UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AERIN MEDICAL INC.
Petitioner

v.

NEURENT MEDICAL LTD.
Patent Owner.

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

Case No.: IPR2025-01127

PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1-20 OF U.S. PATENT 12,096,974 UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. §§ 42.100 ET SEQ.

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1001	U.S. Patent No. 12,096,974 ("the '974 patent")
1002	File history of U.S. Patent No. 12,096,974
1003	Declaration of Dr. Daniel van der Weide
1004	U.S. Patent Appl. Pub. No. 2016/0331459 ("Townley")
1005	U.S. Patent Appl. Pub. No. 2015/0202003 ("Wolf-003")
1006	U.S. Patent Appl. Pub. No. 2019/0282290 ("Wolf-290")
1007	U.S. Patent Appl. Pub. No. 2020/0129223 ("Angeles")
1008	U.S. Patent No. 11,883,091
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1011	File history of U.S. Patent No. 11,998,262 ("'262-FH")
1012	U.S. Patent No. 12,089,889 ("the '889 patent")
1013	File history of U.S. Patent No. 12,089,889
1014	U.S. Patent No. 12,096,973 ("the '973 patent")
1015	File history of U.S. Patent No. 12,096,973
1016	RESERVED
1017	RESERVED
1018	Andrew Lane, *Nasal anatomy and physiology*, Facial Plast. Surg. Clin. N. Am. 12:387-395 (2004)
1019	U.S. Patent Appl. Pub. No. 2011/0021971
1020	U.S. Patent Appl. Pub. No. 2014/0096772
1021	Brook, Itzhak. "*Sinusitis: From Microbiology To Management*" 2006
1022	*Curriculum Vitae* of Dr. Daniel van der Weide
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Exhibit	Description
1024	U.S. Patent No. 6,517,535

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 first electrode that is spaced apart from a second electrode along a length of the multi-electrode end effector, wherein each of the first and second electrodes comprise an active state and an inactive state and comprise a respective location on the multi-electrode end effector,
[1a-4] wherein at least one portion of the multi-electrode end effector comprises a diameter that is larger than a diameter of the shaft, and wherein
[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, wherein the multi-electrode end effector comprises at least one temperature sensor arranged relative to first and second electrode.
[Claim 4] The method of claim 3, wherein the at least one temperature sensor is configured to sense temperature of tissue at the one or more target sites.
[Claim 5] The method of claim 1, [5a] wherein the multi-electrode end effector comprises at least four electrodes, wherein the at least four electrodes are oriented at an angle less than 90 degrees relative to the shaft for the delivery of radiofrequency (RF) energy,
[5b] wherein the shaft is a substantially rigid shaft with a hollow cavity, wherein the shaft comprises an outer sheath and hypotube,
[5c] wherein the first electrode and second electrode is operably coupled to a console unit via wires disposed in the hollow cavity of the substantially rigid shaft, and wherein RF energy is delivered from the first and second electrodes to tissue at the one or more target sites and is controlled via the console unit operably associated with the treatment device and multi-electrode end effector.
[Claim 6] The method of claim 5, wherein the multi-electrode end effector comprises at least six electrodes, and wherein the at least six electrodes are

oriented at an angle less than 90 degrees relative to the shaft for the delivery of RF energy.
[Claim 7] The method of claim 5, wherein the multi-electrode end effector comprises at least eight electrodes, and wherein the at least eight electrodes are oriented at an angle less than 90 degrees relative to the shaft for the delivery of RF energy.
[Claim 8] The method of claim 1, wherein radiofrequency (RF) energy is delivered from the first and second electrodes to tissue at the one or more target sites and is controlled via a console unit operably associated with the treatment device and multi-electrode end effector.
[Claim 9] The method of claim 8, wherein the console unit is operably coupled to an energy generator configured to generate RF energy to be delivered by the first and second electrodes.
[Claim 10] The method of claim 9, wherein the RF energy comprises at least bipolar RF energy.
[Claim 11] The method of claim 8, [11a] wherein the console unit is configured to receive feedback from at least one temperature sensor arranged relative to the first and second electrodes and configured to sense temperature at an interface between tissue and the first and second electrodes,
[11b] wherein the console unit is configured to control energy output from the first and second electrodes based, at least in part, on the feedback in order to maintain a predetermined temperature of tissue at the one or more target sites.
[Claim 12] The method of claim 11, wherein the console unit is configured to receive one or more temperature readings from the at least one temperature sensor and process the readings to determine a level of RF energy to be delivered

by the first and second electrodes that is sufficient to maintain a temperature of tissue at the one or more target sites below a predetermined threshold.
[Claim 13] The method of claim 12, [13a] wherein the console unit is configured to monitor temperature of tissue at the one or more target sites during delivery of RF energy thereto based on temperature readings from the at least one temperature sensor
[13b] and further monitor an elapsed time during delivery of RF energy to tissue at the one or more target sites.
[Claim 14] The method of claim 12, wherein the console unit is configured to provide, via a display, feedback information to an operator during a given treatment application, wherein said feedback information comprises at least an elapsed time during delivery of RF energy to tissue at the one or more target sites.
[Claim 15] The method of claim 14, wherein the display is a touchscreen monitor.
[Claim 16] The method of claim 12, wherein the console unit comprises a hardware processor coupled to non-transitory, computer-readable memory containing instructions executable by the processor to cause the console unit to automatically control and adjust RF energy output from the first and second electrodes based, at least in part, on a predetermined elapsed time period and a predetermined threshold maximum temperature during delivery of RF energy to ensure that application of said RF energy results in the desired effect of reduced engorgement of the tissue at the target site for a given treatment application.
[Claim 17] The method of claim 16, wherein the predetermined threshold maximum temperature is less than 90° C.

[Claim 18] The method of claim 16, wherein the predetermined threshold maximum temperature is greater than 37° C. and less than 90° C.
[Claim 19] The method of claim 16, the predetermined elapsed time period is from about 1 second to about 20 seconds.
[Claim 20] The method of claim 19, wherein the predetermined elapsed time period is from about 10 seconds to about 12 seconds.

I. INTRODUCTION

Aerin Medical Inc. ("Aerin" or "Petitioner") hereby seeks *inter partes* review and cancellation of claims 1-20 ("the Challenged Claims") of U.S. Patent No. 12,096,974 ("the '974 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
- IPR2025-01126 challenging U.S. Patent No. 12,096,973.

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 13,777 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 (2025-01127), 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 IPR2025-01127, Aerin reserves the right to assert any grounds of invalidity in the Litigation against the '974 patent.

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

Petitioner certifies that the '974 patent is available for IPR and Petitioner is not barred/estopped from requesting cancellation of the Challenged Claims per the below Grounds:

Ground	'974 Patent Claims	Basis
Ground 1	1-20	Obvious in view of Townley (Ex-1004)
Ground 2	1-4 and 8-12	Obvious in view of Wolf-003 (Ex-1005) alone or in view of Wolf-290 (Ex-1006)
Ground 3	8-20	Obvious based on the Ground 2 references further in view of Angeles (Ex-1007)

Because the '974 patent is an AIA patent granted September 24, 2024, the '974 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 '974 PATENT

A. The '974 Patent and the Challenged Claims

The '974 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 '974 patent discloses and illustrates a "neuromodulation device 102":

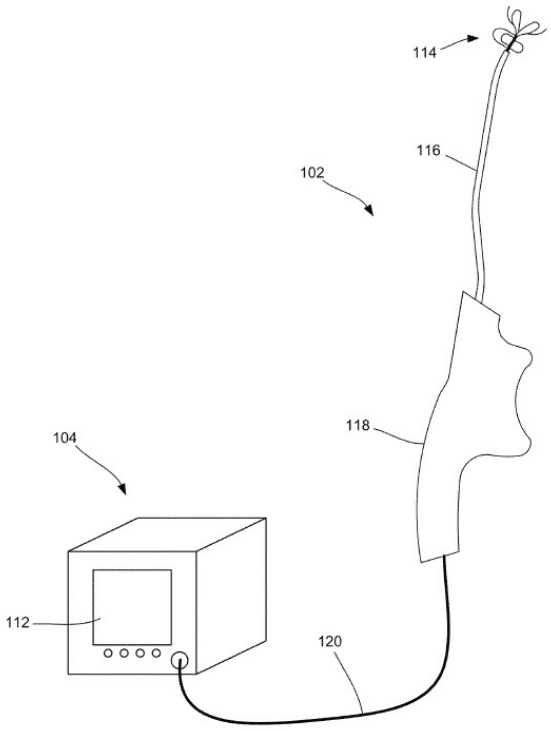


FIG. 2

(*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 '974 patent is April 9, 2020. (Ex-1001, [60].) Petitioner applies this date without conceding the '974 patent is so entitled.

C. Prosecution History

The '974 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, 160.) Prosecution of the '974 patent was minimal. After Neurent filed a terminal disclaimer to the '262 patent, the original claims were allowed without amendment and the allowance issued less than 5 months after the application was filed. (Ex-1002, 15-22 (allowance), 61-66 (response with disclaimer; original claims unamended), 76-82 (action with only a double patenting rejection).)

The Notice of Allowance states "the prior art does not teach" the entirety 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 prior art in view of the terminal disclaimer," and "[t]herefore, it is the Examiner's position that the claimed invention is in condition for allowance." (*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 '974 patent had been broadened relative to the claims of the '091 patent, the '974 patent would not have been allowed.

Specifically, the '091 patent was allowed in view of ***numerous*** limitations that are ***not*** present in the '974 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.) The '974 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 '974 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 '974 patent (Exs. 1005-1007).

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, ¶68.)

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 '974 patent is compliant

with 35 U.S.C. § 112. The '974 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 '974 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 '974 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 '974 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.)

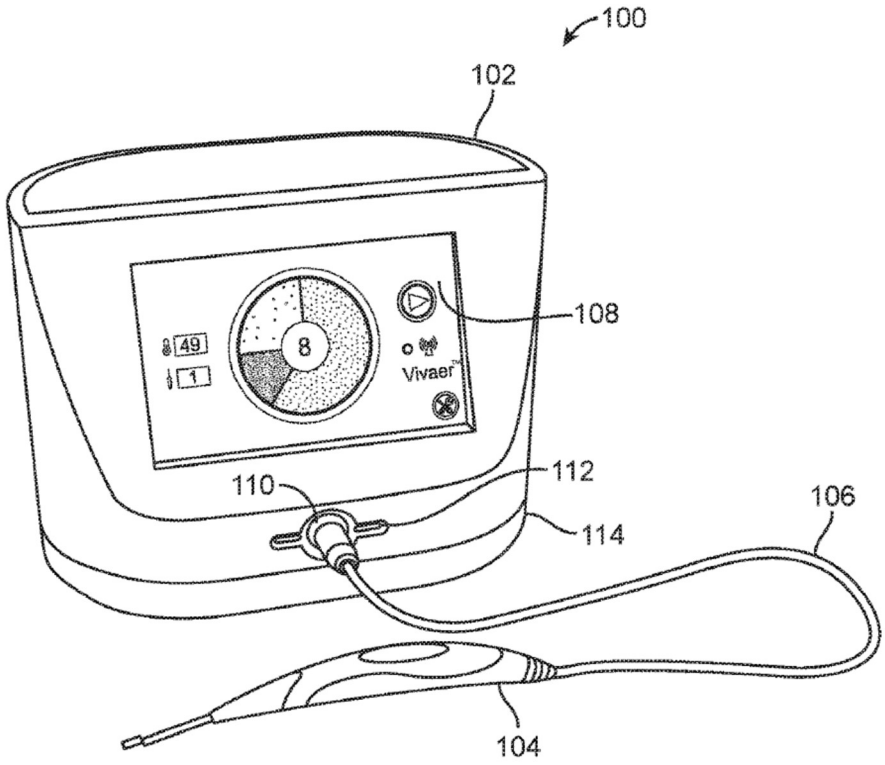
Wolf-290 is analogous to the '974 patent as it discloses minimally invasive systems, devices and methods for treating conditions associated with rhinosinusitis. (Ex-1003-Weide, ¶60.)

E. Angeles (Ex-1007-Angeles)

Angeles is US2020/0129223 owned by Aerin and is §102(a)(2) prior art at least because it was filed October 19, 2019, *i.e.*, prior to the earliest possible priority date of the '974 patent.

Angeles is directed to "an electrosurgery system console and user interface." (Ex-1007-Angeles, [0002].) The console may include "a housing, an energy

generator in the housing, a computer processor in the housing, … [and] a touchscreen display on the housing." (*Id.,* Abstract.) The energy generator may be "a radiofrequency (RF) generator, configured to deliver monopolar and/or bipolar RF energy to the energy delivery treatment device." (*Id.,* [0007].)



(*Id.,* FIG. 1.)

Angeles is analogous to the '974 patent at least because it is in the same field of endeavor as the '974 patent and discloses minimally invasive systems, devices and methods for treating conditions associated with rhinosinusitis. (Ex-1003-Weide, ¶64.)

VIII. SPECIFIC GROUNDS FOR PETITION

A. GROUND 1: Townley Renders Obvious Claims 1-20.

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 Claim 1. 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, ¶74.) Accordingly, Townley renders obvious Claim 1. Townley also discloses, teaches, or suggests Claims 2-20, likewise rendering those claims obvious.

2. 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

Townley discloses the preamble irrespective of whether it is limiting.

Townley discloses methods of treating rhinitis, congestion, and/or rhinorrhea (hereinafter "RCR") within a patient's sino-nasal cavity. (Ex-1003-Weide, ¶¶76, 78; Ex-1004-Townley, [0002], [0041], [0058].)[1]

Thus, Townley discloses limitation [1-PRE]. (Ex-1003-Weide, ¶79.)

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

The '974 patent states that "the terms 'end effector' and 'therapeutic assembly' may be used interchangeably." (Ex-1001, 12:32-34.) Thus, Townley's multi-electrode *therapeutic assemblies* (described below) disclose the claimed multi-electrode *end effector* ("MEEE"). (Ex-1003-Weide, ¶¶81-82.)

Townley discloses many multiple-electrode therapeutic assemblies, *i.e.*, MEEEs. (Ex-1003-Weide, ¶83.) 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

[1] Claims 1 and 2 recite "the nasal cavity" in places, which confirms "the sino-nasal cavity" includes the nasal cavity. (Ex-1003-Weide at ¶77.)

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, 8-9 11A-D. (Ex-1003-Weide, ¶84.)

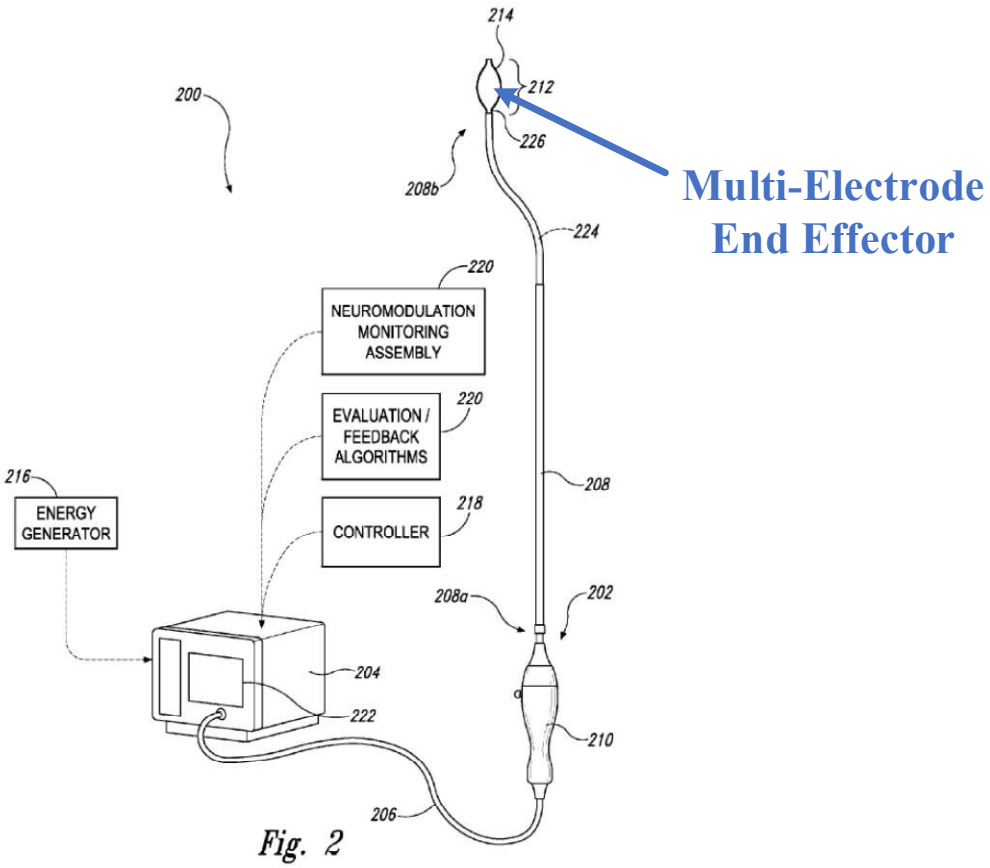


Fig. 2

(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, ¶85.)

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

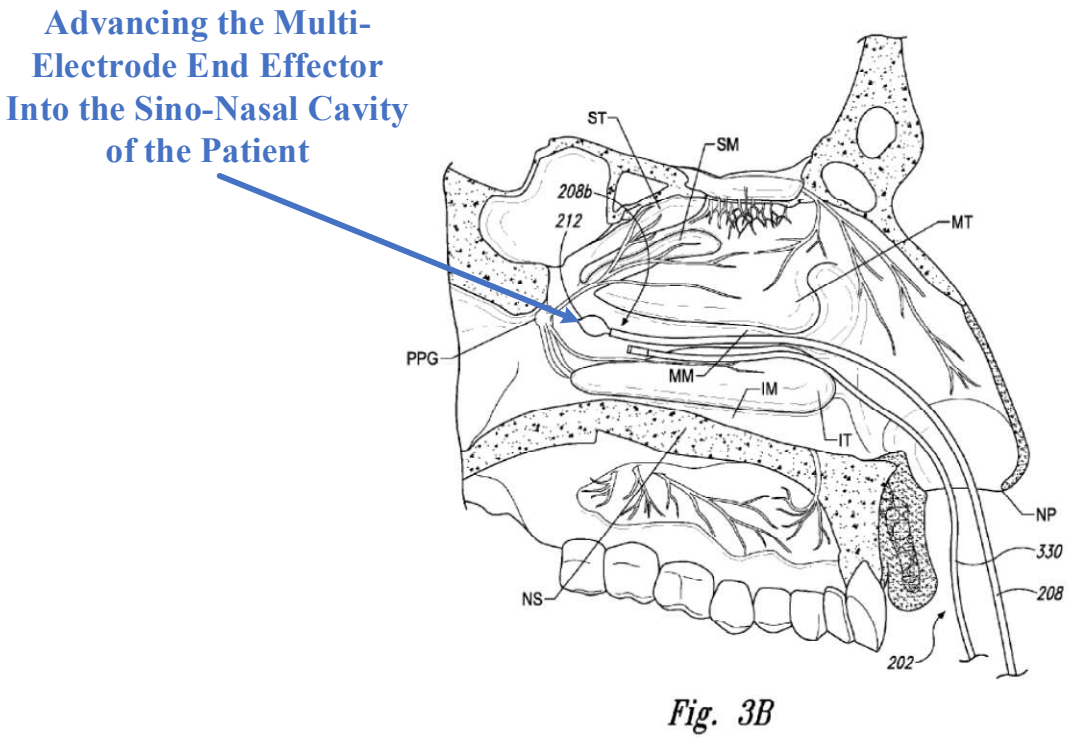


Fig. 3B

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

Thus, Townley discloses limitation [1a-1]. (Ex-1003-Weide, ¶86.)

[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

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, ¶88; Ex-1004-Townley, FIGS. 3A-E, 4, 5A-G, 8-9 and 11A-C, [0042].)

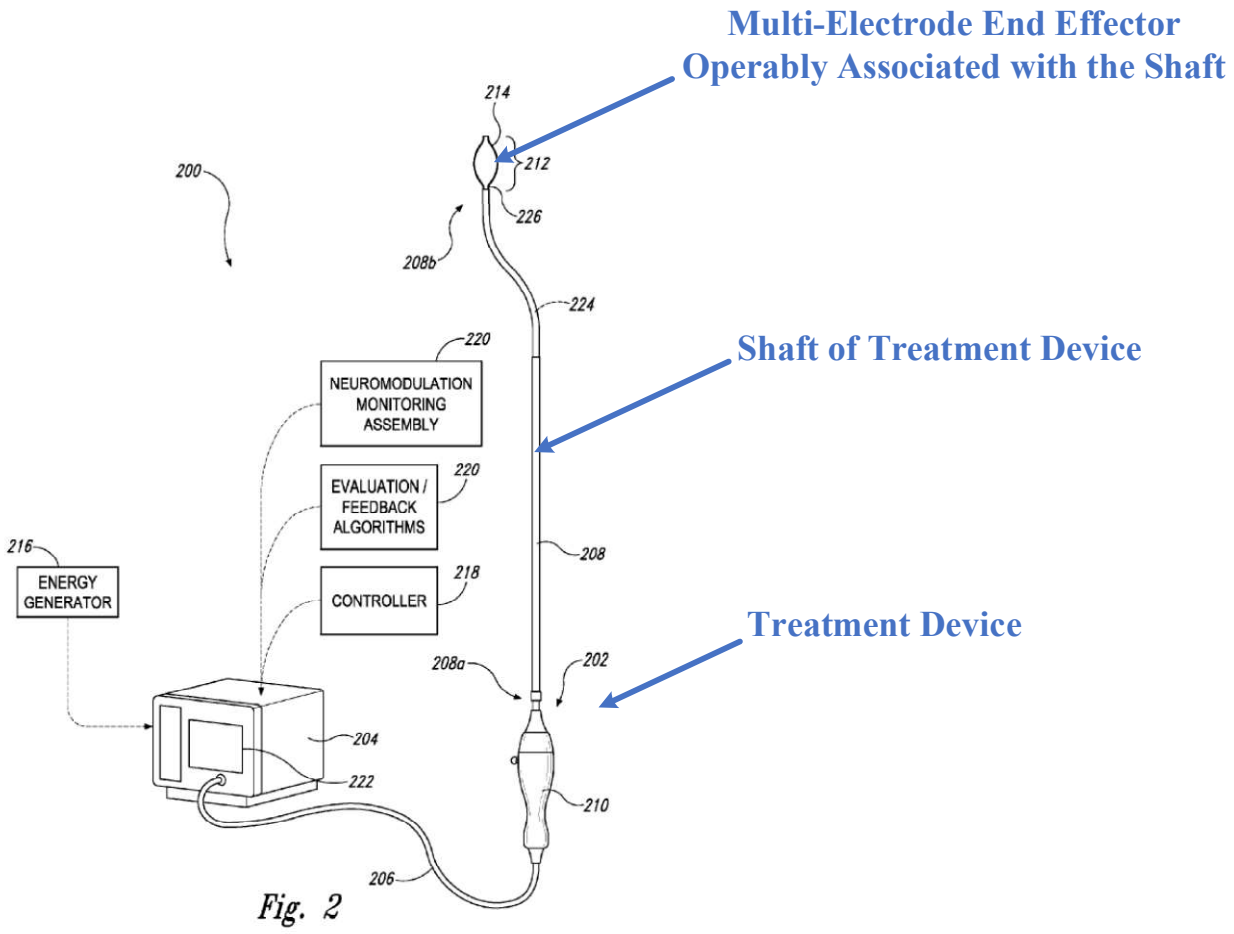


Fig. 2

(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, ¶89; Ex-1004-Townley, [0043].)

Thus, Townley discloses limitation [1a-2]. (Ex-1003-Weide, ¶90.)

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

Townley's MEEEs have electrodes meeting the requirements of [1a-3]. (Ex-1003-Weide, ¶92.) For example, as shown below, the MEEEs of Figures 4, 5A-G,

8-9 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:

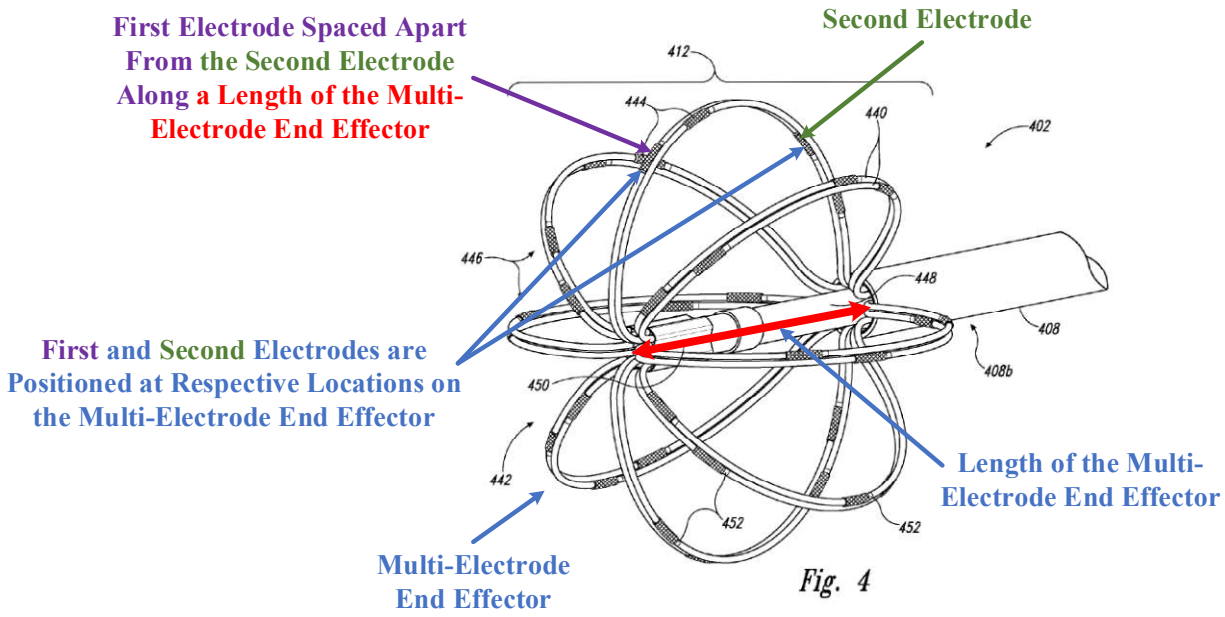


Fig. 4

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

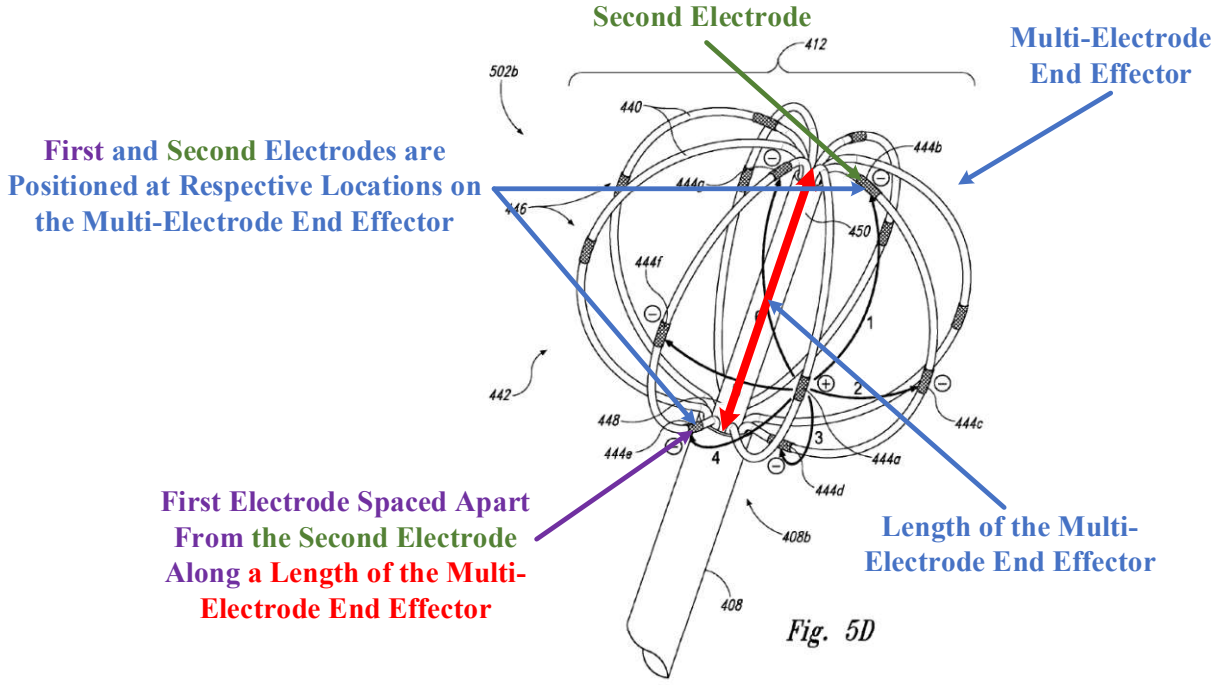


Fig. 5D

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

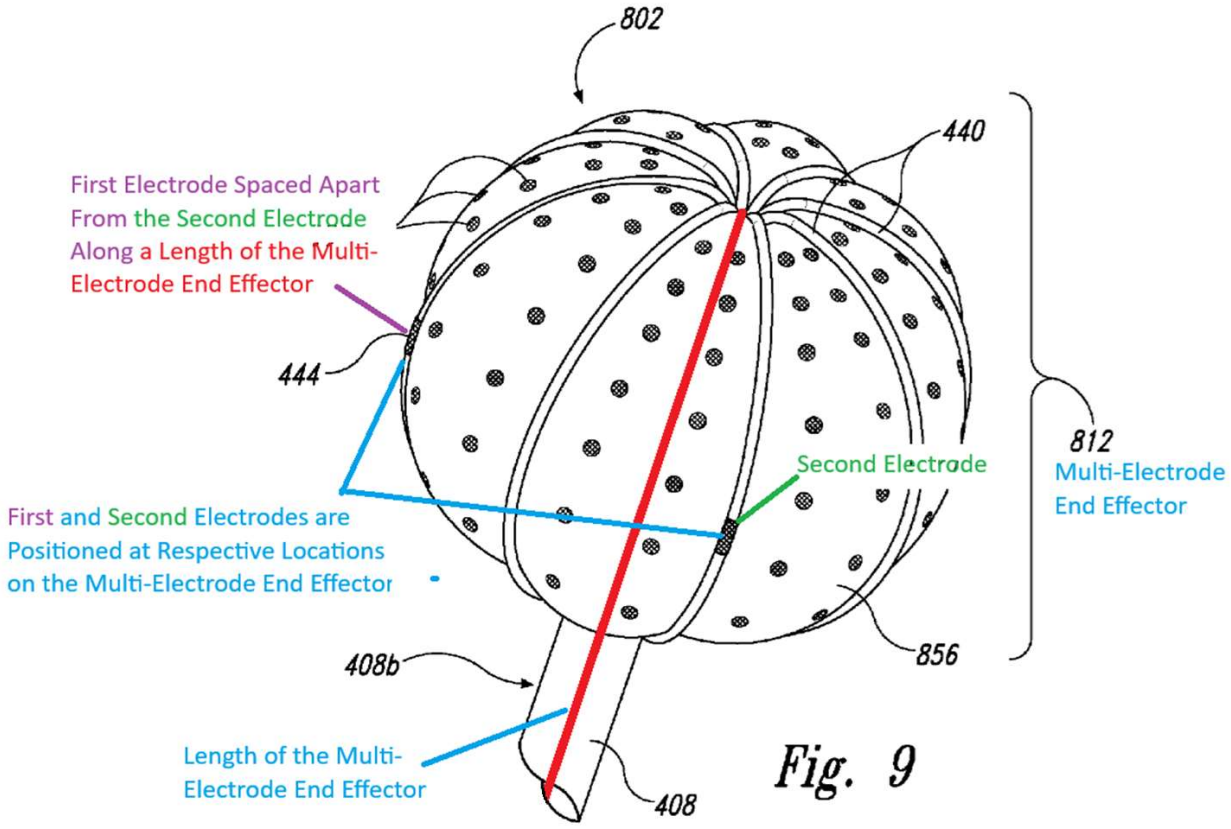
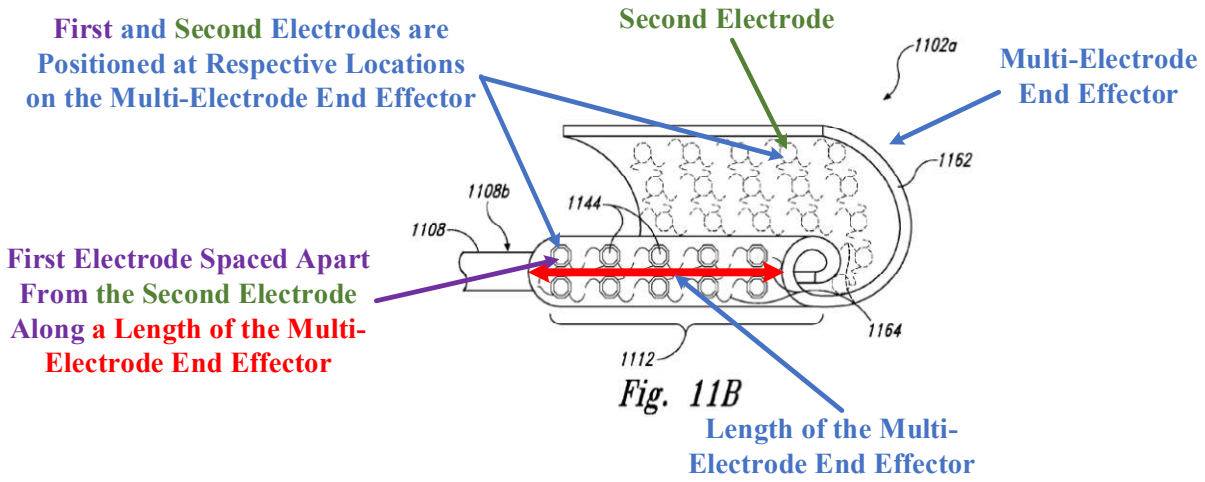


Fig. 9

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



(*Id.,* FIG. 11B; *see also id.,* [0066]-[0073] (explaining electrode arrangements and functionality); *id*., [0066], [0075], [0099],]0105], [0112] (explaining embodiments of FIGS. 2, 4, 5A-G, 8-9, and 11A-D, may include same general features).)

Further, each of the first and second electrodes comprises an active state and an inactive state. (*Id.,* [0072]; Ex-1003-Weide, ¶93.)

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

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

Townley discloses limitation [1a-4].

For example, the basket 442 (*at least one portion*) of the MEEE of Figure 4 forms a "generally spherical structure" having a diameter that is larger than a diameter of the shaft (408). (Ex-1003-Weide, ¶¶96-97.)

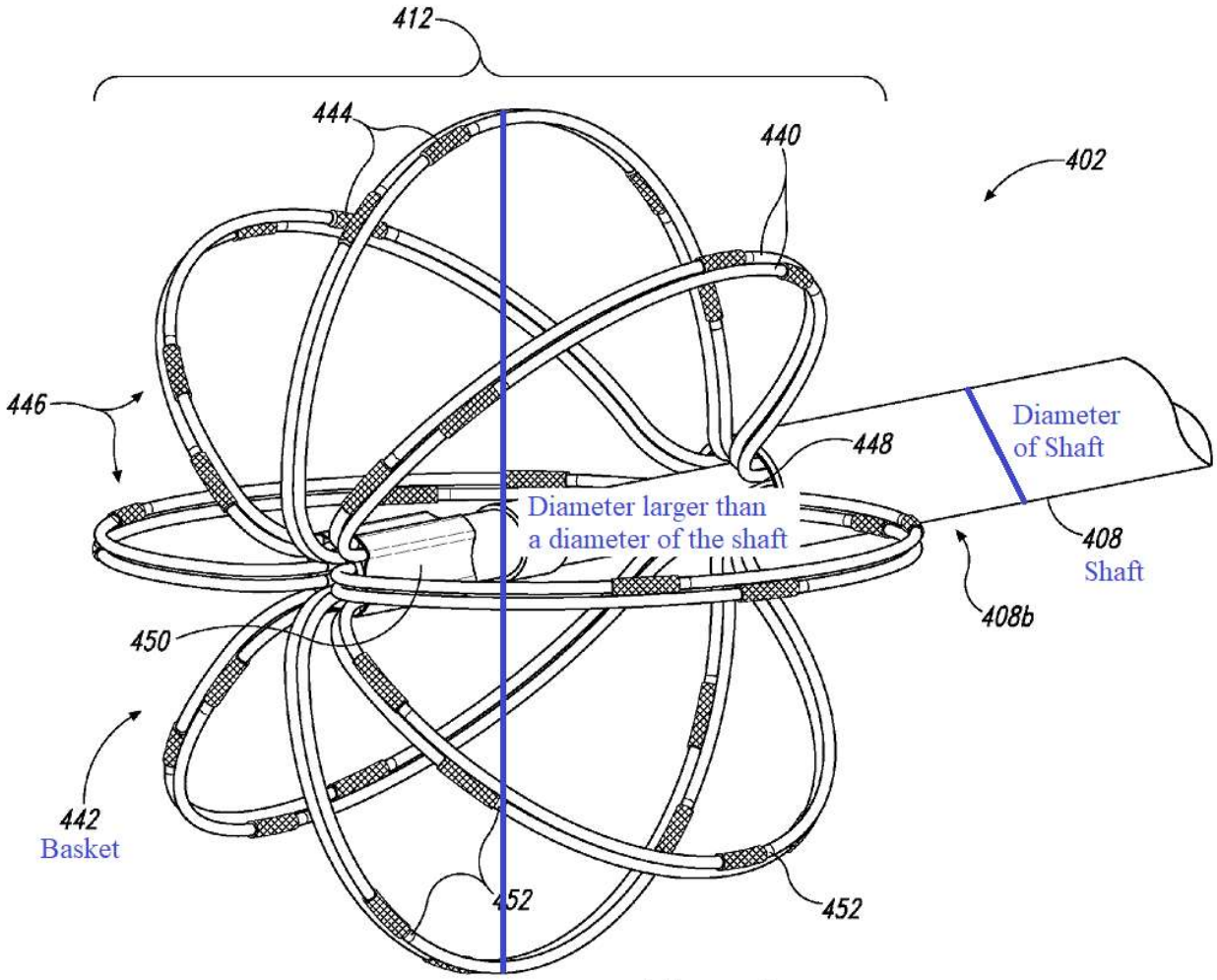


Fig. 4

(Ex-1004-Townley, FIG. 4, [0067] ("the basket 442 includes eight branches 446 spaced radially apart from each other to ***form at least a generally spherical structure***"); *id.*, FIGS. 5A-G (illustrating similar basket assemblies to FIG. 4).)

As another example, Figure 9 illustrates a MEEE (812) having an expandable member (856) (*at least one portion*) with a diameter larger than that of the shaft (408). (Ex-1003-Weide, ¶98.)

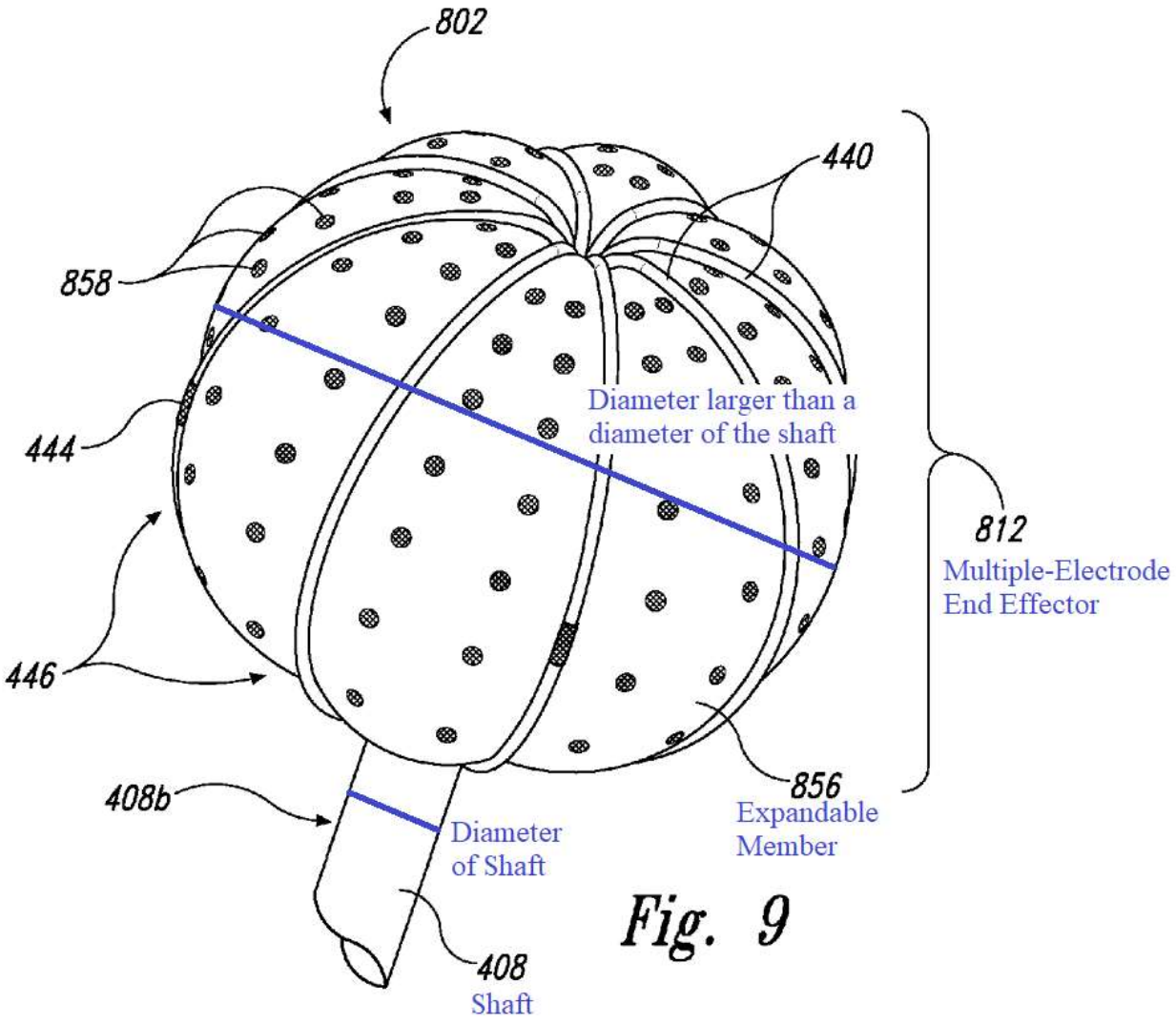


Fig. 9

(Ex-1004-Townley, FIG. 9, [0099].)

Figures 11A-D also illustrate MEEEs (1112) having elements (e.g., 1162) with diameters larger than a diameter of the shaft (1108). (Ex-1003-Weide, ¶99.)

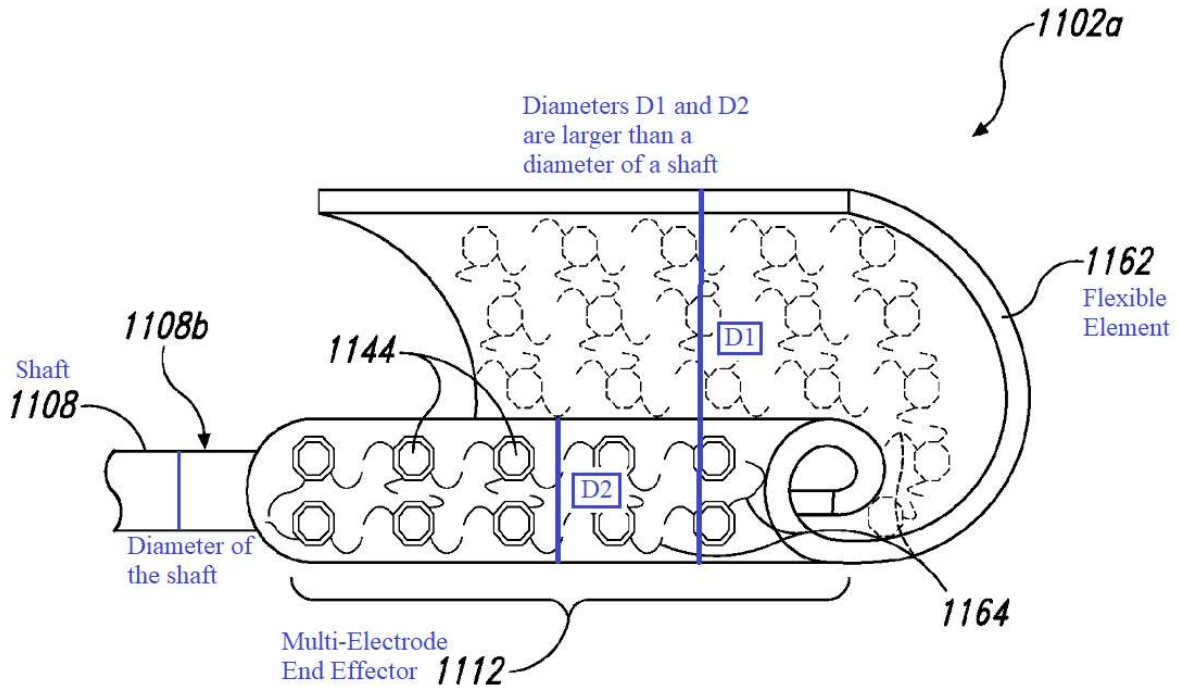


Fig. 11B

(Ex-1004-Townley, FIG. 11B, [0105]-[0106].)

Thus, Townley discloses limitation [1a-4]. (Ex-1003-Weide, ¶100.)

[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

Townley's MEEEs comprise a first electrode per the requirements of [1b]. (Ex-1003-Weide, ¶102.) For example, as shown below, the MEEEs of Figures 4, 5A-G, 8-9, 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:

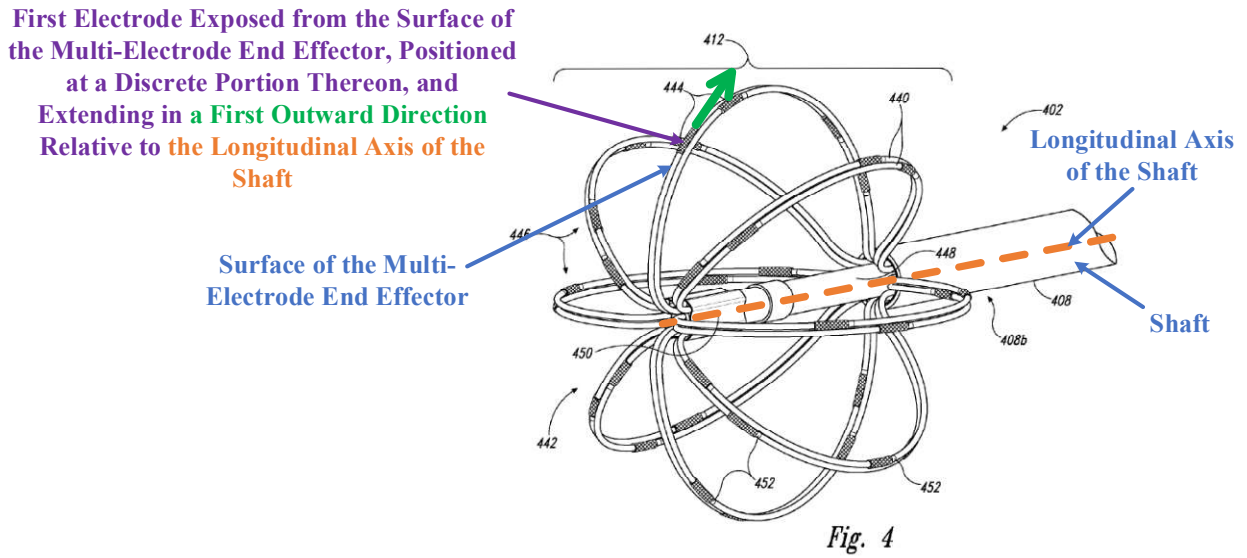


Fig. 4

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

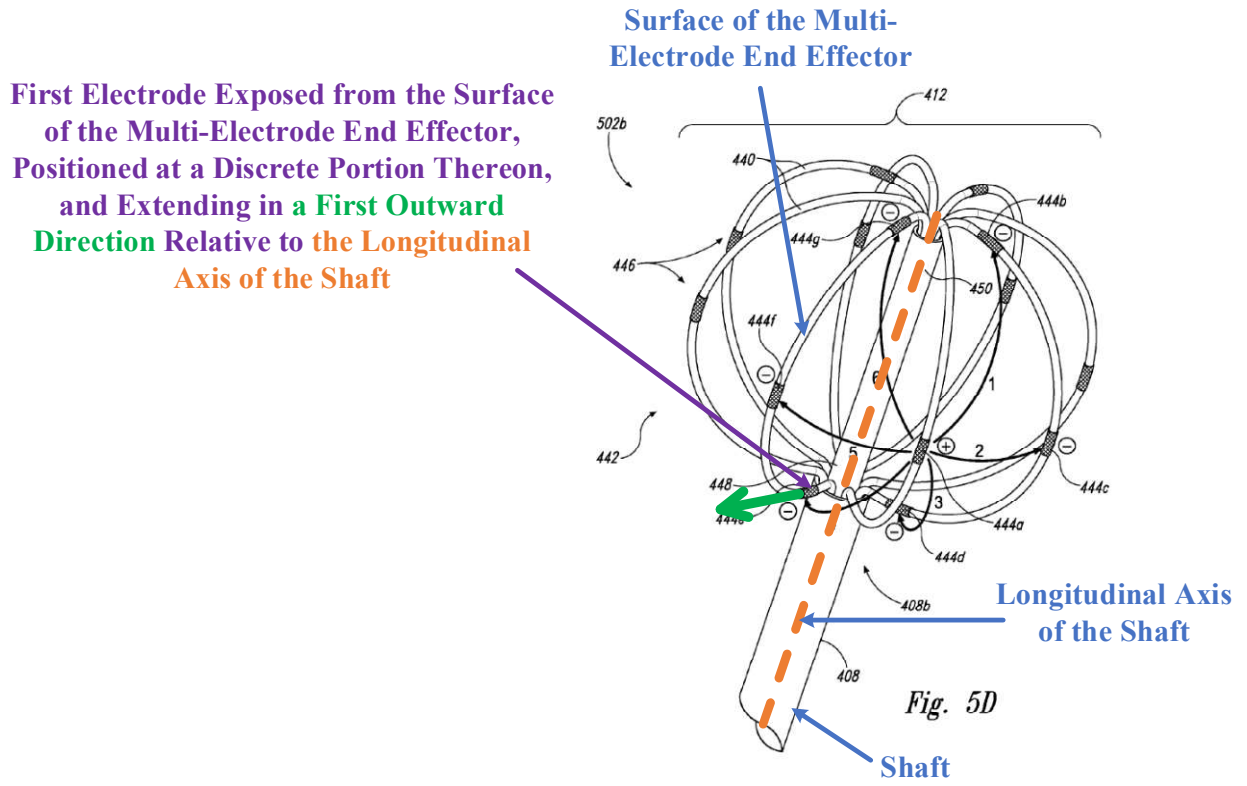


Fig. 5D

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

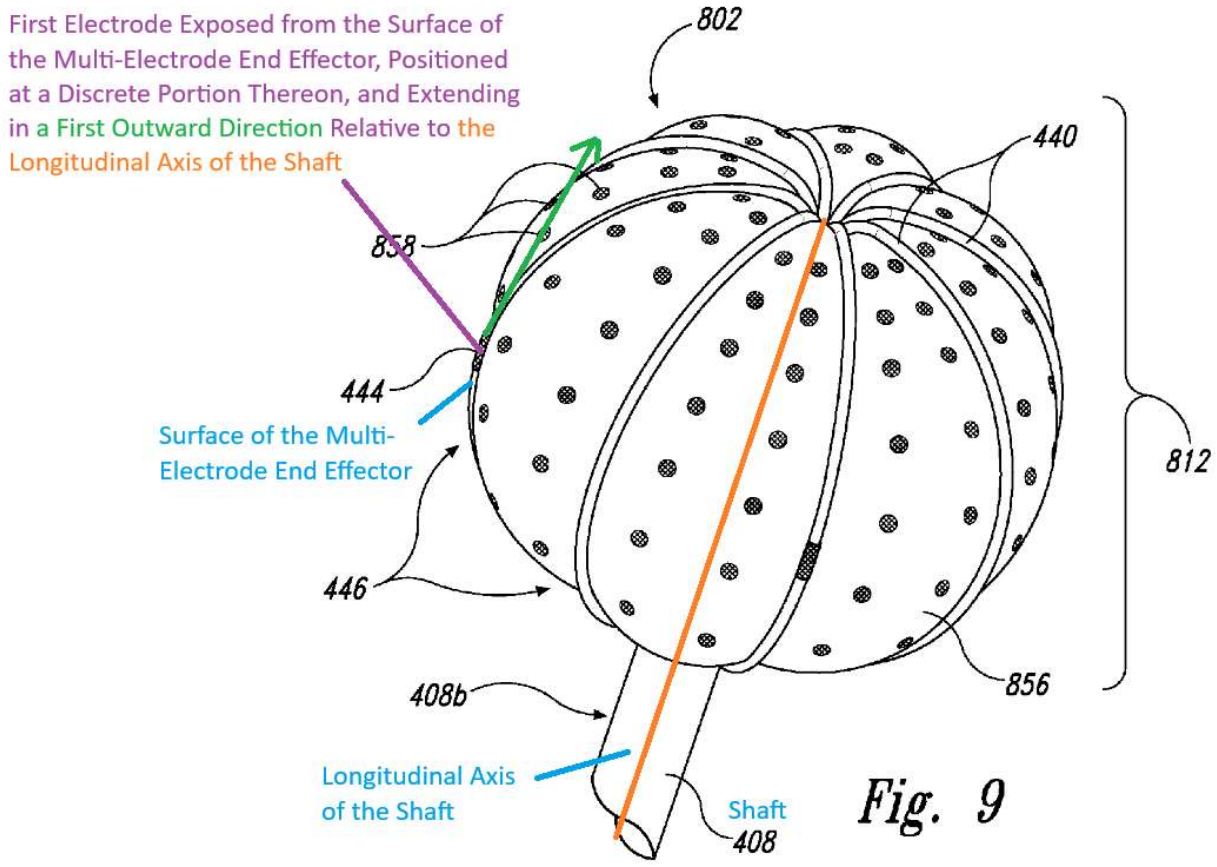


Fig. 9

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

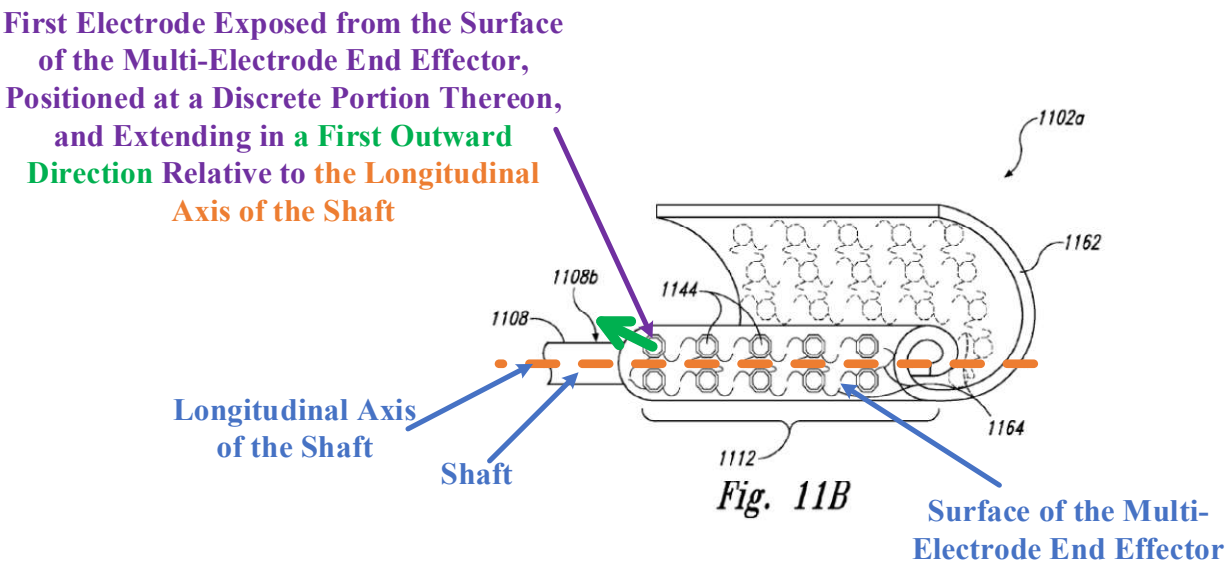


Fig. 11B

(*Id.,* FIG. 11D; *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, ¶103; 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 limitation [1b]. (Ex-1003-Weide, ¶104.)

[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

Townley's MEEEs also comprise a second electrode per the requirements of [1c]. (Ex-1003-Weide, ¶¶105-106.) For example, as shown below, the MEEEs of Figures 4, 5A-6, 8-9, 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:

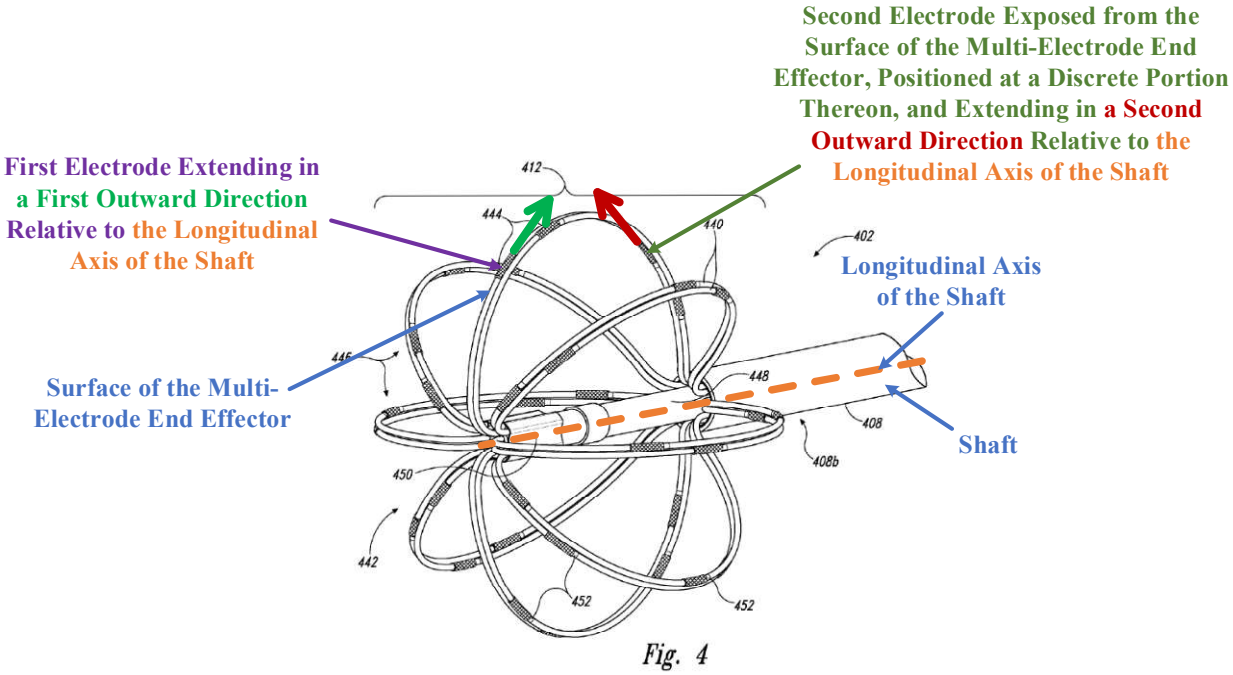


Fig. 4

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

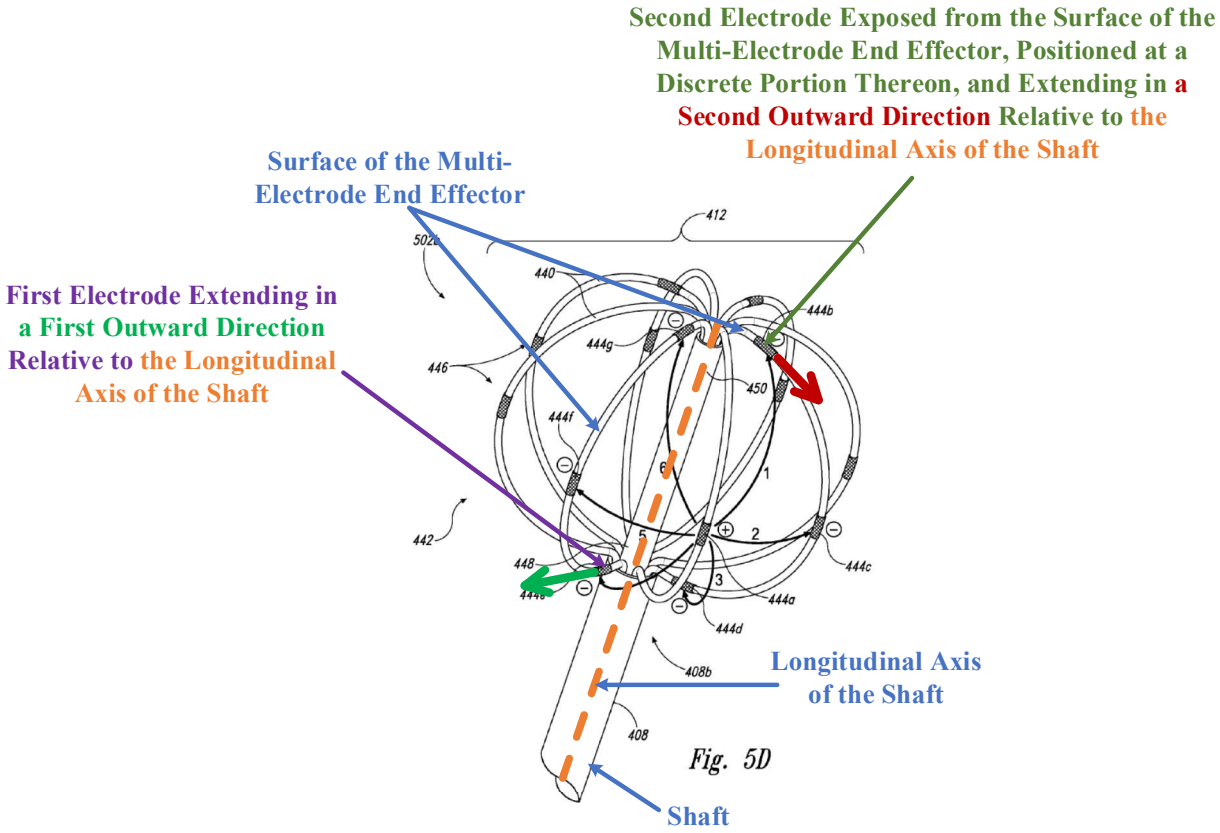


Fig. 5D

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

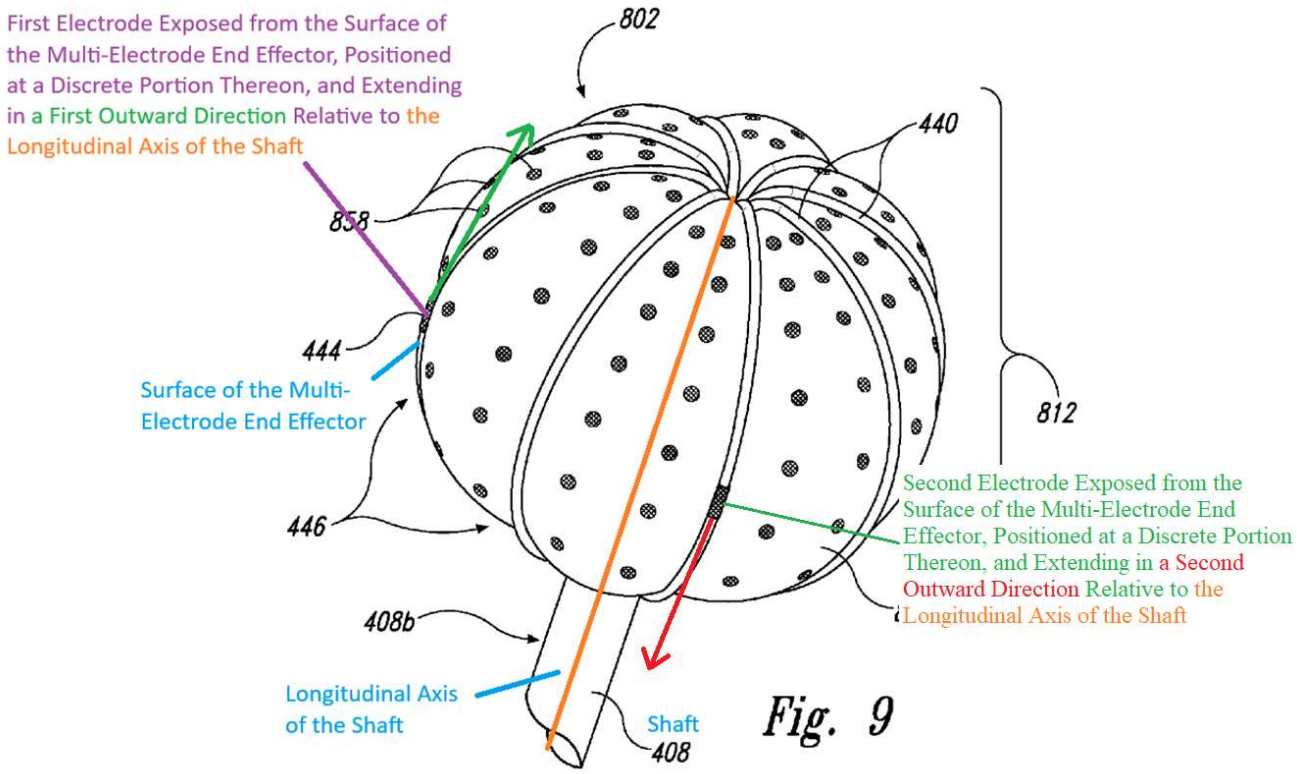


Fig. 9

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

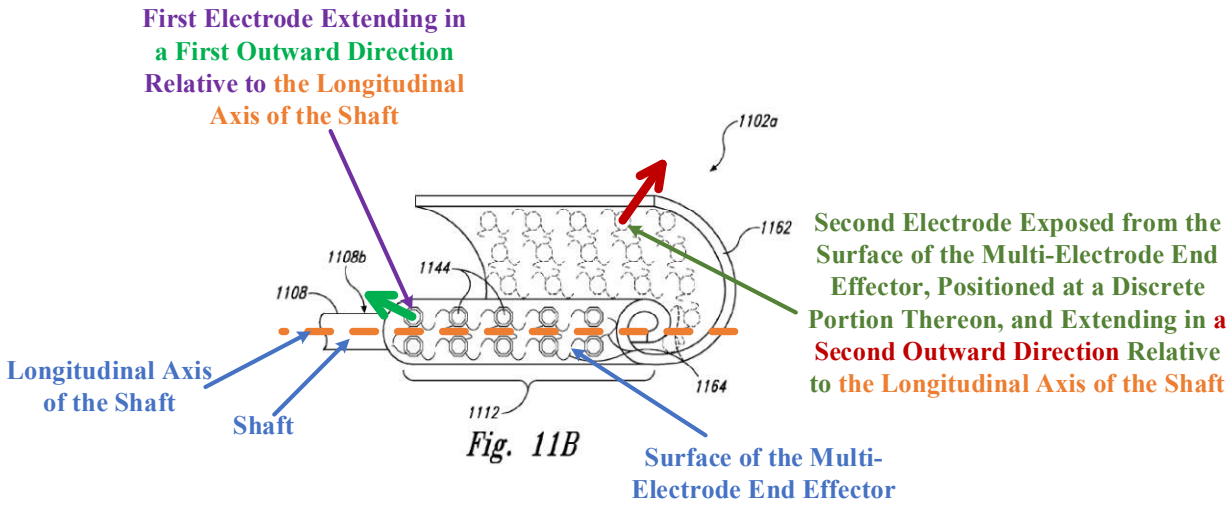


Fig. 11B

(*Id.,* FIG. 11B, [0109].)[3]

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 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, ¶108.)

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, ¶109; Ex-1004-Townley, [0066], [0073].)

Thus, Townley discloses limitation [1c]. (Ex-1003-Weide, ¶110.)

[3] 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, ¶107.)

[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

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, ¶¶112-113; Ex-1004-Townley, [0043].) Thus, Townley discloses limitation [1d-1]. (Ex-1003-Weide, ¶114.)

With respect to limitation [1d-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, ¶116.) 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, ¶117.)

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, ¶118; 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, ¶119; 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, ¶119.)

Thus, Townley teaches and suggests limitation [1d-2]. (*Id.,* ¶120.)

Accordingly, Townley renders obvious Claim 1. (*Id.,* ¶121.)

[Claim 2]

Claim 2 refers to "*the tissue*," yet no prior "tissue" is recited in Claim 1. Assuming "the tissue" of Claim 2 refers to a "target" tissue, Townley teaches Claim 2. 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].)

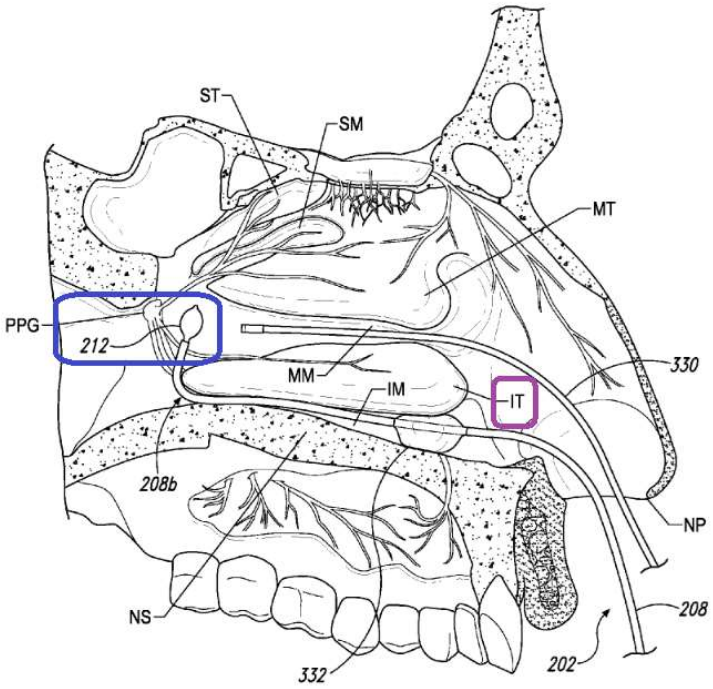


Fig. 3A

(*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].)

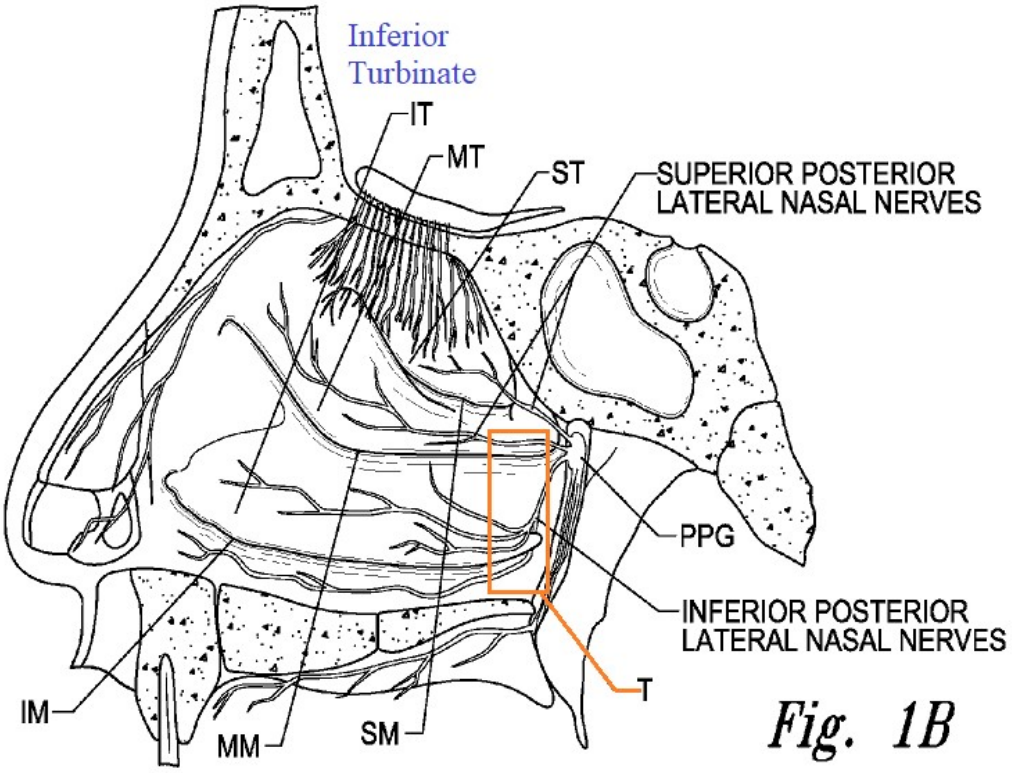


Fig. 1B

(*Id.,* FIG. 1B.) As shown, 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:

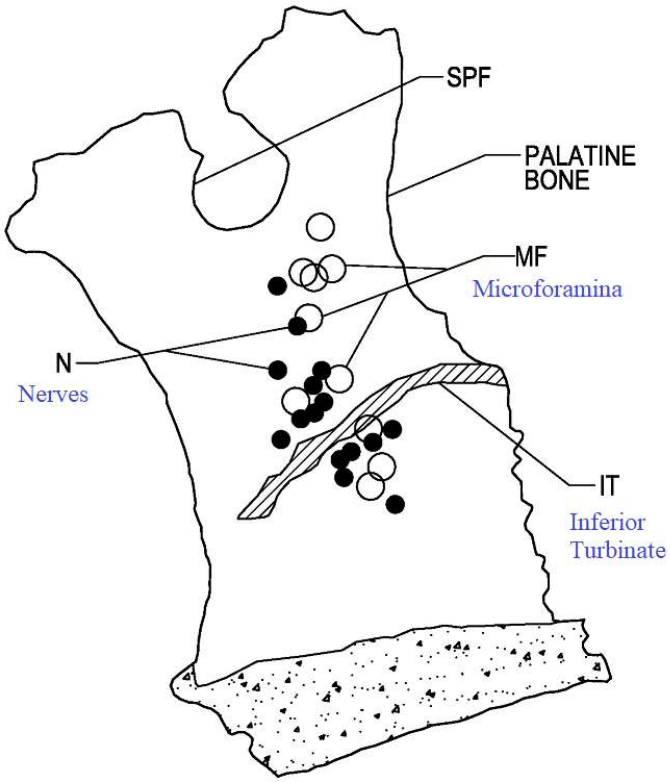


Fig. 1C

(*Id.,* FIG. 1C, [0037].)[4]

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

[4] *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 Claim 2. (Ex-1003-Weide, ¶¶123-127.)

[Claims 3-4]

Townley discloses that its MEEEs include "at least one temperature sensor arranged relative to first and second electrode" "configured to sense temperature of tissue at the one or more target sites." (Ex-1004-Townley, [0074] ("the therapeutic assembly 412 can further include one or more temperature sensors 452 … configured to detect the temperature adjacent to the temperature sensor 452 … 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"); *see also id.*, FIGS. 4, 5A-G, 8-9, and 11A-D; Ex-1003-Weide, ¶129.)

Thus, Townley teaches and renders obvious Claims 3-4. (Ex-1003-Weide, ¶130.)

[Claim 5, 5a]

Townley discloses that the MEEEs of Figures 4, 5A-G, 8-9, and 11A-D comprise at least eight electrodes, wherein the at least eight electrodes[5] are oriented at an angle less than 90 degrees relative to the shaft. (Ex-1003-Weide, ¶133.)

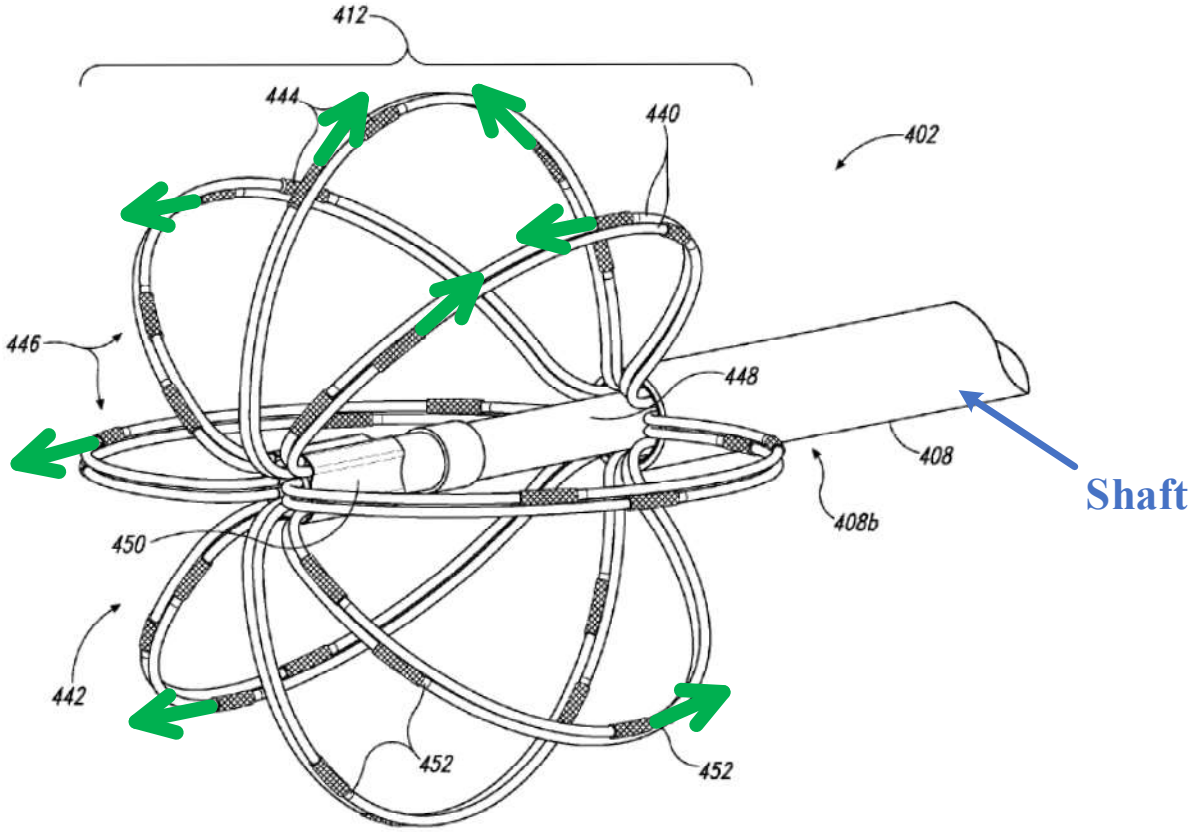


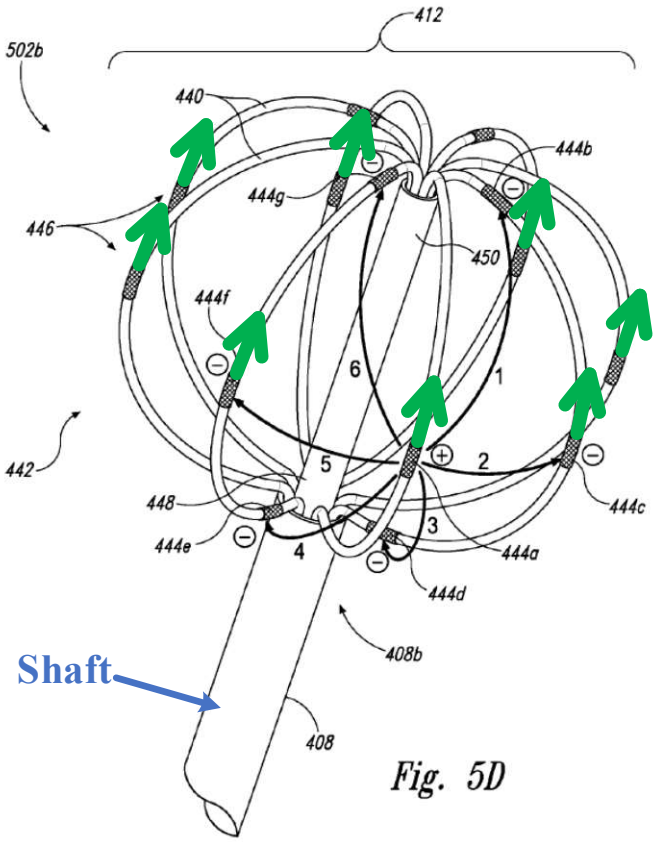
Fig. 4

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

[5] Petitioner demonstrates Townley's use of "at least eight" electrodes in Claim 5 because such demonstration applies to Claims 6-7.

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 are oriented at angles less than 90 degrees relative to the shaft 408. (Ex-1003-Weide, ¶134.)

The electrodes arrangements of Figures 5A-G also disclose limitation [5a]. (*Id*., ¶135.) As one example, Petitioner annotates Figure 5D below:



(Ex-1004-Townley, FIG. 5D (showing at least eight electrodes 444 oriented at an angle less than 90-degrees relative to the shaft 408).)

The electrodes 444 of Figure 9 may have the same or similar arrangements to those of Figures 4 and 5A-G. (Ex-1004-Townley, [0099].) Thus, Figure 9 teaches limitation [5a] for the same reasons as Figures 4 and 5A-G. (Ex-1003-Weide, ¶136.)

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

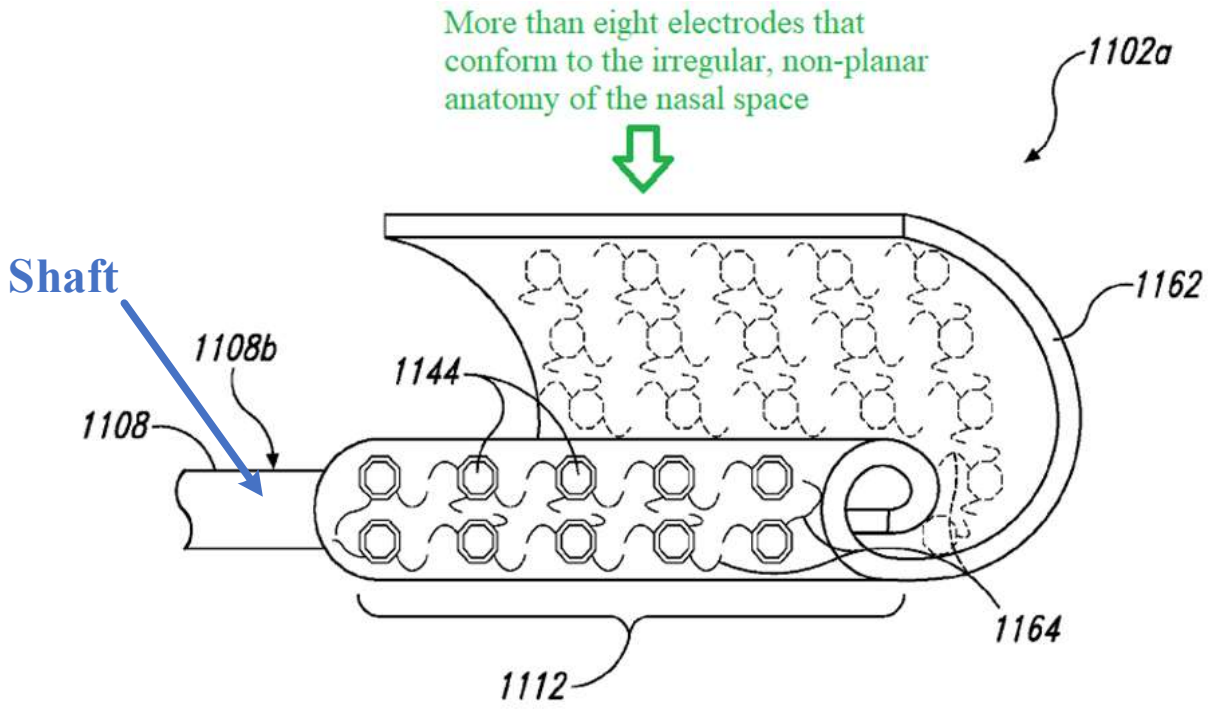


Fig. 11B

(Ex-1004-Townley, FIG. 11B, [0106].)

It was obvious that at least eight of the electrodes of Figure 11B would be non-perpendicular (*i.e.*, at an angle less than 90 degrees) relative to the shaft to confirm to the non-planar anatomy of the nasal space. (Ex-1003-Weide, ¶137.)

Townley discloses that its electrodes may deliver RF energy. (Ex-1003-Weide, ¶132; 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)).)

Thus, Townley discloses limitation [5a]. (Ex-1003-Weide, ¶138.)

[5b]

Townley's shaft may be "a substantially rigid shaft." (Ex-1004-Townley, [0051] ("can be made from a substantially rigid material (e.g., a metal material)."); Ex-1003-Weide, ¶139.)

Townley's shaft may include "an outer sheath," "a hypotube," and "a hollow cavity." 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, ¶140.)

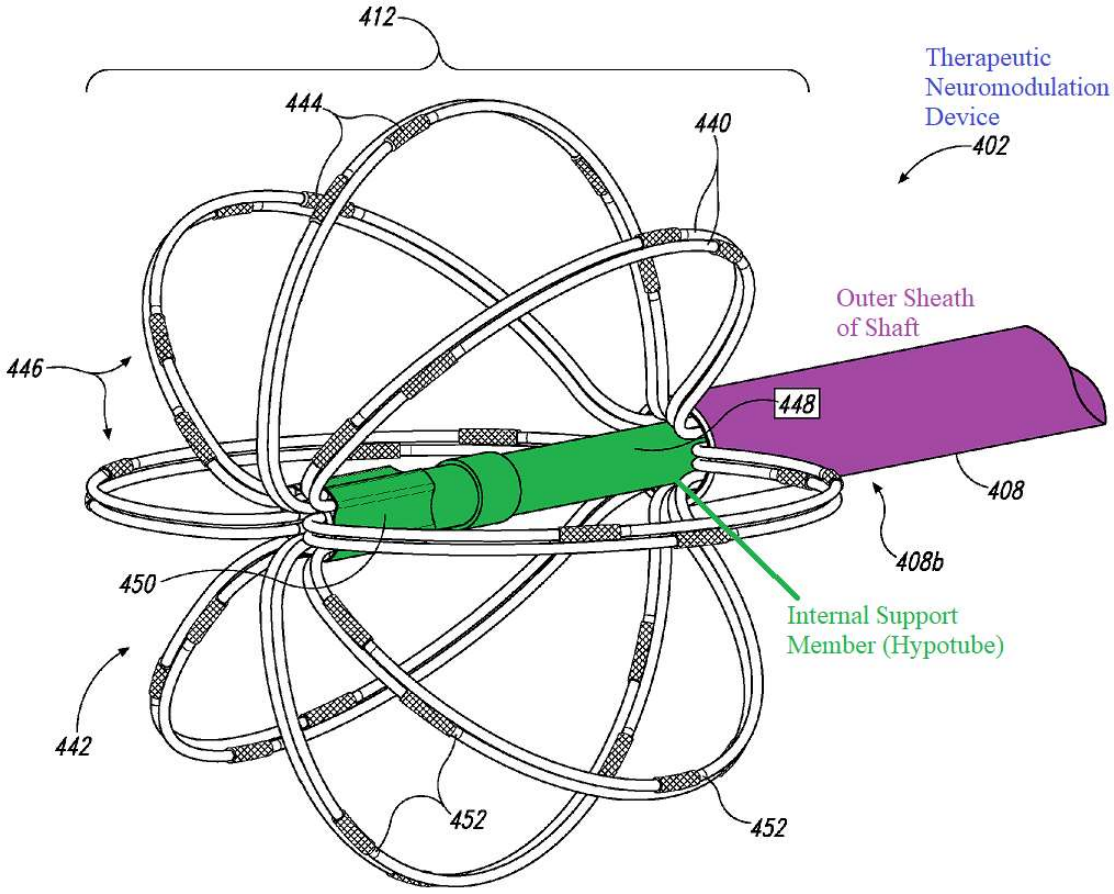


Fig. 4

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

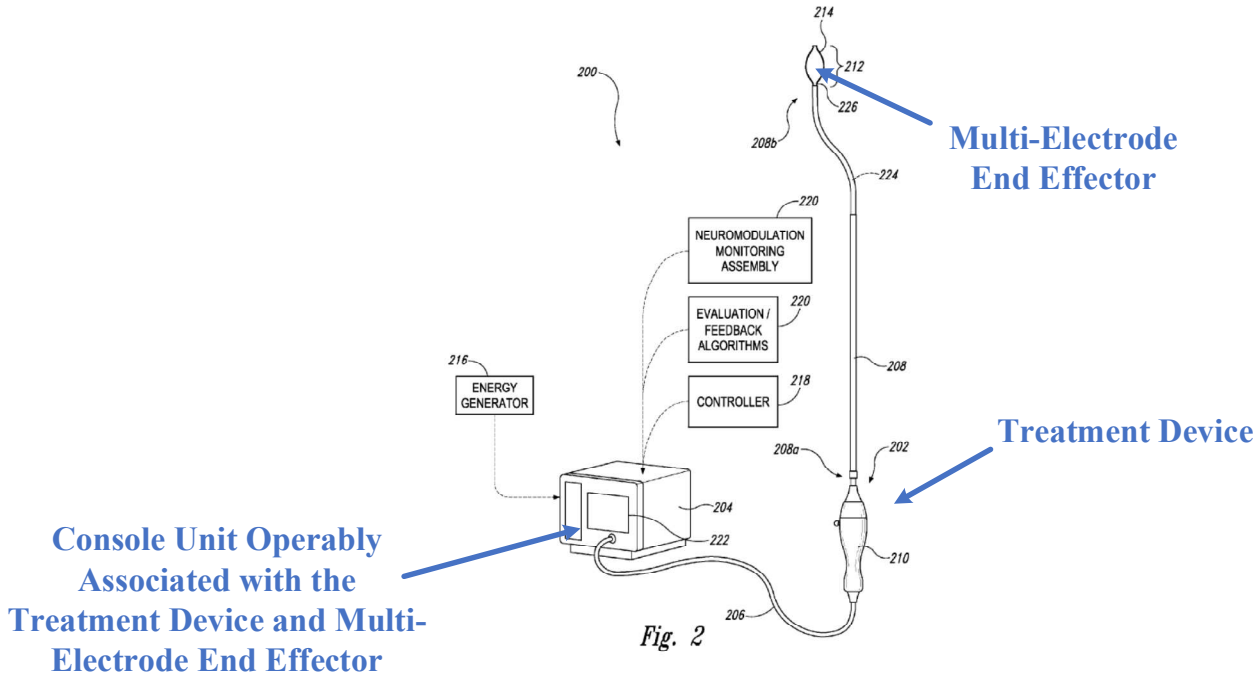
Further, the ***internal support member 448*** is a ***hypotube*** that extends distally from a distal portion 408*b* of the ***outer sheath*** of the shaft. (Ex-1003-Weide, ¶141; Ex-1004-Townley, [0068].) "[T]he support member 448 can include an internal channel (not shown) through which electrical 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, ¶142.)[6] Thus, Townley discloses limitation [5b]. (Ex-1003-Weide, ¶144.)

[5c]

Townley discloses a console unit (204) ("console") operably associated with the treatment device (202) and the MEEEs (212), the console including an RF energy generator (216) for delivering RF energy. (Ex-1003-Weide, ¶¶145, 147; Ex-1004-Townley, [0045].

[6] Townley's description of its "internal support member 448" aligns with the '974 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, ¶143.)



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

The console may be used with the therapeutic assemblies of Figures 4, 5A-G, 8-9, and 11A-D. (*Id.,* [0074]-[0075], [0099], [0111]; Ex-1003-Weide, ¶146.) RF energy delivered from the first and second electrodes to tissue at the target site(s) is controlled by Townley's console. (Ex-1004-Townley, [0045]; Ex-1003-Weide, ¶149.)

The first electrode and second electrodes are operably coupled to the console unit via wires disposed in the hollow cavity of the substantially rigid shaft. (Ex-1003-Weide, ¶148; 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 limitation [5c]. (Ex-1003-Weide, ¶150.)

Accordingly, Townley teaches and renders obvious Claim 5. (*Id.,* ¶151.)

[Claims 6-7]

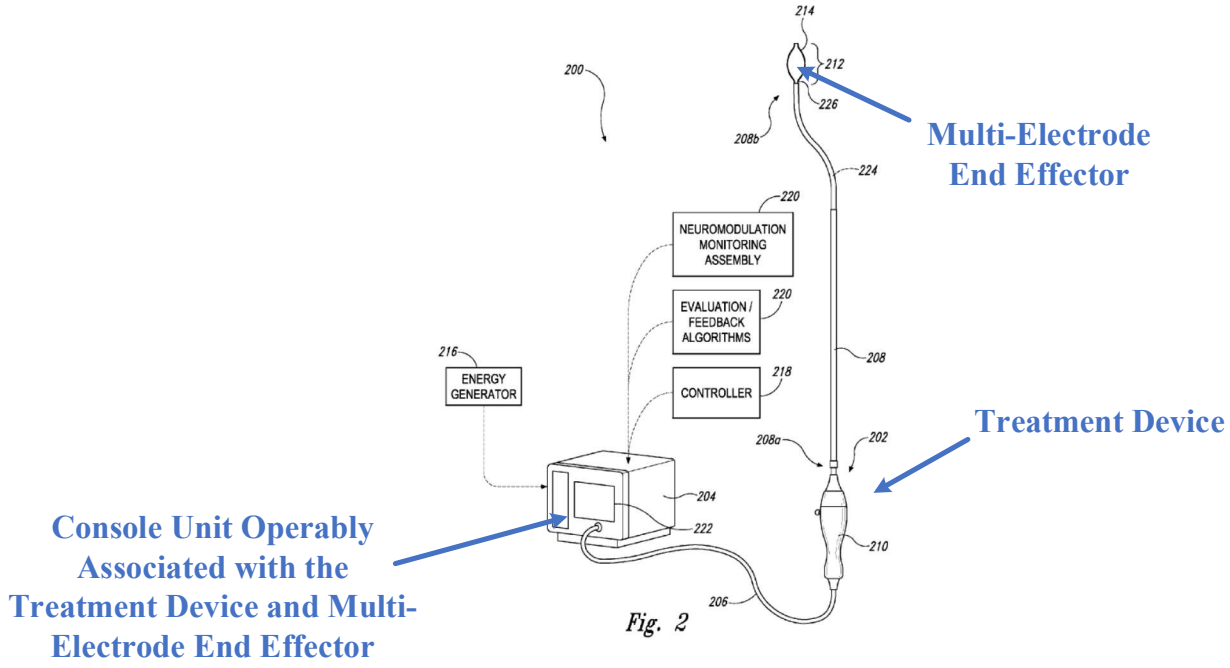
For the reasons provided above relative to Claim 5, Townley discloses MEEEs that have at least six (Claim 6) and at least eight (Claim 7) "electrodes oriented at an angle less than 90 degrees relative to the shaft for the delivery of RF energy." (Ex-1003-Weide, ¶153.)

Accordingly, Townley teaches and renders obvious Claims 6-7. (*Id.,* ¶154.)

[Claim 8]

Townley's MEEEs may apply radiofrequency ("RF") energy from the first and second electrodes to tissue at the target site(s). (Ex-1003-Weide, ¶156; 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, ¶157.)



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

The console may be used with the therapeutic assemblies of Figures 4, 5A-G, 8-9, and 11A-D. (*Id.,* [0074]-[0075], [0099], [0111]; Ex-1003-Weide, ¶158.)

Thus, Townley teaches and renders obvious Claim 8. (Ex-1003-Weide, ¶159.)

[Claims 9-10]

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

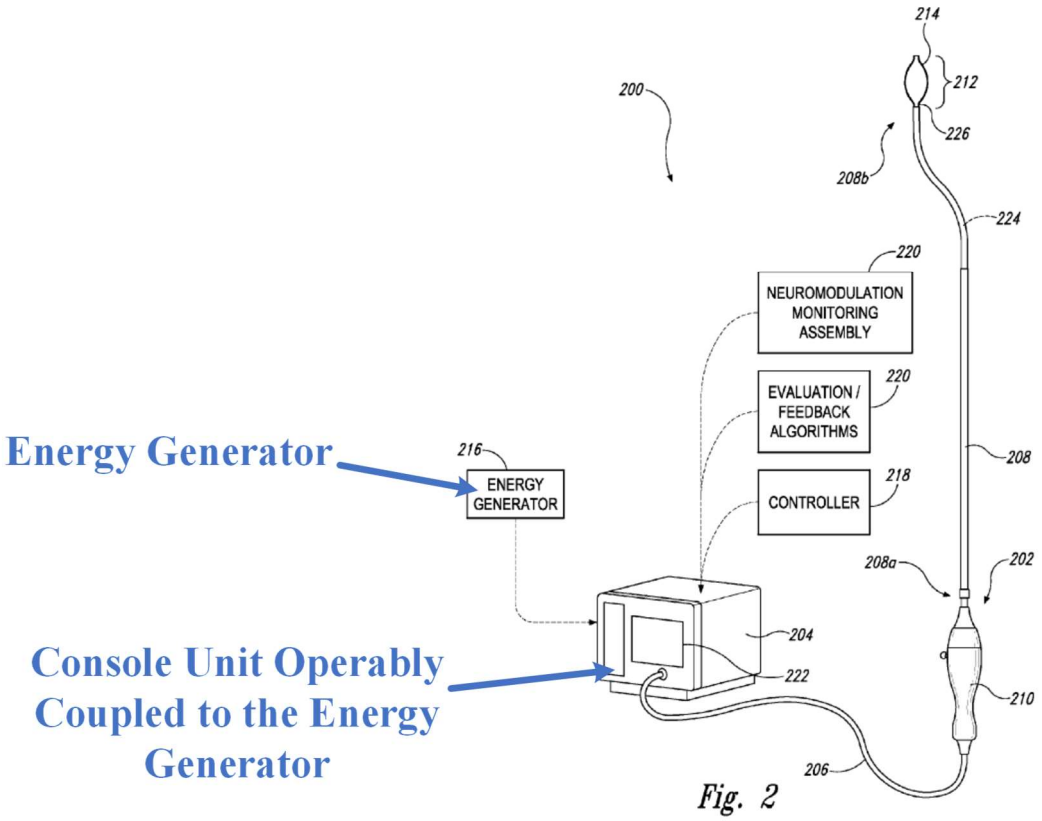


Fig. 2

(*Id.,* FIG. 2.)

Thus, Townley teaches and renders obvious Claims 9-10. (Ex-1003-Weide, ¶162.)

[Claim 11, 11a]

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, ¶164; 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).)

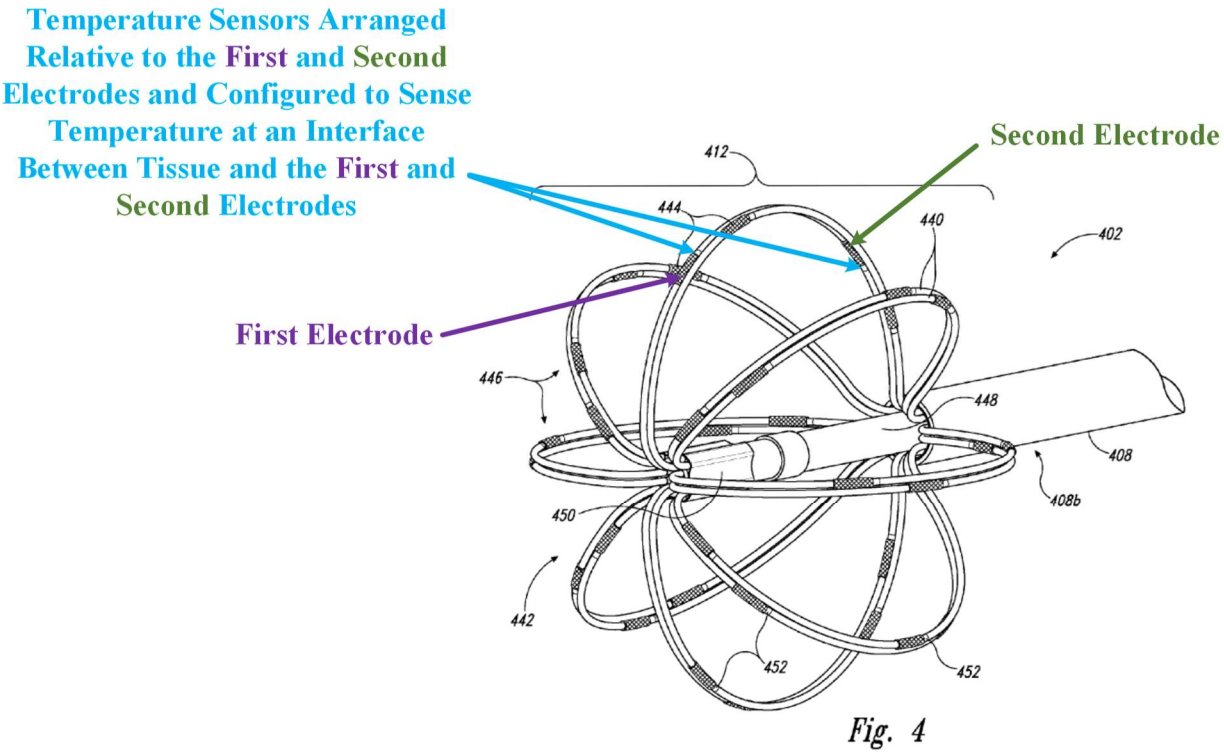


Fig. 4

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

Thus, Townley discloses limitation [11a]. (Ex-1003-Weide, ¶165.)

[11b]

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, ¶167; 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, ¶168; 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, ¶¶169-172; 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 limitation [11b]. (Ex-1003-Weide, ¶173.)

Accordingly, Townley renders obvious Claim 11.

[Claim 12]

As explained in Claim 11, Townley's console is configured to receive temperature readings from temperature sensors. (Ex-1004-Townley, [0047]; Ex-1003-Weide, ¶175.) 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, ¶¶176-177.)

Thus, Townley teaches and renders obvious Claim 12. (*Id.*, ¶178.)

[Claim 13, 13a]

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, ¶180.)

Thus, Townley discloses limitation [13a]. (Ex-1003-Weide, ¶181.)

[13b]

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, ¶¶183-184.)

Thus, Townley teaches limitation [13b]. (*Id.,* ¶185.)

Accordingly, Townley renders obvious Claim 13.

[Claims 14-15]

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, ¶¶187, 191.).) 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, ¶187.) 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.,* ¶188.)

Thus, Townley teaches and renders obvious Claims 14-15. (*Id.,* ¶¶189, 192.)

[Claim 16]

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, ¶194.) Accordingly, a POSITA would have found it obvious for Townley's controller to include "a hardware processor." (Ex-1003-Weide, ¶194)

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-1003-Weide, ¶195; 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.)." (Ex-1004-Townley, [0046].)

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. (*Id.,* [0047], [0074], [0111]; Ex-1003-Weide, ¶196.) 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, ¶196; 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, ¶197; 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 Claim 16. (Ex-1003-Weide, ¶198.)

[Claims 17-18]

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 17-18. (Ex-1003-Weide, ¶¶200-201.)

[Claims 19-20]

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 19-20. (Ex-1003-Weide, ¶¶203-204.)

B. GROUND 2: Wolf-003 Alone and in view of Wolf-290 Renders Obvious Claims 1-4 and 8-12.

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 Claim 1, 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, ¶207; Ex-1005-Wolf-003, [0002], [0004], [0011].) As the '974 patent admits, such energy treatments would be expected to treat symptoms of RCR. (Ex-1001, 5:36-52 (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, ¶208.)

Wolf-290 confirms that it was obvious to use Wolf-003's SDMs to treat RCR. (Ex-1003-Weide, ¶209.) 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].) A POSITA also 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, ¶210.) 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.*, ¶211.)

A POSITA also would have had a reasonable expectation of success in treating RCR using the SDMs of Wolf-003. (*Id*., ¶212.) 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, ¶¶212-214.) Further, as explained above in Ground 1, it was known that treating RCR would have been expected to improve nasal breathability. (Ex-1003-Weide, ¶215; 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, ¶216.)

2. 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

Wolf-003 teaches and suggests the preamble.

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, ¶220.) Accordingly, Wolf-003

alone teaches and suggests that its SDMs may be used to treat RCR "within a sino-nasal cavity of a patient." (Ex-1003-Weide, ¶¶218-220.)[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, 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, ¶221; 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, ¶222.)

Thus, Wolf-003 alone or in view of Wolf-290 teaches limitation [1-PRE]. (*Id.*, ¶223.)

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

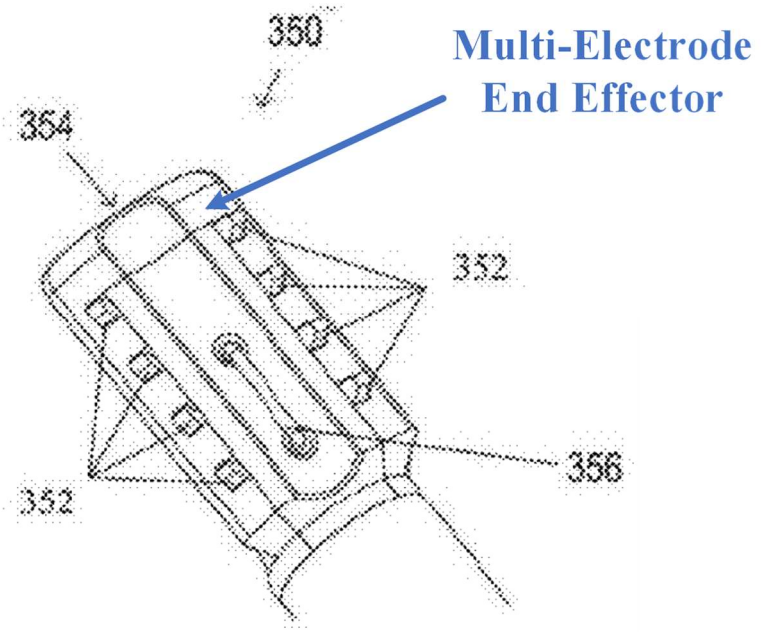
[1a-1] advancing a multi-electrode end effector into the sino-nasal cavity of the patient

Wolf-003 discloses several MEEEs, including device 30 of Figure 6. (Ex-1003-Weide, ¶¶225-226; 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, ¶226.)

Wolf-003 provides additional configurations, including in relation to Figures 19A-B. (Ex-1003-Weide, ¶227; 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, ¶227.) Additional MEEEs are illustrated in Figures 13-14, 25, 26A-F, and 27. (Ex-1003-Weide, ¶227.)

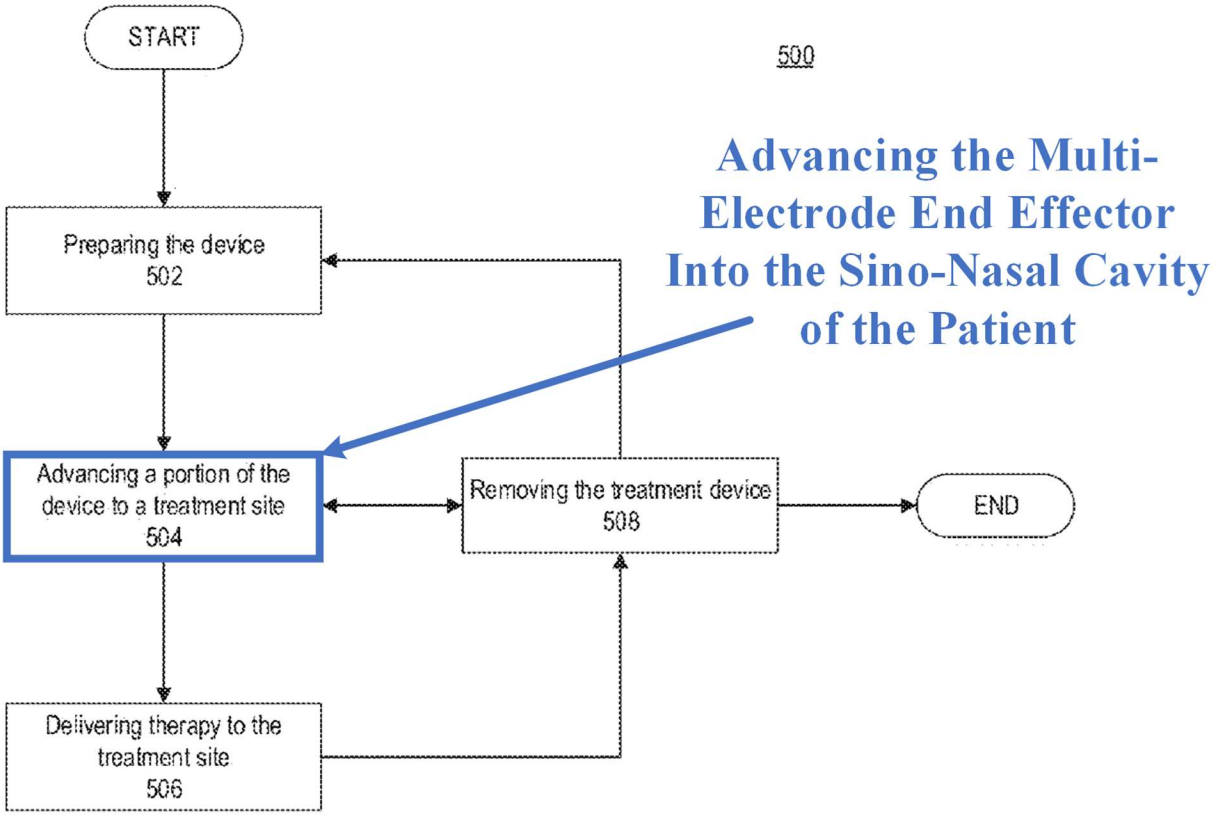
A POSITA would have understood that Wolf-003's multi-electrode treatment elements/portions, including treatment portion 350, disclose MEEEs because they are assemblies of components, including multiple electrodes, that deliver a therapeutic treatment to a patient. (Ex-1003-Weide, ¶228; Ex-1005-Wolf-003,

[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, ¶229.)



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

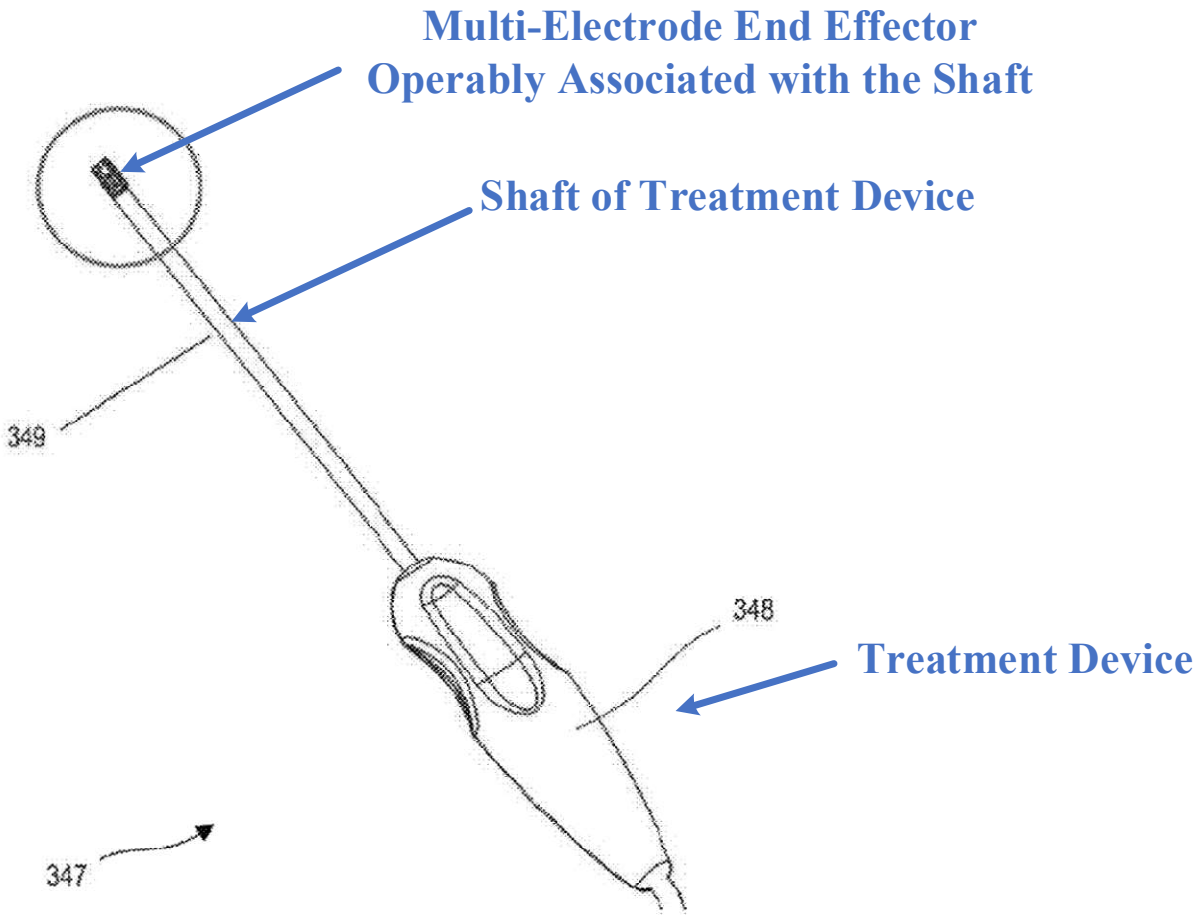
Thus, Wolf-003 discloses limitation [1a-1]. (Ex-1003-Weide, ¶230.)

[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

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

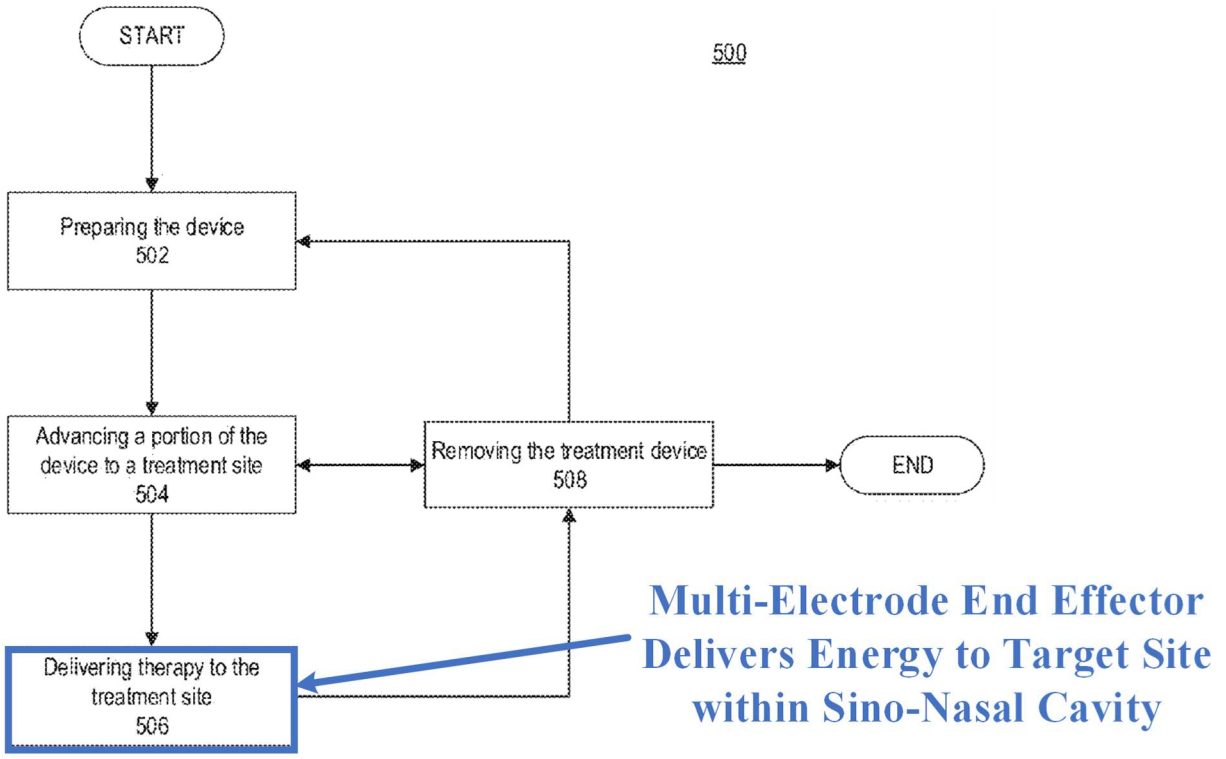
anatomy and enable the electrodes to be positioned to contact tissues to be treated);

Ex-1003-Weide, ¶232.)



(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, ¶233.)

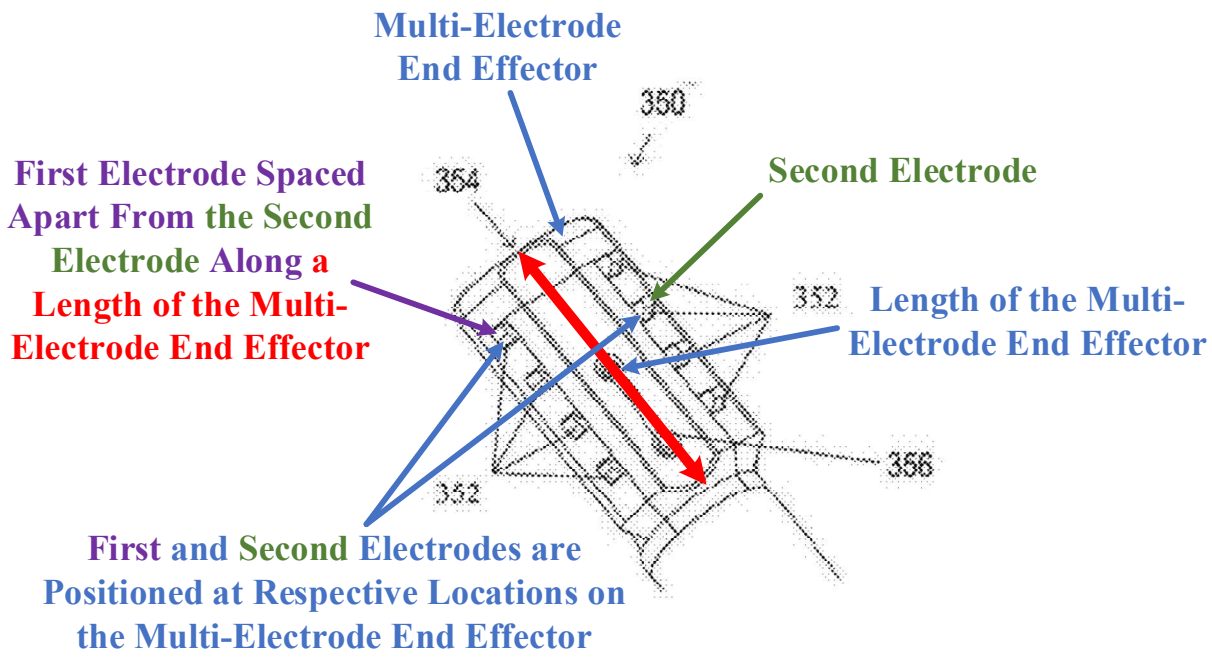


(Ex-1005-Wolf-003, FIG. 20.)

Thus, Wolf-003 discloses limitation [1a-2]. (Ex-1003-Weide, ¶234.)

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

Wolf-003's MEEEs satisfy the requirements of [1a-3]. (Ex-1003-Weide, ¶236.) For example, Wolf-003's MEEE of Figures 19A-B comprises 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, ¶237.)

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, ¶238.) 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, ¶239.)[8]

[8] *See also* Ex-1005-Wolf-003, FIGS. 13-14, 26A-F, and 27 (showing other electrode arrangements meeting the requirements of limitation [1a-3]); Ex-1003-Weide, ¶¶237, n.7; 239.

Thus, Wolf-003 discloses limitation [1a-3]. (Ex-1003-Weide, ¶240.)

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

Wolf-003 teaches "at least one portion of the [MEEE] comprises a diameter that is larger than a diameter of the shaft." (Ex-1003-Weide, ¶241.) For example, as shown below, the MEEE (250) of Figure 13 comprises a ***diameter (D)*** that is larger than a diameter of the shaft. (*Id.*, ¶242.)

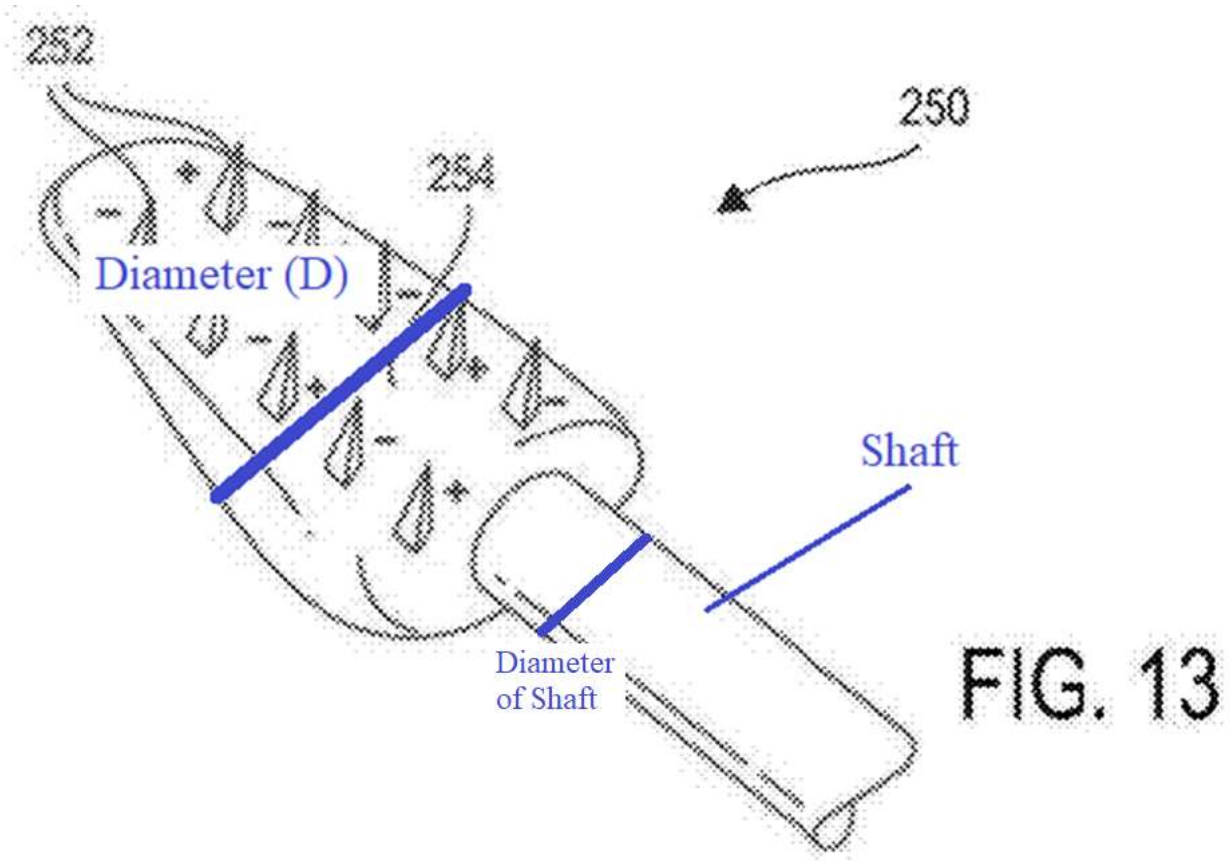


FIG. 13

(Ex-1005-Wolf-003, FIG. 13, [0126].) As illustrated and described, FIG. 13 includes ten needle electrodes 252 located on the treatment element 250. (*Id.*)

Like Figure 13, the embodiment of Figures 19A-B may also have needle electrodes:

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

(*Id.*, [0153].) Further, the embodiment of Figure 19B includes only eight electrodes on its treatment element 354:

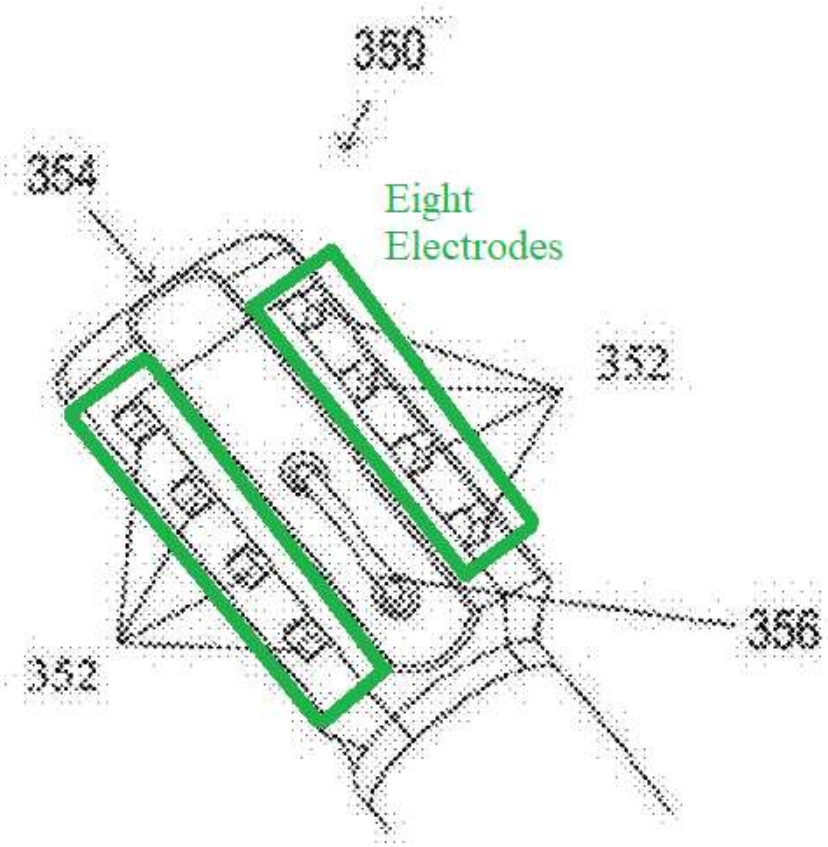


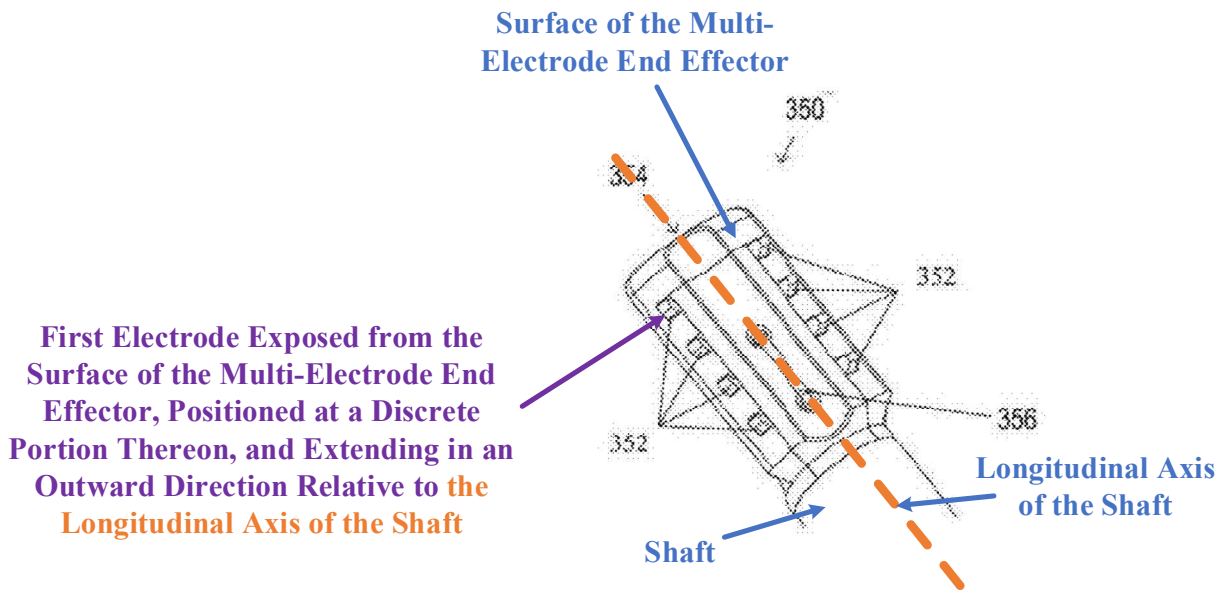
FIG. 19B

(*Id.*, FIG. 19B.) Thus, while Figure 19B does not specifically depict its MEEE (treatment element 350) as having "a diameter that is larger than a diameter of the shaft," a POSITA would have found it obvious that the diameter of treatment element 354 would be "larger than a diameter of the shaft" when the treatment element included needle electrodes and/or additional electrodes, as specifically taught and described by Wolf-003. Accordingly, Wolf-003 teaches that its treatment element 350 "comprises a diameter that is larger than a diameter of the shaft." (Ex-1003-Weide, ¶¶243-248.)

Thus, Wolf-003 teaches limitation [1a-4]. (*Id.*, ¶249.)

[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

Wolf-003 discloses limitation [1b]. (Ex-1003-Weide, ¶251.) 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.*, ¶252.)



(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

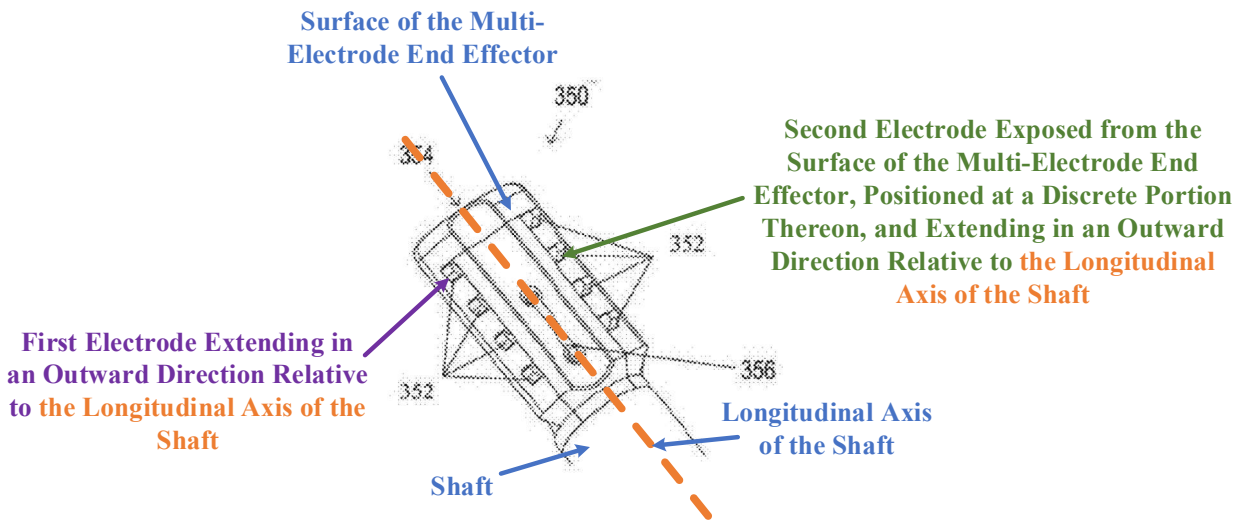
contact surface having multiple features for addressing and treating tissue, such as mucosal tissue); Ex-1003-Weide, ¶253.)[9]

Thus, Wolf-003 discloses limitation [1b]. (Ex-1003-Weide, ¶255.)

[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

Wolf-003 discloses limitation [1c] for generally the same reasons as limitation [1b]. (Ex-1003-Weide, ¶¶256-257.) 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, ¶258.)

[9] *See also* Ex-1005-Wolf-003, FIGS. 13-14, 26A-F, and 27 (showing other electrode arrangements meeting the requirements of limitation [1b]); Ex-1003-Weide, ¶254.



(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].)

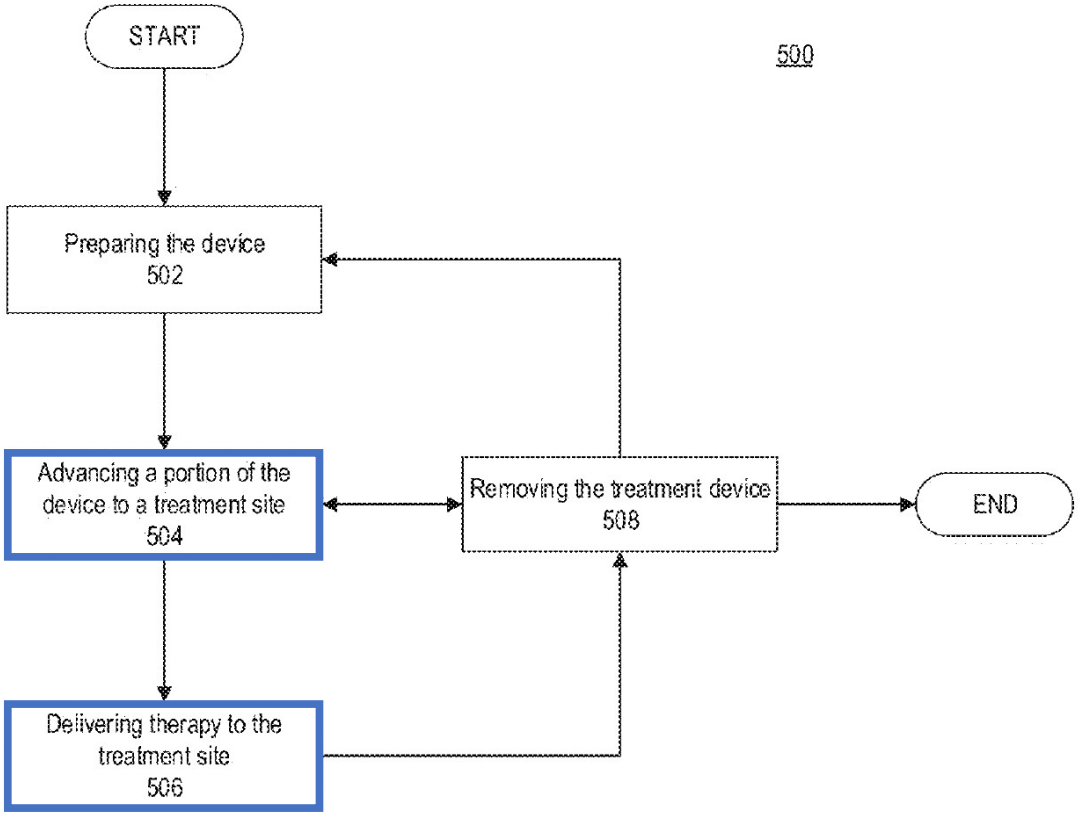
Wolf-003 thus teaches that the second electrode 352 may extend in any direction, including a second outward direction relative to a longitudinal axis of the shaft 349. (Ex-1003-Weide, ¶¶258-259.)

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, ¶260.)[10]

Thus, Wolf-003 discloses limitation [1c]. (Ex-1003-Weide, ¶262.)

[1d-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):



[10] *See also* Ex-1005-Wolf-003, FIGS. 13-14, 26A-F, and 27 (showing other electrode arrangements meeting the requirements of limitation [1c]); Ex-1003-Weide, ¶261.

(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 limitation [1d-1]. (Ex-1003-Weide, ¶¶264-265.)

[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

The '974 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[11] 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[12] 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, ¶268.) 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, ¶¶268-270; 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,

[11] Ablation is known to destroy target tissue. (Ex-1003-Weide at ¶268 n.8; Ex-1001, 56:56-65 (ablation leads to "necrosis").)

[12] 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, ¶271.)

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, ¶271.)

Thus, Wolf-003 teaches and renders obvious limitation [1d-2]. (*Id.*, ¶272.)

Limitation [1d-2] was 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 limitation [1d-2]. (Ex-1003-Weide, ¶¶273-274.)

Accordingly, Wolf-003 alone and in view of Wolf-290 teaches and renders obvious Claim 1. (*Id.,* ¶275.)

[Claim 2]

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

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]; Ex-1003-Weide, ¶277.)

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

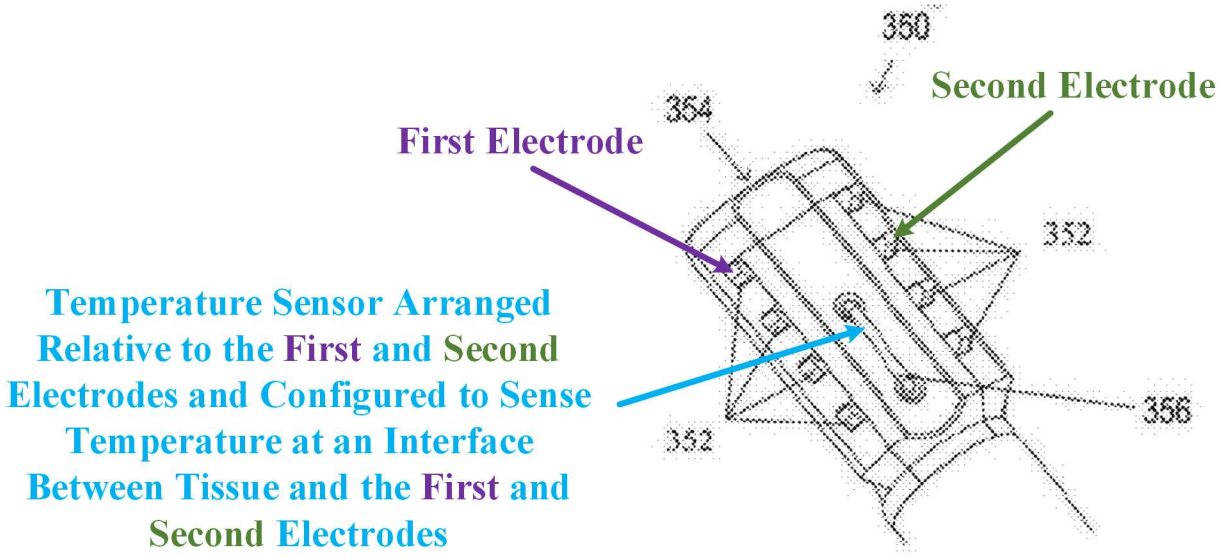
> "In some embodiments, energy may be delivered *into the submucosal tissue* to cause a conformational change and/or a *change in the physical properties and/or type of the submucosal tissue*. Energy delivery may be accomplished by transferring the energy through the tissue covering the submucosa such as the epithelium, mucosa, muscle, ligaments, cartilage, tendon and/or skin."

(Ex-1005-Wolf-003, [0087]; Ex-1003-Weide, ¶277.)

Accordingly, Wolf-003 teaches Claim 2, and Wolf-003 alone and in view of Wolf-290 renders obvious Claim 2. (Ex-1003-Weide, ¶278.)

[Claims 3-4]

Wolf-003 discloses that its MEEEs include "at least one temperature sensor arranged relative to first and second electrode." (Ex-1003-Weide, ¶280.) As shown in Figure 19B, for instance, a thermocouple 356 (temperature sensor) is arranged relative to the electrodes 352:



(Ex-1005-Wolf-003, FIG. 19B; *id.*, [0148] ("the device 347 may include … a thermocouple 356.").)

Wolf-003's temperature sensor(s) is/are configured to sense temperature of tissue at the target site(s). (Ex-1005-Wolf-003, FIG. 19B, [0018] ("A thermocouple or other sensor may be provided to measure a temperature near the tissue"), [0031] ("measuring a temperature of the mucosal tissue using the thermocouple"), [0155] ("The thermocouple 356 may be one or more sensors configured to gather one or more temperature readings of tissue during operation of the device 347."); Ex-1003-Weide, ¶280.)

Thus, Wolf-003 teaches Claims 3-4, and Wolf-003 alone and in view of Wolf-290 renders obvious Claims 3-4. (*Id.*, ¶281.)

[Claim 8]

Wolf-003 discloses delivering radiofrequency ("RF") energy from the first and second electrodes to tissue at the one or more target sites. (Ex-1003-Weide, ¶283; 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").)

Regarding the claimed "console unit," the '974 patent states:

> "The console 104 is configured to provide various functions for the neuromodulation device 102, which may include, but is not limited to, controlling, monitoring, supplying, and/or otherwise supporting operation of the neuromodulation device 102."

(Ex-1001, 13:10-14.)

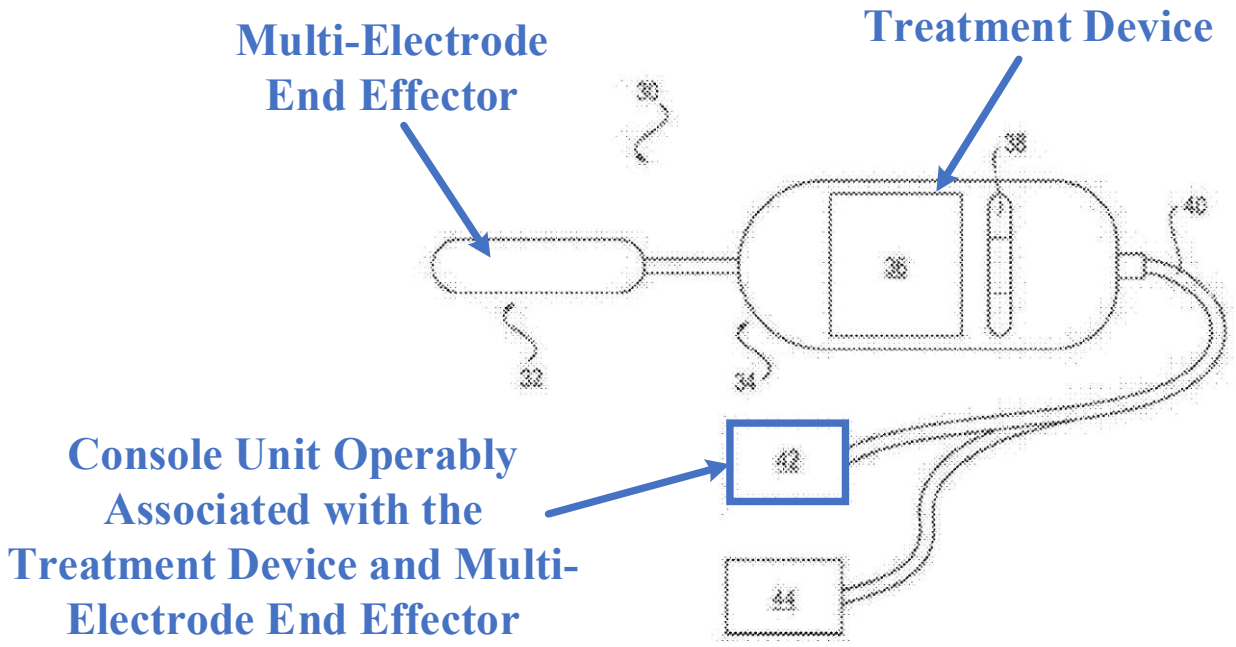
Wolf-003 discloses such a console unit ("console"). (Ex-1003-Weide, ¶284.) Specifically, Wolf-003 discloses an electronic control system 42 ("control system") "configured to control the timing, location, intensity and/or other properties and characteristics of energy or other treatment applied to targeted regions of a nasal passageway." (Ex-1005-Wolf-003, [0092]; *see also id.,* [0017] ("a control system configured to control the characteristics of the energy applied to the tissue."), [0019] ("a control system for controlling the energy source and/or treatment device").) "[T]he control system 42 may be located in an external device which may be configured to communicate with electronics within the handle section 34." (*Id.,*

[0092].) The control system "may be configured to deliver treatment energy to create specific localized tissue damage or ablation, stimulating the body's healing response to create desired conformational or structural changes that reduces the mucus producing ability of the mucus producing cells." (*Id.,* [0101]; *see also id.,* [0100] (explaining treatment element and control system may be configured to deliver treatment energy to a selected tissue depth to target treatment at specific tissues).) The control system may have "any number of sensors, such as thermocouples, electric resistance or impedance sensors… configured to detect treatment variables or other control parameters." (*Id.,* [0092].) (Ex-1003-Weide, ¶285.)

Wolf-003's control system (console unit) controls the delivery of RF energy from an MEEE's electrodes. (*Id.,* [0092] ("an electronic control system 42 configured to control … energy or other treatment applied to targeted regions of a nasal passageway"), [0096] (disclosing that the control system may be configured to engage the electrodes "individually or in selected groups so as to treat only targeted areas of the upper airway passageway."), [0156] ("The electrodes 352 … may be connected with a device control system … attached to the device 347."); Ex-1003-Weide, ¶287-290.)

Wolf-003's control system is operably associated with the MEEEs and treatment devices. (Ex-1005-Wolf-003, FIG. 6, [0019] ("a control system for

controlling the … treatment device"), [0092] (the control system "may be configured to communicate with electronics within the handle section 34."), [0094] ("control system 42 may be configured to engaged [the electrodes of the MEEE]"); Ex-1003-Weide, ¶¶286-287.)



(Ex-1005-Wolf-003, FIG. 6.)

Accordingly, Wolf-003 teaches Claim 8, and Wolf-003 alone and in view of Wolf-290 renders obvious Claim 8. (Ex-1003-Weide, ¶¶283-291.)

[Claims 9-10]

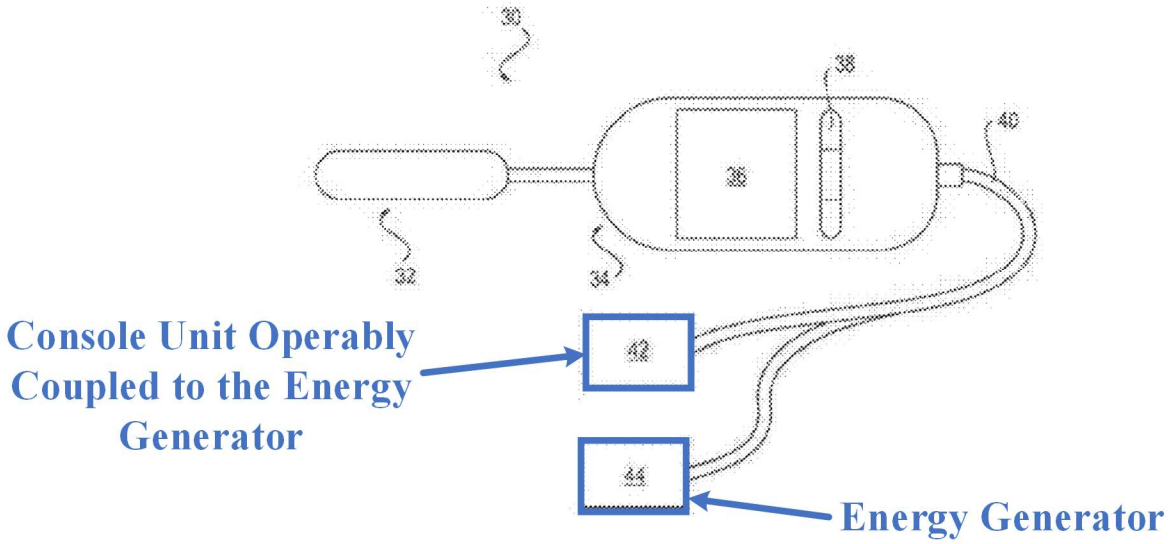
Wolf-003 discloses an external power supply "configured to deliver power to the handle section 34 and/or the treatment element 32 by a cable or other suitable

connection." (Ex-1005-Wolf-003, [0093].)[13] The power supply "may include a battery or other electrical energy storage or energy generation device," or "may be configured to draw electrical power from a standard wall outlet." (*Id*.)

Wolf-003's power supply is configured to generate RF energy, including bi-polar RF energy, to be delivered by an MEEEs' electrodes. (*Id.,* [0017] ("configured to be connected to an energy source, such as a RF energy source"), [0052] ("FIG. 19A [illustrates] a device for applying energy to the upper airway tissues *using a bipolar electrode*"); [0093] (explaining the external power supply may be configured to deliver power to the treatment element by a cable or other suitable connection, and the power supply may include a system configured for driving a specific energy delivery technology in the treatment element, for example, an RF alternating current signal to an RF energy delivery element); [0148] (explaining Figure 19A illustrates a device 347 for applying energy using RF bipolar electrodes); [0168] (same); Ex-1003-Weide, ¶¶294-295, 298.)

Wolf-003's control system (console unit) is operably coupled to the power supply (energy generator). (Ex-1005-Wolf-003, FIG. 6, [0017], [0019], [0092], [0156].)

[13] Wolf-003 also refers to its power supply as an "energy source" or a "remote generator." (Ex-1003-Weide, ¶293 n.10.)



(*Id.,* FIG. 6; Ex-1003-Weide, ¶293.)

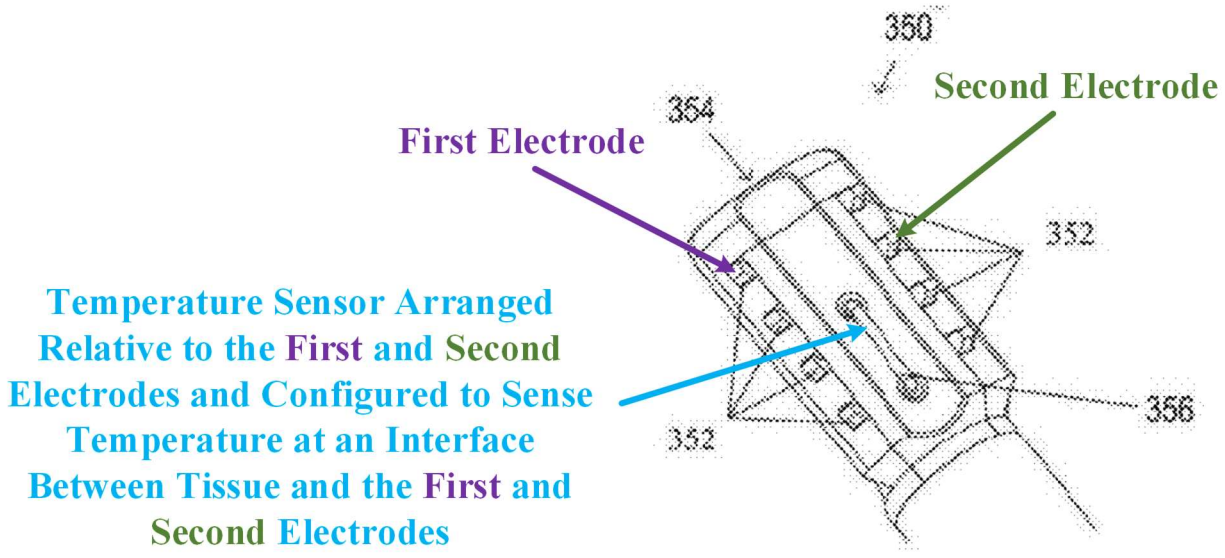
Accordingly, Wolf-003 teaches Claims 9-10, and Wolf-003 alone and in view of Wolf-290 renders obvious Claims 9-10. (Ex-1003-Weide, ¶¶296, 299.)

[Claim 11, 11a]

Wolf-003's control system is configured to receive feedback from temperature sensors (*e.g.*, thermocouple 356). (Ex-1005-Wolf-003, [0092] (explaining the control system may include any number of sensors, such as thermocouples, to detect treatment variables or other control parameters), [0148] ("the device 347 may include … a thermocouple 356."), [0156] ("The electrodes 352 and the thermocouple 356 may be connected with a device control system"), [0188] ("the sensor(s) may provide feedback");Ex-1003-Weide, ¶301.)

Wolf-003's temperature sensor(s) is/are arranged relative to the first and second electrodes such that it/they sense the temperature of the tissue treated by

those electrodes (*i.e.*, are configured to sense temperature at an interface between tissue and the first and second electrodes). (Ex-1005-Wolf-003, FIG. 19B, [0018] ("A thermocouple or other sensor may be provided to measure a temperature near the tissue"), [0031] ("measuring a temperature of the mucosal tissue using the thermocouple"), [0155] ("The thermocouple 356 may be one or more sensors configured to gather one or more temperature readings of tissue during operation of the device 347."); Ex-1003-Weide, ¶302.)



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

Indeed, a POSITA would have wanted temperature sensors in contact with, and arranged as close as possible to, the target tissue so as to effectively measure tissue temperature to properly treat tissue while avoiding unnecessary injury. (Ex-1003-Weide, ¶303.)

Thus, Wolf-003 discloses limitation [11a]. (*Id.*, ¶304.)

[11b]

As explained previously, Wolf-003's control system is "configured to *control the timing, location, intensity* and/or other properties and characteristics *of energy*…applied to targeted regions of a nasal passageway" and "may include a *closed-loop control system* having any number of sensors, *such as thermocouples*…. to detect treatment variables or other control parameters." (Ex-1005-Wolf-003, [0092]; Ex-1003-Weide, ¶306.) Temperature feedback and control are also described:

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

(Ex-1005-Wolf-003, [0031].)

As one example:

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

(*Id.,* [0188]; Ex-1003-Weide, ¶307.)

A POSITA would have recognized that a closed-loop control system that includes sensors to measure temperature and uses those temperature measurements to decrease power delivered to a treatment device discloses, teaches and suggests a "console unit [] configured to control energy output from [] electrodes based, at least in part, on the [temperature sensor] feedback." (Ex-1003-Weide, ¶308.)

Wolf-003 also discloses using temperature sensor feedback to maintain a predetermined temperature of tissue at the one or more target sites. (Ex-1005-Wolf-003, [0135] ("in order *to reach or maintain **set** temperature*"), [0136] (explaining thermocouples act as a feedback-control to ensure that proper temperature is maintained at the site of surgery), [0139] ("the temperature input signals sensed from [the thermocouples] … act as a feedback-control to ensure that proper temperature is maintained at the treatment site."); Ex-1003-Weide, ¶309.)

Thus, Wolf-003 discloses limitation [11b]. (*Id.*, ¶310.)

Accordingly, Wolf-003 teaches Claim 11, and Wolf-003 alone and in view of Wolf-290 renders obvious Claim 11.

[Claim 12]

As shown in Claim 11, Wolf-003's control system is configured to receive temperature readings from temperature sensors (*e.g.*, thermocouple 356). (Ex-1005-Wolf-003, [0031], [0092], [0148], [0155]-[0156], [0188];Ex-1003-Weide, ¶312.)

Wolf-003's control system 42 also adjusts the level of RF energy delivered by the first and second electrodes based on the received temperature readings from the temperature sensors. (Ex-1005-Wolf-003, [0031] ("measuring a temperature of the mucosal tissue using the thermocouple; and delivering a second amount of the radiofrequency energy from the first electrode to the second electrode, wherein the second amount of radiofrequency energy is based at least in part on the measured temperature."), [0092] (explaining the control system is configured to control the timing, location, intensity and/or other properties and characteristics of energy applied to targeted regions of a nasal passageway), [0136] (explaining individual subsystems exist for each electrode pair, which subsystems include a thermocouple for feedback-control to ensure that proper temperature is maintained at the site of surgery);; Ex-1003-Weide, ¶313.)

While Wolf-003 does not expressly disclose that its control system "processes" temperature readings to "determine" the level of RF energy delivered, a POSITA would have found it obvious that Wolf-003's control system was doing so given Wolf-003's control system is an "*electronic* control system." (Ex-1003-Weide, ¶314; Ex-1005-Wolf-003, [0031].) Indeed, it has been commonplace to process temperature measurements and make appropriate adjustments to ensure proper delivery of energy to tissue for many decades. (Ex-1003-Weide, ¶314; Ex-1024-Edwards-535, 9:45-11:45, FIGS. 5-6, 8-10.)

Wolf-003 further teaches that the level of RF energy delivered by the electrodes is sufficient to maintain a temperature of tissue at the one or more target sites below a predetermined threshold. (Ex-1005-Wolf-003, [0135] ("in order to reach or ***maintain set temperature***"); Ex-1003-Weide, ¶315.)

Accordingly, Wolf-003 teaches Claim 12, and Wolf-003 alone and in view of Wolf-290 renders obvious Claim 12. (Ex-1003-Weide, ¶316.)

C. GROUND 3: Claims 8-20 are Obvious Based on the Ground 2 References in View of Angeles.

1. Scope, Content and Motivation to Combine.

As explained in Ground 2, Wolf-003 discloses a control system "configured to control the timing, location, intensity and/or other properties and characteristics of energy or other treatment applied to targeted regions of a nasal passageway." (Ex-1005-Wolf-003, [0092]; Ex-1003-Weide, ¶321.) Wolf-003's control system "may be located in an external device which may be configured to communicate with electronics within the handle section 34." (Ex-1005-Wolf-003, [0092].) Wolf-003 does not provide implementation details for its control system. (*See, e.g., id.,* FIG. 6 (depicting control system 42 as a box).)

However, Angeles (in the same field of endeavor) discloses a "console for an electrosurgical device" that includes "a housing, an energy generator in the housing, a computer processor in the housing, … [and] a touchscreen display on the housing." (Ex-1007-Angeles, Abstract, [0002], [0006].) The energy generator may be "a

radiofrequency (RF) generator, configured to deliver monopolar and/or bipolar RF energy to the energy delivery treatment device." (*Id.*, [0007].) The console includes "an improved user interface" which "allows a physician user to monitor and alter treatment parameters for a particular treatment stylus, applicator, catheter or the like." (*Id.,* [0005].)

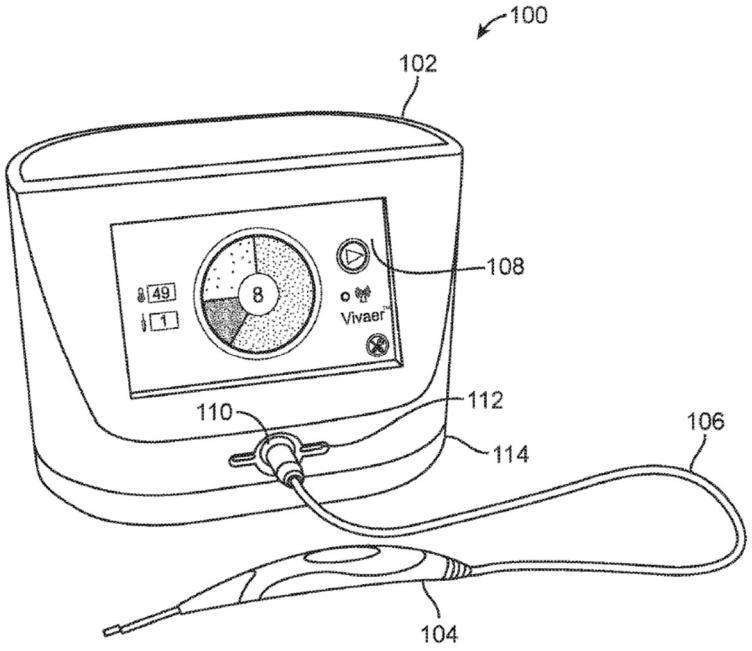


FIG. 1

(*Id.,* FIG. 1.)

A POSITA would have been motivated, and would have found it obvious, to apply Angeles' console teachings to Wolf-003. (Ex-1003-Weide, ¶323.) Angeles discloses that its console may be used with a wide variety of devices for delivering energy to tissue in the nasal airway, including devices developed by Aerin Medical Inc.—that is, including Wolf-003's device. (Ex-1007-Angeles, [0003], [0040]; Ex-

1005-Wolf-003, [71], [73].)[14] Thus, a POSITA would have found Angeles' console akin to the control system of Wolf-003 and suitable for implementing that control system. (Ex-1003-Weide, ¶323.)

A POSITA would have found Angeles' console to be a highly desirable choice for use with Wolf-003 for several reasons. (*Id*., ¶324.) For example, a POSITA would have appreciated that Angeles' console is in the form of a single "box" (*i.e*., has a smaller footprint) that desirably integrates device control and energy generation functionalities. (*Id*.) Angeles' console also includes "an improved user interface" that beneficially "allows [the] physician user to monitor and alter treatment parameters for a particular treatment stylus, applicator, catheter or the like." (*Id*., ¶325; Ex-1007-Angeles, [0005]).) Angeles' console also has a touchscreen display that allows the physician to easily interact with the console, which a POSITA would have recognized is highly desirable because it eliminates additional hardware, such as buttons, knobs, etc., while also providing a convenient manner of interacting with the user interface. (Ex-1003-Weide, ¶326; Ex-1007-Angeles, [0006], [0028].)

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

Angeles' console also beneficially allows the physician to set various treatment conditions, such as power, temperature, treatment time, and/or cool down time. (Ex-1007-Angeles, [0006], [0013], [0049].) A POSITA would have found such functionality highly desirable as it allows the physician to customize treatments for patients. (Ex-1003-Weide, ¶327.)

A POSITA would have had a reasonable expectation of successfully applying Angeles' console teachings to Wolf-003. (Ex-1003-Weide, ¶328.) As noted above, Angeles discloses that its console may be used with devices developed by Aerin Medical Inc., which would include Wolf-003's devices. (Ex-1007-Angeles, [0003], [0040].) Indeed, implementing Angeles' console teachings with Wolf-003 would have been routine to a POSITA, merely requiring conventional hardware and software to implement the user interface and control teachings of Angeles with the control system and related teachings of Wolf-003. (Ex-1003-Weide, ¶328.)

2. The Challenged Claims

[Claim 8]

As explained above, in Ground 3, Angeles' console teachings are used to implement/supplement the control system teachings of Wolf-003.

Wolf-003 discloses "wherein radiofrequency (RF) energy is delivered from the first and second electrodes to tissue at the one or more target sites." (Ex-1005-Wolf-003, [0022].) Wolf-003 in view of Angeles discloses that such RF energy "is

controlled via a console unit operably associated with the treatment device and multi-electrode end effector. (*Id.*, FIG. 6 (showing control system operably associated with the treatment device and multi-electrode end effector); Ex-1007-Angeles, FIG. 1 (showing console 102 operably associated with RF delivery stylus 104), [0028] ("console" is a "controller"), [0043]-[0045] (explaining RF delivery controlled by console).)

Thus, Wolf-003 alone or in view of Wolf-290, further in view of Angeles teaches and renders obvious Claim 8. (Ex-1003-Weide, ¶¶330-332.)

[Claims 9-10]

Angeles' console is operably coupled to an "energy generator" integrated in the console. (Ex-1007-Angeles, Abstract, [0005]-[0007], [0028], claims 1-2.) The energy generator is configured to generate RF energy, including "bipolar RF energy," to be delivered by an energy delivery treatment device. (*Id*.) In the combination of Wolf-003 and Angeles, RF energy (including bipolar RF energy) generated by Angeles' energy generator would be delivered by the first and second electrodes of Wolf-003's MEEEs. (Ex-1003-Weide, ¶¶334, 337.)

Thus, Wolf-003 alone or in view of Wolf-290, further in view of Angeles teaches and renders obvious Claims 9-10. (*Id.,* ¶¶335, 338.)

[Claim 11, 11a & 11b]

As per Ground 2, Claim 11, Wolf-003's control system is configured to receive feedback from at least one temperature sensor arranged relative to the first and second electrodes and configured to sense temperature at an interface between tissue and the first and second electrodes, wherein the control system is configured to control energy output from the first and second electrodes based, at least in part, on the feedback in order to maintain a predetermined temperature of tissue at the one or more target sites. (Ex-1003-Weide, ¶340.)

A POSITA would have been motivated to retain this same helpful functionality in the combination of Wolf-003 and Angeles, with Angeles' console (a) receiving feedback from Wolf-003's temperature sensor(s), and (b) controlling energy output from Wolf-003's electrodes based, at least in part, on the feedback to maintain a predetermined temperature of tissue at the target site(s). (Ex-1003-Weide, ¶341.) Indeed, such functionality is expressly contemplated and desired by the combination of Wolf-003 and Angeles. (*Id*.; Ex-1007-Angeles, [0050] ("During treatment, *the **actual** RF power 617 and **temperature reading** 609 are also shown*."); [0028] (term "console" encompasses a "controller"); [0036] ("the **user** can select … manual treatment settings."); [0047] (the custom **"**settings of the console 102 may have any suitable ranges and combinations for the various parameters of the console 102 … [a] default temperature may also be set for RF delivery"); [0048] (the

physician/user "can…access a custom treatment screen 630" which includes "a graphical treatment progress display 600… a set RF ON time window 607, a set temperature window 608, an actual temperature indicator 609…and a temperature icon 620."); [0049] ("the user can adjust" the power, treatment time, and/or cool down time "to [] a given value;" "the user may touch the power window 618 and then adjust the temperature;" "the power…may be selected at" 3, 4, or 5 Watts; the maximum "stylus temperature may be selected" to be 50-70º Celsius; the "RF energy delivery time (RF ON time) may be selected" to be between 6 seconds and 18 seconds, in 2-second increments;" "[a]ny other suitable ranges and combinations of ranges may be used").)

Thus, Wolf-003 alone or in view of Wolf-290, further in view of Angeles teaches and renders obvious Claim 11. (Ex-1003-Weide, ¶342.)

[Claim 12]

As explained in Claim 11, in the combination of Wolf-003 and Angeles, Angeles's console is configured to receive temperature readings from Wolf-003's temperature sensor(s). (Ex-1003-Weide, ¶344.)

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

a range of 50 degrees Celsius to 70 degrees Celsius in one embodiment."); Ex-1003-Weide, ¶345.)

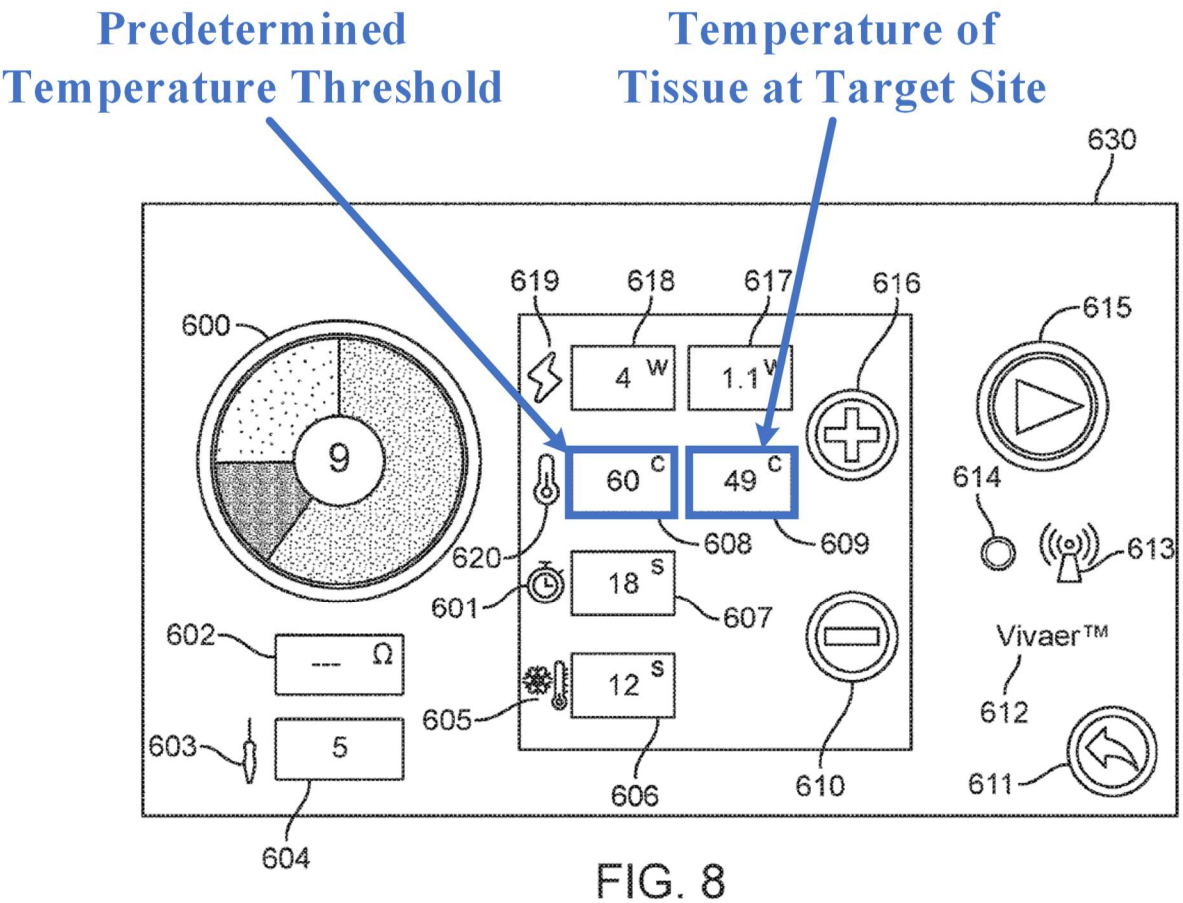


FIG. 8

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

Angeles' console includes a "computer processor" for processing sensed temperature readings (*e.g.*, of the Wolf-003 device) to determine a level of RF energy to be delivered. (Ex-1007-Angeles, Abstract, [0006], [0028], [0036], claim 1; Ex-1003-Weide, ¶346.)

Thus, Wolf-003 alone or in view of Wolf-290, further in view of Angeles teaches and renders obvious Claim 12. (Ex-1003-Weide, ¶347.)

[Claim 13, 13a]

As explained in Claim 11, in the combination of Wolf-003 and Angeles, Angeles's console is configured to receive temperature readings from Wolf-003's temperature sensor(s). (Ex-1003-Weide, ¶349.) Angeles' console is configured to monitor temperature of tissue at a target site during delivery of RF energy thereto based on these temperature readings. (Ex-1007-Angeles, [0004] ("the generator may also *send and/or receive signals* to and from the applicator (for example, treatment algorithms, *tissue temperature measurements*, etc.)"), [0042] ("Other indicators that the treatment is in progress include the temperature indicator"), [0043] ("The stylus *temperature indicator* 501 *shows the actual temperature* of the distal, treatment end of the stylus 104."), [0050] ("During treatment, *the actual* RF power 617 and temperature reading 609 are also shown."); Ex-1003-Weide, ¶350.)

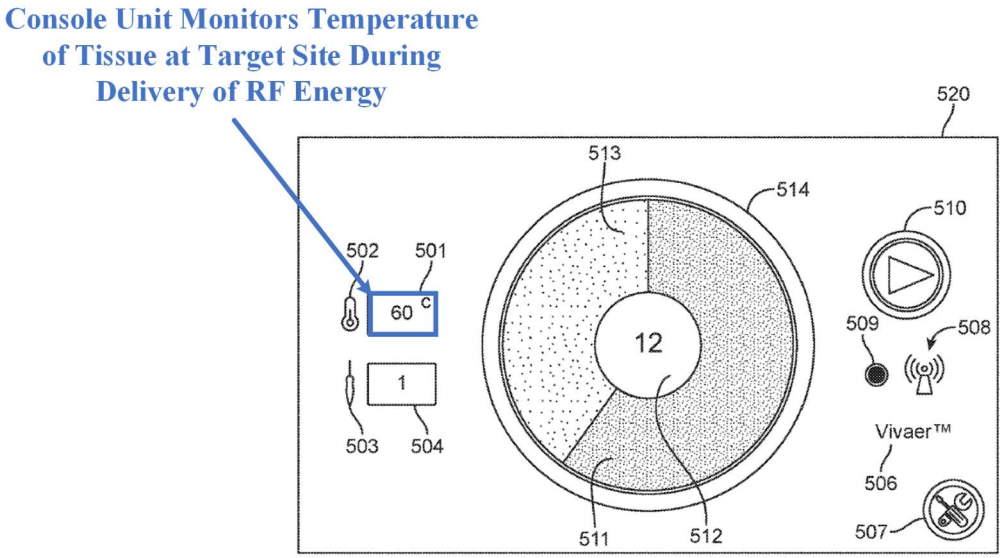


FIG. 6

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

Thus, Wolf-003 in combination with Angeles teaches limitation [13a]. (Ex-1003-Weide, ¶351.)

[13b]

Angeles' console is configured to monitor an elapsed time during delivery of RF energy to tissue at a target site. (Ex-1003-Weide, ¶353.) As shown in Figure 6 (below), a Total Treatment Timer 512 is included, which currently shows "that 12 seconds remain in the treatment—in other words, 18 seconds of the 30-second total time have elapsed," with the "darker RF energy delivery time portion 511, designating the elapsed 18 seconds of RF energy delivery time." (Ex-1007-Angeles, [0041].)

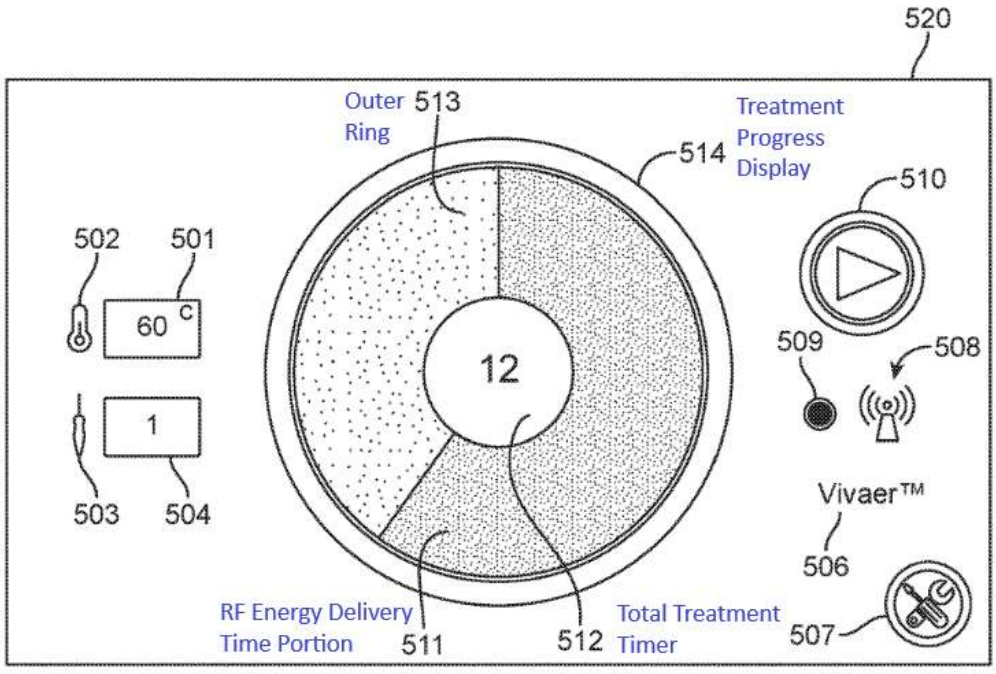


FIG. 6

(*Id.,* FIG. 6, [0007] ("the outer ring changes colors in a clockwise direction *to indicate* ***elapsed time*** *of the energy delivery procedure*."); Ex-1003-Weide, ¶353.)

Of course, to display an elapsed time of RF energy delivery (as per above), a POSITA would have found it obvious that Angeles' console "monitor[s] an elapsed time during delivery of RF energy to tissue at the one or more target sites." (Ex-1003-Weide, ¶354.)

Thus, Wolf-003 alone or in view of Wolf-290, further in view of Angeles teaches and renders obvious Claim 13. (*Id.,* ¶355.)

[Claims 14-15]

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

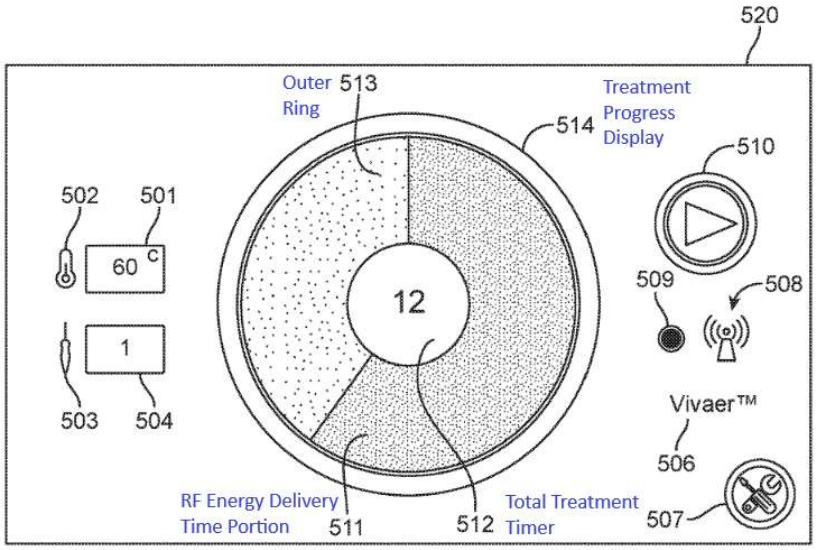


FIG. 6

(Ex-1007-Angeles, FIG. 6; Ex-1003-Weide, ¶357.)

As Angeles explains:

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

(Ex-1007-Angeles, [0041]; Ex-1003-Weide, ¶358.) Angeles' display may be a touchscreen monitor. (Ex-1007-Angeles, [0006], [0010], [0028]; Ex-1003-Weide, ¶361.)

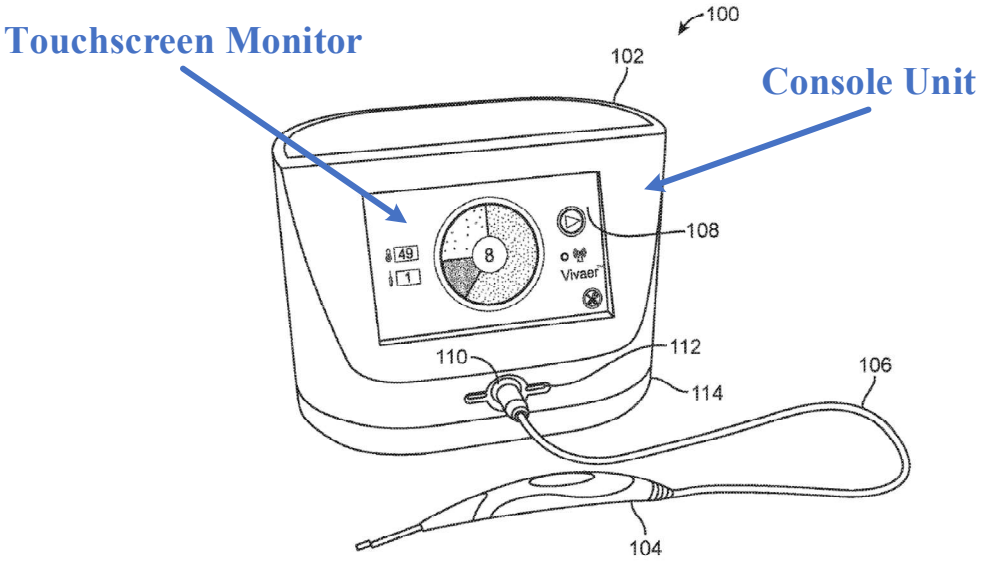


FIG. 1

(Ex-1007-Angeles, FIG. 1.)

Thus, Wolf-003 alone or in view of Wolf-290, further in view of Angeles teaches and renders obvious Claims 14-15. (Ex-1003-Weide, ¶¶359, 362.)

[Claim 16]

Angeles discloses that its console comprises a "computer processor" (*i.e.*, a hardware processor) and a "non-transitory computer readable medium" (*i.e.*, a non-transitory, computer-readable memory) "in the computer processor" (*i.e.*, coupled to the hardware processor). (Ex-1007-Angeles, Abstract, [0006], [0028], claim 1; Ex-1003-Weide, ¶364.) Angeles also discloses that its non-transitory, computer-readable memory contains "computer-executable programming instructions" (*i.e.*, instructions executable by the processor). (*Id.*)

Based on Wolf-003 and Angeles, a POSITA would have found it obvious that the instructions executable by Angeles' processor cause Angeles' console to automatically control and adjust RF energy output from the first and second electrodes based, at least in part, on the predetermined elapsed time period and the predetermined threshold maximum temperature during delivery of RF energy. (Ex-1003-Weide, ¶365.)

Specifically, Angeles teaches that a given treatment application comprises a predetermined elapsed time period and a predetermined threshold maximum temperature of tissue during delivery of RF energy. (*Id.*, ¶366; Ex-1007-Angeles, [0034], [0047], [0049]; *see also id.,* FIG. 12, [0008], [0013], [0048], claim 14.)

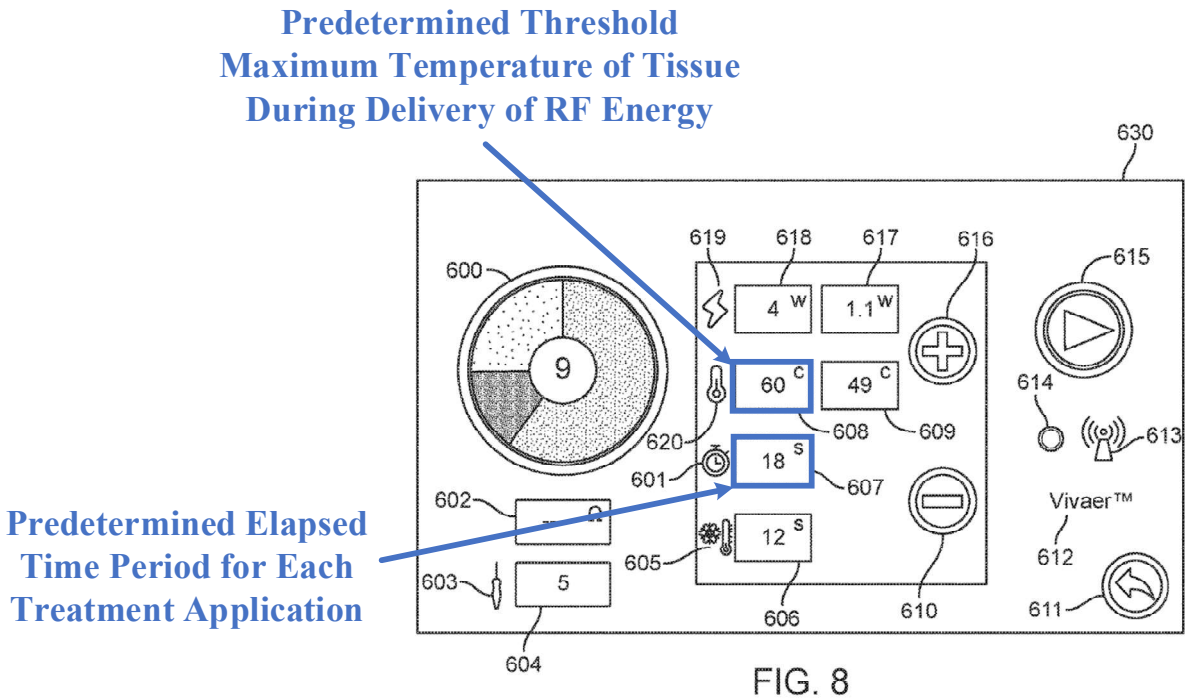


FIG. 8

(*Id.,* FIG. 8.)

Wolf-003 in combination with Angeles teaches that the console automatically controls and adjusts RF energy output from the first and second electrodes based, at least in part, on the predetermined threshold maximum temperature. (Ex-1003-Weide, ¶366; Ex-1005-Wolf-003, [0031] (describing measurement of mucosal tissue temperature and "delivering a second amount of the radiofrequency energy from the first electrode to the second electrode…based at least in part on the measured temperature."), [0188] (explaining power may be decreased or discontinued "if a particular tissue temperature threshold is reached"); Ex-1007-Angeles, [0047], [0049] (disclosing setting a predetermined threshold maximum temperature on the console).) According to Wolf-003, when the predetermined threshold maximum temperature is reached, the RF energy output is automatically decreased or turned off. (Ex-1005-Wolf-003, [0188].)

Additionally, Angeles' console automatically controls and adjusts RF energy output based, at least in part, on the predetermined elapsed time. (Ex-1007-Angeles, [0041] ("In this embodiment, treatment time (during which RF energy is delivered) is 18 seconds, and cool down time (during which RF energy is turned off) is 12 seconds."), [0044] ("At a given amount of time into the procedure, the console 102 stops delivering RF energy to the stylus 104, and a cool down phase begins."); Ex-1003-Weide, ¶367.) When the predetermined elapsed time is reached, the RF energy output is automatically turned off. (*Id*.)

A POSITA would have understood that Angeles' processor-executable instructions in the non-transitory computer readable memory cause Angeles' console to perform the function of automatically controlling and adjusting the RF energy output. (Ex-1003-Weide, ¶368.) Angeles discloses that its "instructions" control the console's "active display," which controls setting the predetermined elapsed time period and the predetermined threshold maximum temperature, setting and adjusting the power (*i.e.*, the RF energy output), and turning the RF energy on and off. (Ex-1007-Angeles, Abstract, [0006], [0008], [0013], [0037], [0041], [0043], [0048]-[0049], claims 1, 7, and 14.) A POSITA would have likewise expected and understood that Angeles' "instructions" control adjusting the RF energy output based on the predetermined elapsed time period and threshold maximum temperature (*e.g.*, turning the RF energy off when the predetermined elapsed time period or threshold maximum temperature is reached). (Ex-1003-Weide, ¶368.) Indeed, electronic devices with a processor, such as Angeles' console, require processor-executable instructions in memory to function. (*Id*.)

Additionally, Wolf-003 teaches ensuring that application of RF energy achieves the "desired therapeutic results" at the target site for a given treatment application. (Ex-1003-Weide, ¶369; Ex-1005-Wolf-003, [0088], [0166]-[0167]; *id.,* [0135], [0141], [0143].) While Wolf-003 does not expressly disclose that the "desired therapeutic result" is reduced engorgement of the tissue at the target site,

Wolf-290 does. (Ex-1003-Weide, ¶369; Ex-1006-Wolf-290, [0076] ("energy may be directed at the mucosa, to shrink the tissue or reduce swelling of the mucosa"); *see also id.,* [0043], [0057], [0077], [0104], [0113].) As explained in Ground 2, a POSITA would have been motivated and would have found it obvious in view of Wolf-290's teachings to use Wolf-003's systems and methods to reduce mucosal engorgement to treat RCR with a reasonable expectation of success. (Ex-1003-Weide, ¶369.)

Thus, Wolf-003 in view of Wolf-290 and Angeles teaches and renders obvious Claim 16. (*Id.,* ¶370.)

[Claims 17-18]

Angeles discloses that the predetermined threshold maximum temperature "may be selected in a range of 50 degrees Celsius to 70 degrees Celsius," "for example 60 degrees Celsius." (Ex-1007-Angeles, [0047], [0049].) This range is within the claimed ranges, and thus reads on Claims 17-18. *See, e.g., Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1346 (Fed. Cir. 1999) (single prior art species within a claimed genus reads on the claim).

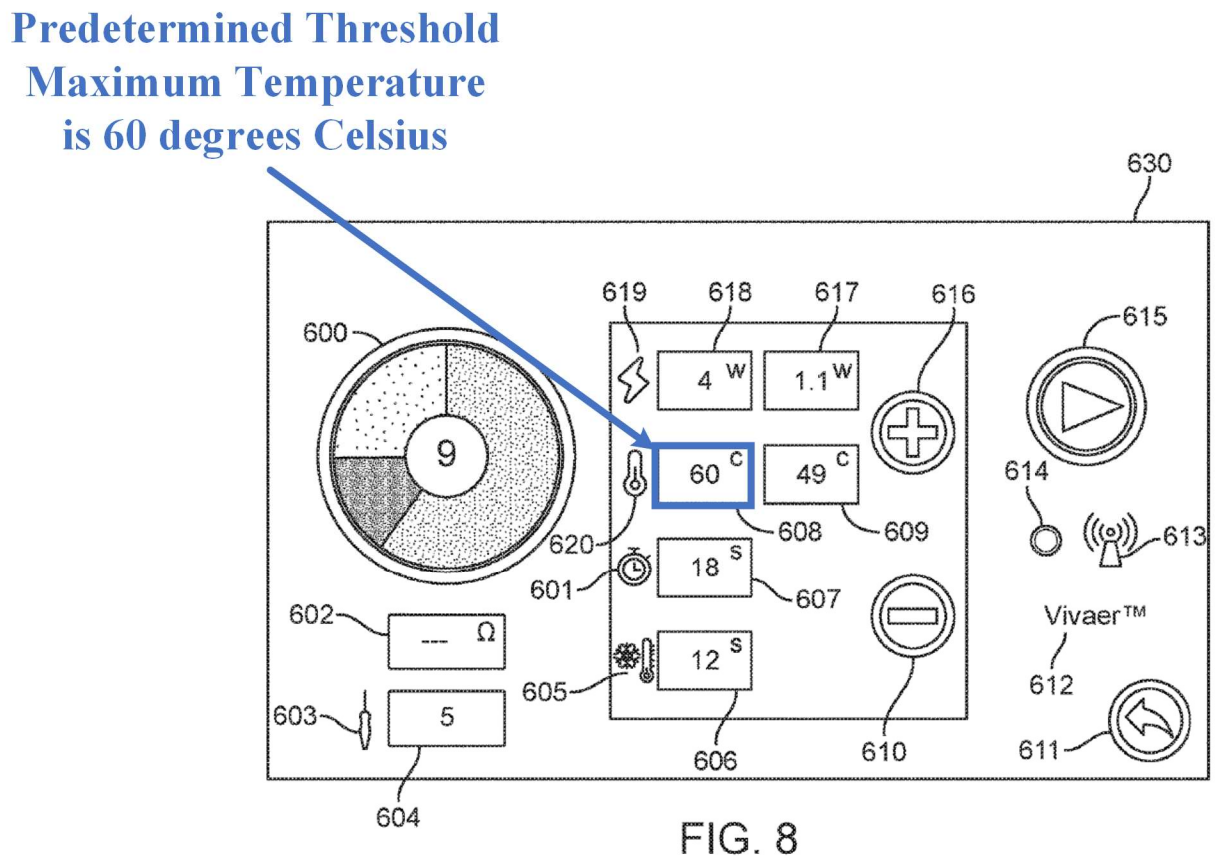


FIG. 8

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

Thus, Wolf-003 in view of Wolf-290 and Angeles teaches and renders obvious Claims 17-18. (Ex-1003-Weide, ¶¶372-373.)

[Claims 19-20]

Angeles discloses that the predetermined elapsed time period for RF energy delivery "may be selected for between 6 seconds and 18 seconds, *in 2-second increments*." (Ex-1007-Angeles, [0049].) Thus, Angeles expressly contemplates the following predetermined elapsed time periods: 6 seconds, 8 seconds, 10 seconds, 12 seconds, 14 seconds, 16 seconds, and 18 seconds. (Ex-1003-Weide, ¶375.)

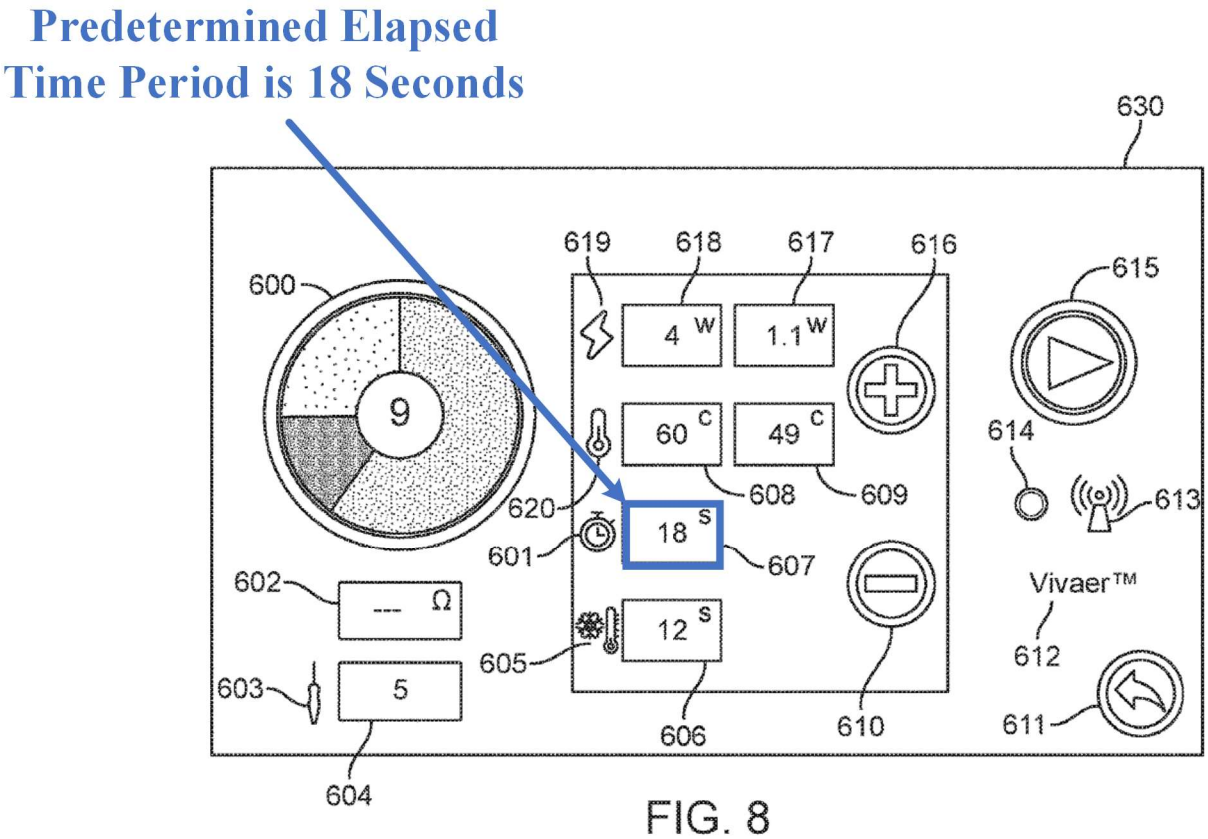


FIG. 8

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

Angeles teaches Claims 19-20 because: (a) Angeles discloses a range of 6-18 seconds, which renders each of the claimed ranges of Claims 19-20 obvious (*In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003)); and (b) at least one of the predetermined times of 6, 8, 10, 12, 14, 16, and 18 seconds falls within each of the claimed ranges (*Atlas Powder*, 190 F.3d at 1346). (Ex-1003-Weide, ¶¶376-377.)

Thus, Wolf-003 in view of Wolf-290 and Angeles teaches and renders obvious Claims 19-20. (*Id.*, ¶378.)

IX. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests that *inter partes* review of the '974 patent be instituted and the Challenged Claims be cancelled as unpatentable.

Respectfully submitted,
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Date: June 27, 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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Respectfully submitted,
GREENBERG TRAURIG, LLP

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