

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.

Petitioners,

v.

THE FOUNDRY, LLC,
Patent Owner.

Case No. IPR2024-00669

U.S. Patent No. 11,679,077

**PETITION FOR *INTER PARTES* REVIEW
OF CLAIMS 1-8 AND 11 OF
U.S. PATENT NO. 11,679,077
UNDER 35 U.S.C. §312 AND 37 C.F.R. §42.104**

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I. INTRODUCTION

The Challenged Claims of U.S. Patent No. 11,679,077 (the “’077 patent”) are directed to the well-known concept that applying energy to tissue in the nose can treat a nasal condition. The apparatuses of the Challenged Claims have been known for decades and are unpatentable for multiple reasons.

The application leading to the ’077 patent was the tenth non-provisional Patent Owner (“PO”) filed in a patent family, but only the third in which it identified the presently claimed subject matter. In a 2005 provisional application, PO discussed using neurotoxin to treat conditions of the bronchial tubes and for cosmetic and myofascial applications after preparing the cells using electroporation. For seven subsequent utility applications, PO copied that application and pursued claims directed to bronchial tube treatment. Then, in October 2019 when it filed the grandparent to the ’077 patent, it changed course. After Petitioners and others developed products to treat nasal conditions, PO inserted new matter from another provisional into a specification, marked it a continuation, and pursued patents with entirely different claims, which are directed to treating nasal conditions with energy, as opposed to neurotoxin for bronchial tube treatment or cosmetic and myofascial applications.

Because the subject matter of the Challenged Claims was not described in any priority application prior to October 22, 2019—the application filing date of the grandparent of the '077 patent—the Challenged Claims are only entitled to priority on October 22, 2019. As of that date, Saadat, a patent application disclosing a radiofrequency (RF) energy device for treating nasal conditions like rhinitis, plainly anticipates or renders obvious the challenged claims (Grounds I, II, III). In addition, to the extent Patent Owner attempts to argue the Challenged Claims have written description in the '077 patent specification, publication of identical parts of that specification in a non-priority application (Deem) anticipates the claims as well (Ground IV).

Regardless, before any application associated with the '077 patent was filed in 2005, it was known not only that nerves in the nasal cavity cause rhinitis symptoms, but also that using devices to apply energy such as radiofrequency (“RF”) energy there would treat such nasal conditions. Makower, Fang, Edwards-535, and Stern render the claims obvious (Ground V, VI).

II. MANDATORY NOTICES

A. Real Parties in Interest

Pursuant to 37 C.F.R. §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. §42.8(b)(2), Petitioners submit that Patent Owner has asserted three patents, including the '077 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). *See* Ex.1035-Complaint. Five other patents owned by Aerin Medical Inc.—which has represented that it is the exclusive licensee of the asserted Foundry patents—are also asserted against Petitioners in that litigation. On January 18, 2024, Petitioners filed *inter partes* review petitions challenging certain claims of the following patents asserted against Petitioners by Patent Owner and/or Aerin Medical Inc.:

Challenged Patent	Patent Owner	Case No.
9,072,597	Aerin Medical Inc.	IPR2024-00275
9,415,194	Aerin Medical Inc.	IPR2024-00276
11,241,271	Aerin Medical Inc.	IPR2024-00277
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

On February 28, 2024, Petitioners filed a motion in IPR2024-00281 requesting withdrawal of the petition without prejudice and with leave to refile. *See Neurent Medical Inc. v. The Foundry, LLC*, IPR2024-00281, Paper 7 (Feb. 28, 2024). Patent Owner did not substantively oppose Petitioners' motion to withdraw and refile IPR2024-00281. Rather, the limited dispute between the parties was whether to extend the procedural deadlines in separate IPRs, IPR2024-00279 and IPR2024-00280.

This proceeding presents the same grounds and arguments that were in Petitioners' IPR2024-00281 Petition, but is filed more than nine months after the issuance of the '077 patent.

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III. CERTIFICATION OF GROUNDS FOR STANDING

Petitioners certify the '077 patent is available for IPR and Petitioners are not barred or estopped from requesting IPR on the grounds identified herein.

IV. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED

Petitioners request cancellation of claims 1-8 and 11 (“Challenged Claims”) of the '077 patent.

A. Prior Art

The '077 patent was filed January 9, 2021, and claims priority to U.S. Provisional No. 60/702,077¹ filed July 22, 2005. Ex.1001-USP077, Cover. As Section IX details, however, the '077 patent is entitled to priority no earlier than October 22, 2019, and the following prior art applies:

1. U.S. Patent No. 10,307,200 to Saadat (“Saadat,” Ex.1003) issued June 4, 2019 and is prior art at least under AIA 35 U.S.C. §102(a)(1).
2. U.S. Pub. 2008/0021369 to Deem (“Deem,” Ex.1004) published January 24, 2008 and is prior art at least under AIA 35 U.S.C. §102(a)(1).

The following prior art also applies, including to the extent PO argues the '077 patent is entitled to priority earlier than October 22, 2019:

3. U.S. Patent 5,562,720 to Stern (“Stern,” Ex.1009) issued October 8, 1996 and is prior art at least under pre-AIA 35 U.S.C. §102(b) or AIA 35 U.S.C. §102(a)(1).
4. U.S. Pub. 2005/0240147 to Makower (“Makower,” Ex.1005) was filed April 21, 2004 and published October 27, 2005, and is prior art at least under pre-AIA 35 U.S.C. §102(e) or AIA 35 U.S.C. §102(a)(1).

¹ All patents and applications abbreviated using last three digits of number.

5. Fang Chao-xin and Zhen Shao-Shao, Nasal endoscopy combined with multiple radiofrequency for perennial allergic rhinitis, 25(07) J. First Mil. Medic Univ. 876 (July 20, 2005) (“Fang,” Ex.1006)² is prior art at least under pre-AIA 35 U.S.C. §102(a) or AIA 35 U.S.C. §102(a)(1). As the Declaration of June Munford details, Fang was publicly available as of July 20, 2005, before the earliest provisional application the ’077 patent claims priority to.³ Ex.1070-Decl., ¶¶39-56; *Telefonaktiebolaget LM Ericsson v. TCL Corp.*, 941 F.3d 1341, 1346-47 (Fed. Cir. 2019).
6. U.S. Patent No. 6,517,535 to Edwards (“Edwards-535,” Ex.1008) issued February 11, 2003 and is prior art at least under pre-AIA 35 U.S.C. §102(b) or AIA 35 U.S.C. §102(a)(1).

B. Grounds for Challenge

Petitioners request cancellation of the Challenged Claims as unpatentable under 35 U.S.C. §§102 and 103. The grounds are:

² See Ex.1073 (translator declaration).

³ Even if the Challenged Claims are entitled to the May 19, 2006 date of U.S. Provisional Application No. 60/747,771—they are not (*see* Section IX)—Fang is prior art because it was publicly available before that date. Ex.1070-Decl., ¶¶39-56.

Ground	35 U.S.C. §	Claims	Reference(s)
I	102	1-8, 11	Saadat
II	103	3, 11	Saadat
III	103	4	Saadat and Stern
IV	102	1-8, 11	Deem
V	103	1-3, 5-8 11	Makower, Fang, and Edwards-535
VI	103	4	Makower, Fang, Edwards-535, and Stern

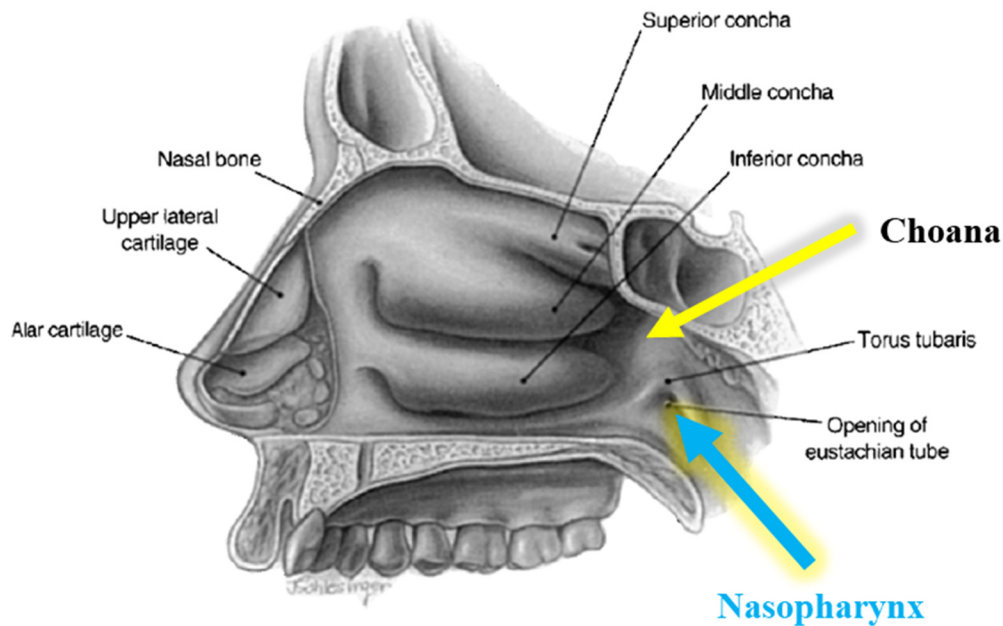
This Petition, supported by the declarations of Dr. Nicolas Bu-Saba (Ex.1002; Ex.1083), Dr. Gregory Martin (Ex.1007; Ex.1084), and June Munford (Ex.1070; Ex.1085), demonstrates there is a reasonable likelihood Petitioners will prevail with respect to at least one Challenged Claim. 35 U.S.C. §314(a). Petitioners respectfully request institution. *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018).

V. TECHNOLOGY BACKGROUND

A. Anatomy of the Nose and Upper Airway

In the early 2000s, the anatomy of the nose and upper airways was well known. The nose has right and left nostrils that lead into right and left nasal cavities separated by the nasal septum. Ex.1005-Makower, [0001], [0131]. Each nasal cavity contains three turbinates lined with mucosal tissue that increase surface area and help transfer warmth and moisture to inhaled air. *Id.*, [0004]. The nasal cavities

merge and “open[] into the nasopharynx.” *Id.*, [0002]. The nasopharynx is the upper portion of the pharynx (throat) closest to the nasal cavity.



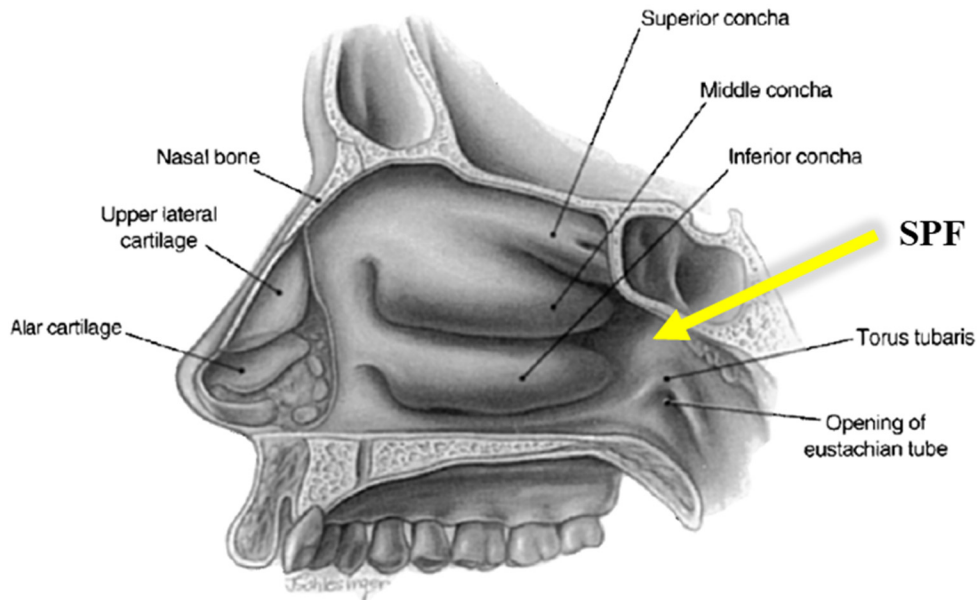
Ex.1064-Lane, 338.⁴ Ex.1002-Decl., ¶31.

Within the passageway that includes the nasal cavity and nasopharynx there are nerve cells that control other cells (goblet cells) that generate mucus. The sphenopalatine ganglion (“SPG”),⁵ located posterior in the nasal cavity near the

⁴ Annotations added unless noted.

⁵ The SPG originates from the Vidian nerve located behind the SPF. Ex.1002-Decl., ¶32.

sphenopalatine foramen (“SPF”), contains parasympathetic nerves that control such cells.



Ex.1064-Lane, 338. Parasympathetic nerves originating at the SPG branch throughout the nasal cavity and nasopharynx and control goblet cells. As a result, their activity can cause symptoms including mucus production and congestion. *E.g.*, Ex.1051-Windsor, 284. Ex.1002-Decl., ¶¶32-33.

B. Neurotoxin Therapy

As of the early 2000s, “[c]ontrolled injection of neurotoxins” was common. Ex.1001-USP077, 1:53-54. Neurotoxins such as botulinum neurotoxin (BOTOX®) “block the release of neurotransmitter[s] from the nerves that control the contraction of...muscles” or disable mucus-producing cells. *Id.*, 1:65-2:12, 3:31-37. For example, injecting neurotoxin treats conditions by “paralyz[ing] or weaken[ing]”

muscles that would otherwise signal nerves to cause symptoms. *Id.*, 1:65-2:31. Use of neurotoxin was known and studied for many conditions, including rhinorrhea, rhinitis, asthma, arthritis, essential tremor, cardiovascular disease, sinus headache, tumors, and others. *Id.*, 2:23-52, 3:41-55, 4:5:22; Ex.1057-Sanders, 2:30-38, 10:14-22, claims 1-4; Ex.1059-Rubisnky, [0013]. For example, it was known that administering neurotoxin “onto the nasal mucosa” by topical application or injection into the SPG reduced rhinitis symptoms. Ex.1057-Sanders, 2:30-38, 10:14-22, claims 1-4; Ex.1001-USP077, 2:23-52, 3:41-55, 4:5:22. Ex.1002-Decl., ¶¶34-35.

C. Use of Energy in Therapy

It has been known for over a century that applying energy to tissue can change its properties and function. As early as 1907, scientists applied “high frequency electrical current” to cauterize tissue. *E.g.*, Ex.1058-De Forest, 1:14-23. Scientists have since studied application of different types of energy such as sound (ultrasonic), light, and heat, in different amounts to have varied effects on tissue. *E.g.*, Ex.1060-Meyer, 1:35-40 (light); Ex.1061-Fry, 1:67-70 (sound). Among others, two different and well-known effects of applying energy to tissue included preparing tissue for application of therapy by making cells more permeable (e.g., electroporation) and damaging or modifying tissue (e.g., ablation). Ex.1002-Decl., ¶36.

Electroporation. Electroporation has been used for over half a century. *E.g.*, Ex.1059-Rubinsky, [0007]. Electroporation involves applying pulses to make cell membranes permeable. *Id.*, [0004], [0007]. This can be reversible, such that the cell membrane reseals and the cell survives, or irreversible, such that the cell breaks down. *Id.*, [0007]. As of the early 2000s, reversible “[t]issue electroporation” was “an increasingly popular minimally invasive surgical technique for introducing small drugs and macromolecules into cells....” *Id.*, [0011], [0014]. Thus, for example, scientists studied reversibly electroporating cells so that cancer drugs could be more easily introduced without permanently damaging cells. *Id.*, [0014]. Electroporation pulses could be delivered using different types of energy, including ultrasonic (sound) energy or heating. *E.g.*, Ex.1001-USP077, 13:34-47. Ex.1002-Decl., ¶37.

Ablation. Ablation has also been used for decades. Ex.1053-McGovern, 3:53-56. Ablation, unlike reversible electroporation, involves applying energy to damage or modify tissue. As of the early 2000s, ablation had been used across the entire body, including the brain, stomach, heart, airways, and nose. *E.g.*, Ex.1040-Stone, 22:21-31. For each, scientists identified tissue involved in causing a condition and treated the condition by effectively stopping operation of the tissue. Ablation and reversible electroporation thus have different goals: the latter is

designed to maintain cells so they can receive additional treatment; the former is designed to alter cells to treat the condition directly. Ex.1002-Decl., ¶¶38-39; Ex.1007-Decl., ¶¶29-34.

Ablation energy can be delivered in many forms, including by heating or cooling. *E.g.*, Ex.1008-Edwards-535, 5:25-45 (RF ablation via heating); Ex.1054-Arora, 80 (cryoablation via cooling). For example, radiofrequency (“RF”) ablation was well known in the early 2000s and involved using bi- or monopolar electrodes to deliver radiofrequency energy as alternating electrical current to heat or cauterize tissue. *E.g.*, Ex.1009-Stern, 2:11-19. While RF electrodes could be used for different purposes at different energy levels, in RF ablation, electrodes are coupled to and use energy from an energy source (e.g., generator) to increase tissue temperature and cause damage. In contrast, in reversible electroporation, electrical pulses are administered at levels to “produce no other substantial effect on biological cells than the permeabilization of the cell membrane.” Ex.1059-Rubisnky, [0004]. Energy used for RF ablation is thus “distinctly different from the pulses which produce electroporation.” *Id.*, [0005]. Ex.1002-Decl., ¶¶40-42; Ex.1007-Decl., ¶¶35-38.

D. Treatment of Nasal Conditions

Rhinitis is a nasal condition caused by excess mucus production, resulting in congestion, chronic cough, and/or runny nose. Rhinitis occurs in many forms, including rhinitis from the common cold, allergic rhinitis (e.g., due to seasonal allergies), and year-round rhinitis. Chronic rhinitis can have serious health consequences. Ex.1002-Decl., ¶43.

As of the early 2000s, rhinitis was a well-known subject of study. There were multiple techniques for affecting parasympathetic nerves deriving from the Vidian and SPG nerves to treat rhinitis and its symptoms. One used **neurotoxin** injections to affect cells involved in mucus production. *E.g.*, Ex.1057-Sanders, 2:30-38, 10:14-22, claims 1-4. The '077 patent discusses pairing such technique with preparatory electroporation to ready cells to receive neurotoxin. *See* Section VII.A. Ex.1002-Decl., ¶¶44-45.

A distinct but well-known technique was to use **ablation** devices to deliver energy to destroy cells that cause rhinitis symptoms. *E.g.*, Ex.1006-Fang, 877; Ex.1054-Arora, 80; Ex.1044-Chen, 240.⁶ By the early 2000s, scientists had developed devices that used various types of energy to ablate the parasympathetic

⁶ *See* Ex.1071 (translator declaration); Ex.1070-Decl., ¶¶17-29.

nerves branching from the SPG that cause rhinitis symptoms. For example, Fang used RF energy to “block[] the parasympathetic pathway of the nasal mucosa,” which “reduce[ed] glandular secretion” to treat rhinitis. Ex.1006-Fang, 877. Chen did the same. Ex.1044-Chen, 240 (“radiofrequency thermocoagulation...can widely block the source of the parasympathetic nerves in the nasal cavity and reduce [their] excitability” to eliminate congestion). And Arora used cryotherapy (cooling). Ex.1054-Arora, 80 (“Cryodestruction of the nasal branches of the Vidian nerve in the region of the sphenopalatine foramen” for “vasomotor rhinitis.” Ex.1002-Decl., ¶46.

VI. THE '077 PATENT

A. Brief Description

The '077 patent relates to delivering “toxins to defined target areas within the nasal cavities” to treat rhinitis. Ex.1001-USP077, 3:62-66, 8:10-28. Ex.1002-Decl., ¶47; Ex.1007-Decl., ¶¶39-40.

'077 patent Figure 23 (first added October 22, 2019) discloses a **porous balloon catheter** that delivers neurotoxins into the nasal cavity. Ex.1001-USP077, 22:30-36, 24:4-17. The **catheter** is positioned in the back of the nasal passages because it has high goblet cell concentration. *Id.*, 24:4-11. To facilitate toxin

delivery, the **catheter** includes ultrasonic transducers to cause “reversible poration” of target cells. *Id.*, 5:4-11, 5:49-59, 17:50-56, 22:36-41, 22:58-65, 24:4-11.

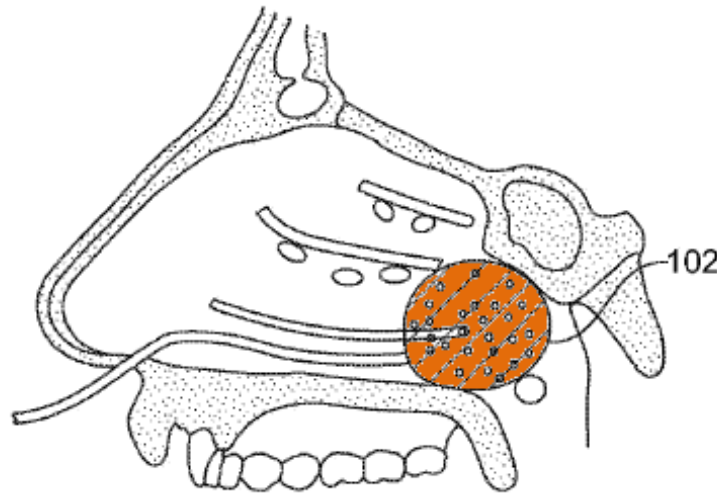


FIG. 23

Ex.1001-USP077, FIG.23. Ex.1002-Decl., ¶¶47-49.

The '077 patent summarily lists other “energy producing devices” to cause reversible poration—including x-ray, radiofrequency (RF), DC current, AC current, microwave, and ultrasound—without any working example. Ex.1001-USP077, 13:34-47. It does not describe using any energy source **alone** to treat any condition, including rhinitis. *See generally id.* Ex.1002-Decl., ¶50; Ex.1007-Decl., ¶41.

The Challenged Claims depart from the '077 patent's specification. While the figures and written description are directed to delivering **neurotoxin** for treatment

following electroporation, the Challenged Claims recite treatment with energy alone. Ex.1002-Decl., ¶51.

B. Prosecution History

Application No. 17/151,938, issued as the '077 patent, was filed January 19, 2021. Ex.1001-USP077, Cover. It was designated a continuation and purports to claim priority through continuation applications to a July 22, 2005 provisional application. Ex.1025-FH077, 3-4 (not designating application as subject to AIA); Section IX. Its filing receipt lists July 22, 2005 as the earliest alleged priority date, and the Examiner applied pre-AIA law. Ex.1025-FH077, 121, 141, 370. Ex.1002-Decl., ¶52.

The claims were not substantively rejected over prior art, and the prosecution history does not reflect Examiner substantively evaluated the priority date or art as of the appropriate priority date. Neither Saadat nor Fang (or their teachings) were of record. Ex.1002-Decl., ¶53.

VII. PERSON OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art (“POSITA”) at relevant times (2005-2019) 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., ¶¶26-27; Ex.1007-Decl., ¶¶24-28.

VIII. CLAIM CONSTRUCTION

For purposes of this IPR, the Board need not construe any terms. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017). Ex.1002-Decl., ¶¶54-57; Ex.1007-Decl., ¶¶42-45.⁷

IX. PRIORITY DATE

The '938 Application is designated a grandchild continuation of Application No. 16/659,893 (filed October 22, 2019). *See* Ex.1001-USP077-Cover; Ex.1021-USP675, Cover. The priority date for the Challenged Claims is no earlier than the '893 Application's October 22, 2019 filing date because this was the first time the subject matter in the Challenged Claims arguably appeared in any priority application.

To rely on the date of any preceding application for priority, PO must prove an unbroken priority chain to that application and that it provides written description

⁷ Petitioners reserve the right to propose or respond to claim constructions in parallel litigation and respond to any claim construction PO advances here.

support for the Challenged Claims. *See Parus Holdings, Inc. v. Google LLC*, 70 F.4th 1365, 1373 (Fed. Cir. 2023); *Droplets, Inc. v. E*TRADE Bank*, 887 F.3d 1309, 1315-20 (Fed. Cir. 2018) (PO “[must] provide a clear, unbroken chain of priority.”). PO cannot do so here.

The ’077 patent claims priority to the ’077 Provisional filed July 22, 2005. The ’077 Provisional is directed to methods of using neurotoxin to treat the bronchial tube or for cosmetic or myofacial application, which is **not** what the ’077 patent claims. Ex.1010-FH077, [0001], [0024], [0068]-[0070], FIGs.7-8; Ex.1001-USP077, claim 1. Following the ’077 Provisional, Applicant filed seven utility applications in the present family before the ’893 Application. *See* Ex.1021-USP675, Cover. Each such utility application and the ’077 patent includes substantially all disclosure and figures from the ’077 Provisional related to bronchial tube treatment or cosmetic applications. Before the ’893 Application, each preceding application claimed treating bronchial tubes, **not** the nasal passage or rhinitis. Ex.1002-Decl., ¶¶58-60.

The ’077 Provisional disclosure repeated in subsequent utility applications (including the ’077 patent), does not provide written description support for the Challenged Claims. Because it is directed to bronchial tube treatment with neurotoxin “via permeabilization of targeted cell membranes” (*e.g.*, Ex.1001-

USP077, Abstract, FIG.7, FIGs.9-10, FIG.13, 17:27-29), and cosmetic applications for external muscle (*e.g., id.*, FIG.14, 20:1-20), it does not provide written description of at least “*a radiofrequency generator...for supplying radiofrequency energy to the multiple radiofrequency electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis.*”⁸ Ex.1001-USP077, claim 1; *see also id.* (“*apparatus for treating rhinitis in a nasal cavity*”), Ex.1024-FH011, 340-342. Discussion of treating lung “bronchial tissue” for, *e.g.*, “asthma” (Ex.1001-USP077, 17:27-29, FIG.10), and “[c]osmetic and [m]yofacial [a]pplications” (*id.*, 20:1, FIG.14), do not provide written description for delivering energy inside the nose to treat rhinitis symptoms. Ex.1002-Decl., ¶¶61-63.

PO also argued during prosecution of a parent application that bronchial tube treatment is “patentably distinct” from treatment in the nasal passage, Ex.1024-FH011, 340-342, which supports that the ’077 Provisional does not provide written description for the challenged nasal cavity treatment claims. Ex.1002-Decl., ¶¶64-68.

PO added claims directed to the nasal passage for the **first** time in the ’893 Application on October 22, 2019. Thus, the Challenged Claims are entitled to

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

priority no earlier than October 22, 2019. *See Anascape, Ltd. v. Nintendo of Am. Inc.*, 601 F.3d 1333, 1340 (Fed. Cir. 2010).

Although the '077 patent does not claim priority to any other provisional application, when PO filed the '893 Application, it—**for the first time** in this patent family—copied passages and figures from U.S. Provisional Application No. 60/747,771 (filed May 19, 2006) into the specification.⁹ Any argument that copying the subject matter of the '771 Provisional into the '893 Application (which the '077 patent repeated, *see generally* Ex.1001-USP077) as new matter allows PO to claim priority to earlier-filed application would be misplaced for four reasons.

First, PO cannot claim the date of the '771 Provisional because the '077 patent does not formally claim priority to it. Ex.1025-FH077, 1-8; 37 C.F.R. § 1.78(a)(3) (requiring reference to provisional applications in application data sheet for priority); MPEP §211.02; *Droplets*, 887 F.3d at 1316-17 (requiring “specific reference” to identify relied-upon date with “minimum of effort”). Indeed, unlike prior applications, PO **dropped** a formal claim of priority to the '771 Provisional

⁹ For some (not all), preceding utility applications, PO only incorporated the '771 Provisional **by reference**. *E.g., compare* Ex.1016-USP283, Cover *with* Ex.1017-USP529, Cover.

during prosecution. *Compare* Ex.1016-USP283, Cover, 1:5-19 (listing '771 Provisional) *with* Ex.1017-USP529, Cover, 1:4-21 (not listing '771 Provisional).

Second, PO broke any priority chain to any preceding utility application referencing the '771 Provisional. Specifically, the '938, '209, and '893 Applications, do not claim priority to the '771 application (*see* Ex.1001-USP077, Cover, 1:6-32; Ex.1021-USP675, Cover; Ex.1022-FH675, 6; Ex.1023-USP011, Cover; Ex.1024-FH011, 6-7; Ex.1025-FH077, 6), and in two utility applications immediately preceding the '893 Application (U.S. App. Nos. 15/358,187 and 16/036,381), PO did not claim priority to the '771 Provisional or incorporate it by reference (*see* Ex.1017-USP529, 1:4-19; Ex.1018-FH529, 3, 10; Ex.1019-USP897, 1:4-21; Ex.1020-FH897, 3, 25). Absent continuity of disclosure, PO cannot rely on subject matter from the '771 Provisional for priority.¹⁰ *See Encyclopedia Britannica, Inc. v. Alpine Elecs. of Am., Inc.*, 609 F.3d 1345, 1351 (Fed. Cir. 2010) (where intermediate application failed to refer to first application, later applications could not claim priority to first); MPEP §211.02 (waiver of priority claim if “proper

¹⁰ Indeed, Examiner objected to Applicant's attempt to add the '771 Provisional to the '381 Application because it was new matter. Ex.1020-FH897, 183, 190, 203-205, 211.

reference to the prior application is not included in the later-filed application.”).¹¹ Instead, at most, added matter supports priority only as of the date it was added (here, October 22, 2019). *See Anascape*, 601 F.3d at 1340.

Third, by rule, PO cannot rely on incorporation by reference of the ’771 Provisional into any utility application before the ’893 Application for earlier written description support. *See* 37 C.F.R. §1.57(d) (2023); 37 C.F.R. §1.57(d) (2005).¹²

¹¹ PO’s addition of ’771 Provisional matter to the ’893, ’209, or ’938 applications and incorporation of earlier applications do not remedy this priority break. *See Hollmer v. Harari*, 681 F.3d 1351, 1355 (Fed. Cir. 2012) (“[I]f **any** application in the priority chain fails to make the requisite disclosure of subject matter, the later-filed application is not entitled to the benefit of the filing date of applications preceding the break....”); *Droplets*, 887 F.3d at 1320 (priority claim to immediately preceding application not enough for priority to separate provisional); *Akeva L.L.C. v. Nike, Inc.*, 817 F. App’x 1005, 1012 (Fed. Cir. 2020) (amending later applications does not avoid disclaimer by intervening application).

¹² Rule 1.57(d) provides “essential material” “necessary to: [p]rovide a written description of the claimed invention” “may be incorporated by reference” only though “a **U.S. patent or U.S. patent application publication.**” 37 C.F.R. §1.57(d)

See NRG Energy, Inc. v. Midwest Energy Emissions Corp., IPR2020-00832, Paper 17, 29-30 (P.T.A.B. Oct. 26, 2020) (even if “provisional application provides support..., [its] incorporation by reference [in priority applications] cannot cure the deficiencies”); *Focal Therapeutics, Inc. v. Senorx, Inc.*, IPR2014-00116, Paper 8, 11-12 (P.T.A.B. Apr. 22, 2014) (patent could not claim priority to provisional when patent did not incorporate provisional, but earlier utility application did (i.e., nested incorporation)). Here, **no** utility application preceding the ’893 Application copied ’771 Provisional material into its specification. Instead, a subset merely incorporated it by reference. Ex.1012-USP275, 1:4-10; Ex.1013-USP497, 1:4-12; Ex.1014-USP164, 1:4-14; Ex.1015-USP391, 1:4-15; Ex.1016-USP283, 1:4-17.

Last and importantly, even if PO could satisfy these technical requirements, the subject matter in the ’771 Provisional copied into the ’893 Application does not provide written description support.

Because the ’893 Application and ’771 Provisional are directed to use of **neurotoxins**, they do not disclose “*a radiofrequency generator...for **supplying radiofrequency energy** to the multiple radiofrequency electrodes **to treat a target***”

(2023); *see also* 37 C.F.R. §1.57(d) (2005). A provisional application is neither. *See* 37 C.F.R. §1.9(a)(2); 35 U.S.C. §122(b)(2)(a)(iii).

tissue in the nasal cavity and thus treat rhinitis.” Ex.1001-USP077, claim 1; *see also id.* (“*apparatus for treating rhinitis in a nasal cavity*”). Instead, those disclosures **solely** use energy to **porate** cells to facilitate neurotoxin delivery, not to treat nasal conditions. *See, e.g.,* Ex.1011-FH771, 56 (“systems...which selectively porate[] target cells to enhance uptake of the toxin”); Ex.1001-USP077, 8:10-18 (“[toxins] are delivered to a patient’s nasal membrane while applying energy to target cells” to “cause a reversible...poration of the cell membrane to enhance delivery of the toxin”).¹³ As Aerin—named licensee of the ’077 patent—represented

¹³ Notably, Applicant pursued patents directed to the ’771 Provisional subject matter in separate applications. Unlike the applications preceding the ’077 patent, these applications were substantially identical to the ’771 Provisional and incorporated the subject matter of the ’077 Provisional by reference. These applications claimed treating a nasal condition **with** not **without** neurotoxins. *See* Ex.1026-USP243; Ex.1029-USP817; Ex.1030-USP684; Ex.1031-Pub.233; Ex.1032-USP707; Ex.1033-USP465. Indeed, Applicant has consistently presented to the Office that in this family, neurotoxin reduces mucus and energy electroporates to increase neurotoxin uptake. *E.g.,* Ex.1028-FH684, 16-18, 21-22, 74-86; Ex. Ex.1002-Decl., ¶72.

during prosecution of another patent: “the **sole purpose** of applying energy described by [the ’771 Provisional] is to porate target cells to **enhance uptake of a nerve toxin.**” Ex.1034-FH221-Aerin, 786. As discussed above, Section V, energy used for RF ablation is “distinctly different from the pulses which produce electroporation,” Ex.1059-Rubinsky, [0005], and the ’893 Application and ’771 Provisional pertain at most to the latter. Ex.1002-Decl., ¶¶69-75.

The priority date of the Challenged Claims is thus no earlier than October 22, 2019.

X. OVERVIEW OF THE ASSERTED PRIOR ART

A. Saadat

Saadat discloses “ablating” “tissue...within the nasal cavity for treating” rhinitis. Ex.1003-Saadat, 1:21-26. Saadat explains ablating posterior nasal nerves “leads to a decrease in or interruption of parasympathetic nerve signals that contribute to congestion and rhinorrhea....” *Id.*, 3:6-14. Figure 20E depicts an RF probe “configured for ablation of the parasympathetic nervous function....” *Id.*, 30:34-38, 31:10-19.

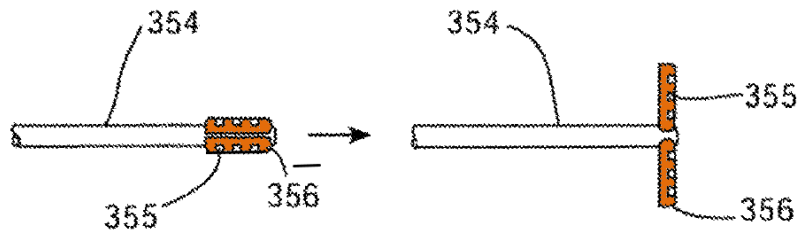


Figure 20E

Ex.1003-Saadat, FIG.20E. Figure 30 shows the probe positioned to target nerves in the posterior portion of the passage including the nasal cavity and nasopharynx. *Id.*, 14:8-10, 16:20-22, 27:10-20, 33:41-49, FIG.14B, FIG.30.

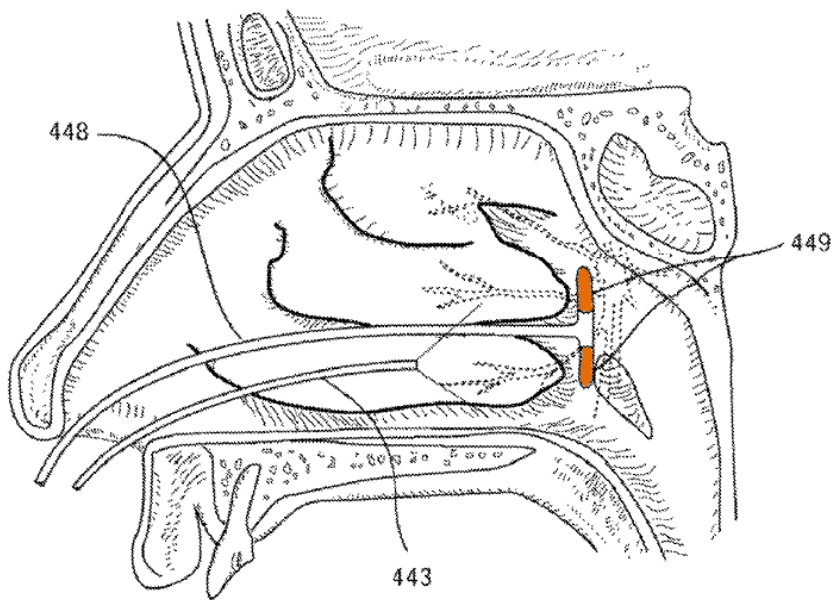


Figure 30

Ex.1003-Saadat, FIG.30. Ex.1002-Decl., ¶78.

B. Stern

Stern discloses an apparatus with an expandable member including multiple “pairs” of **bipolar RF electrodes**. Ex.1009-Stern, 2:26-40, 3:29-40, 12:7-13:55, claim 4, FIG.13, FIG.15, FIGs.17-18. Stern Figure 15 depicts circuitry for two pairs (220-224 and 222-226) of **bipolar radiofrequency electrodes**. *Id.*, 12:41-13:2.

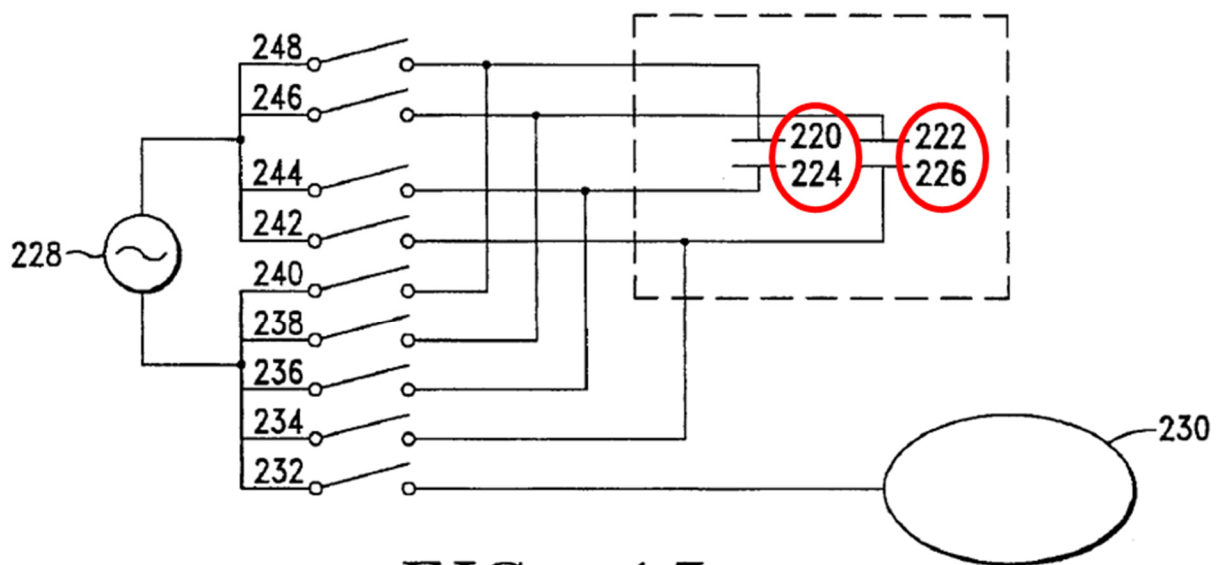


FIG. – 15

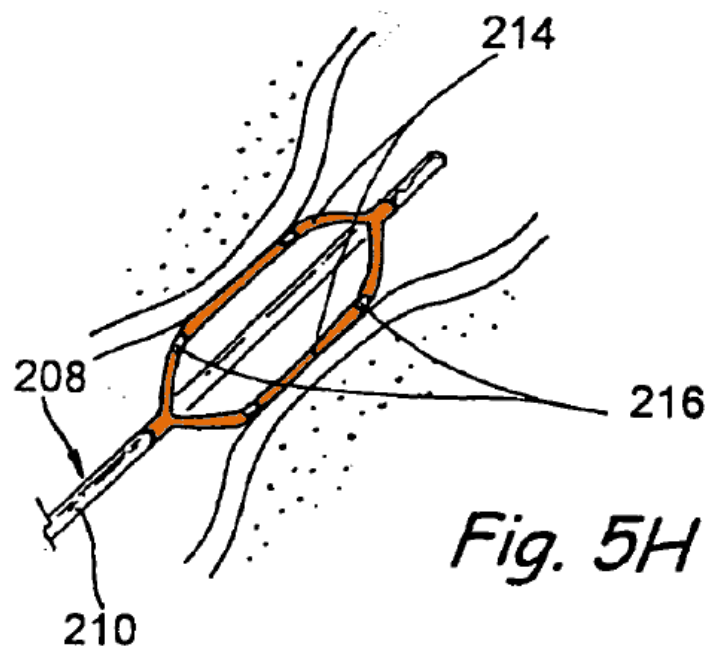
Ex.1009-Stern, FIG.15. Ex.1002-Decl., ¶79.

C. Deem

Deem is a published application that includes the written description and figures of the '771 Provisional. *Compare* Ex.1004-Deem and Ex.1027-FH243, 4-65 *with* Ex.1001-USP077 and Ex.1011-FH771.

D. Makower

Makower teaches “medical devices...for treating sinusitis and other ear, nose & throat disorders.” Ex.1005-Makower, [0001]. Makower teaches electrosurgical devices “to perform diagnostic or therapeutic procedures.” *Id.*, [0161]. Makower Figure 5H depicts a device for the nasal cavity or nasopharynx with **strut members 214** with multiple bipolar electrodes 216. *Id.*, [0043], [0161], [0187].



Ex.1005-Makower, FIG.5H. The **strut members 214** expand to contact surrounding tissue, and “current is applied” causing tissue “to be cauterized or heated.” *Id.*, [0187]. “[S]ensing elements” “monitor various parameters of the...surrounding tissue (e.g., temperature, etc.).” *Id.* Ex.1002-Dec1., ¶80.

E. Fang

Fang teaches “nasal endoscopic surgery combined with multiple radiofrequency” to treat “perennial allergic rhinitis.” Ex.1006-Fang, 876-877. Fang aligns a “firing head” “with the sphenopalatine foramen” and “carr[ies] out radiofrequency at the anterior upper part of the nasal septum....” *Id.*, 876. This “block[s] the posterior parasympathetic fibers of the sphenopalatine nerve” and “parasympathetic pathway of the nasal mucosa,” which “reduces glandular secretion,” and reduces rhinitis symptoms. *Id.*, 877. Ex.1002-Decl., ¶81.

F. Edwards-535

Edwards-535 teaches “an apparatus for ablating a nasal concha,” e.g., turbinates, including “catheter body 126” with “distal portion 128” and “energy delivery device 134.” Ex.1008-Edwards-535, 7:28-36, 8:17-25. “[E]nergy source 162” provides energy to “**electrodes 156**” to “generate[] RF energy [to] ablate[] the turbinate by heat and cell destruction.” *Id.*, 8:17-25, 8:47-53, FIGs.5-6. “Signal generator 165” generates RF energy pulses according to various parameters. *Id.*, 8:54-9:13, 11:46-12:4.

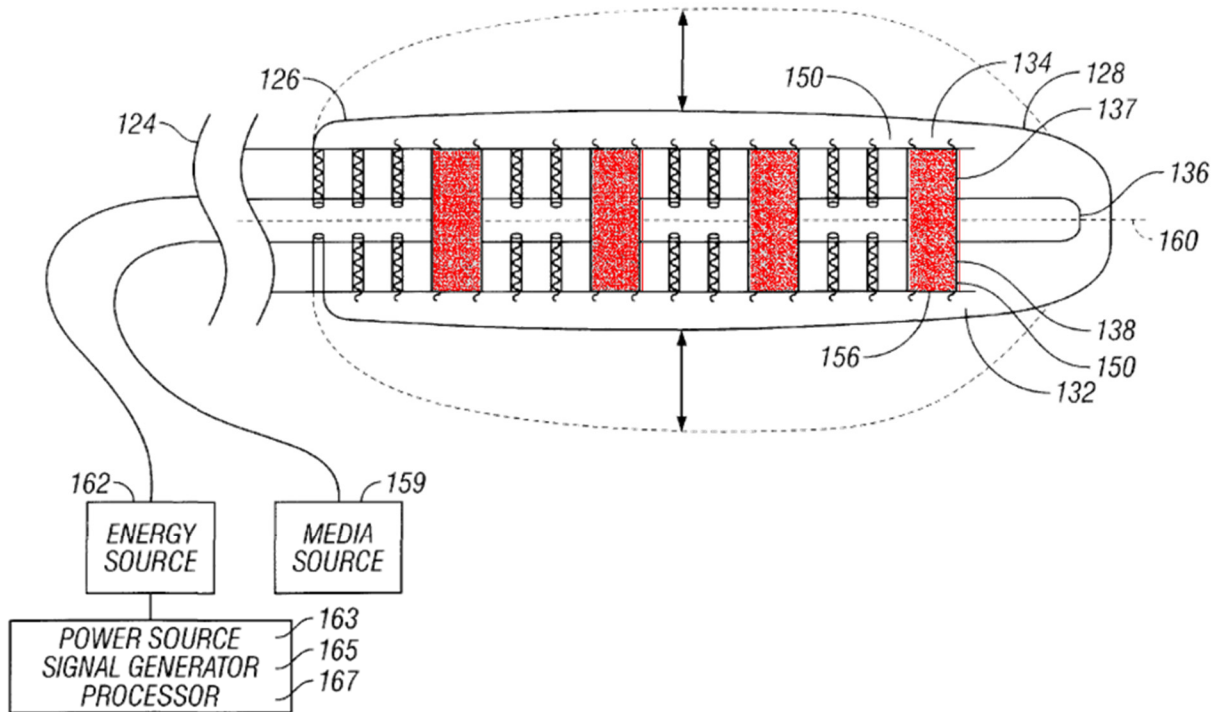


FIG. 6

Ex.1008-Edwards-535, FIG.6. Ex.1002-Decl., ¶82.

XI. SPECIFIC GROUNDS FOR UNPATENTABILITY

Pursuant to Rule 42.104(b)(4)-(5), and as confirmed by Dr. Bu-Saba (Ex.1002), the prior art anticipates and renders obvious every limitation of the Challenged Claims.

A. Ground I: Claims 1-8 and 11 Are Anticipated by Saadat

The Challenged Claims are anticipated because Saadat discloses all their elements arranged as in the claims. *See Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1341 (Fed. Cir. 2016).

1. Claim 1

a. 1[pre]

If the preamble is limiting, Saadat discloses an *apparatus* (e.g., RF ablation probe) *for treating rhinitis* (e.g., rhinitis) *in a nasal cavity* (e.g., passage including posterior nasal nerve). Ex.1002-Decl., ¶84.

Saadat discloses “apparatus[es]...for treating conditions such as rhinitis.” Ex.1003-Saadat, Abstract, Title (“Apparatus...for treating rhinitis”), 1:21-26, 2:16-24, 3:6-14, 10:16-11:14, claims 1 (“treating nerve tissue within a nasal cavity”), 6 (“delivering...energy-based treatment...such that at least one symptom of rhinitis is reduced”); Ex.1001-USP077, 3:13-16 (rhinitis is “condition” in “nasal cavity”). Ex.1002-Decl., ¶85.

Saadat discloses an **RF ablation probe** with a **distal end** with “a bi-polar electrode ablation element 355 on a user deployable ‘T’ shaped structure 356.” Ex.1003-Saadat, 30:34-38, 31:10-19; *see also id.*, 10:16-26, 11:1-14, 33:41-49 (FIG. 30 illustrates “ablation of the posterior nasal nerve using a generic ‘T’ tipped ablation device...”).

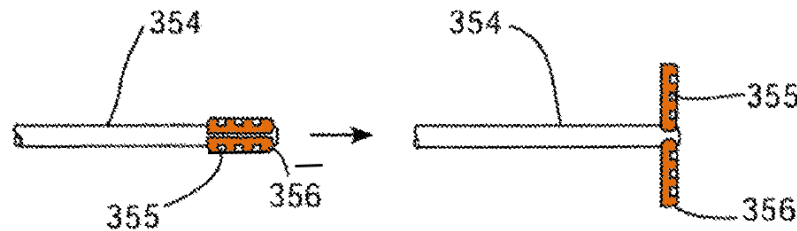


Figure 20E

Ex.1003-Saadat, FIG.20E. Ex.1002-Decl., ¶86.

Figure 30 (below) illustrates a “T” ablation device positioned to target the “posterior nasal nerve,” which is posterior to turbinates. Ex.1003-Saadat, 33:41-49; *see also id.*, 16:20-22. These nerves (in Figure 14B below) originate from the SPG and control parasympathetic nervous functions (i.e., mucus production and congestion). *Id.*, 16:39-51, 27:10-20. Saadat explains “[a]blating these nerves leads to a decrease in or interruption of parasympathetic nerve signals that contribute to congestion and rhinorrhea in patients with chronic rhinitis....” *Id.*, 1:62-66, 3:6-10. Saadat discloses devices that “ablate a single nerve branch or multiple nerve branches,” including the “posterior nasal nerve,” to “reduce or eliminate rhinitis. *Id.*, 3:10-14, 4:17-21. In the Figure 30 embodiment, the “T” device’s distal end is placed proximate to the posterior nasal nerve to ablate parasympathetic nervous function. *Id.*, 30:34-38, 31:10-19, 33:41-49.

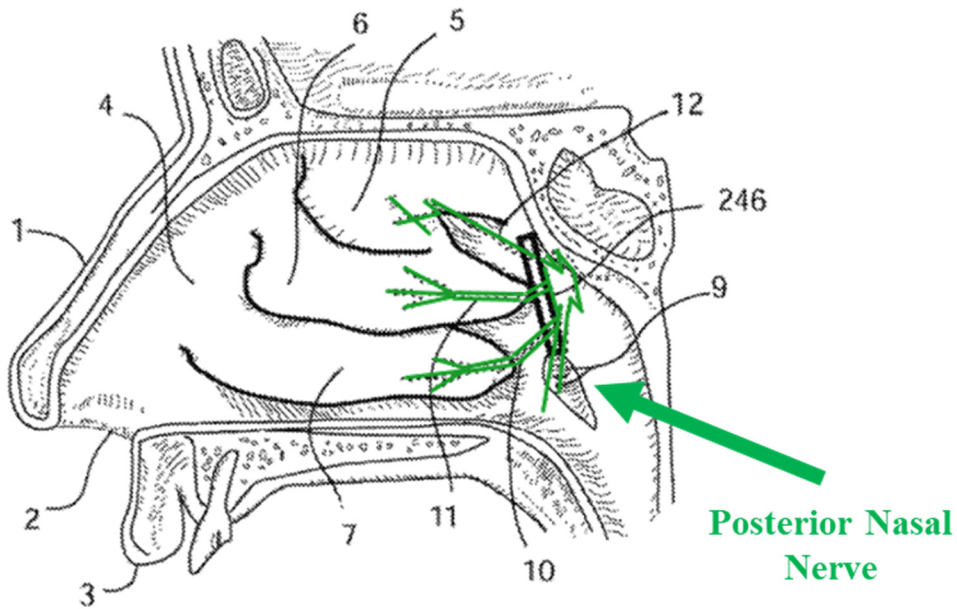


Figure 14B

Ex.1003-Saadat, FIG.14B.

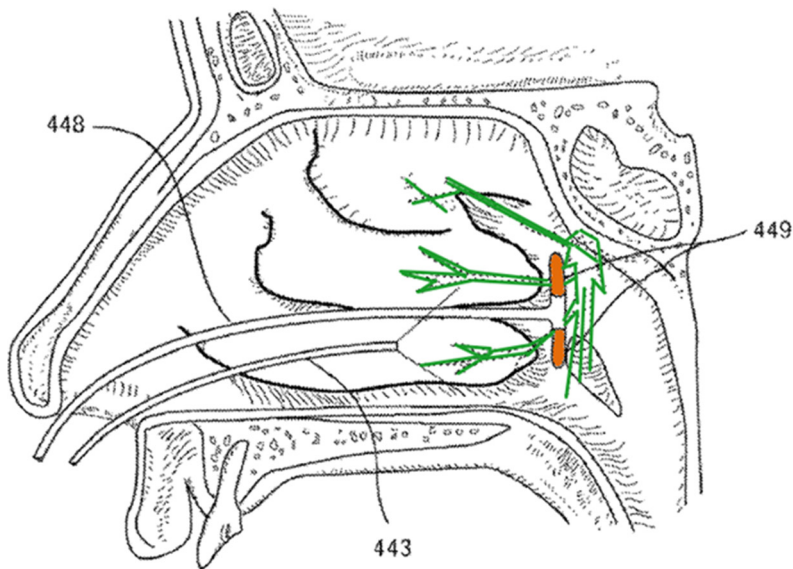
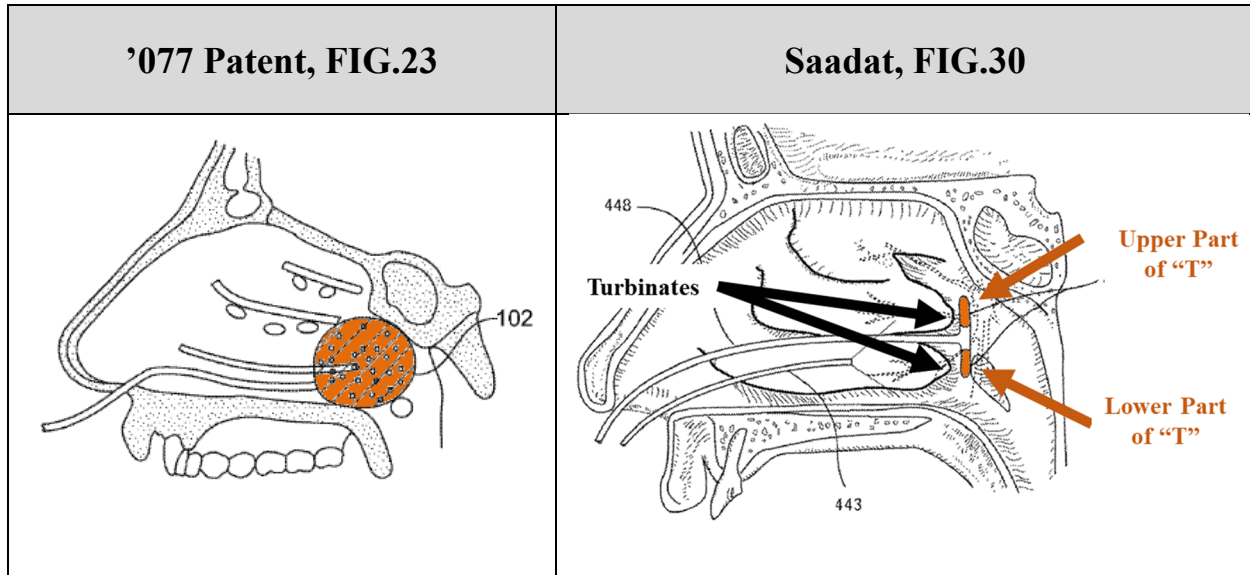


Figure 30

Ex.1003-Saadat, FIG.30B. Ex.1002-Decl., ¶¶87-89.

The **distal end** of Saadat's device is positioned in the *nasal cavity* to target the **posterior nasal nerve**, and *treat rhinitis* by applying RF energy. *E.g.*, Ex.1003-Saadat, FIG.14B, FIG.30, 30:34-38, 31:10-19, 33:41-49; claims 1 (“contacting a mucosal surface of the nasal cavity with the treatment delivery portion,” “delivering an energy-based treatment,” and “treat[ing] the nerve tissue underlying the mucosal surface”), 7. Ex.1002-Decl., ¶¶90-91.

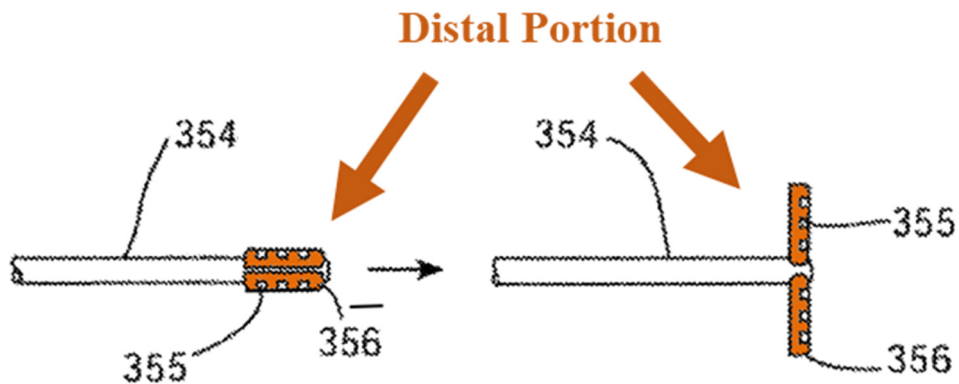
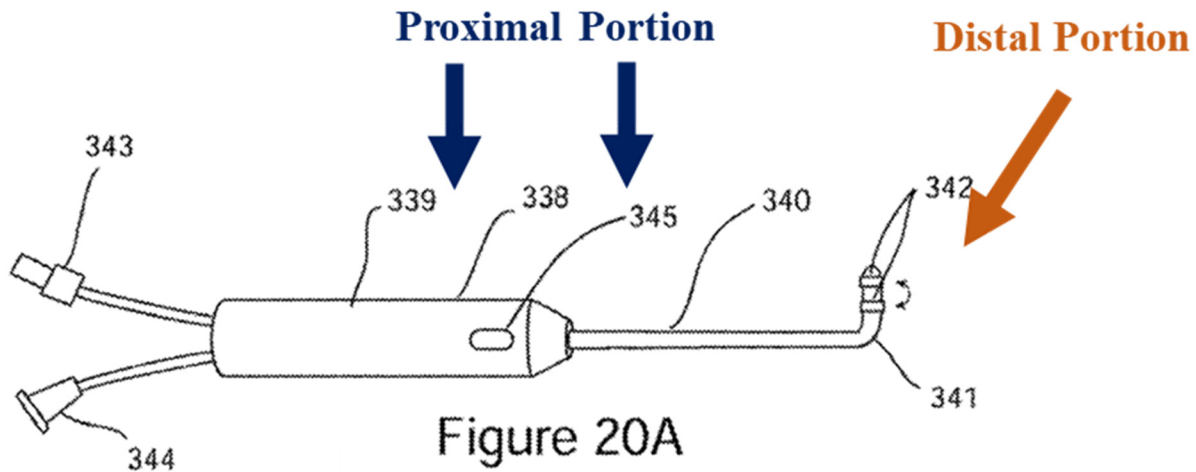
As shown below, the **distal end** of Saadat's device is in the location the '077 patent identifies as the “nasal passage.” *See* Ex.1001-USP077, 24:4-11, FIG.23. The T's upper part is proximate to posterior *nasal cavity* tissue, and the lower part is proximate to nasopharynx tissue. Ex.1002-Decl., ¶92.



b. 1[a]

Saadat discloses *an elongate body, comprising a proximal portion* (e.g., handle or probe shaft) *and distal portion* (e.g., **distal end**) *configured for positioning in the nasal cavity*. Ex.1002-Decl., ¶93.

Saadat discloses an RF ablation probe with “handle 339” and “probe shaft 340” in a *proximal portion* and RF ablation elements at a *distal portion*. Ex.1003-Saadat, 30:34-47; *see also id.*, 10:15-11:14. Saadat discloses multiple embodiments of its probe: Figure 20A includes a “J” shape, and Figure 20E includes a “T” shape (*see* Section XI.A.1.a). Ex.1003-Saadat, 31:10-19, FIG.20E; *see also id.*, 11:1-14, 14:66-15:2; 15:18-21, 33:41-49, FIG.30. In each, the handle and shaft are at the proximal end and probe is at the distal end. *See id.*



Ex.1003-Saadat, FIG.20A, FIG.20E; *see also id.*, claims 1, 2-4, 6-7, 11-12.

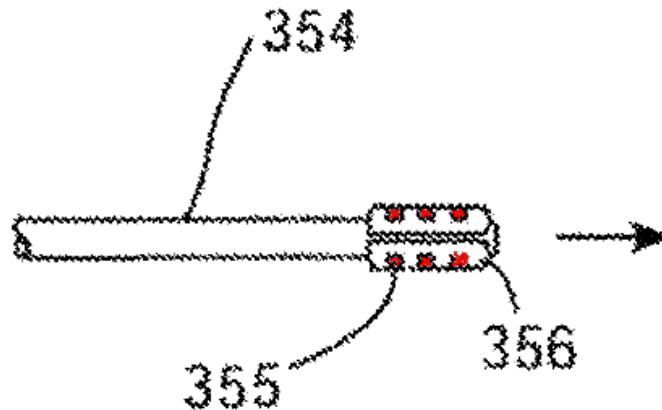
Ex.1002-Decl., ¶¶94-95, 97-98.

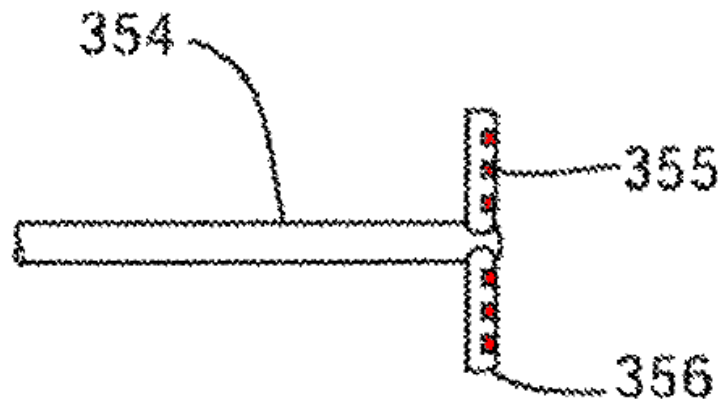
As Section XI.A.1.a details, Saadat discloses *positioning* the **distal end** of its “T” shaped **RF ablation probe** of Figure 20E proximate to *nasal cavity* tissue. *E.g.*, Ex.1003-Saadat, FIG.14B, FIG.20E, FIG.30, 30:34-38, 31:10-19, 33:41-49. Ex.1002-Decl., ¶¶96.

c. 1[b]

Saadat discloses *multiple radiofrequency electrodes* (e.g., electrodes) *coupled with the distal portion* (e.g., distal end) *of the elongate body*. Ex.1002-Decl., ¶99.

The **distal end** of Saadat’s RF ablation probe includes multiple *electrodes* “configured for **ablation of the parasympathetic nervous function[s]**.” Ex.1003-Saadat, 30:34-38, 31:10-19, 33:41-29; *see also id.*, 10:16-26, 30:47-49, 32:62-33:3. This **distal end** includes **electrodes 355** that “operate in a monopolar, bipolar or multipolar fashion.” *Id.*, 31:10-19, 33:41-49 (“RF ablation elements”), FIG.20E, FIG.30; *see also id.* claims 3-4, 9 (“plurality of electrodes” “delivering...radiofrequency energy”), 10-12.





Ex.1003-Saadat, FIG.20E. Ex.1002-Decl., ¶¶100-102.

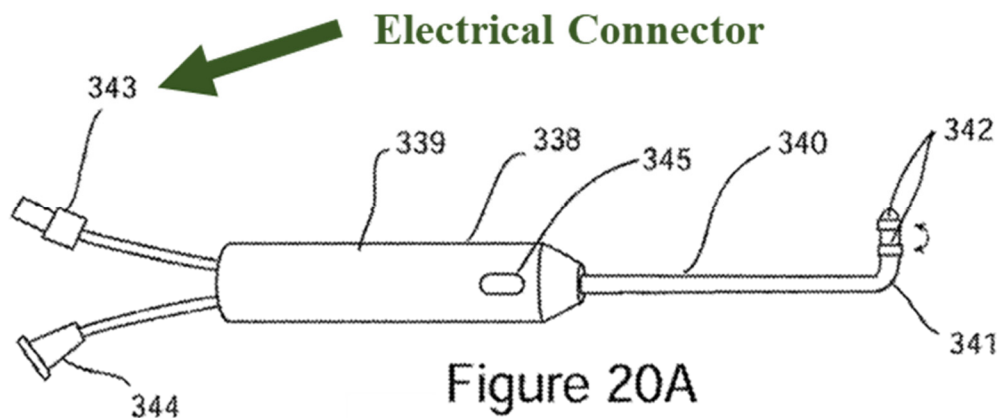
d. 1[c]

Saadat discloses *a radiofrequency generator* (e.g., radiofrequency energy generator) *coupled with the proximal portion of the elongate body* (e.g., handle or probe shaft) *for supplying radiofrequency energy* (e.g., RF energy) *to the multiple radiofrequency electrodes* (e.g., electrodes) *to treat a target tissue* (e.g., tissue including the posterior nasal nerve) *in the nasal cavity and thus treat rhinitis*. Ex.1002-Decl., ¶103.

As Sections XI.A.1.a-c detail, Saadat discloses *positioning the distal end* of its “T” shaped **RF ablation probe** with electrodes “**configured for ablation of the parasympathetic nervous function[s]**” proximate to *nasal cavity* tissue. *E.g.*, Ex.1003-Saadat, 10:16-26, 11:1-14, 30:34-38, 31:10-19, 33:41-49, FIG.14B, FIG.30, claims 1, 6, 7. Ex.1002-Decl., ¶104.

Saadat explains RF ablation reduces or eliminates rhinitis symptoms (e.g., *treats rhinitis*). Saadat teaches nasal nerves (made up of nerve cells) originating from the SPG “are responsible for parasympathetic control of the nasal mucosa” (Ex.1003-Saadat, 16:44-51), and “**ablating** one or more...[nerve] branches” “reduce[s] or eliminate[s] rhinitis.” *Id.*, 3:6-14; *see also id.* (“**Ablating these nerves** leads to a **decrease in or interruption of parasympathetic nerve signals** that contribute to congestion and rhinorrhea....”). Ex.1002-Decl., ¶¶105-106.

Saadat’s RF ablation probe includes “**electrical connector 343**” “configured for connection to a [commercially available] radiofrequency energy generator.” Ex.1003-Saadat, 30:47-49; *see also id.*, 10:16-11:14, 12:5-5-14.



Ex.1003-Saadat, FIG.20A. Ex.1002-Decl., ¶107.

Saadat discloses the radiofrequency generator supplies energy to Saadat’s electrodes *to treat target tissue in the nasal cavity*. As Sections XI.A.1.a-c discuss, Saadat teaches using RF electrodes to ablate nasal cavity tissue. Saadat further

teaches “those skilled in the art of RF ablation probes are familiar” with using various components (Ex.1003-Saadat, 30:41-47) and that RF electrodes are connected to and derive power from an RF generator (*id.*, 12:5-5-14, 30:41-47). A POSITA operating well-known RF electrodes for the disclosed purpose of ablation would have understood Saadat to disclose configuring RF electrodes with its radiofrequency generator to perform that function. Indeed, the ’077 patent assumes a POSITA would have understood this application, as it generically describes an electroporation generator and using RF without implementation details, such as selection of particular parameters. *E.g.*, Ex.1001-USP077, 14:24-36. Ex.1002-Decl., ¶¶108-110.

Saadat therefore discloses applying *RF energy* from an *RF generator* to *nasal cavity tissue* via *multiple RF electrodes* in its probe and doing so reduces or eliminates (e.g., *treats*) *rhinitis* symptoms. Ex.1002-Decl., ¶111.

Correspondingly, Saadat claims “delivering an energy-based treatment from the treatment delivery portion to treat the nerve tissue underlying the mucosa surface [in the nasal cavity],” including delivering “radiofrequency” energy to reduce “at least one symptom of rhinitis.” Ex.1003-Saadat, claims 1, 6; *see also id.*, claims 2 (“delivering...energy-based treatment to treat the nerve tissue underlying the mucosal surface”), 7 (nerve tissue includes “posterior nasal nerve, a branch of a

vidian nerve, a parasympathetic nerve, [or]...a sphenopalatine ganglion nerve”), 8 (“delivering...bipolar radiofrequency energy”). Ex.1002-Decl., ¶112.

Accordingly, Saadat anticipates claim 1.

2. Claim 2

Claim 2 depends from claim 1. Petitioners incorporate Section XI.A.1.

Saadat discloses *multiple radiofrequency electrodes comprising at least two bipolar radiofrequency electrodes*. As Section XI.A.1.c details, the **distal end** of Saadat’s RF ablation probe includes multiple bipolar **electrodes**. *E.g.*, Ex.1003-Saadat, 30:34-38, 31:10-19, 33:41-29; *see also id.*, 10:16-26, 30:47-49, 32:62-33:3, FIG.20E, FIG.30, claims 3-4, 9, 10-12. Ex.1002-Decl., ¶¶113-114.

3. Claim 3

Claim 3 depends from claim 2. Petitioners incorporate Section XI.A.2.

Saadat discloses *at least one sensing electrode*. Saadat’s probe “may...be configured with at least one temperature sensor disposed in the vicinity of the distal end.” Ex.1003-Saadat, 6:35-37; *see also id.*, 17:56-59. Saadat also claims an RF ablation probe with a “thermocouple,” i.e., temperature sensing electrode, “in a vicinity of the treatment delivery portion.” *Id.*, claim 5. It was well-known that an electrode is a conductor, and that a thermocouple comprises two dissimilar metals (i.e., conductors) joined together. *E.g.*, Ex.1063-Cosman, Abstract (describing “two

metal elements which are the two sides of the thermocouple junction” located “in part on the external surface of the electrode’s lesioning tip”). Saadat thus discloses a thermocouple, which is a *sensing electrode*. Ex.1002-Decl., ¶¶115-116.

4. Claim 5

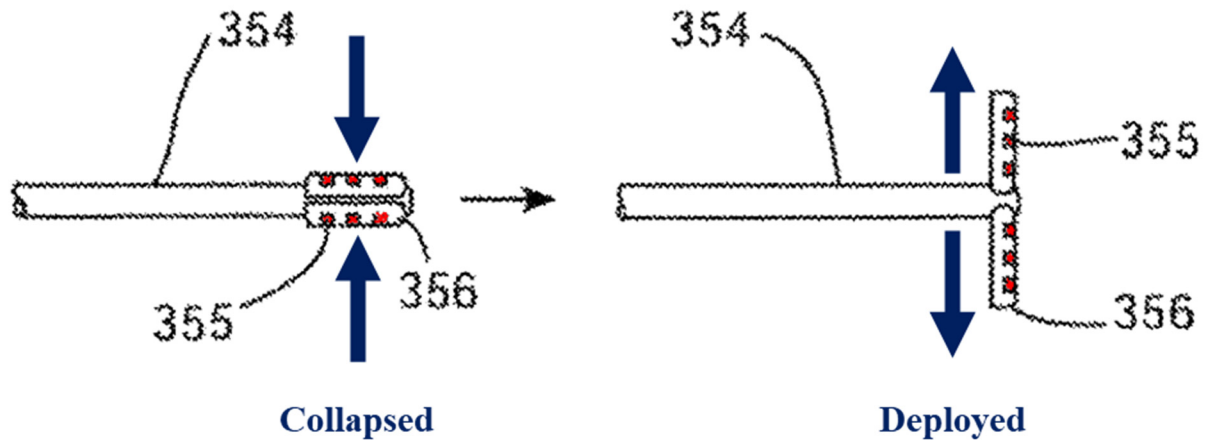
Claim 5 depends from claim 1. Petitioners incorporate Section XI.A.1.

Saadat discloses *target tissue compris[ing] nerve tissue*. As Section XI.A.1 details, Saadat’s RF ablation probe is positioned in the *nasal cavity* to target the *posterior nasal nerve* (e.g., *nerve tissue*). E.g., Ex.1003-Saadat, FIG.14B, FIG.30, 30:34-38, 31:10-19, 33:41-49; claims 1 (“treat[ing] the nerve tissue underlying the mucosal surface”), 7. Ex.1002-Decl., ¶¶117-118.

5. Claim 6

Claim 6 depends from claim 1. Petitioners incorporate Section XI.A.1.

Saadat discloses *radiofrequency electrodes movable relative to the distal portion of the elongate body*. Saadat’s “T” shaped tip is a deployable electrode structure 356 with “two halves [that] can alternately be collapsed and deployed as in FIG. 20E.” Ex.1003-Saadat, 31:10-16. Saadat explains “the two halves...are pivoted to allow them to move laterally relative to the catheter shaft 354,” and each half contains monopolar or bipolar *electrodes 355*. *Id.*, 31:16-19, 33:41-49, FIG.30.



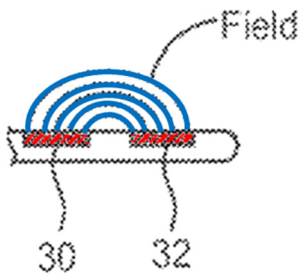
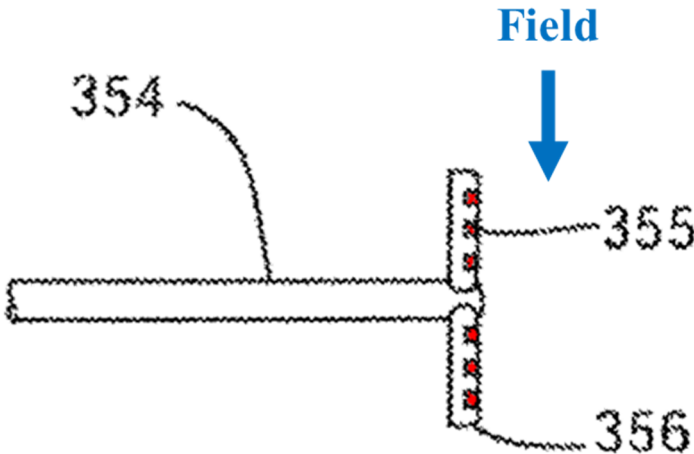
Ex.1003-Saadat, FIG.20E. Ex.1002-Decl., ¶¶119-120.

6. Claim 7

Claim 7 depends from claim 1. Petitioners incorporate Section XI.A.1.

Saadat discloses *multiple radiofrequency electrodes configured to deliver energy laterally relative to the distal portion of the elongate body*. As Sections XI.A.1.c, XI.A.2, and XI.A.5 detail, the distal end of Saadat's probe includes multiple **bipolar electrodes 355** that deliver RF energy. *E.g.*, Ex.1003-Saadat, 31:10-19, 33:41-49, FIG.20E, FIG.30, claims 1, 3-4, 9, 10-12. A POSITA would have understood that bipolar electrodes are conductors that facilitate RF current traveling from one electrode to another to create an electrical field. In Saadat, a POSITA would have understood that current travels from one **electrode** to another **electrode** to create an electrical field that travels through the contacted tissue. The current (*energy*) in this field is *delivered laterally relative to the distal portion of Saadat's*

device (i.e., into the target tissue and above and below the probe). In this way, Saadat concentrates energy laterally just as similarly arranged electrodes do in '077 patent Figure 5A. *E.g.*, Ex.1001-USP011, 16:29-58, FIG.5, FIGs.5A-5B; Ex.1003-Saadat, 30:34-55, 31:10-19, Fig.20E. Ex.1002-Decl., ¶¶121-123.

'077 Patent, FIG.5A	Saadat, FIG.20E
 FIG. 5A	

Foundry alleges in parallel litigation that delivering RF energy from bipolar electrodes meets this limitation. Ex.1038-Complaint-Ex.Z, 13-15. Thus, consistent with the '077 patent and Foundry's allegations, and without concession regarding infringement, Saadat discloses its electrodes *deliver RF energy laterally* into target tissue *relative to the distal portion of the distal end* of Saadat's probe.

7. Claim 8

Claim 8 depends from claim 1. Petitioners incorporate Section XI.A.1.

Saadat discloses *multiple radiofrequency electrodes configured to extend laterally from the distal portion of the elongate body*. As Section XI.A.6 details, Saadat’s “T” shaped structure includes two halves with **electrodes** that expand from a collapsed position at the shaft’s distal portion, i.e., *extend laterally*. E.g., Ex.1003-Sadat, 31:10-19; *see also id.*, 33:41-49, FIG.30. Ex.1002-Decl., ¶¶124-125.

8. Claim 11

Claim 11 depends from claim 1. Petitioners incorporate Section XI.A.1.

Saadat discloses *a monitoring system coupled with the distal portion of the elongate body for monitoring a degree of treatment of the target tissue*. As Section XI.A.3 details, Saadat discloses and claims an RF ablation probe including a thermocouple temperature sensor. Such “temperature sensor” “monitor[s]...a temperature of the tissue region...under treatment.” Ex.1003-Saadat, 23:1-6. A POSITA would have understood that a physician monitoring temperature of target tissue would be monitoring the degree that tissue was being treated. For example, a POSITA would use an ablation device until tissue reached a particular target temperature that indicated the tissue was ablated. Ex.1002-Decl., ¶¶126-127.

B. Ground II: Saadat Renders Claims 3 and 11 Obvious

As Ground I details, Saadat anticipates claims 3 and 11. To the extent PO argues otherwise, Saadat renders these claims obvious. Ex.1002-Decl., ¶128.

1. Claim 3

Claim 3 depends from claim 2. Petitioners incorporate Sections XI.A.2.

Ex.1002-Decl., ¶129.

To the extent PO argues Saadat does not disclose a device with *at least one sensing electrode*, Saadat renders such device obvious. As Section XI.A.3 discusses, Saadat's probe "may...be configured with at least one temperature sensor disposed in the vicinity of the distal end." Ex.1003-Saadat, 6:35-37. Saadat Figure 2 depicts a probe for cryoablating posterior nasal nerves, including "a temperature sensor" "in the vicinity of distal end" to sense tissue temperature. *Id.*, 16:51-54, 17:56-59, 17:62-64. Saadat also claims a "**thermocouple**," i.e., temperature sensor, "in a vicinity of the [device's] treatment delivery portion." *Id.*, claim 5. As Section XI.A.3 details, it was well-known that a thermocouple (junction of two conductors) is an electrode. *E.g.*, Ex.1063-Cosman, Abstract. Ex.1002-Decl., ¶130.

A POSITA would have been motivated to position a thermocouple (i.e., temperature-sensing electrode) on the distal end of Saadat's probe to monitor tissue temperature as Saadat teaches. A POSITA would have understood that monitoring tissue temperature during RF application was a means for measuring the degree of treatment and assuring patient safety, and placing temperature sensors at the distal end of ablation devices was a well-known, routine way to do so. *E.g.*, Ex.1062-

Townley, [0044] (“therapeutic assembly” with “one or more temperature sensors (e.g., thermocouples, thermistors, etc.)”); Ex.1005-Makower, [0187]. Ex.1002-Decl., ¶131.

A POSITA would have had a reasonable expectation of successfully including a temperature sensor on the distal end of Saadat’s probe. Saadat teaches doing so and including temperature sensors such as thermocouples on such probes was well known. *E.g.*, Ex.1003-Saadat, 16:51-54, 17:56-59, 17:62-64, claims 1, 5. A POSITA would have understood that including a thermocouple (i.e., *sensing element*) was simply using one known device (thermocouple) with another (RF ablation probe) to obtain the predictable result of measuring tissue temperature when applying energy. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007); *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1372 (Fed. Cir. 2011) (finding obviousness where missing limitation “nothing more than a **predictable variation**” on prior art). Moreover, the ’077 patent assumes POSITAs would have understood how to implement a monitoring sensor, as it generically describes its “systems may include electrodes or other monitoring systems” without implementation details. Ex.1001-USP077, 18:37-42; *Uber Techs., Inc. v. X One, Inc.*, 957 F.3d 1334, 1339 (Fed. Cir. 2020) (specification silence on implementation “suggest[s]” POSITA

“more than capable of selecting between the known methods.”). Ex.1002-Decl., ¶¶132-133.

2. Claim 11

Claim 11 depends from claim 1. Petitioners incorporate Section XI.A.1.

To the extent PO argues Saadat does not expressly disclose a device with *a monitoring system coupled with the distal portion of the elongate body for monitoring a degree of treatment of the target tissue*, Saadat would have rendered it obvious. As Sections XI.A.3 and XI.B.1 detail, Saadat teaches or suggests a thermocouple on the Saadat probe distal end to measure tissue temperature. Saadat explains temperature sensors “monitor...a temperature of the tissue region...under treatment.” Ex.1003-Saadat, 23:1-6. And POSITAs would have understood that a physician would monitor the degree to which tissue was being treated by monitoring its temperature. Ex.1002-Decl., ¶¶134-135.

A POSITA would have been motivated to couple a thermocouple (i.e., temperature sensor) to a monitoring system, to use it for its intended purpose, i.e., to indicate tissue temperature to the physician. As Section XI.B.1 discusses, monitoring tissue temperature of sensors was a well-known and routine means of measuring degree of treatment and protecting patient safety. *E.g.*, Ex.1062-Townley, [0114] (“temperature sensor 1252 (e.g., a thermocouple)” used to

“provide feedback that may be used to control” device operation). Ex.1002-Decl., ¶136.

A POSITA would have had a reasonable expectation of successfully coupling a temperature sensor on the Saadat probe distal end to a monitoring system. Saadat teaches temperature sensors to monitor tissue temperature and using monitoring systems to do so when applying RF energy was well-known and routine. *E.g.*, Ex.1003-Saadat, 23:1-6. A POSITA would have understood including such monitoring system was simply using one known device (monitoring system) with another (RF ablation probe with thermocouple(s)) to obtain the predictable result of monitoring tissue temperature when applying energy. *See KSR*, 550 U.S. at 417; *Tokai*, 632 F.3d at 1372. Moreover, the '077 patent assumes POSITAs would have understood how to implement monitoring systems, as it generically describes its “systems may include electrodes or other monitoring systems” without implementation details. Ex.1001-USP077, 18:37-42; *Uber*, 957 F.3d at 1339 (Fed. Cir. 2020). Ex.1002-Decl., ¶¶137-138.

C. Ground III: Saadat and Stern Render Claim 4 Obvious

1. Claim 4

Claim 4 depends from claim 2. Petitioners incorporate Section XI.A.2. The combination of Saadat and Stern teaches *at least two bipolar radiofrequency*

electrodes comprising multiple pairs of bipolar radiofrequency electrodes.

Ex.1002-Decl., ¶¶139-140; Ex.1007-Decl., ¶50.

As Sections XI.A.1.c and XI.A.2 detail, Saadat's probe includes multiple **bipolar electrodes 355** that deliver RF energy. *E.g.*, Ex.1003-Saadat, 31:10-19, 33:41-49, FIG.20E, FIG.30, claims 1, 3-4, 9-12. Ex.1002-Decl., ¶141; Ex.1007-Decl., ¶¶51-54.

Stern teaches "selective delivery of...bipolar RF energy to chosen **pairs** of an array of **separate [bipolar] electrodes**...." Ex.1009-Stern, 2:36-40; *see also id.*, 3:29-40, 12:7-13:55, claim 4, FIG.13, FIG.15, FIGs.17-18. Stern discloses, *e.g.*, an apparatus with an array of surface **RF electrodes**. *Id.*, 2:26-35. Stern depicts one exemplary bipolar pair in Figure 17 (below). *Id.*, 2:36-40.

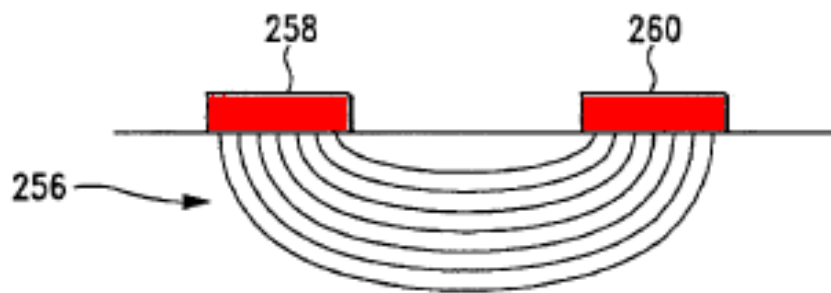


FIG.-17

Ex.1009-Stern, FIG.17. Ex.1002-Decl., ¶142; Ex.1007-Decl., ¶55.

Stern Figure 15 depicts circuitry for *two pairs of bipolar radiofrequency electrodes* connected to a voltage source, i.e., generator. Ex.1009-Stern, 12:41-13:2. Depending on switch configuration, current either flows “from electrode 220 to electrode 224,” i.e., a first pair, or “between electrodes 222 and 226,” i.e., a second pair. *Id.*, 12:55-13:2.

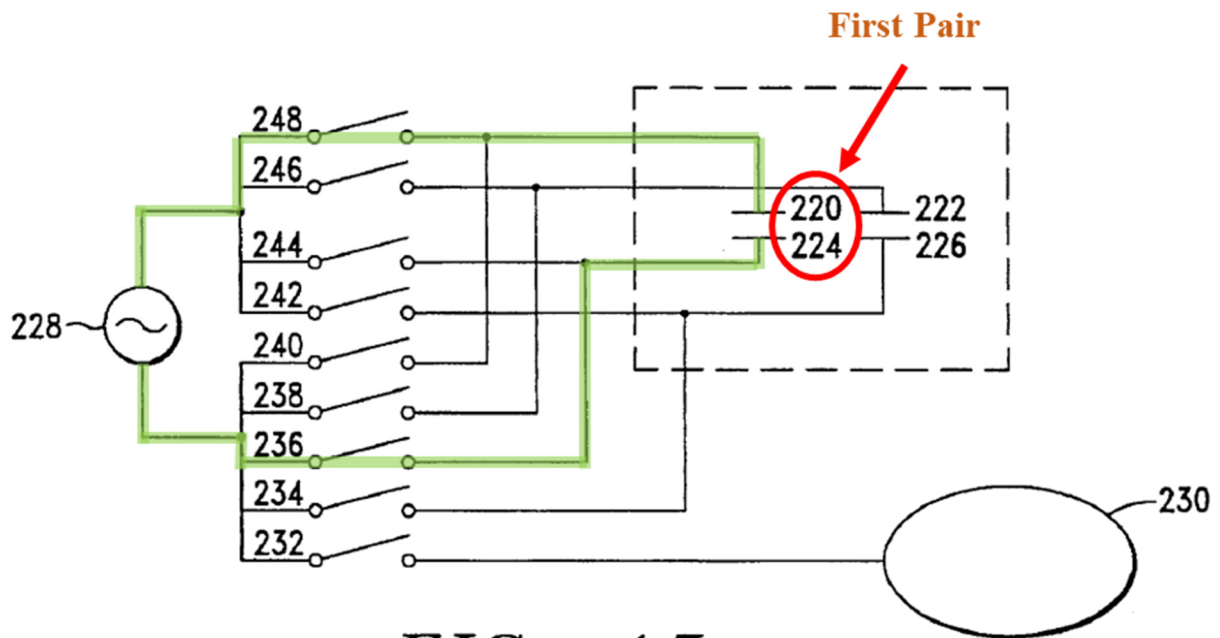


FIG. – 15

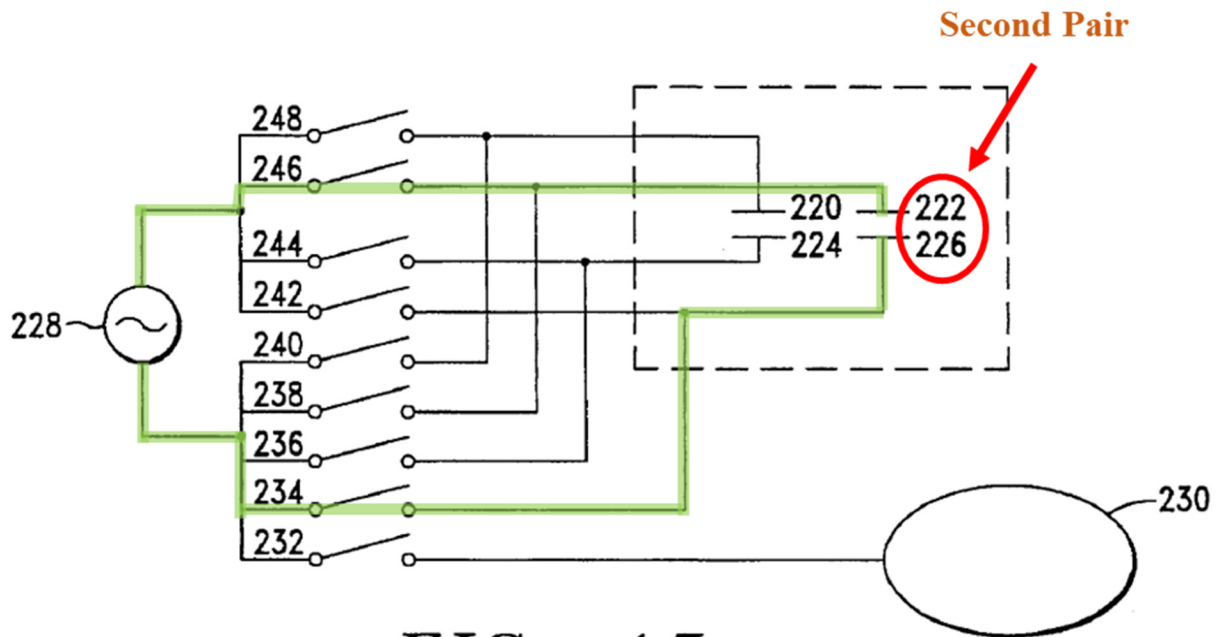


FIG. – 15

Ex.1009-Stern, FIG.15. Ex.1002-Decl., ¶143; Ex.1007-Decl., ¶56.

Saadat and Stern are analogous art, and a POSITA would have been motivated to combine them with a reasonable expectation of success. *See Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1004 (Fed. Cir. 2023). Ex.1002-Decl., ¶¶144-150; Ex.1007-Decl., ¶57.

First, Saadat and Stern are analogous art to the Challenged Claims. Each is in the same field as and is reasonably pertinent to solving the problems addressed in the Challenged Claims—treating tissue—with the same types of solutions—applying energy. *See* Ex.1001-USP077, claim 1. Each teaches devices that apply energy to tissue for treatment. Ex.1003-Saadat, Abstract, 1:21-26, 3:6-14, 10:16-

11:14, 27:10-20, claims 1, 6-7; Ex.1009-Stern, Abstract, 1:15-23, 1:65-2:5. Each uses the same treatment method—RF energy. Ex.1003-Saadat, Abstract, 1:21-26, 3:6-14, 10:16-11:14, 27:10-20, 30:24-47, 31:10-19, 33:41-49, claims 1, 6-7; Ex.1009-Stern, Abstract, 1:15-23, 1:65-2:5, 2:6-19, 2:25-40, 12:46-13:2, 13:11-16. Ex.1002-Decl., ¶145.

Second, a POSITA would have been motivated and have found it obvious to configure Saadat’s bipolar electrodes in multiple pairs as Stern teaches, and as claim 4 recites. As Section XI.A.1 details, Saadat teaches delivering RF energy with bipolar electrodes, and explains “[t]hose skilled in the art of RF ablation probes are familiar with the many possible configurations and construction techniques for RF electrodes and probes....” *E.g.*, Ex.1003-Saadat, 30:41-47, 31:10-19. This would have motivated a POSITA to consider other sources regarding how to configure bipolar electrodes to ablate tissue, and taught that Saadat was ready for improvement with specific implementation details within a POSITA’s discretion and skill. *E.g.*, *id.*, 30:41-47. Ex.1002-Decl., ¶146; Ex.1007-Decl., ¶¶58-62.

Stern exemplifies a known configuration for *multiple pairs of bipolar RF electrodes* and teaches its advantages and benefits. For example, Stern teaches bipolar electrode pairs (1) allow physicians to precisely control current delivery (Ex.1009-Stern, 12:26-37, 13:21-25, FIG.15, FIG.18); (2) direct heat to target tissue

while ensuring surrounding tissue is unaffected, especially for uneven tissue (*id.*, 13:21-39, FIG.15); and (3) facilitate uniform heating (*id.*, 12:25-27). A POSITA would have been motivated to incorporate Stern's bipolar electrode configuration in Saadat's device to realize these benefits. Indeed, doing so would have simply involved using Stern's known bipolar pairing technique to implement missing details of Saadat, which would have been desirable to increase safety and control. Ex.1002-Decl., ¶¶146-149; Ex.1007-Decl., ¶¶63-73.

Third, a POSITA would have reasonably expected success at implementing Stern's pairs of bipolar electrodes in Saadat. Saadat recognizes POSITAs "are familiar with the many possible configurations and construction techniques for RF electrodes." *E.g.*, Ex.1003-Saadat, 30:41-47, 31:10-19. Stern similarly recognizes that its bipolar electrodes "have application in many areas," including "for controlled heat treatment of tissue," i.e., RF ablation (Ex.1009-Stern, 18:27-40), and the '077 patent assumes a POSITA would have understood how to implement multiple pairs of bipolar electrodes, as it simply references them without implementation details (Ex.1001-USP077, 18:42-46). A POSITA would have had a reasonable expectation of successfully incorporating Stern's bipolar electrode pairs into Saadat as a matter of routine implementation well within the skillset of a POSITA, which would have yielded the predictable result of using one known feature (Stern's pairs of bipolar

electrodes) with another (Saadat's bipolar electrodes) to reach the predictable result of applying RF energy to tissue. Ex.1002-Decl., ¶150, Ex.1007-Decl., ¶¶74-77.

D. Ground IV: Deem Anticipates Claims 1-8, 11

As Section IX details, the '077 patent's priority date is October 22, 2019 and the '771 Provisional does not provide written description for the Challenged Claims. Therefore, the '771 Provisional subject matter is prior art, and PO cannot use it to establish earlier priority. *NRG*, IPR2020-00832, Paper 17, at 31; *Nat. Alternatives Int'l, Inc. v. Iancu*, 904 F.3d 1375, 1378 (Fed. Cir. 2018); *Medtronic CoreValve, LLC v. Edwards Lifesciences Corp.*, 741 F.3d 1359, 1361 (Fed. Cir. 2014).

Petitioner asserts Ground IV if the Board confirms an October 22, 2019 priority date and finds the '771 Provisional provides written description, as identical disclosures in Deem would anticipate the Challenged Claims for identical reasons.

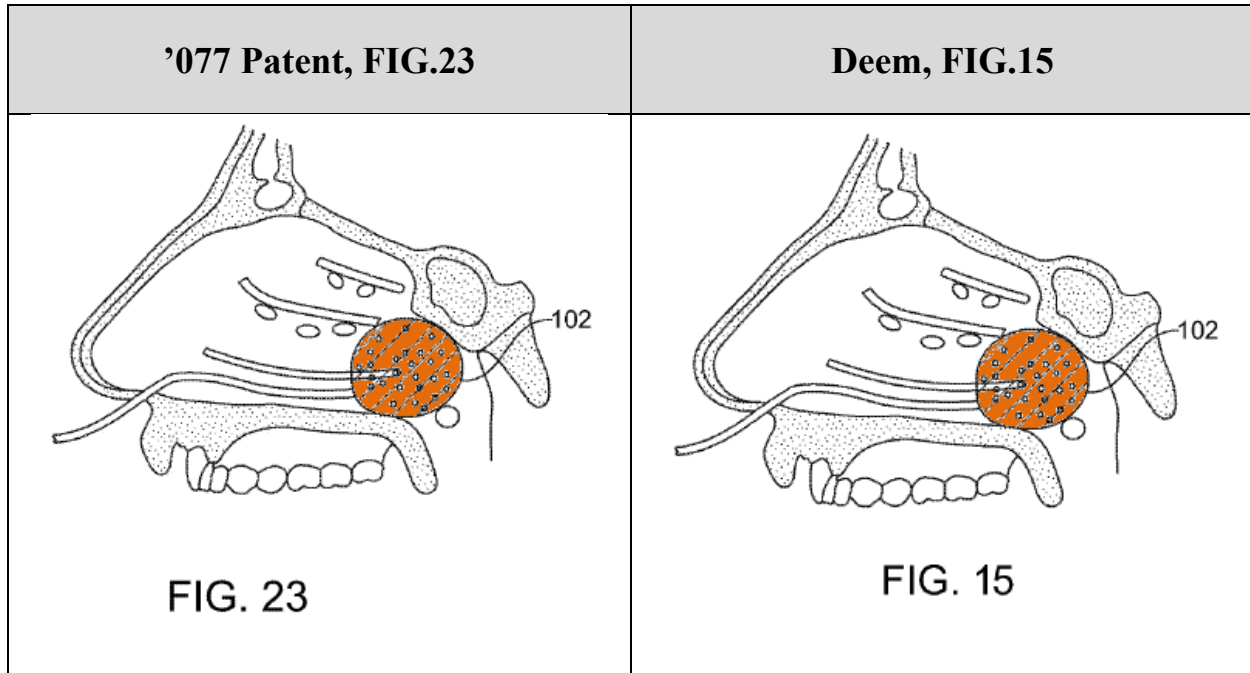
1. Claim 1

a. 1[pre]

If the Board finds the '771 Provisional provides written description for Element 1[pre], Deem discloses an *apparatus for treating rhinitis in a nasal cavity* for identical reasons.

For example, Deem discloses “systems for delivering toxins, such as botulinum toxin” fragments “to target cells in a nasal cavity” to reduce “mucus secretion” (*nasal condition*). Ex.1004-Deem, [0002], [0005], [0024]. Deem

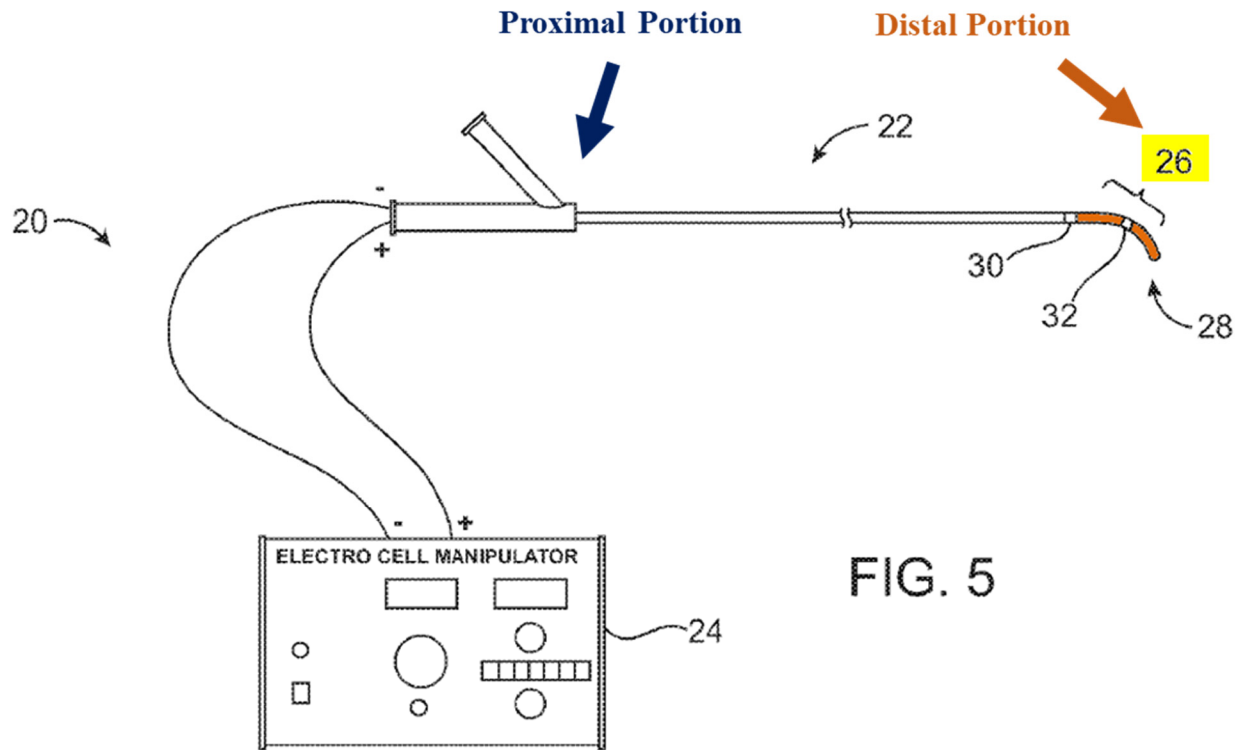
discloses an “electroporation catheter” with a “pulse generator” and a “distal region 26” with multiple electrodes (30, 32) “to induce reversible electroporation at the same time as the catheter delivers the fragmented neurotoxin....” *Id.*, [0015], [0071], [0089]-[0091]. Deem’s target region includes the **“back of the nasal passages,”** which is “susceptible to the disabling mechanism of” neurotoxins. *Id.*, [0015]; *see also id.*, [0106] [0110], [0112], FIG.15 (same as ’077 Patent FIG.23), FIGs.20-21, FIGs.24-25. Figure 15 illustrates placing the **distal region of a balloon catheter** in the “back of the nasal passages” to deliver “ultrasonic poration energy” to “nasal membranes which are receiving the toxin.” *Id.*, [0106], [0098], FIG.15; *see also id.*, FIGs.20-21, FIGs.24-25, [0110], [0112].



b. 1[a]

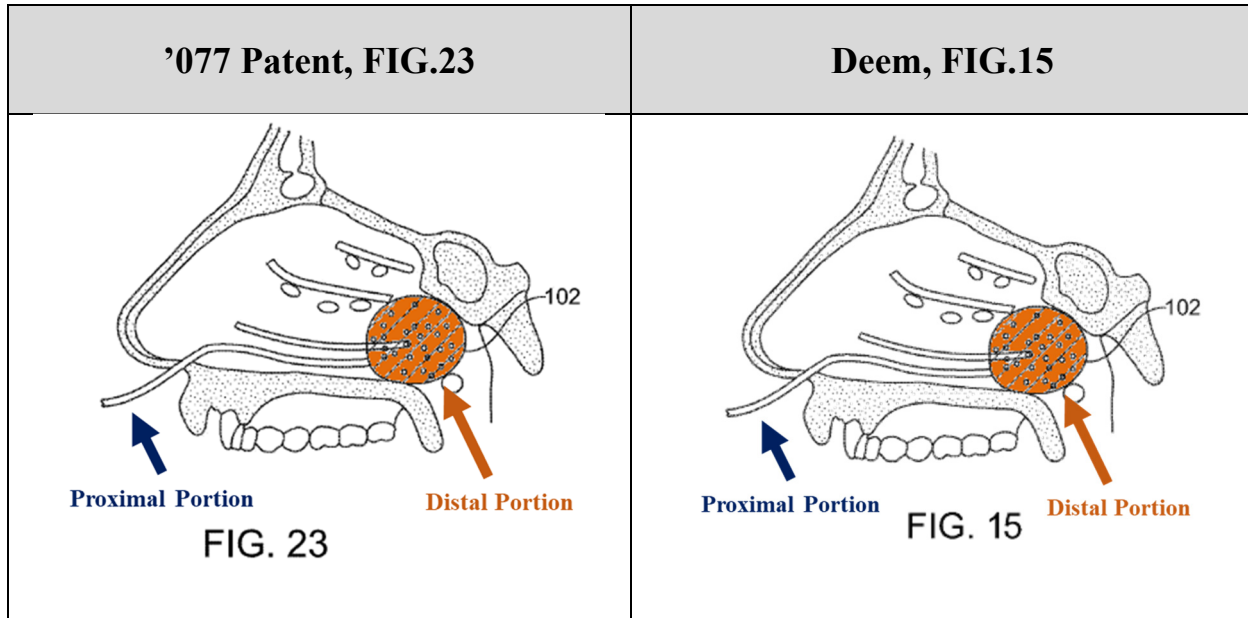
If the Board finds the '771 Provisional provides written description for Element 1[a], Deem discloses *an elongate body, comprising a proximal portion and a distal portion configured for positioning in the nasal cavity* for identical reasons.

For example, Deem Figure 5 (identical to '077 patent Figure 5) depicts an “electroporation catheter system 20 compris[ing] a pulse generator 24...electrically connected to a catheter 22 having a **proximal end** and a **distal region 26**....”
Ex.1004-Deem, [0089]-[0090].



Ex.1004-Deem, FIG.5.

As Section XI.D.1.a discusses, Deem Figure 15 (identical to '077 patent Figure 23) discloses placing a **distal region** in the nasal passage. *E.g.*, Ex.1004-Deem, [0106], FIG.15; *see also id.*, [0110], [0112], FIGs.20-21, FIGs.24-25.



c. 1[b]

If the Board finds the '771 Provisional provides written description for Element 1[pre], Deem discloses *multiple radiofrequency electrodes coupled with the distal portion of the elongate body* for identical reasons.

For example, as Sections XI.D.1.a-b detail, Deem discloses multiple RF electrodes that “produce membrane permeabilization...” *E.g.*, Ex.1004-Deem, [0071].

d. 1[c]

As Section IX sets forth, Deem does not provide written description support for this element. However, if the Board finds the '771 Provisional provides written description for Element 1[c], Deem discloses the claimed *radiofrequency generator coupled with the proximal portion of the elongate body for supplying radiofrequency*

energy to the multiple radiofrequency electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis for identical reasons.

For example, as Sections XI.D.1.a-b detail, Deem discloses applying energy “via the electroporation catheter to induce reversible electroporation [when] the [balloon] catheter delivers the fragmented neurotoxin.” Ex.1004-Deem, [0089], [0098].

Deem explains this creates pores in target cells, allowing neurotoxins to enter. Ex.1004-Deem, [0086], FIGs.2A-2B, FIGs.3A-3B, FIG.4; *see also* Section VI.A. Deem teaches neurotoxins block and disrupt goblet cell “hypersecretion”—i.e., rhinitis symptoms. *Id.*, [0004] (rhinitis symptoms include “nasal congestion” and “runny nose” (i.e., mucus production)), [0011], [0015]-[0017], [0066], [0086].

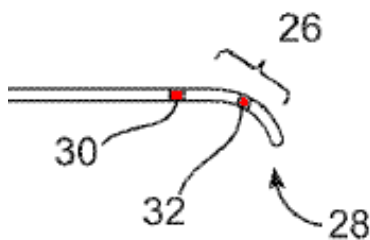
As Sections XI.D.1.a-b detail, Deem discloses a catheter positioned in the nasal passage to target goblet cells connected to a “pulse generator.” Ex.1004-Deem, [0071], [0076], [0089]-[0090], [0106], [0110], [0112], FIG.5, FIG.15, FIGs.20-21, FIGs.24-25.

2. Claim 2

Claim 2 depends from claim 1. Petitioners incorporate Section XI.D.1.

If the Board finds the ’771 Provisional provides written description for Claim 2, Deem discloses *two bipolar radiofrequency electrodes* for identical reasons.

For example, as Sections XI.D.1.a-c details, Deem's Figure 5 catheter includes **two electrodes (30, 32)**, and Figure 15 discloses transducers 104 that are **"one or more [RF] electrodes."** Ex.1004-Deem, [0071], [0089]-[0091], [0098], [0106], FIG.5, FIG.15.



Ex.1004-Deem, FIG.5

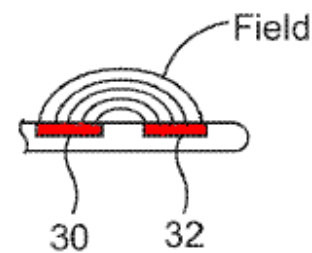


FIG. 5A

Ex.1004-Deem, FIG.5A

Deem explains "electroporation may be achieved" by producing "an electric field" "generated in a bipolar or monopolar electrode configuration." Ex.1004-Deem, [0073].

3. Claim 3

Claim 3 depends from claim 2. Petitioners incorporate Section XI.D.2.

If the Board finds the '771 Provisional provides written description for Claim 3, Deem, for example, discloses *at least one sensing electrode* for identical reasons. Deem's electroporation catheter **"include[s] electrodes or other monitoring**

systems...located on the treatment catheter...including, thermocouple...sensing or stimulating electrodes.” Ex.1004-Deem, [0096]; *see also id.*, [0091].

4. Claim 4

Claim 4 depends from claim 2. Petitioners incorporate Section XI.D.2.

If the Board finds the ’771 Provisional provides written description for Claim 4, Deem discloses *multiple pairs of bipolar radiofrequency electrodes* for identical reasons.

For example, as Section XI.D.2 details, Deem’s catheter includes **two electrodes 30 and 32** (Ex.1004-Deem, [0089]-[0090]; *see also id.*, [0091]) and explains “electroporation may be achieved” by generating “an electric field” in “a bipolar or monopolar electrode configuration” (*id.*, [0073]).

Deem explains “it may be desirable to incorporate multiple pairs of electrodes that may be activated in pairs.” Ex.1004-Deem, [0096].

5. Claim 5

Claim 5 depends from claim 1. Petitioners incorporate Section XI.D.1.

If the Board finds the ’771 Provisional provides written description for Claim 5, Deem discloses *target tissue comprising nerve tissue* for identical reasons. For example, as Section XI.D.1.a details, Deem explains the electroporation and neurotoxin target region includes “goblet cells which are responsible for mucus

secretion” at the “**back of the nasal passages.**” Ex.1004-Deem, [0106], FIG.15; *see also id.* FIGs.20- FIG.21, FIGs.24-25, [0006], [0110], [0112].

6. Claim 6

Claim 6 depends from claim 1. Petitioners incorporate Section XI.D.1.

If the Board finds the '771 Provisional provides written description for Claim 6, Deem discloses *at least one radiofrequency electrode movable relative to the distal portion of the elongate body* for identical reasons. For example, Deem Figure 6D (identical to '077 patent Figure 6D and a modification of Deem Figure 5) depicts “catheter device 70 having **electrode elements (72 and 74)**” that “extend laterally” and “penetrate the surrounding tissue prior to application of energy.” Ex.1004-Deem, [0091], [0093]; Ex.1001-USP077, FIG.6D.

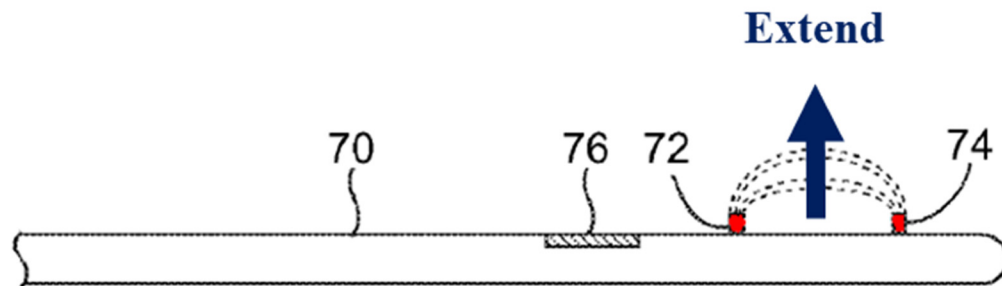


FIG. 6D

Ex.1004-Deem, FIG.6D.

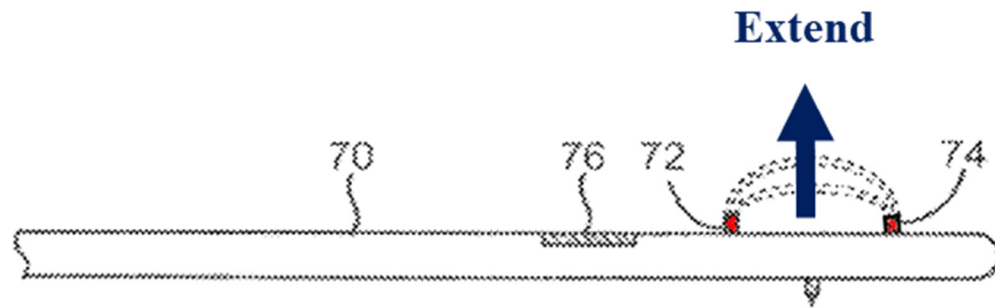


FIG. 6D

Ex.1001-USP077, FIG.6D.

7. Claim 7

Claim 7 depends from claim 1. Petitioners incorporate Section XI.D.1.

If the Board finds the '771 Provisional provides written description for Claim 7, Deem discloses *multiple radiofrequency electrodes configured to deliver energy laterally relative to the distal portion of the elongate body* for identical reasons. For example, Deem Figure 5A illustrates “arrangement of **electrodes 30 and 32** that **produces an electric field concentrated in a lateral direction from the catheter.**”

Ex.1004-Deem, [0091]; *see also id.*, [0093], FIG.6D.

8. Claim 8

Claim 8 depends from claim 1. Petitioners incorporate Section XI.D.1.

If the Board finds the '771 Provisional provides written description for Claim 8, Deem discloses *at least one radiofrequency electrode configured to extend laterally from the distal portion of the elongate body* for identical reasons. For

example, as Section XI.D.6 details, Deem Figure 6D depicts “catheter device 70 having **electrode elements (72 and 74)** that are adapted to extend laterally from the main catheter body....” Ex.1004-Deem, [0091], [0093], FIG.6D.

9. Claim 11

Claim 11 depends from claim 1. Petitioners incorporate Section XI.D.1.

If the Board finds the ’771 Provisional provides written description for Claim 11, Deem discloses *a monitoring system coupled with the distal portion of the elongate body for monitoring a degree of treatment of the target tissue* for identical reasons. For example, as Section XI.D.3 details, Deem’s electroporation catheter system “**include[s] electrodes or other monitoring systems...located on the treatment catheter**” and “thermocouple...sensing or stimulating electrodes.” Ex.1004-Deem, [0096]; *see also id.*, [0091].

E. Ground V: Claims 1-8 and 11 Are Obvious over Makower, Fang, and Edwards-535

Even if the Board finds the Challenged Claims are entitled to priority before October 22, 2019, they would have been obvious over the combination of Makower, Fang, and Edwards-535. Ex.1002-Decl., ¶151.

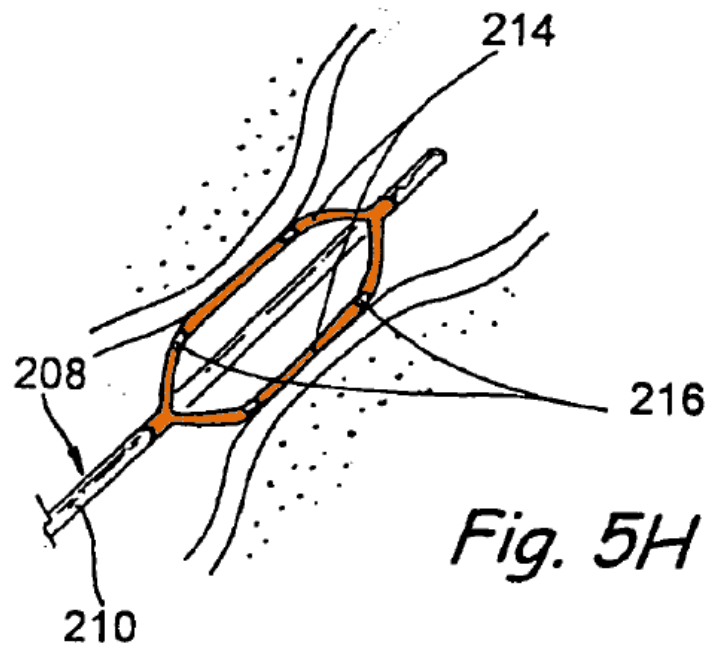
1. Claim 1

a. 1[pre]

If the preamble is limiting, the combination of Makower and Fang teaches an *apparatus* (e.g., electrosurgical device (Makower)/radiofrequency therapy instrument (Fang)) *for treating rhinitis in a nasal cavity* (e.g., passage including the nasal cavity (Makower/Fang)). Ex.1002-Decl., ¶152.

Makower discloses “medical devices...for treating sinusitis..., nose & throat disorders.” Ex.1005-Makower, [0001], [0043], [0161], [0187], claim 1. Ex.1002-Decl., ¶153

Makower teaches placing an electrosurgical device in the nasal cavity and/or nasopharynx to ablate (e.g., *alter*) tissue. Ex.1005-Makower, [0043] (“flexible catheters or other...devices...are inserted [into] the...nose...to perform an interventional or surgical procedure.”), [0161]; *see also* Ex.1022-FH675, 122. Makower teaches electrosurgical devices inserted into the nasal cavity or nasopharynx “to perform diagnostic or therapeutic procedures.” Ex.1005-Makower, [0161]; *see also id.*, [0043]. For example, Makower Figure 5H (below) teaches an electrosurgical device with bipolar electrodes on **strut members 214** contacting surrounding nasal cavity tissue. *Id.*, [0164], [0187], claim 1.



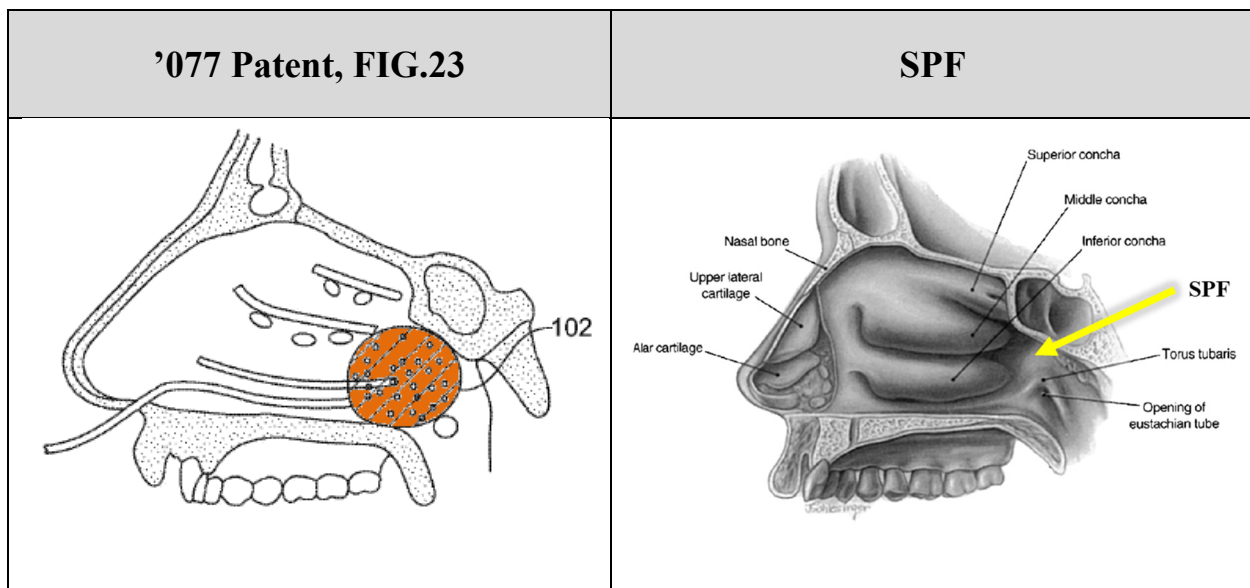
Ex.1005-Makower, FIG.5H. Ex.1002-Decl., ¶154.

Fang discloses performing “nasal endoscopic surgery combined with multiple radiofrequency” to treat nasal condition “perennial allergic rhinitis.” Ex.1006-Fang, 876-877. Ex.1002-Decl., ¶155.

Fang discloses “align[ing]” the “firing head” of an “SHP-I five-organ radiofrequency therapy instrument” with “the sphenopalatine foramen” “to carry out radiofrequency at the anterior upper part of the nasal septum on both sides,...the nasal ridge, and the anterior part of the inferior nasal turbinate....” Ex.1006-Fang, 876. Fang explains such “radiofrequency ablation of sphenopalatine foramen” “block[s] the posterior parasympathetic fibers of the sphenopalatine nerve,” and thus “completely blocks the parasympathetic pathway of the nasal mucosa,” which

“reduces glandular secretion, and thus achieves the therapeutic purposes.” *Id.*, 877.
Ex.1002-Decl., ¶¶155-156.

The SPF is located posterior in the nasal cavity. *See* Section V. As shown below, the SPF is in the location the '077 patent identifies as the “nasal passage.” The Figure 23 balloon 102 (below) is positioned posterior in the nasal cavity to target cells in the “nasal passages.” Ex.1001-USP077, 24:4-11; FIG.23.



Thus, consistent with the '077 patent, Fang's device is positioned in the *nasal cavity*.
Ex.1006-Fang, 876-877. Ex.1002-Decl., ¶157.

As Section V details, the SPF contains parasympathetic nerve branches of the SPG that innervate the nasal cavity and nasopharynx. *E.g.*, Ex.1006-Fang, 877 (sphenopalatine nerve includes ganglionic fibers). Fang explains that because such nerves “regulate the vascular dilation and contraction of the nasal mucus membrane

and the secretion of glands,” blocking them will regulate rhinitis symptoms, including congestion and mucus production. *Id.*, 877. As Section V details, nerves Fang targets are present throughout the nasal cavity. Fang thus teaches applying radiofrequency energy to nasal cavity tissue reduces symptoms of (e.g., *treats*) rhinitis. Ex.1002-Decl., ¶158.

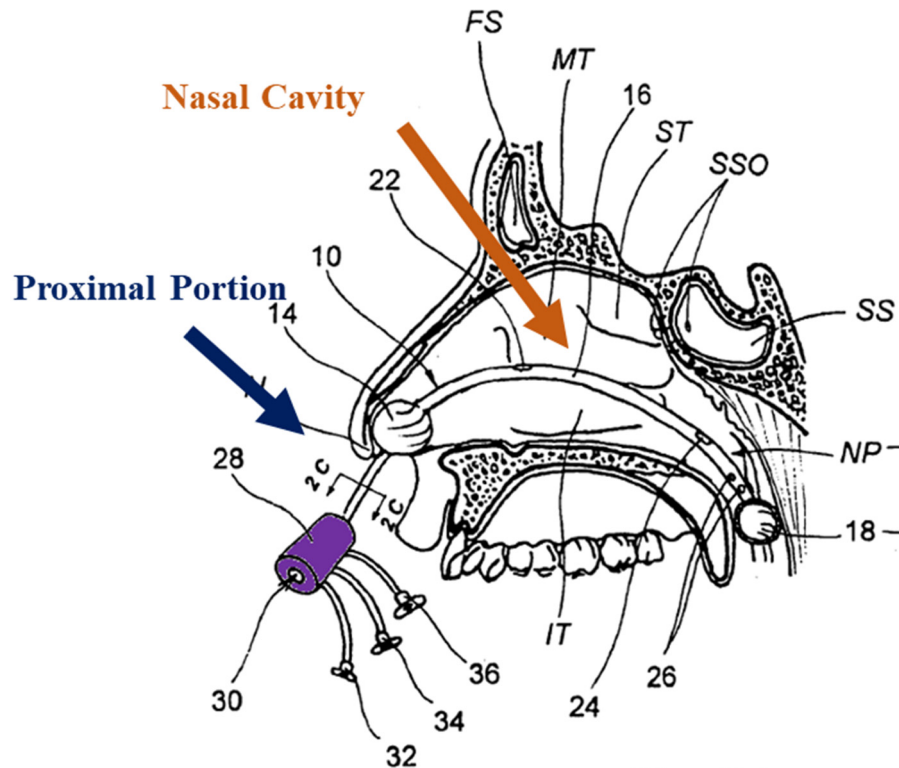
As this section and Section XI.E.1.e detail, Fang teaches the obvious result of administering current (RF energy) by Makower’s electrodes in the *nasal cavity*. A POSITA would have been motivated to use Makower’s device to reduce rhinitis symptoms in the *nasal cavity* to disrupt neural activity as Fang teaches with a reasonable expectation of success, including because Makower and Fang teach treatment of nasal conditions using RF energy where parasympathetic fibers of the SPG (which contribute to mucus production) are located. *See* Sections V and XI.E.1.e. Ex.1002-Decl., ¶159.

b. 1[a]

Makower and Fang teach *an elongate body* (e.g., electrosurgical device (Makower)/radiofrequency therapy instrument (Fang)), *comprising a proximal portion and a distal portion* (e.g., strut member (Makower)/firing head (Fang)) *configured for positioning in the nasal cavity*. Ex.1002-Decl., ¶160.

As Section XI.E.1.a details, Makower teaches an electrosurgical device with “flexible shaft 210 (e.g., a catheter or solid shaft)” and electrodes on **strut members** (e.g., *distal portion*) contacting surrounding nasal cavity tissue. Ex.1005-Makower, [0161], [0164], [0187], FIG.5H, claim 1. Makower explains that the flexible shaft allows the device “to be delivered and positioned to perform the desired diagnostic or therapeutic procedures....” *Id.*, [0161]. Ex.1002-Decl., ¶161.

Correspondingly, Figure 2A (below), discloses a device through which the flexible shaft 210 could be inserted into the body. Figure 2A illustrates an occluder access device that positions the flexible shaft 210’s distal portion (i.e., **strut members**) in the *nasal cavity* while maintaining the *proximal portion* the physician holds outside. Ex.1005-Makower, [0133]-[0135], [0162]. Makower thus teaches the Figure 5H device shaft can be positioned by inserting it from outside into occluder access device “**insertion opening 30**” and “advanc[ing]” it through outlet opening 22 in the nasal cavity. *Id.*, [0135], [0161], [0164], [0187], FIGs.2A-2B, FIG.5H.



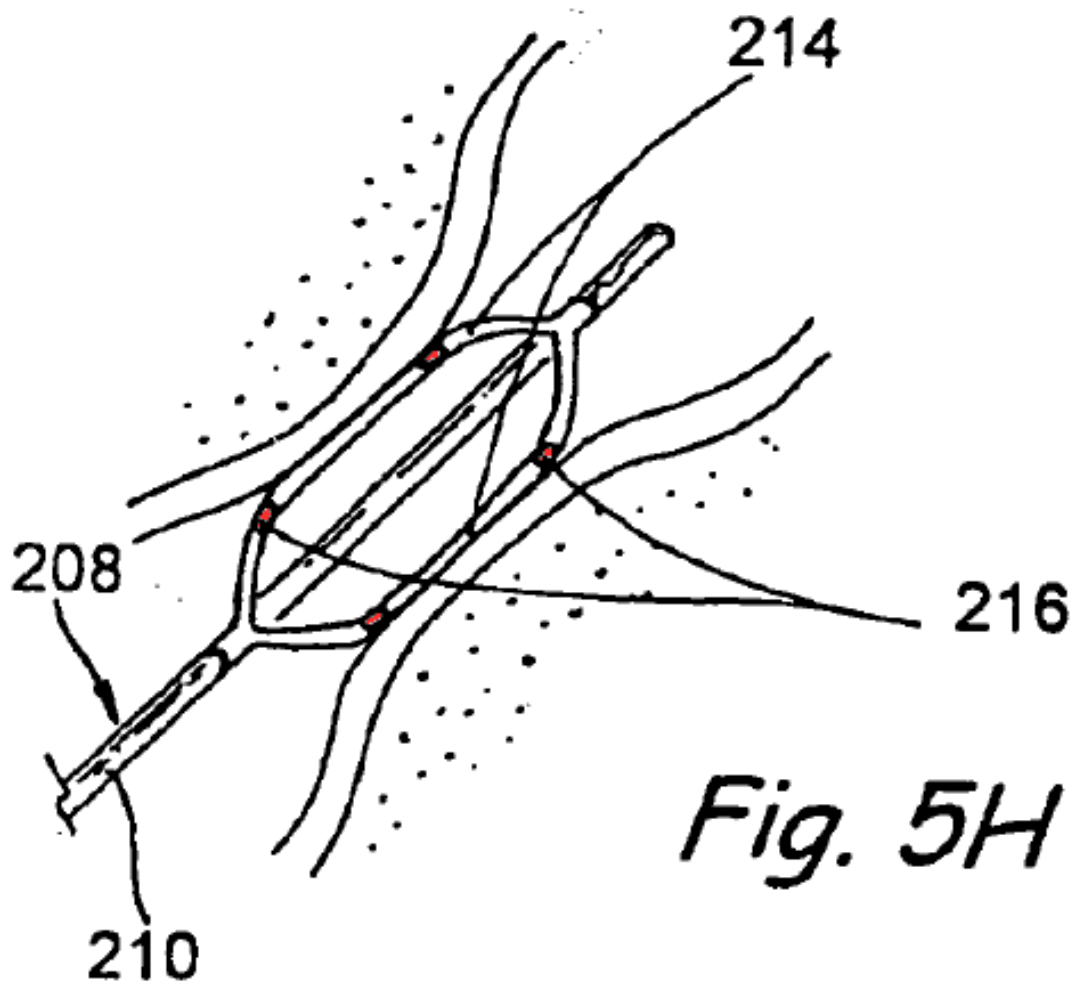
Ex.1005-Makower, FIG.2A. Ex.1002-Decl., ¶¶162-164.

As Section XI.E.1.a discusses, Fang teaches the physician “align[s]” the “radiofrequency therapy instrument” “firing head” (e.g., *distal portion*) with “the sphenopalatine foramen” (e.g., *in the nasal cavity*). Ex.1006-Fang, 876-877. Fang thus teaches the well-known concept of advancing the device *distal portion* proximate to tissue being treated such that it is inside the treatment area with the device *proximal portion* (held by the physician) outside the body. Ex.1002-Decl., ¶165.

c. 1[b]

Makower teaches *multiple radiofrequency electrodes coupled with the distal portion of the elongate body*. Ex.1002-Decl., ¶166.

As Sections XI.E.1.a-b discuss, Makower's **electrosurgical device** includes multiple bipolar or monopolar **electrodes 216** that apply **current** to “tissue adjacent to the struts 214 to be cauterized or heated.” Ex.1005-Makower, [0187].



Id., FIG.5H. Makower thus teaches the well-known concept of treating tissue using bipolar electrodes to administer RF energy through electrical current. *Id.*, [0043], [0164], [0187]; *see also id.*, [0040]. Ex.1002-Decl., ¶¶167-168.

d. 1[c]

The combination of Makower, Fang, and Edwards-535 teaches *a radiofrequency generator (generator (Edwards-535/Makower/Fang)) coupled with the proximal portion of the elongate body for supplying radiofrequency energy (e.g., RF energy (Edwards-535/Makower/Fang) to the multiple radiofrequency electrodes (e.g., electrode(s) (Edwards-535/Makower/Fang) to treat a target tissue in the nasal cavity (e.g., ablating nasal cavity tissue) and thus treat rhinitis.* Ex.1002-Decl., ¶169.

As Sections XI.E.1.a-c discuss, Makower teaches delivering RF energy to nasal cavity tissue via electrodes to cause “heat[ing]” and treat a nasal condition (e.g., Ex.1005-Makower, [0001], [0043], [0161], [0187], FIG.5H, claim 1), and Fang teaches delivering RF energy to nasal cavity tissue to “block the posterior parasympathetic fibers of the sphenopalatine nerve” to treat rhinitis (e.g., reduce nasal congestion) (e.g., Ex.1006-Fang, 876-877). Thus, as Sections XI.E.1.a and XI.E.1.e discuss, a POSITA would have found it obvious that the combination of

Makower and Fang discloses RF electrodes that apply RF energy *to treat a target tissue in the nasal cavity and thus treat rhinitis*. Ex.1002-Decl., ¶170.

Electrodes that deliver RF energy to tissue operate by being coupled to an energy source (e.g., to a generator using an electrical connection), that supplies energy to the electrodes so that they may operate according to parameters chosen for their intended purpose (here, ablation of nasal cavity tissue to treat rhinitis). The '077 patent recognizes this basic operating principle—including that generators for connecting to and creating energy for electrodes were well-known and commercially available—and does not reference specific steps for generating RF energy. *See, e.g.*, Ex.1001-USP077, 16:42-58 (citing commercially available generators). A POSITA would have understood that by teaching RF energy delivery for an intended purpose (i.e., *treating nasal cavity* tissue), Makower and Fang teach application of that energy using an energy source (e.g., *radiofrequency generator*) coupled to the electrodes that provide energy for that purpose. Ex.1002-Decl., ¶¶171-173.

To the extent PO argues Makower and Fang do not expressly teach *a radiofrequency generator*, Edwards-535 teaches the well-known concept of an RF energy source for supplying energy to electrodes to ablate tissue. Edwards-535

teaches “an apparatus for ablating a nasal concha,” e.g., turbinates.¹⁴ Ex.1008-Edwards-535, 7:28-29. Edwards-535’s apparatus includes “a catheter body 126” with “a distal portion 128” and “an energy delivery device 134 for delivering ablative energy.” *Id.*, 7:29-36, 8:17-25. As Figure 6 shows, Edwards-535’s device “includes one or more ring **electrodes 156**” for delivering ablative energy. *Id.*, 8:17-25. Edwards-535 teaches that ablative energy for the electrodes is supplied by an “energy source 162” (e.g., *radiofrequency generator*) connected to the electrodes via the catheter body that functions by “generat[ing] RF energy” using parameters set to “ablate[] the turbinate [(i.e., tissue)] by heat and cell destruction.” *Id.*, 8:47-53, FIGs.5-6. The energy source includes a “signal generator 165” that generates RF energy.¹⁵ *Id.*, 8:54-9:13, 11:46-12:4 (“modifications will readily occur to those skilled in the art”).

¹⁴ The turbinates are in the nasal cavity. Section V.A.

¹⁵ Edwards teaches exemplary frequency ranges for RF energy. *See, e.g.*, Ex.1008-Edwards, 8:61-67, 11:46-12:4. A POSITA would have understood Edwards’ reference to “megahertz” may be a typographical error, as the frequency unit for RF energy to ablate tissue was typically “kilohertz.” Ex.1002-Decl., ¶174.

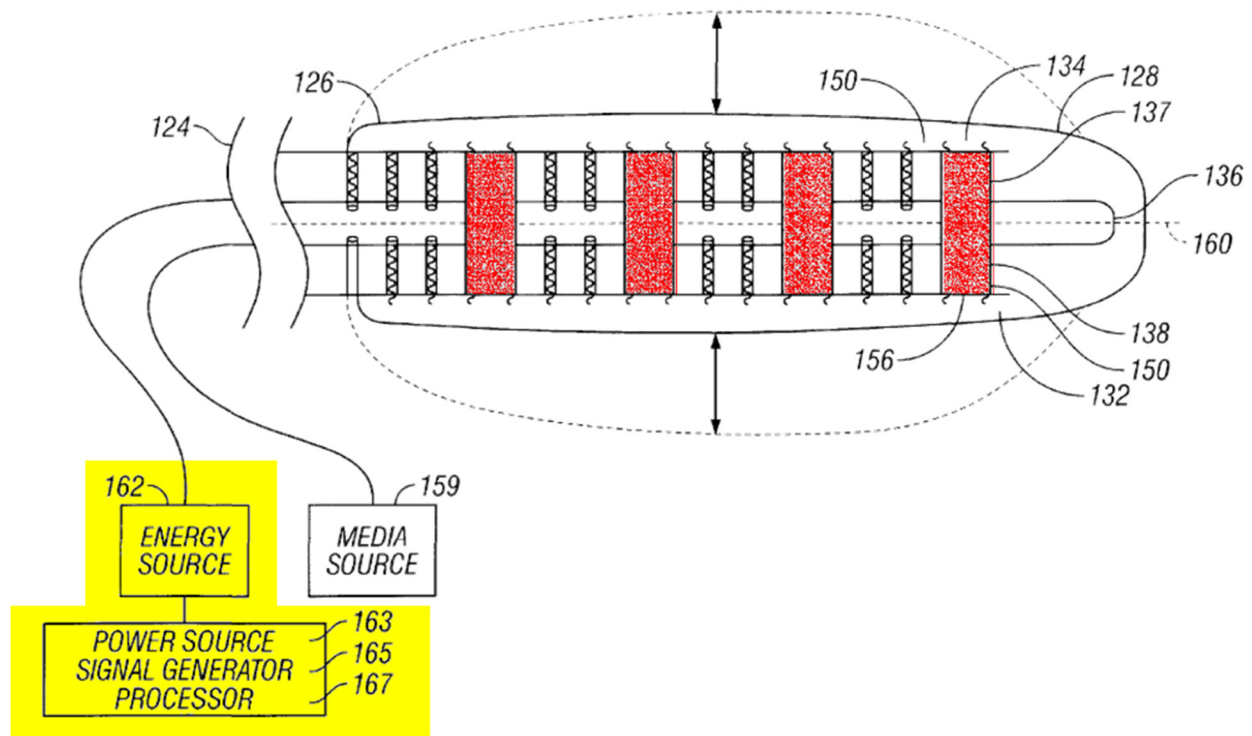


FIG. 6

Ex.1008-Edwards-535, FIG.6. Ex.1002-Decl., ¶¶174-177.

As this section and Section XI.E.1.e discuss, a POSITA would have found it obvious to apply Edwards-535's teaching regarding RF generators to the combination of Makower and Fang. That is, a POSITA would have been motivated to use an RF generator as Edwards-535 teaches with RF electrodes of Makower's device to reduce rhinitis symptoms in the nasal cavity by altering tissue as Fang teaches with a reasonable expectation of success. *See* Section XI.E.1.e. Ex.1002-Decl., ¶178.

e. Motivation to Combine and Reasonable Expectation of Success

Makower, Fang, and Edwards-535 are analogous art and a POSITA would have been motivated to combine them with a reasonable expectation of success. Ex.1002-Decl., ¶179.

First, Makower, Fang, and Edwards-535 are analogous art to the Challenged Claims. All are in the same field as the Challenged Claims and are reasonably pertinent to solving the problems addressed in the Challenged Claims—treating tissue—with the same types of solutions—applying energy to tissue. Ex.1006-Fang, 876-877; Ex.1005-Makower, [0043], [0164], [0187]; Ex.1008-Edwards-535, Abstract, 2:53-3:36, 4:19-32. Makower, Edwards-535, and Fang teach that their devices treat disorders by applying energy to tissue. Ex.1005-Makower, [0001], [0043], [0132]; Ex.1008-Edwards-535, Abstract, 2:53-3:36, 4:19-32; Ex.1006-Fang, 876-877. Similarly, each uses RF energy to treat tissue. Ex.1005-Makower, [0043], [0164], [0187]; Ex.1006-Fang, 876-877; Ex.1008-Edwards-535, Abstract, 2:53-3:36, 8:47-9:13. Ex.1002-Decl., ¶180.

Second, a POSITA would have been motivated to and would have found it obvious to apply Fang’s method (disrupting neural activity using ablation) with Makower’s device (electrosurgical device for the nasal cavity) to treat rhinitis, including as claim 1[pre] and 1[c] recite. Ex.1002-Decl., ¶181.

During prosecution of a grandparent application, the Examiner found Makower teaches an energy emitting device to treat nasal disorders, but does not teach “treating nasal conditions with a device so as to disrupt neural activity such that mucus secretion is reduced in the nasopharyngeal passage [i.e., nasal cavity and nasopharynx, *see* Ex.1048-Stedman’s, 1177; Ex.1049-Webster’s, 1504], and wherein the target tissue has a change in temperature.” Ex.1022-FH675, 122. To the extent that is the case, a POSITA would have understood from Fang that Makower’s electrodes, like the similar RF device in Fang, would treat nasal disorders by disrupting neural activity in the same way as Fang, by heating parasympathetic nerves downstream of the SPG and Vidian nerve, thereby inhibiting their signaling of mucus-producing goblet cells. Makower’s device would not require modification to achieve this result. Makower already teaches its device treats a nasal disorder, and Fang simply clarifies that Makower operates the same way as claimed. Ex.1002-Decl., ¶181.

A POSITA would have been motivated to modify Makower’s device in view of Fang. Makower describes “working devices for [e.g.]...ablating...soft tissue,” “procedures” using such devices, and embodiments in Figure 5 (e.g., Figure 5H) and states that “designs and constructions of such components and assemblies are w[e]ll known in the art.” Ex.1005-Makower, [0001], [00043], [0132], [0160]-[0164],

[0187], claim 1. Fang provides additional details regarding the well-known design, construction, and operation of Makower's RF device. Ex.1002-Decl., ¶182.

Specifically, Makower teaches positioning strut members with electrodes of an electrosurgical device in the nasal cavity to apply energy to surrounding tissue to treat nasal disorders. Ex.1005-Makower, [0001], [0043], [0132], [0161], [0164], [0187], claim 1. Fang also teaches applying energy to nasal cavity tissue to treat nasal disorders and further teaches such application of energy treats rhinitis by disrupting the sphenopalatine ganglion and branching parasympathetic nerves. Ex.1006-Fang, 877. Fang explains “[n]umerous studies [had] shown that the parasympathetic nerves in the nasal cavity...regulate the vascular dilation and contraction of the nasal mucus membrane and the secretion of glands.” *Id.*, 877. In other words, Fang teaches the well-known fact that the parasympathetic nerves regulate mucus production. *Id.*; *see also* Ex.1044-Chen, 240-241. Ex.1002-Decl., ¶183.

Consistent with Fang, it was well known before 2005 that parasympathetic nerves and cells are located throughout the nasal cavity. For example, it was known that the SPG nerve is downstream of the Vidian nerve and located near the sphenopalatine foramen, and that parasympathetic nerves branch from the SPG throughout the nasal cavity. *See* Section V. It was also well known parasympathetic

nerves that branch from the Vidian nerve and SPG were responsible for mucus production and congestion, as they control activity of mucus-producing goblet cells. *E.g.*, Ex.1051-Windsor, 284. Thus, a POSITA would have understood before the '077 patent that parasympathetic nerves regulate mucus production (e.g., goblet cells) in the nasal cavity. Ex.1002-Decl., ¶184.

It was also well-known that disrupting the Vidian, SPG, and related parasympathetic nerves reduces mucus production and secretion (rhinitis symptoms). For example, it has been known since the 1960s that cutting the Vidian nerve treats rhinitis. *E.g.*, Ex.1003-Saadat, 2:39-47. Fang also taught disrupting the nerves with radiofrequency energy would reduce rhinitis symptoms: it teaches RF energy in tissue surrounding the SPF “completely blocks the parasympathetic pathway of the nasal mucosa,” which “reduces glandular secretion, and thus” relieves “perennial allergic rhinitis” while minimizing adverse effects. Ex.1006-Fang, 876-877. Ex.1002-Decl., ¶185.

In view of Makower’s statement that additional details regarding its devices were well known, a POSITA would have been motivated to combine Fang’s teachings regarding known outcomes of applying RF therapy with Makower’s device because the two teach similar energy-delivery devices in the same part of the body, for the same purpose (treating nasal conditions), and Fang explains the

mechanism and outcome of Makower's device. Ex.1006-Fang, 876; Ex.1005-Makower, [0161], [0164], [0187], claim 1. Ex.1002-Decl., ¶¶186-187.

Third, a POSITA would have been motivated and would have found it obvious to use an energy source as Edwards-535 teaches with the combination of Makower and Fang, including as claim 1[c] recites. As this section and Section XI.E.1.d detail, Makower and Fang teach delivering RF energy to tissue via electrodes, and Fang teaches doing so alters tissue to reduce nasal congestion. A POSITA would have been motivated to use the device taught by Makower and Fang for its intended purpose. Edwards-535 teaches well-known details for operating electrodes to deliver RF energy to tissue as Makower and Fang teach. It was well-known such electrodes operated by being coupled to an energy source (e.g., generator) configured to generate energy suitable for its desired purposes (e.g., tissue ablation) using parameters such as frequency (e.g., hertz) and power (e.g., Watts). Correspondingly, Makower describes "working devices for [e.g.]...ablating...soft tissue," "procedures" using such devices, and embodiments in Figure 5 (e.g., Figure 5H) and states "designs and constructions of such components and assemblies are w[e]ll known in the art." Ex.1005-Makower, [0001], [00043], [0132], [0160]-[0164], [0187], claim 1. Edwards-535 exemplifies well-known RF-energy source design, construction, and operation used with Makower and Fang's devices; an

“energy source” for nasal tissue ablation connected to RF electrodes and operated according to chosen frequencies and wattages. *E.g.*, Ex.1008-Edwards-535, 8:54-9:13, 11:46-12:4, FIGs.5-6. Ex.1002-Decl., ¶¶188-189.

A POSITA would have been motivated to use an energy source as Edwards-535 teaches (RF generator) for powering RF electrodes to treat nasal tissue with Makower and Fang because Edwards-535, Makower, and Fang each teach delivering RF energy to nasal cavity tissue and Edwards-535 teaches a specific, routine, implementation step for doing so. Ex.1002-Decl., ¶189.

Fourth, a POSITA would have had a reasonable expectation of successfully combining Makower, Fang, and Edwards-535. A POSITA would have reasonably expected Makower’s electrosurgical device to obtain Fang’s clinical result. Fang and others taught applying RF energy to the nasal cavity treats rhinitis. *See* Section XI.E.1.c. For example, Chen taught applying RF energy to sphenopalatine nerves treats rhinitis. Ex.1044-Chen, 239. Chen explained “parasympathetic nerves in the nasal cavity mainly originate from the sphenopalatine nerves,” and applying RF energy to them “block[s] the source of the parasympathetic nerves in the nasal cavity and reduce[s] the excitability of the parasympathetic nerves” to disrupt rhinitis symptoms. *Id.*, 240-241. Because Makower and Fang are directed to the same problem (treating nasal conditions), types of energy-delivery devices, and solutions

(applying energy to tissue), a POSITA would have had a reasonable expectation of successfully using Makower’s known RF device according to a known method to reach the predictable result taught in Fang (and Chen).¹⁶ Ex.1002-Decl., ¶¶190-192.

Moreover, a POSITA would have reasonably expected Edwards-535’s energy source (RF generator) to connect to and apply energy for Makower’s RF electrodes to achieve treatment Makower teaches, i.e., *treating a target tissue in the nasal cavity*. Edwards-535 teaches its RF generator can produce signals at different frequencies and wattages, and recognizes “modifications will readily occur” to

¹⁶ To the extent PO argues Fang’s results would not have been expected with Makower’s device, such argument would be misplaced. Fang does not teach or suggest a specialized device is required to treat rhinitis. Ex.1006-Fang, 876. Instead, Fang used a generic catheter, a SPH-I five-organ radiofrequency therapy instrument, using factory settings. *Id.* A POSITA would have understood that Fang’s generic catheter would operate similarly to Makower’s electrosurgical device with bipolar electrodes. Indeed, the ’077 patent assumes a POSITA would have understood how to position a catheter proximate to target tissue, as it describes positioning a **balloon 102** without any implementation details. Ex.1001-USP077, 24:4-17; *Uber*, 957 F.3d at 1339 (Fed. Cir. 2020). Ex.1002-Decl., ¶191.

skilled artisans. *E.g.*, Ex.1008-Edwards-535, 8:47-9:13, 11:46-12:4, FIGs.5-6. Similarly, Makower recognizes design and construction of RF devices was well-known (Ex.1005-Makower, [0164]), Makower and Fang do not teach or suggest a specialized RF energy source or connection is required to ablate nasal cavity tissue to treat rhinitis, and the '077 patent assumes POSITAs would have understood the parameters required to deliver RF energy to alter tissue, as it simply references a generator without implementation details (Ex.1001-USP077, 16:42-58). A POSITA would thus have had a reasonable expectation of successfully using a known energy source (RF generator) as Edwards-535 teaches with Makower's and Fang's known RF ablation devices to reach the predictable result of treating rhinitis as Fang teaches. Ex.1002-Decl., ¶193.

Accordingly, the combination of Makower, Fang, and Edwards-535 renders claim 1 obvious. Ex.1002-Decl., ¶194.

2. Claim 2

Claim 2 depends from claim 1. Petitioners incorporate Section XI.E.1.

The combination of Makower, Fang, and Edwards-535 teaches *multiple radiofrequency electrodes compris[ing] at least two bipolar radiofrequency electrodes* (e.g., bipolar electrodes). As Section XI.E.1.c details, Makower's

electrosurgical device includes multiple bipolar electrodes. Ex.1005-Makower, [0187]. Ex.1002-Decl., ¶¶195-196.

3. Claim 3

Claim 3 depends from claim 2. Petitioners incorporate Section XI.E.2.

The combination of Makower, Fang, and Edwards-535 teaches *at least one sensing electrode* (e.g., sensing elements/thermal sensor). Makower discloses “sensing elements may also be attached to the...strut members to monitor various parameters of the catheter and/or surrounding tissue (e.g., temperature, etc.).” Ex.1005-Makower, [0187]. Makower also teaches its electrosurgical device includes an “electromagnetic positioning sensor/detector,” “RF Sensor/transmitter,” or “thermal sensor,” (*id.*, [0192]), and the “design and construction” of such components was well-known (*id.*, [0164]). Makower recognizes that “designs and constructions of [ablation] components and assemblies are w[e]ll known in the art” (Ex.1005-Makower, [0164]), and it was well-known to use “thermal sensor[s],” e.g., thermocouples, or “sensing elements” to monitor tissue temperature. *E.g.*, Ex.1046-Lehmann, 5:28-33; Ex.1047-Flaherty, 17:53-57. Because such sensors are conductors (e.g., Ex.1063-Cosman, Abstract), Makower discloses *at least one sensing electrode*. Ex.1002-Decl., ¶¶197-199.

4. Claim 5

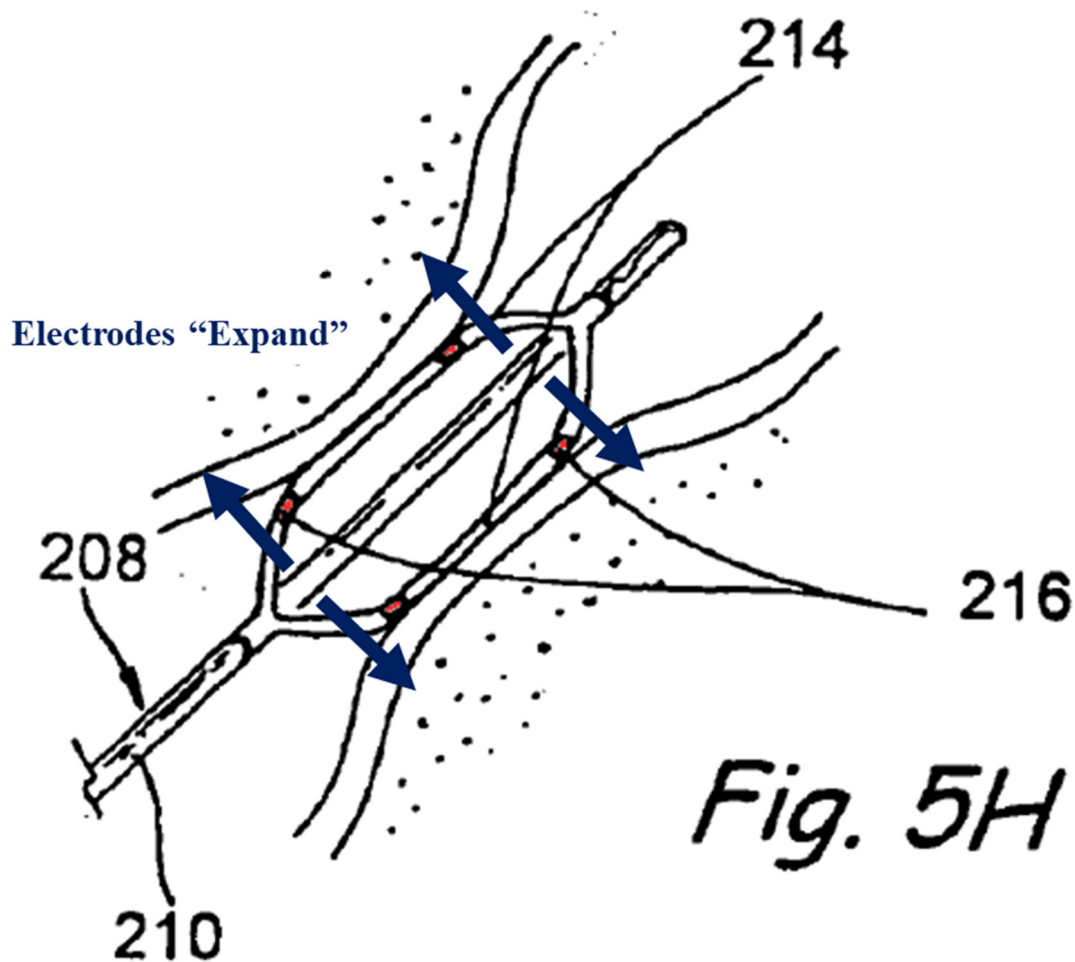
Claim 5 depends from claim 1. Petitioners incorporate Section XI.E.1.

The combination of Makower, Fang, and Edwards-535 teaches *target tissue compris[ing] nerve tissue*. As Sections XI.E.1.a, d-e detail, Makower discloses applying energy to nasal cavity tissue (Ex.1005-Makower, [0161], [0187]), and Fang discloses ablating tissue with parasympathetic nerves (e.g., *target tissue* with *nerve tissue*) reduces the symptoms of rhinitis (Ex.1006-Fang, 877-878). As Section XI.E.1.e details, a POSITA would have been motivated to use Makower's device to reduce rhinitis symptoms in the nasal cavity by targeting parasympathetic nerves (e.g., *nerve tissue*) as taught in Fang with a reasonable expectation of success. Ex.1002-Decl., ¶¶200-203.

5. Claim 6

Claim 6 depends from claim 1. Petitioners incorporate Section XI.E.1.

The combination of Makower, Fang, and Edwards-535 teaches *at least one multiple radiofrequency electrode* (e.g., electrode(s)) *is movable relative to the distal portion of the elongate body* (e.g., collapsible and expandable shaft). Makower teaches that the strut members that include the multiple bipolar electrodes and are attached to the flexible shaft 210 are “collapsible and expandable” and therefore *movable relative to the shaft distal portion*. Ex.1005-Makower, [0187].

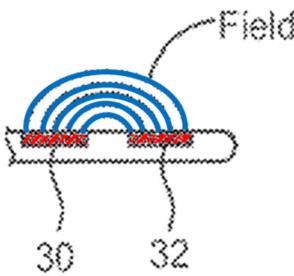
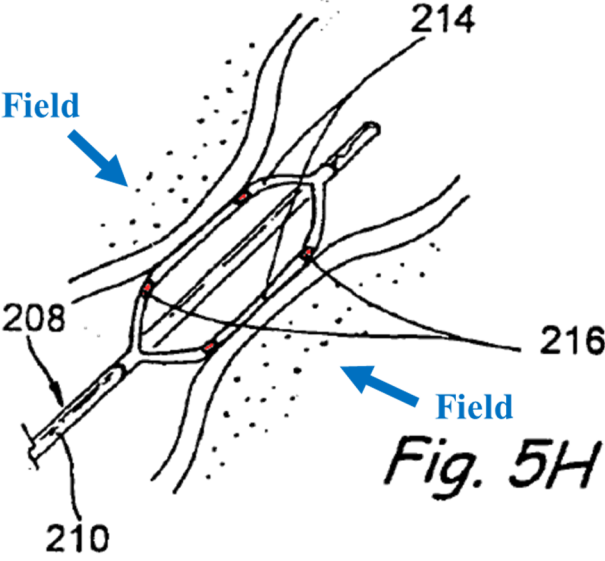


Ex.1005-Makower, FIG.5H. Additionally, Makower teaches embodiments of the same working device, including e.g., Figure 5B, positioned in the nasopharyngeal passage and used for RF ablation in the same manner as Figure 5H, that include electrodes that move out from a flexible catheter shaft to distal portion and become inserted into adjacent target tissue. *Id.*, [0167], FIG.5B. Ex.1002-Decl., ¶¶204-206.

6. Claim 7

Claim 7 depends from claim 1. Petitioners incorporate Section XI.E.1.

The combination of Makower, Fang, and Edwards-535 teaches *multiple radiofrequency electrodes* (e.g., electrode(s)) *configured to deliver energy laterally relative to the distal portion of the elongate body*. As Section XI.E.1.c details, Makower's electrosurgical device includes strut members with multiple **bipolar electrodes** that apply energy to adjacent tissue. *E.g.*, Ex.1005-Makower, [0187], FIG.5H. Bipolar electrodes are conductors that facilitate current traveling from one electrode to another. Ex.1009-Stern, 13:11-20. In Makower, a POSITA would have understood that current travels from one **bipolar electrode** to another electrode to create an electrical field that travels through the contacted tissue. The current (*energy*) in this field is *delivered laterally relative to the distal portion* (i.e., into the target tissue and away from the shaft). Makower teaches delivering energy laterally just as similarly arranged electrodes do in '077 patent Figure 5A . *E.g.*, Ex.1001-USP011, Fig.5, Figs.5A-5B, 16:29-58; Ex.1005-Makower, [0161], [0164], [0187], FIG.5H; *see also* Ex.1068-Imran, 3:2-7, FIG.1. Ex.1002-Decl., ¶¶207-209.

'011Patent, FIG.5A	Makower, FIG.5H
 FIG. 5A	 Fig. 5H

Moreover, Foundry alleges in litigation that delivering RF energy from bipolar electrodes constitutes *deliver[ing] energy laterally relative to the distal portion of the elongate body*. Ex.1038-Complaint-Ex.Z, 13-15. Consistent with Foundry’s allegations, and without concession regarding infringement, Makower discloses its electrodes *deliver energy laterally* into the target tissue *relative to the distal portion of* electro-surgical device **strut members**.

7. Claim 8

Claim 8 depends from claim 1. Petitioners incorporate Section XI.E.1.

The combination of Makower, Fang, and Edwards-535 teaches *at least one of the multiple radiofrequency electrodes is configured to extend laterally from the*

distal portion of the elongate body. As Section XI.E.5 details, Makower teaches flexible shaft 210 strut members are “collapsible and expandable.” Ex.1005-Makower, [0187]. Thus, because the electrodes expand outward from the shaft distal portion, they are configured to *extend laterally*. Additionally, Makower teaches other embodiments, including Figure 5B, with electrodes that move out laterally from the catheter’s distal portion into adjacent tissue. Ex.1002-Decl., ¶¶210-211.

8. Claim 11

Claim 11 depends from claim 1. Petitioners incorporate Section XI.E.1.

The combination of Makower, Fang, and Edwards-535 teaches *a monitoring system (e.g., sensing elements/thermal sensor) coupled with the distal portion of the elongate body for monitoring a degree of treatment of the target tissue.* As Section XI.E.3 details, Makower discloses sensing elements on its strut members “**monitor various parameters of the catheter and/or surrounding tissue (e.g., temperature, etc.)**.” Ex.1005-Makower, [0187]. Makower thus teaches monitoring tissue temperature during treatment (e.g., *monitoring system for monitoring a degree of treatment*). A POSITA would have understood that by monitoring the temperature of target tissue (e.g., a target temperature for ablation), a physician would be monitoring the degree to which that tissue was being treated. Edwards-535 also teaches this well-known monitoring apparatus, which includes “sensors” “to monitor

the amount of energy delivered and the amount of heat generated.” Ex.1008-Edwards-535, 9:14-45. Ex.1002-Decl., ¶¶212-213.

F. Ground VI: Claim 4 Is Obvious over Makower, Fang, Edwards-535, and Stern

1. Claim 4

Claim 4 depends from claim 2. Petitioners incorporate Section XI.E.2. The Makower, Fang, Edwards-535, and Stern combination teaches *at least two bipolar radiofrequency electrodes* (e.g., bipolar electrodes (Makower/Stern)) *comprising multiple pairs of bipolar radiofrequency electrodes* (e.g., pairs of bipolar RF electrodes (Stern)). Ex.1002-Decl., ¶¶214-215; Ex.1007-Decl., ¶78.

As Section XI.E.1.c details, Makower’s **electrosurgical device** includes multiple bipolar **electrodes**. Ex.1005-Makower, [0187]. Ex.1002-Decl., ¶216; Ex.1007-Decl., ¶79-88.

As Section XI.C.1 details, Stern teaches delivering RF energy to multiple **bipolar electrode** “pairs.” *E.g.*, Ex.1009-Stern, 12:55-13:2. Ex.1002-Decl., ¶217; Ex.1007-Decl., ¶89.

Makower, Fang, Edwards-535, and Stern are analogous art that a POSITA would have been motivated to combine with a reasonable expectation of success. *See Intel Corp. v. Xmtt, Inc.*, IPR2020-00145, Paper 37, 20 (P.T.A.B. May 11, 2021) (number of references, “without more, does not demonstrate nonobviousness”)

(citations omitted); *In re Gorman*, 933 F.2d 982, 986 (Fed. Cir. 1991). Ex.1002-Decl., ¶¶218-224; Ex.1007-Decl., ¶90.

First, each reference is analogous art to the Challenged Claims. As Sections XI.E.1.a and XI.E.1.e detail, each is in the same field as the Challenged Claims and is reasonably pertinent to solving the problems the Challenged Claims address—treating tissue—with the same types of solutions—applying energy to tissue. Ex.1002-Decl., ¶219.

Second, a POSITA would have been motivated and have found it obvious to configure Makower’s bipolar electrodes in multiple pairs as Stern teaches, including as claim 4 recites. As Section XI.E.1 details, Makower teaches delivering energy with bipolar electrodes and states “designs and constructions of such components and assemblies are w[e]ll known.” Ex.1005-Makower, [0164]. Fang and Edwards-535 similarly teach applying RF energy without specific implementation details. *E.g.*, Ex.1006-Fang, 877-878; Ex.1008-Edwards-535, 7:28-36, 8:17-25. POSITAs would have been motivated to reference other sources to configure bipolar electrodes to ablate tissue, and understood Makower was ready for improvement and left implementation details to POSITAs’ discretion and skill. *E.g.*, *id.*, 30:41-47. Ex.1002-Decl., ¶220; Ex.1007-Decl., ¶¶91-95.

As Section XI.C.1 explains, Stern exemplifies a known configuration for *multiple pairs of bipolar RF electrodes* and teaches its advantages and benefits. A POSITA would have been motivated to incorporate Stern's bipolar electrode configuration in the Makower, Fang, and Edwards-535 combination to realize these benefits, i.e., increasing safety and control. Doing so would have simply involved using Stern's known bipolar pairing technique to implement missing details of Makower, Fang, and Edwards-535. Ex.1002-Decl., ¶¶221-223; Ex.1007-Decl., ¶¶96-100.

Third, a POSITA would have reasonably expected success at implementing Stern's bipolar electrode pairs in the Makower, Fang, and Edwards-535 combination. Makower recognizes RF electrode "design and construction" was "w[e]ll known" (Ex.1005-Makower, [0164]), and Fang and Edwards-535 teach applying RF energy without implementation details. As Section XI.C.1 details, Stern similarly recognizes its bipolar electrodes have various applications "for controlled heat treatment of tissue," i.e., RF ablation (Ex.1009-Stern, 18:27-40), and the '077 patent assumes POSITAs would have understood how to implement multiple pairs of bipolar electrodes (Ex.1001-USP675, 18:39-43). Thus, a POSITA would have reasonably expected success incorporating Stern's bipolar electrode pairs into the Makower, Fang, and Edwards-535 combination. Such routine

implementation was well within a POSITA's skillset and would have yielded the predictable result of using one known feature (Stern's bipolar electrode pairs) with another (Makower's bipolar electrodes) to reach the predictable result of applying RF energy to tissue. Ex.1002-Decl., ¶224; Ex.1007-Decl., ¶¶101-108.

XII. DISCRETIONARY DENIAL IS NOT WARRANTED

Discretionary denial is inappropriate. **First**, no *Fintiv* factor favors denial. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 (P.T.A.B. May 13, 2020). Discovery only recently begun and has not substantially progressed, and the Final Written Decision would be expected well before the approximately 3-year median time to trial in the District of Delaware (*see* Ex.1039) and April 2026 trial (*see* Ex.1086, ¶23). And the Petition presents compelling merits underlying multiple Grounds.

Second, each *Advanced Bionics* factor weighs against denial under 35 U.S.C. §325(d). *Advanced Bionics v. MED-EL*, IPR2019-01469, Paper 6, 8-9 (Feb. 13, 2020) (precedential).

This Petition presents prior art and arguments not previously considered during prosecution. During prosecution, Applicant represented it was entitled to a pre-AIA priority date, and there is no evidence Examiner evaluated that priority claim or art as of October 22, 2019 as presented herein. *See* Ex.1025-FH077, 4, 139-

146. The '077 patent was not substantively rejected during prosecution. *See id.* Neither Saadat (Ground I) nor Fang (Ground IV) were considered by Examiner. And Fang provides teachings Examiner found were not before the Office during prosecution of a parent application. *See* Ex.1022-FH675, 122. Factor 1 therefore weighs against denial. *See Cisco Systems, Inc. v. Ramot at Tel Aviv University Ltd.*, IPR2022-01283, Paper 12, 13 (P.T.A.B. Feb. 22, 2023).

Factor 2 also weighs against denial. Deem and Makower are cited on the '077 patent, but were not a basis for rejection, which “weighs strongly against exercising...discretion.” *Cisco*, IPR2022-01283, Paper 12, 13 (internal quotations and citation omitted).

Additionally, even if Examiner “considered” the '077 patent priority date, they materially erred by applying a pre-AIA priority date and pre-AIA law and not considering subsequent art. *See* Ex.1025-FH077, 141. *See* Section IX.

This Petition also presents evidence—Dr. Bu-Saba’s declaration and evidence regarding the scope of the prior art and POSITA’s knowledge—that was not before the Office and demonstrates why the Grounds herein render the Challenged Claims unpatentable, weighing against denial. *E.g., TwinStrand Biosciences, Inc. v. Huardant Health, Inc.*, IPR2022-01400, Paper 9, 11 (P.T.A.B. Feb. 8, 2023).

XIII. CONCLUSION

Petitioners request institution of *inter partes* review and cancellation of the Challenged Claims.

Respectfully submitted,

By: /David L. Cavanaugh/
David L. Cavanaugh
Registration No. 36,476

Counsel for Petitioners

Appendix of Claims

Claim 1	
Limitation	Claim Language
1[pre]	An apparatus for treating rhinitis in a nasal cavity, the apparatus comprising:
1[a]	an elongate body, comprising: a proximal portion; and a distal portion configured for positioning in the nasal cavity;
1[b]	multiple radiofrequency electrodes coupled with the distal portion of the elongate body; and
1[c]	a radiofrequency generator coupled with the proximal portion of the elongate body for supplying radiofrequency energy to the multiple radiofrequency electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis.

Claim 2
The apparatus of claim 1, wherein the multiple radiofrequency electrodes comprise at least two bipolar radiofrequency electrodes.

Claim 3

The apparatus of claim 2, further comprising at least one sensing electrode.

Claim 4

The apparatus of claim 2, wherein the at least two bipolar radiofrequency electrodes comprise multiple pairs of bipolar radiofrequency electrodes.

Claim 5

The apparatus of claim 1, wherein the target tissue comprises nerve tissue.

Claim 6

The apparatus of claim 1, wherein at least one of the multiple radiofrequency electrodes is movable relative to the distal portion of the elongate body.

Claim 7

The apparatus of claim 1, wherein the multiple radiofrequency electrodes are configured to deliver energy laterally relative to the distal portion of the elongate body.

Claim 8

The apparatus of claim 1, wherein at least one of the multiple radiofrequency electrodes is configured to extend laterally from the distal portion of the elongate body.

Claim 11

The apparatus of claim 1, further comprising a monitoring system coupled with the distal portion of the elongate body for monitoring a degree of treatment of the target tissue.

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing, Petition for *Inter Partes* Review, contains 13,992 words as measured by the word processing software used to prepare the document, in compliance with 37 C.F.R. §42.24(d), excluding the parts of the Petition exempted from the word count by 37 C.F.R. §42.24(a)(1).

/Gilbert Smolenski/
Gilbert Smolenski
Registration No. 78,549

CERTIFICATE OF SERVICE

Pursuant to an agreement between Petitioners and Patent Owner, I hereby certify that, on April 3, 2024, I caused a true and correct copy of the following materials:

- Petition for Inter Partes Review of U.S. Patent No. 11,679,077
- Appendix of Claims
- Petitioners' Table of Exhibits
- Exhibits 1001-1035, 1038-1054, 1056-1086
- Certificate of Compliance Regarding Word Count
- Fee Authorization
- Power of Attorney

to be served on Patent Owner (Merchant & Gould P.C., P.O. Box 2903, Minneapolis, Mn 55402-0903, United States) via electronic mail to:

Kathleen.Daley@finnegan.com;
Sonja.Sahlsten@finnegan.com; and
Mike.Jakes@finnegan.com.

/Gilbert Smolenski/
Gilbert Smolenski
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Petitioners' Table of Exhibits

No.	Description
1001.	U.S. Patent No. 11,679,077
1002.	Declaration of Dr. Nicolas Bu-Saba from IPR2024-00281
1003.	U.S. Patent No 10,307,200 to Saadat
1004.	U.S. Patent Pub. No. 2008/0021369 to Deem
1005.	U.S. Patent Pub. No. 2005/0240147 to Makower
1006.	Fang (Translation)
1007.	Declaration of Dr. Gregory Martin from IPR2024-00281
1008.	U.S. Patent No. 6,517,535 to Edwards
1009.	U.S. Patent No. 5,562,720 to Stern
1010.	U.S. Provisional Appl. No. 60/702,077
1011.	U.S. Provisional Appl. No. 60/747,771
1012.	U.S. Patent No. 7,608,275
1013.	U.S. Patent No. 8,133,497
1014.	U.S. Patent No. 8,338,164
1015.	U.S. Patent No. 8,961,391
1016.	U.S. Patent No. 9,498,283
1017.	U.S. Patent No. 10,022,529
1018.	Prosecution history for U.S. Patent No. 10,022,529
1019.	U.S. Patent No. 10,729,897
1020.	Prosecution history for U.S. Patent No. 10,729,897
1021.	U.S. Patent No. 10,610,675
1022.	Prosecution History for U.S. Patent No. 10,610,675
1023.	U.S. Patent No. 10,894,011
1024.	Prosecution History for U.S. Patent No. 10,894,011
1025.	Prosecution History for U.S. Patent No. 11,679,077
1026.	U.S. Patent No. 7,655,243
1027.	Prosecution History for U.S. Patent No. 7,655,243
1028.	Prosecution History for U.S. Patent No. 8,636,684
1029.	U.S. Patent No. 8,105,817
1030.	U.S. Patent No. 8,636,684
1031.	U.S. Patent Pub. No. 2014/0114233
1032.	U.S. Patent No. 9,700,707
1033.	U.S. Patent No. 10,052,465

No.	Description
1034.	File History for U.S. Patent No. 10,335,221 assigned to Aerin
1035.	<i>Aerin Medical Inc. v. Neurent Medical Inc.</i> , 1:23-cv-00756-GBW, Amended Complaint for Patent Infringement, Dkt. 17 (October 16, 2023) (“Amended Complaint”)
1036.	Reserved
1037.	Reserved
1038.	Exhibit Z to Amended Complaint – Foundry’s Infringement Allegations for U.S. Patent No. 11,679,077
1039.	Docket Navigator District of Delaware Statistics as of January 18, 2024
1040.	U.S. Patent No. 8,939,970 to Stone
1041.	Stedman’s Medical Dictionary (27th ed. 2001)
1042.	PDR Medical Dictionary (2nd ed. 2000)
1043.	Kong Yonggang, <i>Low-temperature plasma ablation of inferior turbinate for the treatment of perennial allergic rhinitis</i> , 19(5) J Clin. Otorhinolaryngol 214 (Mar. 2005) (Translation) (“Kong”)
1044.	Chen Shi-qiang et al., <i>Preliminary study on radiofrequency thermocoagulation of the posterior inferior nerve, anterior ethmoidal nerve, and inferior turbinate under nasal endoscopy for the treatment of perennial allergic rhinitis</i> , 11(3) China Journal of Endoscopy 239 (Mar. 2005) (Translation) (“Chen”)
1045.	Liang Jianping, <i>Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy</i> , 13(8) J Clin. Otorhinolaryngol 341 (Aug. 1999) (Translation) (“Liang”)
1046.	U.S. Patent No. 6,669,689 to Lehmann
1047.	U.S. Patent No. 6,685,648 to Flaherty
1048.	Stedman’s Medical Dictionary (26th ed. 1995)
1049.	Webster’s Third New International Dictionary (2002)
1050.	S. Waxman, <i>Correlative Neuroanatomy</i> (23rd ed. 1996)
1051.	Robert E. Windsor and Scott Jahnke, <i>Sphenopalatine Ganglion Blockage: A Review and Proposed Modification of the Transnasal Technique</i> , Pain Physician 7:283-286 (2004)

No.	Description
1052.	Ralph Fenton, <i>Current Evaluation of Nasopharyngeal Defense Mechanisms</i> (1955)
1053.	U.S. Patent No. 6,517,534 to McGovern
1054.	M.M. L. Arora, <i>Cryodestruction of Vidian Nerve Branches</i> , 32:3 Indian J. Otolaryngology 80 (Sept. 1980)
1055.	Reserved
1056.	Maureen McDaniel Sackenheim, <i>Radio Frequency Ablation</i> , JDMS 19:88-92 (March/April 2003)
1057.	U.S. Patent No. 5,766,605 to Sanders
1058.	U.S. Patent No. 874,178 to De Forest
1059.	U.S. Patent Pub. No. 2005/0171574 to Rubinsky
1060.	U.S. Patent No. 3,538,919 to Meyer
1061.	U.S. Patent No. 3,117,571 to Fry
1062.	International Pub. No. 2016/183337 to Townley
1063.	U.S. Patent No. 4,411,266 to Cosman
1064.	Andrew Lane, <i>Nasal anatomy and physiology</i> , Facial Plast. Surg. Clin. N. Am. 12:387-395 (2004)
1065.	Gray's Anatomy (2003)
1066.	U.S. Patent No. 6,273,886 to Edwards ("Edwards '886")
1067.	Joseph D. Bronzino, <i>Medical Devices and Systems</i> , The Biomedical Engineering Handbook (3rd ed. 2006)
1068.	U.S. Patent No. 5,255,679 to Imran
1069.	Dhanalakshmi Koyyalagunta and Danesh Mazloomdoost, <i>Radiofrequency and cryoablation for cancer pain</i> , Techniques in Regional Anesthesia and Pain Management 14:3-9 (2010)
1070.	Declaration of June Munford from IPR2024-00281
1071.	Translator Declarations for Chen
1072.	Translator Declarations for Liang
1073.	Translator Declarations for Fang
1074.	Translator Declarations for Kong
1075.	Munford Appendices for Chen
1076.	Munford Appendices for Liang
1077.	Munford Appendices for Fang
1078.	Munford Appendices for Kong
1079.	Munford Appendices for Shanghai

U.S. Patent No. 11,679,077
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No.	Description
1080.	U.S. Patent No. 5,891,134 to Goble
1081.	U.S. Patent No. 5,575,788 to Baker
1082.	International Pub. No. 99/30655 to Hovda
1083.	April 1, 2024 Declaration of Dr. Nicolas Bu-Saba
1084.	April 2, 2024 Declaration of Dr. Gregory Martin
1085.	April 2, 2024 Declaration of June Munford
1086.	<i>Aerin Medical Inc. v. Neurent Medical Inc.</i> , 1:23-cv-00756-GBW, Scheduling Order, Dkt. 42 (March 26, 2024).