

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.

Petitioners,

v.

AERIN MEDICAL INC.

Patent Owner.

Case No. IPR2024-00277

U.S. Patent No. 11,241,271

**PETITION FOR *INTER PARTES* REVIEW
OF CLAIMS 1-4, 6-12, 16 OF
U.S. PATENT NO. 11,241,271
UNDER 35 U.S.C. Section 312 AND 37 C.F.R. Section 42.104**

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I. INTRODUCTION

The challenged claims of U.S. Patent No. 11,241,271 (“’271 patent”), which claims a June 14, 2011, priority date, are directed to a “method for treating a nasal airway to reduce mucus production” that involves applying radiofrequency (“RF”) energy through nasal mucosa to an underlying target tissue. Ex.1001-USP271, Clm.1. The ’271 patent provides no specific guidance as to how this can be achieved, and simply notes in a concluding paragraph that the disclosed embodiments may reduce mucus production. *Id.*, 48:1-4.

Applying RF energy to nasal tissue to reduce mucus production was a well-known technique by 2011. Two references relied on in this Petition, Kong and Liang, each disclose applying RF energy to at least one turbinate of the nose to treat rhinitis and reduce mucus production. And unlike the ’271 patent, which cursorily suggests that **any** disclosed treatment for the “structure and function of the nasal valve” may also result in less mucus, *id.*, 48:1-7, Kong and Liang disclose the specific mechanism for reducing mucus: targeting the submucosal nerves that control mucus production.

The only other requirement in the claims is that the RF energy be applied using a device that has two rows of bipolar electrode pairs. However, this feature was also well known by 2011. Edwards-’535 discloses a row of bipolar electrodes

used to apply RF energy through nasal mucosa. Ex.1010-Edwards-'535, 6:66-7:4. Stern discloses controlling two rows of bipolar RF electrodes in pairs on an expandable component to facilitate targeted and even heating of tissue—a requirement of Edwards-'535. Ex.1033-Stern, 12:25-37, 13:21-39, FIGs.15, 19. It would have been obvious to use a device like that taught by Edwards-'535 as augmented by Stern's teachings to perform the techniques taught by Kong or Liang. Accordingly, Petitioners respectfully request that the Board institute this IPR and cancel claims 1-4, 6-12, and 16 as unpatentable.

II. MANDATORY NOTICES

A. Real Parties in Interest

Pursuant to 37 C.F.R. Section 42.8(b)(1), Petitioners certify that Neurent Medical Inc. and Neurent Medical Ltd. are the real parties-in-interest.

B. Related Matter

Pursuant to 37 C.F.R. Section 42.8(b)(2), Petitioners submit that PO has asserted five patents, including the '271 patent in *Aerin Medical Inc. and The Foundry LLC v. Neurent Medical Inc. and Neurent Medical Ltd.*, Case No. 1:23-cv-00756-JLH (D. Del) (Exs.1006-1007). Three other patents owned by The Foundry LLC and allegedly exclusively licensed by PO are also asserted against Petitioners in this litigation. Petitioners are concurrently filing *inter partes* review petitions

challenging certain claims of the following patents asserted against Petitioners by
Patent Owner and The Foundry LLC:

Challenged Patent	Patent Owner	Case No.
9,072,597	Aerin Medical Inc.	IPR2024-00275
9,415,194	Aerin Medical Inc.	IPR2024-00276
11,033,318	Aerin Medical Inc.	IPR2024-00278
10,610,675	The Foundry LLC	IPR2024-00279
10,894,011	The Foundry LLC	IPR2024-00280
11,679,077	The Foundry LLC	IPR2024-00281
11,766,286	Aerin Medical Inc.	IPR2024-00282

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III. CERTIFICATION OF GROUNDS FOR STANDING

Petitioners certify under 37 C.F.R. Section 42.104(a) that the '271 patent is available for IPR and that Petitioners are not barred or estopped from requesting IPR on the grounds identified herein.

IV. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED

Under Rules 42.22(a)(1) and 42.104(b)(1)-(2), Petitioners request cancellation of claims 1-4, 6-12, and 16 ("Challenged Claims") of the '271 patent.

A. Prior Art

The '271 patent was filed on July 17, 2019, and claims priority through multiple parent applications to U.S. Provisional No. 61/496,930 filed on June 14, 2011.¹ Ex.1001-USP271, Cover. Petitioners rely upon the documents in the Table of Exhibits, including:

1. **USP 6,517,535** to Edwards (“Edwards-’535”), Ex.1010-Edwards-’535, published February 11, 2003, and filed November 9, 1999, as §§102(a)(1) and 102(a)(2) prior art.²
2. **Kong et al.**, “Low-temperature plasma ablation of inferior turbinate for the treatment of perennial allergic rhinitis,” 19:5 J Clin Otorhinolaryngol (China) 214 (March 2005) (“Kong”), Ex.1040-Kong, published March 2005, as §§102(a)(1) art. See Ex.1070-Munford-Decl.; Ex.1074-Kong-Decl.;

¹ Petitioners assume for purposes of this Petition that the '271 patent is entitled to the claimed priority date but reserve the right to argue in the parallel litigation that it is not.

² The '271 patent was examined under the provisions of the AIA, but each of the relied-upon references qualifies as prior art regardless of whether the AIA or pre-AIA provisions apply.

Ex.1078-Kong-Appx.; *Telefonaktiebolaget LM Ericsson v. TCL Corp.*, 941 F.3d 1341, 1346-47 (Fed. Cir. 2019).

3. **USP 5,562,720** to Stern (“Stern”), Ex.1033-Stern, published October 8, 1996, and filed October 6, 1994, as §§102(a)(1) and 102(a)(2) prior art.
4. **USP 6,273,886** to Edwards (“Edwards-’886,”), Ex.1016-Edwards-’886, published May 7, 2000, and filed September 26, 1996, as §§102(a)(1) and 102(a)(2) prior art.
5. **Liang et al.**, “RF treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy,” 13:8 J. Clin Otorhinolaryngol (China) 341 (August 1999) (“Liang”), Ex.1056-Liang, as §102(a)(1) prior art. *See* Ex.1070-Munford-Decl.; Ex.1072-Liang-Decl.; Ex.1076-Liang-Appx.; *Ericsson*, 941 F.3d 1346-47.

B. Discretionary Denial Under §325(d) Is Not Warranted

As detailed below, none of references in the Grounds presented in this petition were previously applied to the claims during the prosecution of the ’271 patent. Neither Edwards-’535, Stern, Liang, nor Edwards-’886 were before the patent office, and although Kong was cited by PO during prosecution, it was buried among nearly 200 other references and was not discussed materially during prosecution. Furthermore, Kong was originally published in Chinese, and there is no evidence

that PO submitted a full English translation, as here. *See generally*, Ex.1040-Kong; *see also* Ex.1003-USP271FH, 574 (listing Kong without a checkmark indicating a translation). Furthermore, there is no evidence that Kong was considered in view of Edwards-'535 or Stern. Accordingly, discretionary denial is not warranted.

C. Discretionary Denial Under §314(a) Is Not Warranted

No *Fintiv* factor favors denial. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 (P.T.A.B. May 13, 2020). The parallel litigation has not progressed past the pleadings, and there is no current case schedule or trial date. The Final Written Decision here would be expected well before the approximately 3-year median time to trial in the District of Delaware. *See* Ex.1008. And the Petition presents compelling merits underlying four Grounds.

D. Grounds for Challenge

Petitioners request cancellation of the Challenged Claims as unpatentable under 35 U.S.C. Section 103. The grounds for challenge are:

Ground	35 U.S.C. Section	Claims	References
I	103	1-3, 6-12, 16	Edwards-'535 + Kong + Stern
II	103	4	Edwards-'535 + Kong + Stern + Edwards-'886
III	103	1-3, 6-12, 16	Edwards-'535 + Liang + Stern
IV	103	4	Edwards-'535 + Liang + Stern + Edwards-'886

This Petition, supported by the declarations of Dr. John DelGaudio, Ex.1002-Decl., and Dr. Gregory T. Martin, Ex.1004-Decl., demonstrates that there is a reasonable likelihood that Petitioners will prevail with respect to at least one challenged claim. 35 U.S.C. §314(a). Petitioners respectfully request institution. *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018).

V. TECHNOLOGY BACKGROUND

The below sections detail (1) known concepts for RF ablation and RF ablation devices, including bipolar devices with two rows of electrode pairs; (2) known aspects of nasal anatomy; and (3) known methods for treating nasal conditions.

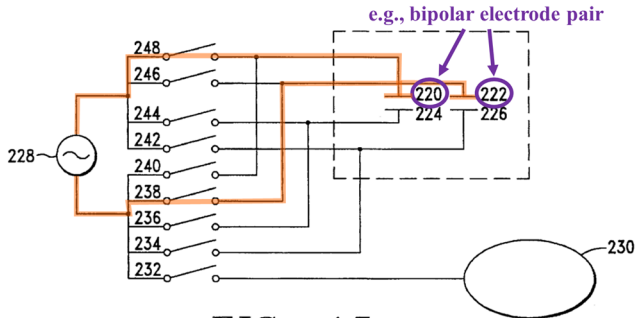
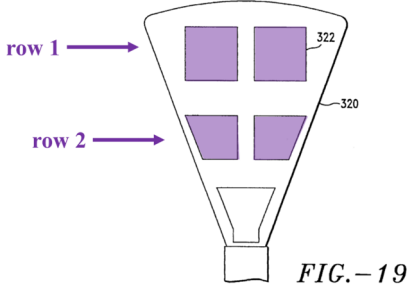
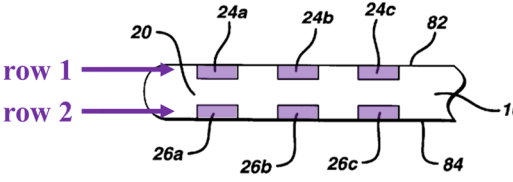
A. RF Ablation

Radiofrequency or “RF” ablation uses high frequency alternating electric current, typically in the range of 300kHz-700KHz, to modify tissue. The current

flows through tissue and causes tissue temperature to rise, creating lesions and damaging or killing portions of tissue for therapeutic effect. Ex.1004-Decl., ¶¶29, 46.

B. RF Ablation Devices

RF ablation devices for the treatment of chronic pain have been known for decades. Ex.1054-Koyyalagunta, 6. By 2011, many types of RF ablation devices had been disclosed for a wide range of uses. For example, RF ablation devices had been designed to include bipolar and monopolar configurations (Ex.1011-Baker, 5:47-58; Ex.1012-Goble, 6:33-68, 11:23-49), handles (Ex.1011-Baker, 5:27-47), multiple bipolar electrodes (Ex.1012-Goble, 6:33-68, 11:23-49), steerable shafts (Ex.1021-Makower, [0186]), visualization (Ex.1010-Edwards-'535, 10:39-45), expandable cages (Ex.1015-Laufer, 9:5-14; Ex.1012-Goble, 10:61-12:30), ablating forceps (Ex.1022-Odom, [0002]), feedback to physicians (Ex.1010-Edwards-'535, 9:14-11:44), penetrating or non-penetrating electrodes (Ex.1016-Edwards-'886, 26:54-28:8 (penetrating); Ex.1010-Edwards-'535, 4:55-60 (non-penetrating)), cooling systems (Ex.1010-Edwards-'535, 4:60-65, 6:10-40, 11:23-44), and techniques for targeting subsurface tissue (*id.*, 4:60-65). Devices with two rows of bipolar electrode pairs were also well known:

Ex.1033-Stern, FIGs. 15, 19 ³ (showing pair 220-222) ⁴	Ex.1012-Goble, FIG. 4 (showing pairs 24a, 26a; 24b, 26b; 24c, 26c) ⁵
 FIG. -15  FIG. -19	FIG. 4 

Ex.1004-Decl., ¶¶30-35.

It was well known that RF energy could be delivered to (and modify) tissue in various ways. For example, electrodes could directly contact tissue and apply RF current to heat and destroy the tissue. Ex.1010-Edwards-'535, 5:27-32, 8:12-14,

³ All annotations added unless otherwise stated.

⁴ See also Ex.1033-Stern, 2:36-40, 3:29-40, 12:7-13:55.

⁵ See also Ex.1012-Goble, 8:46-57.

8:26-39; Ex.1017-Chen, 240; Ex.1033-Stern, 3:12-15, 3:29-37. Other systems used RF energy to heat a liquid, where the liquid either transfers heat to the tissue or produces ionization that destroys tissue. Ex.1038-Thapliyal, 26:12-40, 4:38-58; Ex.1040-Kong, 215. Some devices could do both. *See, e.g.*, Ex.1038-Thapliyal, 26:12-44. Ex.1004-Decl., ¶¶36-37.

C. Monopolar and Bipolar RF Electrode Configurations

As noted above, RF ablation devices included both monopolar and bipolar configurations before 2011. Both configurations involve electrical current flowing from a generator to an active (+) electrode and back to a return (-) electrode. In a monopolar device, current passes from the active electrode (252 and 256 in Stern Figure 16), through target tissue in a patient's body, and out of the patient via a return electrode (usually a grounding pad) placed on the patient's body.

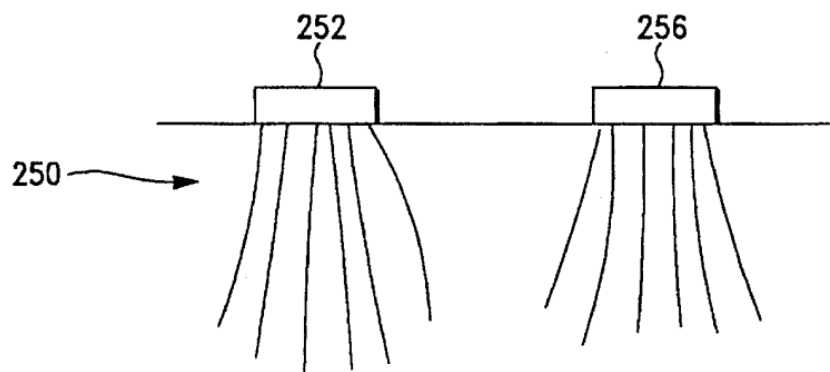


FIG. - 16

Ex.1033-Stern, FIG.16. In a bipolar device, the return electrode (260 in Stern Figure 17) is placed inside the body, normally near the active electrode (258 in Stern Figure 17), and current only passes through the tissue between the active and return electrodes.

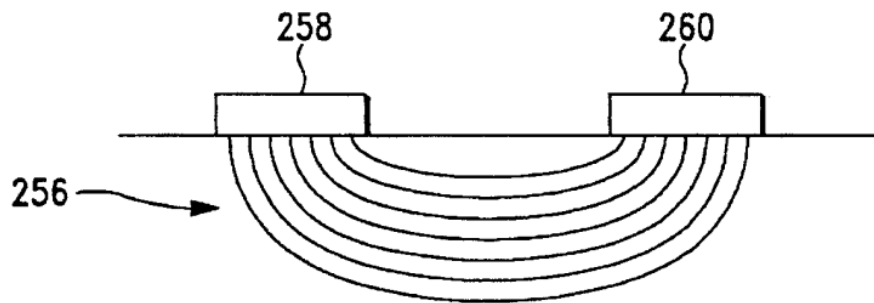


FIG.-17

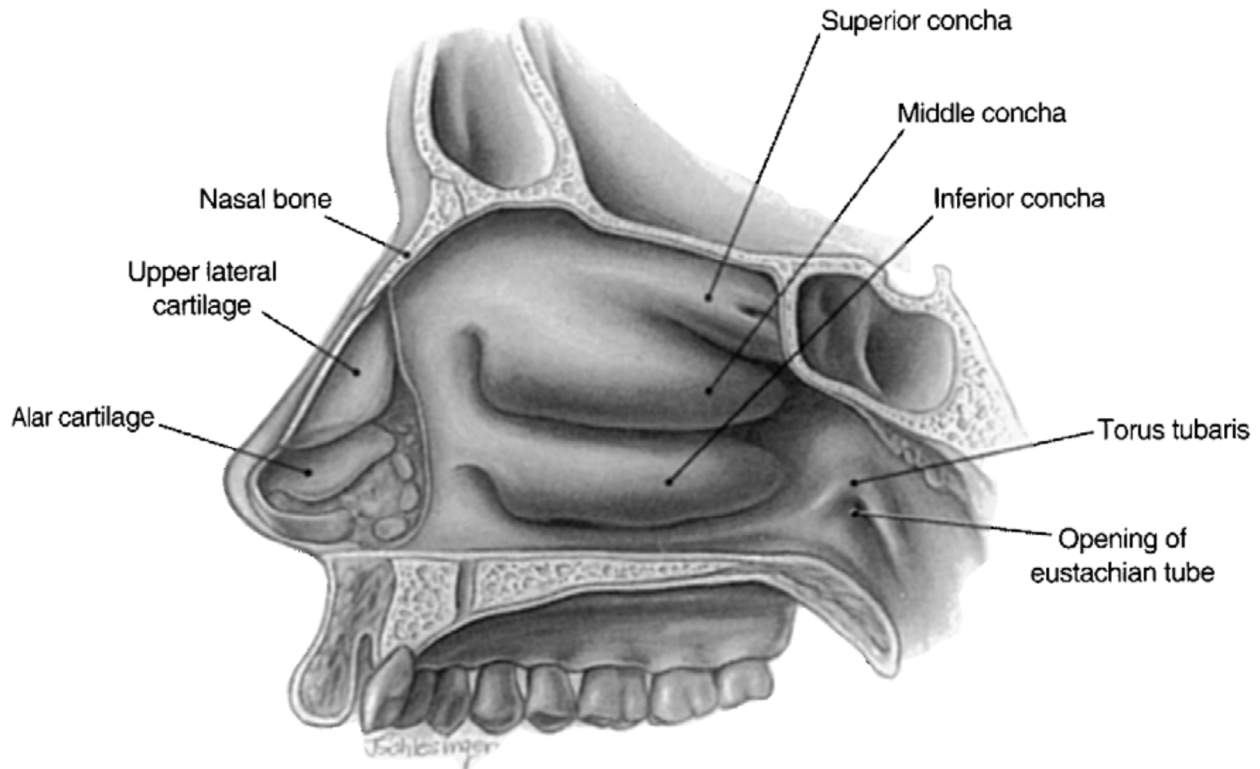
Ex.1033-Stern, FIG.17. Ex.1004-Decl., ¶¶38-40.

Bipolar RF electrodes may have particular benefit when ablating tissue located in a patient's head. Ex.1024-Hovda, 5:4-18. The proximity between the active and return electrodes renders bipolar electric field lines more controllable than in a monopolar arrangement, allowing for precise direction of energy to specific locations. This can be safer than a monopolar arrangement where current flows more broadly through a patient's body and could interfere with the electrical signals in a patient's brain. Ex.1004-Decl., ¶40.

Other known techniques can be used with bipolar RF ablation to ablate subsurface tissue while leaving the surface tissue intact, such as cooling systems that cool surface tissue while allowing underlying uncooled tissue to heat and become ablated. *See, e.g.*, Ex.1010-Edwards-'535, 4:53-67, 6:10-51, 6:66-24; Ex.1015-Laufer, 7:45-54. Ex.1004-Decl., ¶¶41-42.

D. Anatomy of the Nose

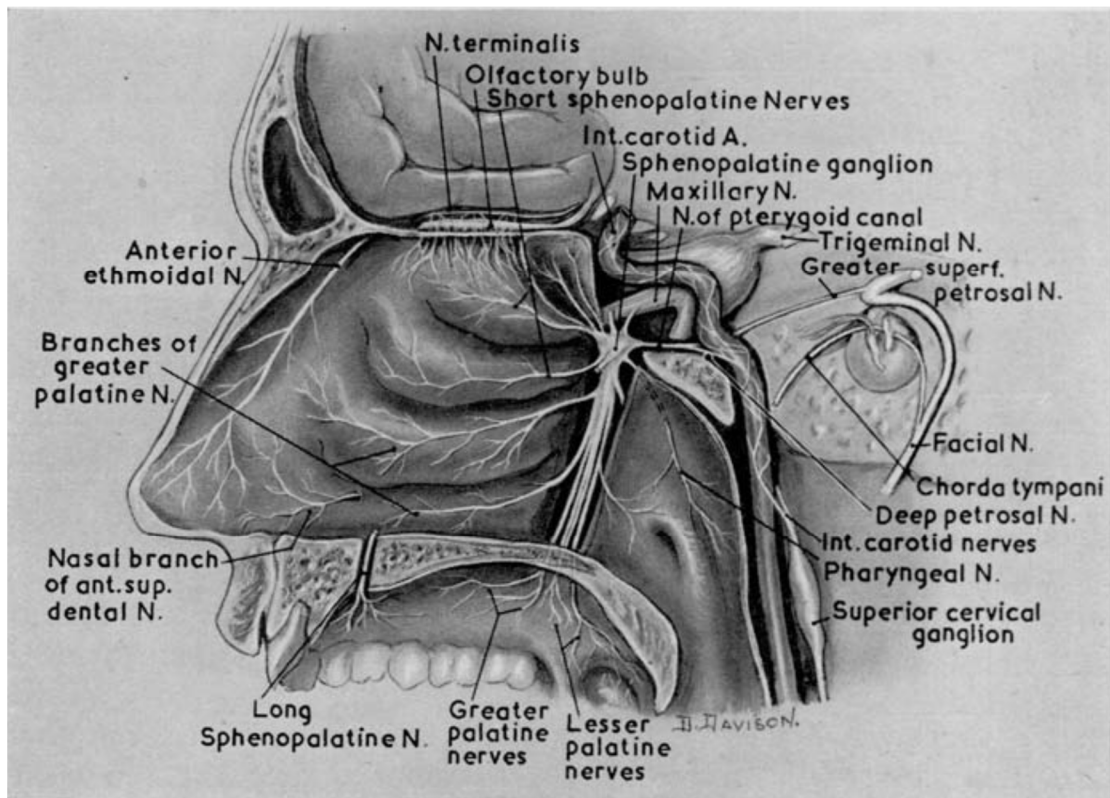
The nose has right and left nostrils that lead into separate right and left nasal cavities. Ex.1021-Makower, [0131], [0002]. Each nasal cavity is bounded in the middle (medial side) by a layer of cartilage called the nasal septum and on the outside (lateral side) by the lateral wall. Ex.1060-Lane, 387-88. The lateral wall includes three nasal turbinates, or concha—inferior, middle, and superior—lined with mucosal tissue. Ex.1021-Makower, [0004], [0002], [0014]; Ex.1060-Lane, 387-88.



Ex.1060-Lane, FIG.1. Ex.1002-Decl., ¶30.

A network of nerves branch throughout the face and nose, which are responsible for, *inter alia*, mucus production in the nose and eyes. Ex.1060-Lane, 392; Ex.1064-Mitchel, 505-06. As illustrated below, the Vidian nerve extends to the sphenopalatine foramen—an opening on the lateral nasal wall. Ex.1064-Mitchel, 505-507. From there, referred to as the sphenopalatine ganglion, the nerves branch outwardly and extend into other locations throughout the skull. The branches that innervate (supply nerve signals to) the turbinates are known as the “posterior nasal nerves,” which are subdivided into the “posterior superior nasal nerves” behind and in the upper and middle turbinate, and “posterior inferior nasal nerves” behind and

in the inferior turbinate. Another nerve—the nasociliary nerve—descends from a different path and branches into the ethmoidal nerve branches, which innervate the anterior portions of the turbinates. Ex.1060-Lane, 507.



Ex.1064-Mitchel, FIG. 7. Ex.1002-Decl., ¶¶31-32.

The Vidian nerve, posterior nasal nerves, and ethmoidal nerve are part of both the parasympathetic and sympathetic nervous systems. The parasympathetic nerves control “rest and digest” functions, i.e., decreasing heart rates, activating the immune system, and releasing mucosal/salivary glandular secretions, whereas the sympathetic nerves control “fight or flight” functions, i.e., increasing heart rate,

suppressing the immune system, and increasing sweat secretions. Ex.1002-Decl., ¶¶33-34.

E. Mucus Production

Rhinitis is a condition characterized by inflammation of mucosal tissue, and its symptoms include excess mucus production. Ex.1037-Chung, 110. By 2011, it was well known that excess mucus production results from sensory or parasympathetic nerve stimulation in the nose. Ex.1048-Nomura, 498, Abstract; Ex.1049-Konno, 106; Ex.1060-Lane, 392; Ex.1064-Mitchel, 505-06. Ex.1002-Decl., ¶¶36-39.

F. Treating Excess Mucus Production

Given the known causal link between overactive nerves and excess mucus production, practitioners have long treated excessive nasal mucus by destroying such nerves or disrupting their function. As early as the 1970s, practitioners treated rhinitis with “Vidian neurectomies,” which involve cutting (“transecting”) the Vidian nerve. Ex.1048-Nomura, 493-495; Ex.1049-Konno, 105-106. Ex.1002-Decl., ¶¶37-38.

Due to unwanted side effects, by the early 2000s practitioners sought to interrupt nerves downstream in the nasal cavity. Ex.1049-Konno, 110. For example, a 2000 study reported that cutting/cauterizing the posterior nasal nerves near the

sphenopalatine foramen had “superb clinical effectiveness.” *Id.* The prior art Kong reference relied on herein is another example of RF energy rhinitis treatment of the posterior inferior nasal nerves to “damage[e]...the parasympathetic nerve fibers from the inferior turbinate” and “reduc[e] gland secretion.” Ex.1040-Kong, 215. Ex.1002-Decl., ¶39.

G. RF Energy in the Nasal Cavity

By the 2000s, commercial RF devices were being used in the nose. Ex.1021-Makower, [0020]-[0021], [0038]-[0040]; Ex.1042-Bäck, Abstract, 1808; Ex.1044-Lee, Abstract, 108-09. Prior to 2011, RF ablation was used in the nasal cavity to treat a variety of different conditions. For example, by 2011, RF ablation was used to treat snoring and nasal obstruction secondary to non-allergic or allergic rhinitis (Ex.1031-Hytönen, Abstract), and to remove a blockage or shrink enlarged tissue (Ex.1010-Edwards-’535, Abstract; Ex.1023-Coste, 894; Ex.1024-Hovda, 11:13-12:4; Ex.1031-Hytönen, Abstract). Indeed, some even reported reduced nasal discharge (i.e., mucus production) from treatment. Ex.1042-Bäck, 1808-10. Ex.1002-Decl., ¶¶40-44.

Also prior to 2011, others had begun using those same RF devices to treat rhinitis and reduce mucus production by targeting the nerves in the nasal cavity. Ex.1040-Kong, 215; Ex.1017-Chen, 240; Ex.1055-Fang, 876; Ex.1056-Liang, 341;

Ex.1031-Hytönen (surveying RF ablation for nasal obstruction and rhinitis).

Ex.1002-Decl., ¶45.

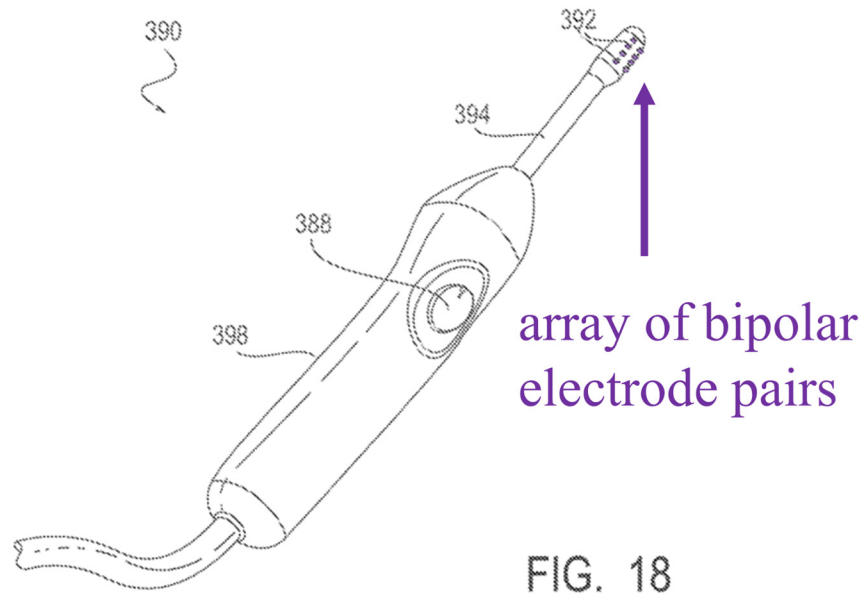
VI. The '271 Patent

A. Brief Description

The '271 patent provides minimal direction regarding how RF energy can reduce mucus production. The '271 patent places an emphasis on ways to modify the structure and function of the nasal valve, for example by “altering a structure, shape or conformation of” nasal structures. Ex.1001-USP271, 48:4-7, 5:56-61. The specification’s penultimate paragraph posits that **any** embodiment might also be used to reduce mucus production, without disclosing any details as to the energy, position, device, or duration requirements for such a result. *Id.*, 48:1-7 (“**[A]ny** of the embodiments described above may be [used] to reduce mucus production...around **any** treated areas....[M]ucus reduction may also be part the beneficial result of **any** treatment, in some embodiments.”).⁶ The challenged claims are directed to this concept which, as discussed above, was well known. Ex.1002-Decl., ¶¶47-48; Ex.1004-Decl., ¶¶43-44.

⁶ Emphasis added unless otherwise noted.

The challenged claims also require a treatment device with two rows of bipolar electrode pairs. Ex.1001-USP271, Clm.1. Figure 8F illustrates an example of “pairs of bipolar electrodes 392.” *Id.*, 26:63-67.



Id., FIG.18. As discussed in Section V.C, the use of two rows of bipolar RF electrode pairs was already known. Ex.1002-Decl., ¶49; Ex.1004-Decl., ¶¶45, 32-35.

B. Prosecution History

The '271 patent was filed as application 16/514,316 on July 17, 2019, and claims priority to provisional application 61/496,930 filed on June 14, 2011. Ex.1003-USP271FH, 411. PO filed a preliminary amendment to replace claims 1-16 with 16-31. *Id.*, 416, 420-421. The examiner rejected all claims for double

patenting over USP 10,398,489—the '271 patent's parent—but otherwise indicated all claims as allowable without comment. *Id.*, 49. After PO filed a terminal disclaimer, *Id.*, 30-31, the application was allowed, again without comment. *Id.*, 7-11. Ex.1002-Decl., ¶¶50-53.

During prosecution of the **parent** application, PO amended the claims to require “contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway”—the same limitation that appears in the challenged claims—to distinguish USP 6,109,268 to Thapliyal (Ex.1038-Thapliyal). Ex.1057-USP489FH, 47. PO argued “[a] primary objective of the Thapliyal device and method is to apply energy to fluid and not directly to tissue, in an attempt to reduce unwanted damage of the tissue.” *Id.*, 44. As explained below, Edwards-'535 discloses directly contacting tissue with RF electrodes and avoiding unwanted damage to surface tissue by cooling the surface with a balloon. Ex.1002-Decl., ¶¶53-54.

VII. PERSON OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art (“POSITA”) at relevant times (2011-2019) would have had (1) a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline and (2) at least three years of experience in the clinical use, design, development, and/or testing of medical devices, including

medical devices that deliver energy to tissue. Less work experience may be compensated by a higher level of education, and vice versa. Ex.1002-Decl., ¶¶27-29; Ex.1004-Decl., ¶¶24-28.

VIII. CLAIM CONSTRUCTION

For the purposes of this IPR, the Board need not construe any terms because the Challenged Claims are invalid under any reasonable interpretation. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017). Ex.1002-Decl., ¶¶63-66; Ex.1004-Decl., ¶¶46-49.⁷

IX. OVERVIEW OF THE ASSERTED PRIOR ART

All of the Grounds in this Petition are based on new combinations that were not before the Examiner during prosecution. The combinations are also supported by new evidence, including the expert testimony of Dr. DelGaudio, Ex.1002-Decl., and Dr. Martin, Ex.1004-Decl.

⁷ Petitioners reserve the right to propose constructions for claim terms in the parallel litigation and respond to any claim construction arguments advanced by PO or any real party in interest in this proceeding and the parallel litigation.

A. Edwards-'535

Edwards-'535 discloses an RF device “introduced through a nostril” and used “for ablating an **internal section** of a **nasal concha**” to “improv[e] airflow.” Ex.1010-Edwards-'535, 5:20-26, 3:18-19, 4:30-32. The device has an **expandable member 132** that contacts and applies cooling to the surface of the **nasal concha 114** to deliver RF energy to an **interior section** of the **nasal concha 114** to reduce its size. *Id.*, 4:53-67, 5:27-30, 6:10-51, 6:66-7:24, FIGs.3A-4C. Energy is delivered with an **energy delivery member 134**, which can include “a plurality of energy delivery devices where energy is independently deliverable to each energy delivery device” that are “positioned on a surface 147 of the expandable member.” *Id.*, 8:12-17.

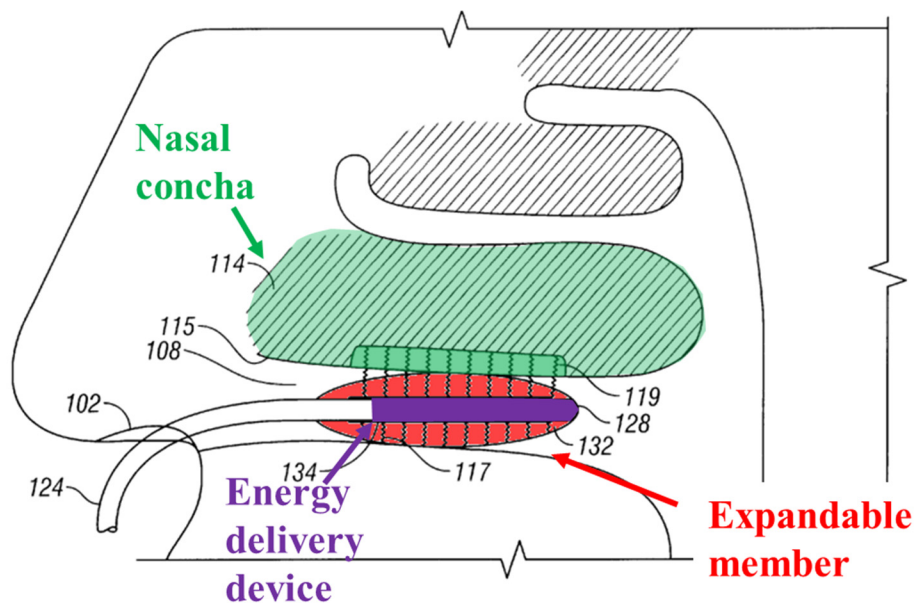


FIG. 3B

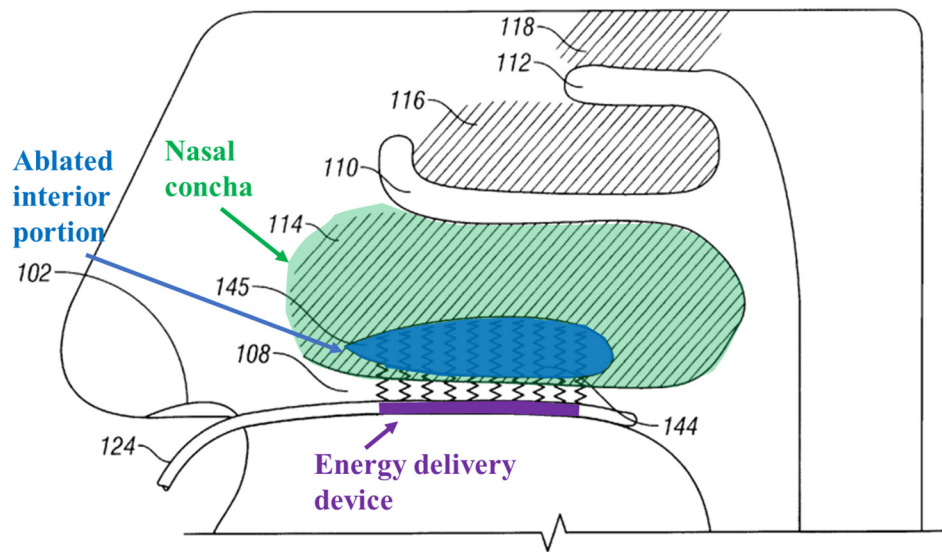


FIG. 4A

Ex.1010-Edwards-'535, FIGs. 3B, 4A. Ex.1002-Decl., ¶55; Ex.1004-Decl., ¶¶55-58.

B. Kong

Kong discloses a method of treating perennial allergic rhinitis with an effectiveness of 94.3%. Ex.1040-Kong, 214. Kong uses a “Hummingbird or ReFlex 45 RF electrode” device to apply RF energy through holes “at the lower or medial edge of the inferior turbinate.” *Id.* The holes were made in “three parts [of the turbinate], i.e., the anterior, middle, and posterior part.” *Id.* Ex.1002-Decl., ¶56.

Kong discloses the causal mechanism that links the disclosed treatment technique with the result of treating rhinitis. As was well known, “removing some parasympathetic nerve fibers” reduces symptoms of rhinitis, including excess “nasal

mucus.” Ex.1040-Kong, 215; *see also id.* (applying RF energy “damage[es]...parasympathetic nerve fibers from the inferior turbinate” to “reduc[e] gland secretion.”). Ex.1002-Decl., ¶57.

C. Liang

Liang—another clinical study—reports “significant” “therapeutic effect” from applying RF energy to heat the ethmoidal nerve to treat allergic rhinitis. Ex.1056-Liang, Abstract, 343. Such RF energy “can cause varying degrees of damage to the deep ethmoidal nerve, ...reducing runny nose[]...achieving the goal of treating allergic rhinitis.” *Id.*, 342. Ex.1002-Decl., ¶¶58-59.

D. Stern

Stern discloses an ablation device for ablating “the inner lining of body organs.” Ex.1033-Stern, 1:16-18, Abstract, 2:6-18, 18:27-40. Stern’s device has an expandable member with surface RF electrodes. *Id.*, 2:26-35. An exemplary arrangement uses two rows of multiple bipolar RF electrode pairs and a mechanism for delivering RF energy to each electrode pair. *Id.*, FIG.19, 2:36-40, 3:29-40, 12:7-13:55. Certain electrode pairs can be selectively energized based on a switching arrangement. *Id.*, Abstract.

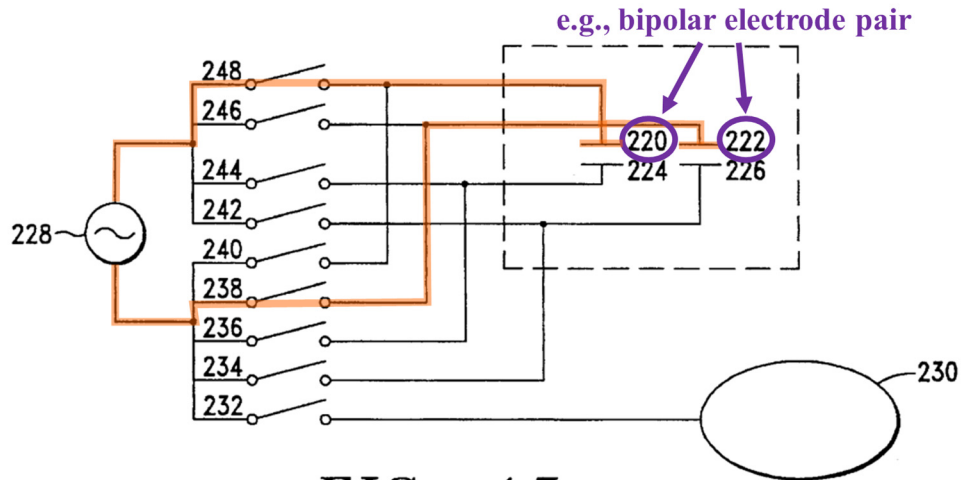


FIG. - 15

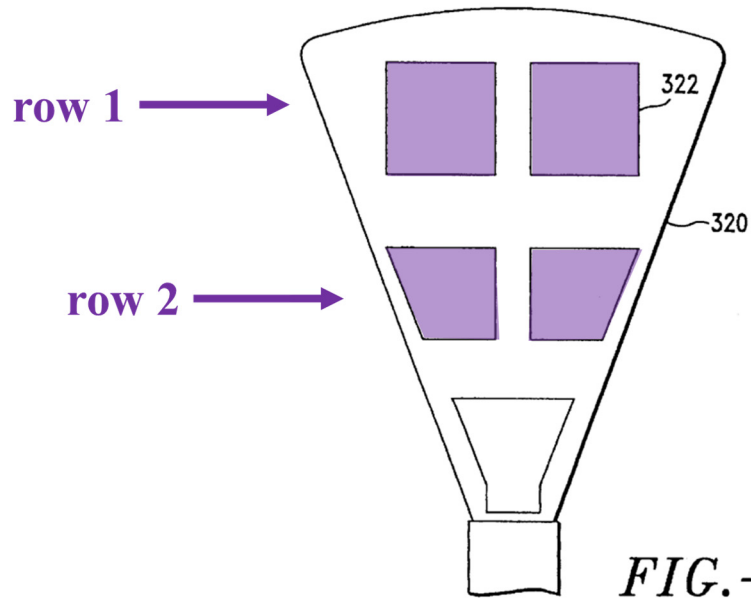


FIG. - 19

Id., FIGs.15, 19. Ex.1002-Decl., ¶¶60-61; Ex.1004-Decl., ¶¶59-62.

E. Edwards-'886

Edwards-'886 discloses a device for delivering RF energy “with a sinusoidal waveform at 460 kHz” to human tissue. Ex.1016-Edwards-'886, 39:35-40:3, 36:66-37:2. Ex.1002-Decl., ¶¶62; Ex.1004-Decl., ¶¶63-64.

X. SPECIFIC GROUNDS FOR UNPATENTABILITY

A. Ground I: Claims 1-3, 6-12, 16 Are Invalid as Obvious Over Edwards-'535 in View of Kong and Stern

1. Claim 1

a. 1[pre]:

Whether the preamble is limiting or not, Edwards-'535 in view of Kong discloses *a method for treating a nasal airway* (e.g., ablating interior section of a turbinate / ablating inferior turbinate) *to reduce mucus production* (e.g., reduce glandular secretions and nasal mucus).⁸ Ex.1002-Decl., ¶¶68-72.

Edwards-'535 discloses *treating a nasal airway* by “introducing ablative energy 144 into an interior section of a nasal concha through the surface of the nasal concha” and “[c]ooling of the surface of the nasal concha...to prevent the ablation of the surface of the nasal concha.” Ex.1010-Edwards-'535, 6:66-7:4,6:9-65, 4:53-

⁸ Apart from citations, *italicized text* indicates claim language unless otherwise noted.

67, 7:5-17, 11:23-44, FIGs.4A-4C. The nasal concha is also known as a turbinate.

Ex.1010-Edwards-'535, 1:63-66.

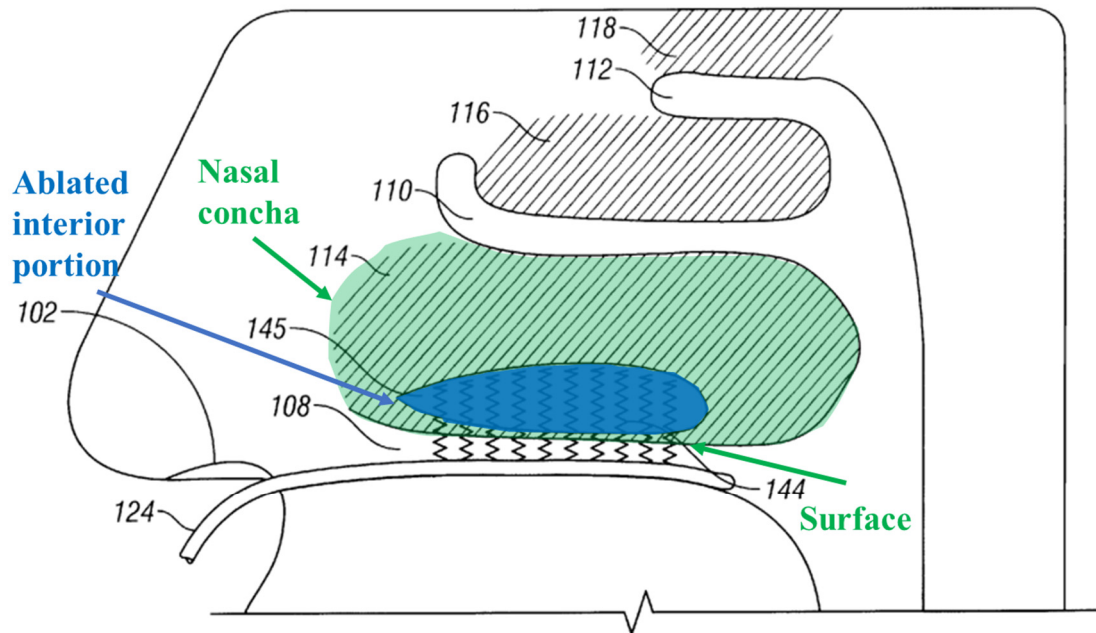


FIG. 4A

Ex.1010-Edwards-'535, FIG.4A. Edwards-'535 discloses treating any of the three turbinates. *Id.*, Abstract, 1:60-2:29, 4:19-52, 6:39-42. Ex.1002-Decl., ¶¶69-70.

Kong discloses *treating a nasal airway* with a “bipolar” “RF electrode” that ablates the same portions of the nasal airway as Edwards-'535 (“anterior, middle, and posterior part[s]” of the “lower or medial edge of the inferior turbinate”). Ex.1040-Kong, 214-15, Abstract; *see also* Ex.1010-Edwards-'535, 4:33-5:15, 6:9-7:4. Kong teaches that applying RF energy to tissue “under the mucosa” of the inferior turbinate

reduces mucus production (e.g., “reducing gland secretion” and “reducing nasal mucus”) by damaging nerves. Ex.1040-Kong, 214-215. Ex.1002-Decl., ¶¶71-72.

i. *Motivation to Combine Edwards-’535 and Kong*

Obviousness requires the references in a combination “are analogous to the claims being challenged,” and that a POSITA would have been motivated to combine the references with a reasonable expectation of success. *See Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1004 (Fed. Cir. 2023). Each is met here.

Edwards-’535 and Kong are analogous art to the Challenged Claims. Both are in the same field as the ’271 patent and are reasonably pertinent to solving the problems addressed in the ’271 patent—treating tissue in a body cavity—with the same types of solutions—applying RF energy to tissue. *See, e.g.*, Ex.1010-Edwards-’535, Abstract, 5:43-51, 8:47-53, 10:25-31, 10:51-57; Ex.1040-Kong, 214-15. Ex.1002-Decl., ¶74.

A POSITA would have also been motivated to combine Edwards-’535 and Kong with a reasonable expectation of success. Edwards-’535 teaches a method of using RF energy to ablate an interior portion of tissue on any of the turbinates, including the surface of the inferior turbinate. *See, e.g.*, §§X.A.1.a-c, e-f. Kong discloses techniques for using RF energy to treat nasal airway conditions, including

ablating tissue containing parasympathetic nerves underneath the surface of the inferior turbinate. A POSITA would have been motivated to combine these teachings—namely, by using the method taught by Edwards-’535’s to target specified nerve tissue as taught by Kong—to reduce mucus production by applying RF energy to parasympathetic nerves underneath the lower surface of the interior turbinate (i.e., through the mucosal tissue at the “anterior, middle, and posterior part[s]” of the “lower or medial edge of the inferior turbinate,” Ex.1040-Kong, 214), with a reasonable expectation of success for the following reasons. Ex.1002-Decl., ¶73.

First, Kong discloses the benefits of using RF energy to treat the same location (interior of the inferior turbinate) as Edwards: “treating perennial allergic rhinitis,” including by “reducing the glandular secretion, its sensitivity to external physical and chemical adverse stimuli, and the secretion of vasoactive peptides, inhibiting sneezing reflex, reducing nasal mucus[,]” “reducing the sensitivity of nerve endings, reducing gland secretion, and improving nasal ventilation.” Ex.1040-Kong, 215. In the clinical results from Kong’s treatment, 30/35 patients “showed significant improvement [and] 3 patients showed improvement.” *Id.*, 214. “The total effective rate was 94.3%” and “[n]o surgical complications or other discomfort were observed.” *Id.*, 214. Ex.1002-Decl., ¶75.

Second, Kong discusses shortcomings of its approach to delivering treatment that Edwards-'535 expressly overcomes, further motivating combining the teachings of Edwards-'535 and Kong. For example, Kong's technique requires inserting a device through nasal mucosa, which Kong recognizes can be damaging, and involves a reduced "surgical field of view" that increases "the difficulty of surgery." Ex.1040-Kong, 215. By contrast, Edwards-'535 uses a non-puncturing balloon that provides cooling to the contacted tissue and is less damaging to the surface mucosa. Ex.1010-Edwards-'535, 4:53-67, 6:10-22. Furthermore, unlike Kong's procedure, Edwards-'535's "procedure can be performed bloodlessly and without the need to penetrate tissue, thereby significantly reducing the risk of infection." *Id.*, 4:53-67. These teachings would have motivated a POSITA to use a method like that of Edwards-'535 (which does not damage mucosal tissue) to deliver treatment to the specific tissue identified by Kong to avoid the shortcomings of Kong's technique while preserving its benefits. Ex.1002-Decl., ¶76.

Third, as discussed above, Edwards-'535 and Kong describe similar techniques such that their combination would have yielded predictable results. Both teach delivering RF energy to tissue within the inferior turbinate, which results in reducing the turbinate's size. *See, e.g.*, Ex.1010-Edwards-'535, 5:30-34 ("[E]nergy 117 is delivered through the surface 115 of the nasal concha 114 to ablate at least a

portion 119 of the nasal concha 114.”), 6:66-7:17, 6:9-65 (applying energy and cooling), 4:53-5:15 (targeting an “anterior portion” that constitutes “about one-third of the inferior nasal concha 114”), FIGs.3A-4C; Ex.1040-Kong, 214 (treating “anterior, middle, and posterior part[s]” of the “lower or medial edge of the inferior turbinate”), 215 (“removing the target tissues and causing tissue shrinkage” with RF energy), Abstract. Indeed, both treat the same lower turbinate surface. *See, e.g.*, Ex.1010-Edwards-’535, FIGs. 4A; Ex.1040-Kong, 214 (ablating “lower or medial edge of the inferior turbinate”). Thus, using Edwards-’535’s method to ablate specified nerve tissue taught by Kong and thereby treat rhinitis is simply applying Kong’s teachings to improve Edwards-’535’s technique in the same way as those teachings are applied in Kong. Ex.1002-Decl., ¶77.

Prior to 2011, many others had used Kong’s equipment—the Hummingbird or ReFlex 45 RF electrodes—for turbinate reduction, which is the same procedure disclosed by Edwards-’535. *See, e.g.*, Ex.1042-Bäck, 1808; Ex.1043-Ilgner, 323, Ex.1044-Lee, 108-109. Indeed, researchers had already noted that doing so could reduce nasal discharge—the same result realized in Kong. Ex.1042-Bäck, 1808, FIG.2 (showing ~25% nasal discharge reduction); Ex.1040-Kong, 215. Some had even evaluated RF treatment for obstruction and rhinitis treatments (including Kong) in the same survey publication, thereby highlighting the similarities between the

treatments. *See generally* Ex.1031-Hytönen. Because using off-the-shelf turbinate reduction devices for reducing nasal discharge was well-known, a POSITA would have found it obvious to substitute Kong's target tissue—which had known benefits including reducing mucus—for Edwards-'535's target tissue to obtain predictable results of reducing mucus production without damaging mucosal tissue. Ex.1002-Decl., ¶78.

Fourth, a POSITA would have had a reasonable expectation of success in using Edwards-'535's method to deliver treatment to nerve tissue identified by Kong given that, as explained above, Edwards-'535 ablates the same portions of tissue as ablated in Kong, and Kong uses a turbinate reduction device like Edwards-'535's. Indeed, prior to 2011, other researchers recognized reduction in mucus production resulting from ablation of the nasal turbinates. Ex.1042-Bäck, 1808, FIG.2. Moreover, in the combination, the known techniques of Edwards-'535 and Kong would have been reasonably likely to achieve successful clinical outcomes, for example:

- Edwards-'535's apparatus 124 delivers RF energy to ablate an interior portion of the inferior turbinate (including from a lower surface), and Kong discloses a promising clinical application of that RF ablation (e.g., ablating nerve tissue to treat rhinitis and reduce mucus production). Thus, Kong's teachings of

treating rhinitis and reducing mucus production would be applied to the use of Edwards-'535's apparatus 124 in the same way those teachings are used in Kong itself.

- Kong discloses using a commercial RF electrode commonly used for turbinate reduction for the additional indication of treating rhinitis and reducing mucus production, and Edwards-'535 discloses an improved turbinate reduction device that minimizes damage to the mucosa and reduces the risk of infection. Thus, the improvements realized by Edwards-'535's RF energy device for turbinate reduction would have likewise been applied Kong's alternative use for an RF energy-based turbinate reduction device.

Accordingly, combining the teachings of Edwards-'535 and Kong would have been a matter of routine implementation well within the skill of a POSITA and would have yielded predictable results—e.g., Edwards-'535's method being used to deliver RF energy to specified nerve tissues to treat allergic rhinitis and reduce mucus production, as taught by Kong—with a reasonable expectation of success.⁹ Kong's

⁹ This is consistent with the '271 patent itself, which does not specify any technical prerequisites for reducing mucus production. Ex.1001-USP271, 48:1-7, 10:44-53.

See In re Epstein, 32 F.3d 1559, 1568 (Fed. Cir. 1994).

reported 94.3% effectiveness rate using a standard RF energy, Ex.1040-Kong, 214, would have further led a POSITA to expect success using other RF energy devices like that disclosed by Edwards-'535. The examiner of the '271 patent agreed that "causing a reduction in mucus production in the nasal airway is an obvious result from the claimed radio frequency energy passing through the nasal mucosa to underlying submucosal tissue." Ex.1003-USP271FH, 49. Ex.1002-Decl., ¶¶44-45, 78-81.

Thus, a POSITA would have been motivated to combine the teachings of Edwards-'535 and Kong. Ex.1002-Decl., ¶82.

b. 1[a]:

Edwards-'535 in view of Kong and Stern discloses *contacting a treatment element* (e.g., **expandable member 132** having **energy delivery device 134**) *of a nasal airway treatment device* (e.g., apparatus 124) *directly with nasal mucosa* (e.g., surface of the **nasal concha** / lower or medial edge of the inferior turbinate) *of the nasal airway, wherein the treatment element comprises two rows of bipolar electrode pairs* (e.g., plurality of **bipolar energy delivery devices**). Ex.1002-Decl., ¶¶83-94; Ex.1004-Decl., ¶¶66-97.

i. Edwards-'535 in view of Kong teaches contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein

the treatment element comprises [a row] of bipolar electrode[s].

Edwards-'535 discloses “an apparatus 124 having a distal portion 128 with an expandable member 132 and an energy delivery device 134” that is used to treat a nasal airway (e.g., nasal concha). Ex.1010-Edwards-'535, 5:20-26, 5:27-35 (e.g., applying expandable member 132 to a “nasal concha 114 to be treated”), 5:51-61, 7:33-53, FIGs.3A-C. Ex.1002-Decl., ¶¶84-91; Ex.1004-Decl., ¶¶66-67.

Edwards-'535 discloses that the energy delivery device 134 can include “a plurality of energy delivery devices” that each independently deliver energy. Ex.1010-Edwards-'535, 8:12-32, FIGs.3A-3B, 3D, 4A, 6. Edwards-'535 further teaches delivering RF energy in a bipolar mode, *id.*, 8:17-32, 8:50-54, 10:30-32, 10:52-61, and that these energy delivery devices (or ring electrodes 156) “may be disposed in parallel with their axes aligned with a long axis 160 of the catheter body 126” (i.e., placed in a row). *Id.*, 8:19-33, FIG.6. Ex.1002-Decl., ¶84; Ex.1004-Decl., ¶67.

Edwards-'535 discloses multiple configurations of energy delivery device 134, including on the surface of expandable member 132 and inside the expandable member, each of which involves *contacting a treatment element...directly with nasal mucosa of the nasal airway*. Ex.1002-Decl., ¶¶84-86; Ex.1004-Decl., ¶¶68-69.

First, Edwards-’535 discloses a configuration of “apparatus 124 having a distal portion 128” where “distal portion 128” (i.e., *treatment element*) includes an energy delivery device 134 positioned within expandable member 132. Ex.1010-Edwards-’535, 4:53-67, 5:18-35, 8:8-17, Clm.1, FIGs.3A-3C. Energy delivery device 134 delivers “ablative energy” to a nasal airway (nasal concha). *Id.*, 5:18-27, FIGs.3A-4A. As discussed above for limitation 1[p], delivery of such energy is used for treatment (ablating tissue). Ex.1002-Decl., ¶87.

In this configuration, “the expandable member 132 is expanded [and] brought into contact with the surface 115 of the nasal concha 114 to be treated.” Ex.1010-Edwards-’535, 5:27-35, 4:53-67, 5:46-51, 7:18-25, Clm.1, FIG.3B. The treated surface 115 comprises *mucosal tissue*. *Id.*, 7:18-25, FIG.3B; Ex.1021-Makower, [0004] (“The nasal turbinates [(i.e., part of the nasal passages)]...are covered with mucosal tissues”); Ex.1060-Lane, 392. Ex.1002-Decl., ¶87.

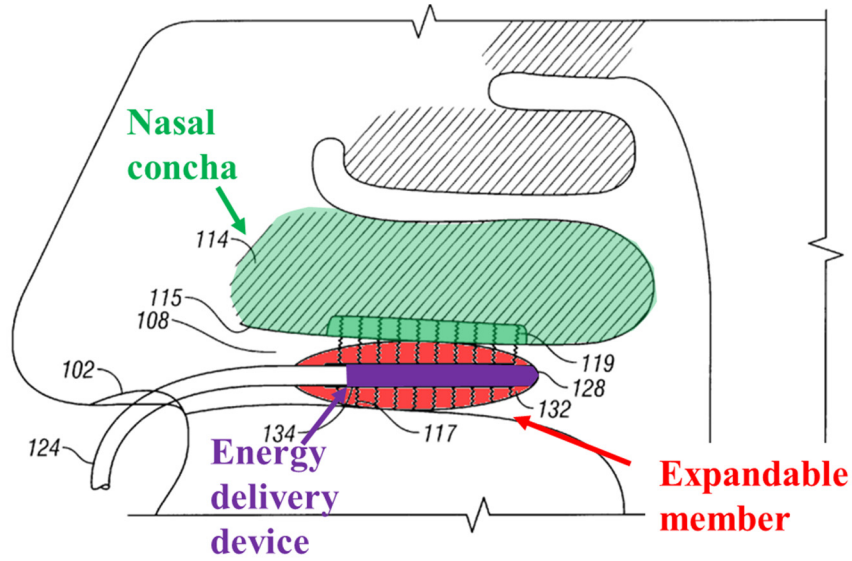


FIG. 3B

Second, Edwards-’535 discloses that **energy delivery device 134** can include RF electrodes (such as ring electrodes 156) that are “disposed on the surface” of, rather than inside **expandable member 132**. Ex.1010-Edwards-’535, 8:8-25, FIGs. 5-6. By providing the electrodes on the surface of **expandable member 132**, which

contacts the surface of the **nasal concha 114**, the electrodes would also contact the **nasal concha 114**.¹⁰ Ex.1002-Decl., ¶¶88-89.

As discussed above for limitation 1[pre], the surface of the **nasal concha 114** is the same surface through which Kong directs treatment. It would have been obvious to combine Edwards-'535 with Kong with a reasonable expectation of success for the reasons above. Ex.1002-Decl., ¶¶85, 90-91.

ii. Stern teaches wherein the treatment element comprises two rows of bipolar electrode pairs.

Stern teaches an exemplary arrangement of *two rows of bipolar RF electrodes* and a mechanism for delivering RF energy to each electrode. Ex.1033-Stern, 2:36-40, 3:29-40, 12:7-13:55, Clm.4, FIGs.13, 15, 17, 18, Title. For example, like Edwards-'535, Stern provides that an array of *bipolar RF electrodes* can be placed

¹⁰ Edwards-'535's contact-based energy delivery is different from the liquid-based energy transfer disclosed in Thapliyal that was distinguished by PO during prosecution of the parent. *See supra*, §VI.B. Although Edwards-'535 discloses the use of a conductive medium when electrodes are position on the inside of the expandable member, Ex.1010-Edwards-'535, 7:28-8:8:12, Edwards-'535 does not discuss a conductive medium for surface-mounted energy delivery devices. *Id.*, 8:12-33.

on the surface of its expandable member. *Id.*, 2:26-35. Stern further teaches circuitry for “selective delivery of...bipolar RF energy to chosen *pairs* [within the] array.” *Id.*, 2:36-40, 13:1-44. An example *bipolar electrode pair* is shown below:

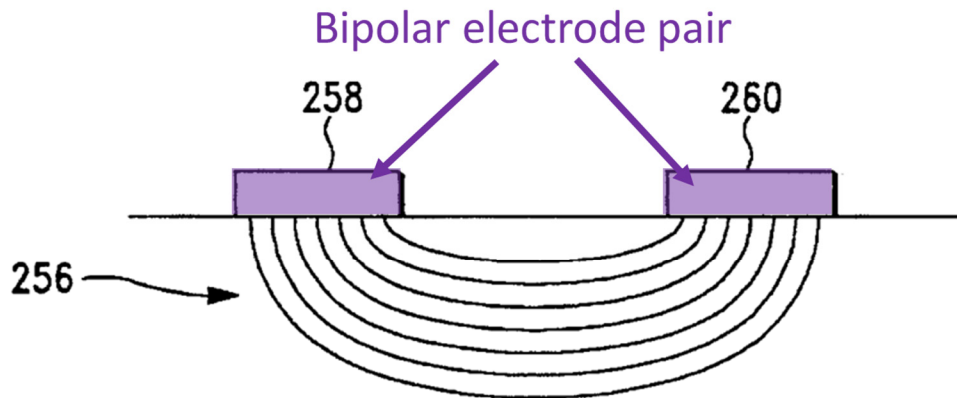


FIG. – 17

Ex.1033-Stern, FIG.17. Ex.1002-Decl., ¶92; Ex.1004-Decl., ¶70.

Stern’s Figure 15, annotated below, shows circuitry to operate bipolar pairs that includes four electrodes 220, 222, 224 and 226 and various switches 232-248 to pair electrodes in a bipolar configuration. Ex.1033-Stern, FIG.15. Electrodes can be paired by closing particular subsets of switches. *Id.*, 12:41-45. For example, “[i]f switch 248 and switch 238 are closed there will be bipolar operation between the electrodes 220 and 222.” *Id.*, 12:65-13:2.

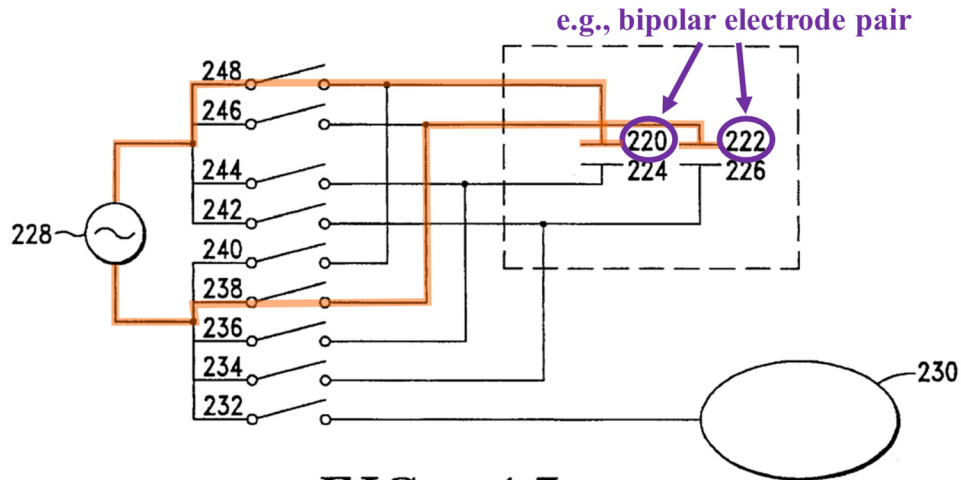


FIG. – 15

Ex.1033-Stern, FIG.15. Ex.1002-Decl., ¶92; Ex.1004-Decl., ¶71.

Stern also discloses various physical arrangements of electrodes on the surface of a bladder that can be used to implement the “device of the invention” (i.e., circuit of Figure 15). Stern’s Figures 15 and 19 illustrate electrodes arranged in *two rows*:¹¹

¹¹ Regardless of which two electrodes in Figures 15 or 19 are paired, Stern’s figures disclose *two rows of bipolar electrode pairs*. Ex.1004-Decl., ¶74.

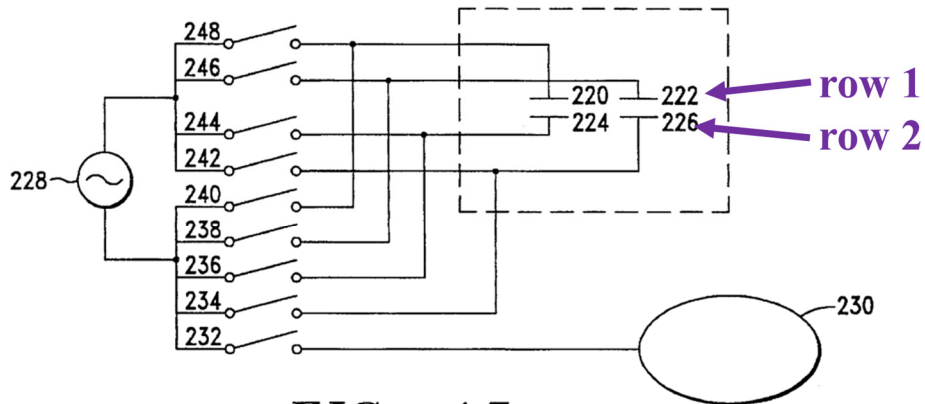


FIG. 15

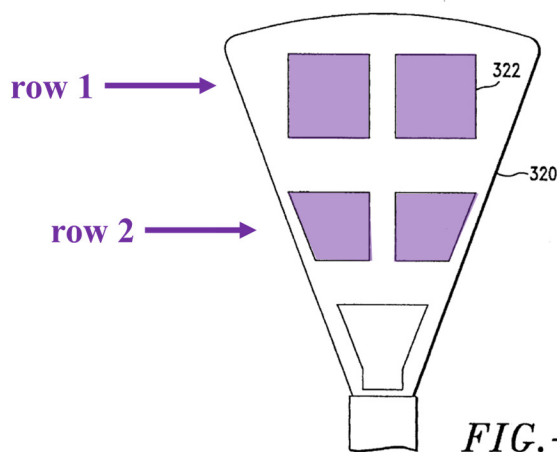


FIG. 19

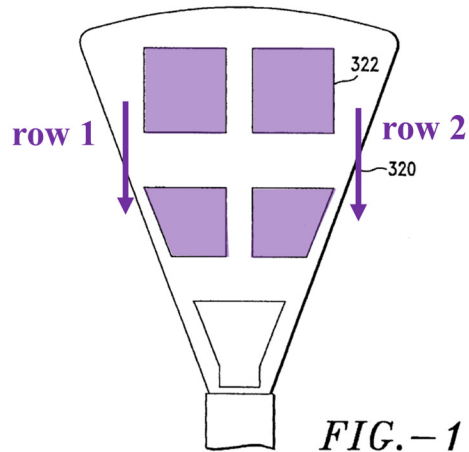


FIG. 19

Ex.1033-Stern, FIGs.15, 19, 14:26-28. Ex.1002-Decl., ¶¶92; Ex.1004-Decl., ¶¶72-74.

iii. Motivation to Combine Edwards-'535 and Stern

First, Edwards-'535 and Stern are analogous art to the Challenged Claims. Both are in the same field as the '271 patent and are reasonably pertinent to solving the problems addressed in the '271 patent—treating tissue in a body cavity—with the same types of solutions—applying RF energy to tissue. *See, e.g.,* Ex.1010-

Edwards-'535, Abstract, 5:43-51, 8:47-53, 10:25-31, 10:51-57; Ex.1033-Stern, Abstract, 1:15-23, 10:4-10, 10:40-65, 12:38-45. Ex.1002-Decl., ¶93.

Second, a POSITA would have been motivated to combine Edwards-'535 and Stern with a reasonable expectation of success. As explained throughout this Section, Edwards-'535 in view of Kong teaches a method of using RF energy to ablate and remove/damage tissue in the inferior turbinate. *See, e.g.*, §§X.A.1.a-f. Stern discloses implementation details for how an RF device like Edwards-'535's can be implemented, including devices with *two rows of bipolar electrode pairs*. A POSITA would have been motivated to combine these teachings—namely, by implementing Edwards-'535's **energy delivery device 134** with Stern's *two rows of bipolar RF electrode pairs* on the surface of the **expandable member 132**—with a reasonable expectation of success. Ex.1002-Decl., ¶94; Ex.1004-Decl., ¶¶75-76.

Edwards-'535 demonstrates that it was well known to provide RF ablation devices with multiple bipolar surface electrodes for ablation of various locations in the body. Although Edwards-'535 explains that “energy...may be independently delivered to each [electrode],” Ex.1010-Edwards-'535, 8:18-25, and delivering “bipolar or monopolar energy,” *id.*, 10:52-57, Edwards-'535 omits details on how to implement such energy delivery. Thus, Edwards-'535 is therefore ready for improvement, and a POSITA would have been motivated to turn to other sources for

information regarding how to specifically implement independent energy delivery through each bipolar electrode. A POSITA would have found Stern to be a good source for this information given its detailed disclosure and schematic Figures. Ex.1002-Decl., ¶91; Ex.1004-Decl., ¶¶76-78.

A POSITA would have also been motivated to improve Edwards-'535's device to include Stern's *two rows of bipolar electrode pairs* and would have looked to Stern for a teaching on how to implement bipolar pairs of electrodes for the reasons set forth below. Ex.1002-Decl., ¶94; Ex.1004-Decl., ¶79.

(a) *Bipolar Electrode Pairs*

Stern teaches that its *bipolar electrode pairs* provide a number of advantages and benefits. **First**, Stern explains that *bipolar electrode pairs* allow a physician to precisely control the location of electrical current delivered by the device. Ex.1033-Stern, 13:21-27, 12:26-37, FIGs.15, 18. This precise control would be particularly useful for Kong's technique, in which visualization during a nasal procedure is difficult and proper placement of the electrodes is paramount. Ex.1040-Kong, 215. Kong further emphasizes the importance of ensuring a "good conductive layer locally," *id.*, 215, which would have been addressed by Stern's local control of bipolar electrode pairs by specifically targeting the anterior, middle, and posterior

portion of the lower surface of the inferior turbinate—the three locations Kong teaches to ablate. *Id.*, 214. Ex.1002-Decl., ¶94; Ex.1004-Decl., ¶80.

Second, Stern describes that configuring electrodes in bipolar pairs allows heating of targeted tissue while ensuring that surrounding tissue is unaffected, especially where there is uneven (i.e., heterogeneous) tissue morphology. Ex.1033-Stern, 13:21-39, FIG.15. This would have been especially important when ablating the turbinate, as taught by Edwards-’535 and Kong. **Third**, Stern teaches how pairs of bipolar electrodes can ensure even heating. Ex.1033-Stern, 12:25-27. This would be particularly important for Edwards-’535 technique, which involves “maintaining tissue...at a desired temperature.” Ex.1010-Edwards-’535, 9:65-10:1. **Finally**, in view of the above, Stern teaches it would have been desirable to have more than one pair of bipolar electrodes to allow for selective tissue destruction over an entire area of tissue, as opposed to a single discrete portion. Ex.1033-Stern, 2:6-19 (discussing “entire surface” of tissue), 6:44-62, 10:49-65. Ex.1002-Decl., ¶94; Ex.1004-Decl., ¶¶81-83.

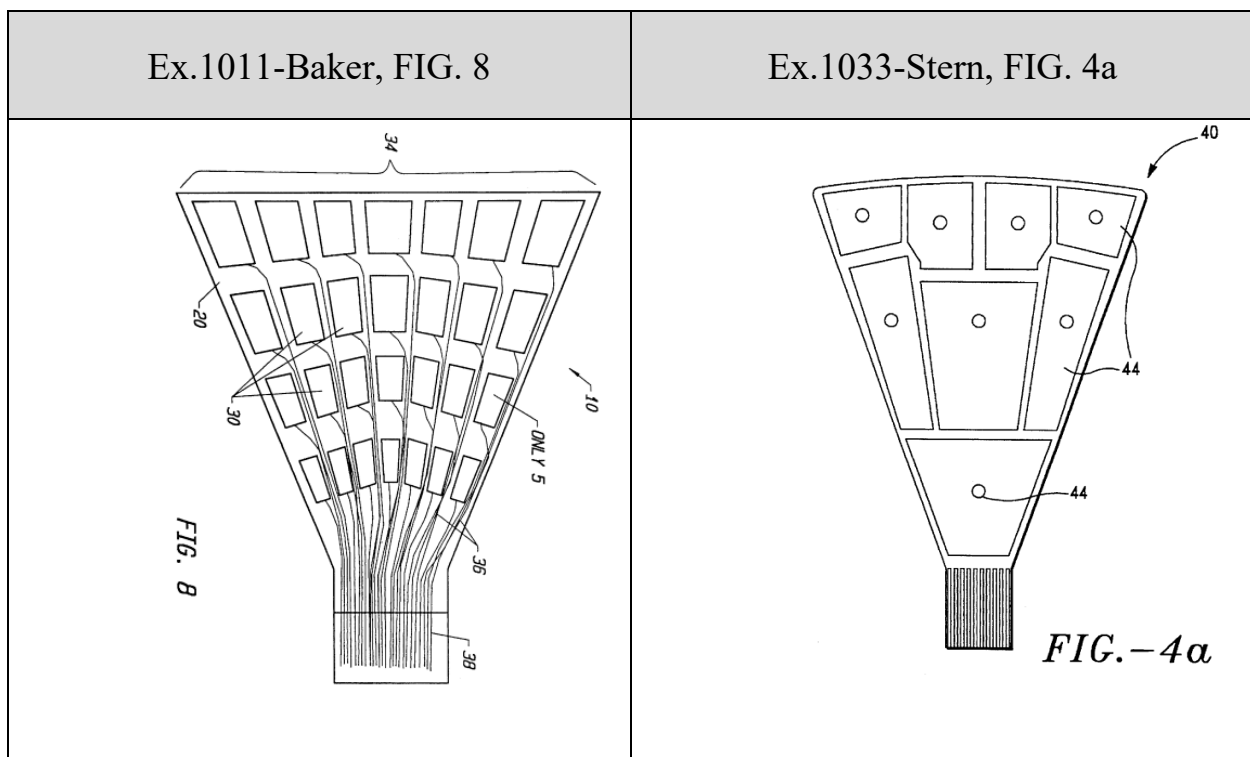
These benefits are teachings, suggestions, and motivations that would have led a POSITA to modify Edwards-’535 in view of Stern to realize these same results in Edwards-’535’s device with a reasonable expectation of success. Doing so would have simply involved using Stern’s known bipolar pairing technique to implement

the missing details of Edwards-'535 in the way that Stern teaches, which would have been particularly desirable in the nose for increased safety, control, and even heating. Moreover, using Stern's known bipolar pairing technique would have improved Edwards-'535's similar device in the same way as Stern's. Further, combining Edwards-'535 and Stern involves applying Stern's known bipolar pairing technique to Edwards-'535's known device that was ready for improvement (because Edwards-'535 omits electrode wiring details) to yield predictable results. A POSITA would have recognized that the above advantages of pairing and controlling electrodes would have predictably accomplished Edwards-'535's temperature maintenance requirement by allowing a physician to control the amount of RF energy applied by each respective electrode pair, and to heat the tissue evenly. *See* Ex.1010-Edwards-'535, FIGs.4A-4C, 6:66-7:17. Ex.1002-Decl., ¶94; Ex.1004-Decl., ¶¶84-85.

Edwards-'535 and Stern each describe similar techniques of delivering bipolar RF ablation energy with independently controllable electrodes through expandable devices to the mucosal tissue of different body cavities, such that their combination would have been straightforward and yielded predictable results. Ex.1010-Edwards-'535, 4:53-66, 5:21-23, 7:33-46, 7:61-8:46, 5:36-44, 6:9-22, 8:17-25, 9:1-44, 10:18-

32; Ex.1033-Stern, 1:16-43, 7:38-8:38, 10:48-65. Ex.1002-Decl., ¶¶94; Ex.1004-Decl., ¶¶86-88.

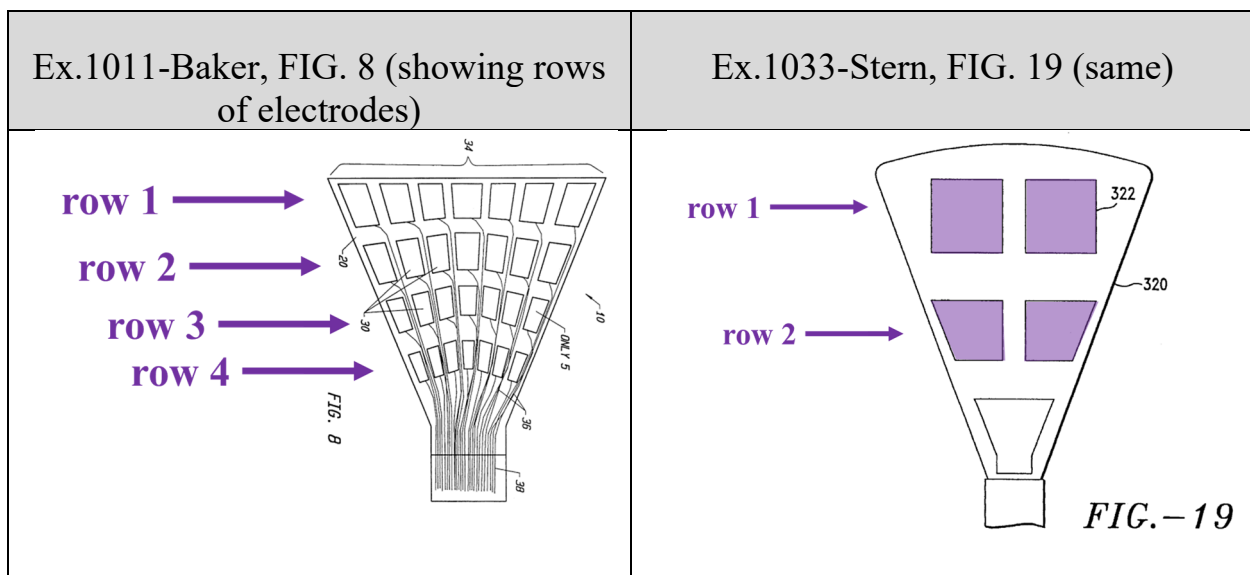
Furthermore, Edwards-'535's silence regarding the circuitry to independently control bipolar electrodes demonstrates that implementing Stern's bipolar electrode pairing technique would have been within a POSITA's skill and that a POSITA would have expected doing so to be successful. Additionally, a POSITA would have had reasonable expectation of success in incorporating teachings from Stern at least because Edwards-'535 points a POSITA to references that have similar attributes as Stern. Ex.1010-Edwards-'535, 8:25-33 (incorporating USP 5,575,788 to Baker), Baker and Stern depict similar devices for ablating tissue:



Compare Ex.1011-Baker, Abstract, 5:60-67, 9:13-23, FIGs.8,9, *with* Ex.1033-Stern, 2:26-35. A POSITA would have therefore known that technology from ablation devices for one part of the body would be applicable to others. *See, e.g.,* Ex.1033-Stern, 18:27-40. Ex.1002-Decl., ¶¶94; Ex.1004-Decl., ¶¶89-93.

(b) Two Rows

A POSITA also would have been motivated to implement Edwards-'535's electrodes as **two rows** of bipolar electrodes as disclosed by Stern. Edwards-'535 instructs a POSITA to look to Baker for how to dispose electrodes on the surface of a membrane, Ex.1010-Edwards-'535, 8:26-33, and Baker, like Stern, also discloses electrodes in rows. *Compare* Ex.1011-Baker, FIG.8 *with* Ex.1033-Stern, FIG.19:



A POSITA would have recognized that arranging electrodes in rows, as opposed to a more disorganized pattern or a single row, facilitates simple spatial resolution of

the applied energy. As discussed above, Kong teaches that proper placement of the electrodes is paramount, and thus control of electrode pairs in rows enables targeting particular portions of tissue (e.g., the anterior, middle, and posterior of the inferior turbinate). This electrode layout would have been an obvious arrangement or rearrangement of parts. *In re Kuhle*, 526 F.2d 553, 554-555 (C.C.P.A. 1975). Edwards-'535 already discloses one row of electrodes, *see, e.g.*, Ex.1010-Edwards-'535, FIG.6, and thus adding another row of electrodes would have involved an obvious duplication of parts. *See, e.g., In re Harza*, 274 F.2d 669 (C.C.P.A. 1960). Ex.1002-Decl., ¶94; Ex.1004-Decl., ¶¶94-95.

A POSITA would have had a reasonable expectation of success in implementing *two rows of bipolar RF electrodes* on the surface of Edwards-'535's **expandable member 132**. By acknowledging the need for selective delivery of energy to tissue, Ex.1010-Edwards-'535, 6:10-51, 7:38-50,8:17-32, and giving a POSITA discretion on how to implement that scheme, Edwards-'535 demonstrates that arranging electrodes into two rows of bipolar pairs would have been well within the level of ordinary skill. *Id.*, 6:10-51, 7:38-50. Ex.1002-Decl., ¶94; Ex.1004-Decl., ¶96.

Using Stern's two rows of electrode pairs on Edwards-'535's **expandable member 132** would have merely involved combining known prior art elements

(Edwards-'535's apparatus 124 with Stern's electrodes and control scheme) according to known methods (e.g., Stern's and Edwards-'535's selective control techniques) to yield predictable results (fine-tuned energy delivery and control). Likewise, it would have involved simply substituting one known element (Edwards-'535's energy delivery device 134 on the surface of expandable member 132) for another (Stern's two rows of paired bipolar electrodes and control scheme) to obtain predictable results (finer control of energy delivery and temperature control). It also would have involved using a known technique (Stern's individual bipolar electrode control and arrangement) to improve similar devices in the same way (providing finer granularity for energy/temperature control). Finally, it would have involved applying a known technique (Stern's control and electrode arrangements) to a known device (Edwards-'535's apparatus 124) ready for improvement (i.e., that leaves electrode arrangement/control details to a POSITA) to yield predictable results (finer granularity for temperature control/maintenance). Ex.1002-Decl., ¶94; Ex.1004-Decl., ¶97.

c. 1[b]:

Edwards-'535 in view of Kong and Stern discloses *applying RF energy with the bipolar electrode pairs* (e.g., energy delivery device 134 / chosen pairs of bipolar electrodes) *through the nasal mucosa* (e.g., surface of the nasal concha / mucosa of

turbinates) *to a target tissue underlying the nasal mucosa* (e.g., interior section of the nasal concha / parasympathetic nerves and/or submucosa) *for an amount of time* (e.g., selected period of time / 10 seconds / time sufficient to destroy the cells) *to heat the target tissue*. Ex.1002-Decl., ¶¶95-99.

As discussed above for limitations 1[pre] and 1[a], Edwards-'535, Kong, and Stern each disclose applying *RF energy through* the surface of the **nasal concha**—which a POSITA would understand to include *mucosal tissue*—to an interior portion of the concha (i.e., *target tissue underlying the nasal mucosa*). See, e.g., Ex.1010-Edwards-'535, 4:53-67, 5:27-35, 6:9-7:17, 11:23-44, FIGs.4A-4C. Similarly, Kong discloses applying RF energy through holes in the “anterior, middle, and posterior part[s]” of the “lower or medial edge of the inferior turbinate” (i.e., *through the nasal mucosa*) to destroy “submucosal tissues” (i.e., *target tissue underlying the nasal mucosa*). Ex.1040-Kong, 214-15. It would have been obvious to combine Edwards-'535 with Kong with a reasonable expectation of success for the reasons above. See *supra*, §X.A.1.a.i. Ex.1002-Decl., ¶¶96-97.

Edwards-'535 and Stern each apply RF energy *for an amount of time to heat the target tissue*. Ex.1010-Edwards-'535, 9:65-10:3 (disclosing “feedback control system” that “maintain[s] tissue adjacent to an energy delivery device at a desired temperature for a selected period of time.”); Ex.1033-Stern, 6:66-7:3 (passing RF

energy through tissue “for a time sufficient to destroy the...cells by elevating the temperature of the endometrium^[12] to between 45° C. and 90° C. and preferably within 10 seconds.”), 1:25-61, 2:6-19, 7:21-34, Abstract, 2:41-49, 3:13-37, 7:3-7, 10:54-11:7, 12:25-36, 13:21-38, 1:25-61. Ex.1002-Decl., ¶¶98-99.

d. 1[c]:

Edwards-’535 in view of Kong discloses *removing the treatment element* (e.g., **expandable member 132** having **energy delivery device 134**) *from the nasal airway*. Ex.1002-Decl., ¶¶100-102.

In contrast to Edwards-’535’s Figure 4A, which illustrates distal portion 128 in the nasal airway during ablation, Figures 4B and 4C illustrate distal portion 128 *removed from the patient’s nasal airway* after ablation. Ex.1010-Edwards-’535, 6:66-7:25.

¹² The endometrium, like the nasal turbinates, comprises mucosal tissue. Ex.1002-Decl., ¶¶99, 60.

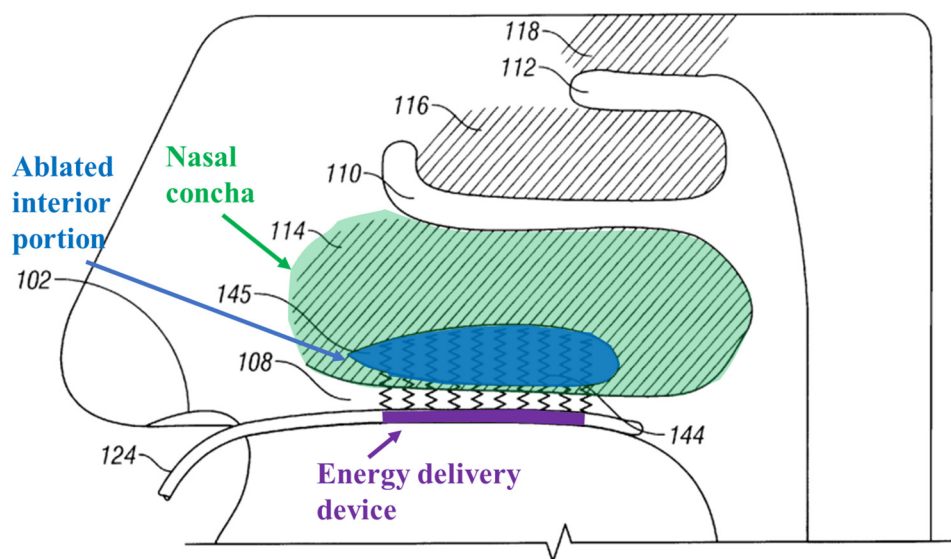


FIG. 4A

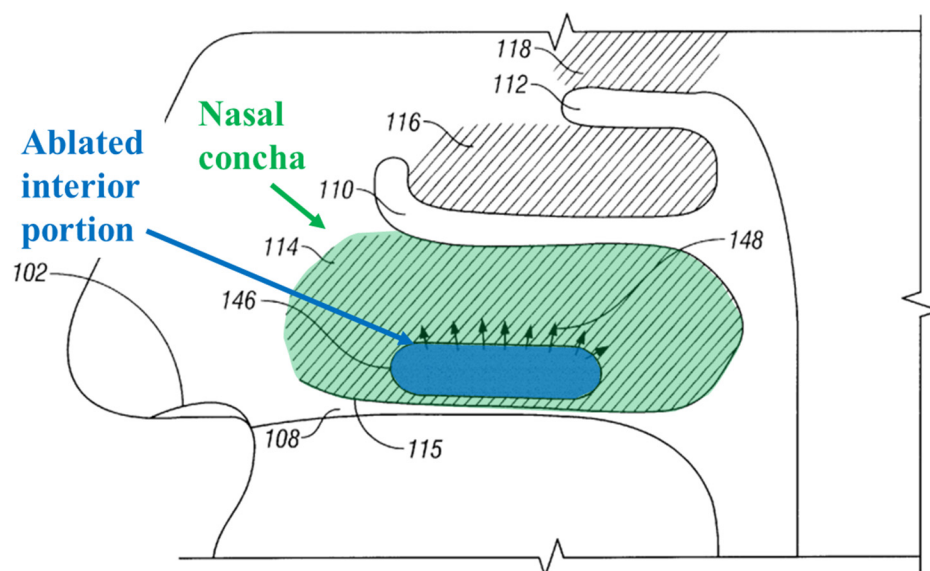


FIG. 4B

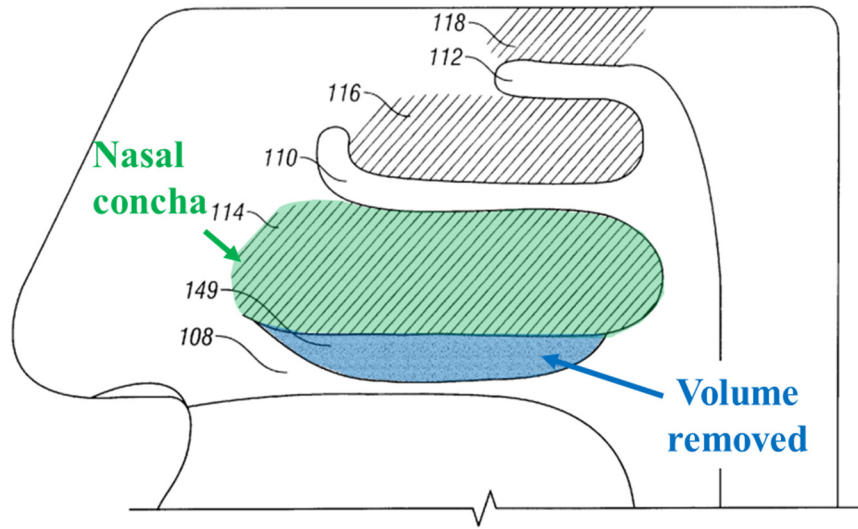


FIG. 4C

Ex.1010-Edwards-'535, FIGs.4A-4C. Ex.1002-Decl., ¶101.

Similarly, Kong discloses that “the electrode was slowly removed” after applying energy and deactivating the electrode. Ex.1040-Kong, 214. It would have been obvious to combine Edwards-'535 with Kong with a reasonable expectation of success in doing so for the reasons above. *See supra*, §X.A.1.a.i. Ex.1002-Decl., ¶102.

e. 1[d]:

Edwards-'535 in view of Kong discloses that *heating the target tissue with the applied RF energy modifies at least one property* (e.g., reducing or removing via ablation / disintegration) *of the target tissue*. Ex.1002-Decl., ¶¶103-105.

As discussed for limitation 1[b], Edwards-'535 teaches that RF energy ablates the tissue via heating to reduce and/or remove an interior section of the nasal concha. Ex.1010-Edwards-'535, 1:20-26, 3:18-36 (describing “ablative heating”), 4:19-32, 4:53-67, 5:9-15, 5:36-45, 6:59-7:25, 8:46-53, Abstract, FIGs.4A-4C, Clm.1. Ex.1002-Decl., ¶104.

Likewise, Kong teaches that RF energy application causes numerous modifications, including coagulating, denaturing, or otherwise destroying mucosal and submucosal tissue, including nerve fibers. Ex.1040-Kong, 214-215. It would have been obvious to combine Edwards-'535 with Kong with a reasonable expectation of success for the reasons above. *See supra*, §X.A.1.a.i. Furthermore, a POSITA would have understood that applying ablative RF energy as disclosed in Edwards-'535 using the method disclosed in Kong would produce a similar effect as disclosed in Edwards-'535—destroying submucosal tissue such as nerves. *See, e.g.*, Ex.1010-Edwards-'535, 8:46-53. Ex.1002-Decl., ¶105.

f. 1[e]:

Edwards-'535 in view of Kong discloses that *the modified at least one property of the target tissue* (e.g., interior section of the nasal concha / parasympathetic nerves under the mucosa) *causes a reduction in mucus production*

(e.g., reducing gland secretion and/or reducing nasal mucus) *in the nasal airway*.

Ex.1002-Decl., ¶¶106-108.

Kong discloses that “damaging” various parasympathetic and sensory nerves (e.g., in the inferior turbinate) “*reduc[es] gland secretion.*” Ex.1040-Kong, 215; *see also id.*, 214-215 (“removing some parasympathetic nerve fibers... *reduc[es] the glandular secretion,...reduc[es] nasal mucus,...[and] treat[s] perennial allergic rhinitis.*”). A POSITA would have understood that a reduction in “gland[ular] secretion” refers to mucus production, and that by ablating the parasympathetic nerves in the turbinate, mucus production would be reduced *in the nasal airway*. It would have been obvious to combine Edwards-’535 with Kong with a reasonable expectation of success for the reasons above. *See supra*, §X.A.1.a.i. Ex.1002-Decl., ¶107.

* * *

Accordingly, a POSITA would have found it obvious to use a device like that taught in Edwards-’535, as modified by Stern’s teachings, to treat rhinitis and reduce mucus secretions as taught by Kong by contacting the lower surface of the inferior turbinate with the electrode pairs on the **expandable member 132**, applying RF energy with the electrode pairs to heat and damage underlying tissue (including

parasympathetic nerves), and removing the device. Ex.1002-Decl., ¶¶68-108; Ex.1004-Decl., ¶¶66-97.

2. Claim 2

Edwards-'535 in view of Kong discloses that *the target tissue is selected from the group consisting of mucosa* (e.g., surface 115 of the nasal concha 114 / mucosa of turbinates), *submucosa* (e.g., interior portion of a nasal concha / submucosa of turbinates), *cartilage, muscle, ligament, and tendon*. Ex.1002-Decl., ¶¶109-110.

As discussed above for limitation 1[b], Edwards-'535 discloses applying energy *through* the surface of the **nasal concha** to an interior portion thereof, which includes submucosal tissue or *submucosa*. *See, e.g.*, Ex.1010-Edwards-'535, 4:53-67, 5:27-35, 6:9-7:17, 11:23-44, FIGs.4A-4C (applying energy through turbinate surface). Edwards-'535 also discloses that the energy can be applied to the surface of the nasal concha, which includes *mucosa*. *See, e.g., id.*, 2:63-3:6, FIGs.3B-3D. Ex.1002-Decl., ¶109.

As similarly discussed for limitation 1[b], Kong discloses applying RF energy through holes in the “lower or medial edge of the inferior turbinate” to destroy “submucosal tissues” (i.e., *submucosa*). Ex.1040-Kong, 214-215. Kong also discloses applied RF energy that coagulates and denatures the nasal *mucosa*. Ex.1040-Kong, 215. Ex.1002-Decl., ¶109.

It would have been obvious to direct the RF energy of Edwards-'535 to the submucosal tissues and/or nasal mucosa, as taught by Kong with a reasonable expectation of success for at least the reasons discussed for limitation 1[pre]. Ex.1002-Decl., ¶¶109-110.

3. Claim 3

Edwards-'535 discloses *controlling at least one characteristic of the applied RF energy* (e.g., amount of energy output, duty cycle, wattage, and/or use of monopolar and/or bipolar energy) *with a control system* (e.g., feedback control system *coupled with the nasal airway treatment device*). Ex.1002-Decl., ¶¶111-114.

Edwards-'535 discloses a “feedback *control system*” that uses temperature and/or impedance sensor “feedback” to “control[] the operation of an [RF] energy source which delivers energy to the **energy delivery device**.” Ex.1010-Edwards-'535, 9:65-10:3, 9:14-9:64, 10:4-11:22, 11:23-44, 8:54-9:13, FIGs.5-6, 8-10. For example, depending on the measured impedance of the target tissue, “the delivery of RF energy can be reduced, modified or interrupted” (i.e., *controlling at least one characteristic of the applied RF energy*). *Id.*, 11:12-22, 9:1-64 (adjusting an “amount of energy being delivered”), 10:46-51, FIGs.8, 10. Similarly, feedback can be used to “change[] (i) the selected energy (ii) the duty cycle (on-off and wattage) [of the applied energy], [and] (iii) bipolar or monopolar energy delivery....” *Id.*,

10:52-61. For example, output from a temperature sensor can be used to “control the delivery of RF energy...to achieve a selected temperature.” *Id.*, 9:24-44. Ex.1002-Decl., ¶112-114.

4. Claim 6

Edwards-’535 discloses *displaying one or more parameters of treatment on a console* (e.g., user interface and display 196) *attached to the nasal airway treatment device while the RF energy is applied, the one or more parameters selected from the group consisting of treatment time, power level* (e.g., calculated energy values), *temperature sensed by the treatment element* (e.g., temperatures), *electric impedance* (e.g., calculated impedance values), *electric current, and depth of treatment*. Ex.1002-Decl., ¶¶115-119.

For example, Edwards-’535 discloses a user interface display 196 that receives and displays various values from (or calculated from) sensors included on the apparatus 124, including calculated energy values (i.e., *power level*), calculated *impedance* values, and *temperature*. Ex.1010-Edwards-’535, 10:4-11, 10:18-22, 10:32-45, 11:12-22, 9:14-53, FIGs.8-9. The energy, impedance, and temperature are displayed while adjusting control signals and monitoring for limits, and therefore occurs *while the RF energy is applied*. *Id.*

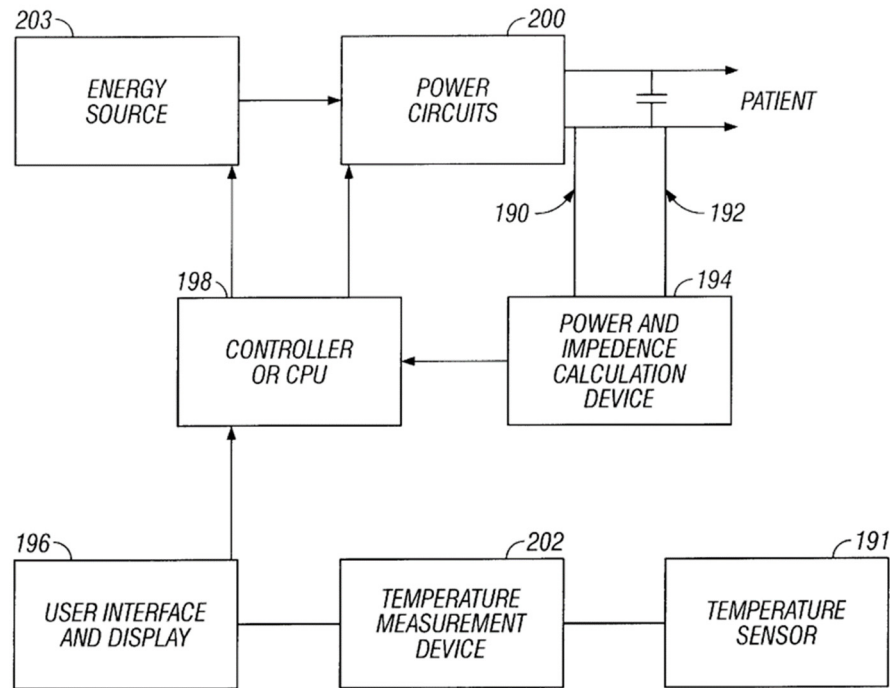


FIG. 8

Ex.1010-Edwards-'535, FIG.8. Ex.1002-Decl., ¶¶116-117

Edwards-'535's user interface and display 196 is attached to the treatment device, e.g., it is coupled to a RF generator (e.g., energy source 203) that provides energy to the treatment device. For example, Edwards-'535 discloses that the user interface and display 196 receives energy, impedance, and temperature information from the apparatus 124 and also provides the temperature to a controller or CPU 198, which in turn directs the energy source 203 to provide RF energy to the electrodes 191. Ex.1010-Edwards-'535, FIGs.8-9, 10:4-31, 10:45-11:3, 11:12-22, 11:23-26. Ex.1002-Decl., ¶¶118-119.

5. Claim 7

Kong discloses *applying local anesthesia to at least one of the nasal mucosa or the target tissue before applying the RF energy*. Ex.1040-Kong, 214 (applying “[s]urface anesthesia” using a “spray in the nasal cavity” (i.e., on the *nasal mucosa*) and “infiltration anesthesia” “under the bilateral inferior turbinate mucosa (i.e., the *target tissue*)), Abstract, 215. Ex.1002-Decl., ¶¶120-122.

A POSITA would have found it obvious to use anesthesia before applying RF energy as taught by Kong to reduce the patient’s discomfort during the procedure. A POSITA would have had a reasonable expectation of success because anesthesia had been used for more than a century, including for several procedures in the nose. *See, e.g.*, Ex.1041-Snow, xi-xii, 153, 190; Ex.1055-Fang, 876 (applying anesthesia before RF energy in the nose); Ex.1017-Chen, 240 (same); Ex.1056-Liang, 341 (same). Further, as discussed for claim 1, Edwards-’535 and Kong disclose applying RF radiation to the same location (surface and interior of the turbinates), and therefore a POSITA would have expected the anesthesia to improve the method of Edwards-’535 in a similar way. Ex.1002-Decl., ¶¶121-122.

6. Claim 8

Edwards-’535 discloses that *the RF energy is produced by a RF energy source* (e.g., energy source 203 / generator 38) *configured to run between 1 Watt and 100*

Watts (e.g., between 5-30 watts). Ex.1002-Decl., ¶¶123-125; Ex.1004-Decl., ¶¶98-100.

As discussed above for limitations 1[pre] and 1[b], and claim 6, Edwards-'535 discloses applying RF energy with an energy source 203. Edwards-'535 further teaches that the generated “pulses of RF energy...provide between about 5 and about 30 watts of RF energy to at least a portion of the turbinate.” Ex.1010-Edwards-'535, 9:1-11, 5:48-51, 10:52-58. Ex.1002-Decl., ¶¶124-125; Ex.1004-Decl., ¶¶98-100.

7. Claim 9

Edwards-'535 in view of Stern discloses *applying the RF energy comprises heating the target tissue to a temperature between 50 degrees Celsius to 70 degrees Celsius* (e.g., above 40°C / between 55° C to 65° C). Ex.1002-Decl., ¶¶126-128; Ex.1004-Decl., ¶¶101-112.

Edwards-'535 discloses using RF energy for “*heating* at least a portion of the nasal concha being treated to a temperature above about 40° C,” but does not expressly state how much above 40° C. Ex.1010-Edwards-'535, 5:35-44. Ex.1002-Decl., ¶126; Ex.1004-Decl., ¶103.

Stern teaches that mucosal tissue destruction can be “optimally accomplished by a temperature between by heating tissue between 55° C. to 65° C,” which is *between 50 degrees Celsius to 70 degrees Celsius*. Ex.1033, 6:63-7:6; *see Titanium*

Metals Corp. v. Banner, 778 F.2d 775, 782 (Fed. Cir. 1985). Ex.1002-Decl., ¶126; Ex.1004-Decl., ¶104.

A POSITA would have found it obvious to heat Edwards-'535's interior section of tissue to a temperature of between 55° C to 65° C as taught by Stern. 55° C to 65° C is above 40°C, as taught by Edwards-'535, and Stern expressly discloses that such temperatures can be used to destroy tissue, as is required by the combination of Edwards-'535 and Kong to reduce symptoms of rhinitis. *See supra*, §§X.A.1.a-b, e-f (discussing using Edwards-'535 apparatus to ablate nerve tissue to reduce mucus). Further, the claimed temperature range was a well-known temperature range that could ablate tissue. Ex.1002-Decl., ¶¶126-128; Ex.1004-Decl., ¶¶105-111.

The '271 patent does not disclose anything critical about heating tissue to *between 50 degrees Celsius to 70 degrees Celsius*—it is just one “example” from a broader range. Ex.1001-USP271, 43:19-30. Thus, selecting a tissue temperature for ablation would have involved mere routine optimization. *See generally E.I. du Pont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996 (Fed. Cir. 2018). Ex.1002-Decl., ¶112.

8. Claim 10

Edwards-’535 in view of Stern renders obvious that *the amount of time the RF energy is applied to the target tissue is between fifteen seconds and one minute*. Ex.1002-Decl., ¶¶129-131; Ex.1004-Decl., ¶¶113-117.

Edwards-’535 teaches heating tissue to a “desired temperature for a selected period of time without impeding out,” but leaves selection of that time up to the discretion of a POSITA. Ex.1010-Edwards-’535, 9:65-10:3. As Edwards-’535 recognizes, treatment time is a well-known parameter that can be varied to obtain a desired result, such as tissue temperature. *Id.* (discussing, without specifying, a “selected period of time”). Several references that demonstrate the knowledge generally available to a POSITA teach applying RF energy to target tissue for a range of 3 seconds to 10 minutes. *See, e.g.,* Ex.1058-Wong, [0053] (requiring 3-30 seconds of bipolar RF energy application to denature protein, which is representative of tissue);¹³ Ex.1033-Stern, 6:63-7:6 (applying RF electric current to heat tissue surface for 10 seconds to 10 minutes); Ex.1016-Edwards-’886, FIG.79 (showing

¹³ During prosecution of the parent to the ’271 patent, the Examiner found Wong renders obvious applying RF energy for “about 15 seconds,” which PO did not contest. Ex.1057-USP489FH, 63, 43-55.

tissue temperature stabilizing at times between 15 seconds to 1 minute). A POSITA would have therefore known that energy application in the *fifteen second to one minute* time range were not only contained within the prior art's disclosed ranges (e.g., Stern's 10 seconds to 10 minutes or Wong's 3-30 seconds), but also would have been obvious based on the knowledge in the prior art and in light of the routine experimentation routinely engaged in by a POSITA.¹⁴ *See In re Peterson*, 315 F.3d 1325, 1329-1330 (Fed. Cir. 2003) (“[s]electing a narrow range from within a somewhat broader range disclosed in a prior art reference” is obvious). Ex.1002-Decl., ¶¶130-131; Ex.1004-Decl., ¶¶115-117.

9. Claim 11

a. 11[a]:

Edwards-'535 in view of Kong discloses *before removing the treatment element from the nasal airway*. *See infra*, §§X.A.9.b-c. Ex.1002-Decl., ¶¶132-136.

¹⁴ The '271 patent does not disclose any criticality to the 15 seconds to 1 minute range, and even suggests a longer period. Ex.1001-USP271, 20:63-21:4, 43:31-48. Ex.1004-Decl., ¶¶119.

b. 11[b]:

Edwards-'535 in view of Kong discloses *repositioning the treatment element to contact a different portion of nasal mucosa* (e.g., anterior, middle, or posterior part of the turbinate) *before removing the treatment element from the nasal airway*. Ex.1002-Decl., ¶¶132-136.

As discussed for limitations 1[pre]-1[c], Edwards-'535 discloses contacting the lower surface of the **nasal concha** (i.e., *nasal mucosa*), applying energy to an interior portion thereof, and then removing the apparatus. As shown in FIGs.3B and 3D below, Edwards-'535 discloses that its device contacts various parts along the lower surface of the **nasal concha** to apply RF energy, including an anterior or middle portion:

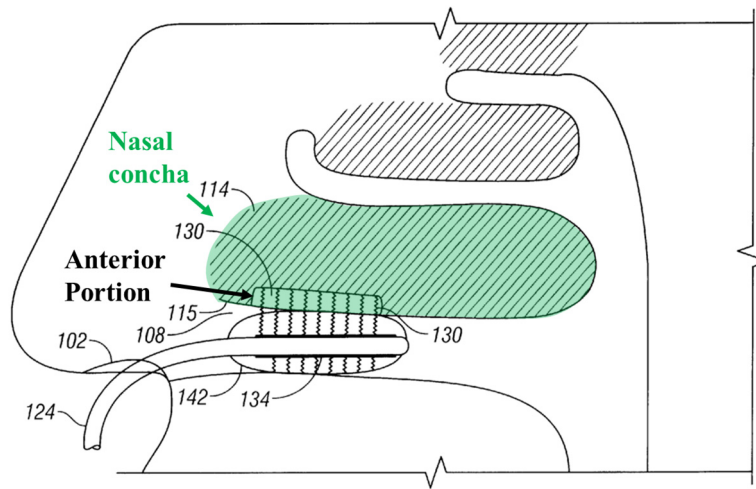


FIG. 3D

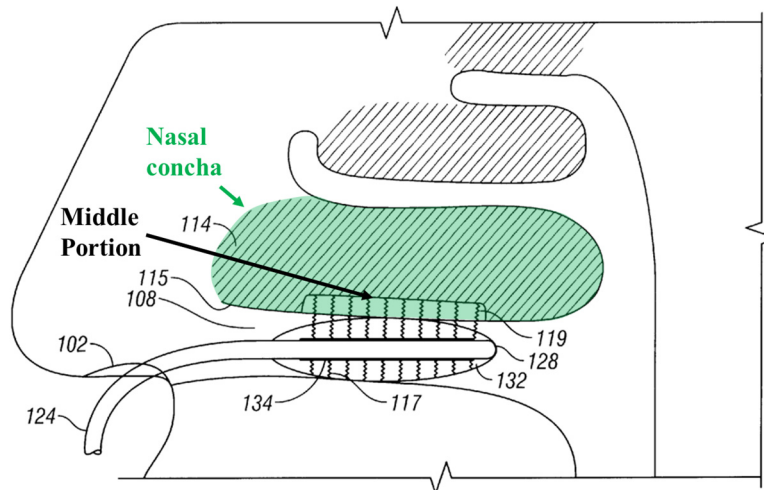


FIG. 3B

Ex.1010-Edwards-'535, FIGs.3D, 3B. Ex.1002-Decl., ¶¶133-134.

Kong similarly discloses delivering RF energy to locations “at the lower...edge of the inferior turbinate” *before* the “electrode [is] slowly *removed*,” including to the “the anterior, middle, and posterior part.” Ex.1040-Kong, 214. Ex.1002-Decl., ¶135.

Therefore, when using the apparatus of Edwards-'535 to ablate nerve tissue in the turbinates as taught by Kong, a POSITA would have found it obvious to move the [expandable member 132](#) to different locations (e.g., the anterior, middle, and posterior part of the turbinate) *before removing* the device with a reasonable expectation of success for at least the same reasons as discussed in for claim 1. A POSITA would have also reasonably expected success at least because Kong had already demonstrated treatment of rhinitis by ablating three parts of the turbinate using one submucosal RF ablation device, and a POSITA would have expected submucosal ablation from the Edwards-'535's device to have a similar effect. Ex.1002-Decl., ¶136.

c. 11[c]:

Edwards-'535 in view of Kong discloses *applying RF energy with the bipolar electrode pairs through the different portion of nasal mucosa to a different portion of target tissue* (e.g., the anterior, middle, or posterior part) *for the amount of time to heat the different portion of target tissue before removing the treatment element from the nasal airway.* Ex.1002-Decl., ¶¶137-139.

As discussed for limitations 11[a] and 11[b] above, Edwards-'535 in view of Kong disclose positioning Edwards-'535's [expandable member 132](#) to different locations (e.g., the anterior, middle, and posterior part of the turbinate) to apply RF

energy to each location. Accordingly, it would have been obvious to *apply* RF energy to each of these portions to *heat* each portion, as discussed above for limitation 1[b], before removing the device as discussed above for limitation 1[c]. Since the additional locations are all on the mucosa of the turbinate, which would have similar thermal and electrical properties, a POSITA would have been motivated to apply energy for the same amount of time so as to heat the tissue to the same temperature. A POSITA would have been motivated to do so with a reasonable expectation of success for at least the same reasons as those discussed in Sections X.A.1.a.i and X.A.9.a-b. Ex.1002-Decl., ¶¶138-139.

10. Claim 12

Edwards-'535 and Kong discloses that *the modified at least one property of the target tissue is selected from the group consisting of shrinking (e.g., reducing/removing), tightening, stiffening, and deactivating (e.g., damaging nerves) the target tissue.* Ex.1002-Decl., ¶¶140-142.

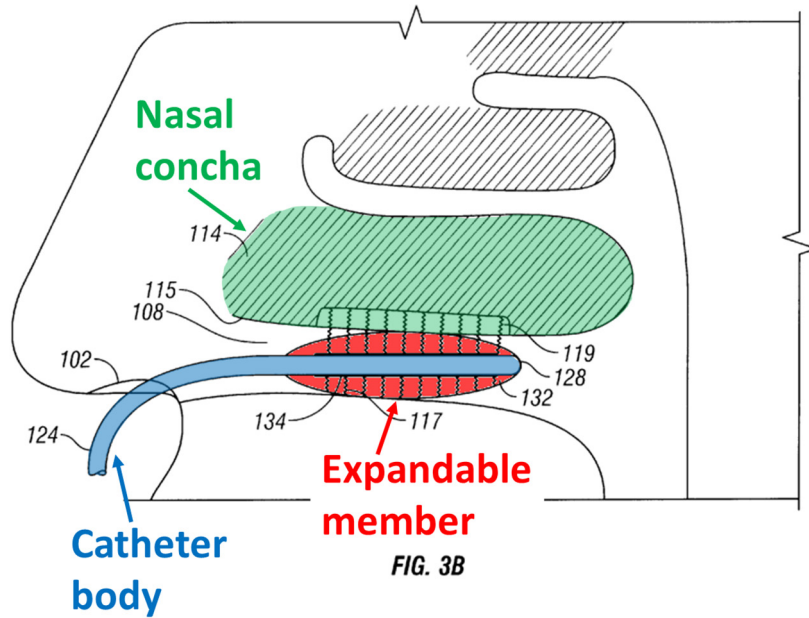
As discussed for limitations 1[pre], 1[d], and 1[e], Edwards-'535 discloses applying RF energy to reduce (i.e., *shrink* and destroy) the size of the nasal concha. Furthermore, as discussed for limitations 1[pre], 1[a], 1[d], and 1[e], Kong teaches applying RF energy to parasympathetic nerves and/or submucosa on the lower surface of the inferior turbinate, and that the application of energy “damage[es] the

cholinergic microganglia and parasympathetic nerve fibers from the inferior turbinate, the unmyelinated sensory nerve fibers (SP energy nerves) and parasympathetic nerve endings from the pterygoid and anterior ethmoidal nerves in the nose.” Ex.1040-Kong, 215. A POSITA would have understood that damaging parasympathetic nerves would *deactivate* the nerves. Using Edwards-’535’s submucosal ablative heating would have the same destructive, and therefore *deactivating* effect on nerves. It would have been obvious to combine Edwards-’535 with Kong with a reasonable expectation of success for the reasons above. *See supra*, §X.A.1.a.i. Ex.1002-Decl., ¶¶141-142.

11. Claim 16

Edwards-’535 discloses or renders obvious *bending a shaft* (e.g., shaft surrounding lumen 135) *of the nasal airway treatment device before contacting the treatment element with the nasal mucosa*. Ex.1002-Decl., ¶¶143-148.

As shown in Figure 3B, reproduced below, Edwards-’535 depicts an apparatus 124 (i.e., *treatment device*) with a bent catheter body (i.e., *shaft*) inserted into a patient’s nostril.



Ex.1010-Edwards-'535, FIG.3B; *see also id.*, 2:63-3:6. Ex.1002-Decl., ¶144.

However, to the extent PO argues that claim 16 requires, and Edwards-'535 does not teach, a particular mechanism for forming the bend shown in Figure 3B, a POSITA would have found it obvious to implement Edwards-'535 teachings using any number of well-known mechanisms for forming bends in catheter shafts. For example, bendable catheter shafts that facilitate inserting a device into a patient's nose were commonplace by 2011 such that they would have been background knowledge to a POSITA. Therefore, applying a POSITA's background knowledge of bendable catheter shafts to Edwards-'535 would have amounted merely to using a known technique (i.e., one or more techniques for forming a bend in a catheter

shaft) to improve a similar device (Edwards-'535's apparatus 124, which includes a bent catheter shaft) in the same way. Ex.1002-Decl., ¶¶145-146.

Edwards-'535's omission of detailed disclosure about its catheter confirms that these features would have been considered routine and well-known. Moreover, given that Edwards-'535 does not teach a particular mechanism for forming the bend in the catheter shaft (e.g., Edwards-'535 does not identify the material the catheter is made of), a POSITA would have recognized that Edwards-'535 is ready for the improvements provided by known techniques for forming a bend in the catheter shaft. Selecting among these known techniques would have been a matter of routine implementation and yielded predictable results (i.e., the ability to form a bend in the catheter shaft). Moreover, by using these techniques, a POSITA would have had a reasonable expectation of success in achieving the goals of forming a bend in a catheter shaft, such as more accurate placement of the distal end of Edwards-'535's catheter shaft and/or the ability to contact surfaces (e.g., portions of the inferior turbinate) that would otherwise be obstructed. *See also* Ex.1003-USP271FH, 49 (examiner of the '271 patent stating that "it would have obvious to bend a shaft of the treatment device...to position the device for interfacing the treatment device with the nasal mucosa"). Ex.1002-Decl., ¶¶147-148.

B. Ground II: Claim 4 Is Invalid as Obvious Over Edwards-'535 in View of Kong and Stern in Further View of Edwards-'886

1. Claim 4

Edwards-'535 in view of Edwards-'886 discloses that *the RF energy is applied in the form of a 460 KHz sinusoid wave*. Ex.1002-Decl., ¶¶149-152; Ex.1004-Decl., ¶¶120-131.

As discussed above for limitations 1[pre] and 1[b], Edwards-'535 discloses applying RF energy. Ex.1002-Decl., ¶149; Ex.1004-Decl., ¶¶121-122.

Edwards-'886 discloses applying a *460 KHz sinusoid wave* with a RF device. Ex.1016-Edwards-'886, 36:66-37:2 (supplying RF energy “with a sinusoidal waveform at 460 kHz”), 39:35-55, 39:56-40:3, FIGs.77, 2. Ex.1002-Decl., ¶149; Ex.1004-Decl., ¶¶123.

It would have been obvious to apply RF energy with the modified device of Edwards-'535 using a sinusoidal waveform at 460 kHz as taught by Edwards-'886.¹⁵ Like Edwards-535, Kong, and Stern, Edwards-'886 is directed to treating tissue in a

¹⁵ *Intel Corp. v. Xmtt, Inc.*, IPR2020-00145, Paper 37, 20 (P.T.A.B. May 11, 2021) (number of references in an obviousness combination, “without more, does not demonstrate nonobviousness”) (citations omitted); *In re Gorman*, 933 F.2d 982, 986 (Fed. Cir. 1991).

body cavity and does so by applying RF energy to the tissue, Ex.1016-Edwards-'886, Abstract, 10:58-11:15, 11:42-48, 36:66-37:10, and is therefore analogous art to the '271 patent. Furthermore, a POSITA would have understood the need to balance tissue impedance (which decreases with increasing frequency, but yields only marginal improvements past the hundreds of kHz range) with the difficulty transmitting energy from a generator to electrodes and then to tissue (which increases as the frequency approaches the MHz range). Based on these considerations, a POSITA would have known that a frequency in the kHz range would be the most desirable to ensure reduced impedance of tissue while avoiding the challenges associated with delivering energy at higher frequencies. Selecting a number from this range would have been a matter of routine experimentation and optimization. Indeed, most RF ablation generators sold prior to 2011 operated at a frequency of 460 kHz, making this frequency selection an almost necessary choice. Likewise, using a sinusoid—the most common and widely known RF waveform and one waveform used in Edwards-'535—would have also been obvious. Ex.1010-Edwards-'535, 8:54-60. Ex.1002-Decl., ¶¶149-152; Ex.1004-Decl., ¶¶124-130.

Because Edwards-'535 and Edwards-'886 have a common inventor and relate to similar devices used for similar purposes (as do Stern and Kong), a POSITA would have been motivated to perform ablation in the same way, and would have

reasonably expected success in doing so. The '271 patent does not disclose anything critical about ablation at 460 kHz—in fact, it is described as just one “example” from the entire RF range. Ex.1001-USP271, 33:53-57. Thus, selecting an appropriate frequency for ablation would have involved mere routine optimization. *See generally E.I. du Pont de Nemours & Co.*, 904 F.3d 996. Ex.1002-Decl., ¶¶149-152; Ex.1004-Decl., ¶¶127, 130-131.

C. Ground III: Claims 1-3, 6-12, 16 Are Invalid as Obvious Over Edwards-'535 in View of Liang and Stern

1. Claim 1

a. 1[pre]:

Whether the preamble is limiting or not, Edwards-'535 in view of Liang discloses *a method for treating a nasal airway* (e.g., ablating interior section of a turbinate / thermocoagulation of ethmoidal nerve on middle turbinate) *to reduce mucus production* (e.g., reduce runny nose). Ex.1002-Decl., ¶¶153-163.

As explained above for Ground I, Edwards-'535 discloses *treating a nasal airway*. Edwards-'535's device is also used to treat the middle turbinate. Ex.1010-Edwards-'535, Abstract, 1:60-2:29, 4:19-52, 6:39-42. Ex.1002-Decl., ¶153.

Liang also discloses *treating a nasal airway* via thermocoagulation of the “middle turbinate” (also referred to as the “nasal ridge”) with an RF device. Ex.1056-Liang, 341. Liang further teaches that applying RF energy

“damage[s]...the deep ethmoidal nerve,” which *reduces mucus production* (e.g., “reducing runny nose,” which a POSITA would understand to result from reducing *mucus production*). *Id.*, 341-42. Ex.1002-Decl., ¶¶154-155.

i. *Motivation to Combine Edwards-’535 and Liang*

As explained herein, Edwards-’535 teaches a method of using RF energy to ablate an interior portion of tissue on any of the turbinates, including the middle turbinate. *See, e.g.*, §§X.A.1.a-c, e-f, C.1.a-c, e-f. Liang discloses techniques for using RF energy to treat nasal airway conditions, including damaging the “deep ethmoidal nerve” in the middle turbinate. Like Edwards-’535 and Stern, Liang is directed to treating tissue in a body cavity and does so by applying RF energy to the tissue, Ex.1056, 341-42, and is therefore analogous art to the ’271 patent. Furthermore, a POSITA would have been motivated to combine these teachings—namely, by using Edwards-’535’s method to target specified nerve tissue as taught by Liang—to reduce mucus production by applying RF energy to the ethmoidal nerve within the middle turbinate, Ex.1056-Liang, 341-42, with a reasonable expectation of success for the following reasons. Ex.1002-Decl., ¶156.

First, Liang discloses the benefits of using RF energy to treat the same location (middle turbinate) as Edwards-’535, reporting an “effective rate of 95.5%” in treating allergic rhinitis, including by “reducing its sensitivity to adverse external

physical and chemical stimuli, reducing the secretion of vasoactive peptides, inhibiting sneezing reflex, reducing runny nose, and improving nasal ventilation.” Ex.1056-Liang, 341-42. Of 88 patients, 83% “showed marked effectiveness.” *Id.*, 341. Ex.1002-Decl., ¶157.

Second, Liang discusses shortcomings of its approach to delivering treatment that Edwards-’535 overcomes, providing further motivation to combine Edwards-’535 and Liang. For example, Liang also discloses that its technique resulted in “bloody secretions due to nasal reactions” to treatment and that some patients “developed nasal adhesion” (where two ablated surfaces heal together). *Id.*, 341-42. By contrast, Edwards-’535 provides cooling to the contacted tissue, which is less damaging to the surface mucosa. Ex.1010-Edwards-’535, 4:53-67, 6:10-22. Furthermore, unlike Liang’s procedure, Edwards-’535’s “procedure can be performed bloodlessly..., thereby significantly reducing the risk of infection.” *Id.*, 4:53-67, 6:10-22. These teachings would have motivated a POSITA to use a method like that of Edwards-’535 (which does not damage surrounding tissue) to deliver treatment to the specific tissue identified by Liang to avoid the shortcomings of Liang’s technique while obtaining its benefits. Ex.1002-Decl., ¶158.

Third, as discussed above, Edwards-’535 and Liang describe similar techniques such that their combination would have yielded predictable results. Both

Edwards-'535 and Liang teach delivering RF energy to tissue within the middle turbinate, which destroys tissue. *See, e.g.*, Ex.1010-Edwards-'535, 5:30-34, 6:66-7:17, 6:9-65, 4:53-5:15, FIGs.3A-4C; Ex.1056-Liang, 341-42. Thus, using Edwards-'535's method to ablate specified nerve tissue taught by Liang and thereby reduce mucus production is simply applying Liang's teachings to improve Edwards-'535's technique in the same way as those teachings are applied in Liang. As discussed for Ground I, practitioners had already used turbinate reduction devices to treat rhinitis, which would have led POSITAs to use similar devices and methods for Liang's purpose. Ex.1002-Decl., ¶159.

Fourth, a POSITA would have had a reasonable expectation of success in using Edwards-'535's method to deliver treatment to nerve tissue identified by Liang given that, as explained above, Edwards-'535 expressly discloses that its methods can be used to ablate the same portions of tissue as ablated in Liang, and Liang uses a turbinate reduction device like Edwards-'535's. Indeed, prior to 2011, other researchers recognized reduction in mucus production resulting from ablation of the nasal turbinates. Ex.1042-Bäck, 1808, FIG.2. Accordingly, combining the teachings of Edwards-'535 and Liang would have been a matter of routine implementation well within the skill of a POSITA and would have yielded predictable results—e.g., Edwards-'535's method being used to deliver RF energy

to specified nerve tissue to treat allergic rhinitis and reduce mucus production, as taught by Liang—with a reasonable expectation of success.¹⁶ Liang’s 95.5% effectiveness rate using a standard RF device, Ex.1056-Liang, 341, would have further led a POSITA to expect success using other improved RF energy delivery methods like Edwards-’535’s. Ex.1002-Decl., ¶¶160-163.

Thus, a POSITA would have been motivated to combine the teachings of Edwards-’535 and Liang. Ex.1002-Decl., ¶¶153-163.

b. 1[a]:

Edwards-’535 in view of Liang and Stern discloses *contacting a treatment element* (e.g., **expandable member 132** having **energy delivery device 134**) *of a nasal airway treatment device* (e.g., apparatus 124) *directly with nasal mucosa* (e.g., surface of the **nasal concha** / middle turbinate) *of the nasal airway, wherein the treatment element comprises two rows of bipolar electrode pairs* (e.g., plurality of **bipolar energy delivery devices**). Ex.1002-Decl., ¶¶164-166.

i. Edwards-’535 in view of Liang teaches contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein

¹⁶ As above, this is consistent with the ’271 patent itself. *See supra*, n.12.

the treatment element comprises [a row] of bipolar electrode[s].

As discussed in Ground I, Edwards-'535 discloses contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises [a row] of bipolar electrode[s]. As discussed above for limitation 1[pre], Edwards-'535 and Liang both disclose directing energy to the interior of the middle turbinate. Furthermore, the SHP-I device used in Liang is specifically designed so as to “*contact...patient’s tissue to produce an internal thermal effect..., which causes protein tissues to heat...and gradually subside or disappear*” Ex.1059-Liang’227, 1 (describing SHP-I). It would have been obvious to combine Edwards-'535 with Liang with a reasonable expectation of success in doing so for the reasons above and in Ground I. Ex.1002-Decl., ¶164.

ii. Stern teaches wherein the treatment element comprises two rows of bipolar electrode pairs.

As discussed for Ground I, Stern discloses *two rows of bipolar RF electrodes*. Ex.1002-Decl., ¶165.

iii. Motivation to Combine Edwards-'535 and Stern

As explained throughout this Section, Edwards-'535 in view of Liang teaches a method of using RF energy to ablate and remove/damage tissue in the middle

turbinate. As explained for Ground I, Stern discloses implementation details for how an RF device like Edwards-'535's can be implemented, including devices with *two rows of bipolar electrode pairs*. A POSITA would have been motivated to combine these teachings—namely, by implementing Edwards-'535's *energy delivery device 134* with Stern's two rows of bipolar RF electrodes on the surface of the *expandable member 132*—with a reasonable expectation of success for the reasons in Ground I and below. Ex.1002-Decl., ¶166.

The precise control afforded by Stern's electrode pairing and arrangement would have been particularly useful for the combination of Edwards-'535 and Liang. Liang emphasizes the need to avoid perforating the nasal septum. Ex.1056-Liang, 342. Using two rows of bipolar electrode pairs to direct and control energy, a practitioner could specifically target the middle turbinate without perforating the nasal septum. Ex.1002-Decl., ¶166.

c. 1[b]:

Edwards-'535 in view of Liang and Stern discloses *applying RF energy with the bipolar electrode pairs* (e.g., *energy delivery device 134 / chosen pairs of bipolar electrodes*) *through the nasal mucosa* (e.g., surface of the *nasal concha* / mucosa of turbinates) *to a target tissue underlying the nasal mucosa* (e.g., interior section of the nasal concha / parasympathetic nerves and/or submucosa) *for an amount of time*

(e.g., selected period of time / 10 seconds / time sufficient to destroy the cells) *to heat the target tissue*. Ex.1002-Decl., ¶¶167-169.

As discussed above for limitations 1[pre] and 1[a], Edwards-'535, Liang, and Stern disclose applying *RF energy* to tissue using *two rows of bipolar electrode pairs*. Furthermore, as discussed above for limitations 1[pre] and 1[a], Edwards-'535 discloses applying energy *through the nasal concha* (e.g., a middle turbinate)—which a POSITA would understand to include *mucosal tissue*—to an interior portion of the concha (i.e., *target tissue underlying the nasal mucosa*). *See, e.g.*, Ex.1010-Edwards-'535, 4:53-67, 5:27-35, 6:9-7:17, 11:23-44, FIGs.4A-4C. Similarly, Liang discloses applying RF energy both to and through the surface of the mucosa on the middle turbinate (i.e., *through the nasal mucosa*) to cause “thermocoagulation” (i.e., *heat*) and “damage...the deep ethmoidal nerve” (i.e., *target tissue underlying the nasal mucosa*). Ex.1056-Liang, 341-42; *see also id.*, 342 (damaging “deep tissues”); Ex.1059-Liang'227, 1 (describing SHP-I). It would have been obvious to combine Edwards-'535 with Liang for the reasons above. *See supra*, §X.C.1.a.i. Ex.1002-Decl., ¶168.

As discussed in Ground I, Edwards-'535 and Stern each disclose (and render obvious) that the RF energy is applied *for an amount of time to heat the target tissue*. Ex.1002-Decl., ¶169.

d. 1[c]:

As discussed in Ground I, Edwards-'535 discloses *removing the treatment element* (e.g., expandable member 132 having energy delivery device 134) *from the nasal airway*. Ex.1002-Decl., ¶170.

It would have been obvious to combine Edwards-'535 with Liang with a reasonable expectation of success for the reasons above. Ex.1002-Decl., ¶170.

e. 1[d]:

Edwards-'535 in view of Liang discloses that *heating the target tissue with the applied RF energy modifies at least one property* (e.g., reducing or removing via ablation / disintegration) *of the target tissue*. Ex.1002-Decl., ¶¶171-173.

As discussed in Ground I, Edwards-'535 discloses heating tissue using RF energy to reduce and/or remove an interior section of the nasal concha. Ex.1002-Decl., ¶172.

Likewise, Liang teaches that RF thermocoagulation (i.e., heating) causes numerous modifications, including:

[G]enerat[ing] strong endogenous heat effects in local cells, causing thermal coagulation of protein..., tissue degeneration, and atrophy.... of the sensitive mucosa..., ...damage to the glands, ...varying degrees of damage to the deep ethmoidal nerve, reducing its sensitivity to

adverse external physical and chemical stimuli..., [and] reducing runny nose..., thus achieving the goal of treating allergic rhinitis.

Ex.1056-Liang, 341-42; *see also* Ex.1059-Liang’227, 1 (describing effects of SHP-I). It would have been obvious to combine Edwards-’535 with Liang with a reasonable expectation of success for the reasons above. *See supra*, §X.C.1.a.i. Furthermore, a POSITA would have understood that applying ablative RF energy as disclosed in Edwards-’535 would have a similar effect—namely heating and destroying submucosal tissue such as nerve fibers—as disclosed in Liang. Ex.1002-Decl., ¶¶172-173.

f. 1[e]:

Edwards-’535 in view of Liang discloses that *the modified at least one property of the target tissue* (e.g., interior section of the nasal concha / nerves under the mucosa) *causes a reduction in mucus production* (e.g., reducing runny nose) *in the nasal airway*. Ex.1002-Decl., ¶¶174-176.

Liang discloses that RF thermocoagulation heats tissue, which “damage[s]...the deep ethmoidal nerve, reducing its sensitivity to adverse external physical and chemical stimuli, reducing the secretion of vasoactive peptides, inhibiting sneezing reflex, reducing runny nose, and improving nasal ventilation, thus achieving the goal of treating allergic rhinitis.” Ex.1056-Liang, 341-42,

Abstract (discussing results for treating rhinitis). A POSITA would have understood that “reducing runny nose” refers to reducing mucus production that causes runny nose, and further that by ablating the ethmoidal nerves in the turbinate, mucus production would be reduced *in the nasal airway*. It would have been obvious to combine Edwards-’535 with Liang with a reasonable expectation of success for the reasons above. *See supra*, §X.C.1.a.i. Ex.1002-Decl., ¶175.

* * *

Accordingly, a POSITA would have found it obvious to use a device like that taught in Edwards-’535 as modified by Stern’s teachings to treat rhinitis and reduce mucus production as taught by Liang by contacting middle turbinate with the electrode pairs on the **expandable member 132**, applying RF energy with the electrode pairs to heat and damage underlying tissue (such as ethmoidal nerves), and removing the device. Ex.1002-Decl., ¶153-176.

2. Claim 2

Edwards-’535 in view of Liang discloses that *the target tissue is selected from the group consisting of mucosa* (e.g., surface 115 of the nasal concha 114 / mucosa of turbinates), *submucosa* (e.g., interior portion of a nasal concha / ethmoidal nerve underneath the turbinate), *cartilage, muscle, ligament, and tendon*. Ex.1002-Decl., ¶¶177-178.

As discussed above for limitation 1[b] and in Ground I, Edwards-'535 discloses applying energy *through* the *mucosa* and to the *submucosa*. Similarly, as discussed above for limitation 1[b], Liang discloses applying RF energy to the surface of the middle turbinate and to the underlying ethmoidal nerve, which would include applying energy to the intermediary *submucosa* as well. Ex.1056-Liang, 341-42 (damaging *mucosa* and underlying ethmoidal nerve), 341 (causing “white spots of local mucosa”). Ex.1002-Decl., ¶177.

It would have been obvious to direct the RF energy of Edwards-'535 to the submucosal tissues and/or nasal mucosa, as taught by Liang with a reasonable expectation of success for at least the reasons discussed for Claim 1. Ex.1002-Decl., ¶¶177-178.

3. Claim 3

Claim 3 depends from claim 1, and the analysis in Section X.C.1 is incorporated by reference. As discussed in Ground I, Edwards-'535 discloses claim 3. Ex.1002-Decl., ¶179.

4. Claim 6

Claim 6 depends from claim 1, and the analysis in Section X.C.1 is incorporated by reference. As discussed in Ground 1, Edwards-'535 discloses claim 6. Ex.1002-Decl., ¶180.

5. Claim 7

Liang discloses *applying local anesthesia* (e.g., nasal mucosal anesthesia) *to at least one of the nasal mucosa* (e.g., surface of middle turbinate/nasal ridge) *or the target tissue before applying the RF energy* (e.g., “[t]hen, the SHP-I...was used). Ex.1056-Liang, 341. A POSITA would have found it obvious to do so and reasonably expected success for the same reasons discussed in Ground I for claim 7. Ex.1002-Decl., ¶¶181-182.

6. Claim 8

Claim 8 depends from claim 1, and the analysis in Section X.C.1 is incorporated by reference. As discussed in Ground 1, Edwards-’535 discloses claim 8. Ex.1002-Decl., ¶183.

7. Claim 9

Claim 9 depends from claim 1, and the analysis in Section X.C.1 is incorporated by reference. As discussed in Ground 1, Edwards-’535 in view of Stern discloses claim 9. *See also* Ex.1059-Liang-’227, 1 (Liang’s SHP-I device heats tissue to 60-80°C). Ex.1002-Decl., ¶184.

8. Claim 10

Claim 10 depends from claim 1, and the analysis in Section X.C.1 is incorporated by reference. As discussed in Ground 1, Edwards-’535 in view of Stern renders obvious claim 10. Ex.1002-Decl., ¶185.

9. Claim 11

a. 11[a]:

Edwards-'535 in view of Liang discloses *before removing the treatment element from the nasal airway*. See *infra*, §§X.C.9.b-c. Ex.1002-Decl., ¶¶186-188.

b. 11[b]:

Edwards-'535 in view of Liang discloses *repositioning the treatment element to contact a different portion of nasal mucosa* (e.g., nasal septum mucosa) *before removing the treatment element from the nasal airway*. Ex.1002-Decl., ¶186.

As discussed for limitations 1[pre]-1[c] and claim 9, Edwards-'535 discloses contacting a turbinate, applying energy, and then removing the apparatus. Liang discloses applying RF energy at multiple locations, including the “nasal septum mucosa.” Ex.1056-Liang, 341. Ex.1002-Decl., ¶186.

Therefore, when using the apparatus of Edwards-'535 to ablate tissue as taught by Liang, a POSITA would have found it obvious to move the [expandable member 132](#) to different locations (e.g., from the middle turbinate to the nasal septum) *before removing* the device for at least the same reasons as discussed in Section X.C.1.a.i. A POSITA would have had a reasonable expectation of success, at least because Liang had demonstrated successfully treating rhinitis by ablating different locations in the nose using one repositioned RF ablation device that targets

submucosal tissue, and a POSITA would have expected submucosal ablation from Edwards-'535's similar RF ablation device to have a similar effect. Ex.1002-Decl., ¶186.

c. 11[c]:

Edwards-'535 in view of Liang discloses *applying RF energy with the bipolar electrode pairs through the different portion of nasal mucosa to a different portion of target tissue* (e.g., nasal septum mucosa) *for the amount of time to heat the different portion of target tissue before removing the treatment element from the nasal airway*. Ex.1002-Decl., ¶¶187-188.

As discussed in Ground I and for limitations 11[a] and 11[b] above, Edwards-'535 in view of Liang disclose positioning Edwards-'535's [expandable member 132](#) to different locations (e.g., middle turbinate and nasal septum mucosa) to apply RF energy. Accordingly, it would have been obvious to *apply* RF energy to each of these portions to *heat* each portion, as discussed above for limitation 1[b], before removing the device as discussed above for limitation 1[c]. Since the additional locations are on the mucosa of the septum, which would have similar properties, a POSITA would have been motivated to apply energy for the same amount of time so as to heat the tissue to the same temperature. A POSITA would have been

motivated to do so for at least the same reasons as those discussed in Sections X.C.1.a.i, X.C.9.a-b, and X.A.9. Ex.1002-Decl., ¶¶187-188.

10. Claim 12

Edwards-'535 and Liang discloses that *the modified at least one property of the target tissue is selected from the group consisting of shrinking (e.g., reducing/removing), tightening, stiffening, and deactivating (e.g., damaging nerves) the target tissue.* Ex.1002-Decl., ¶¶189-191.

As discussed for limitations 1[pre], 1[d], and 1[e], Edwards-'535 discloses applying RF energy to reduce (i.e., *shrink* and destroy) the size of the nasal concha. Furthermore, as discussed for limitations 1[pre], 1[a], 1[d], and 1[e], Liang teaches applying RF energy to ethmoidal nerves and/or submucosa on the middle turbinate, and that application of the energy “damage[s]...the deep ethmoidal nerve.” Ex.1056-Liang, 341-42. A POSITA would have understood that damaging ethmoidal nerve would deactivate the nerve. Using Edwards-'535's submucosal ablative heating would have the same destructive, and therefore deactivating effect on nerves. It would have been obvious to combine Edwards-'535 with Liang with a reasonable expectation of success for the reasons above. *See supra*, §X.C.1.a.i. Ex.1002-Decl., ¶¶190-191.

11. Claim 16

Claim 16 depends from claim 1, and the analysis in Section X.C.1 is incorporated by reference. As discussed in Ground 1, Edwards-'535 discloses or renders obvious claim 16. Ex.1002-Decl., ¶192.

D. Ground IV: Claim 4 is Invalid as Obvious Over Edwards-'535 in View of Liang and Stern in Further in View of Edwards-'886

1. Claim 4

It would have been obvious to modify the combination of Edwards-'535, Stern, and Liang to apply energy *in the form of a 460 kHz sinusoid wave* in view of Edwards-'886 for the same reasons discussed in Ground II. Ex.1002-Decl., ¶193.

XI. CONCLUSION

The Challenged Claims of the '271 patent and rendered obvious by the prior art grounds set forth herein. Accordingly, Petitioners request institution of an *inter partes* review to cancel these claims.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing, Petition for *Inter Partes* Review, contains 13,989 words as measured by the word processing software used to prepare the document, in compliance with 37 C.F.R. Section 42.24(d), excluding the parts of the Petition exempted from the word count by 37 C.F.R. Section 42.24(a)(1).

/Alexander Nemtzow/
Alexander Nemtzow
Registration No. 82,130

CERTIFICATE OF SERVICE

Pursuant to an agreement between Petitioners and Patent Owner, I hereby certify that, on January 18, 2024, I caused a true and correct copy of the following materials:

- Petition for *Inter Partes* Review of U.S. Patent No. 11,241,271
- Appendix of Claims
- Petitioners' Table of Exhibits
- Exhibits 1001-1004, 1006-1008, 1010-1013, 1015-1017, 1019, 1021-1027, 1029, 1031, 1033, 1035, 1037-1044, 1046-1060, 1062, 1064, 1066, 1070-1080
- Certificate of Compliance Regarding Word Count
- Fee Authorization
- Power of Attorney

to be served on the Patent Owner's correspondence address listed on Patent Center (Merchant & Gould P.C., P.O. Box 2903, Minneapolis, MN 55402-0903, United States) via electronic mail to:

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Petitioners’ Table of Exhibits

Exhibit	Description
1001	U.S. Patent No.11,241,271 (“’271 patent”)
1002	Declaration of Dr. John DelGaudio (“Decl.”)
1003	File History of U.S. Patent No.11,241,271
1004	Declaration of Dr. Gregory Martin (“Decl.”)
1005	RESERVED
1006	District Court Amended Complaint
1007	District Court Amended Complaint Exhibit Y
1008	Docket Navigator District of Delaware Statistics as of January 18, 2024
1009	RESERVED
1010	U.S. Patent No. 6,517,535 (“Edwards-’535”)
1011	U.S. Patent No. 5,575,788 (“Baker”)
1012	U.S. Patent No. 5,891,134 (“Goble”)
1013	WO 2010/077980 (“Baker-’980”)
1014	RESERVED
1015	U.S. Patent No. 6,033,397 (“Laufer”)
1016	U.S. Patent No. 6,273,886 (“Edwards-’886”)
1017	Chen et al., Radiofrequency Treatment of Nasal Posterior-Under Nerve, Ethmoidal Nerve and Infratubinal for Perennial Allergic Rhinitis Under Nasal Endoscope, CHINA J. ENDOSCOPY 11:3 (2005) (English translation) (“Chen”)
1018	RESERVED
1019	U.S. Patent App. No. 2007/0219600 (“Gertner”)
1020	RESERVED
1021	U.S. Patent App. No. 2005/0240147 (“Makower”)

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1023	Coste et al., Radiofrequency Is a Safe and Effective Treatment of Turbinate Hypertrophy, LARYNGOSCOPE, 111(5) (2001) (“Coste”)
1024	WO1999030655A1 (“Hovda”)
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1026	U.S. Patent No. 3,538,919 (“Meyer”)
1027	U.S. Patent No. 3,117,571 (“Fry”)
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1034	RESERVED
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1038	U.S. Patent No. 6,109,268 (“Thapliyal”)
1039	Banhiran, Quality of life in patients with chronic rhinitis after radiofrequency inferior turbinate reduction, J. MED ASSOC THAI, Vol. 93 No.8 (2010) (“Banhiran”)

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1041	Snow, Blessed Days of Anesthesia (Oxford U. Press, 2008) (available at: http://ndl.ethernet.edu.et/bitstream/123456789/3165/1/360.pdf) (“Snow”)
1042	Bäck et al., Submucosal Bipolar Radiofrequency Thermal Ablation of Inferior Turbinates: A Long-Term Follow-up With Subjective and Objective Assessment, 112 LARYNGOSCOPE 1806 (October 2002) (“Bäck”)
1043	Ilgner et al., Feasibility of coblation versus laser resection in recurrent nasal polyps, 5686 PROC. OF SPIE 322 (April 25, 2005)
1044	Lee et al., Surgical Management of Turbinate Hypertrophy in the Office: Three Mucosal Sparing Techniques, 12:2 OPERATIVE TECHNIQUES IN OTOLARYNGOLOGY—HEAD AND NECK SURGERY 107 (June 2001) (“Lee”)
1045	RESERVED
1046	U.S. Patent No. 3,941,121 (“Olinger”)
1047	U.S. Patent No. 4,271,848 (“Turner”)
1048	Nomura et al., Distribution and Clinical Significance of Autonomic Nervous System in the Human Nasal Mucosa, 73 ACTA OTOLARYNG 493 (1972) (“Nomura”)
1049	Akiyoshi Konno, Historical, Pathophysiological, and Therapeutic Aspects of Vidian Neurectomy, 10 CURR ALLERGY ASTHMA REP 105 (2010) (“Konno”)
1050	Hong, Radiofrequency Ablation: Mechanism of Action and Devices, J. VASC. INTERV. RADIOL. 21 (2010) (“Hong”)
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1070	Declaration of June Munford

1071	Translator Declaration for Chen
1072	Translator Declaration for Liang
1073	Translator Declaration for Fang
1074	Translator Declaration for Kong
1075	Munford Appendices for Chen
1076	Munford Appendices for Liang
1077	Munford Appendices for Fang
1078	Munford Appendices for Kong
1079	Additional Appendices to Munford Declaration
1080	Translator Declaration for Liang '227

Appendix of Claims

Claim 1	
Limitation	Claim Language
1[pre]	1. A method for treating a nasal airway to reduce mucus production, the method comprising:
1[a]	contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises two rows of bipolar electrode pairs;
1[b]	applying radiofrequency energy with the bipolar electrode pairs through the nasal mucosa to a target tissue underlying the nasal mucosa for an amount of time to heat the target tissue; and
1[c]	removing the treatment element from the nasal airway,
1[d]	wherein heating the target tissue with the applied radiofrequency energy modifies at least one property of the target tissue, and
1[e]	wherein the modified at least one property of the target tissue causes a reduction in mucus production in the nasal airway.

Claim 2

The method of claim 1, wherein the target tissue is selected from the group consisting of mucosa, submucosa, cartilage, muscle, ligament, and tendon.

Claim 3

The method of claim 1, further comprising controlling at least one characteristic of the applied radiofrequency energy with a control system coupled with the nasal airway treatment device.

Claim 4

The method of claim 1, wherein the radiofrequency energy is applied in the form of a 460 kHz sinusoid wave.

Claim 6

The method of claim 1, further comprising displaying one or more parameters of treatment on a console attached to the nasal airway treatment device while the radiofrequency energy is applied, the one or more parameters selected from the group consisting of treatment time, power level, temperature sensed by the treatment element, electric impedance, electric current, and depth of treatment.

Claim 7

The method of claim 1, further comprising applying local anesthesia to at least one of the nasal mucosa or the target tissue before applying the radiofrequency energy.

Claim 8

The method of claim 1, wherein the radiofrequency energy is produced by a radiofrequency energy source configured to run between 1 Watt and 100 Watts.

Claim 9

The method of claim 1, wherein applying the radiofrequency energy comprises heating the target tissue to a temperature between 50 degrees Celsius to 70 degrees Celsius.

Claim 10

The method of claim 1, wherein the amount of time the radiofrequency energy is applied to the target tissue is between fifteen seconds and one minute.

Claim 11

Limitation	Claim Language
11[a]	The method of claim 1, further comprising, before removing the treatment element from the nasal airway:
11[b]	repositioning the treatment element to contact a different portion of nasal mucosa; and
11[c]	applying radiofrequency energy with the bipolar electrode pairs through the different portion of nasal mucosa to a different portion of target tissue for the amount of time to heat the different portion of target tissue.

Claim 12

The method of claim 1, wherein the modified at least one property of the target tissue is selected from the group consisting of shrinking, tightening, stiffening, and deactivating the target tissue.

Claim 16

The method of claim 1, further comprising bending a shaft of the nasal airway treatment device before contacting the treatment element with the nasal mucosa.