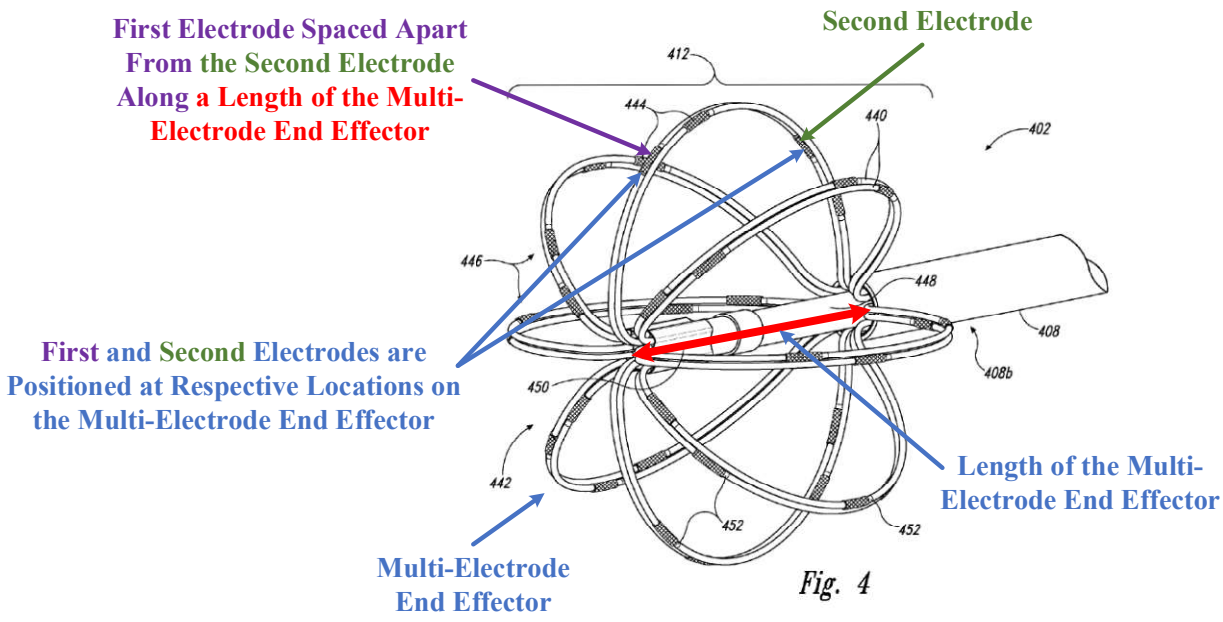
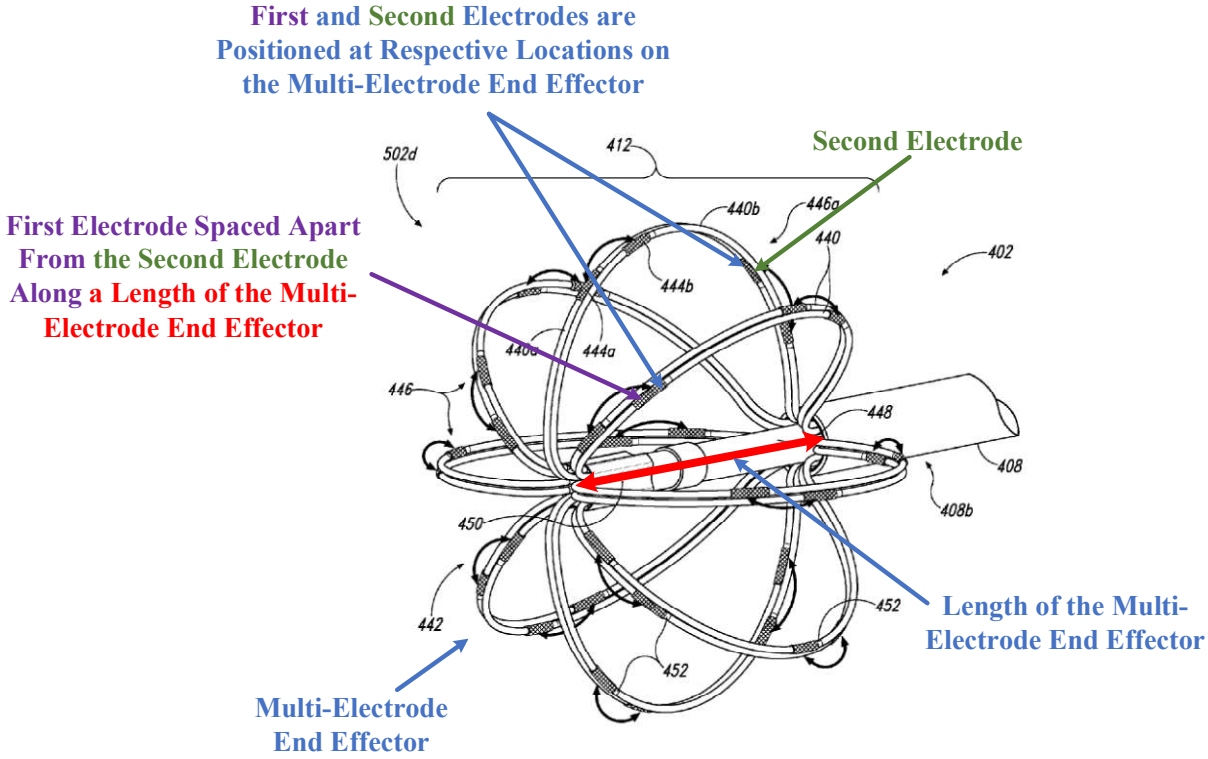


Fig. 4

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



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

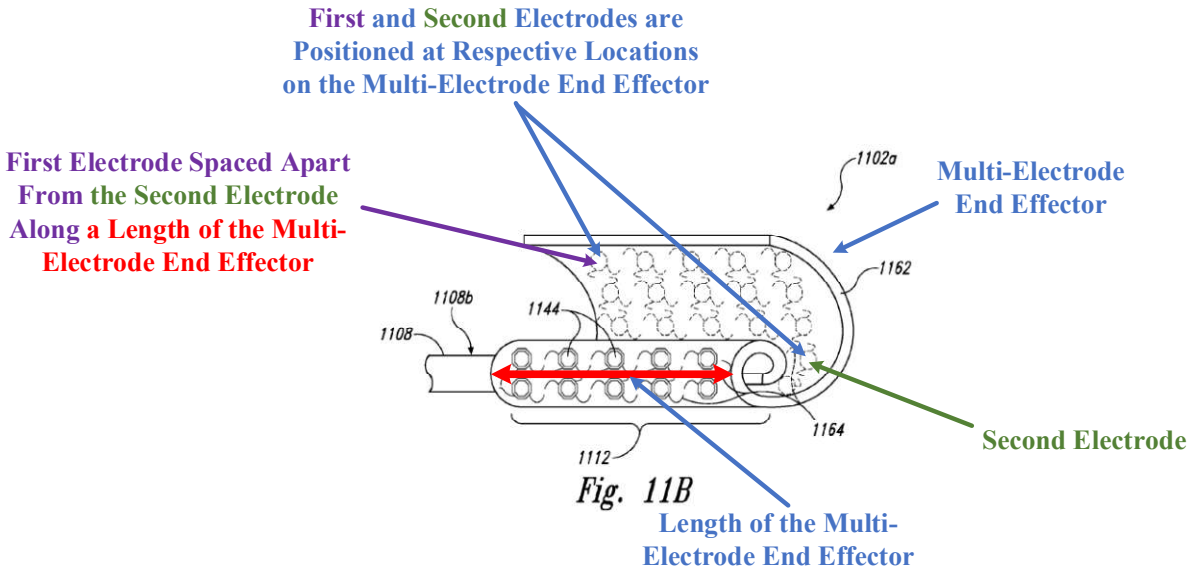


Fig. 11B

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

Further, each of the first and second electrodes comprises an active state and an inactive state. (*Id.,* [0072]; Ex-1003-Weide, ¶97.)

Thus, Townley discloses limitations [1a-4] and [16a-4]. (Ex-1003-Weide, ¶98.)

[1b and 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

Townley's MEEEs comprise a first electrode per the requirements of limitations [1b] and [16b]. (Ex-1003-Weide, ¶100.) For example, as shown below, the MEEEs of Figures 4, 5A-G, and 11A-D comprise a first electrode that: (i) is exposed from the surface of the MEEE; (ii) is positioned at a discrete portion

thereon; and (iii) extends in a first outward direction relative to a longitudinal axis of the shaft:

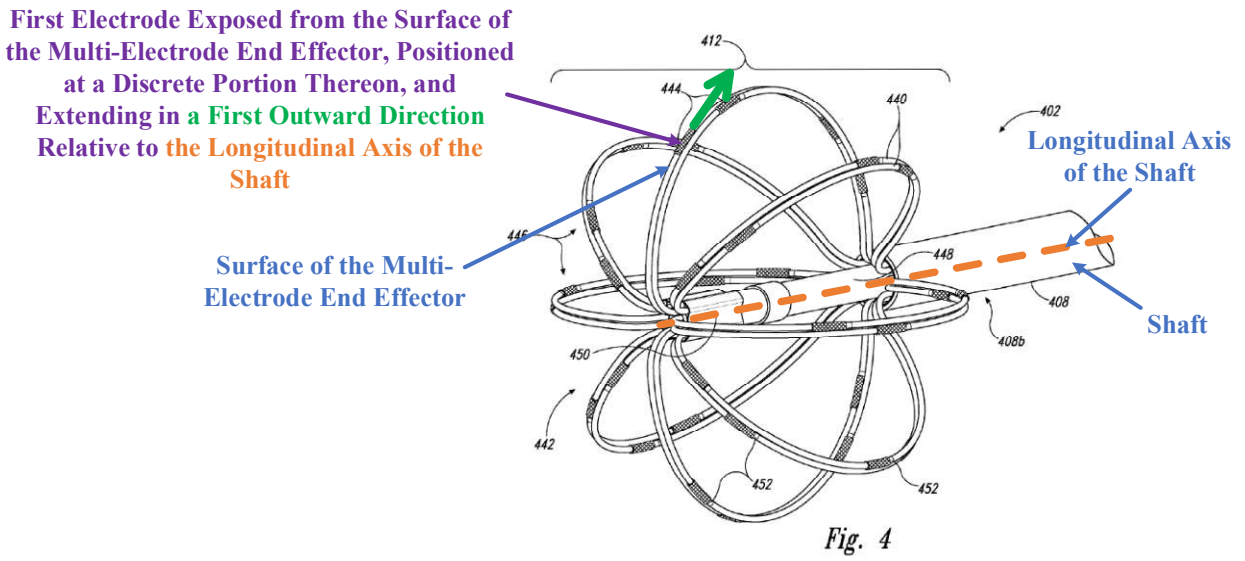
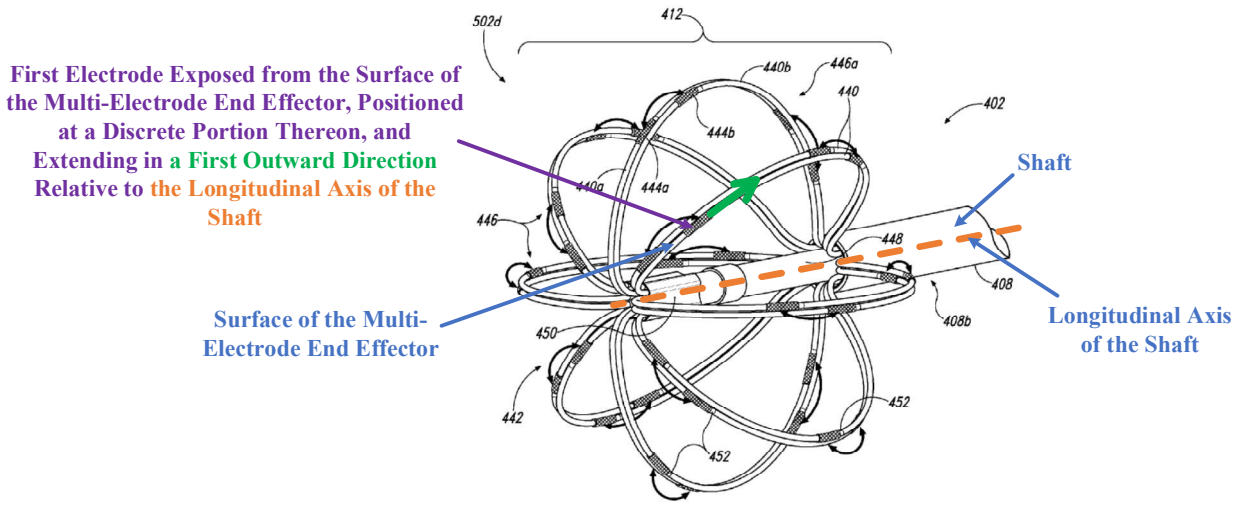


Fig. 4

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



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

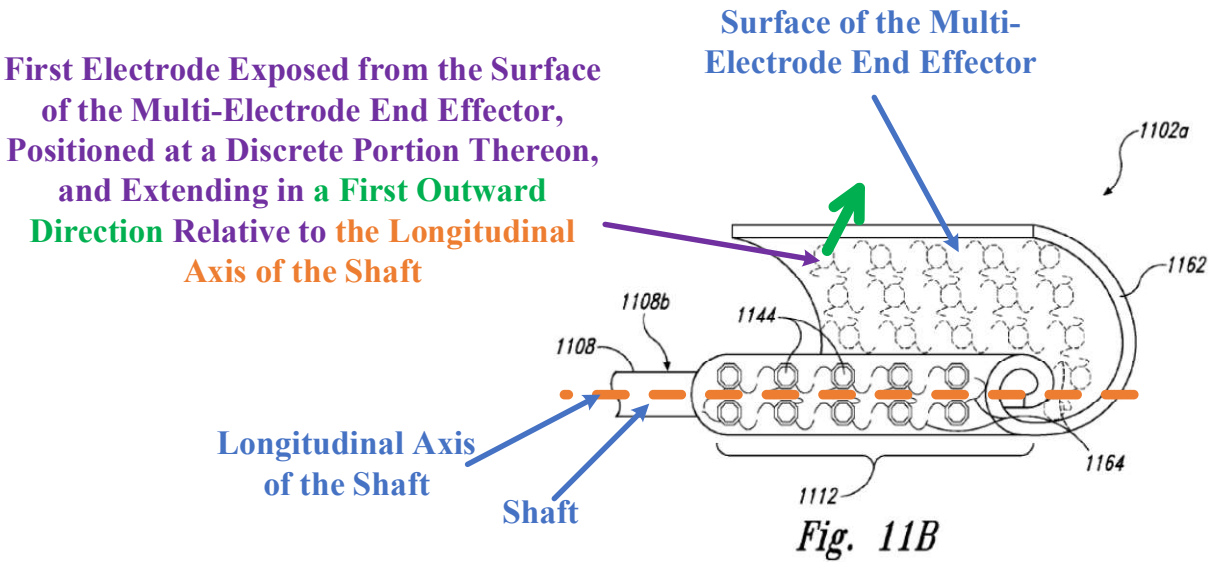


Fig. 11B

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

Additionally, Townley discloses that the first electrode is configured to contact (interact with) nasal anatomy at a first location within the nasal cavity. (Ex-1003-Weide, ¶101; Ex-1004-Townley, [0066] (explaining struts can position the electrodes 444 against tissue at a target site within the nasal region); [0073] (explaining the RF generator can deliver RF power while activating electrodes in a predetermined pattern selected based on the position of the therapeutic element relative to the treatment site and/or the identified locations of the target nerves).)

Thus, Townley discloses limitations [1b] and [16b]. (Ex-1003-Weide, ¶102.)

[1c and 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

Townley's MEEEs also comprise a second electrode per the requirements of limitations [1c] and [16c]. (Ex-1003-Weide, ¶¶103-104.) For example, as shown below, the MEEEs of Figures 4, 5A-G, and 11A-D comprise a second electrode that: (i) is exposed from the surface of the MEEE; (ii) is positioned at a discrete portion thereon; and (iii) extends in a second outward direction relative to a longitudinal axis of the shaft:

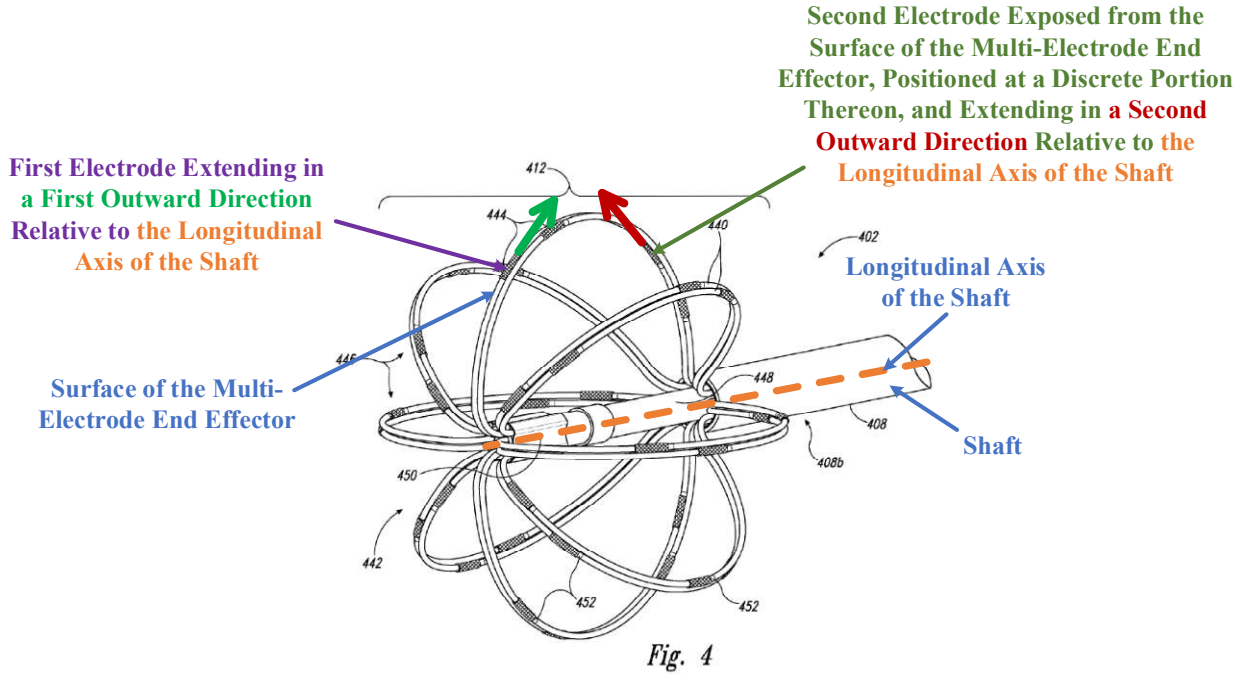
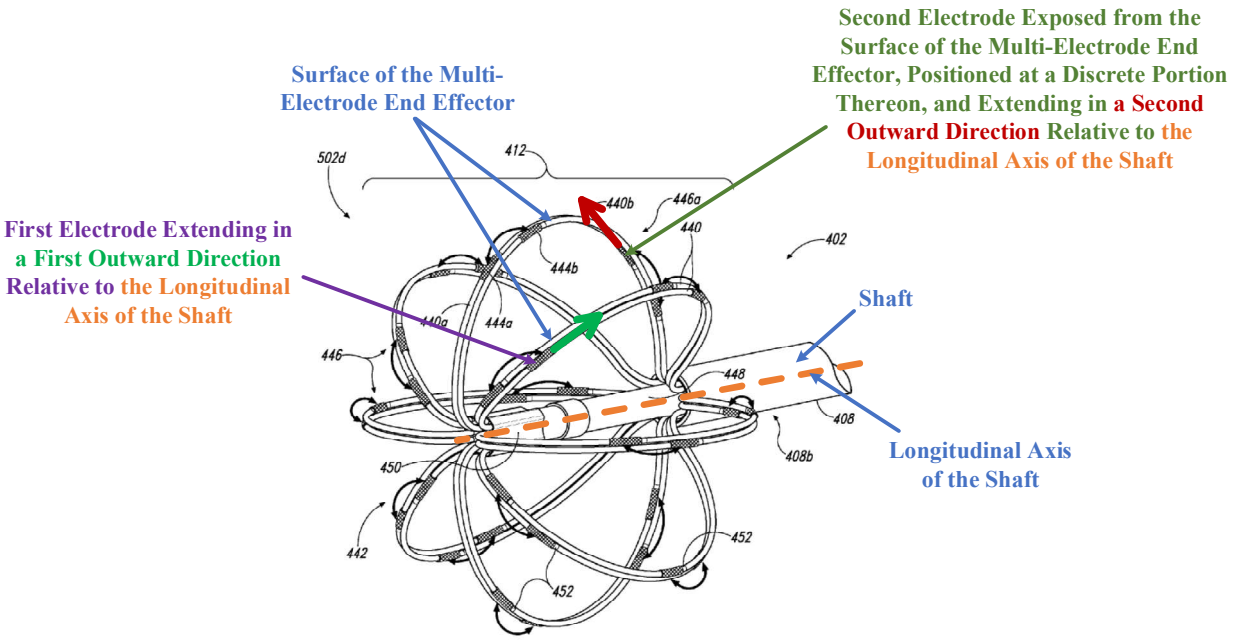


Fig. 4

(Ex-1004-Townley, FIG. 4, [0071].)



(*Id.,* FIG. 5F, [0075].)

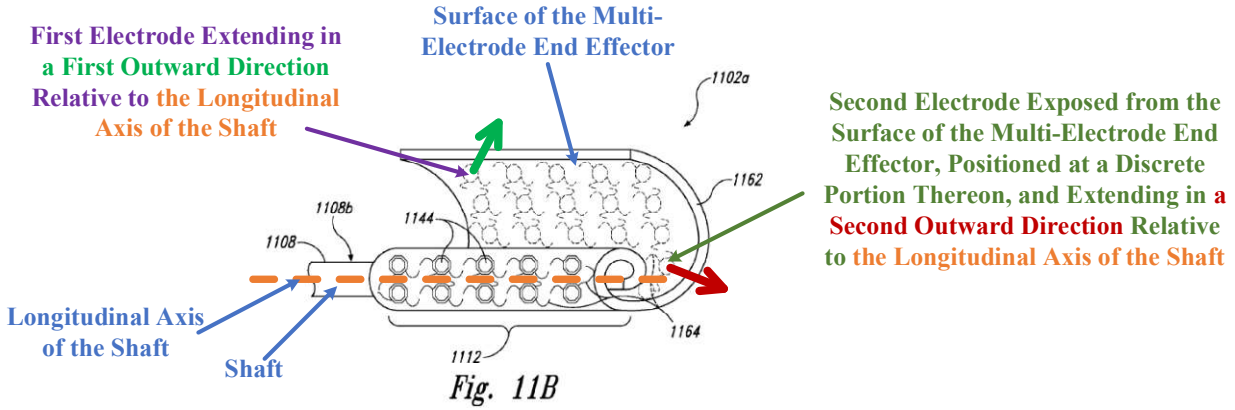


Fig. 11B

(*Id.,* FIG. 11B, [0109].)[4]

Townley's MEEEs include struts 440 or a flexible membrane 1162 that "conform" to the "irregular anatomy of the nasal space (e.g., turbinates, sinus, and/or

[4] Petitioner's annotations are merely a few examples of the many different ways in which Townley discloses the limitations of the claims. (Ex-1003-Weide, ¶105.)

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 MEEEs extend in different directions to conform to the "irregular anatomy of the nasal space." (Ex-1003-Weide, ¶106.)

Townley's second electrode is configured to contact (interact with) nasal anatomy at a second location within the nasal cavity for the same reasons provided above relative to the first electrode. (Ex-1003-Weide, ¶107; Ex-1004-Townley, [0066], [0073].)

Thus, Townley discloses limitations [1c] and [16c]. (Ex-1003-Weide, ¶108.)

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

[1d-2 and 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.

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

Townley states "'*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, [0032].) The first and second electrodes of Townley's MEEEs deliver energy to target sites within a patient's sino-nasal cavity for purposes of *therapeutic neuromodulation*. (Ex-1003-Weide, ¶¶110-111; Ex-1004-Townley, [0043].) Thus, Townley discloses limitations [1d-1] and [16d-1]. (Ex-1003-Weide, ¶112.)

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

As Townley's definition of "therapeutic neuromodulation" (above) shows, when Townley's assemblies therapeutically neuromodulate nerves, such assemblies are "disrupting neural activity." (Ex-1003-Weide, ¶114.) Further, Townley's 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, [0038], [0058]; Ex-1003-Weide, ¶115.)

Townley further discloses that 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" RCR. (Ex-1003-Weide, ¶116; Ex-1004-Townley, [0042] (describing various locations where therapeutic modulation may occur); [0038] (explaining 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."); [0058] (explaining therapeutic modulation "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.").)

While Townley does not expressly disclose that its therapeutic modulation treatments would "improve nasal breathability of the patient," it would have been obvious that Townley's treatments would improve nasal breathability because treating RCR was known to improve breathability by reducing mucus secretion and/or removing nasal blockage(s) and/or obstruction(s). (Ex-1003-Weide, ¶117; Ex-1004-Townley, [0003] ("Symptoms of rhinosinusitis include nasal blockage, obstruction, congestion"); Ex-1024, Abstract, 4:18-32, 7:18-22.) A POSITA (and even laymen) would have recognized it is easier to breathe through one's nose after blockage(s)/obstruction(s) are removed and when mucus secretion is reduced. (Ex-1003-Weide, ¶117.)

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

Accordingly, Townley renders obvious Claims 1 and 16. (*Id.,* ¶119.)

[Claims 2 and 17] The method of claim [1, 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.

Claims 2 and 17 refer to "*the* *tissue*," yet no prior "tissue" is recited in Claims 1 or 16. Assuming "the tissue" of Claims 2 and 17 refers to a "target" tissue, Townley teaches Claims 2 and 17.

Townley illustrates and describes its MEEE (212) "deployed at a treatment site" within the nasal cavity, proximal the inferior turbinate (IT). (Ex-1004-Townley, [0060].)

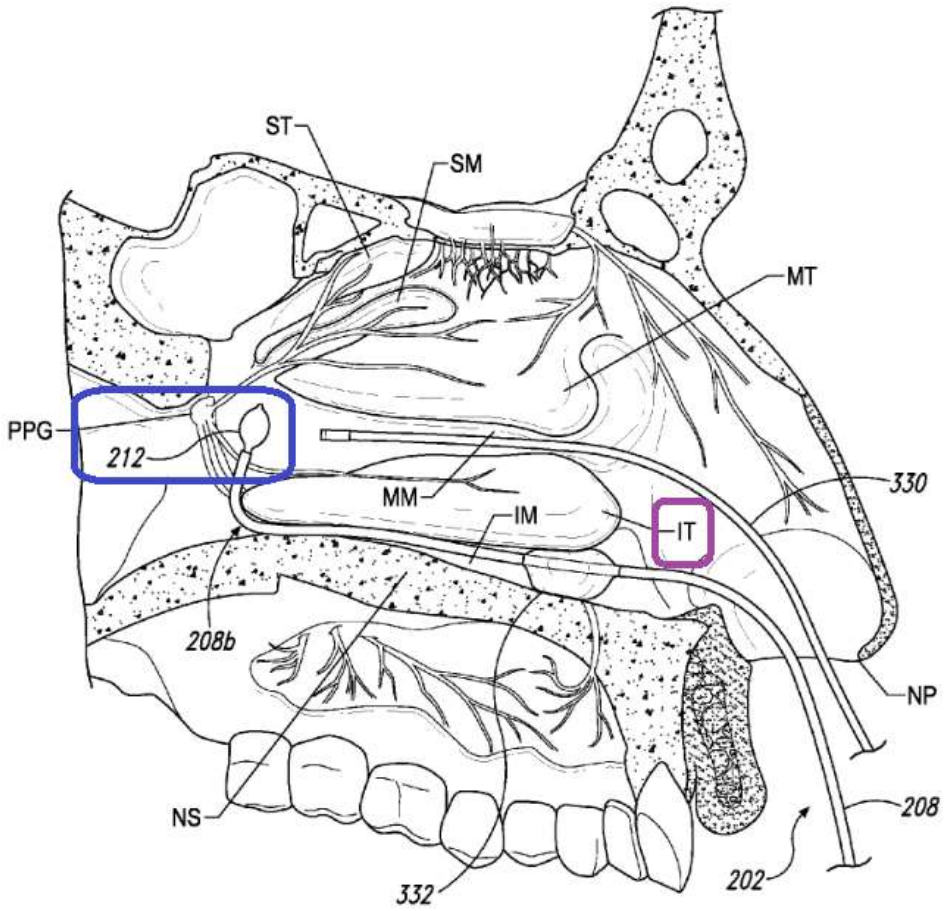


Fig. 3A

(*Id.,* FIG. 3A)

Townley also describes and illustrates therapeutically modulating "nerves at precise and focused treatment sites," including at the "***target region T*** shown in FIG. 1B." (*Id.,* [0041].)

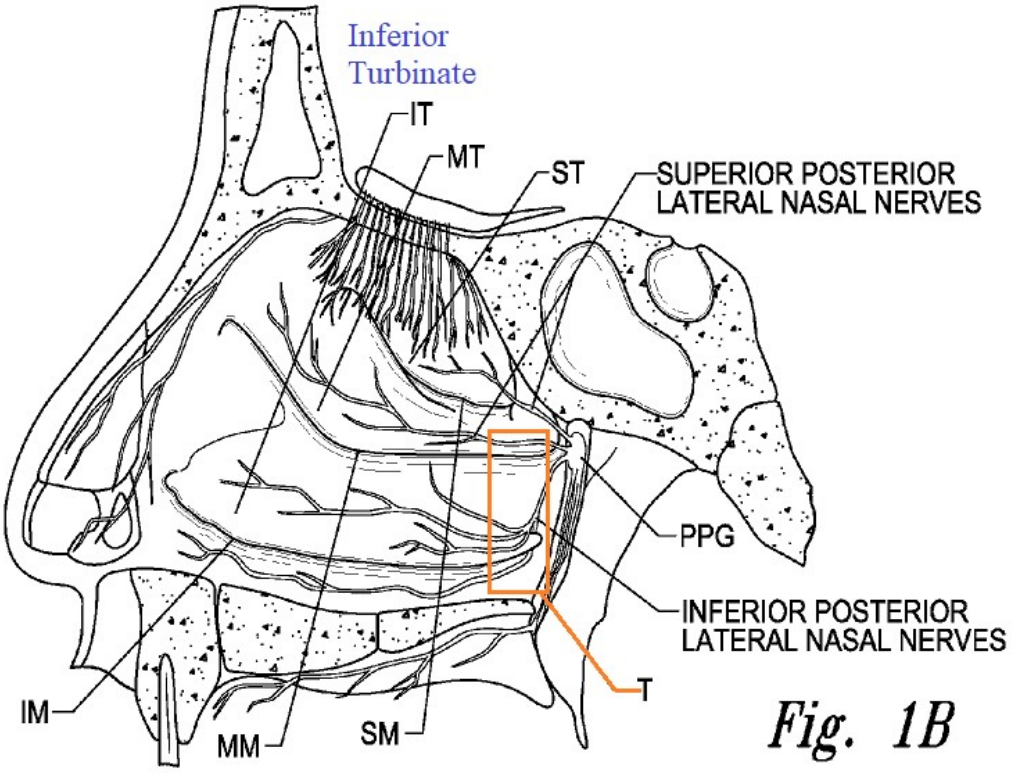


Fig. 1B

(*Id.,* FIG. 1B.)

As shown above, the ***target region T*** includes the inferior posterior lateral nasal nerves of the inferior turbinate. (*Id.*) Figure 1C (below) also shows that the treated nerves may be located adjacent or proximal to the inferior turbinate:

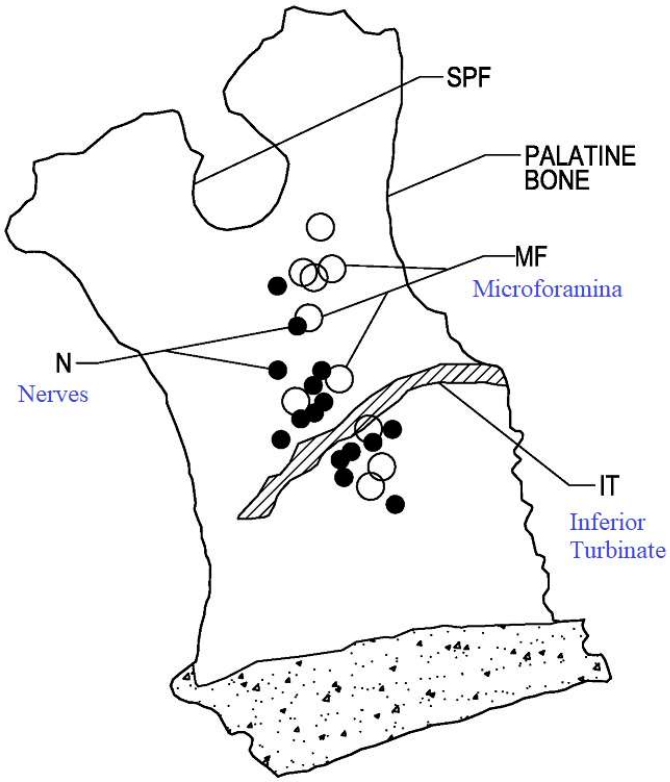


Fig. 1C

(*Id.,* FIG. 1C, [0037].)[5]

Townley also discloses that the target tissues may be those associated with the submucosa and that the target tissue may include nerves. (*Id.,* [0038] (explaining that mucus is secreted by submucosal glands and that "modulating the parasympathetic pathways that innervate the mucosa [is] expected to reduce or eliminate the hyper activation of the submucosal glands and engorgement of vessels

[5] *Id*., [0070], [0104] (MEEEs may be used to deliver energy to, or proximal to, the turbinates, including the inferior turbinate).

that cause symptoms associated with rhinosinusitis").) 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.,* [0042].)

Accordingly, Townley teaches and renders obvious Claims 2 and 17. (Ex-1003-Weide, ¶¶122-128.)

[Claims 3 and 18] The method of claim [1, 16], [3a, 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,

Townley's MEEEs may apply radiofrequency ("RF") energy from the first and second electrodes to tissue at the target site(s). (Ex-1003-Weide, ¶130; Ex-1004-Townley, [0043] ("one or more electrodes configured to apply electromagnetic neuromodulation energy (e.g., RF energy) to target sites."), [0066] (explaining the electrodes can apply bipolar radiofrequency energy to target site(s)).) RF energy delivery is controlled by a console unit (204) (hereinafter "console") operably associated with the treatment device 202 and MEEE 212. (Ex-1004-Townley, [0045]; Ex-1003-Weide, ¶131.)

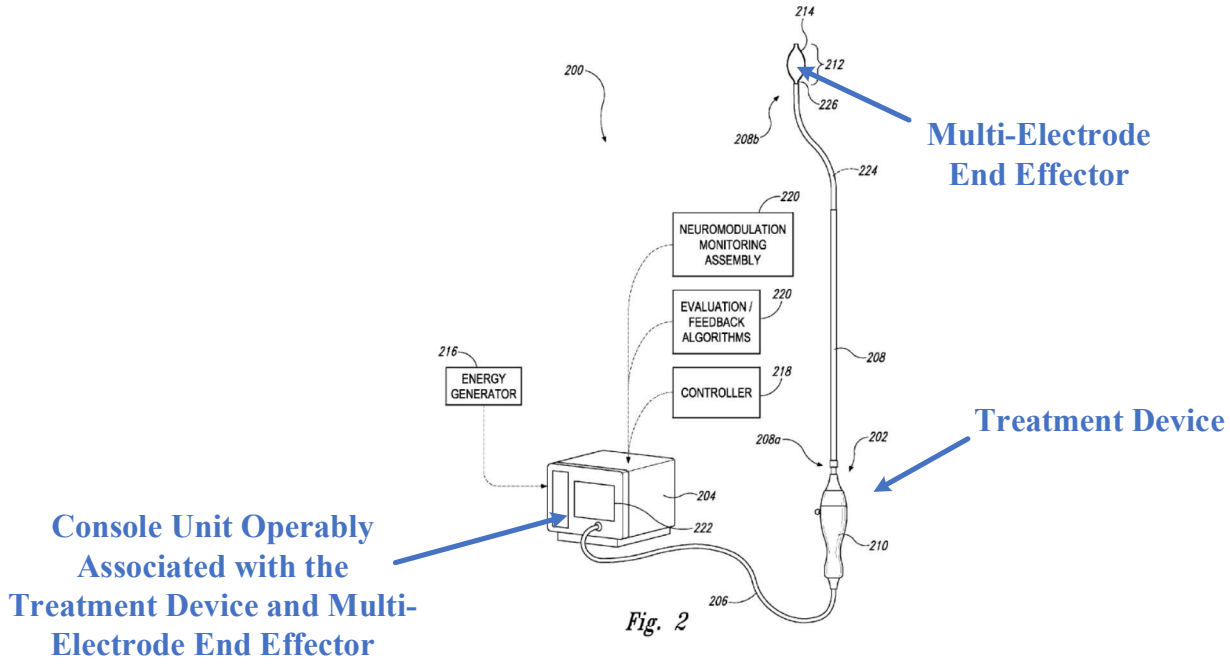


Fig. 2

(Ex-1004-Townley, FIG. 2.)

The console may be used with the therapeutic assemblies of Figures 4, 5A-G, and 11A-D. (*Id.,* [0074]-[0075], [0111]; Ex-1003-Weide, ¶132.)

Thus, Townley discloses limitations [3a] and [18a]. (Ex-1003-Weide, ¶133.)

[3b and 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.

Townley discloses "the shaft is a substantially rigid shaft." (Ex-1004-Townley, [0051] ("can be made from a substantially rigid material (e.g., a metal material)."); Ex-1003-Weide, ¶134.)

Townley also discloses that the shaft may include "an outer sheath," "a hypotube," and "a hollow cavity." (Ex-1003-Weide, ¶135.) As illustrated 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, [0068]; Ex-1003-Weide, ¶135.)

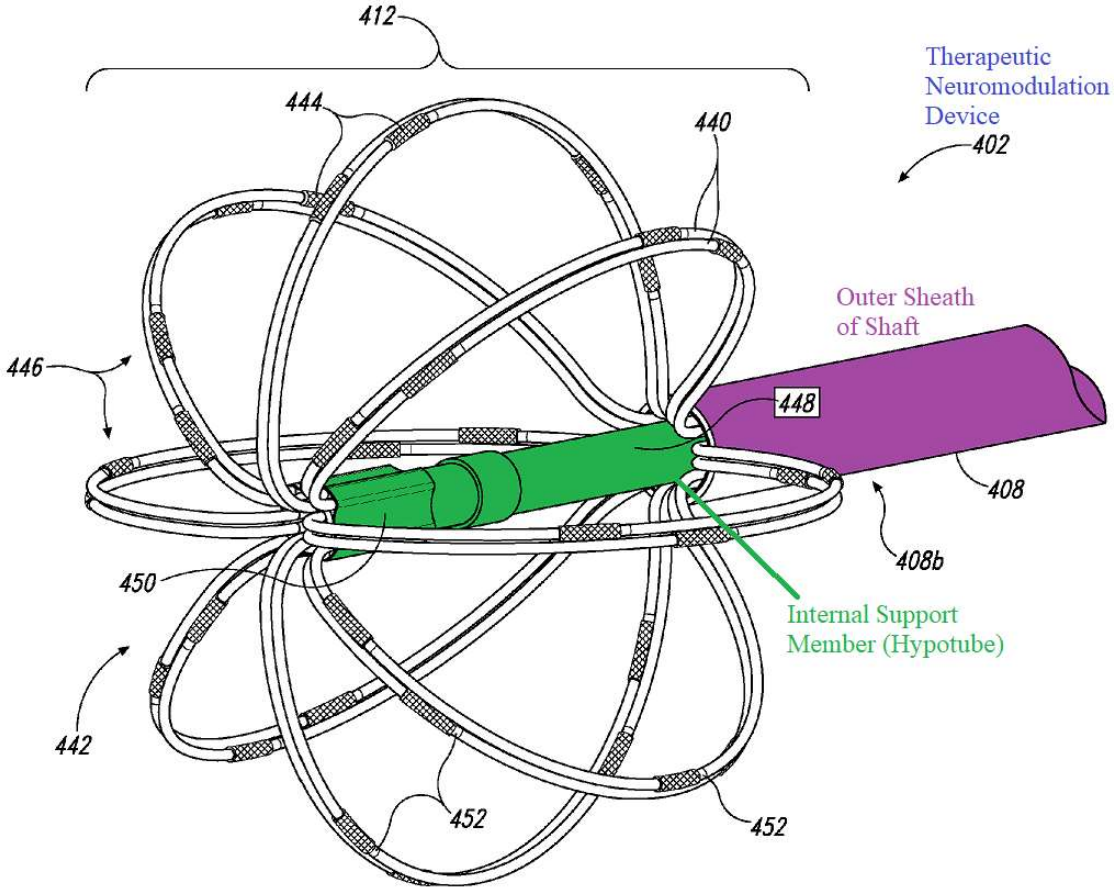


Fig. 4

(Ex-1004-Townley, [0068], FIG. 4.)

Further, the ***internal support member 448*** is a ***hypotube*** that extends distally from a distal portion 408*b* of the ***outer sheath*** of the shaft. (Ex-1003-Weide, ¶136; Ex-1004-Townley, [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.*) ***Support member 448*** is also moveable relative to the outer sheath and is expandable from a low profile configuration (pre-deployment) to an expanded state. (*Id.* at [0066], [0069]; Ex-1003-Weide, ¶137.)[6]

Townley further discloses that the first and second electrodes of its MEEEs are operably coupled to the console via wires disposed in the hollow cavity of the substantially rigid shaft. (Ex-1003-Weide, ¶139; Ex-1004-Townley, [0073] ("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."); *id.,* FIGS. 2 and 14, [0044], [0048], [0068], [0074].)

Thus, Townley discloses limitations [3b] and [18b]. (Ex-1003-Weide, ¶140.)

[6] Townley's description of its "internal support member 448" aligns with the '973 patent's description of a "hypotube." (Ex-1001, 22:4-6, 22:25-32 (explaining outer sheath surrounds the hypotube, which is further assembled over support elements or wires to protect and support those elements/wires, and that the hypotube moves relative to the outer sheath during deployment and retraction); Ex-1003-Weide, ¶138.)

Accordingly, Townley teaches and renders obvious Claims 3 and 18. (*Id.*, ¶141.)

[Claims 4 and 19] The method of claim [3, 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.

[Claims 5 and 20] The method of claim [4, 19], wherein the RF energy comprises at least bipolar RF energy.

Townley's console is 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. (Ex-1003-Weide, ¶143; Ex-1004-Townley, [0045] ("can include an energy generator 216 configured *to generate RF energy* (e.g., monopolar, *bipolar*, or multi-polar RF energy)").)

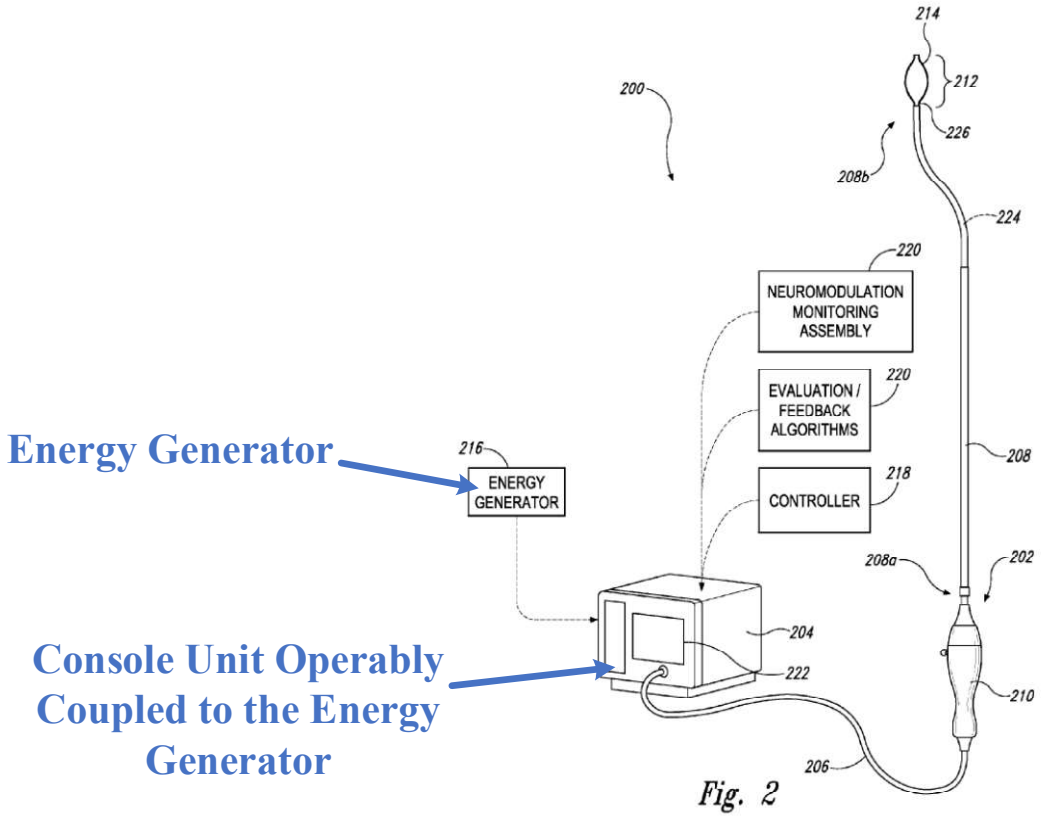


Fig. 2

(*Id.,* FIG. 2.)

Thus, Townley discloses and renders obvious Claims 4-5 and 19-20. (Ex-1003-Weide, ¶144.)

[Claims 6 and 21] The method of claim [3, 18], [6a, 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,

Townley's console is configured to receive feedback from temperature sensors arranged relative to the first and second electrodes and configured to sense temperature at an interface between tissue and the first and second electrodes. (Ex-1003-Weide, ¶146; Ex-1004-Townley, [0074] (explaining temperature sensors can be electrically coupled to the console of FIG. 2 and can be positioned proximate to electrodes to detect the temperature at the interface between tissue at the target site and the electrodes).)

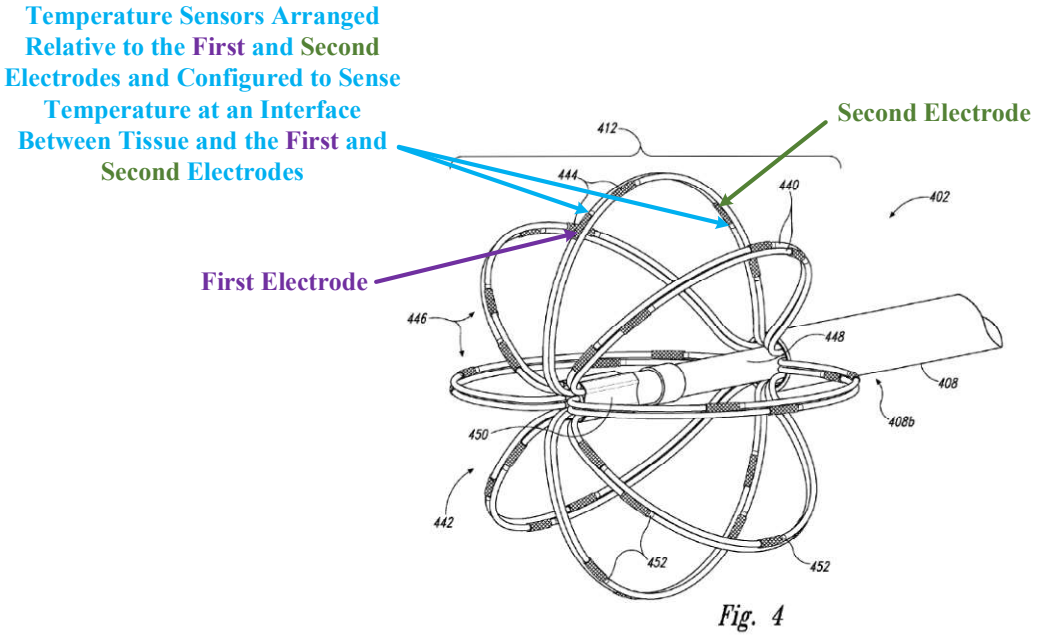


Fig. 4

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

Thus, Townley discloses limitations [6a] and [21a]. (Ex-1003-Weide, ¶147.)

[6b and 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.

Townley's console is configured to control energy output from the first and second electrodes based, at least in part, on feedback from the temperature sensors. (Ex-1003-Weide, ¶149; Ex-1004-Townley, [0047] (explaining the console's evaluation/feedback algorithm and controller 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)").)

Townley discloses maintaining a predetermined "target temperature" of tissue at the one or more target sites. (Ex-1003-Weide, ¶150; Ex-1004-Townley, [0055] (explaining "therapeutic modulation may be applied via the energy delivery element…to precise, localized regions of tissue to induce one or more desired therapeutic neuromodulating effects to disrupt parasympathetic motor sensory function," that "[d]esired 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," and that "***target*** temperature[s]" may be selected "(e.g., 70-75° C.) for

non-ablative thermal alteration" or "100° C or higher (e.g., 110° C., 120° C., etc.) for the ablative thermal alteration.").)

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 unnecessarily damaging tissue. (Ex-1003-Weide, ¶¶151-154; Ex-1004-Townley, FIG. 7, [0017], [0095] (illustrating threshold levels of electrical conductivity of nasal tissue with respect to temperature and explaining its systems "can be configured 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.").)

Thus, Townley teaches and renders obvious limitations [6b] and [21b]. (Ex-1003-Weide, ¶155.)

Accordingly, Townley renders obvious Claims 6 and 21. (*Id.,* ¶156.)

[Claims 7 and 22] The method of claim [6, 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.

As explained in Claims 6 and 21, Townley's console is configured to receive temperature readings from temperature sensors. (Ex-1004-Townley, [0047]; Ex-1003-Weide, ¶158.) Townley's console also comprises an evaluation/feedback

algorithm 220 that, in conjunction with controller 218, is configured to process the temperature 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." (Ex-1004-Townley, [0047], [0055]; Ex-1003-Weide, ¶¶159-160.)

Thus, Townley teaches and renders obvious Claims 7 and 22. (*Id.*, ¶161.)

[Claims 8 and 23] The method of claim [7, 22], [8a, 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

Townley's console 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. (Ex-1004-Townley, [0047]; Ex-1003-Weide, ¶163.)

Thus, Townley discloses limitations [8a] and [23a]. (Ex-1003-Weide, ¶164.)

[8b and 23b] and further monitor an elapsed time during delivery of RF energy to tissue at the one or more target sites.

Townley's console is "configured to control, *monitor*, supply, and/or otherwise support operation of" its therapeutic neuromodulation device. (Ex-1004-Townley, [0045].) Townley's console is also "configured to automatically terminate treatment after a predetermined maximum time." (*Id.,* [0047]; *see also id.,* [0055], claim 81.) A POSITA would have understood that Townley's console monitors the elapsed time during treatment (*i.e.*, during delivery of RF energy) to determine when

the "predetermined maximum time" has been reached. (Ex-1003-Weide, ¶¶166-167.)

Thus, Townley teaches and renders obvious limitations [8b] and [23b]. (*Id.,* ¶168.)

Accordingly, Townley renders obvious Claims 8 and 23. (*Id.,* ¶169.)

[Claims 9 and 24] The method of claim [7, 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.

[Claims 10 and 25] The method of claim [9, 24], wherein the display is a touchscreen monitor.

Townley's console comprises a display 222 (*e.g.*, a touchscreen display) configured to provide feedback information to an operator during treatment applications. (Ex-1004-Townley, [0047]-[0048]; Ex-1003-Weide, ¶¶171, 175.) The feedback information may be that the "predetermined maximum time" has been reached or "other information associated with the operation of the system 200." (*Id.*) A "predetermined maximum time" reads on "an elapsed time during delivery of RF energy to tissue at" the target site(s). (Ex-1003-Weide, ¶171.) 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 the treatment, thus dissuading the operator from deactivating the treatment device before treatment is completed. (*Id.,* ¶172.)

Thus, Townley teaches and renders obvious Claims 9-10 and 24-25. (*Id.,* ¶¶173, 176.)

[Claims 11 and 26] The method of claim [7, 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.

Townley's console comprises a controller 218 "configured to execute an automated control algorithm" and/or execute "a computer-readable medium carrying instructions," which are commonly executed by a "hardware processor." (Ex-1004-Townley, [0046]; Ex-1003-Weide, ¶178.) Accordingly, a POSITA would have found it obvious for Townley's controller to include "a hardware processor." (Ex-1003-Weide, ¶178)

Townley's controller 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. (Ex-1004-Townley, FIG. 2, [0046]-[0047], claims 32-33 and 39-40.) When executed by the controller, 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.,* [0046]; Ex-1003-Weide, ¶179.)

Townley's automated control algorithm causes the console to "automatically" adjust and terminate (*i.e.*, automatically control and adjust) RF energy output from the first and second electrodes for each treatment application. (Ex-1004-Townley, [0047], [0074], [0111]; Ex-1003-Weide, ¶180.) 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) during delivery of RF energy. (*Id*.) A POSITA would have found it obvious to include an automated control algorithm in Townley's controller-executable instructions to cause Townley's therapeutic assembly to "apply energy in a specific manner," which is the express purpose of Townley's "instructions." (Ex-1003-Weide, ¶180; Ex-1004-Townley, [0046]).)

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. (Ex-1003-Weide, ¶181; Ex-1004-Townley, [0038] ("to reduce or eliminate the … engorgement of vessels"), [0047] ("the evaluation/feedback algorithm 220 can include features to confirm efficacy of the treatment"); *id*. at [0049], [0055], [0058], [0074], [0089], [0096], [0101], [0111], [0141]-[0142].)

Thus, Townley teaches and renders obvious Claims 11 and 26. (Ex-1003-Weide, ¶182.)

[Claims 12 and 27] The method of claim [11, 26], wherein the predetermined threshold maximum temperature is less than 90° C.

[Claims 13 and 28] The method of claim [11, 26], wherein the predetermined threshold maximum temperature is greater than 37° C and less than 90° C.

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, [0055]; *id.,* [0095].)

Thus, Townley teaches and renders obvious Claims 12-13 and 27-28. (Ex-1003-Weide, ¶¶184-185.)

[Claims 14 and 29] The method of claim [11, 26], the predetermined elapsed time period is from about 1 second to about 20 seconds.

[Claims 15 and 30] The method of claim [14, 29], wherein the predetermined elapsed time period is from about 10 seconds to about 12 seconds.

Townley discloses that the predetermined elapsed time period for each separate and discrete treatment application is between "1-20 [seconds] (e.g., 5-10 seconds, 8-10 seconds, 10-12 seconds, etc.)." (Ex-1004-Townley, [0055].)

Thus, Townley teaches and renders obvious Claims 14-15 and 29-30. (Ex-1003-Weide, ¶¶187-188.)

B. GROUND 2: Wolf-003 Alone and in view of Wolf-290 Renders Obvious Claims 1-2 and 16-17.

1. Scope, Content and Motivation to Combine

For Ground 2, the prior art is Wolf-003 alone or in view of Wolf-290. As shown 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 ("SDMs") treat RCR or that improved nasal breathability would be realized.

However, Wolf-003 discloses that its SDMs 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-1003-Weide, ¶191; Ex-1005-Wolf-003, [0002], [0004], [0011].) As the '973 patent admits, such energy treatments would be expected to treat symptoms of RCR. (Ex-1001, 5:37-52 (tying reduced production of mucus to the reduction or elimination of "one or more symptoms associated with at least one of rhinitis, congestion, and rhinorrhea to improve nasal breathability of the patient," including symptoms such as "nasal congestion, coughing, sneezing, and nasal or throat irritation and itching"); 5:53-6:14 (tying ablative energy treatment of tissues

and/or nerves associated with excess mucus production to treatment of RCR).) Accordingly, Wolf-003 alone teaches and suggests that its SDMs may be used to treat "at least one of rhinitis, congestion, and rhinorrhea." (Ex-1003-Weide, ¶192.)

Wolf-290 confirms that it was obvious to use Wolf-003's SDMs to treat RCR. Specifically, Wolf-290 discloses that, when energy is delivered to appropriate nasal airway tissues to ablate nerve fibers and/or goblet cells, rhinitis is expected to be reduced/treated. (Ex-1006-Wolf-290, [0009], [0053]; Ex-1003-Weide, ¶193.) Further, a POSITA would have known that using Wolf-003's SDMs 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. (Ex-1003-Weide, ¶194.) Accordingly, to the extent not already obvious based on Wolf-0003 alone, a POSITA would have been motivated to treat, and would have found it obvious to treat, RCR using the SDMs of Wolf-003. (*Id.*, ¶195.)

A POSITA also would have had a reasonable expectation of success in treating RCR using the SDMs of Wolf-003. The SDMs 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), which contain nerve fibers and goblet cells responsible for mucus production. (Ex-1005-Wolf-003, [0027]; Ex-1018-Lane, 390 ("Posteroinferior nasal branches give sensation to the mucosa of the turbinates and lateral nasal wall..), 392 ("*respiratory epithelium* characterized by five cell types: basal cells, *goblet cells*…[i]n 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*."), FIGS. 4-5.) Accordingly, Wolf-003's SDMs are already configured to treat RCR. (Ex-1003-Weide, ¶¶196-198.) Further, as explained above in Ground 1, it was known that treating RCR would have been expected to improve nasal breathability. (Ex-1003-Weide, ¶199; Ex-1001, 1:38-60; Ex-1004-Townley, [0003]; Ex-1019, [0004]; Ex-1020, [0002-3]; Ex-1024, 1:29-41, 4:18-32, 7:18-22.)

Thus, it was obvious to treat RCR and improve a patient's nasal breathability using the SDMs of Wolf-003 with a reasonable expectation of success. (Ex-1003-Weide, ¶200.)

2. The Challenged Claims

[Claims 1 and 16, 1-PRE and 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

Wolf-003 teaches and suggests the preambles of Claims 1 and 16.

Wolf-003 discloses "*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," including post nasal drip syndrome (PNDS) or upper airway cough syndrome (UACS). (Ex-1005-Wolf-003, [0003], [0011].) Wolf-003's methods deliver "energy to mucosal tissue and/or a tissue underlying mucosal tissue in the upper airway," including "inside the nasal cavity, nasal passage, [and] nasal airway," which treatment 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.,* [0011], [0089].) As explained above, it was obvious to treat RCR with such energy delivery methods. (Ex-1001, 5:37-6:14; Ex-1003-Weide, ¶204.) Accordingly, Wolf-003 alone teaches and suggests that its SDMs may be used to treat RCR "within a sino-nasal cavity of a patient." (*Id.*, ¶¶202-204.)[7]

Further, as explained above: (a) Wolf-290 confirms that Wolf-003's SDMs may be used to treat RCR and it would have been obvious to do so because 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, [0009], [0053]); (b) a POSITA would have been motivated to,

[7] As noted in Ground 1, the "sino-nasal cavity" includes the nasal cavity.

and would have found it obvious, to treat RCR using the SDMs of Wolf-003; and (c) a POSITA would have had a reasonable expectation of success because the SDMs of Wolf-003 are already configured to treat locations in the nasal cavity with 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-1003-Weide, ¶205; Ex-1005-Wolf-003, [0027]; Ex-1018-Lane, 390, 392, FIGS. 4-5.) Accordingly, Wolf-003 in view of Wolf-290 also teaches and suggests that Wolf-003's SDMs may be used to treat RCR "within a sino-nasal cavity of a patient." (Ex-1003-Weide, ¶206.)

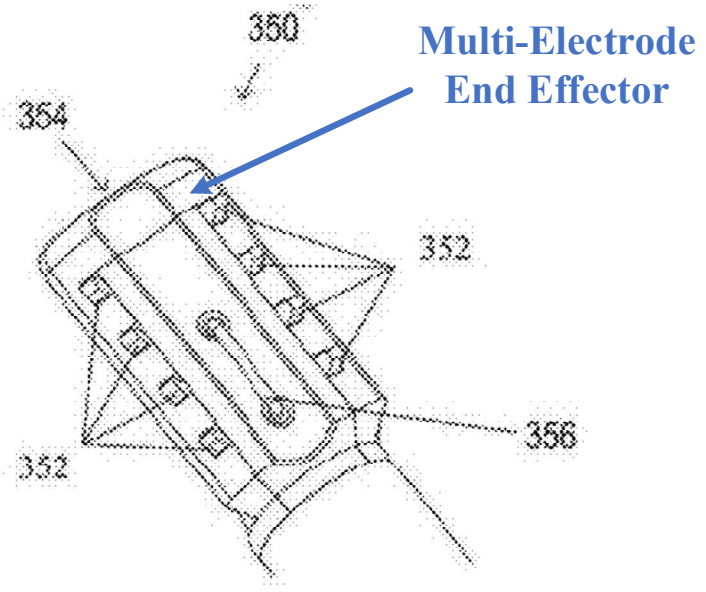
Thus, Wolf-003 alone or in view of Wolf-290 renders obvious limitations [1-PRE] and [16-PRE]. (*Id.*, ¶207.)

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

Wolf-003 discloses several MEEEs, including device 30 of Figure 6. (Ex-1003-Weide, ¶210; Ex-1005-Wolf-003, [0039], [0089].) Wolf-003's device includes "a treatment element 32 which may be *configured to be placed inside* the nasal cavity, nasal passage [and] nasal airway…to deliver the desired treatment." (Ex-1005-Wolf-003, [0089].) "The treatment element comprises one or more electrodes," such as multiple RF electrodes. (*Id.,* [0021], [0099]; Ex-1003-Weide, ¶210.)

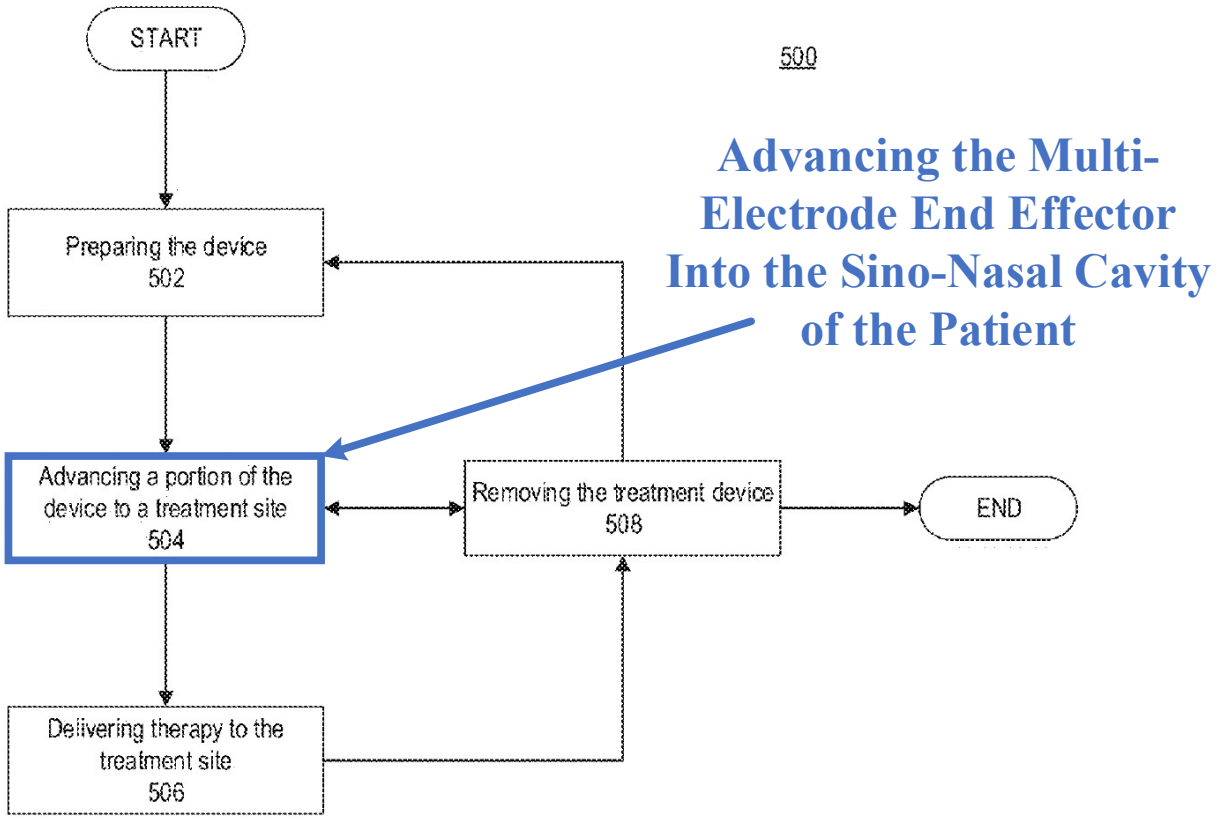
Wolf-003 provides additional configurations, including in relation to Figures 19A-B. (Ex-1003-Weide, ¶211; Ex-1005-Wolf-003, [0145] ("The designs described in the [Figure 17-19B] embodiments may be used in various devices, for example the device 30, described above.").) The device of Figures 19A-B includes a treatment portion 350 having eight radiofrequency electrodes 352. (*Id.,* FIG. 19B, [0148], Ex-1003-Weide, ¶211.) Additional MEEEs are illustrated in Figures 13-14, 25, 26A-F, and 27. (Ex-1003-Weide, ¶211.)

A POSITA would have understood that Wolf-003's multi-electrode treatment elements/portions, including treatment portion 350, disclose MEEEs because they are assemblies of components, including multiple electrodes, that deliver a therapeutic treatment to a patient. (Ex-1003-Weide, ¶212; Ex-1005-Wolf-003, [0151], [0157]; Ex-1001, 12:32-34 ("the terms 'end effector' and 'therapeutic assembly' may be used interchangeably.").)



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

Wolf-003 discloses advancing its MEEEs into the nasal cavity of the patient. (Ex-1005-Wolf-003, 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."); Ex-1003-Weide, ¶213.)

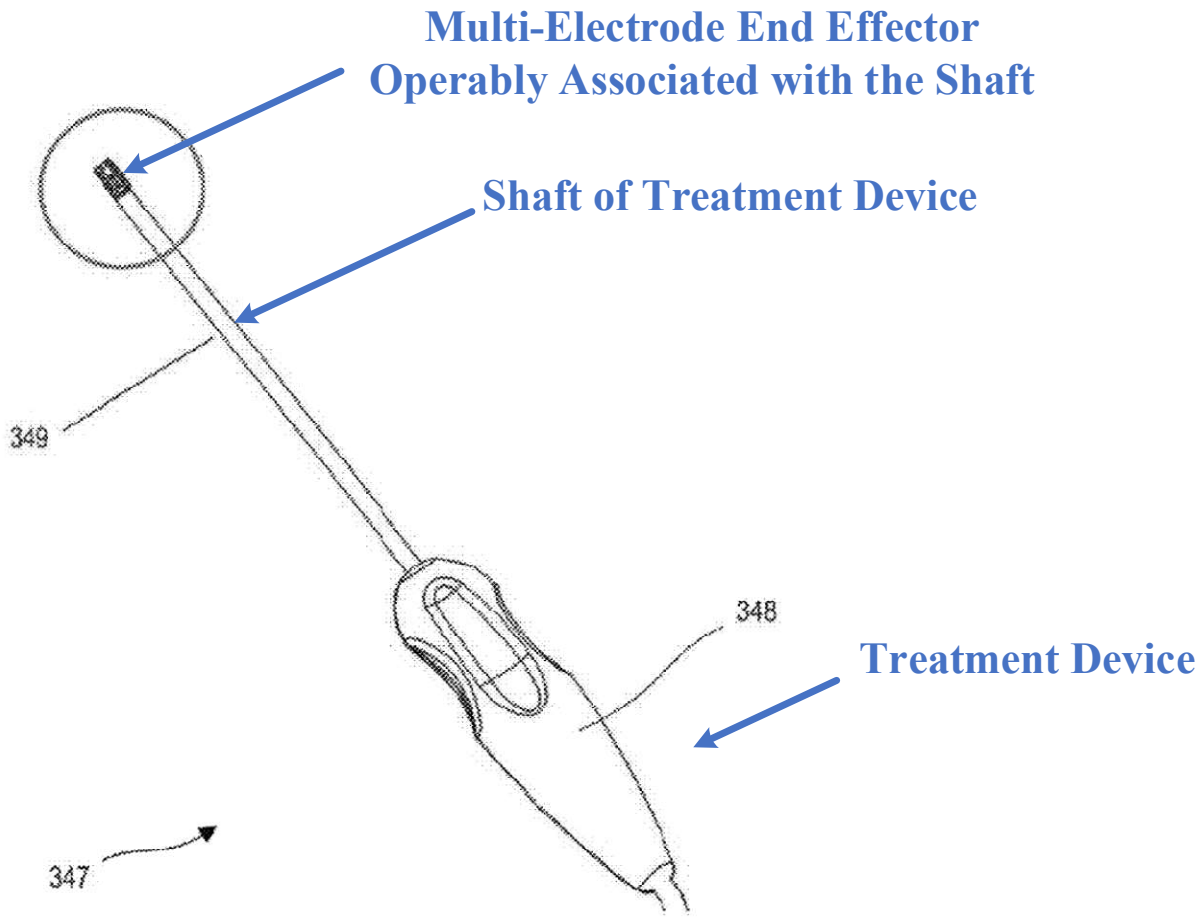


(Ex-1005-Wolf-003, FIG. 20.)

Thus, Wolf-003 discloses limitations [1a-1] and [16a-1]. (Ex-1003-Weide, ¶214.)

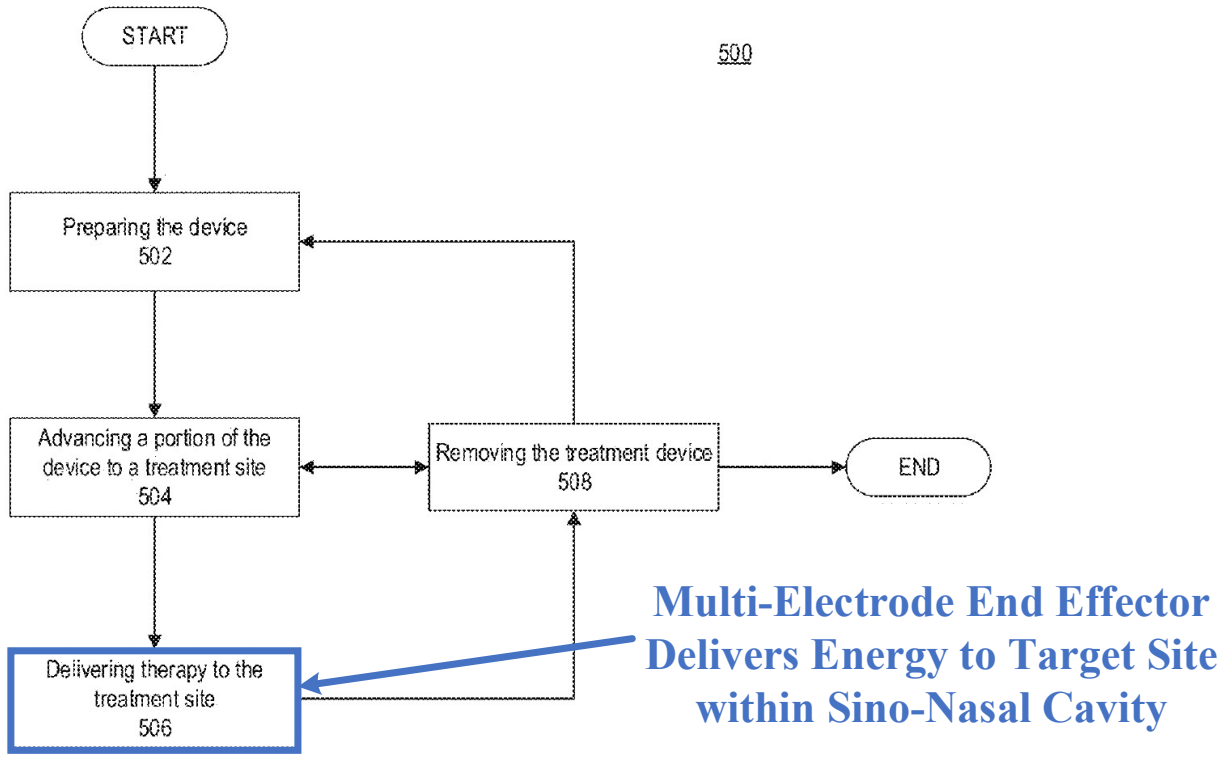
[1a-2 and 16a-2] wherein the multi-electrode end effector is operably associated with a shaft of a treatment device and configured for delivering energy to one or more target sites within the sino-nasal cavity of the patient

Wolf-003's MEEEs are operably associated with a "shaft" of a treatment device (*e.g.*, shaft 349 of treatment device 347) for advancing the MEEE into a patient's nasal cavity and placing it in contact with the tissue to be treated. (Ex-1005-Wolf-003, FIG. 19A, [0148], [0150] (explaining shaft adjustability enables a clinician to re-shape the shaft to improve the ability of the device to navigate nasal anatomy and enable the electrodes to be positioned to contact tissues to be treated); Ex-1003-Weide, ¶216.)



(Ex-1005-Wolf-003, FIG. 19A.)

Wolf-003's MEEEs are configured to deliver energy to one or more target sites within the patient's nasal cavity. (Ex-1005-Wolf-003, FIG. 20, [0089], [0151]-[0152], [0157], [0164]-[0165]; Ex-1003-Weide, ¶217.)

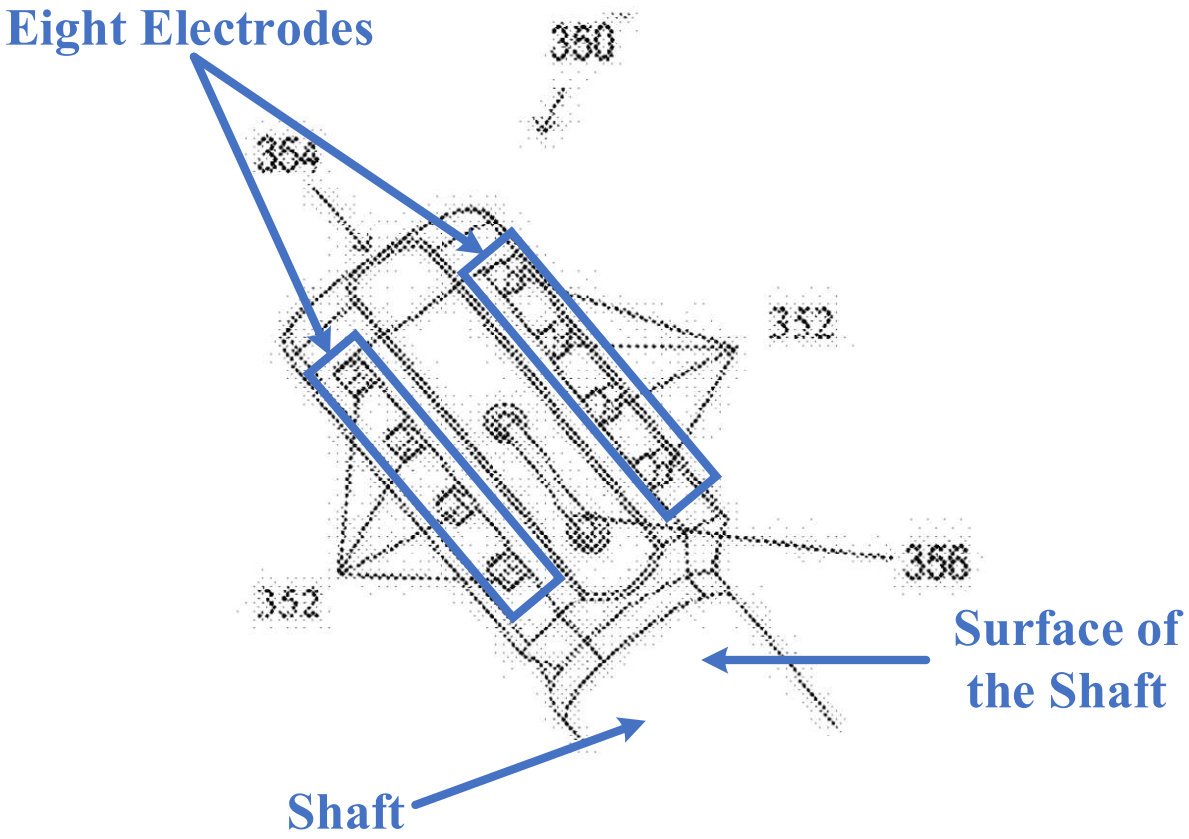


(Ex-1005-Wolf-003, FIG. 20.)

Thus, Wolf-003 discloses limitations [1a-2] and [16a-2]. (Ex-1003-Weide, ¶218.)

[1a-3 and 16a-3] 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

Wolf-003's MEEEs have electrodes meeting the requirements of limitations [1a-3] and [16a-3]. (Ex-1003-Weide, ¶220.) For example, the MEEE described relative to Figures 19A-B discloses eight electrodes that extend beyond the surface of the shaft and oriented at an angle of less than 90 degrees relative to the shaft. (*Id*., ¶¶220-23)



(Ex-1005-Wolf-003, FIG. 19B; *id*., [0153] ("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*."

(Ex-1005-Wolf-003, [0153].) Thus, Townley discloses that the eight electrodes 352 extend beyond the surface of the shaft and at an angle less than 90 degrees relative to the shaft. (Ex-1003-Weide, ¶¶221-23.) Indeed, as shown, Wolf-003 teaches that its electrodes 352 may be oriented *in any direction*, including at a "non-perpendicular" angle, which includes an angle less than 90 degrees relative to the shaft. (Ex-1003-Weide, ¶¶222-223.)

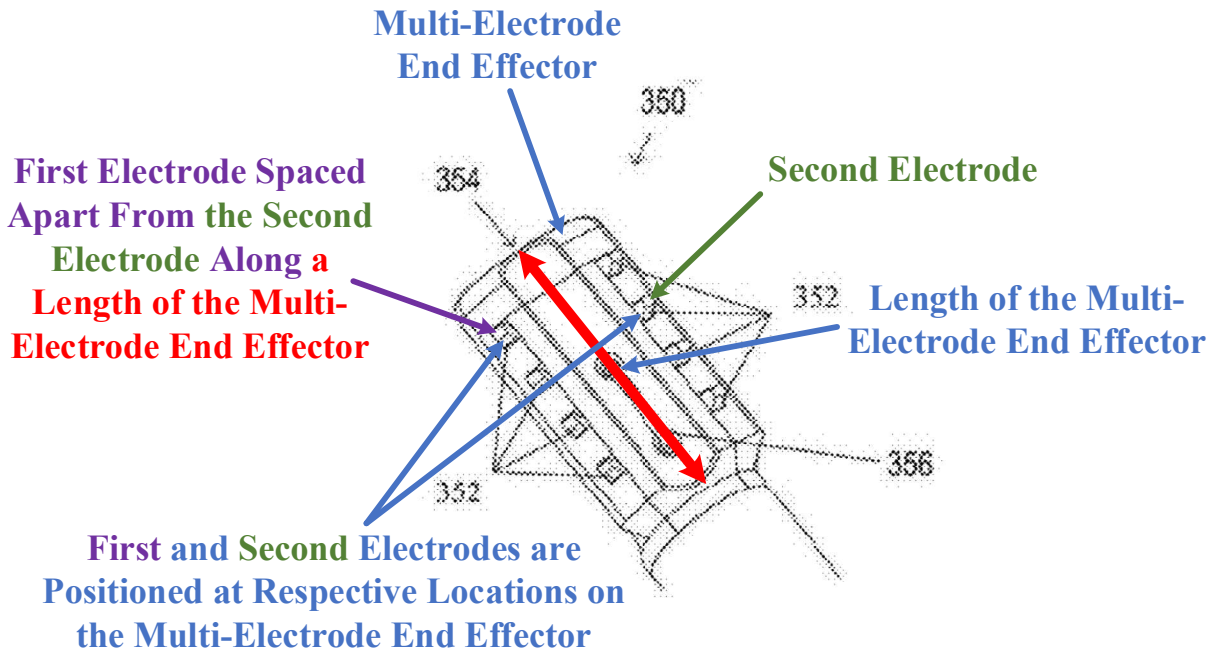
Additionally, Wolf-003 discloses that its electrodes are configured to deliver RF energy. (Ex-1005-Wolf-003, [0022] ("the method may further comprise delivering radiofrequency (RF) energy to the one or more electrodes to locally heat the tissue to be treated"); Ex-1003-Weide, ¶224.)[8]

Thus, Wolf-003 discloses limitations [1a-3] and [16a-3]. (Ex-1003-Weide, ¶226.)

[8] *See also* Ex-1005-Wolf-003, FIGS. 13-14, 26A-F, and 27 (showing other electrode arrangements meeting the requirements of limitations [1a-3] and [16a-3]); Ex-1003-Weide, ¶225.

[1a-4 and 16a-4] 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

Wolf-003's MEEEs have electrodes meeting the requirements of limitations [1a-4] and [16a-4]. (Ex-1003-Weide, ¶228.) For example, as shown below, the at least eight electrodes of the MEEE of Figures 19A-B comprise first and second electrodes 352 that are spaced apart from each other along a length of the MEEE and are positioned at respective locations on the MEEE:



(Ex-1005-Wolf-003, FIG. 19B, [0151], [0153]; Ex-1003-Weide, ¶229.)

Additionally, Wolf-003 discloses that each of the first and second electrodes comprises an active state and an inactive state. (Ex-1005-Wolf-003, [0162] ("the clinician may activate one or more pairs of electrodes 352 to deliver therapy to the

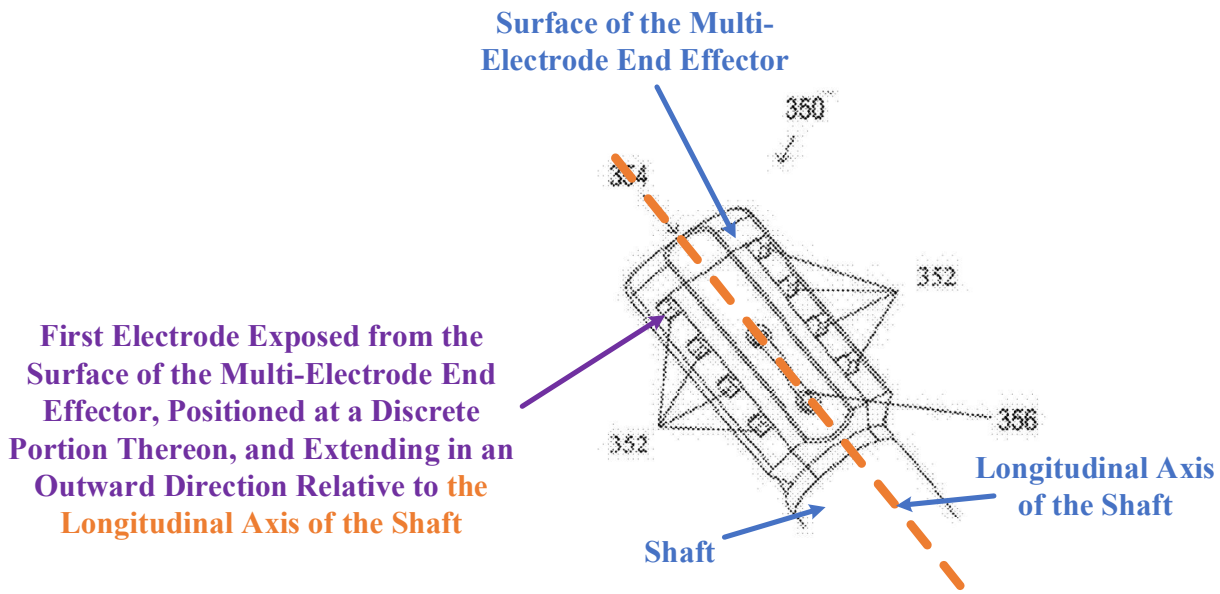
treatment site."); [0168] ("used to activate and deactivate the electrodes"); Ex-1003-Weide, ¶230.) Wolf-003 further discloses that the first and second electrodes may be activated individually/separately to achieve the desired treatment. (Ex-1005-Wolf-003, [0096]; Ex-1003-Weide, ¶231.)[9]

Thus, Wolf-003 discloses limitations [1a-4] and [16a-4]. (Ex-1003-Weide, ¶233.)

[1b and 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

Wolf-003 discloses limitations [1b] and [16b]. (Ex-1003-Weide, ¶235.) For instance, Wolf-003's MEEE of Figures 19A-B comprises a first electrode 352 that: (i) is exposed from the surface of the MEEE 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*., ¶236.)

[9] *See also* Ex-1005-Wolf-003, FIGS. 13-14, 26A-F, and 27 (showing other electrode arrangements meeting the requirements of limitations [1a-4] and [16a-4]); Ex-1003-Weide, ¶232.



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

As Wolf-003 explains:

> "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*., [0153].)

Additionally, Wolf-003 discloses that the first electrode is configured to interact with nasal anatomy at a first location within the nasal cavity. (Ex-1005-Wolf-003, [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] (explaining the treatment portion has a tissue

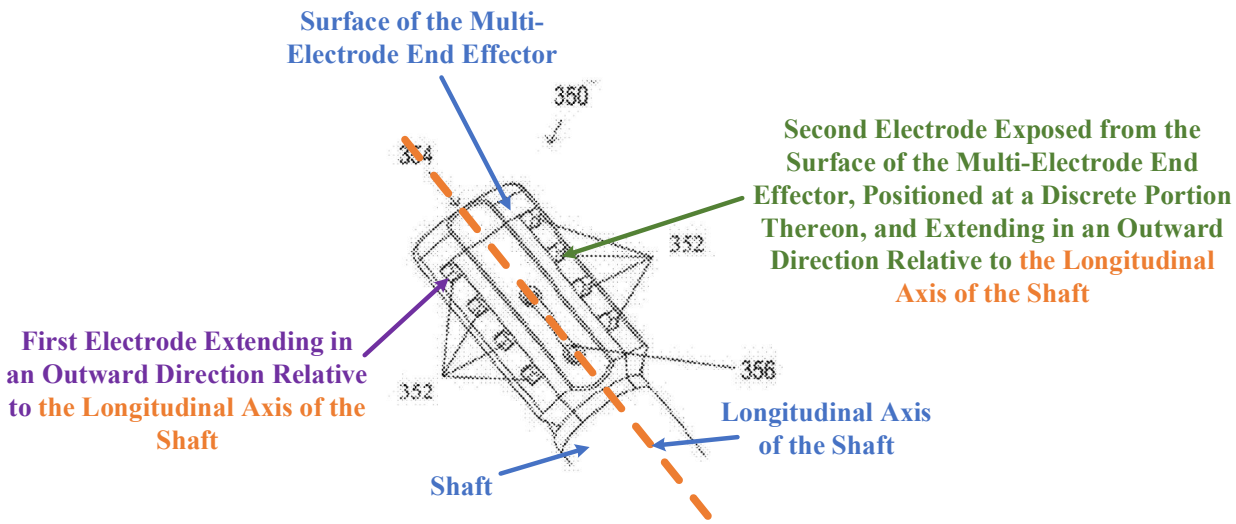
contact surface having multiple features for addressing and treating tissue, such as mucosal tissue); Ex-1003-Weide, ¶237.)[10]

Thus, Wolf-003 discloses limitations [1b] and [16b]. (Ex-1003-Weide, ¶239.)

[1c and 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

Wolf-003 discloses limitations [1c] and [16c] for generally the same reasons as limitations [1b] and [16b]. (Ex-1003-Weide, ¶¶240-241.) For instance, the MEEE of Figures 19A-B comprises a second electrode 352 that: (i) is exposed from the surface of the MEEE; (ii) is positioned at a discrete portion thereon; and (iii) extends in an outward direction relative to a longitudinal axis of the shaft 349. (Ex-1005-Wolf-003, FIG. 19B, [0029], [0151], [0153]; Ex-1003-Weide, ¶242.)

[10] *See also* Ex-1005-Wolf-003, FIGS. 13-14, 26A-F, and 27 (showing other electrode arrangements meeting the requirements of limitations [1b] and [16b]); Ex-1003-Weide, ¶238.



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

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*., [0153].)

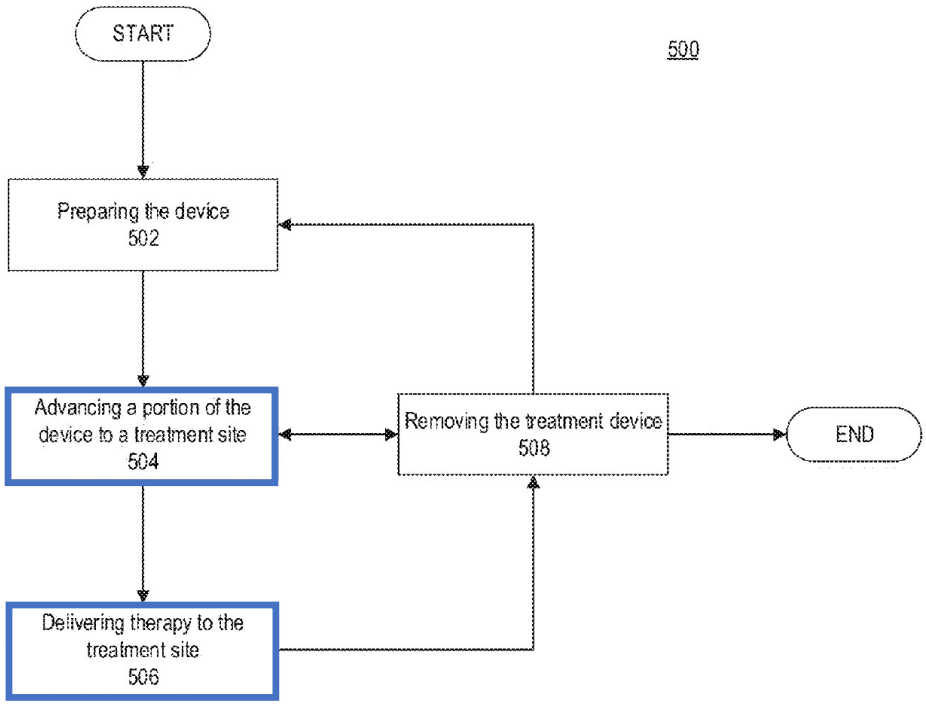
Wolf-003 thus teaches that the second electrode 352 may extend in any direction, including a second outward direction relative to a longitudinal axis of the shaft 349. (Ex-1003-Weide, ¶¶242-243.)

Additionally, Wolf-003's second electrode is configured to interact with nasal anatomy at a second location within the nasal cavity. (Ex-1005-Wolf-003, [0089], [0150]-[0151]; Ex-1003-Weide, ¶244.)[11]

Thus, Wolf-003 discloses limitations [1c] and [16c]. (Ex-1003-Weide, ¶246.)

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

As illustrated in Figure 20 (below), Wolf-003 discloses that, once the device has advanced to a treatment site (504), therapy is delivered (506):



[11] *See also* Ex-1005-Wolf-003, FIGS. 13-14, 26A-F, and 27 (showing other electrode arrangements meeting the requirements of limitations [1c] and [16c]); Ex-1003-Weide, ¶245.

(Ex-1005-Wolf-003, 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.,* [0165].)

Further as illustrated in Figure 20 (above), energy delivery may be repeated as necessary to achieve the desired treatment. (*Id.,* [0167].)

Thus, Wolf-003 discloses limitations [1d-1] and [16d-1]. (Ex-1003-Weide, ¶¶248-249.)

[1d-2 and 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.

The '973 patent recognizes that ablating nerves associated with mucosal tissue "disrupt[s] multiple neural signals to the mucus producing and/or mucosal engorgement elements within the nose." (Ex-1001, 5:53-65, 29:36-67.)

Wolf-003's MEEEs deliver energy, including ablative[12] energy, to injure target tissue, such as "goblet cells, *nerves*, and submucosal tissue," and "in a manner that decreases a volumetric rate of mucus production of the mucosal tissue[13] without changing a shape of the mucosal tissue." (Ex-1005-Wolf-003, [0027]; *see also id.* [0088] ("energy may be delivered *to nerve tissue* that controls the behavior of mucus producing cells or tissue.); claim 6 ("wherein the at least one tissue comprises *nerve tissue underlying the mucosal tissue*, and wherein delivering the energy comprises *ablating the nerve tissue*."); Ex-1003-Weide, ¶252.) A POSITA would have recognized that such injured nerves cannot adequately send "signals to mucus producing and/or mucosal engorgement elements" because their neural signaling has been disrupted, which disruption results in a reduced production of mucus within a nose of a patient, and with an expected reduction of (or elimination of) symptom(s) associated with RCR. (Ex-1003-Weide, ¶¶252-254; Ex-1005-Wolf-003, [0011], [0089]; Ex-1001, 5:37-6:14.) Wolf-003 also discloses that delivering energy to target tissue(s) reduces or eliminates PNDS, UACS, and excess mucus production,

[12] Ablation is known to destroy target tissue. (Ex-1003-Weide, ¶252 n. 8; Ex-1001, 56:56-65 (ablation leads to "necrosis").)

[13] Mucosal tissue is mucus producing tissue. (Ex-1005-Wolf-003 at [0005].)

which are symptoms of RCR. (Ex-1005-Wolf-003, Abstract, [0003], [0012]-[0013]; Ex-1003-Weide, ¶255.)

It would have been obvious to a POSITA that reducing or eliminating PNDS, UACS, and/or excess mucus production would improve the patient's nasal breathability, as each of these symptoms impacts a patient's ability to breathe through his or her nose. (Ex-1003-Weide, ¶255.)

Thus, Wolf-003 teaches and renders obvious limitations [1d-2] and [16d-2]. (*Id.*, ¶256.)

Limitations [1d-2] and [16d-2] were also obvious in view of Wolf-290. As explained previously, Wolf-290 discloses that applying energy, such as ablative energy, to appropriate nasal airway tissues to damage the nerve fibers and/or goblet cells associated therewith treats rhinitis. (Ex-1006-Wolf-290, [0009], [0053].) Thus, Wolf-003 in view of Wolf-290 also renders obvious limitations [1d-2] and [16d-2]. (Ex-1003-Weide, ¶¶257-258.)

Accordingly, Wolf-003 alone and in view of Wolf-290 teaches and renders obvious Claims 1 and 16. (*Id.,* ¶259.)

[Claims 2 and 17] The method of claim [1, 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.

Assuming "the tissue" of Claims 2 and 17 was meant to refer to a "target" tissue, Wolf-003 discloses Claims 2 and 17.

Wolf-003 discloses that a target site may comprise an inferior turbinate within the nasal cavity:

> "Delivering therapy to the treatment site 506 may follow advancing a portion of the device to a treatment site 504. In this step, the clinician may cause the device to apply energy to the treatment site. For example, in certain implementations, a clinician may use the device *to apply energy to the posterior aspect of the inferior turbinate*."

(Ex-1005-Wolf-003, [0164].)

Wolf-003 also discloses that a target tissue may be submucosal tissue associated with the inferior turbinate:

> "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*. Energy delivery may be accomplished by transferring the energy through the tissue covering the submucosa such as the epithelium, mucosa, muscle, ligaments, cartilage, tendon and/or skin."

(*Id*., [0087].)

Accordingly, Wolf-003 discloses Claims 2 and 17, and Wolf-003 alone and in view of Wolf-290 renders obvious Claims 2 and 17. (Ex-1003-Weide, ¶¶261-262.)

IX. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests that *inter partes* review of the '973 patent be instituted and the Challenged Claims be cancelled as unpatentable.

Respectfully submitted,
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Date: June 25, 2025

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CERTIFICATE OF SERVICE

The undersigned certifies that a true and correct copy of the Petition together with all exhibits identified in the above Table of Exhibits and Petitioner's Power of Attorney, have been served on the Patent Owner via Priority Mail Express or by means at least as fast and reliable as Priority Mail Express on the below date, at the following addresses:

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