

**UNITED STATES PATENT AND TRADEMARK OFFICE**  
**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.  
Petitioners

v.

THE FOUNDRY, LLC  
Patent Owner

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Case No.: IPR2024-00669  
U.S. Patent No. 11,679,077

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**PATENT OWNER RESPONSE**

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**TABLE OF EXHIBITS**

| <b>Exhibit</b> | <b>Description</b>                                                                                                                  |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------|
| 2001           | Lewis, David, and Nicolas Y. Busaba. “Surgical Management.” Sinusitis. CRC Press, 2006. 233-268.                                    |
| 2002           | October 17, 2024 deposition transcript of Dr. Nicolas Bu-Saba (“Ex-2002-Bu-Saba Tr.”)                                               |
| 2003           | Declaration of Dr. Howard L. Levine (“Ex-2003-Levine”)                                                                              |
| 2004           | CV of Dr. Howard L. Levine                                                                                                          |
| 2005           | Declaration of Dr. Marom Bikson (“Ex-2005-Bikson”)                                                                                  |
| 2006           | CV of Dr. Marom Bikson                                                                                                              |
| 2007           | Brook, Itzhak. “Sinusitis: From Microbiology To Management” 2006                                                                    |
| 2008           | October 23, 2024 printout of<br><a href="https://europepmc.org/article/med/16027090">https://europepmc.org/article/med/16027090</a> |
| 2009           | Transcript of the September 24, 2024, Deposition of Dr. Gregory T. Martin                                                           |
| 2010           | Transcript of the September 25, 2024, Deposition of Dr. Gregory T. Martin                                                           |

**I. INTRODUCTION**

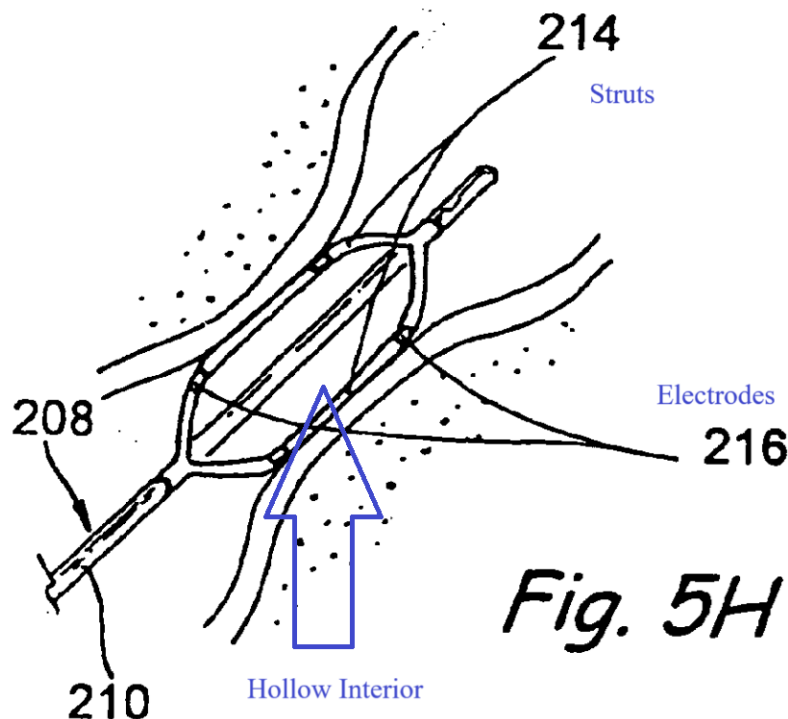
Petitioners Neurent Medical Inc. and Neurent Medical Ltd. (“Petitioners”) offer six grounds of invalidity against claims 1-8 and 11 (“the Challenged Claims”) of U.S. Patent No. 11,679,077 (“the ’077 patent”), all of which should be rejected.

For Grounds 1-4, neither Saadat nor Deem are prior art because the specification of the ’077 patent (and its predecessors) provides written description support for the Challenged Claims. In the Institution Decision (“Decision”), the Board found that the ’077 patent’s specification failed to provide written description support “an RF generator ‘for supplying [RF] energy to the multiple [RF] electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis.’” (Decision at 23-26.) Accordingly, the Board applied an effective filing date of October 22, 2019. (Decision at 26.) However, all parties agree that non-reversible poration (i.e., ablation) can treat target tissue in the nasal cavity to address rhinitis, and non-reversible energy delivery is specifically disclosed by the ’077 patent and its predecessors. Thus, the priority date of the ’077 patent is at least July 21, 2006, thereby removing Grounds 1-4.

As to Grounds 5-6, Petitioners’ failed to establish a persuasive rationale for the proposed combination and instead rely upon hindsight. Petitioners’ primary reference (Makower) relates to the development of flexible catheters and provides over *forty* figures disclosing various embodiments for implementing Makower’s

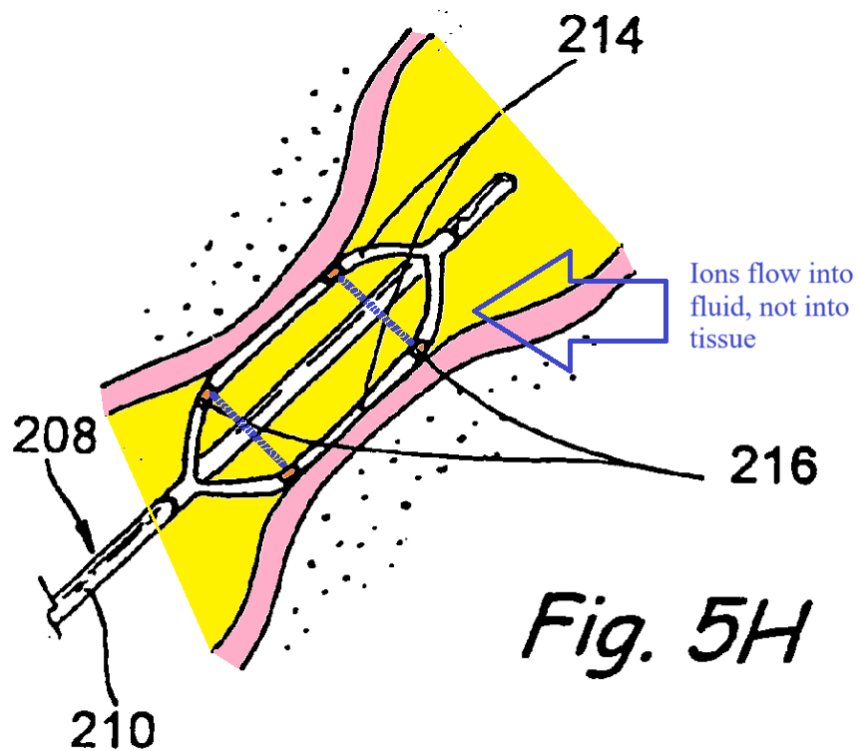
flexible catheter teachings. Only one of Makower's figures shows an RF device (FIG. 5H), an experimental device unknown to the experts in this proceeding.

Petitioners failed to establish why a POSITA would have had a reasonable expectation of "supplying radiofrequency energy to the multiple radiofrequency electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis," as required by all claims, with Makower's device. Specifically, Makower's FIG. 5H device includes a hollow interior with electrodes (216) located on its struts (214):



As confirmed by Dr. Levine, due to the configuration of Makower's FIG. 5H device reproduced above, including its hollow interior, electrolytic fluid (e.g., mucus) would be present in that interior of the device during use. This electrolytic fluid

would cause ions from the electrodes to predominately flow into that fluid and not the surrounding tissue, as illustrated in the annotated Fig. 5H below:



Accordingly, a POSITA would not reasonably expect the Makower FIG. 5H device to successfully apply meaningful ablation to the target tissues.

Furthermore, Petitioners failed to sufficiently establish why a POSITA would have been motivated to rely upon Makower, a reference almost entirely dedicated to improvements in flexible catheters, with the teachings of Fang to treat perennial allergic rhinitis, when Fang is at best inconclusive as to whether conventional RF treatment is even useful in treating perennial allergic rhinitis. In fact, the rationale Petitioners propose for its combination is the opposite of how the analysis would

have been performed by a POSITA, as confirmed by Dr. Levine.<sup>1</sup> As Dr. Levine testifies, a POSITA seeking to determine whether RF energy would be useful in the treatment of perennial allergic rhinitis would first look to Fang (not Makower), and a POSITA would have found Fang's data to be inconclusive even with the use of a conventional RF treatment device. Nonetheless, even assuming *arguendo* a POSITA would have found Fang's data to potentially indicate RF energy may be beneficial in treating perennial allergic rhinitis, Petitioners failed to sufficiently establish why a POSITA would have looked to the flexible catheter-based teaching of Makower and combined Fang with Makower's highly unusual RF device in an effort to determine whether Fang's teachings were, in fact, true.

For at least these reasons, Petitioners' proposed Grounds 5-6 are also defective and should be rejected.

## II. NASAL ANATOMY

As Dr. Levine explains, nasal anatomy and physiology are complex with many interrelated anatomical features; there are multiple nerves, bones, tissues, and

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<sup>1</sup> Patent Owner's expert, Dr. Howard L. Levine, M.D., is a renowned expert in the field of Otolaryngology. Dr. Levine serves on several scientific advisory boards, has received numerous awards for his work, and has published dozens of articles and book chapters in the field. (Ex-2004; Ex-2003 at ¶¶5-11.)

cartilage components throughout the nose, nasal cavity and nasopharyngeal passage, and one cannot treat a properly diagnosed nasal issue without fundamentally understanding the complete nasal anatomy and physiology of that issue. (Ex-2003-Levine at ¶40.)

The Lane reference cited by Petitioners provides a good overview of nasal anatomy, and includes several helpful diagrams:

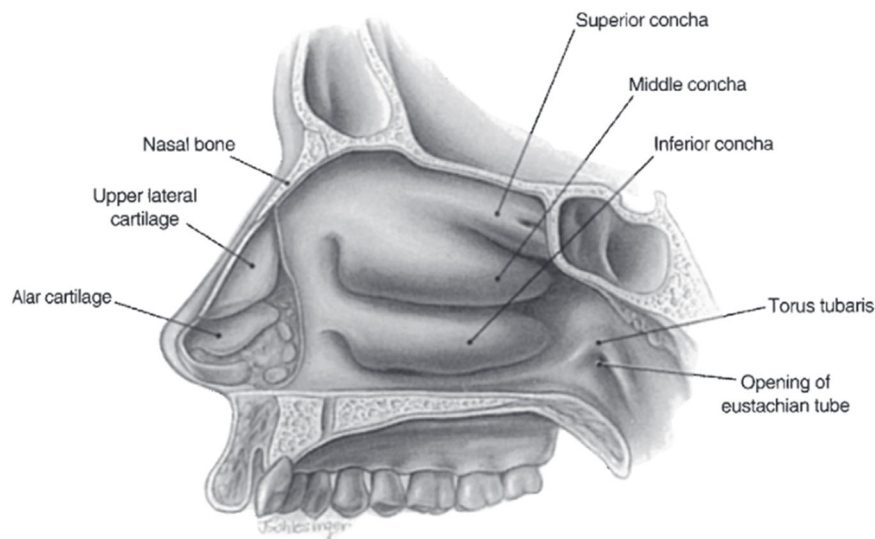


Fig. 1. Lateral nasal wall anatomy. Left side of the nose with nasal septum removed. (From O'Neal RM, Beil Jr RJ, Schlesinger J. Surgical anatomy of the nose. Otolaryngol Clin N Am 1999;32(1):175 [Fig. 29]; with permission.)

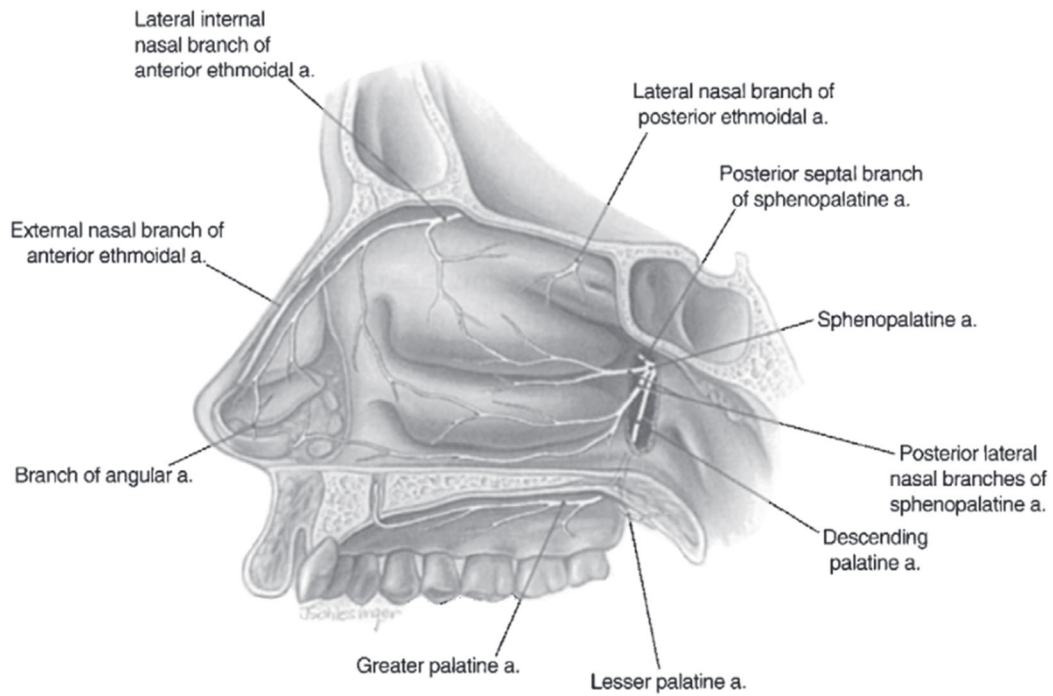


Fig. 2. Right lateral wall of the nose showing arterial blood supply. (From Otolaryngol Clin N Am 1999;177 [Fig. 32]; with permission.)

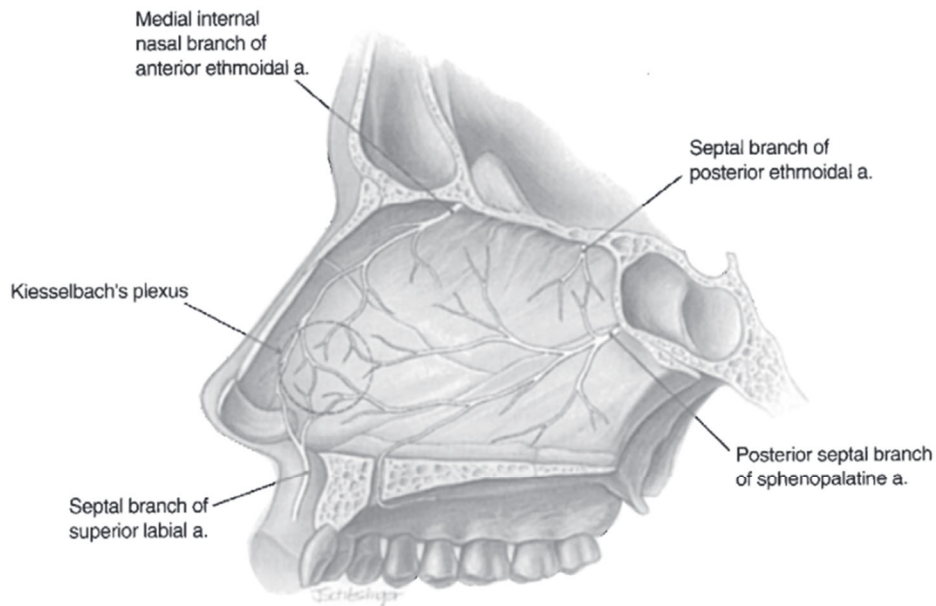


Fig. 3. Left side of the nasal septum showing arterial blood supply. Circle demonstrates Kesselbach's plexus. (From Otolaryngol Clin N Am 1999;177 [Fig. 33]; with permission.)

(Ex-1064-Lane at FIGS. 1-3; Ex-2003-Levine at ¶41.) Several important features of the nose and its conditions as it relates to this IPR are provided below.

- Lateral Wall and Concha/Turbinates<sup>2</sup>:
  - The lateral nasal wall presents an irregularly shaped surface characterized by the inferior, middle, and superior turbinates ... Scroll-like in shape and pitted, the conchal bones support the soft tissue erectile component of the turbinates. The projection of each concha into the nasal cavity creates a space beneath the turbinate called a meatus. The inferior meatus lies between the inferior turbinate and the floor of the nose. Contained within this space is the orifice of the nasolacrimal duct. Between the inferior and middle turbinate lies the middle meatus, a region critical to the function of the anterior paranasal sinuses. The frontal, maxillary, and ethmoid sinuses all have their outflow through this area either directly or by means of the ethmoidal infundibulum. (Ex-1064-Lane at 388.)
- Septum:
  - The midline of the nose consists of a structure known as the nasal septum. This structure is composed of both bone and cartilage, and divides the nasal cavity roughly into two equal halves. The anterior portion of the nasal septum is composed of the quadrilateral cartilage, while the more posterior portion of the septum is composed of the

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<sup>2</sup> A POSITA knows that the terms “turbinate” and “concha” are generally interchangeable. (Ex-2003-Levine-¶42; Ex-2002-Bu-Saba-Tr. at 69:7-70:6.)

perpendicular plate of the ethmoid bone superiorly and the vomer inferiorly. At its posterior limit, the vomer ends at the posterior choanae of the nose. (Ex-2007 at 100-101.)

- Deviated Septum:

- Nasal septal deviation is an asymmetric bowing of the nasal septum that may compress the middle turbinate laterally, narrowing the middle meatus. Bony spurs are often associated with septal deviation. Nasal septal deviation is usually congenital but may be a post traumatic finding in some patients. Nasal septal deviation occurs with a similar frequency in asymptomatic persons with no CT evidence of sinusitis and in patients with sinusitis. When the angle of deviation is high, it may contribute to the mechanical obstruction of the anterior ostiomeatal complex. (Ex-2007 at 67.)

- Nasopharyngeal Passage:

- The nasopharyngeal passage includes the nasal cavity and the nasopharynx. (Ex-1002-Bu-Saba at ¶32.)
- The nasal cavity includes, *inter alia*, the inferior, middle and superior turbinates/concha. (Ex-1064-Lane at FIG. 1.)

- Nasal Arteries, the Sphenopalatine and the Sphenopalatine Foremen:

The major arterial source for the remainder of the nasal cavity is the internal maxillary artery, which branches terminally within the pterygopalatine fossa. The sphenopalatine branch exits into the nose via the sphenopalatine foramen, located near the posteroinferior attachment of the middle turbinate. This artery divides into posterior lateral and posterior septal branches that supply the turbinates, lateral nasal wall, sinuses, and

septum. The posterior septal artery gives off the nasopalatine artery, which continues anteriorly in a groove along the vomer to reach the incisive foramen. Another branch of the internal maxillary artery, the descending palatine artery, exits into the oral cavity through the greater palatine foramen. An important area of arterial anastomosis occurs at the anterior nasal septum, linking branches of the greater palatine, superior labial, sphenopalatine, and anterior ethmoid arteries. (Ex-1064-Lane at 390.)

- Anterior Ethmoidal Nerve:
  - The nasociliary nerve in turn divides into anterior and posterior ethmoid nerves that enter the nose together with their respective arteries. *The anterior ethmoid nerve supplies the anterior lateral nasal wall*, while the posterior ethmoid nerve innervates the posterior and superior septum and lateral nasal wall. (Ex-1064-Lane at 391; *see also id.* at FIGS. 2-3.)<sup>3</sup>
- Bony Anatomy and Paranasal Sinuses:
  - Understanding the relationship of the *bony anatomy* of the face and the pneumatized cells within this bony framework *is essential in appreciating the anatomy of the paranasal sinuses*. The structures that make up the framework of the face include the nasal bones and cartilages, the ethmoid bones, the maxillary bones, and the frontal and sphenoid bones. The outer structure of the nose is formed by the paired nasal bones, as well as the upper lateral and lower lateral cartilages inferiorly. These structures provide prominence to the nasal pyramid,

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<sup>3</sup> Emphasis added herein unless otherwise noted.

as well as allowing for an aperture to provide airflow through the nasal cavity (Fig. 5). (Ex-2007 at 100.)

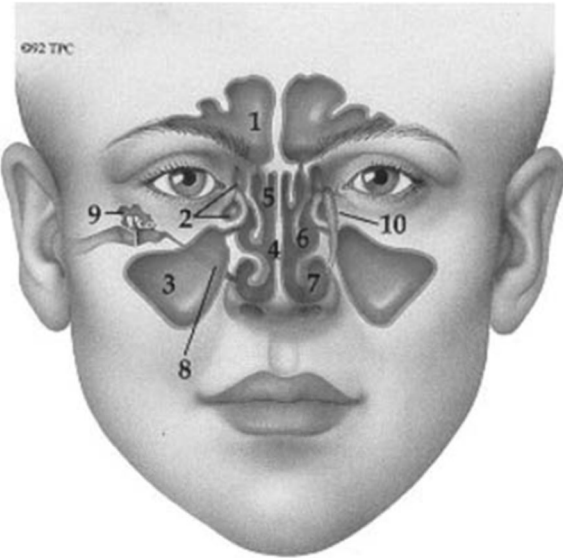


**Figure 5** Coronal view of the paranasal sinuses. 1. Frontal sinuses. 2. Ethmoid sinuses. 3. Maxillary sinuses. 4. Nasal septum. 5. Superior turbinate. 6. Middle turbinate. 7. Inferior turbinate. 8. Eustachian tube. 9. Middle ear. 10. Nasolacrimal duct.

(Ex-2007 at 101.)

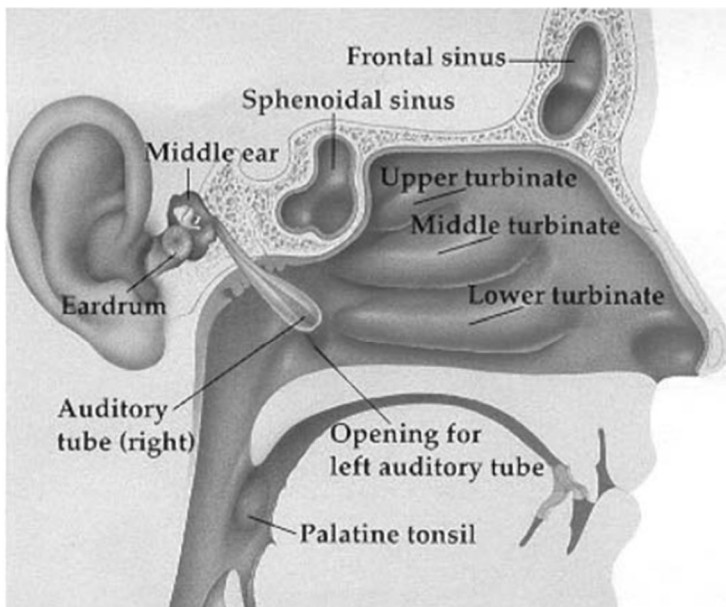


**Figure 6** Sagittal view of the nose, paranasal sinuses, Eustachian tube, and middle ear.

(Ex-2007 at FIG. 102.)

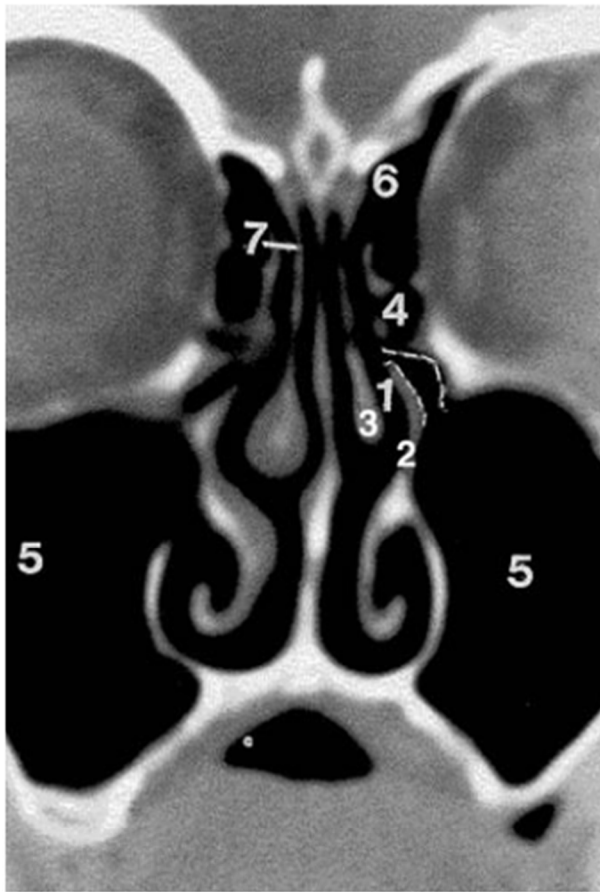


**Figure 7** Coronal CT radiograph of the paranasal sinuses with ostiomeatal complex outlined. 1. Middle meatus. 2. Uncinate process. 3. Middle turbinate. 4. Ethmoid sinuses. 5. Maxillary sinuses. 6. Frontal recess. 7. Middle turbinate. Dashed lines outline the area of the infundibulum and OMC. *Abbreviation:* OMC, ostiomeatal complex.

(Ex-2007 at 103.)

- Sinusitis versus rhinitis:
  - Sinusitis refers to an inflammatory process localized within one or more of the paranasal sinuses, whereas rhinitis is an inflammatory process within the nasal cavity. Since it is unusual for sinusitis to be present without a concurrent rhinitis, rhinosinusitis may be a more appropriate descriptor for this clinical disease process. (Ex-2007 at 40.)
- Allergic and non-allergic rhinitis:

- Allergic rhinitis is an immunologic response modulated by IgE and characterized predominantly by sneezing, rhinorrhea, nasal congestion, and pruritus of the nose. It may be seasonal (a condition commonly referred to as hay fever) or perennial. The seasonal form is caused by allergens released during tree, grass, or weed pollination, whereas the perennial form is caused by allergies to animal dander, dust mites, or mold spores with or without associated pollinosis. ... Nonallergic rhinitis is a diagnosis of rhinitis without any immunoglobulin E (IgE) mediation, as documented by allergen skin testing. Hence, the rhinorrhea, sneezing, pruritus, and congestion do not result from allergy or hypersensitivity and continue to persist, whether continuously or sporadically. ... Patients may or may not present with the same symptoms seen in allergic rhinitis. (Ex-1001 at 7:49-8:3.)

(Ex-2003-Levine at ¶¶42-43.) As Dr. Levine explains, and as may be appreciated by even a layperson, the nose is highly complex and requires a thorough understanding of its complete anatomy and physiology to properly design and develop medical devices that safely and effectively treat the nasopharyngeal passage. (*Id.* at ¶44.)

As Dr. Levine further explains, there is a significant difference between treatments addressing nasal obstructions and those addressing rhinitis. In particular, treating a nasal obstruction typically involves reducing the volume of the blockage, such as by tissue shrinkage and/or removal of the blocking material. Conversely, treating the underlying cause of rhinitis (e.g., mucus secretion) typically involves

addressing the underlying issue, such as by treating the nerves associated with the excess mucus secretion. (Ex-2003-Levine at ¶¶45-49.) Petitioners inappropriately lump these issues together when they are, in fact, materially different.

### **III. THE '077 PATENT**

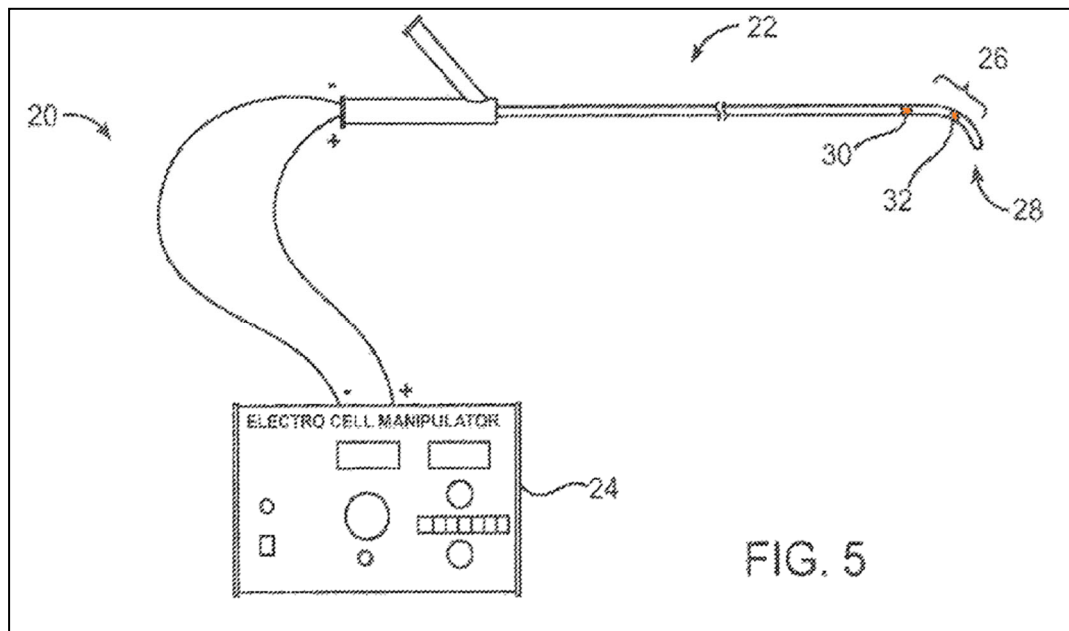
#### **A. Summary of the '077 patent**

The '077 patent discloses methods and apparatuses “for the control of autonomic nerve function” of target cells in the nasal passageway. (Ex-1001 at 1:38-47.) The '077 patent’s treatment method is generally a two-step process. First, an apparatus uses “an electric field or ultrasonic energy generated by a pulse or pulses of a designated duration and amplitude to alter tissue at the cellular level via permeabilization of the cell membrane.” (Ex-1001 at 4:61-64.) The '077 patent discloses that this cell membrane permeabilization, which is also referred to as “poration,” may be reversible or non-reversible. (Ex-1001 at 8:11-18.) Second, an active neurotoxin, *e.g.*, BoNT-LC, is delivered to permeabilized or even non-permeabilized cells. (Ex-1001 at 4:56-58; 8:33-36 (“It will be appreciated that the energy may be applied to regions of the nasal membrane which are the same or different from the regions to which the toxin has been introduced.”).)

A goal of the '077 patent is to alter the autonomic nerve function of target tissue cells in a desired manner. In some embodiments, the altered autonomic nerve function relates to treating a “disease or condition for which rhinorrhea is a result or

a symptom.” (Ex-1001 at 7:44-46 (disclosing that rhinorrhea is “the effluence of mucus from the lining of the nasal passages, nasopharynx, or paranasal sinuses”).)

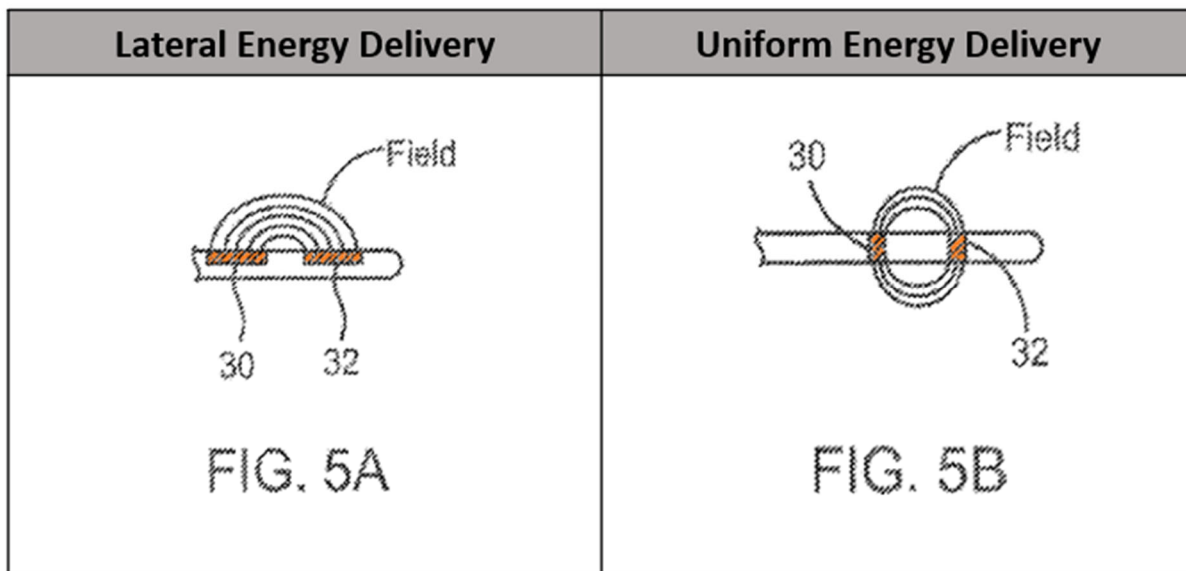
The '077 patent further discloses embodiments of the treatment device for carrying out the disclosed method, an example of which is shown in FIG. 5 (below). The treatment device, referred to in the '077 patent as an “electroporation catheter system 20” includes a “pulse generator 24” and a “catheter 22.” The catheter 22 includes a distal end 28 with electrodes 30, 32 (*orange*).



(Ex-1001 at FIG. 5 (annotated); Ex-2003-Levine at ¶¶23-26; Ex-2005-Bikson at ¶¶43-46.)

The '077 patent describes multiple embodiments of the electrode arrangement. (Ex-2003-Levine at ¶27; Ex-2005-Bikson at ¶¶46-47.) For example, in FIG. 5A (below) the electrodes are arranged to “produce[] an electric field

concentrated in a lateral direction from the catheter body.,” and in FIG. 5B (below) the electrodes are arranged “to create a more uniform electric field about the shaft of the catheter body.” (Ex-1001 at 16:62-63; Ex-2003-Levine at ¶27; Ex-2005-Bikson at ¶¶46-47.)



(Ex-1001 at FIGS. 5A-B (annotated); Ex-2005-Bikson at ¶47.)

### **B. The Priority Chain**

The '077 patent claims priority through a series of applications to a first non-provisional application (11/459,090; “the '090 application”) filed July 21, 2006, and a provisional application (60/702,077; “the '077 Provisional”) filed July 21, 2005. The Board correctly found that (1) the '077 patent has an unbroken priority claim to the '090 application; (2) the '090 application properly includes the '771 Provisional’s written description (i.e., the written description of provisional application no.

60/747,771); and (3) “the subject matter disclosed in the ’077 patent has an effective priority claim to the ’090 application.” (Decision at 21-22.) As discussed in detail below, the claims of the ’077 patent are entitled to at least the July 21, 2006, priority date because the specification of the ’077 patent and its predecessors provide written description support for the claims.

### **C. The Challenged Claims**

The ’077 patent includes 15 claims. Claims 1-8 and 11 are the Challenged Claims. Claim 1 is independent, and directed to an “apparatus for treating rhinitis in a nasal cavity,” and includes the following:

- “an elongate body, comprising: a proximal portion; and a distal portion configured for positioning in the nasal cavity;”
- “multiple radiofrequency electrodes coupled with the distal portion of the elongate body; and”
- “a radiofrequency generator coupled with the proximal portion of the elongate body for supplying radiofrequency energy to the multiple radiofrequency electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis.”

Thus, independent claim 1 is directed to “a radiofrequency generator” “for supplying radiofrequency energy to the multiple radiofrequency electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis.” Dependent claims 2-8 and 11, which depend from claim 1, recite additional features of the apparatus. But that is not to

say that '077 patent does not claim the second part of its typical two-step (delivering an agent)—it does. Specifically, non-challenged dependent claim 14 recites “*further* comprising a source of the therapeutic agent coupled with the proximal portion of the elongate body,” and claim 15 requires “wherein the therapeutic agent comprises a neurotoxin.” (Ex-1001 at 28:43-47.)

**D. Prosecution History of the '077 patent**

The prosecution history of the '077 patent does not bear on the outcome of this case. (Petition at 17.) Nonetheless, Petitioners rely on the prosecution history of the '077 patent's grandparent (U.S. Patent No. 10,610,675; “the '675 patent”) to make its case. (Petition at 67, 79.) Contrary to Petitioners' contentions, during prosecution of the '675 patent, the Examiner did *not* make any specific findings with respect to Makower FIG. 5H. (*See, e.g.*, Petition at 67, 79.) Rather, the Examiner's Reasons for Allowance for the '675 patent were limited to the following short paragraph, which simply identified Makower as the “closest prior art”:

The closest prior art is Makower et al (US Publication 2005/0240147) of record. Makower et al teach of treating disorders of the ear, nose and throat via inserting an energy emitting device into the nasopharynx. (See abstract). However, Makower et al do 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.

(Ex-1022 at 122.)

#### IV. PERSON OF ORDINARY SKILL IN THE ART

All claims of the '077 patent require “supplying radiofrequency energy to the multiple radiofrequency electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis.” (Ex-1001 at 27:43-28:47.) As explained in §II, nasal anatomy and physiology are complex with many interrelated anatomical features; there are multiple nerves, bones, tissues, and cartilage components throughout the nose, nasal cavity and nasopharyngeal passage, and one cannot treat a properly diagnosed nasal issue without fundamentally understanding the complete nasal anatomy and physiology of that issue. (Ex-2003-Levine at ¶40.) Petitioners’ POSITA definition ignores this reality.

Petitioners’ POSITA definition is:

- (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.” (Petition at 20-21.)

As shown, Petitioners’ definition allows for a person with no knowledge of nasal anatomy to opine on issues in this proceeding. That is improper. (Ex-2003-Levine at ¶¶32-36, citing Ex-1064-Lane at 387 and Ex-2007 at 95, 108.)) Indeed, Petitioners’ own expert agrees that a POSITA must have knowledge of the

nasopharyngeal passage given the scope of the claims. (Ex-2002-Bu-Saba-Tr. at 125:15-127:11.)<sup>4</sup>

Petitioners' definition also allows for a M.D. who has only clinically used or tested a medical device to opine on issues in this proceeding, i.e., allows an M.D. without any medical device design or development experience to opine on issues in this proceeding. That is likewise improper. Such a person is unqualified to speak to the technical requirements necessary to successfully and safely energize tissue in the nasopharyngeal passage.<sup>5</sup> (Ex-2003-Levine at ¶37.)

Accordingly, the proper scope of a POSITA is as follows:

(1) a Doctor of Medicine (M.D.) or at least a Bachelor of Science degree in engineering or a related discipline and

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<sup>4</sup> Dr. Bu-Saba does not have any experience developing or designing medical devices, so his opinion should be given little weight. (Ex-2002-Bu-Saba-Tr. at 43:20-45:11.) *Incyte Corp. v. Concert Pharms., Inc.*, PGR2021-00006, Paper 68, 8-9 (P.T.A.B. May 11, 2022). This is also Dr. Bu-Saba's first patent case. (Ex-2002-Bu-Saba-Tr. at 10:21-11:4, 35:19-36:6, 64:6-66:2.) Dr. Martin also has no nasal medical device experience, so his testimony should also be given no weight. Ex-2009-Martin-Tr. at 70:12-71:1, 73:21-74:2, 71:14-16, 72:12-73:5, 77:11-15.)

<sup>5</sup> The nasal cavity is part of the nasopharyngeal passage. (Ex-1002-Bu-Saba at ¶32.)

(2) at least three years of experience in the **design and development** of **nasal medical devices**, including **nasal medical devices** that deliver energy to tissue.

(Ex-2003-Levine at ¶38.)

**V. CLAIM CONSTRUCTION**

Petitioners assert that “[f]or purposes of this IPR, the Board need not construe any terms.” (Petition at 18.) Patent Owner takes no position on Petitioners’ assertion because the Board need not construe of any terms to determine Petitioners have failed to carry their burden in this proceeding. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017). Patent Owner reserves the right to propose claim construction(s) in the underlying litigation.

**VI. THE CLAIMS ARE ENTITLED TO A PRIORITY DATE OF AT LEAST JULY 21, 2006**

The ’077 patent was filed on January 19, 2021, and claims priority through a series of continuation and divisional applications to the ’090 application, filed July 21, 2006, and to the ’077 Provisional, filed July 22, 2005. The Board preliminarily determined that the ’077 patent is not entitled to claim priority to the July 21, 2006, filing date of the ’090 application based on an alleged lack of written description as to an “apparatus delivering energy in a manner that provides the treatment contemplated by independent claim 1.” (Decision at 23-26.)

Specifically, the Board reasoned (1) “claim 1 does not require the apparatus be configured for delivery of a neurotoxin for treatment of any nasal condition, but instead only supplying RF energy (via the RF generator) “to treat a target tissue in the nasal cavity and thus treat rhinitis,” and (2) the ’077 patent specification energy “is applied only to achieve cell membrane permeabilization or poration and effectuate the delivery of neurotoxin into target cells.” (Decision at 23-24.) The Board further reasoned:

That the energy and the toxin might be applied separately to the targeted tissues does not equate with the treatment contemplated by the challenged claims being provided without the toxin. And, it is not apparent that the passage above supports the use of energy as the treatment, only the use of energy to selectively porate target cells in order to facilitate the uptake of neurotoxin. (Decision at 25.)

However, as shown herein, the ’077 patent and its predecessors expressly disclose non-reversible energy delivery which results in the claimed invention. Accordingly, the ’077 patent’s claims are entitled to a July 21, 2006, priority date, thereby removing the art of Saadat and Deem cited in Grounds 1-4.<sup>6</sup>

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<sup>6</sup> To prevail in this IPR, Patent Owner need not prove the ’077 patent is entitled to claim priority to the provisional application filed July 21, 2005; Patent Owner reserves the right to do so in the underlying litigation, if required.

**A. Legal Standard**

To claim priority to a prior application, that prior application’s specification must “contain a written description of the invention...in such full, clear, concise, and exact terms to enable an ordinarily skilled artisan to practice the invention *claimed* in the *non-provisional* application.” *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375, 1377 (Fed. Cir. 2015) (citations omitted) (emphasis in original); *see Celltrion, Inc. v. Biogen, Inc.*, No. IPR2017-01229, Paper 10 at 7 (P.T.A.B. Oct. 23, 2017) (“every feature recited in a particular claim at issue must be described in the prior application”). To make this showing, “the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue.” *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000). Rather, “the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010).

**B. The ’077 patent Discloses and Claims a Two-Step Therapy for Treating a Nasal Condition**

The ’077 patent relates to an apparatus “for altering autonomic nerve function by utilizing an electric field or ultrasonic energy.” (Ex-1001 at 4:60-61.) Indeed, the ’077 patent explains that an “aspect of the invention is to provide methods and

apparatus for *treating or inhibiting a variety of diseases or syndromes* that have an underlying neurogenic component,” including, for example, rhinorrhea<sup>7</sup>, “*by disrupting the neurogenic activities of the promoters or mediators of the disease or syndrome.*” (Ex-1001 at 4:66-5:3.) The ’077 patent further specifies that the “disruption” is “facilitated” by delivering “an electric field or ultrasonic energy applied to permeabilize the wall of targeted cells” (i.e., the energy delivery step) and “delivering an active fragment of botulinum toxin” (i.e., the toxin delivery step). (Ex-1001 at 5:3-5:11.) The claims of the ’077 patent follow the two-step approach.

Claim 1 of the ’077 patent recites:

1. An apparatus for treating rhinitis in a nasal cavity, the apparatus comprising:  
an elongate body, comprising: a proximal portion; and a distal portion configured for positioning in the nasal cavity;  
multiple radiofrequency electrodes coupled with the distal portion of the elongate body; and  
a radiofrequency generator coupled with the proximal portion of the elongate body for supplying radiofrequency energy to the multiple

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<sup>7</sup> The ’077 patent specification defines rhinorrhea as the “effluence of mucus from the lining of the nasal passages, nasopharynx, or paranasal sinuses.” (Ex-1001 at 7:38-40.) The ’077 patent further discloses that rhinitis symptoms include “sneezing, itching, nasal congestion, and a runny nose.”

*radiofrequency electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis.*

Claims 14-15 of the '077 patent recite:

14. The apparatus of claim 13, *further* comprising a source of the therapeutic agent coupled with the proximal portion of the elongate body.

15. The apparatus of claim 14, wherein the therapeutic agent comprises a neurotoxin.

There is no dispute that dependent claims 14-15 are supported by the written description of the '077 patent. Indeed, as the Board stated:

[T]he Specification [of the '077 patent] discloses the use of neurotoxins to treat nasal conditions, and more specifically, that neurotoxins are used to disrupt neural signals in the targeted tissue and, therein, disable mucus secretion by such tissues. *See, e.g.*, Ex. 1001, 3:31–40, 8:11–67, 21:46–22:6.19 In the Specification, energy is applied only to achieve cell membrane permeabilization or poration and effectuate the delivery of neurotoxin into target cells. *See e.g., id.* at 4:56–58, 8:10–28. Here, we note that claim 1 does not require the apparatus be configured for delivery of a neurotoxin for treatment of any nasal condition, but instead only supplying RF energy (via the RF generator) “to treat a target tissue in the nasal cavity and thus treat rhinitis. (Decision at 23-24.)

Thus, the sole issue as it relates to the priority date of the independent claims is whether a POSITA would have recognized that the specification of the '077 patent

shows possession of the use of energy alone “to treat a target tissue in the nasal cavity and thus treat rhinitis.” As shown herein, the ’077 patent and its predecessors disclose non-reversible energy treatments, which a POSITA would have recognized as supplying energy to “electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis.” Thus, the Challenged Claims of the ’077 patent and have an effective filing date of at least July 21, 2006.

**C. The ’077 patent And Its Predecessors Include The Same Written Description Support**

As shown in §VI.D, various disclosures of the ’077 patent support the claim limitations believed to be defective. Those same disclosures of the ’077 patent are included in the ’771 Provisional, as shown by the below chart.

| ’077 patent Disclosure (Ex-1001) | Corresponding ’771 Provisional Disclosures (Ex-1011) |
|----------------------------------|------------------------------------------------------|
| Col. 8, Lines 11-28 (8:11-28)    | Pages 29-30, ¶0013                                   |
| 8:29-44                          | Page 30, ¶0014                                       |
| 9:65-10:10                       | Page 32, ¶0020                                       |
| 16:58-65                         | Page 40, ¶0067                                       |
| 7:41-50                          | Page 27, ¶¶0003, 0009-10                             |

Because the ’771 Provisional is incorporated by reference throughout the priority chain of the ’077 patent, the entire priority chain of the ’077 patent includes the disclosures of the ’771 Provisional. Indeed, as the Decision noted:

We also agree that the introduction of subject matter from the '771 provisional application into the specification of the '077 patent does not constitute new matter, because the '090 application incorporates by reference the entirety of the '771 provisional application and because the '077 patent, along with each intervening non-provisional application, has an unbroken chain of priority to the '090 application. (Decision at 21-22.)

**D. The '077 patent Reasonably Conveys to a POSITA that Energy Delivery Alone Treats Tissue in the Nasal Cavity To Address Rhinitis**

In the Decision, the Board preliminarily determined:

In the ['077 patent] Specification, energy is applied only to achieve cell membrane permeabilization or poration and effectuate the delivery of neurotoxin into target cells. *See e.g., id.* at 4:56–58, 8:10–28. (Decision at 16-17.)

We disagree. The specification of the '077 patent discloses the use of energy for more purposes than “to achieve cell membrane permeabilization or poration and effectuate the delivery of neurotoxin into target cells.”

First, the '077 patent specifically discloses reversible or ***non-reversible*** energy treatment:

According to the present invention, botulinum toxin, ricin, exotoxin A, diphtheria toxin, cholera toxin, tetanus toxin, other neurotoxins, and active fragments thereof are delivered to a patient's nasal membrane *while **applying energy** to target cells within the membrane under conditions which cause a **reversible** (or in some instances **non-***

*reversible*) poration of the cell membranes to enhance delivery of the toxin into the cells. (Ex-1001 at 8:11-18; *see also* Ex-1011 at 29, ¶0013.)

A POSITA would recognize that non-reversible poration is ablation, as Petitioners' expert, Dr. Bu-Saba, admits. (*e.g.*, Ex-1002-Bu-Saba at ¶¶36-38, 41, 46.)

Specifically, in his declaration, Dr. Bu-Saba explained that “[e]lectroporation is ‘defined as the phenomenon that makes cell membranes permeable by exposing them to certain electric pulses,’” and acknowledged that electroporation “can be reversible or *irreversible*.” (Ex-1002-Bu-Saba at ¶37 (quoting Ex-1059-Rubinsky, [0004]).) Dr. Bu-Saba further explained that “[i]rreversible poration occurs when the cell membrane does not reseal and the cell breaks down.” (Ex-1002-Bu-Saba at ¶37.) That is, irreversible (i.e., non-reversible) poration is a process by which a cell is destroyed upon application of energy. (*Id.*) Dr. Bu-Saba also testified that irreversible electroporation is ablation, opining that, like irreversible poration, “ablation involves applying energy to damage or modify tissue for therapeutic effect.” (Ex-1002-Bu-Saba at ¶38.) Indeed, according to Dr. Bu-Saba, “ablation is designed to alter (or destroy) the cells and thereby treat the condition or symptom.” (*Id.*) That is, “[f]or each location in the body where ablation is used, tissue causing a condition or symptom is destroyed or modified such that the treatment reduces or stopes the ablated tissue’s operation, and thereby addresses the condition or

symptom.” (Ex-1002-Bu-Saba at ¶38.)

The '077 patent further states that “embodiments of the present invention provide treatments for any disease or condition for which rhinorrhea is a result or symptom” and also ties rhinorrhea to mucus secretion (Ex-1001 at 7:41-50 (“Rhinorrhea is the term describing the effluence of mucus from the lining of the nasal passages, nasopharynx, or paranasal sinuses. Rhinorrhea can be a symptom of a number of diseases such as the common cold, sinusitis or rhinitis, Rhinitis (inflammation of the airways) falls into two major categories—allergic and non-allergic (or vasomotor) rhinitis. Each can have several subcategories.”).) (Ex-2003-Levine at ¶56.) Dr. Bu-Saba agrees that irreversible energy delivery (ablation) can be used to address “the cells responsible for controlling or causing rhinitis and its symptoms.” (*Id.* at ¶46.) Patentee’s expert agrees with Petitioners’ expert on this front. (Ex-2003-Levine at ¶¶56-58.) Because the '077 patent discloses the use of energy delivery to irreversibly porate, and because the '077 patent discloses the destruction of cells to reduce mucus secretion, which may address rhinitis, the '077 patent specification “reasonably conveys to those skilled in the art that the inventor had possession of the” claimed invention at least as of July 21, 2006.

Second, the '077 patent discloses applying energy in different locations, including applying energy in regions that do not receive the neurotoxin. For example, the '077 patent specification states:

When the energy applicator is incorporated with or within the catheter, the delivery pattern of *the energy will **usually be at least partially overlapping** with the toxin delivery pattern of the catheter.* For example, when a porous balloon is used for toxin delivery, the acoustic transducer, electroporation electrodes, or the like, will usually be disposed to deliver energy which at least partly overlaps with the dispersion pattern of the toxin. *In some instances, **the region of applied energy will be coextensive** with the region of toxin dispersion. In other instances, the two regions will only partially overlap. In the latter case, the delivery of the toxin will be enabled or enhanced principally within the regions of overlap.* (Ex-1001 at 9:65-10:10; see also Ex-1011 at 32, ¶0020.)

The '077 patent specification further states:

The energy is preferably selectively applied to a targeted region containing a variety of cell types, including ***goblet cells***, epithelial cells, ciliated and non-ciliated columnar cells, basal cells, and less or no energy applied to untargeted regions. *It will be appreciated that the energy may be applied to regions of the nasal membrane **which are the same or different from the regions where toxin has been introduced.*** (Ex-1001 at 8:29-36 see also Ex-1011 at 30, ¶0014.)

Thus, a POSITA would recognize the '077 patent specification discloses applying energy in regions that may or may not overlap with the region of neurotoxin delivery and that those regions may relate to, for instance, goblet cells. (Ex-2003-Levine at ¶¶50-54.) Based on the above disclosures and the '077 patent's disclosures that the

applied energy may be reversible or non-reversible, a POSITA would recognize the '077 patent as disclosing at least the following distinct energy delivery options in relation to neurotoxin delivery:

- Reversible energy applied; region of energy delivery *co-extensive* with region of neurotoxin delivery;
- Reversible energy applied; region of energy delivery *partially overlapping* with region of neurotoxin delivery; and
- ***Irreversible*** energy applied; region of energy delivery *partially overlapping* with region of neurotoxin delivery. (Ex-2003-Levine at ¶55.)

Moreover, based on the above disclosures, a POSITA would recognize the '077 patent specification discloses applying irreversible energy in regions of the nasal cavity that have cells responsible for mucus secretion and congestion (e.g., goblet cells and nasal membrane, respectively). A POSITA would have appreciated, based on at least the above teachings of the '077 patent, that applying irreversible energy to such tissues in the nasal cavity treats the underlying conditions causing rhinitis (e.g., mucus secretion) and “thus treat[s] rhinitis,” as required by claim 1. (Ex-2003-Levine at ¶¶55-57.) Indeed, as explained previously, both mucus secretion and congestion may be related to rhinitis. Accordingly, the '077 patent “reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” Although not in dispute, for completeness,

Patent Owner notes that the '077 patent also discloses the remainder of the limitation disputed by Petitioner, i.e., “a radiofrequency generator coupled with the proximal portion of the elongate body for supplying radiofrequency energy to the multiple radiofrequency electrodes.” (Ex-1001 at 10:42-58; FIGS. 5A-5B.)<sup>8</sup>

For at least the above reasons, the specification of the '077 patent reasonably conveys that the inventors had possession of “a radiofrequency generator coupled with the proximal portion of the elongate body *for supplying radiofrequency energy to the multiple radiofrequency electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis*,” as set forth in the claims, as of the filing date of the '090 application. There is also no dispute that the remaining limitations of the independent claim are disclosed by the '077 patent and its predecessors, and no priority date arguments were made by Petitioner as to the dependent Challenged Claims. (Petition at 24-25.) Thus, the Challenged Claims are entitled to a priority date at least as early as July 21, 2006, thereby removing Sadaat and Deem as prior art. Accordingly, Petitioners' Grounds 1-4 fail.

## **VII. PETITIONERS' GROUNDS 5-6 ARE NOT PERSUASIVE**

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<sup>8</sup> This limitation is disclosed in the '090 application (Ex-1012 at 10:45-65; FIGS. 5A-5B), and all of its pertinent child applications through the '011 patent. Thus, Patent Owner need not show this limitation is disclosed by the '077 Provisional.

Petitioners' Grounds 5-6 allege that the Challenged Claims are unpatentable for being obvious based on combinations that at least involve Makower and Fang. (Petition at 8.) Here, Petitioners failed to carry their burden as there was no motivation to combine Makower and Fang, and even assuming *arguendo* a motivation existed, the combination fails to establish a reasonable expectation of successfully achieving the claimed invention. (Ex-2003-Levine at ¶¶86-98; Ex-2005-Bikson at ¶¶57-72.)

Below, Patent Owner first shows why, irrespective of any alleged motivation to combine, Petitioners' failed to establish that Makower's device would have reasonably been expected to successfully achieve treatment of targeted tissue, as required by all claims. Patent Owner then addresses Petitioners' defective motivation to combine.

**A. Petitioners Failed to Sufficiently Establish a Reasonable Expectation of Success In Treating Nasal Tissue With The Makower Device**

Obviousness is a question of law based on multiple underlying factual determinations, including whether a POSITA would have been motivated to combine the prior art to achieve the claimed invention and whether there would have been a reasonable expectation of success in doing so. *TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1375 (Fed. Cir. 2019). The reasonable-expectation-of-success analysis must be tied to the scope of the claimed invention. *Teva Pharm. v. Corcept*

*Therapeutics*, 18 F.4th 1377, 1382-83 (Fed. Cir. 2021), citing *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 966 (Fed. Cir. 2014).

Petitioners' Grounds 5-6 rely on a combination of Makower and Fang. Here, Petitioners argue:

Makower Figure 5H depicts an electrosurgical device for the nasal cavity or nasopharynx with strut members 214 with multiple bipolar electrodes 216. (Petition at 30.)

[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. (Petition at 68.)

Patent Owner disputes that a POSITA would have been motivated to combine Makower and Fang, as shown below. Yet, irrespective of any motivation, Petitioners' case is defective because Petitioners failed to establish that Makower's FIG. 5H device would reasonably be expected to properly deliver energy to target

tissue to achieve the claimed therapeutic results.<sup>9</sup> (Ex-2003-Levine at ¶¶86-101; Ex-2005-Bikson at ¶¶62-63.)

Independent claim 1 of the '077 patent requires treatment of target tissue to achieve a specified result:

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

Petitioners failed to establish that the FIG. 5H device of Makower would have reasonably been expected to successfully achieve the claimed therapeutic results. (Ex-2003-Levine at ¶¶99-101.)

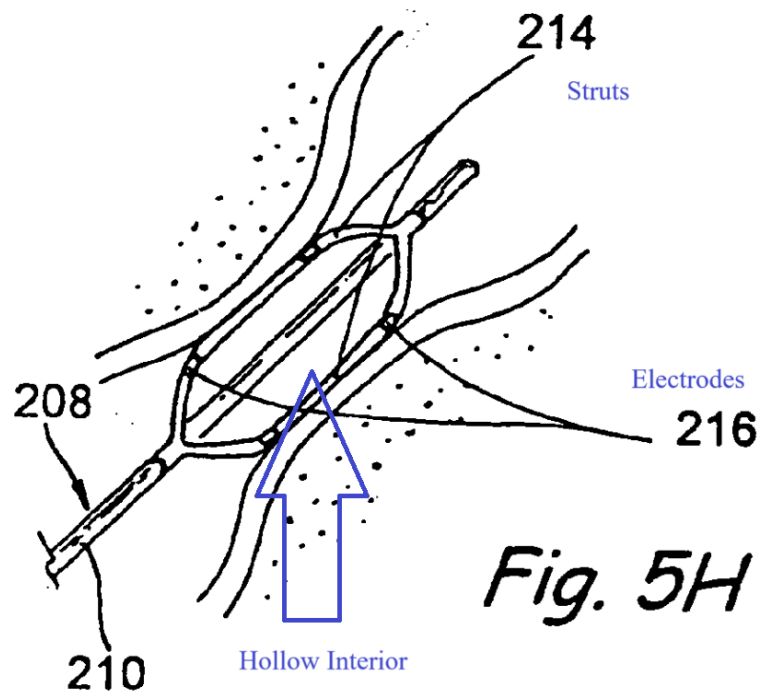
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<sup>9</sup> It is undisputed that Petitioners are not proposing any modifications to Makower's FIG. 5H device. (Petition at 79 ("Makower's device would not require modification to achieve this result.").)

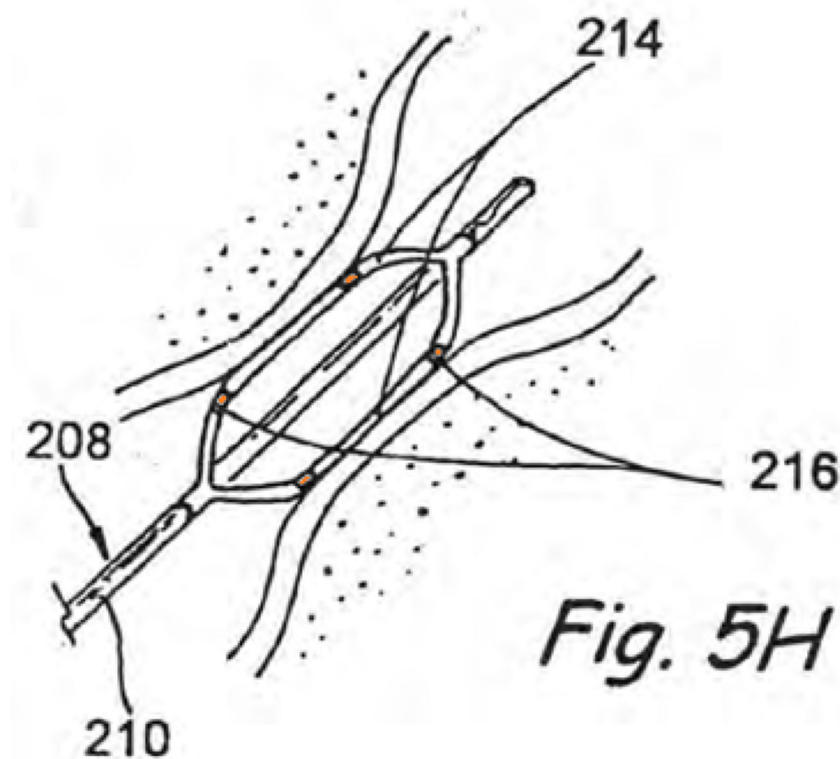
*First*, Makower is not directed to RF energy delivery devices. Instead, it is directed to the use of flexible catheters attached to numerous potential medical devices, only one of which is an RF energy delivery device. *See* §VII.B, *infra*. Thus, it is unsurprising that Makower includes almost no detail on the FIG. 5H device. Indeed, the entirety of Makower’s description of FIG. 5H is contained in a total of nine sentences spanning two paragraphs ([0092], [0187]) in a patent application that contains 242 total paragraphs of text. (Ex-2003-Levine at ¶¶77-85; Ex-2005-Bikson at ¶66.)

*Second*, the RF energy device of Makower FIG. 5H is entirely hypothetical. Petitioners’ expert is a Medical Doctor who has been practicing Otolaryngology since 1985. (Ex-1002 at ¶4.) Patent Owner’s expert is also a Medical Doctor who has been practicing Otolaryngology since 1975. (Ex-2003-Levine at ¶¶6-7.) Neither expert has ever seen or used a device like that of Makower in their over 80 combined years of clinical practice. (Ex-2002-Bu-Saba-Tr. at 303:13-18; Ex-2003-Levine at ¶89.)

*Third*, the design of Makower’s hypothetical device is fatally defective. (Ex-2003-Levine at ¶¶92-96; Ex-2005-Bikson at ¶¶70-71.) Specifically, as shown below, the Makower FIG. 5H device includes struts (214) on the outside thereof, defining an empty space or a “hollow interior:”



(Ex-1005-Makower at FIG. 5H (annotated); Ex-2003-Levine at ¶¶91-93; Ex-2005-Bikson at ¶¶61-64.) Makower's device includes four electrodes (216) located on the struts adjacent tissue (shown in *orange* below).



(Ex-1005-Makower at FIG. 5H, annotated; *see* Ex-2003-Levine at ¶¶91-93; Ex-2005-Bikson at ¶¶53, 61-63.)

A POSITA would have understood Makower's FIG. 5H electrodes to be ring electrodes, i.e. rings that wrap around the surface of the struts of Makower's device. (Ex-2003-Levine at ¶¶93-94; Ex-2005-Bikson at ¶64.) As Makower explains, FIG. 5H is a "partial perspective view" of the device, i.e., is a two-dimensional representation of device. (Ex-2003-Levine at ¶¶48, 94-95; Ex-2005-Bikson at ¶¶64-65.) It is, therefore, not a cross-sectional view showing a slice of the device. (*Id.*) Makower's perspective view tells a POSITA that the electrodes (216) are ring electrodes. (*Id.*) Indeed, the electrodes appear ring like, and, as is common with

ring electrodes, only a portion of the electrodes are in contact with adjacent tissue<sup>10</sup> while the majority of the surface area of each electrode is illustrated as being not in contact with tissue. (Ex-2003-Levine at ¶¶94-96; Ex-2005-Bikson at ¶65.) A POSITA would understand based on the perspective view of in FIG. 5H and the depictions of the electrodes in relation to the struts 216 that the electrodes wrap around the struts, which is also consistent with a POSITA's understand of ring electrodes. (Ex-2003-Levine at ¶¶94-96; Ex-2005-Bikson at ¶¶64-65.) Thus, a POSITA would have concluded that Makower's FIG. 5H electrodes (216) are ring electrodes. (*Id.*) Accordingly, a POSITA would have known that Makower's FIG. 5H electrodes were configured to emit energy about their entire circumference. (Ex-2003-Levine at ¶94; Ex-2005-Bikson at ¶76.)

As it relates to operation of the FIG. 5H device, Makower includes a total of three sentences:

“In operation, the device 208 is advanced into a passageway such as a nostril, nasal cavity, meatus, ostium, interior of a sinus, etc. Thereafter, current is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated. The electrodes 216 may be

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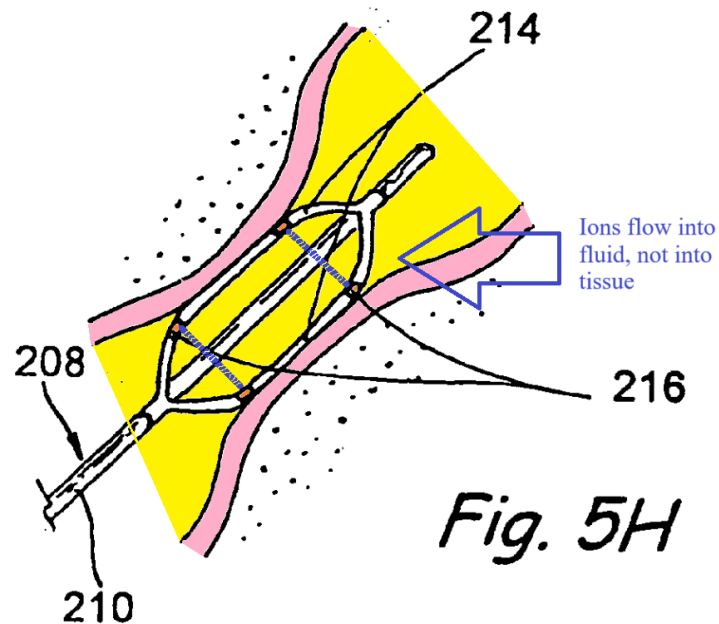
<sup>10</sup> At least the top left electrode of FIG. 5H is illustrated as not being in contact with tissue.

bipolar, monopolar or facilitated by any other suitable form of energy such as a gas or plasma arc.” (Ex-1005-Makower at [0187].)

As Makower notes, the device is first “advanced into a passageway such as a nostril, nasal cavity, meatus, ostium, interior of a sinus.” (Ex-1005-Makower at [0187].)

The '077 patent claims all require treatment of the nasopharyngeal passage. A POSITA would recognize that the nasopharyngeal passage would include bodily fluids, such as mucus or blood, and/or saline (e.g., if the passage was irrigated prior to treatment). (Ex-2003-Levine at ¶¶95; Ex-2005-Bikson at ¶¶70-71.) These fluids are all electrolytic fluids, i.e., are highly conductive to current due to, for example, their salt content (e.g. the fluid is an electrolyte). (Ex-2003-Levine at ¶¶95; Ex-2005-Bikson at ¶¶70-71.) When Makower’s device is placed into the nose and advanced into the nasopharyngeal passage, it would accumulate such electrolytic fluids in its hollow interior. (Ex-2003-Levine at ¶¶94-95; Ex-2005-Bikson at ¶70.)

Makower’s next step is to apply current to the ring electrodes. As Drs. Levine and Bikson testify, it does not matter whether Makower’s arrangement is monopolar or bipolar—in either case, the application of current to Makower’s electrodes would not result in the treatment of target tissue. (Ex-2003-Levine at ¶¶96-97; Ex-2005-Bikson at ¶69.) Instead, due to the presence of electrolytic fluid within Makower’s hollow interior, ions would preferentially flow into this electrolytic fluid and not the target tissue:



(Ex-1005-Makower at FIG. 5H, annotated; Ex-2003-Levine at ¶¶96-97; Ex-2005-Bikson at ¶¶66-70.)<sup>11</sup> Indeed, it was well-known to a POSITA that RF energy will be drawn to the path that it can travel through with the least resistance. (Ex-2003-Levine at ¶¶94-96; Ex-2005-Bikson at ¶71.) A POSITA would have understood that, as between tissue and an electrolytic fluid, such as a mucus, blood, or saline,

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<sup>11</sup> The above is just one illustration presenting one potential pathway for the ions to flow; it will be appreciated that, irrespective of which electrodes of Makower are energized, the ions will preferentially flow through the electrolytic fluid and not into the tissue.

the path of least resistance would be the electrolytic fluid due to the conductive property of the medium. (Ex-2003-Levine at ¶¶94-96; Ex-2005-Bikson at ¶71.) In the context of bodily fluids and saline, a POSITA would have understood that when RF energy encounters these fluids, the ions will be drawn to that medium. (Ex-2003-Levine at ¶¶94-97; Ex-2005-Bikson at ¶71.) This is because these fluids are highly conductive to current due to, for example, their salt content (e.g. the fluid is an electrolyte). (Ex-2003-Levine at ¶96; Ex-2005-Bikson at ¶71.)

Given the foregoing, a POSITA would have recognized that Makower's hypothetical FIG. 5H device would not have reasonably been expected to ablatively treat target tissue.<sup>12</sup> (Ex-2003-Levine at ¶¶89-98; Ex-2005-Bikson at ¶72.) Instead, energy applied to the electrodes would preferentially flow into the interior of Makower's device, i.e., the use of Makower's device would not have reasonably been expected to successfully achieve:

a radiofrequency generator coupled with the proximal portion of the elongate body for supplying radiofrequency energy to the multiple radiofrequency electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis. (Claim 1.)

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<sup>12</sup> As explained below, Makower's arrangement also raises meaningful safety concerns.

(Ex-2003-Levine at ¶¶99-101; Ex-2005-Bikson at ¶¶22, 72.) Accordingly, Petitioners failed to establish obviousness of the Challenged Claims.

Tellingly, the Petition fails to meaningfully address the Makower FIG. 5H device and its operation. Petitioners' reasonable expectation of success argument regarding the use of Makower's device with Fang spans a single paragraph. (Petition at 83-84.) Nowhere do Petitioners address Makower's device and explain why it would be expected to successfully ablate tissue. Instead, Petitioners focus on Fang and another reference outside its ground (Chen). Petitioners argument is:

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. (*Id.*)

Petitioners have failed to carry its burden. Neither Petitioners nor their expert ever address the threshold issue of whether Makower's hypothetical device is even suited to ablate tissue in the nose. Instead, Petitioners simply assume so and without any analysis. Petitioners' expert makes the same mistake. (Ex-1002 at ¶¶177-79.) Indeed, on cross-examination Dr. Bu-Saba (Petitioners' expert) admitted he had not really considered Makower as a whole (Ex-2002-Bu-Saba-Tr. at 272:20-273:10), and that there are numerous unknowns regarding Makower's device. (*Id.* at 279:16-

280:4 (reason for Makower's tip is unknown); 281:6-282:8 (unknown strut configuration); 285:20-286:6 (unknown location in the body); 288:3-289:7 (unknown whether the FIG. 5H device can be used in the sinuses, even though Makower discloses it can be); 290:2-291:9 (unknown manner of energizing the electrodes); 297:11-298:12 (unknown why Makower refers to "gas or plasma arc" in the context of FIG. 5H).) Merely stating that the Makower-Fang combination has a reasonable expectation of success, without more, as Petitioners have done "fails to explain why a person of ordinary skill in the art would have combined the elements from specific references in the way that the claimed invention does." *See ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1328 (Fed. Cir. 2012).

Patent Owner notes that Petitioners include a footnote (16) asserting that "[t]o the extent PO argues Fang's results would not have been expected with Makower's device, such argument would be misplaced." (Petition at 84.) Nothing in this footnote addresses the real issue of whether Makower's device is actually suited to ablate tissue in the nose—it is not. Moreover, Petitioners assertion here that a "POSITA would have understood that Fang's generic device would operate similarly to Makower's electrosurgical device with bipolar electrodes" is patently false. Both experts agree that Fang's SHP-I device is an unknown quantity—despite both doctors having practiced for over 38 years (each) and both having conducted

thousands of surgeries, neither of them had ever seen or heard of Fang’s “SHP-I” device prior to this case. (Ex-2002-Bu-Saba-Tr. at 180:8-181:4; 184:18-21; Ex-2003-Levine at ¶¶69-70; ¶12.) Indeed, Dr. Bu-Saba admitted he has no idea what Fang’s device is arranged or how it operates. (Ex-2002-Bu-Saba-Tr. at 182:4-10 (“As I told you before, I’m not familiar with this device, I’ve not used this device....”).) Accordingly, Petitioners’ assertion that “Fang’s generic device would operate similarly to Makower’s electrosurgical device with bipolar electrodes” (Petition at 84) is entirely unsupported and should be rejected. For these same reasons, Petitioner’s statement that “Fang provides additional details regarding the well-known design, construction, and operation of Makower’s RF device” should also be rejected as being unsupported. (Petition at 80.)

The above facts and analysis underscore the importance of adopting and applying a proper POSITA definition. Here, Petitioners employed a medical doctor (Bu-Saba) with no design or development experience relating to medical devices in general, let alone medical devices that employ RF energy in the nose. Had Petitioners applied the proper POSITA definition and undertaken the proper technical analysis from that perspective, they would have realized that Makower’s FIG. 5H device is fatally flawed.

Petitioners other arguments are likewise unpersuasive. Petitioners assert that a person of ordinary skill in the art “would have reasonably expected Makower’s

electrosurgical device to obtain Fang’s clinical results.” (Petition at 83.) This is false even without considering the inability of Makower’s FIG. 5H device to properly ablate target tissue. Petitioners’ assumption is based on the fact that both Makower and Fang treat nasal conditions using energy-delivery devices. (*Id.*) Petitioners take this generalization and make the unsupported leap that Makower’s FIG. 5H device could successfully be used to treat rhinitis by applying RF energy to parasympathetic nerves in the nasal cavity that originate from the sphenopalatine nerves. (*Id.*) This is incorrect.

Initially, neither Petitioner’s expert nor Dr. Bu-Saba could decipher “Fang’s clinical results.” *See* §VII.B.1, *infra*. Thus, Petitioners cannot assume Makower’s FIG. 5H will have a reasonable expectation of success when Fang’s data is inconclusive. Petitioners’ assumption further lacks merit in view of Dr. Bu-Saba’s testimony that he could not identify where in the nose the FIG. 5H device was positioned. (Ex-2002-Bu-Saba-Tr. at 285:20-286:6) Fang’s method appears to contemplate multiple ablation locations—namely, both sides of the sphenopalatine foramen, the anterior upper part of the nasal septum, the anterior upper part of the lateral wall of the nasal cavity, the nasal ridge, and the anterior part of the inferior nasal turbinate (Ex-1006-Fang at 876, Section 1.2); and Petitioners have provided no evidence that Makower’s FIG. 5H device would be used in each of those locations. A POSITA would have understood that Makower’s struts limit the tissue

that can actually be treated to that which the struts can contact. But in the instance of rigid struts, which are unable to conform to the curvature of the nasal cavity, a POSITA would understand that Makower's FIG. 5H electrodes would not necessarily even contact the target tissue. This is even shown in FIG. 5H, as not all electrodes are depicted as being in contact with target tissue in the passageway—at least the upper, northwestern electrode is not in contact with the tissue, as Dr. Bu-Saba confirmed during his deposition. (Ex-2002-Bu-Saba-Tr. at 298:13-22.)

For at least the above reasons, Petitioners have not met their burden of showing that a POSITA would have had a reasonable expectation of successfully achieving the claimed inventions.

**B. Petitioners Failed to Sufficiently Establish That a POSITA Would Have Been Motivated To Combine Makower and Fang**

In addition to failing to establish a reasonable expectation of success, Petitioners' also failed to establish a motivation to combine. Below, Patent Owner first addresses the teachings of Fang followed by Makower as this is the analysis a POSITA would have done without hindsight. Then, Patent Owner shows why Petitioners failed to sufficiently establish a motivation to combine for Grounds 5-6.

**1. Fang's Study is Inconclusive**

Petitioners argue that a POSITA would have been motivated to combine Makower and Fang because, *inter alia*, Fang "clarifies" that Makower's device can

operate according to Fang’s method. (Petition at 79.) Petitioners’ argument is false. Fang does not provide any clarity to a POSITA. Rather, as the experts admit, they “don’t know what exactly Fang means” as it relates to numerous ones of its disclosures. (Ex-2002-Bu-Saba-Tr. at 188:7-189:15; *see also id.* 194:19-195:7; 196:7-197:13; 202:7-19; 203:14-22; 208:8-21; 214:1-11; Ex-2003-Levine at ¶75.)

Fang purports to disclose a method for treating perennial rhinitis based on a study involving 83 patients determined to have both (a) a deviated nasal septum, and (b) met the “diagnostic criteria for perennial rhinitis.” (Ex-1006-Fang at 876, Section 1.1.) Yet, a careful review shows that no conclusions regarding RF energy can be made because Fang conducted multiple operations on an unidentified number of patients in the experimental group, rendering Fang’s hypothesis unsupported.

It is undisputed that Fang conducted tests on 83 patients. 20 of these patients were the control group and received a deviated septum surgery only. (Fang at 876, Section 1.1; Ex-2002-Bu-Saba-Tr. at 206:5-207:1; Ex-2003-Levine at ¶66.) The other 63 patients received a deviated septum surgery plus treatment by RF energy, plus additional surgeries, if required. (Fang at 876, Section 1.2; Ex-2002-Bu-Saba-Tr. at 190:9-191:1; Ex-2003-Levine at ¶72.) Specifically, “for those who had hypertrophy of the uncinate process, sinusitis, hypertrophy or polypoid lesion of the middle turbinate, or nasal polyps,” “[f]urther submucosal resection of the nasal septum was performed, and uncinate process resection, sinus opening, lateral part

resection of the middle turbinate or nasal polypectomy were performed.” Both experts agree that Fang does not disclose how many patient in the treatment group received the additional surgeries of “submucosal resection of the nasal septum was performed” *plus* one or more of “uncinate process resection, sinus opening, lateral part resection of the middle turbinate or nasal polypectomy.” (Fang at 876, Section 1.2; Ex-2002-Bu-Saba-Tr. at 190:9-191:1, 204:11-205:14; Ex-2003-Levine at ¶72.) Any of these additional procedures may have been wholly or partially responsible for the end results Fang’s patients reported. Accordingly, it is not possible to know whether Fang’s hypothesis is true—too many additional surgeries were performed on an unknown number of patients in the treatment group to properly determine whether RF energy was, in fact, the reason for Fang’s allegedly improvement in perennial allergic rhinitis. (Ex-2003-Levine at ¶¶72-74.)

The above issue is just one of many issues with Fang and Petitioners lack of analysis of the same. For instance, Fang states “all the patients complied with the diagnostic criteria for perennial rhinitis [1].” That is, Fang does not specifically disclose the diagnostic criteria it used for perennial rhinitis, but refers the reader to citation [1]. Fang’s citation [1] is a Chinese Journal of Otolaryngology document from 1998, which is not of record in this proceeding, and Dr. Bu-Saba testified he did not review citation [1] as part of his analysis. (Ex-2002-Bu-Saba-Tr. at 194:5-15; 207:2-15.) Yet, citation [1] is not only important for diagnostic criteria, but also

for efficacy, as this same document is cited by Fang in support of his efficacy criteria:

### 1.3 Evaluation criteria for efficacy

The efficacy was evaluated according to the evaluation criteria for allergic rhinitis [1].”

Indeed, neither doctor in this proceeding was able to determine how Fang determined efficacy, or Fang’s basis for doing so. (Ex-2002-Bu-Saba-Tr. at 207:2-208:21; Ex-2003-Levine at ¶¶74-75.) For at least the above reasons, a POSITA would have determined that Fang’s results were inconclusive as it relates to the application of RF energy for the treatment of perennial allergic rhinitis. Simply put, too many variables were changed by Fang at once across an unknown number of patients, while the criteria for perennial allergic rhinitis and efficacy according to Fang remain unknown. Indeed, Dr. Levine testifies that if he would have been presented with Fang as a peer reviewer, he would not have recommended the study for publication given its confusing, inconclusive results with unknown variables and treatment methods. (Ex-2003-Levine at ¶¶63, 75.) Perhaps this is the reason that Fang has been cited a single time even though it was published over 19 years ago. (Ex-2008.)

## **2. Makower Is Directed to Flexible Catheters, Not RF Devices**

Petitioners contend that Makower is directed to the “problem” of “treating nasal conditions” and that Makower solves this problem by “applying energy to

tissue.” (Petition at 83-84.) Not true. An examination of Makower reveals that Makower is directed to improved ear, nose, and throat procedures using a *flexible* catheter. (Ex-2003-Levine at ¶¶77-85.)

Specifically, Makower describes the “Field of Invention” as “minimally invasive, *catheter based devices*, systems and methods for treating sinusitis and other ear, nose, and through disorders.” (Ex-1005-Makower at [0001].) In the Background, after reviewing nasal anatomy, nasal polyps, sinusitis, deviated septum, nasal turbinates, sinus tumors, and endoscopic surgery, among other things, Makower explains that there are issues with surgeries and other medical procedures because those procedures use devices having rigid shafts:

*One of the reasons why FESS and sinus surgery is so bloody and painful relates to the fact that straight instrumentation with rigid shafts are used.* Due to the fact that the sinuses are so close to the brain and other important structures, physicians have developed techniques using straight tools and image guidance to reduce the likelihood of penetrating into unwanted areas. In an effort to target deep areas of the anatomy, this reliance on straight instrumentation has resulted in the need to resect and remove or otherwise manipulate any anatomical structures that may lie in the path of the instruments, regardless of whether those anatomical structures are part of the pathology. (Ex-1005-Makower at [0036].)

Makower then goes on to state the purpose of his invention, i.e., to provide flexible

catheters/instrumentation:

With the advances in catheter based technology and imaging developed for the cardiovascular system, **there exists a significant opportunity** to reduce the morbidity of sinus interventional through the use of flexible instrumentation and guidance.

If flexible tools could be developed such that sinus intervention may be able to be carried out with even less bleeding and post-operative pain, these procedures may be applicable to a larger group of patients. Further, as described here, flexible instrumentation may allow the application of new diagnostic and therapeutic modalities that have never before been possible. (*Id.* at [0036]-[0037].)

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Many of the above-described procedures and techniques may be adaptable to minimally invasive approaches and/or the use of flexible instrumentation. There exists a need in the art for the development of such minimally invasive procedures and techniques as well as instrumentation (e.g., flexible instruments or catheters) useable to perform such procedures and techniques.

#### SUMMARY OF THE INVENTION

In general, the present invention provides methods, devices and systems for diagnosing and/or treating sinusitis or other conditions of the ear, nose or throat.

In accordance with the present invention, there are provided methods wherein one or more flexible catheters or other flexible elongate devices as described herein are inserted into the nose, nasopharynx, paranasal sinus, middle ear or associated anatomical passageways to

perform an interventional or surgical procedure. Examples of procedures that may be performed using these **flexible catheters or other flexible elongate devices** include but are not limited to ...” (*Id.* at [0040]-[0042].)

Near the beginning of the Detailed Description section, Makower continues:

In a number of embodiments, *the present invention uses **flexible catheters and various working devices** that are mounted or delivered through **elongate flexible members or catheters***, to diagnose and treat a wide range of ear, nose and throat disorders including: nasal polyps, sinusitis, enlarged turbinates, deviated septum, tumors, infections, deformities, etc. The following pages describe a number of specific devices that are usable in accordance with this invention. (Ex-1005-Makower at [0132].)

Many of the procedures of the present invention require the insertion and positioning of one or more **flexible catheters or other working devices** (examples of which are shown in FIGS. 5A-5Y”). (Ex-1005-Makower at [0134].)

Makower then continues to disclose numerous embodiments of devices and instrumentation that may use a flexible catheter.

Specifically, Makower’s detailed description discloses several groups of flexible catheters and instrumentation according to the present invention under the following headings: “Occluders & Access Port Devices” (Ex-1005-Makower at [0133]-[0143]), “Variations in Occluder Design and Suction Apparatus” (Ex-1005-Makower at [0144]-[0159]), “Working Devices for Delivering Substances or for

Cutting, Ablating, Remodeling or Expanding Bone or Soft Tissue” (Ex-1005-Makower at [0160]-[0204]), “Pre(-Shaped Guide Catheters” (Ex-1005-Makower at [0205]-[0213]), “Devices and Methods for Treatment within Paranasal Sinuses” (Ex-1005-Makower at [0214]-[0221]), “General Examples of Interventions Using the Occluder & Access Devices and/or Other Working Devices” (Ex-1005-Makower at [0222]-[0238]), and “Cochlear Implant Procedures (Ex-1005-Makower at [0239]-[0242]).

The device upon which Petitioners predicate Grounds 5-6 is buried in Makower’s “Working Devices” section, described in a single figure (FIG. 5H), whose functionality is explained in a single paragraph. (Ex-1005-Makower at [0187].) In the “Working Devices” section alone, Makower discloses over *twenty* embodiments that “may be delivered through or incorporated into *flexible catheters* or *flexible rod-like shafts*.” (Ex-1005-Makower at [0161].) As Makower explains,

such *flexible construction* allows these devices to be delivered and positioned to perform the desired diagnostic or therapeutic procedures with minimal trauma to other tissues, as can result from the insertion of *rigid scopes and rigid instruments in accordance with the methodology of the prior art. (Id.)*

Makower’s “working devices” include cutting or ablation devices (Fig. 5A), devices with laterally deployable projections (Figs. 5B, 5D), a drill (Fig. 5C), a catheter (Fig. 5D), various balloon catheters (Figs. 5E-5G’’’), a tissue shrinking electrode (Fig.

5H), a cryogenic device (Fig. 5I), a tissue expanding device (Fig. 5J), various forward cutting/suction catheter/endoscope devices (Figs. 5K-5O), various balloon catheter/stent/endoscope devices (Figs. 5P-5R’), a snare catheter (Fig. 5S), forceps (Fig. 5T), a guide catheter and guidewire and endoscope (Fig. 5U-5U’), a microbrider catheter (Fig. 5V), various bone remodeling devices (Figs. 5W-5X’’’’), and a substance delivering implant device (Figs. 5Y-5Y’’’’). Notably, Makower’s FIG. 5H is the *only* illustrated “working device” having electrodes for energy delivery.

In short, Makower is directed to *flexible* catheters and other instrumentation for use in ear, nose, and throat procedures. Other than the prosecution history of the ’077 patent, discussed below, Petitioners have provided no reason why a POSITA would have looked to Makower for an energy delivery device that address the underlying condition causing rhinitis—it is not the problem that Makower purported to solve.

**3. Petitioners Fail to Sufficiently Establish That a POSITA Would Have Been Motivated to Use Makower’s Obscure Device According to Fang’s Unreliable, Unproven Method**

In addition to failing to sufficiently establish a reasonable expectation of successfully achieving the claimed invention, Petitioners also failed to sufficiently establish a motivation to combine the teachings of Makower and Fang. At the outset, Patent Owner notes Petitioners’ analysis is tainted by hindsight, and it is well-

settled that the patent must not be used “as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims.” *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1012 (Fed. Cir. 1983). Yet Petitioners did exactly that here. Contrary to Petitioners’ contention, a POSITA would not have been motivated to use Makower’s FIG. 5H device according to Fang’s treatment method. (Ex-2003-Levine at ¶¶86-88.)

Patent Owner submits a POSITA without hindsight would not look to Makower at all, let alone as a primary reference. If a POSITA was truly interested in addressing perennial allergic rhinitis, as Petitioners argue (Petition at 81), a POSITA would look to references on that issue, and not to a disclosure (Makower) focused on flexible catheters and with a passing reference to a device that might shrink tissue. (Ex-2003-Levine at ¶90; Ex-1005-Makower at [0092].)

A POSITA would not have been motivated to use Makower’s FIG. 5H device to apply energy for purposes of damaging nerves. As Dr. Levine testifies, shrinking tissue (as per Makower) is for removing obstructions and has no bearing on treating nerves in the nasopharyngeal passage to reduce mucus secretion. (Ex-2003-Levine at ¶¶45-49.) For at least this reason, a POSITA would not have considered Makower. That Makower’s FIG. 5H device is also unproven and admittedly unknown by all experts in this proceeding further demonstrates the inappropriateness of its basis for obviousness. (Ex-2003-Levine at ¶89) The simple truth is if a

POSITA were interested in treating the nasal cavity to address rhinitis, as claimed, a POSITA would look to references addressing that issue and not a reference dedicated to flexible catheters with a passing reference to a medical device that might shrink tissue. Treating patients with perennial allergic rhinitis is no trivial matter, and a POSITA would not be inclined to risk the safety of a patient based on the unreliable and unproven teachings of both Makower and Fang. (Ex-2003-Levine at ¶¶63-64.)

A POSITA also would not have looked to apply the teachings of Makower to Fang because the references have diametrically opposed objectives and treatment effects. Makower identifies a significant problem in nasal treatments – bloody and painful surgical treatments as a result of rigid treatment devices. Makower purports to solve this problem with *flexible* treatment devices to “perform the desired diagnostic or therapeutic procedures with minimal trauma to other tissues.” (*Id.*) Makower’s FIG. 5H device is a “tissue shrinking device,” which does not cut or penetrate the nasal tissue. (Ex-2003-Levine at ¶¶45-48; Ex-1005-Makower at [0092].) In contrast, Fang’s treatment method always involves destructive surgical methods because Fang’s patients all received deviated septum surgery along with potentially receiving other cuts and resections of the nasal ridge and walls of the nasal cavity:

Further submucosal resection of the nasal septum was performed, and uncinat process resection, sinus opening, lateral part resection of the

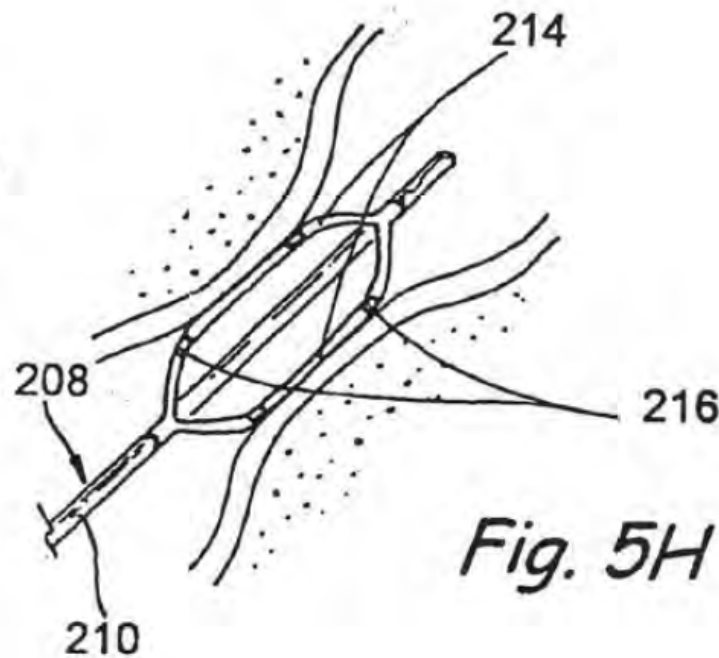
middle turbinate or nasal polypectomy were performed for those who had hypertrophy of the uncinate process, sinusitis, hypertrophy or polypoid lesion of the middle turbinate, or nasal polyps. (Ex-1006-Fang at 876, Section 1.3.)

Indeed, Fang intended that any radiofrequency treatment be conducted with a surgical procedure, contrary to the purpose of Makower. (*Id.* at 877, Section 3 (stating that surgical interventions should be carried out and referencing surgical interventions when concluding that, “[t]hrough the joint action of multiple links, the therapeutic effect of perennial allergic rhinitis is significantly improved.”).)

Thus, a POSITA having knowledge of Makower’s FIG. 5H device would not have been motivated to combine it with Fang’s unreliable, unproved treatment method, which uses surgical intervention in a manner contrary to Makower’s use and purpose. (Ex-2003-Levine at ¶¶89-98.) “The obviousness inquiry does not merely ask whether a skilled artisan could combine the references, but instead asks whether ‘they would have been motivated to do so.’ ... Fundamental differences between the references are central to this motivation to combine inquiry.” *Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1359 (Fed. Cir. 2020) (emphases added) (quoting *InTouch Techs., Inc. v. VGO Commc’ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014)) (affirming Board’s finding of no motivation to combine where there were “fundamental differences” in the references, which the “Board properly considered” in its motivation to combine analysis).

Moreover, a POSITA would not have chosen Makower's FIG. 5H device because its strut and electrode structure result in ineffective and/or undesirable energy delivery to the targeted and surrounding tissue. Even assuming *arguendo* Makower's device ablates tissue (it does not), its electrode arrangement would result in treatment of additional tissues beyond those targeted for treatment. A POSITA does not desire such a result—instead a POSITA seeks to minimize surgical intrusion, as Dr. Bu-Saba's own writing confirm. (Ex-2001 at 233 ("The amount of tissue removed during sinus surgery is minimized now..."), 241 ("By minimizing mucosal disruption, one can minimize postoperative scarring."), 248 ("When used correctly, these mechanical microdebriders can minimize trauma to the tissues and help to preserve normal tissue."), 267 ("Endoscopic approaches that are made possible with the technological advances in fiberoptics have gained widespread use. They offer a minimally invasive technique ...").)

Specifically, Makower's FIG. 5H device is depicted as having two struts with two electrodes on each strut.



As explained previously, a POSITA would understand that the electrodes are ring electrodes surrounding the corresponding struts. *See* §VII.A. Makower discloses that, in operation, the device is “advanced into a passageway” and “current is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated.”<sup>13</sup> (Ex-1005-Makower at [0187].) As shown in FIG. 5H, struts and electrodes are positioned to “cauterize or heat” tissue on *both sides* of the “passageway” in which the device is positioned. This arrangement is undesirable for Fang’s method.

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<sup>13</sup> For the reasons stated in §VII.A, Patent Owner disagrees Makower’s device would “cauterize or heat” target tissue.

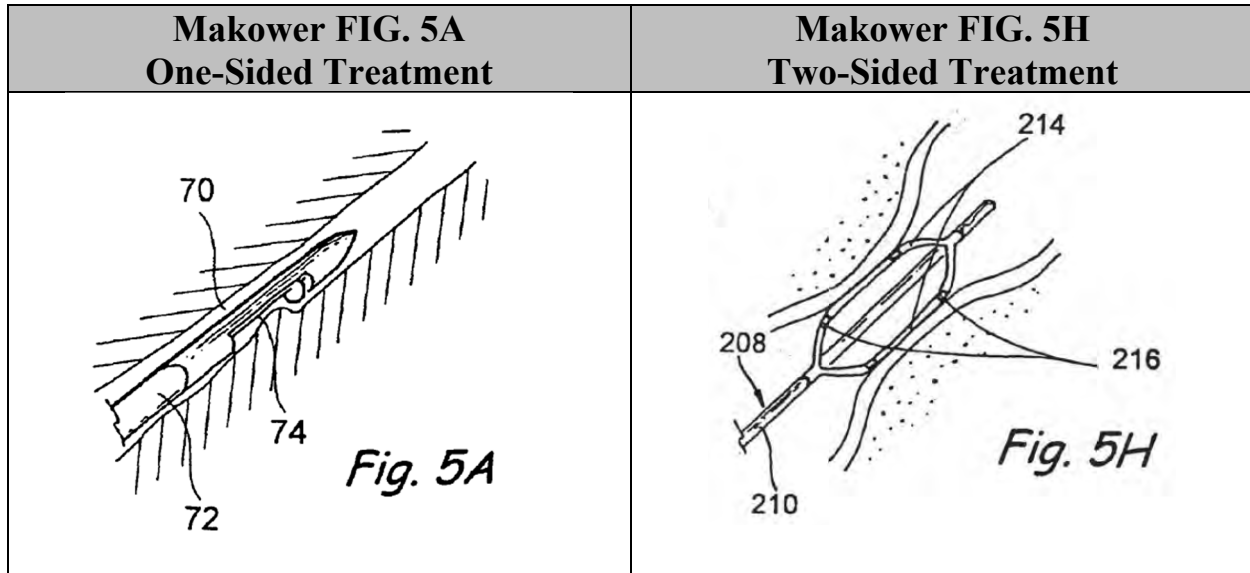
Fang's disclosed treatment locations are at least "the sphenopalatine foramen on both sides," "the anterior upper part of the nasal septum on both sides" and "the anterior upper part of the lateral wall of the nasal cavity, the nasal ridge, and the anterior part of the inferior nasal turbinate."<sup>14</sup> (Ex-1006-Fang at 876, Section 1.3.) For each of these treatment locations, targeted tissue is positioned on the lateral nasal wall—opposite the nasal septum. Using Makower's FIG. 5H treatment device in these locations, with its two, oppositely positioned struts, would result in heat application to not only the lateral nasal wall, but also the nasal septum, opposite the lateral nasal wall. Applying RF energy in this manner unnecessarily risks perforating the nasal septum—an outcome that Fang expressly seeks to prevent. (Ex-1006-Fang at 876, Section 1.3 ("the radio frequency points on both sides were staggered by 5 mm to *prevent perforation of the nasal septum*").)

Indeed, Petitioners fail to sufficiently establish why a POSITA would have chosen Makower's FIG. 5H device to implement Fang's method and unnecessarily risk perforating the nasal septum when Makower discloses devices that are better suited for treating tissue located only on the lateral wall of the nasal cavity, such as

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<sup>14</sup> It is unclear what additional areas Fang treated with RF energy. (Ex-2002-Bu-Saba-Tr. at 200:5-202:19.)

the device of FIG. 5A, which depicts a “side opening catheter” that can be positioned adjacent to the target tissue. (Ex-1005-Makower at [0166], FIG. 5A.)



In sum, Petitioners’ choice to use Makower as a primary reference highlights its hindsight rationale, and Petitioners’ choice of the FIG. 5H device further emphasizes that the proposed combination is rooted in hindsight—Petitioners did not choose Makower’s FIG. 5H device because a POSITA would understand that it was well-suited to implement Fang’s method.

Petitioners use of the prosecution history of the ’675 patent further confirms their hindsight basis and lack of analysis in their motivation to combine. Petitioners’ simply adopt the Examiner’s use of Makower for the ’675 patent without any analysis. (Petition at 79.) Petitioners failed to conduct an analysis of whether Makower is even applicable to treatment of the underlying causes of rhinitis (e.g.,

mucus secretion), as the claims require—instead, Petitioners simply relied on the Examiner’s incorrect statement. As shown herein, Makower is not directed to the treatment of nerves to address rhinitis. Instead, Makover is primarily directed to flexible catheters, with the FIG. 5H being one or more than 40 potential devices that could use a flexible catheter, and is the only device illustrated with electrodes, and even then Makower states the FIG. 5H device is for shrinking tissue. (Ex-1005-Makower at [0092].) As Dr. Levine testifies, shrinking tissue is for removing obstructions and has no bearing on treating nerves in the nasopharyngeal passage to reduce mucus secretion, which can be an underlying cause of rhinitis. (Ex-2003-Levine at ¶¶45-49.)

Also, while the Examiner deemed Makower to be the closest prior art in the prosecution of the ’675 patent,<sup>15</sup> the Examiner allowed the claims because Makower purportedly did not teach “treating nasal conditions with a device so as to disrupt neural activity such that mucus secretion is reduced in the nasopharyngeal passage [i.e., nasal cavity and nasopharynx...] and wherein the target tissue has a change in temperature.” (Petition at 79.) Armed with this information, the Petition is nothing

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<sup>15</sup> The Examiner was wrong that Makower is “the closest prior art.” A POSITA would not have considered Makower to be “close” prior art as the evidence herein shows.

more than an allegation that this very same prior art reference (Makower) can be combined with an inconclusive, once-cited study (Fang) to satisfy the missing limitation. (Ex-2008 (showing that in the last 19 years the Fang study has been cited once).) That is, Petitioners used the specific claim limitations of the patent as a blueprint for Grounds 5-6, which is the epitome of impermissible hindsight. *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004) (“This form of hindsight reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new result—often the very definition of invention”) Indeed, despite Dr. Bu-Saba’s decades of clinical experience he had never seen or used a device like Makower’s FIG. 5H device. (Ex-2002-Bu-Saba-Tr. at 303:13-18.) Neither has Dr. Levine. (Ex-2003-Levine at ¶89.) It is apparent that Petitioners chose Makower’s FIG. 5H device in view of the structural elements recited in the Challenged Claims, identified Fang as purportedly disclosing Makower’s missing claim element, and then attempted to reverse engineer a motivation to combine these two prior art references. But “obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.” *Cheese Sys., Inc. v. Tetra Park Cheese and Powder Sys., Inc.*, 725 Fed 1341, 1352 (Fed. Cir. 2013). This is quintessential hindsight that the well-settled law seeks to guard against. *In re Kahn*, 441 F.3d 977, 986-87 (Fed. Cir. 2006).

Petitioner’s “reasons” for the combination are not persuasive. Petitioner’s first argument (analogous art) says nothing about motivation. (Petition at 78-79.) In fact, it is simply a jumping off point for an obviousness analysis.

Petitioner second argument (commonality between the teachings) fails to address the fatal issues identified previously. (Petition at 78-81.) As explained previously, a POSITA would have found Fang inconclusive on whether RF energy alone effectively addresses perennial allergic rhinitis, and a POSITA would not have looked to a reference (Makower) dedicated to flexible catheter teachings to address perennial allergic rhinitis. A POSITA also would not have found cherry-picked Makower’s unproven, fatally flawed FIG. 5H device in an effort to treat perennial allergic rhinitis.

Petitioner’s third and final argument (nerve locations and effect on nasal conditions) fails to address the deficiencies noted above. (Petition at 80-81.) Further, as Dr. Levine explains, Makower’s device is for tissue shrinking to remove obstructions whereas the claims relate to the treatment of rhinitis, which may be addressed by nerve treatments. (Ex-2003-Levine at ¶¶48-49.) A POSITA would not adopt Makower’s unproved, fatally flawed device to treat nerves when it is designed to shrink tissue. (Ex-2003-Levine at ¶¶45-49.)

For at least the above reasons, Petitioners have failed to sufficiently establish that a POSITA would have been motivated to combine the teachings of Makower

ands Fang.

**C. Stern Fails to Disclose Claim 4**

Challenged Claim 4 requires that the apparatus comprise “*multiple pairs* of bipolar radiofrequency electrodes.” (Ex-1001 at claim 4.) Relying on Dr. Bu-Saba and Dr. Martin—neither of whom meet the definition of a POSITA—Petitioners contend that claim 4 is unpatentable over the combination of Makower in view of Fang, Edwards, and Stern. Specifically, Petitioners contend that Stern’s FIG. 15 teaches “multiple pairs of bipolar electrodes” and that “a POSITA would have been motivated to incorporate Stern’s bipolar electrode configuration in the Makower, Fang and Edwards-535 combination.” (Petition at 51-53, 92-94.) Petitioners are incorrect.

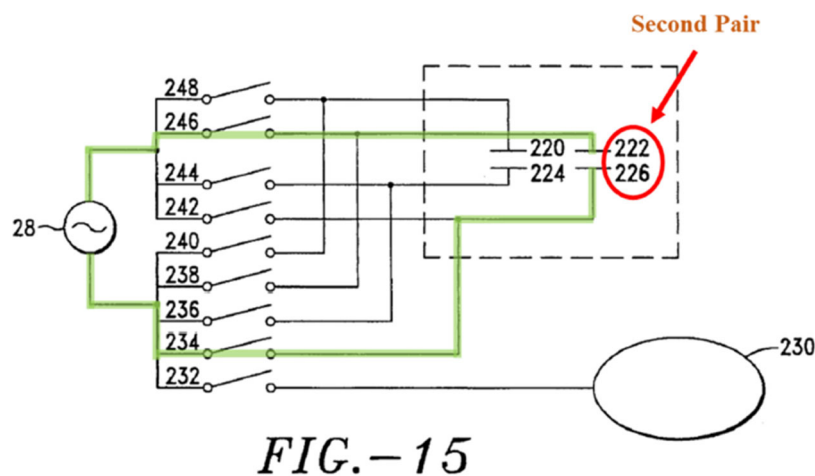
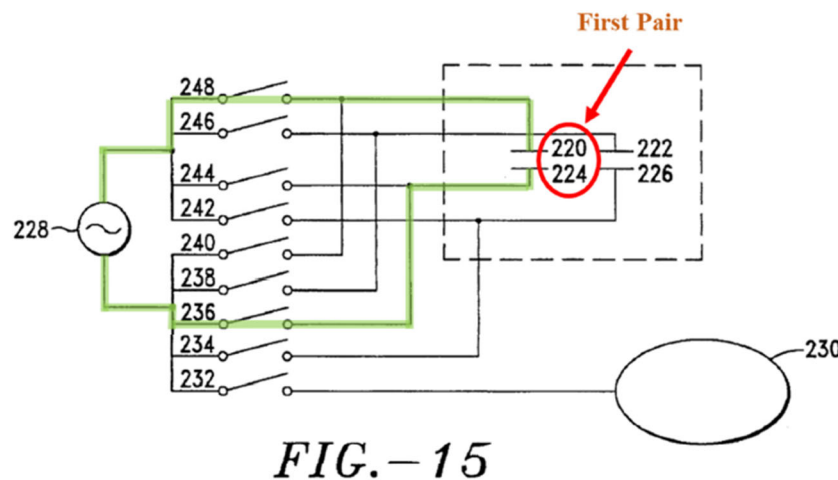
Stern’s FIG. 15 device does not disclose “multiple pairs of bipolar radiofrequency electrodes.” (Ex-2003-Levine at ¶¶115-121; Ex-2005-Bikson at ¶¶92-99.) Rather, Stern’s FIG. 15 device is configured to have a *single pair* of electrodes. Specifically, Stern discloses a voltage source 228, four electrodes 220, 222, 224, and 226, a grounding pad 230, and nine switches 232, 234, 236, 238, 240, 242, 244, 246, and 248. (Ex-1009-Stern at FIG. 15; *id.* at 12:46-13:2; Ex-2005-Bikson, ¶94; Ex-2003-Levine at ¶117.) Stern describes its electrodes as “an array of separate electrodes.” (Ex-1009-Stern at 2:26-29, 2:39-40, 2:59-60; Ex-2005-Bikson, ¶95; Ex-2003-Levine at ¶118.) Depending on which switches are closed,

any of electrodes 220, 222, 224, and 226 can be a monopolar electrode. (Ex-2009-Martin-Tr. at 261:2-16, 264:18-265:1; Ex-2005-Bikson, ¶95; Ex-2003-Levine at ¶118.) Similarly, depending on which switches are closed, any of electrodes 220, 222, 224, and 226 can be a positive electrode or a negative electrode. (Ex-2009-Martin-Tr. at 265:2-13, 265:14-19; Ex-2005-Bikson, ¶95; Ex-2003-Levine at ¶118.)

Both parties' experts agree that a "pair" of bipolar electrodes comprises two electrodes located near each other that have opposite polarities. (Ex-1007-Martin, ¶37; Ex-2009-Martin-Tr. at 254:20-22, 256:4-6, 263:19-264:16; *id.* at 253:15-21; Ex-2005-Bikson, ¶93; Ex-1001 at 22:28-30, FIGS. 8F-G; Ex-2003-Levine at ¶116.) When all the switches in Stern's Figure 15 are open, none of the electrodes in FIG. 15 have opposite polarities. (Ex-2005-Bikson, ¶96; Ex-1009-Stern at FIG. 15, 12:37-13:2; Ex-2003-Levine at ¶118.) Thus, when all the switches in Figure 15 are open there are no electrode "pairs." (*Id.*) As Petitioners' expert, Dr. Martin, conceded on cross examination, a bipolar electrode "pair" is formed in Stern's Figure 15 ***only when certain switches are closed.*** (Ex-2009-Martin-Tr. at 254:11-255:3, 265:20-266:18; Ex-1007-Martin, ¶56 ("Stern teaches examples in which electrodes can be paired by closing particular subsets of switches."); Ex-1009-Stern at 12:37-13:2; Ex-2005-Bikson, ¶96; Ex-2003-Levine at ¶118.)

Consistent with Dr. Martin's admission that a bipolar electrode "pair" is formed only when certain switches are closed, three or more of Figure 15's switches

must be closed at the same time to form *multiple pairs* of bipolar electrodes, as claimed. (Ex-2005-Bikson, ¶97; Ex-2003-Levine at ¶119.) However, Petitioners and Dr. Martin do not identify where Stern teaches closing three or more switches at the same time. (Petition at 51-53; Ex-1002-Bu-Saba at ¶¶142-143; Ex-1007-Martin, ¶¶55-56.) In Petitioners' cited disclosure from Stern only two switches are closed to form a single pair of electrodes. (*Id.*)



(Petition at 52-53.)

To be sure, Stern teaches closing *one* of switches 242, 244, 246, and 248 and *one* of switches 234, 236, 238, and 240 to form a *single pair* of bipolar electrodes. (Ex-1009-Stern at 12:55-13:2; Ex-2005-Bikson, ¶97; Ex-2003-Levine at ¶119.) Stern’s disclosure of having only a single pair of electrodes at a time is consistent with Stern’s express teaching that the RF electrodes are “*independently and sequentially energized*.” (Ex-1004-Martin, ¶65 (quoting Ex-1009-Stern at 2:31-35); Ex-2005-Bikson, ¶97; Ex-1009-Stern at 2:31-33, 2:49-53, 10:48-52, 17:54-55; Ex-2003-Levine at ¶119.) To energize Stern’s electrodes “independently and sequentially,” at most two of Stern’s switches would be closed at a time. (Ex-2005-Bikson, ¶97; Ex-2003-Levine at ¶119.) Thus, Stern itself confirms that its device is configured to have at most a single pair of bipolar electrodes. (*Id.*)

Accordingly, Petitioners have failed to show that Makower in view of Fang, Edwards, and Stern teaches an apparatus comprising “multiple pairs of bipolar electrodes,” as claimed.

Petitioners’ failure on this Ground is exemplified by the legally insufficient and unreliable testimony of Drs. Martin and Bu-Saba. For example, Dr. Martin purports to offer opinions regarding claim 4 including, that a POSITA would have been motivated to combine these Ground 6 references. (Ex-1007-Martin at ¶47.) Despite being aware that claim 4 depends from claim 2, which depends from claim 1, Dr. Martin only opined on the prior art as related to the single limitation of claim

4. (Ex-2010-Martin-Tr. at 375:13-376:5.) Indeed, he was not even asked to provide opinions regarding claims 1 or 2. (*Id.* at 376:6-16.) But a proper obviousness analysis requires consideration of the claim as a *whole*. See *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). Dr. Martin admitted did not do this, and therefore his opinions should be given little or no weight.

Dr. Martin’s unreliable testimony is further exemplified in his inability to explain his obviousness analysis. For example, in his declaration, Dr. Martin opined that a POSITA “would have been motivated to incorporate the teachings from Stern when implementing the device taught by the combination of Makower, Fang, and Edwards-355.” (Ex-1007-Martin at ¶92.) But when asked what this “device” was he simply could not answer. (Ex-2010-Martin-Tr. at 394:18-398:3.) This makes sense as Dr. Martin is not a POSITA, having no experience or knowledge about the nose or the nasopharyngeal passage. (*See, e.g.*, Ex-2009-Martin-Tr. at 70:12-71:1, 73:21-74:2, 71:14-16, 72:12-73:5, 77:11-15.)

Dr. Bu-Saba’s testimony regarding claim 4 should also be given little or no weight, as Dr. Bu-Saba does not have any experience developing or designing medical devices. (Ex-2002-Bu-Saba-Tr. at 43:20-45:11.)

In view of the foregoing, Petitioners have not established that claim 4 is unpatentable over the combination of Makower, Fang, Edwards, and Stern.

## **VIII. CONCLUSION**

In view of the foregoing, Petitioners have not established that any of the Challenged Claims are unpatentable, and the Board should issue a Final Written Decision recognizing the same.

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

Patent Owner certifies that the word count in this Patent Owner Response is 12,810 words, as counted by the word-processing program (Microsoft Word for Office 365) used to generate this Patent Owner Response, where such word count excludes the table of contents, table of authorities, mandatory notices, certificate of service, appendix of exhibits, and this certificate of word count. This Patent Owner Response complies with the 14,000 word limit set forth in 37 C.F.R. §42.24(b)(2).

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**§ 42.6(E)—CERTIFICATE OF SERVICE**

Pursuant to 37 C.F.R. §§ 42.6(e), I certify that on this 25th day of October 2024, a copy of this **PATENT OWNER RESPONSE** and Exhibits 2001-2010 were served by electronic mail on Petitioners' lead and backup counsel at the following email addresses:

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