

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. IPR2024-00279

U.S. Patent No. 10,610,675

**PETITION FOR *INTER PARTES* REVIEW
OF CLAIMS 1-3, 7, 9-10, AND 17-25 OF
U.S. PATENT NO. 10,610,675
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. 10,610,675 (the “’675 patent”) are directed to the well-known concept that applying energy to tissue in the nose can treat a nasal condition. The methods of the Challenged Claims have been known for decades and are unpatentable for multiple reasons.

The application leading to the ’675 patent was the eighth non-provisional Patent Owner (“PO”) filed in a patent family, but the first 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, 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, including the presently challenged patent, with entirely different claims directed to treating nasal conditions with energy, as opposed to neurotoxin for bronchial tube treatment or cosmetic and myofascial applications.

Because they were brand new and are not described in a proper priority application, the challenged claims are only entitled to priority on the date they were

filed, 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). In addition, to the extent Patent Owner attempts to argue the challenged claims have written description in the '675 patent specification, publication of identical parts of that specification in a non-priority application (Deem) anticipates the claims as well (Ground III).

Regardless, before any application associated with the '675 patent was filed in 2005, it was known not only that nerves in the nasopharyngeal passage cause rhinitis symptoms, but also that application of energy such as radiofrequency ("RF") energy in that passage would treat such nasal conditions. Makower and Fang together render the claims obvious (Ground IV).

For the reasons discussed herein, any of four grounds renders the Challenged Claims unpatentable.

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 '675 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. Petitioners are concurrently filing *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

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III. CERTIFICATION OF GROUNDS FOR STANDING

Petitioners certify the '675 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 1-3, 7, 9-10, and 17-25 (“Challenged Claims”) of the '675 patent.

A. Prior Art

The '675 patent was filed on October 22, 2019, and claims priority to U.S. Provisional No. 60/702,077¹ filed on July 22, 2005. Ex.1001-USP675, Cover. As detailed in Section IX, however, the '675 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), which issued on 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), which published on January 24, 2008 and is prior art at least under AIA 35 U.S.C. §102(a)(1).

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

The following prior art also applies, including to the extent PO argues the '675 patent is entitled to priority earlier than October 22, 2019:

3. U.S. Pub. 2005/0240147 to Makower (“Makower,” Ex.1005), which was filed on April 21, 2004 and published on 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).
4. 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 which is prior art at least under pre-AIA 35 U.S.C. §102(a) or AIA 35 U.S.C. §102(a)(1). As detailed in the Declaration of June Munford, Fang was publicly available as of July 20, 2005, before the earliest provisional application '675 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).

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.

B. Grounds for Challenge

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

Ground	35 U.S.C. §	Claims	Reference(s)
I	102	1-3, 7, 9-10, 17-25	Saadat
II	103	24-25	Saadat
III	102	1-3, 7, 9-10, 17-25	Deem
IV	103	1-3, 7, 9-10, 17-25	Makower and Fang

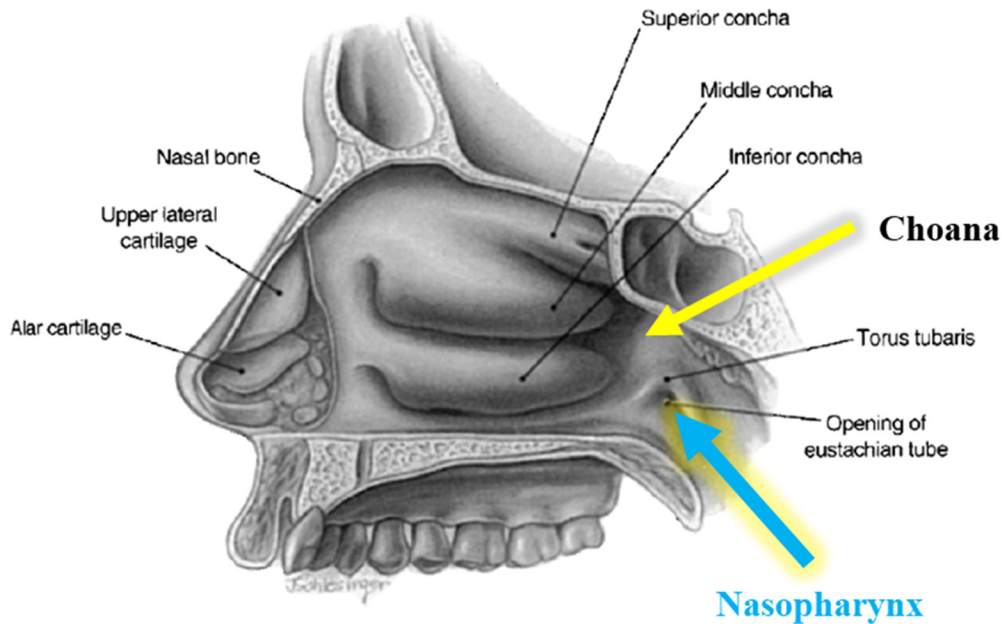
This Petition, supported by the declarations of Dr. Nicolas Bu-Saba (Ex.1002) and June Munford (Ex.1070), demonstrates there is a reasonable likelihood that Petitioners will prevail with respect to at least one challenged claim. 35 U.S.C. §314(a). Petitioners respectfully request institution. *SAS Institute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

V. TECHNOLOGY BACKGROUND

A. 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.



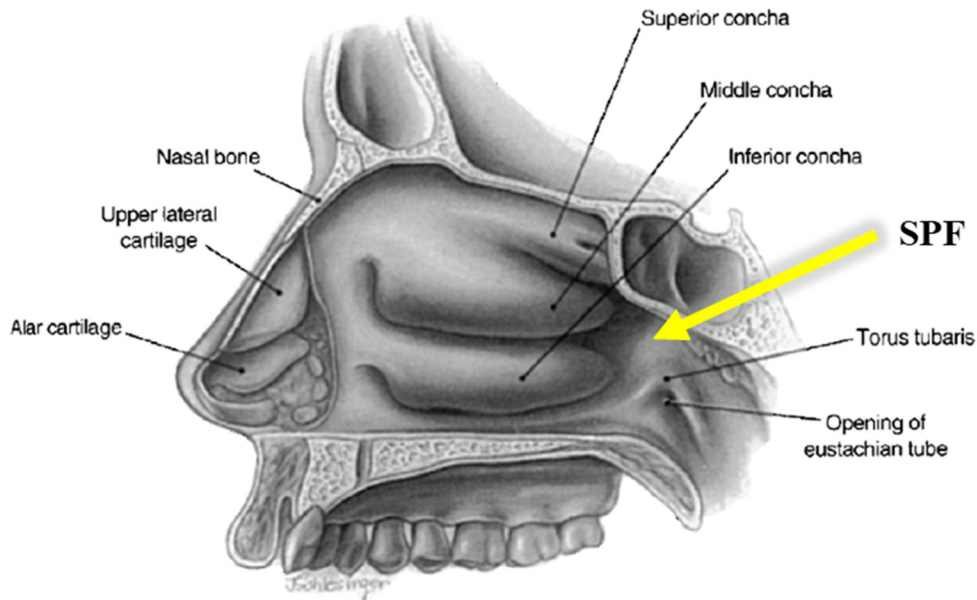
Ex.1064-Lane, 338.⁴ Ex.1002-Decl., ¶31.

Within the passageway that includes the nasal cavity and nasopharynx (sometimes referred to as the nasopharyngeal passage⁵) there are nerve cells that control other cells (goblet cells) that generate mucus. The sphenopalatine ganglion

⁴ Annotations added unless noted.

⁵ See *infra* Section XI.A.1.b.

(“SPG”),⁶ located posterior in the nasal cavity near the 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-USP675, 1:48-49. Neurotoxins such as botulinum neurotoxin (BOTOX[®])

⁶ The SPG originates from the Vidian nerve located behind the SPF. Ex.1002-Decl., ¶32.

“block[] the release of neurotransmitter[s] from the nerves that control the contraction of...muscles” or disable mucus-producing cells. *Id.*, 1:60-2:12, 3:25-34. For example, injecting neurotoxin treats conditions by “paralyz[ing] or weaken[ing]” muscles that would otherwise signal nerves to cause symptoms. *Id.*, 1:60-2:25. 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.*, 2:17-46, 3:35-49, 3:66-4:15; 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-USP675, 2:19-25, 3:35-49, 3:66-4:15. 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-Rubisnky, [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-USP675, 13:27-40. 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.

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.” Ex.1059-Rubisnky, [0005]. Ex.1002-Decl., ¶¶40-42.

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 '675 patent discusses pairing such technique with preparatory electroporation to ready cells to receive neurotoxin. *See* Section VI.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, 240.⁷ By the early 2000s, scientists had developed devices that used various types of energy to ablate the parasympathetic

⁷ *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. *See* 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 nasal congestion). And Arora used cryotherapy (cooling). *See* 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 ’675 PATENT

A. Brief Description

The ’675 patent relates to delivering “toxins to defined target areas within the nasal cavities” to treat rhinitis. Ex.1001-USP675, 3:56-64; 8:4-21. Ex.1002-Decl., ¶47.

’675 patent Figure 23 discloses a **porous balloon catheter** that delivers neurotoxins into the nasal cavity. Ex.1001-USP675, 22:27-33, 23:67-24:6. The **catheter** is positioned in the back of the nasal passages because it has high goblet cell concentration. *Id.*, 23:67-24:6. To facilitate toxin delivery, the **catheter** includes

ultrasonic transducers to cause “reversible poration” of the target cells. *Id.*, 4:63-5:4, 5:43-53; 17:45-51, 22:34-38, 22:55-62, 23:67-24:6.

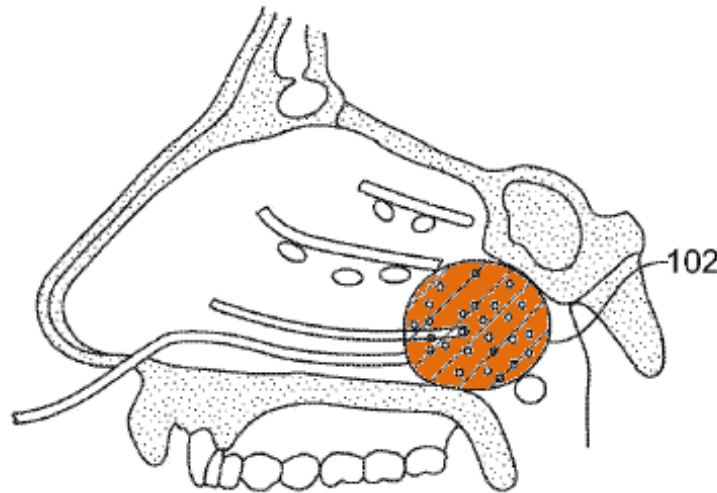


FIG. 23

Ex.1001-USP675, FIG.23. Ex.1002-Decl., ¶¶48-49.

The '675 patent summarily lists other “energy devices” to cause reversible poration—including x-ray, radiofrequency (RF), DC current, AC current, microwave, and ultrasound—without any working example. Ex.1001-USP675, 13:27-40. The '675 patent does not describe using any energy source alone to treat any condition, including rhinitis. *See generally id.* Ex.1002-Decl., ¶50.

The Challenged Claims, which were included in the '675 patent's original application, depart from the '675 patent's specification. While the figures and written description of the patent 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. 16/659,893, which issued as the '675 patent, was filed on October 22, 2019. Ex.1001-USP675, Cover. The '893 Application was designated a continuation application and purports to claim priority through a chain of continuation applications to a July 22, 2005 provisional application. Ex.1022-FH675, 6-7 (not designating application as subject to AIA); Section IX. Ex.1002-Decl., ¶52.

The Examiner issued a Notice of Allowance on November 22, 2019, one month after the application was filed and without issuing an office action. Ex.1022-FH675, 117-123. The Examiner identified Makower as the “closest prior art” because it taught most limitations of the claims, namely, “treating disorders of the ear, nose and throat via inserting an energy emitting device into the nasopharynx.” Ex.1022-FH675, 122. However, the Examiner found Makower did “not teach or fairly suggest treating nasal conditions with a device so as to disrupt neural activity such that mucus secretion is reduced in the nasopharyngeal passage, and wherein the target tissue has a change in temperature.” *Id.*, 122, 124. The filing receipt for the '893 Application lists July 22, 2005 as the earliest alleged priority date, and the

Examiner reviewed the application under pre-AIA law. *Id.*, 111; 122. Ex.1002-Decl., ¶53.

Following allowance, the applicant submitted an information disclosure statement (“IDS”) listing over 280 references. Ex.1022-FH675, 133-150. Less than one month later, the Examiner issued a miscellaneous communication stating that the IDS was considered, and the application then issued. *Id.*, 656; Ex.1001-USP675, Cover.

The Examiner never substantively rejected the claims, and the prosecution history does not reflect that Examiner substantively evaluated the priority date for the ’893 Application or art as of the appropriate priority date. Neither Saadat nor Fang (or their teachings) were of record. Ex.1002-Decl., ¶54.

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., ¶¶26-30.

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., ¶¶55-58.⁸

IX. PRIORITY DATE

The priority date for the Challenged Claims is October 22, 2019, the filing date of the '893 Application (*see* Ex.1001-USP675, Cover), because new subject matter in the Challenged Claims was added on that date. Ex.1002-Decl., ¶¶59-76.

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 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 '675 patent claims priority to the '077 Provisional filed July 22, 2005. The '077 Provisional is directed to methods of using neurotoxins to treat the

⁸ Petitioners reserve the right to propose or respond to claim constructions in parallel litigation and respond to any claim construction PO advances here.

bronchial tube or for cosmetic or myofacial application, which is **not** what the '675 patent claims. Ex.1010-FH077, [0001], [0024], [0068]-[0070], FIGs.7-8; Ex.1001-USP675, claims 1, 17. Following the '077 Provisional, Applicant filed seven utility applications before the '893 Application. *See* Ex.1001-USP675, Cover. Each such utility application 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 nasopharyngeal passage or rhinitis. Ex.1002-Decl., ¶¶60-61.

The '077 Provisional disclosure repeated in subsequent utility applications (including the '675 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-USP675, Abstract, FIG.7, FIGs.9-10, FIG.13, 17:22-24), and cosmetic applications for external muscle (*e.g.*, *id.*, FIG.14, 19:65-20:17), it does not provide written description of at least “*positioning...a treatment device proximate to target tissue in a nasopharyngeal passage*” or delivering energy to the target tissue “*to disrupt neural activity such that mucus secretion [or congestion] is reduced in the*

nasopharyngeal passage.”⁹ *Id.*, claims 1, 17; *see also* Ex.1024-FH011, 340-342. Discussion of treating lung “bronchial tissue” for, e.g., “asthma” (*id.*, 17:22-24, FIG.10), and “[c]osmetic and [m]yofacial [a]pplications” (*id.*, 19:65, FIG.14), do not provide written description for delivering energy inside the nose to treat rhinitis symptoms. Ex.1002-Decl., ¶¶62-65.

PO also argued during prosecution of a child application that bronchial tube treatment is “patentably distinct” from treatment in the nasopharyngeal passage, Ex.1024-FH011, 340-342, which supports that the ’077 Provisional does not provide written description for the challenged nasopharyngeal passage claims. Ex.1002-Decl., ¶¶66-69.

Instead, the Challenged Claims are the **first** purported disclosure by PO of the methods they claim. They therefore are entitled only to priority on the day they were filed—October 22, 2019. *See Anascape, Ltd. v. Nintendo of Am. Inc.*, 601 F.3d 1333, 1340 (Fed. Cir. 2010) (claims only entitled to priority on application filing date).

Although the ’675 patent does not claim priority to any other provisional application, when PO filed the ’675 patent application, it—**for the first time** in this family—copied passages and figures from U.S. Provisional Application No.

⁹ Apart from citations, *italicized* text indicates claim language unless noted.

60/747,771 (filed May 19, 2006) into the specification.¹⁰ Any argument that copying the subject matter of the '771 Provisional into the '675 patent allows PO to claim priority to any earlier-filed application would be misplaced for four reasons.

First, PO cannot claim the date of the '771 Provisional because the '675 patent does not claim priority to it. Ex.1022-FH675, 4-11; 37 C.F.R. §1.78(a)(3) (requiring reference to provisional applications in application data sheet for priority); *see also* 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 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 two utility applications immediately preceding the '675 patent (U.S. App. No. 15/358,187 and 16/036,381) do not claim priority to the '771 Provisional or incorporate it by reference. *See*

¹⁰ 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.

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.¹¹ 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 reference to the prior application is not included in the later-filed application.”).¹² Instead, at most,

¹¹ Indeed, Examiner objected to Applicant’s attempt to add the '771 Provisional to the preceding '381 Application because it was new matter. Ex.1020-FH897, 183, 190, 203-205, 211.

¹² PO’s addition of '771 Provisional matter to the '893 application specification 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 filing date); *Akeva L.L.C.*

added matter supports priority only as of the date it was added. *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 written description support. *See* 37 C.F.R. §1.57(d) (2023); 37 C.F.R. §1.57(d) (2005).¹³ *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

v. Nike, Inc., 817 F. App'x 1005, 1012 (Fed. Cir. 2020) (amending later application does not avoid disclaimer by intervening application).

¹³ Rule 1.57(d) provides “essential material” “necessary to: [p]rovide a written description of the claimed invention” “may be incorporated by reference” only through “a **U.S. patent or U.S. patent application publication.**” 37 C.F.R. §1.57(d) (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).

incorporation)). Here, **no** utility application preceding the '675 patent 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 '675 patent specification does not provide written description support.

Because the '675 patent specification and '771 Provisional are directed to use of **neurotoxins**, they do not disclose **delivering energy** to or increasing the temperature of the target tissue “*to disrupt neural activity such that mucus secretion [or congestion] is reduced in the nasopharyngeal passage.*” Ex.1001-USP675, claims 1, 17. Instead, those disclosures solely use RF energy to porate cells to facilitate neurotoxin delivery, not to treat nasal conditions. *See, e.g.*, Ex.1011-FH771, 56 (“Methods and systems...which selectively porate[] target cells to enhance uptake of the toxin”); Ex.1001-USP675, 8:4-11 (“[toxins] are delivered...while applying energy to target cells” to “cause a reversible...poration

of the cell membrane to enhance delivery of the toxin”).¹⁴ As Aerin—named licensee of the ’675 patent—represented 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-Rubisnky, [0005], and the ’675 patent specification and ’771 Provisional pertain at most to the latter. Ex.1002-Decl., ¶¶70-76.

¹⁴ Notably, Applicant pursued patents directed to the ’771 Provisional subject matter in a separate applications. Unlike applications preceding the ’675 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 nasal conditions with neurotoxins, and not *without* neurotoxin. 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 uptake of the neurotoxin. *E.g.*, Ex.1028-FH684, 16-18, 21-22, 74-86. Ex.1002-Decl., ¶73.

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 regions of tissue...within the nasal cavity for treating conditions such as 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.

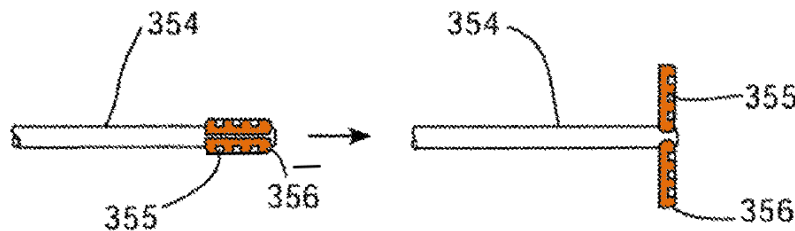


Figure 20E

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.

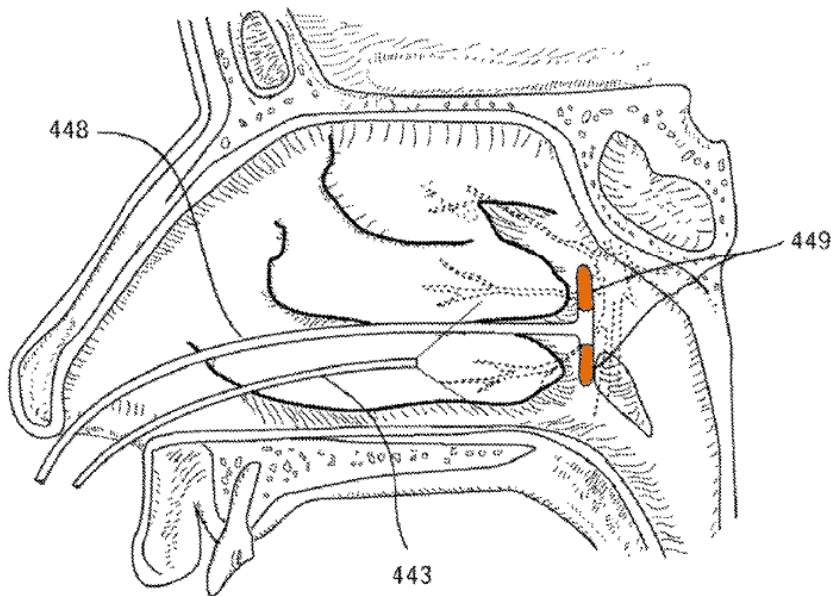


Figure 30

Ex.1003-Saadat, FIG.30. Ex.1002-Decl., ¶79.

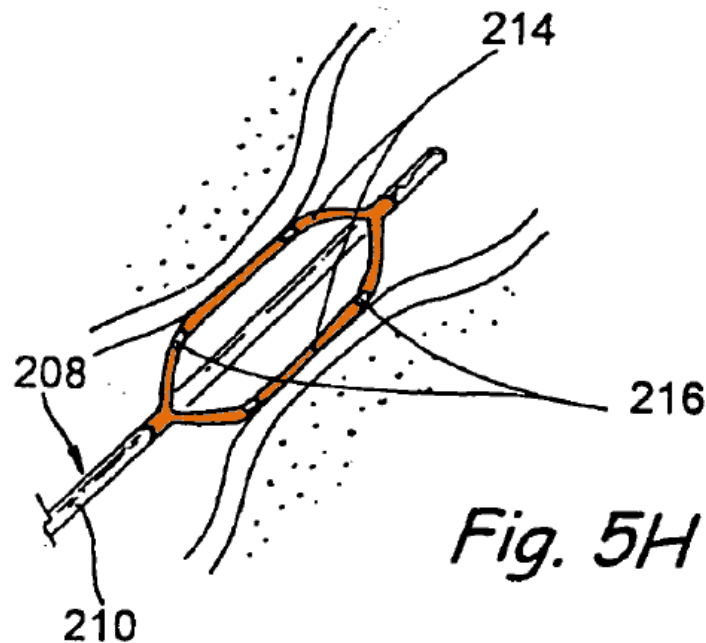
B. Deem

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-USP675 and Ex.1011-FH771.

C. Makower

Makower teaches “medical devices and methods...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 an electrosurgical 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 to the electrodes 216 causing” tissue “to be cauterized or heated.” *Id.*, [0187]. “[S]ensing elements” can be attached “to monitor various parameters of the catheter and/or surrounding tissue (e.g., temperature, etc.).” *Id.* Ex.1002-Decl., ¶80.

D. Fang

Fang teaches “nasal endoscopic surgery combined with multiple radiofrequency” to treat “perennial allergic rhinitis.” Ex.1006-Fang, 876-877. Fang aligns the “firing head” of an instrument “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 thus reduces rhinitis symptoms. *Id.*, 877. Ex.1002-Decl., ¶81.

XI. SPECIFIC GROUNDS FOR UNPATENTABILITY

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

A. Ground I: Claims 1-3, 7, 9-10, and 17-25 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]

Saadat discloses *a method of treating a patient’s nasal condition* (e.g., rhinitis). Ex.1002-Decl., ¶¶83-84.

Saadat discloses “methods for treating conditions such as rhinitis,” a *patient’s nasal condition*. Ex.1003-Saadat, Abstract, Title (“[M]ethods for treating rhinitis”),

1:21-26, 2:16-24 (“Rhinitis is...characterized by nasal symptoms, including...rhinorrhea, and/or nasal congestion.”), 3:6-14 (“methods...for ablating one or more [nerve] branches to reduce or eliminate rhinitis....”), 10:16-26, 10:41-11:14, claims 1 (“method for treating nerve tissue within a nasal cavity of a patient”), 6 (“delivering...energy-based treatment...such that at least one symptom of rhinitis is reduced”); Ex.1001-USP675, 3:7-10 (rhinitis is “condition” in “nasal cavity”). Ex.1002-Decl., ¶84.

b. 1[a]

Saadat discloses *positioning a distal portion* (e.g., distal end) *of a treatment device* (e.g., RF ablation probe) *proximate to target tissue* (e.g., tissue with parasympathetic nerves) *in a nasopharyngeal passage of a patient* (e.g., passage including posterior nasal nerve). Ex.1002-Decl., ¶¶85-99.

Saadat discloses an RF ablation probe with a **distal end** that includes “a bipolar 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 (Figure 30 illustrates “ablation of the posterior nasal nerve using a generic ‘T’ tipped ablation device 448...”).

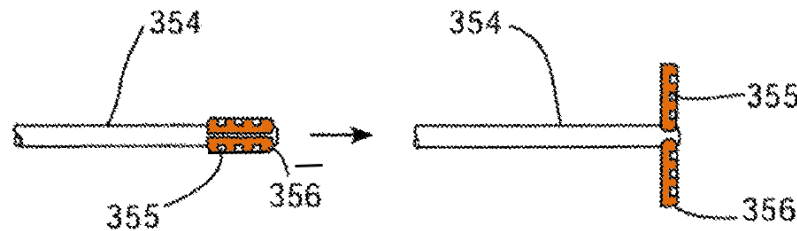


Figure 20E

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

Figure 30 (below) illustrates a “T” ablation device *positioned* to target the “posterior nasal nerve” (e.g., *target tissue*), which is posterior to the turbinates. Ex.1003-Saadat, 33:41-49; *see also id.*, 16:20-22. Saadat explains these nerves, shown in Figure 14B (below), originate from the SPG and control parasympathetic nervous function (i.e., mucus production and congestion). *Id.*, 16:39-51, 27:10-20. Saadat explains “[a]blating these nerves [i.e., *target tissue*] leads to a decrease in or interruption of parasympathetic nerve signals that contribute to congestion and rhinorrhea in patients with chronic rhinitis.” Ex.1003-Saadat, 1:62-66, 3:6-10. Saadat discloses multiple ablation 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 distal end of the “T” shaped device is placed proximate to the posterior nasal nerve to ablate parasympathetic nervous function. *Id.*, 30:34-38, 31:10-19, 33:41-49.

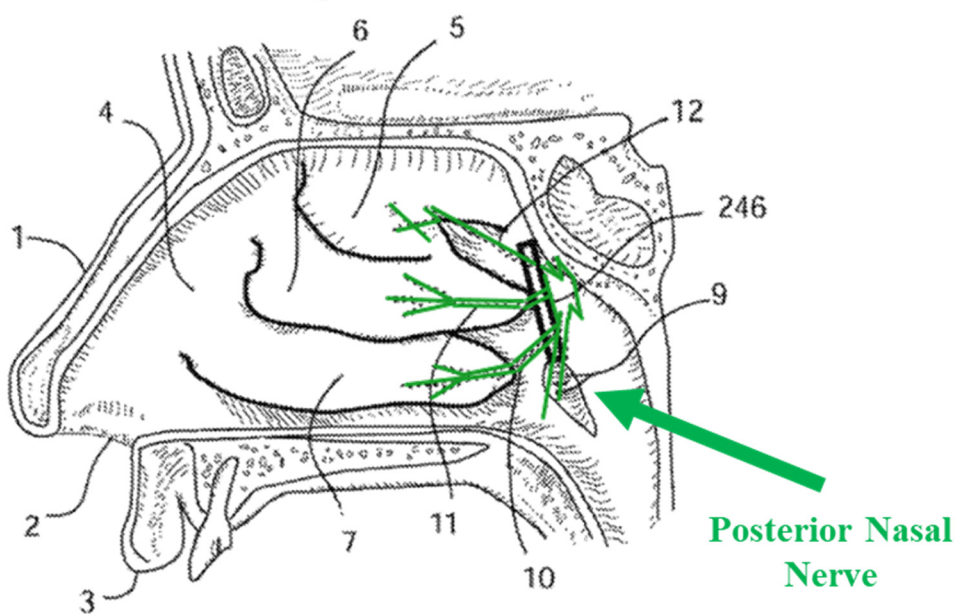


Figure 14B

Ex.1003-Saadat, FIG.14B.

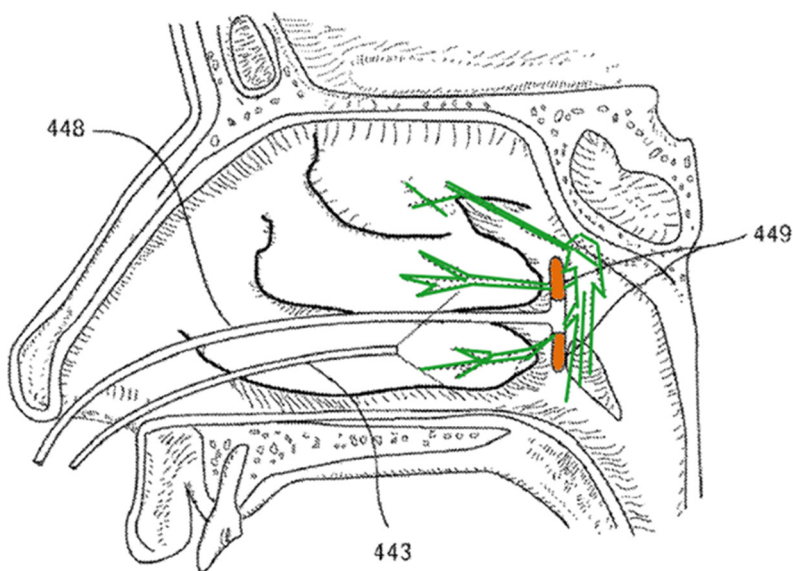


Figure 30

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

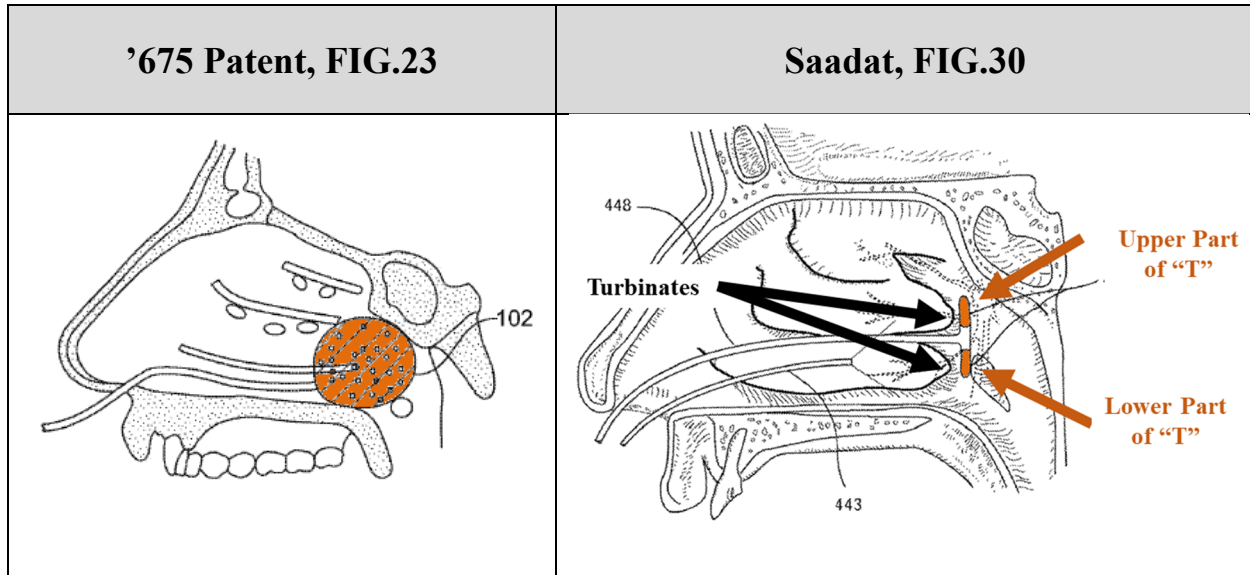
The **distal end** of Saadat's ablation device is thus positioned in the *nasopharyngeal passage*, the passage including the **nasal cavity** (naso-) and **pharynx** (-pharyngeal). *See, e.g.,* Ex.1048-Stedman's, 1177 ("nasopharyngeal" means "[r]elating to the nose or nasal cavity and the pharynx"); Ex.1049-Webster's, 1504 ("nasopharyngeal" means "relating to the nose and pharynx or the nasopharynx").¹⁵ Within the nasopharyngeal passage, the **distal end** of Saadat's

¹⁵ The term "*nasopharyngeal*" only appears in the Challenged Claims. However, the claims, figures, and written description of the '675 patent support that, consistent with extrinsic definitions, "nasopharyngeal" refers to the passage including the nasal cavity and pharynx. The claims recite treatment methods "*within a nasal cavity*" and Figure 23 depicts "distribution of toxin...into the **nasal cavity**," confirming the nasal cavity is within the scope of target tissue. Ex.1001-USP675, claims 1, 17, 11:1-2. Further, the Figure 23 balloon targets the "nasal membrane" and is "positioned...**in the back of the nasal passages in the area of the nasopharynx**," referring to the target nasopharyngeal passage as including the nasal cavity and nasopharynx. *Id.*, 23:66-24:6; *see also id.* FIGs.18-19, 10:62-63. Although Petitioners submit construction is unnecessary, to the extent PO argues "*nasopharyngeal passage*" requires construction, under *Phillips v. AWH Corp.*, 415

ablation device is positioned to target the **posterior nasal nerve**, and is thus *proximate to target tissue in the nasopharyngeal passage*. *E.g.*, Ex.1003-Saadat, 30:34-38, 31:10-19, 33:41-49, FIG.14B, FIG.30, claims 1 (“contacting a mucosal surface of the nasal cavity with the treatment delivery portion [of an energy-based treatment device],” “delivering an energy-based treatment” and “treat[ing] the nerve tissue underlying the mucosal surface”), 7. Ex.1002-Decl., ¶¶90-98.

Additionally, as shown below, the distal end of Saadat’s ablation device is in the location the ’675 patent identifies as the “nasopharynx” and “nasal passage” (i.e., *nasopharyngeal passage*). The upper part of the “T” is positioned proximate to tissue in the posterior nasal cavity, and the lower part is positioned in and proximate to tissue in the nasopharynx. Ex.1002-Decl., ¶¶99.

F.3d 1303 (Fed. Cir. 2005), this evidence supports that its plain meaning is a passageway including the nasal cavity and pharynx. *E.g.*, Ex.1001-USP675, FIGs.18-19, FIGs.23-24, claims 1, 17, 10:62-63; 11:1-2; 23:66-24:6; Ex.1048-Stedman’s, 1177; Ex.1049-Webster’s, 1504. Moreover, PO has used the term “nasopharyngeal” consistent with the above in other patent filings. *E.g.*, Ex.1055-Morriss, [0014]-[0020], [0073]-[0078], FIGs.5A-5F, FIGs.7A-7B. Ex.1002-Decl., ¶¶91-96.



c. 1[b]

Saadat discloses administering therapy (e.g., RF energy) to the target tissue (e.g., nasal tissue) with the treatment device (e.g., RF ablation probe) so as to disrupt neural activity (e.g., parasympathetic nerves) such that mucus secretion (e.g., nasal congestion) is reduced in the nasopharyngeal passage (e.g., area of posterior nasal nerve). Ex.1002-Decl., ¶¶100-105.

As discussed in Section XI.A.1.b, Saadat discloses positioning the **distal end** of its **RF ablation probe** proximate to tissue in the nasopharyngeal passage. *E.g.*, Ex.1003-Saadat, FIG.14B, FIG.30, 30:34-38, 31:10-19, 33:41-49. Ex.1002-Decl., ¶101.

The **distal end** of Saadat's RF ablation probe includes electrode ablation elements that are "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. Ex.1002-Decl., ¶102.

Saadat explains that RF ablation *disrupts neural activity* to reduce or eliminate rhinitis symptoms, including *mucus secretion* and congestion. Saadat teaches that nasal nerves originating from the SPG “are responsible for parasympathetic control of the nasal mucosa” (Ex.1003-Saadat, 16:44-51), and “**ablating** one or more...branches” of these nerves to “reduce[s] or eliminate 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., ¶103.

As discussed in Section XI.A.1.b, Saadat discloses performing RF ablation in the *nasopharyngeal passage*. Thus, the distal end of Saadat’s RF ablation probe disrupts neural activity of the posterior nasal nerve (i.e., parasympathetic nerves) to reduce or eliminate symptoms of rhinitis (e.g., *mucus secretion* and congestion) in the *nasopharyngeal passage*. Ex.1002-Decl., ¶104.

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], wherein the delivering of the energy-based treatment comprises delivering energy in a form selected from the group consisting of ultrasound, radiofrequency,

and electrical energy,” and doing so 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 (claiming specific nerve tissue including “posterior nasal nerve, a branch of a [V]idian nerve, a parasympathetic nerve, [or]...a sphenopalatine ganglion nerve”), 8 (“delivering...bipolar radiofrequency energy”). Ex.1002-Decl., ¶105.

d. 1[c]

Saadat discloses that *administering therapy comprises at least one of delivering energy* (e.g., RF energy) *to the target tissue and changing the temperature of the target tissue* (e.g., RF energy to thermally ablate tissue). Ex.1002-Decl., ¶¶106-108.

As discussed in Section XI.A.1.c, Saadat discloses applying RF energy to nasal tissue in the nasopharyngeal passage to disrupt neural activity, i.e., *delivering RF energy to the target tissue* (e.g., posterior nasal nerves). Ex.1002-Decl., ¶107.

Moreover, because Saadat discloses applying RF energy to tissue in the nasopharyngeal passage to ablate nerves (*see* Sections XI.A.1.b-c), Saadat discloses that applying RF energy increases the *temperature of the target tissue*. As discussed in Section V, it was well-known that RF energy used to ablate tissue changes the temperature of tissue, and thus, a POSITA would have understood that Saadat’s RF

ablation probe changes the temperature of tissue when it applies RF energy.

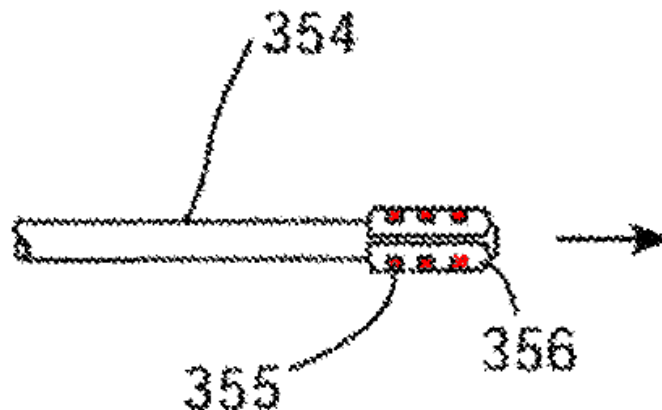
Ex.1002-Decl., ¶108.

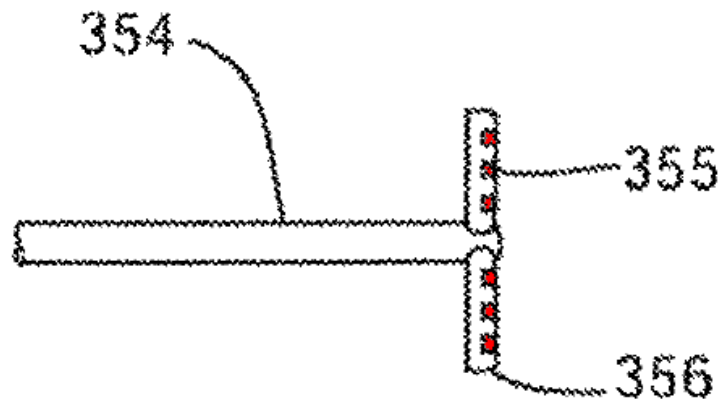
Accordingly, Saadat anticipates claim 1.

2. Claim 2

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

Saadat discloses that *administering therapy comprises delivering energy* (e.g., RF energy) *from at least one energy delivery element* (e.g., electrode(s)) *on the treatment device* (e.g., RF ablation probe). Saadat discloses that the **distal end** of the RF ablation probe includes **electrodes 355** that “operate in a monopolar, bipolar or multipolar fashion.” Ex.1003-Saadat, 31:10-19, 33:41-49 (“RF ablation elements”), FIG.20E, FIG.30; *see also id.* claims 3-4, 9 (“treatment delivery portion comprises a plurality of electrodes and the delivering of the energy-based treatment comprises delivering radiofrequency energy”), 10-12.





Ex.1003-Saadat, FIG.20E. Ex.1002-Decl., ¶¶109-111.

3. Claim 3

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

As detailed in Section XI.A.1.c, Saadat discloses **electrodes** on the **distal end** of its RF ablation probe deliver *RF energy*. *E.g.*, Ex.1003-Saadat, 30:34-38, 30:46-49, 31:10-19, 33:41-49, claims 1 (“delivering of the energy-based treatment comprises delivering energy in a form selected from the group consisting of...radiofrequency...energy”), 3, 8 (“delivering...energy-based treatment comprises delivering bipolar radiofrequency energy”), 9. Ex.1002-Decl., ¶¶112-113.

4. Claim 7

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

Saadat discloses *changing the temperature of the target tissue* (e.g., nasal tissue) *compris[ing] transferring thermal energy between the treatment device and the target tissue*. As explained in Section XI.A.1.d, Saadat discloses applying RF energy to increase temperature of nerves in the nasopharyngeal passage and thereby disrupt neural activity. Ex.1002-Decl., ¶¶114-116.

Moreover, Foundry alleges in parallel litigation that transferring RF energy to tissue *comprises transferring thermal energy between the treatment device and the target tissue*. Ex.1036-Complaint-Ex.V, 15. Consistent with Foundry’s allegations, and without concession regarding infringement, Saadat’s disclosure of methods of using RF energy discloses this limitation.

5. Claim 9

Claim 9 depends from claim 1. Petitioners incorporate Section XI.A.1.

Saadat discloses *administering therapy* (e.g., RF energy) *compris[ing] contacting target tissue* (e.g., nasal tissue) *with a delivery portion* (e.g., distal end) *of the treatment device* (e.g., RF ablation probe). As detailed in Section XI.A.1.c, Saadat discloses **electrodes** on the **distal end** of its RF ablation probe deliver RF energy. Moreover, Saadat explains the **distal end** is “shaped to *contact*” tissue. Ex.1003-Saadat, Abstract, 3:15-27; *see also id.*, FIG.30, 33:41-49. Saadat also claims “***contacting*** a mucosal surface of the nasal cavity with the treatment delivery

portion.” *Id.*, claim 1; *see also id.*, claims 3 (“delivering radiofrequency energy from a first electrode on a **tissue contact surface** to a second electrode on the tissue contact surface”), 4, 11 (adjusting device “to increase **contact with the mucosal surface** or pressure against the mucosal surface”). Ex.1002-Decl., ¶¶117-119.

6. Claim 10

Claim 10 depends from claim 9. Petitioners incorporate Section XI.A.5.

Saadat discloses *the target tissue* (e.g., nasal tissue) *is contacted without penetrating the target tissue*. As detailed in Section XI.A.5, Saadat discloses the expandable **distal end** of its RF ablation probe *contacts* nasal tissue when delivering RF energy. Saadat does not depict or describe that the distal end or electrodes penetrate the target tissue when delivering energy. *E.g.*, Ex.1003-Saadat, Abstract, 31:10-19, 33:41-49. Ex.1002-Decl., ¶¶120-121.

Moreover, Foundry alleges in parallel litigation that an expandable probe that administers RF does not penetrate target tissue. Ex.1036-Complaint-Ex.V, 18-20. Therefore, consistent with Foundry’s allegations, and without concession regarding infringement, Saadat discloses this limitation.

7. Claim 17

a. 17[pre]

For the reasons in Section XI.A.1.a, Saadat discloses *a method of treating a nasal condition*. Ex.1002-Decl., ¶122.

b. 17[a]

For the reasons in Section XI.A.1.b, Saadat discloses *positioning a distal portion of a treatment device proximate to target tissue in a nasopharyngeal passage of a patient*. E.g., Ex.1003-Saadat, Ex.1002-Decl., ¶123.

c. 17[b]

For the reasons in Section XI.A.1.c (discussing, e.g., congestion), Saadat discloses *administering therapy to the target tissue with the treatment device to alter nasopharyngeal cells such that congestion in the nasopharyngeal passage is reduced*. Ex.1002-Decl., ¶124.

d. 17[c]

For the reasons in Section XI.A.1.d, Saadat discloses *wherein administering therapy comprises delivering energy to the target tissue*. Ex.1002-Decl., ¶125.

8. Claim 18

Claim 18 depends from claim 17. Petitioners incorporate Section XI.A.7. For the reasons in Section XI.A.2, Saadat discloses *the energy is delivered from an energy delivery element on the treatment device*. Ex.1002-Decl., ¶¶126-127.

9. Claim 19

Claim 19 depends from claim 18. Petitioners incorporate Section XI.A.8. For the reasons in Section XI.A.3, Saadat discloses *the energy comprises RF energy*. Ex.1002-Decl., ¶¶128-129.

10. Claim 20

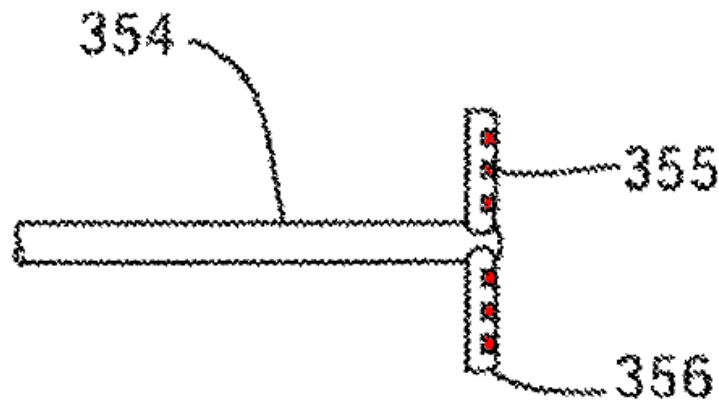
Claim 20 depends from claim 19. Petitioners incorporate Section XI.A.9.

Saadat discloses *the energy delivery element* (e.g., electrode(s)) *comprises a monopolar or bipolar electrode*. As detailed in Section XI.A.2, the **distal end** of Saadat's RF ablation probe includes **electrodes 355** that “operate in a **monopolar, bipolar or multipolar fashion** as known in the art.” Ex.1003-Saadat, 31:10-19, 33:41-49 (“RF ablation elements”), FIG.20E, FIG.30; *see also id.* claims 3-4, 9 (“plurality of electrodes” and “radiofrequency energy”), 10-12. Ex.1002-Decl., ¶¶130-131.

11. Claim 21

Claim 21 depends from claim 18. Petitioners incorporate Section XI.A.8.

Saadat discloses *the energy delivery element comprises a plurality of electrodes*. Specifically, as detailed in Section XI.A.2, the distal end of Saadat's RF ablation probe includes multiple **electrodes 355**. Ex.1003-Saadat, 31:10-19, 33:41-49, FIG.20E, FIG.30, claims 3-4, 9, 10-12.



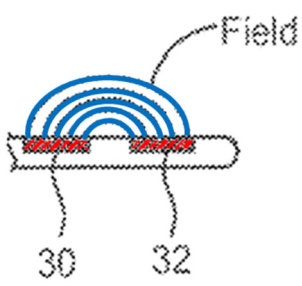
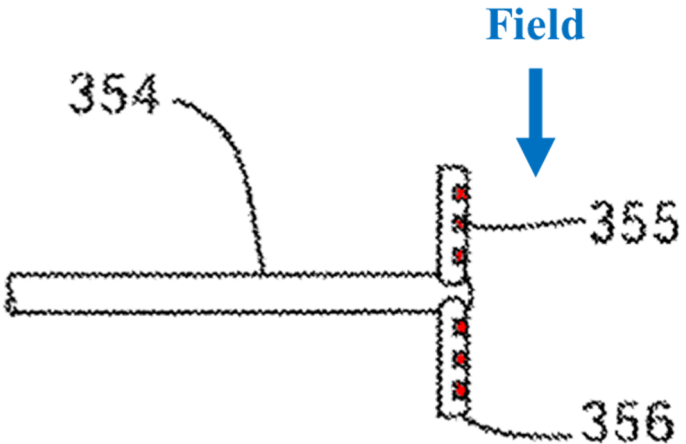
Ex.1003-Saadat, FIG.20E. Ex.1002-Decl., ¶¶132-133.

12. Claim 22

Claim 22 depends from claim 18. Petitioners incorporate Section XI.A.8.

Saadat discloses *the energy delivery element is configured to concentrate energy laterally relative to the distal portion of the treatment device*. As detailed in Section XI.A.10, the distal end of Saadat's RF ablation 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 *concentrated 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 '675 patent Figure 5A. *E.g.*, Ex.1001-USP675, 16:29-58, FIG.5, FIGs.5A-5B; Ex.1003-Saadat, 30:34-55, 31:10-19, Fig.20E. Ex.1002-Decl., ¶¶134-136.

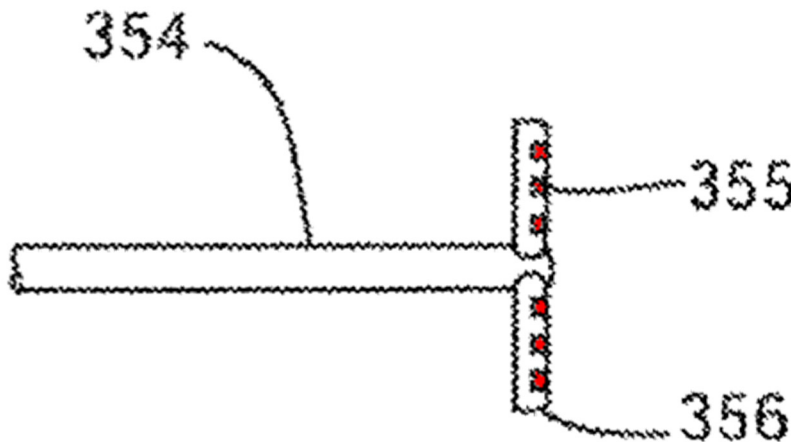
'675 Patent, FIG.5A	Saadat, FIG.20E
 FIG. 5A	

Foundry has alleged in parallel litigation that delivering RF energy from bipolar electrodes meets this limitation. Ex.1036-Complaint-Ex.V, 37-39. Thus, consistent with the '675 patent and Foundry's allegations, Saadat discloses that its electrodes *concentrate RF energy laterally* into the target tissue *relative to the distal portion of the distal end* of Saadat's RF ablation probe.

13. Claim 23

Claim 23 depends from claim 22. Petitioners incorporate Section XI.A.12.

Saadat discloses *the energy delivery element comprises at least one electrode* (e.g., electrode(s)) *disposed on a lateral side of the distal portion of the treatment device*. As Figure 20E (below) shows, **electrodes** are disposed on a lateral side of the **distal end** of Saadat's RF ablation probe. Ex.1003-Saadat, 31:10-19, 33:41-49.



Ex.1003-Saadat, FIG.20E; *see also id.*, FIG.30. Ex.1002-Decl., ¶¶137-138.

14. Claim 24

Claim 24 depends from claim 18. Petitioners incorporate Section XI.A.8.

Saadat discloses a *monitoring electrode or system* (e.g., temperature sensor) *on the treatment device*. Saadat explains that its 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. Moreover, Saadat claims an RF ablation probe with a “thermocouple,” i.e., temperature sensor, “in a vicinity of the treatment delivery portion.” *Id.*, claim 5. Ex.1002-Decl., ¶¶139-140.

15. Claim 25

Claim 25 depends from claim 24. Petitioners incorporate Section XI.A.14.

Saadat discloses the *monitoring electrode or system comprises a thermocouple or sensing electrode* (e.g., thermocouple). As detailed in Section XI.A.14, Saadat discloses and claims an RF ablation probe including a thermocouple temperature sensor. Ex.1002-Decl., ¶¶141-142.

B. Ground II: Claims 24 and 25 Are Obvious in view of Saadat

To the extent PO argues Saadat does not anticipate claims 24 and 25, Saadat renders these claims obvious. Ex.1002-Decl., ¶143.

1. Claim 24

Claim 24 depends from claim 18. Petitioners incorporate Sections XI.A.8 and XI.A.14. Ex.1002-Decl., ¶144.

To the extent PO argues and the Board agrees that Saadat does not expressly disclose a method using a *monitoring electrode or system on the treatment device*, it would have been obvious in view of Saadat. As discussed in Section XI.A.14, Saadat explains that its 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...disposed in the vicinity of distal end” “to sense the temperature

of a tissue of surgical interest.” *Id.*, 16:51-54, 17:56-59, 17:62-64. Saadat also claims an RF ablation probe including a “**thermocouple**,” i.e., temperature sensor, “in a vicinity of the treatment delivery portion” of a treatment device. *Id.*, claim 5. Ex.1002-Decl., ¶145.

A POSITA would have been motivated to position a thermocouple (i.e., temperature sensor) on the distal end of Saadat’s RF ablation probe to measure the tissue temperature as Saadat teaches. A POSITA would have understood that it was important to monitor tissue temperature during RF application for patient safety, and placing temperature sensors at the distal end of RF ablation devices was well known and routine to assure temperatures of the device were in the proper range. *E.g.*, Ex.1062-Townley, [0044] (“therapeutic assembly 212 can include...one or more temperature sensors (e.g., thermocouples, thermistors, etc.)”); Ex.1005-Makower, [0187]. Ex.1002-Decl., ¶146.

A POSITA would have had a reasonable expectation of success at including a temperature sensor on the distal end of Saadat’s RF ablation probe. Saadat teaches doing so and including temperature sensors such as thermocouples on RF ablation probes was well known in the art. *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., temperature sensor) 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 because the missing limitation was “nothing more than a **predictable variation** on the prior art.”). Moreover, the '675 patent assumes a POSITA would have understood how to implement a monitoring sensor, as it generically describes that “any of [its] foregoing systems may include electrodes or other monitoring systems” without implementation details. Ex.1001-USP675, 18:34-39; *Uber Techs., Inc. v. X One, Inc.*, 957 F.3d 1334, 1339 (Fed. Cir. 2020) (silence of specification on implementation details “suggest[s] that a [POSITA] was more than capable of selecting between the known methods.”). Ex.1002-Decl., ¶¶147-148.

2. Claim 25

Claim 25 depends from claim 24. Petitioners incorporate Sections XI.B.1 and XI.A.14-15. Ex.1002-Decl., ¶149.

C. Ground III: Deem Anticipates Claims 1-3, 7, 9-10, and 17-25

As Section IX details, the '675 patent's priority date is October 22, 2019 and the '771 Provisional does not provide written description for the Challenged Claims. Therefore, the subject matter of the '771 Provisional is prior art, and PO cannot use

it to establish earlier priority. *NRG*, IPR2020-00832, Paper 17, 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 III if the Board confirms an October 22, 2019 priority date and PO alleges—and the Board agrees—that the ’771 Provisional provides written description support for the claims. In such instance, the Challenged Claims would be anticipated by Deem for the same reasons because Deem is prior art and its disclosure is identical in all relevant respects to the ’771 Provisional.

1. Claim 1

a. 1[pre]

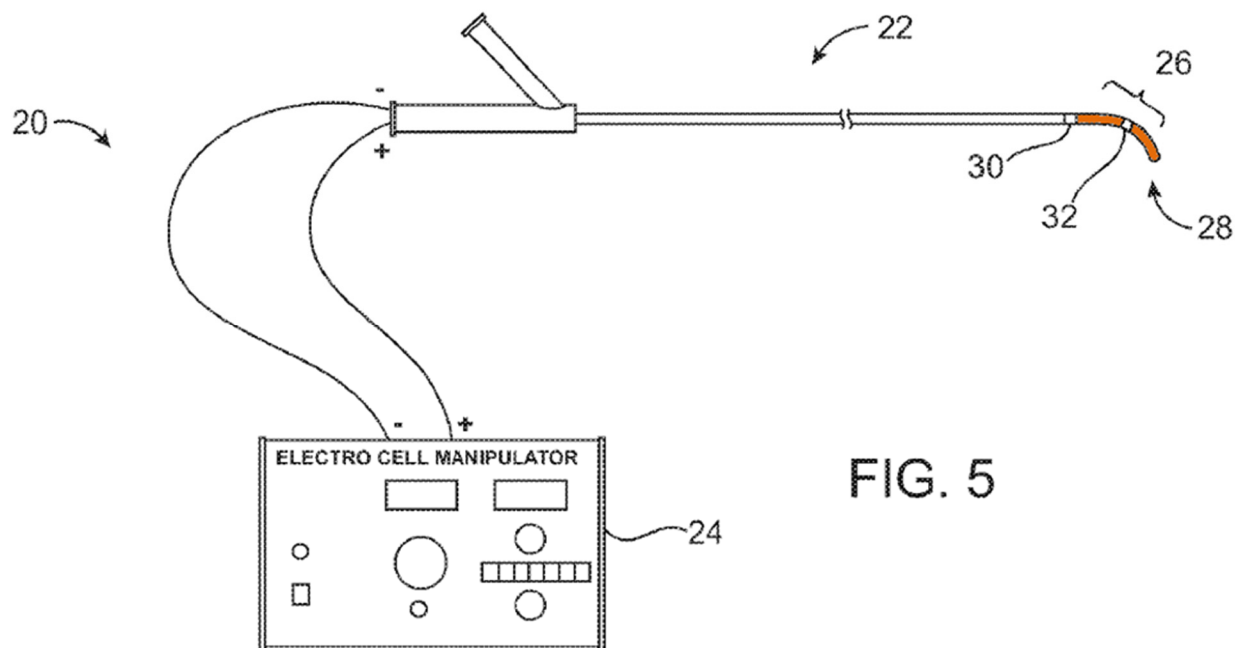
If the Board finds the ’771 Provisional provides written description for Element 1[pre], Deem discloses *a method of treating a patient’s nasal condition* for identical reasons.

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

b. 1[a]

If the Board finds the ’771 Provisional provides written description for Element 1[a], Deem discloses *positioning a distal portion of a treatment device to target tissue in a nasopharyngeal passage of a patient* for identical reasons.

For example, Deem discloses “electroporation catheter for selective electroporation of targeted cells.” Ex.1004-Deem, [0089]. Deem’s “electroporation catheter system 20 comprises a pulse generator...electrically connected to a catheter 22 having...a distal region 26....” *Id.*, [0090].

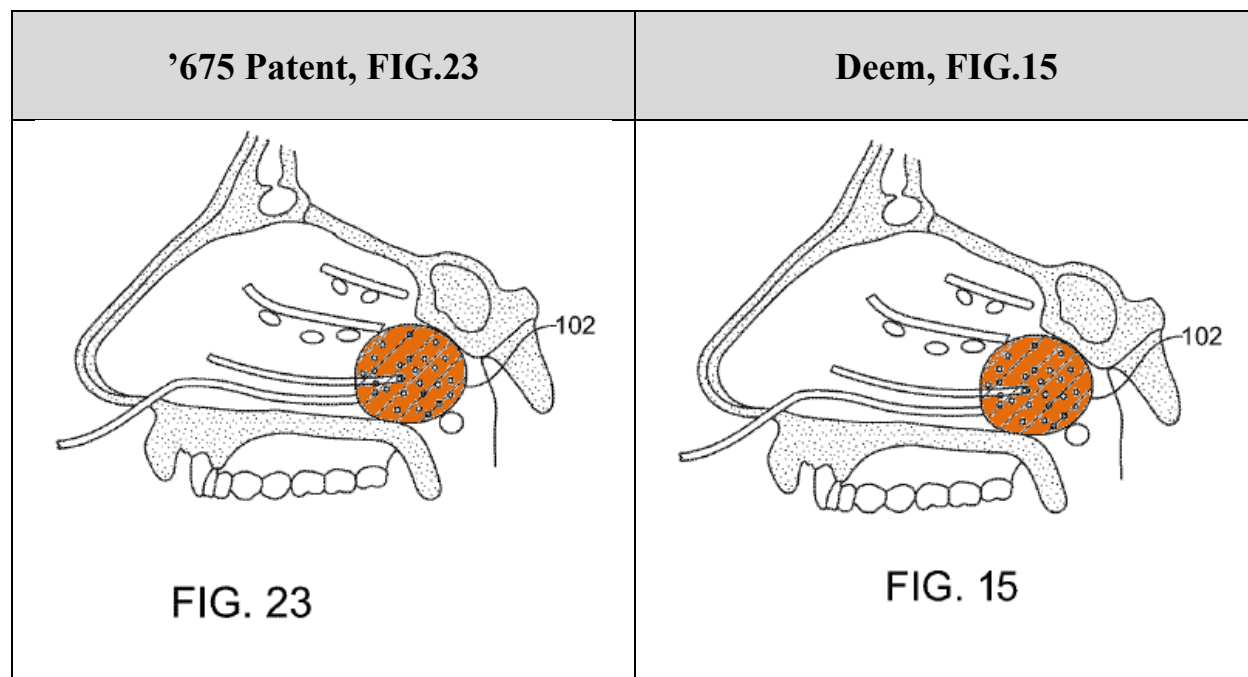


Ex.1004-Deem, FIG.5. The distal region includes “first electrode 30 and...second electrode 32 operatively connected to the pulse generator for delivering...pulses to affect the targeted cells.” *Id.*, [0090]. The catheter applies energy “to induce reversible electroporation at the same time as the catheter delivers the fragmented neurotoxin.” *Id.*, [0089].

Deem discloses delivering neurotoxins “while applying energy to target cells within the membrane under conditions which cause a reversible...poration of the

cell membranes to enhance delivery of the toxin into the cells.” Ex.1004-Deem, [0015]. Deem explains the target region includes the **nasopharynx**, which has “a cluster of...goblet cells which are responsible for mucus secretion and...susceptible to the disabling mechanism of the” neurotoxins. *Id.*

Figure 15 (identical to '675 patent Figure 23), discloses placing the **distal region of a balloon catheter** in the nasopharynx to target “a high percentage of mucus-secreting...goblet cells.” Ex.1004-Deem, [0106], FIG.15; *see also* FIGs.20-21, FIGs.24-25, [0110], [0112]. Deem explains this **distal region** includes “**one or more ultrasonic transducers 104** within the balloon [(not shown) that deliver] ultrasonic poration energy...to the adjacent **nasal membranes** which are receiving the toxin.” *Id.*, [0098]. Deem also includes RF electrodes that “produce membrane permeabilization in the targeted cell[s].” *Id.*, [0071], [0089]-[0091].



c. 1[b]

As set forth in Section IX, Deem does not provide written description support for this element. However, if the Board finds the '771 Provisional provides written description for Element 1[b], Deem discloses *administering therapy to the target tissue with the treatment device so as to disrupt neural activity such that mucus secretion is reduced in the nasopharyngeal passage* for identical reasons.

For example, as discussed in Section XI.C.1.b, Deem discloses applying energy “via the electroporation catheter to induce reversible electroporation [when] the [balloon] catheter delivers the fragmented neurotoxin to the targeted region.” Ex.1004-Deem, [0089], [0098].

Deem explains that applying energy via the catheter creates pores in the target goblet cells to allow neurotoxins to enter. Ex.1004-Deem, [0086], FIGs.2A-2B, 3A-3B, 4; *see also* Section VI.A. Deem teaches that neurotoxins block and disrupt “hypersecretion” from mucus-producing goblet cells—i.e., a rhinitis symptom. Ex.1004-Deem, [0004], [0066], [0086]. Deem also teaches rhinitis symptoms include “nasal congestion” and “a runny nose” (i.e., mucus production), and using electroporation with neurotoxins can reduce these symptoms. *Id.*, [0004], [0011], [0015]-[0017].

As also discussed in Section XI.C.1.b, Deem discloses a catheter positioned in the nasopharynx to target its high concentration of goblet cells. Ex.1004-Deem, FIG.15, [0106]; *see also id.* FIGs.20-21, 24-25, [0110], [0112].

d. 1[c]

As set forth in Section IX, 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 *administering therapy comprises at least one of delivering energy to the target tissue and changing the temperature of the target tissue* for identical reasons.

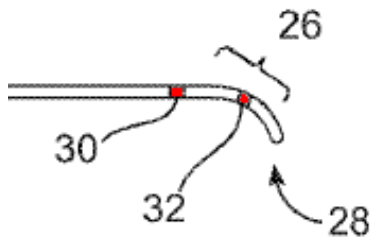
For example, Deem discloses the catheter **distal region** delivers electroporation energy to target cells to facilitate delivery of neurotoxins. Ex.1004-Deem, [0089]-[0091], [0098], [0106], FIG.5, FIG.15.

Deem further discloses the catheter **distal region** includes electrodes, and that such electrodes change tissue temperature by applying radiofrequency (RF) energy. Ex.1004-Deem, [0071], [0096].

2. Claim 2

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

If the Board finds the '771 Provisional provides written description for Claim 2, Deem discloses *administering therapy comprises delivering energy from at least one energy delivery element on the treatment device* for identical reasons. For example, Deem's catheter **distal region** includes **two electrodes 30 and 32** that deliver electroporation energy to the targeted cells. Ex.1004-Deem, [0089]-[0090]; *see also id.*, [0091].



Ex.1004-Deem, FIG.5

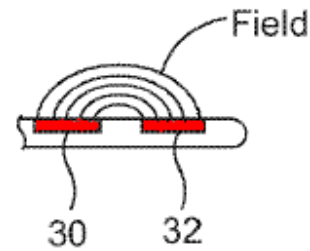


FIG. 5A

Ex.1004-Deem, FIG.5A

As discussed in Section XI.C.1.b, Deem discloses transducers 104 in the **distal region** of the Figure 15 catheter can be **one or more RF electrodes** that deliver energy to “produce membrane permeabilization in the targeted cell[s].” Ex.1004-Deem, [0071], [0098], [0106], FIG.15.

3. Claim 3

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

If the Board finds the '771 Provisional provides written description for Claim 3, Deem, for example, discloses delivering *RF energy* with **electrodes** in the **distal region** for identical reasons. Ex.1004-Deem, [0071] (“‘[E]lectrode’ or ‘energy source’ used herein, encompasses...radiofrequency (RF)..., adapted and applied in ranges to produce membrane permeabilization”); [0071], [0098], [0106], FIG.15.

4. Claim 7

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

If the Board finds the '771 Provisional provides written description for Claim 7, Deem discloses *changing the temperature of the target tissue comprises transferring thermal energy between the treatment device and the target tissue* for identical reasons. For example, Deem discloses the **electrodes** on the catheter **distal region** deliver RF energy to “produce membrane permeabilization in the targeted cell[s].” Ex.1004-Deem, [0071].

5. Claim 9

Claim 9 depends from claim 1. Petitioners incorporate Section XI.C.1.

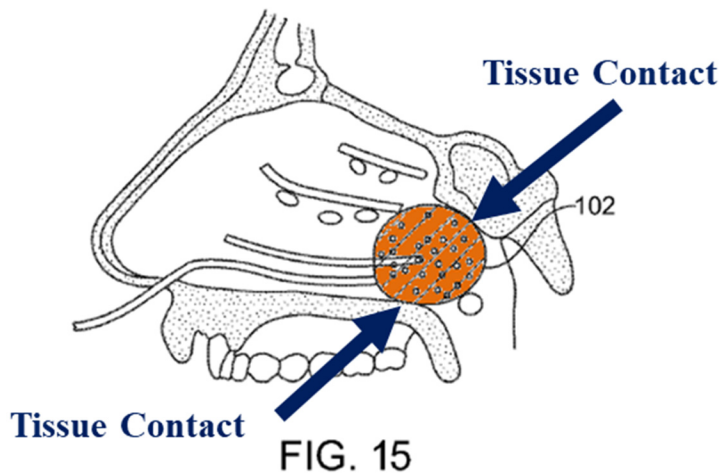
If the Board finds the '771 Provisional provides written description for Claim 9, Deem discloses *administering therapy comprises contacting target tissue with a delivery portion of the treatment device* for identical reasons. For example, the **distal region** of Deem’s Figure 5 catheter includes **electrodes** that apply electroporation energy to target tissue. Ex.1004-Deem, [0090]-[0091].



Ex.1004-Deem, FIG.5

Ex.1004-Deem, FIG.5A

Deem Figure 15 discloses a balloon catheter with distal electrodes. The balloon catheter contacts target nasopharynx tissue when applying electroporation energy and releasing neurotoxins. Ex.1004-Deem, [0106], [089].



Ex.1004-Deem, FIG.15.

6. Claim 10

Claim 10 depends from claim 9. Petitioners incorporate Section XI.C.5.

If the Board finds the '771 Provisional provides written description for Claim 10, Deem discloses *the target tissue is contacted without penetrating the target tissue* for identical reasons. For example, the distal region of Deem's catheter includes a rounded tip. *E.g.*, Ex.1004-Deem, FIG.5, FIG.5A.

To the extent the rounded tip of the catheter disclosed in the '675 patent would contact without penetrating target tissue, Deem discloses the same rounded tip. Deem contrasts such embodiment with catheters that penetrate tissue. Ex.1004-Deem, [0091], FIG.6A.

Moreover, Deem Figure 15 discloses the balloon catheter contacts tissue when electroporation energy is applied with release of neurotoxins. Figure 15 does not depict the balloon catheter penetrating tissue. Ex.1004-Deem, FIG.15.

7. Claim 17

a. 17[pre]

If the Board finds the '771 Provisional provides written description for Element 17[pre], for the reasons in Section XI.C.1.a, Deem discloses *a method of treating a nasal condition*.

b. 17[a]

If the Board finds the '771 Provisional provides written description for Element 17[a], for the reasons in Section XI.C.1.b, Deem discloses *positioning a*

distal portion of a treatment device proximate to target tissue in a nasopharyngeal passage of a patient.

c. 17[b]

As set forth in Section IX, Deem does not provide written description support for this element. However, if the Board finds the '771 Provisional provides written description for Element 17[b], for the reasons in Section XI.C.1.c, Deem discloses *administering therapy to the target tissue with the treatment device to alter nasopharyngeal cells such that congestion in the nasopharyngeal passage is reduced.*

d. 17[c]

As set forth in Section IX, Deem does not provide written description support for this element. However, if the Board finds the '771 Provisional provides written description for Element 17[c], for the reasons in Section XI.C.1.d, Deem discloses *wherein administering therapy comprises delivering energy to the target tissue.*

8. Claim 18

Claim 18 depends from claim 17. Petitioners incorporate Section XI.C.7. If the Board finds the '771 Provisional provides written description for Claim 18, for the reasons in Section XI.C.2, Deem discloses *the energy is delivered from an energy delivery element on the treatment device.*

9. Claim 19

Claim 19 depends from claim 18. Petitioners incorporate Section XI.C.8. If the Board finds the '771 Provisional provides written description for Claim 19, for the reasons in Section XI.C.3, Deem disclose *the energy comprises RF energy*.

10. Claim 20

Claim 20 depends from claim 19. Petitioners incorporate Section XI.C.9.

If the Board finds the '771 Provisional provides written description for Claim 20, Deem discloses *the energy delivery element comprises a monopolar or bipolar electrode* for identical reasons. For example, Deem explains that “electroporation may be achieved utilizing a device adapted to activate an electrode set or series of electrodes to produce an electric field,” and that “[s]uch a field can be generated in a bipolar or monopolar electrode configuration.” Ex.1004-Deem, [0073]. As detailed in Section XI.C.1.b, Deem discloses its catheter’s **distal region** includes **electrodes** that apply energy “to induce reversible electroporation at the same time as the catheter delivers the fragmented neurotoxin.” *Id.*, [0089].

11. Claim 21

Claim 21 depends from claim 18. Petitioners incorporate Section XI.C.8.

If the Board finds the '771 Provisional provides written description for Claim 21, Deem discloses *the energy delivery element comprises a plurality of electrodes* for identical reasons. For example, as detailed in Section XI.C.1.b, Deem discloses

its catheter's **distal region** includes **multiple electrodes**. *E.g.*, Ex.1004-Deem, FIG.5, FIG.5A, [0090]-[0091], [0071], [0098], [0106], FIG.15.

12. Claim 22

Claim 22 depends from claim 18. Petitioners incorporate Section XI.C.8.

If the Board finds the '771 Provisional provides written description for Claim 22, Deem discloses *the energy delivery element is configured to concentrate energy laterally relative to the distal portion of the treatment device* for identical reasons. For example, Deem Figure 5A “depicts an 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.

13. Claim 23

Claim 23 depends from claim 22. Petitioners incorporate Section XI.C.12.

If the Board finds the '771 Provisional provides written description for Claim 22, Deem discloses *the energy delivery element comprises at least one electrode disposed on a lateral side of the distal portion of the treatment device* for identical reasons. For example, as discussed in Section XI.C.12, Deem Figure 5A (like '675 patent Figure 5A) depicts **electrodes 30 and 32** on the lateral side of the catheter. Ex.1004-Deem, [0091], FIG.5A; Ex.1001-USP675, 16:54-58, FIG.5A.

14. Claim 24

Claim 24 depends from claim 18. Petitioners incorporate Section XI.C.8.

If the Board finds the '771 Provisional provides written description for Claim 24, Deem discloses a *monitoring electrode or system on the treatment device* for identical reasons. For example, Deem's electroporation catheter **“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].

15. Claim 25

Claim 25 depends from claim 24. Petitioners incorporate Section XI.C.14.

If the Board finds the '771 Provisional provides written description for Claim 24, Deem discloses the *monitoring electrode or system comprises a thermocouple or sensing electrode* for identical reasons. For example, as detailed in Section XI.C.14, Deem discloses its electroporation catheter “include[es], thermocouple,...sensing or stimulating electrodes.” Ex.1004-Deem, [0096]; *see also id.*, [0091].

D. Ground IV: Claims 1-3, 7, 9-10, And 17-25 Are Invalid as Obvious over Makower and Fang

Even if the Board finds the Challenged Claims are entitled to priority before October 22, 2019, the Challenged Claims would have been obvious over the combination of Makower and Fang.

During prosecution, the Examiner found Makower was the “closest prior art” because it taught most claim limitations, namely, “treating disorders of the ear, nose and throat via inserting an energy emitting device into the nasopharynx.” Ex.1022-FH675, 122. The Examiner allowed the claims only after finding Makower did “not teach or suggest treating nasal conditions with a device so as to disrupt neural activity such that mucus secretion is reduced in the nasopharyngeal passage, and wherein the target tissue has a change in temperature.” *Id.* To the extent that is the case, Fang, which was not before the Office, teaches disrupting neural activity to treat rhinitis (e.g., reduce mucus secretion and congestion) by ablating tissue in the nasopharyngeal passage with RF energy to change its temperature. The Challenged Claims would therefore have been obvious.

1. Claim 1

a. 1[pre]

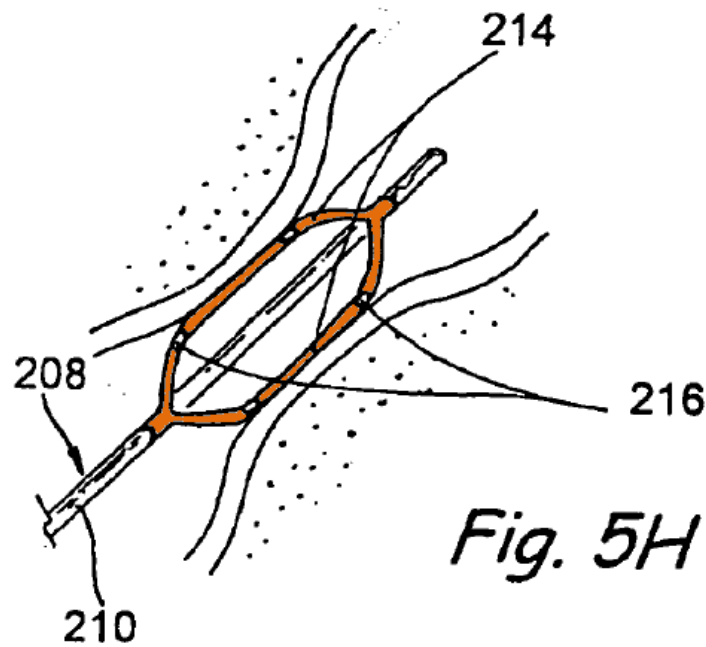
As the Examiner found during prosecution (*see* Ex.1022-FH675, 122), Makower teaches the preamble. Makower discloses “medical devices and methods...for treating sinusitis..., nose & throat disorders.” Ex.1005-Makower, [0001], [0043], [0161], [0187], claim 1. Ex.1002-Decl., ¶¶151-152.

Fang also teaches the preamble. 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., ¶153.

b. 1[a]

The combination of Makower and Fang teaches this element. Makower teaches *positioning a distal portion* (e.g., strut members) *of a treatment device* (e.g., electrosurgical device) *proximate to target tissue* (e.g., nasal tissue) *in a nasopharyngeal passage of a patient* (e.g., passage including the nasal cavity and nasopharynx). Ex.1002-Decl., ¶¶154-159.

As the Examiner found during prosecution (Ex.1022-FH675, 122), Makower teaches placing an electrosurgical device in the nasopharynx to ablate tissue. Ex.1005-Makower, [0043] (“flexible catheters or other...devices...are inserted [into] the...nasopharynx”). Makower teaches inserting electrosurgical devices into the nasopharynx “to perform diagnostic or therapeutic procedures.” *Id.*, [0161]. As shown in Figure 5H (below), Makower teaches an electrosurgical device with electrodes on **strut members 214** contacting surrounding nasopharynx tissue. *Id.*, [0164], [0187], claim 1.

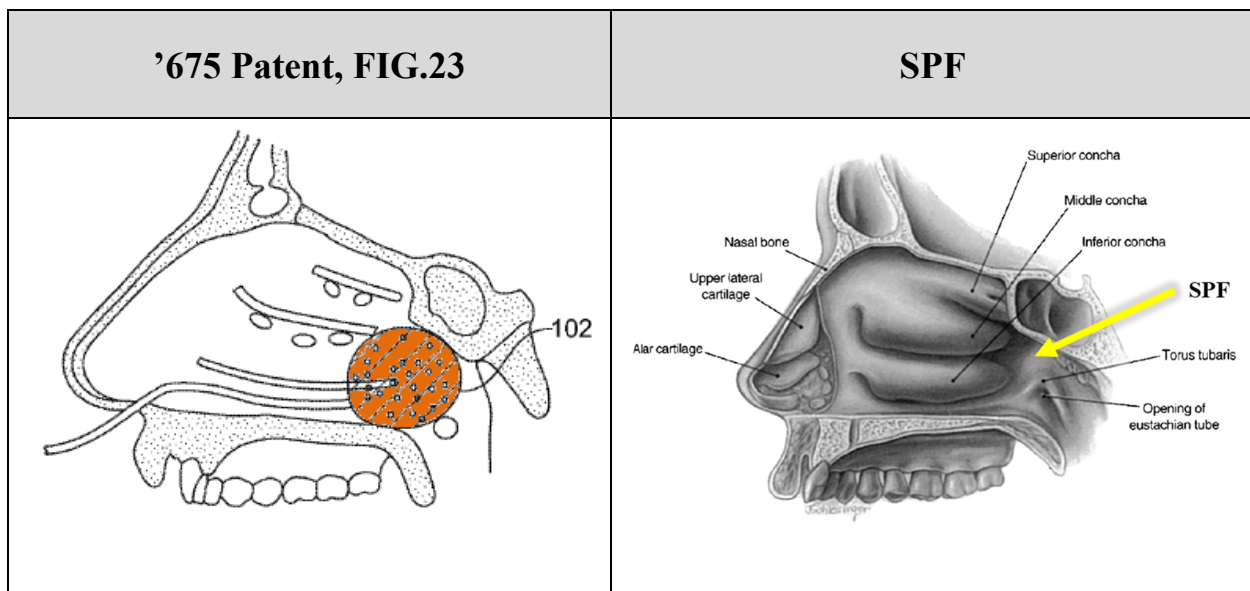


Ex.1005-Makower, Fig5H. Ex.1002-Decl., ¶¶155-156.

Fang also teaches *positioning a distal portion* (e.g., firing head) *of a treatment device* (e.g., SHP-I five-organ radiofrequency therapy instrument) *proximate to target tissue* (e.g., nasal tissue) *in a nasopharyngeal passage of a patient* (e.g., nasal cavity). Fang teaches “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 “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, 157.

The sphenopalatine foramen (“SPF”) is located posterior in the nasal cavity, in the nasopharyngeal passage. *See* Sections V and XI.A.1.b. As shown below, the SPF is in the location the ’675 patent identifies as the “nasopharynx” and “nasal passage” (i.e., *nasopharyngeal passage*). The Figure 23 porous balloon 102 (below) is positioned to target cells in the “nasopharynx” and “nasal passages.” Ex.1001-USP675, 23:66-24:2 (balloon targets “back of the nasal passages in the area of the nasopharynx.”); FIG.23.



Thus, consistent with the ’675 patent, Fang’s device is positioned *proximate to target tissue in the nasopharyngeal passage*. Ex.1006-Fang, 876-877. Ex.1002-Decl., ¶158.

As detailed in Section V, 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). Thus, Fang’s device targeting tissue and nerves surrounding the SPF teaches targeting nerves in the nasopharyngeal passage. *Id.*, 876-877. Ex.1002-Decl., ¶159.

c. 1[b]

The combination of Makower and Fang teaches *administering therapy* (e.g., current (Makower)/radiofrequency therapy (Fang)) *to the target tissue* (e.g., nasal tissue in the nasal cavity and/or nasopharynx) *with the treatment device* (e.g., electrosurgical device (Makower)/radiofrequency therapy instrument (Fang)) *so as to disrupt neural activity* (e.g., sphenopalatine nerves) *such that mucus secretion* (e.g., rhinitis symptom) *is reduced in the nasopharyngeal passage*. Ex.1002-Decl., ¶¶160-164.

As discussed in Section XI.D.1.b, Makower and Fang teach positioning the distal portion of a treatment device proximate to tissue in the nasopharyngeal passage. Ex.1002-Decl., ¶161.

Makower’s device uses bipolar electrodes to *administer therapy* by delivering current to the adjacent *target tissue* and causing “heat[ing].” Ex.1005-Makower, [0187]. Makower thus teaches the well-known concept that one could treat tissue

by using bipolar electrodes to administer RF energy through electrical current. *Id.*, [0043], [0164], [0187]; [0040]. Makower teaches using this RF-energy method in the nasopharynx for treatment. *Id.*, [0043], [0164], [0187]; *see also id.*, claim 1 (“advancing...device...to a location within the...nasopharynx” “to perform a...therapeutic procedure”). Ex.1002-Decl., ¶162.

Fang likewise teaches using RF energy to heat (thereby treating) tissue. Ex.1006-Fang, 876-877. Fang teaches aligning the firing head of a radiofrequency therapy instrument with tissue to “block[s] the posterior parasympathetic fibers of the sphenopalatine nerve.” *Id.* 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 discussed in Section V, nerves targeted by Fang are present throughout the passage including the nasal cavity and nasopharynx. Fang thus teaches that applying radiofrequency energy (e.g., *administering therapy*) to tissue in the nasopharyngeal passage (e.g., *target tissue*) *disrupts neural activity* in order to reduce rhinitis symptoms in the *nasopharyngeal passage* (e.g., *mucus secretion* or congestion). Ex.1002-Decl., ¶163.

As discussed in Sections XI.D.1.b and XI.D.1.e, Fang teaches the obvious result of administering current (RF energy) by electrodes of Makower’s device in

the nasopharynx. That is, a POSITA would have been motivated to use Makower's device to reduce rhinitis symptoms in the *nasopharyngeal passage* to disrupt neural activity as taught in Fang 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.D.1.e. Ex.1002-Decl., ¶164.

d. 1[c]

The combination of Makower and Fang teaches *administering therapy compris[ing] at least one of delivering energy* (e.g., current (Makower)/radiofrequency therapy (Fang)) *to the target tissue and changing the temperature of the target tissue* (e.g., heating). Ex.1002-Decl., ¶¶165-167.

As discussed in Sections XI.D.1.c and XI.D.1.e, the combination of Makower and Fang teaches applying RF energy to nasal tissue in the nasopharyngeal passage to disrupt neural activity, and therefore discloses *delivering RF energy to the target tissue*. Ex.1002-Decl., ¶166.

Makower teaches that applying current through bipolar electrodes on its electrosurgical device heats (i.e., changes temperature of) the adjacent tissue (e.g., tissue in the nasopharynx). Ex.1005-Makower, [0187] (“[C]urrent is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated.”).

Likewise, Fang discloses applying RF energy to tissue surrounding the sphenopalatine foramen in the nasopharyngeal passage (e.g., *target tissue in the nasopharyngeal passage*). Ex.1006-Fang, 876-877. A POSITA would have understood that delivering RF energy to tissue, as taught by Makower and Fang, heats it and thereby changes its temperature. *See* Section V. Ex.1002-Decl., ¶167.

e. Motivation to Combine With a Reasonable Expectation of Success

Obviousness requires the references in a combination “are analogous to the claims being challenged,” and that a POSITA would have been motivated to combine the references with a reasonable expectation of success. *See Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1004 (Fed. Cir. 2023). Each is met here. Ex.1002-Decl., ¶¶168-180.

First, Makower and Fang are analogous art to the Challenged Claims. Both 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]. Makower and Fang specifically teach that their devices treat disorders by applying energy to tissue. Ex.1005-Makower, [0001], [0043], [0132]; 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.1002-Decl., ¶169.

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 and method (using electrosurgical device in nasopharynx) to treat rhinitis. Ex.1002-Decl., ¶¶170-176.

During prosecution, the Examiner found Makower teaches an energy emitting device in the nasopharynx 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, 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, by heating parasympathetic nerves downstream of the SPG and Vidian nerve, thereby inhibiting their signaling of goblet cells that produce mucus. Makower’s device would not require modification to achieve this result. Indeed, Makower already teaches its device treats a nasal disorder, and Fang simply clarifies Makower operates in the same way as claimed. Ex.1002-Decl., ¶170.

A POSITA would have been motivated to combine Makower’s method and device with Fang’s teachings. Specifically, Makower describes its “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., ¶171.

Specifically, Makower teaches positioning strut members with electrodes of an electrosurgical device in the nasopharynx to apply energy to the surrounding tissue to treat nasal disorders. Ex.1005-Makower, [0001], [0043], [0132], [0164], [0187], claim 1. Fang also teaches applying energy to tissue in the nasal cavity to treat nasal disorders and further teaches that such application of energy treats rhinitis by disrupting the sphenopalatine ganglion and branching parasympathetic nerves. Ex.1006-Fang, 877. Specifically, 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 and congestion. *Id.*; *see also* Ex.1044-Chen, 240-241. Ex.1002-Decl., ¶172.

Consistent with Fang, it was well-known before 2005 that parasympathetic nerves and cells are located throughout the nasopharyngeal passage. For example, it was known that the SPG is downstream of the Vidian nerve and located near the sphenopalatine foramen, and that parasympathetic nerves branch from the SPG throughout the nasal cavity and nasopharynx. *See* Section V. It was also well known that parasympathetic nerves which branch from the Vidian nerve and SPG were responsible for mucus production and congestion, as they control activity of goblet cells that generate mucus. *E.g.*, Ex.1051-Windsor, 284. Thus, a POSITA would have understood well before the '675 patent that parasympathetic nerves regulate mucus production (e.g., goblet cells) throughout the passageway including both the nasal cavity and the nasopharynx. Ex.1002-Decl., ¶173.¹⁶

¹⁶ Fang teaches and suggests heating of these nerves will disrupt their function without limiting its teaching to a particular location. To the extent PO argues treatment in the “nasopharyngeal passage” requires treatment in the nasopharynx alone (which is wrong, *see supra* note 15), Makower teaches placement of its device in the nasopharynx, a POSITA would have understood the relevant parasympathetic

It was also well-known that disrupting the Vidian, SPG, and related parasympathetic nerves reduces mucus production, mucus secretion and congestion (rhinitis symptoms). For example, it has been known since the 1960s that cutting the Vidian nerve would treat rhinitis. *E.g.*, Ex.1003-Saadat, 2:39-47. Fang taught that disrupting the nerves with radiofrequency energy would also disrupt them and reduce rhinitis symptoms. Fang thus teaches RF energy in tissue surrounding the SPF “completely blocks the parasympathetic pathway of the nasal mucosa,” which “reduces glandular secretion, and thus achieves the therapeutic purposes” of relieving “perennial allergic rhinitis” while minimizing adverse effects. Ex.1006-Fang, 876-877. Ex.1002-Decl., ¶174.

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 the known outcome of application of RF therapy with Makower’s device and method because the two teach similar energy-delivery devices in the same part of the body and for the same purpose (treating nasal

nerves and goblet cells are in the nasopharynx, and Fang teaches application of RF energy disrupts those nerves and prevents a nasal condition including rhinitis. Ex.1002-Decl., ¶175.

conditions) and Fang explains the mechanism and outcome of Makower’s method. Ex.1006-Fang, 876; Ex.1005-Makower, [0161], [0164], [0187], claim 1. Ex.1002-Decl., ¶176.

Third, a POSITA would have had a reasonable expectation of successfully combining Makower and Fang. A POSITA would have reasonably expected Makower’s electrosurgical device to obtain Fang’s clinical result. Fang and others taught that applying RF energy to the nasopharyngeal passage would treat rhinitis. *See* Section XI.D.1.c. For example, Chen taught that applying RF energy to sphenopalatine nerves treats rhinitis. Ex.1044-Chen, 239. Chen explained that “parasympathetic nerves in the nasal cavity mainly originate from the sphenopalatine nerves,” and that applying RF energy to these nerves “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. Makower discloses an RF-delivery device for treating nasal conditions. 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 success in using

Makower's known RF device according to a known method to reach the predictable result taught in Fang and Chen.¹⁷ Ex.1002-Decl., ¶¶177-179.

Accordingly, the combination of Makower and Fang renders claim 1 obvious.

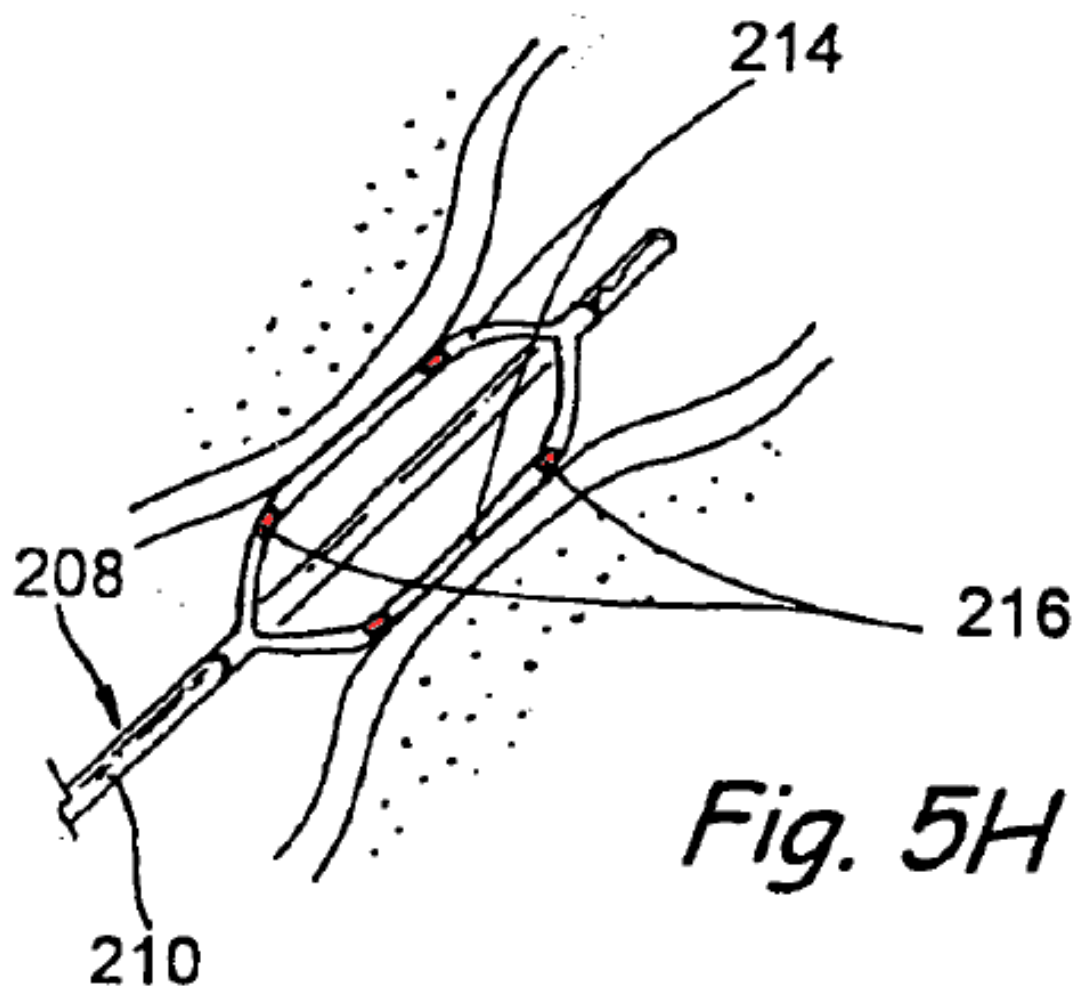
2. Claim 2

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

The combination of Makower and Fang further teaches *administering therapy comprising delivering energy* (e.g., current/RF energy) *from at least one energy delivery element* (e.g., electrode(s)) *on the treatment device* (e.g., **electrosurgical**

¹⁷ Any argument Fang's results would not have been expected with Makower's device would be misplaced. Fang does not teach a specialized device is required to treat rhinitis. Ex.1006-Fang, 876. Instead, Fang used a generic device, a SPH-I five-organ radiofrequency therapy instrument, using factory settings. *Id.* A POSITA would have understood that Fang's generic device would operate similarly to Makower's electrosurgical device with bipolar electrodes. Indeed, the '675 patent assumes a POSITA would have understood how to position a catheter proximate to target tissue, as it describes positioning **porous balloon 102** without implementation details. Ex.1001-USP675, 23:66-24:2; *Uber*, 957 F.3d at 1339 (Fed. Cir. 2020). Ex.1002-Decl., ¶178.

device). 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].



Ex.1005-Makower, FIG.5H. Ex.1002-Decl., ¶¶181-182.

3. Claim 3

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

The combination of Makower and Fang teaches **electrodes** on the **therapeutic assembly** deliver *energy* that comprises *RF energy*. Specifically, Makower’s **electrodes are radiofrequency electrodes**, i.e., electrodes that deliver radiofrequency energy. Ex.1005-Makower, [0164] (“devices shown in FIGS. 5A-5Y” and described herein incorporate...(e.g.,...radiofrequency electrodes).”). A POSITA would have understood that monopolar or bipolar radiofrequency electrodes taught by Makower deliver *RF energy* via current to heat tissue. Ex.1005-Makower, [0187]; Ex.1009-Stern, 2:11-19 (current is applied via electrodes to deliver RF energy to heat tissue); *see also* Ex.1006-Fang, 876-877 (teaching ablation device). Ex.1002-Decl., ¶¶183-184.

4. Claim 7

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

The combination of Makower and Fang teaches *changing temperature of target tissue* (e.g., nasal tissue) *comprising transferring thermal energy between the treatment device and the target tissue*. As detailed in Sections XI.D.1.b-c, the strut members of Makower’s electrosurgical device contain electrodes that contact tissue in the nasopharynx and deliver current, causing it to be “heated.” *E.g.*, 1005-Makower, [0043], [0164], [0187]. Thus, Makower discloses that the current

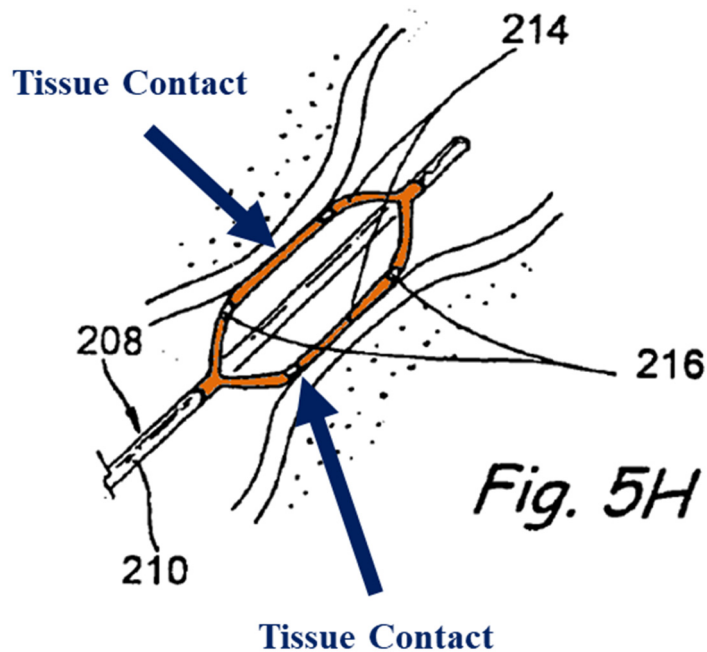
delivered via its electrodes applies *thermal energy* between the electrodes and adjacent tissue to *change the tissue's temperature*. Ex.1002-Decl., ¶¶185-186.

Moreover, Foundry alleges in parallel litigation that transferring RF energy to tissue *comprises transferring thermal energy between the treatment device and the target tissue*. Ex.1036-Complaint-Ex.V, 15. As explained in Section XI.D.3, Makower discloses delivering RF energy. Consistent with Foundry's allegations, and without concession regarding infringement, the combination of Makower and Fang discloses this limitation.

5. Claim 9

Claim 9 depends from claim 1. Petitioners incorporate Section XI.D.1.

The combination of Makower and Fang teaches *administering therapy* (e.g., current) *comprising contacting target tissue* (e.g., nasal tissue) *with a delivery portion* (e.g., electrodes) *of the treatment device* (e.g., electrosurgical device). As discussed in Sections XI.D.1.b-d, Makower Figure 5H teaches an electrosurgical device that includes **strut members** with **electrodes** that apply energy to nasal tissue in the nasopharynx. Makower teaches the **strut members** and electrodes *contact* the adjacent tissue when delivering energy. Ex.1005-Makower, [0161], [0187].



Ex.1005-Makower, FIG.5H; *see also* Ex.1006-Fang, 876-877. Ex.1002-Decl., ¶¶187-188.

6. Claim 10

Claim 10 depends from claim 9. Petitioners incorporate Section XI.D.5.

The combination of Makower and Fang further teaches *the target tissue* (e.g., nasal tissue) *is contacted without penetrating the target tissue*. Makower includes embodiments that “penetrat[e]” (i.e., through a “needle, drill or cutter”) and different embodiments that expand to “contact” tissue. Ex.1005-Makower, FIG.5H, [0187], [0240]. As detailed in Section XI.D.5, Makower Figure 5H describes an electrosurgical device that expands to contact target tissue to deliver energy. *Id.*, FIG.5H, [0187]. Unlike alternative embodiments that discuss penetration, Makower

nowhere describes the Figure 5H embodiment as penetrating tissue, and the Figure itself depicts expansion of the device in a manner that leaves the tissue intact. Ex.1002-Decl., ¶¶189-190.

Moreover, Foundry alleges in litigation that an expandable probe that administers RF does not penetrate target tissue. Ex.1036-Complaint-Ex.V, 18-20. Therefore, consistent with Foundry's allegations, and without concession regarding infringement, Makower teaches this limitation.

7. Claim 17

a. 17[pre]

For the reasons in Section XI.D.1.a, Makower and Fang teach *methods of treating a nasal condition*. Ex.1002-Decl., ¶191.

b. 17[a]

For the reasons in Section XI.D.1.b, Makower and Fang teach *positioning a distal portion of a treatment device proximate to target tissue in a nasopharyngeal passage of a patient*. Ex.1002-Decl., ¶192.

c. 17[b]

For the reasons in Section XI.D.1.c (discussing, e.g., congestion), Makower and Fang teach *administering therapy to the target tissue with the treatment device to alter nasopharyngeal cells such that congestion in the nasopharyngeal passage is reduced*. Ex.1002-Decl., ¶193.

d. 17[c]

For the reasons in Section XI.D.1.d, Makower and Fang teach *wherein administering therapy comprises delivering energy to the target tissue*. Ex.1002-Decl., ¶194.

e. Motivation to Combine With a Reasonable Expectation of Success

For the reasons in Section XI.D.1.e, a POSITA would have been motivated to combine the teachings of Makower and Fang with a reasonable expectation of success. As discussed therein, a POSITA would have been motivated to consider Makower's method and device in view of Fang and would have reasonably expected it to *deliver energy to target tissue to alter nasopharyngeal cells such that congestion in the nasopharyngeal passage is reduced*. See Section XI.D.1.e. Ex.1002-Decl., ¶195.

8. Claim 18

Claim 18 depends from claim 17. Petitioners incorporate Section XI.D.7. For the reasons in Section XI.D.2, the combination of Makower and Fang teaches *the energy is delivered from an energy delivery element on the treatment device*. Ex.1002-Decl., ¶¶196-197.

9. Claim 19

Claim 19 depends from claim 18. Petitioners incorporate Section XI.D.8. For the reasons in Section XI.D.3, the combination of Makower and Fang teaches *the energy comprises RF energy*. Ex.1002-Decl., ¶¶198-199.

10. Claim 20

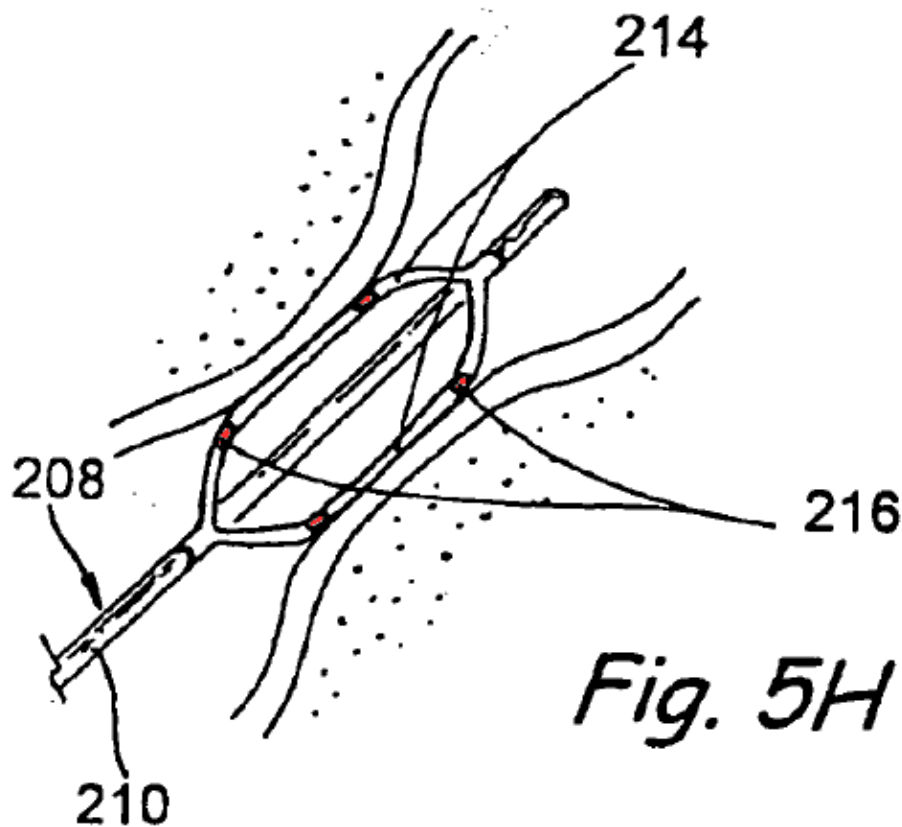
Claim 20 depends from claim 19. Petitioners incorporate Section XI.D.9.

The combination of Makower and Fang teaches *the energy delivery element comprises a monopolar or bipolar electrode*. As detailed in Section XI.D.2, Makower's electrosurgical device includes strut members with **monopolar or bipolar electrodes** that apply current to adjacent tissue. *E.g.*, Ex.1005-Makower, [0187]. Ex.1002-Decl., ¶¶200-201.

11. Claim 21

Claim 21 depends from claim 18. Petitioners incorporate Section XI.D.8.

The combination of Makower and Fang teaches *the energy delivery element comprises a plurality of electrodes*. Specifically, as detailed in Section XI.D.2, Makower's electrosurgical device includes strut members with multiple **monopolar or bipolar electrodes** that apply current to adjacent tissue. *E.g.*, Ex.1005-Makower, [0187], FIG.5H.



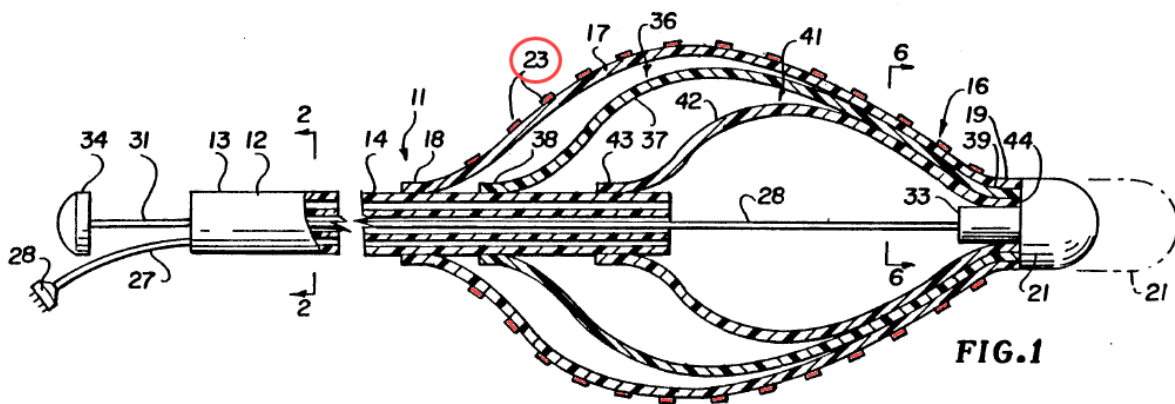
Ex.1005-Makower, FIG.5H. Ex.1002-Decl., ¶¶202-203.

12. Claim 22

Claim 22 depends from claim 18. Petitioners incorporate Section XI.D.8.

The combination of Makower and Fang further teaches *the energy delivery element is configured to concentrate energy laterally relative to the distal portion of the treatment device*. As detailed in Section XI.D.11, 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 to create an

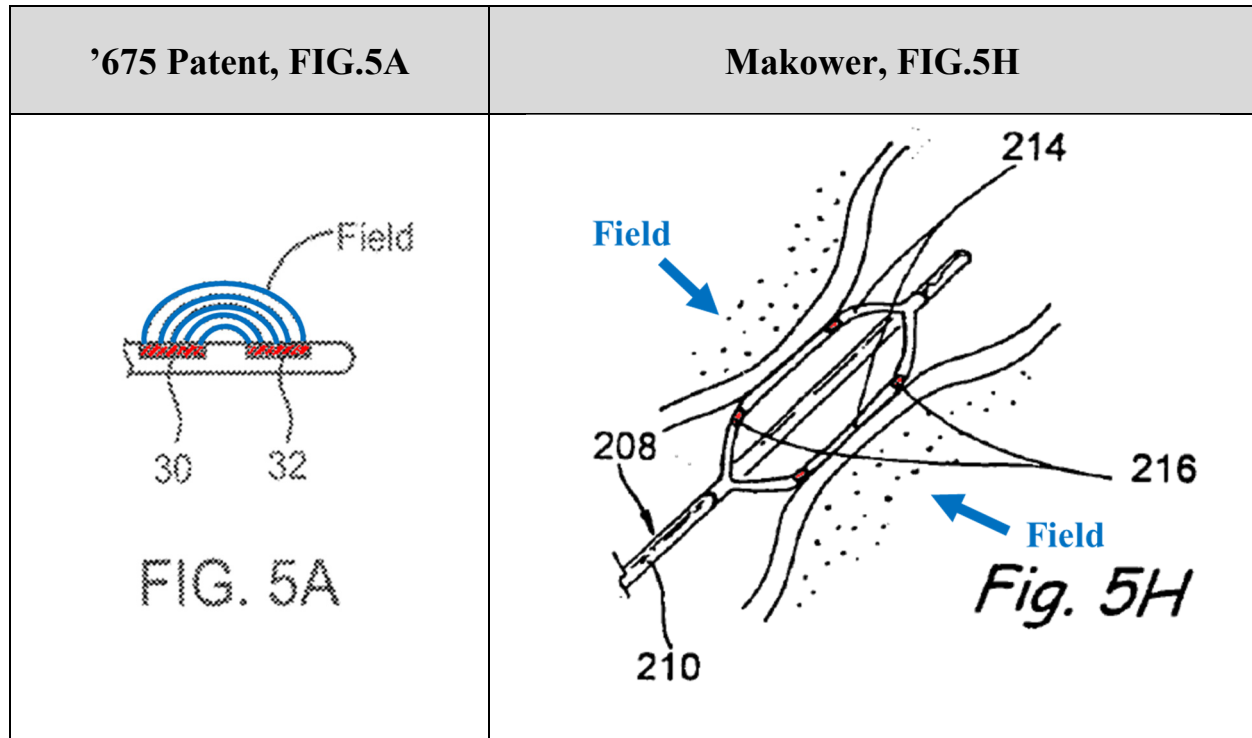
electrical field. *E.g.*, Ex.1009-Stern, 13:11-20. In Makower, a POSITA would have understood that current travels from one **bipolar electrode** to another **electrode to create an electrical field that travels** through the contacted tissue. The current (*energy*) in this field is *concentrated laterally relative to the distal portion of the device* (i.e., into the target tissue and away from the shaft). For example, Makower teaches that the RF electrodes in the Figure 5H electrosurgical device can be implemented as electrodes disposed on the lateral side of the strut as set forth in Imran. Ex.1005-Makower, [0164] (citing U.S. Patent No. 5,255,679 to Imran); *see* Ex.1068-Imran, 3:2-7 (electrodes 23 disposed on a lateral side of the distal portion of the treatment device that concentrate energy laterally into target tissue), claim 1.



Ex.1068-Imran, FIG.1; Ex.1002-Decl.¶¶204-206.

In this way, Makower teaches concentrating energy laterally just as similarly arranged electrodes do in '675 patent Figure 5A. *E.g.*, Ex.1001-USP675, Fig.5,

Figs.5A-5B, 16:29-58; Ex.1005-Makower, [0161], [0164], [0187], FIG.5H.
Ex.1002-Decl., ¶206.



Moreover, Foundry alleges in litigation that delivering RF energy from bipolar electrodes constitutes *concentrat[ing] energy laterally relative to the distal portion of the treatment device*. Ex.1036-Complaint-Ex.V, 37-39. Consistent Foundry's allegations, and without concession regarding infringement, Makower discloses its electrodes *concentrate RF energy laterally* into the target tissue *relative to the distal portion of the **strut members*** on its electrosurgical device.

13. Claim 23

Claim 23 depends from claim 22. Petitioners incorporate Section XI.D.12.

The combination of Makower and Fang further teaches *the energy delivery element comprises at least one electrode* (e.g., **electrodes 216**) *disposed on a lateral side of the distal portion of the treatment device*. As shown in Figure 5H, Makower's **electrodes** are on a strut member at the distal portion of the electrosurgical device. And as discussed in Section XI.D.13, Makower's Figure 5H electrodes can be implemented as taught by Imran. Ex.1005-Makower, [0164]; Ex.1068, Imran, FIG.1, 3:2-7. Such outward-facing electrodes are disposed on the *lateral side* of the distal strut member. *See id.*; Ex.1005-Makower, [0187].



Ex.1005-Makower, FIG.5H. Ex.1002-Decl., ¶¶207-208.

14. Claim 24

Claim 24 depends from claim 18. Petitioners incorporate Section XI.D.8.

The combination of Makower and Fang further teaches a *monitoring electrode or system* (e.g., sensing elements/thermal sensor) *on the treatment device* (e.g., electrosurgical device). 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]). Ex.1002-Decl., ¶¶209-210.

15. Claim 25

Claim 25 depends from claim 24. Petitioners incorporate Section XI.D.14.

The combination of Makower and Fang teaches a *monitoring electrode or system* [that] *comprises a thermocouple or sensing or stimulating electrode* (e.g., sensing elements). As detailed in Section XI.D.14, Makower’s **strut members** include sensing elements that “monitor various parameters of the catheter and/or surrounding tissue (e.g., temperature, etc.),” and the “designs and constructions of [the] components and assemblies” in its electrosurgical devices were well “known in the art.” Ex.1005-Makower, [0164], [0187]. A POSITA would have understood Makower’s sensing elements are *sensing electrodes* because it was well known that

sensing elements (e.g., temperature sensors such as thermocouples) were implemented via electrodes. *See, e.g.*, Ex.1046-Lehmann, 5:13-33 (catheter with “multiple thermally-transmissive elements” and “[t]hermocouples”); Ex.1047-Flaherty, 17:53-57 (“thermocouple or other temperature sensor may be provided” on ablation devices); *also* Ex.1005-Makower, [0164] (citing Lehmann and Flaherty as well-known devices). Indeed, Makower discloses as much or more than the ’675 patent, which states in one summary sentence that “any of the foregoing systems may include electrodes or other monitoring systems...to determine the degree of treatment to the region, including, thermocouple, ultrasound transducers, fiberoptics, sensing or stimulating electrodes.” Ex.1001-USP675, 18:34-39. Ex.1002-Decl., ¶¶211-214.

XII. DISCRETIONARY DENIAL IS NOT WARRANTED

Discretionary denial is inappropriate. **First**, no *Fintiv* factor favors discretionary denial. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 (P.T.A.B. May 13, 2020). For example, the parallel litigation has not progressed past the pleadings, and there is no current case schedule or trial date. The Final Written Decision here would be expected well before the approximately 3-year median time to trial in the District of Delaware. *See* Ex.1039. And the Petition presents compelling merits underlying four Grounds.

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

This Petition presents prior art and arguments that were not previously considered. During prosecution, the Applicant represented that 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 in this Petition. *See generally* Ex.1022-FH675; *see also id.*, 7, 111, 122. Indeed, the '675 patent did not receive **any** rejections during prosecution. *Id.*, 115-123. Neither Saadat (Ground I) nor Fang (Ground IV) were considered by the Examiner. And, as discussed above, Fang provides teachings the Examiner found were not before the Office during prosecution. *See* Section XI.D.1. *Advanced Bionics* 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).

Advanced Bionics factor 2 also weighs against denial. Deem is cited on the face of the '675 patent, but was 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 priority date of the ’675 patent, the Examiner materially erred by affording the ’675 patent a pre-AIA priority date, applying pre-AIA law, and not considering subsequent art. *See* Ex.1022-FH675, 122; Section IX.

This Petition also presents evidence—Dr. Bu-Saba’s declaration and evidence regarding the scope of the prior art and knowledge of a POSITA—that was not previously before the Office and demonstrates why the prior art in this Petition renders the Challenged Claims unpatentable, which weighs 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

The Challenged Claims are anticipated and rendered obvious by the foregoing grounds. Petitioners request institution of *inter partes* review and cancellation of the Challenged Claims.

Respectfully submitted,

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Counsel for Petitioners

Appendix of Claims

Claim 1	
Limitation	Claim Language
1[pre]	A method of treating a nasal condition of a patient comprising:
1[a]	positioning a distal portion of a treatment device proximate to target tissue in a nasopharyngeal passage of a patient; and
1[b]	administering therapy to the target tissue with the treatment device so as to disrupt neural activity such that mucus secretion is reduced in the nasopharyngeal passage;
1[c]	wherein administering therapy comprises at least one of delivering energy to the target tissue and changing the temperature of the target tissue.

Claim 2
The method of claim 1, wherein administering therapy comprises delivering energy from at least one energy delivery element on the treatment device.

Claim 3
The method of claim 2, wherein the energy comprises RF energy.

Claim 7

The method of claim 1, wherein changing the temperature comprises transferring thermal energy between the treatment device and the target tissue.

Claim 9

The method of claim 1, wherein administering therapy comprises contacting target tissue with a delivery portion of the treatment device.

Claim 10

The method of claim 9, wherein the target tissue is contacted without penetrating the target tissue.

Claim 17

Limitation	Claim Language
17[pre]	A method of treating a nasal condition of a patient comprising:
17[a]	positioning a distal portion of a treatment device proximate to target tissue in a nasopharyngeal passage of a patient; and

Claim 17	
Limitation	Claim Language
17[b]	administering therapy to the target tissue with the treatment device to alter nasopharyngeal cells such that congestion in the nasopharyngeal passage is reduced;
17[c]	wherein administering therapy comprises delivering energy to the target tissue.

Claim 18
The method of claim 17, wherein the energy is delivered from an energy delivery element on the treatment device.

Claim 19
The method of claim 18, wherein the energy comprises RF energy.

Claim 20
The method of claim 19, wherein the energy delivery element comprises a monopolar or bipolar electrode.

Claim 21

The method of claim 18, wherein the energy delivery element comprises a plurality of electrodes.

Claim 22

The method of claim 18, wherein the energy delivery element is configured to concentrate energy laterally relative to the distal portion of the treatment device.

Claim 23

The method of claim 22, wherein the energy delivery element comprises at least one electrode disposed on a lateral side of the distal portion of the treatment device.

Claim 24

The method of claim 18, further comprising a monitoring electrode or system on the treatment device.

Claim 25

The method of claim 24, wherein the monitoring electrode or system comprises a thermocouple, ultrasound transducer, fiberoptic, or sensing or stimulating electrode.

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing, Petition for *Inter Partes* Review, contains 13,996 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/
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CERTIFICATE OF SERVICE

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

- Petition for *Inter Partes* Review of U.S. Patent No. 10,610,675
- Appendix of Claims
- Petitioners' Table of Exhibits
- Exhibits 1001-1006, 1008-1020, 1022-1024, 1026-1036, 1039-1055, 1057-1065, 1068, 1070-1079
- Certificate of Compliance Regarding Word Count
- Fee Authorization
- Power of Attorney

to be served on Patent Owner (Husch Blackwell, 80 South 8th Street, 4800 IDS Center, Minneapolis, MN 55402-2100, United States) via electronic mail to:

Kathleen.Daley@finnegan.com;
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Petitioners’ Table of Exhibits

No.	Description
1001.	U.S. Patent No. 10,610,675
1002.	Declaration of Dr. Nicolas Bu-Saba
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 Chao-xin and Zhen Shao-Shao, <i>Nasal endoscopy combined with multiple radiofrequency for perennial allergic rhinitis</i> , 25(07) J. First Mil. Medic Univ. 876 (July 20, 2005) (Translation) (“Fang”)
1007.	Reserved
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.	Reserved
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.	Reserved
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

No.	Description
1032.	U.S. Patent No. 9,700,707
1033.	U.S. Patent No. 10,052,465
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.	Exhibit V to Amended Complaint – Foundry’s Infringement Allegations for U.S. Patent No. 10,610,675
1037.	Reserved
1038.	Reserved
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.	Seth Waxman, <i>Correlative Neuroanatomy</i> (23rd ed. 1996)

No.	Description
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)
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.	U.S. Patent Pub. No. 2014/0243793 to Morriss
1056.	Reserved
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.	Reserved
1067.	Reserved
1068.	U.S. Patent No. 5,255,679 to Imran
1069.	Reserved
1070.	Declaration of June Munford
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