

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.

Petitioners,

v.

AERIN MEDICAL INC.,
Patent Owner.

Case No. IPR2024-00276

U.S. Patent No. 9,415,194

**PETITION FOR *INTER PARTES* REVIEW
OF CLAIMS 1-3, 6, 12, 14, 16, 18, AND 19 OF
U.S. PATENT NO. 9,415,194
UNDER 35 U.S.C. § 312 AND 37 C.F.R. § 42.104**

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I. INTRODUCTION

U.S. Patent No. 9,415,194 (the “’194 patent”), which claims a June 14, 2011, priority date, concerns techniques for treating upper airway conditions including “post nasal drip” and “chronic cough.” Ex.1001-USP194, 1:8-17, 1:23-28, Abstract. To accomplish the intended therapeutic results, challenged claim 1 simply requires advancing part of an “energy-based treatment device” into a patient’s nostril; contacting mucosal tissue without piercing it; and delivering treatment. The challenged claims were never rejected on the basis of prior art during examination, and no reasons for allowance were provided. *See* Ex.1003-USP194FH, 524 (Notice of Allowance).

By 2011, there was nothing new or nonobvious about using an energy-based treatment device to treat post nasal drip and/or chronic cough without piercing mucosal tissue. For example, Baker previously disclosed using non-piercing, energy-based treatment devices that deliver “acoustic energy” (e.g., ultrasound) to treat these conditions in the same way, anticipating the challenged claims and/or rendering them obvious. Ex.1013-Baker, 16:19-32. Baker also contemplated using its devices to deliver “radio frequency energy,” *id.*, 5:28-33, which in combination with radio frequency (RF) treatment details found in other prior art teachings (e.g.,

those of Edwards-'535 and Chen) would have rendered each of the challenged claims obvious.

Accordingly, Petitioner respectfully requests that the Board institute this IPR and cancel claims 1-3, 6, 12, 14, 16, 18, and 19 as unpatentable.

II. MANDATORY NOTICES

A. Real Parties-in-Interest

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

B. Related Matters

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioners submit that Aerin Medical Inc. (“Aerin,” “Patent Owner,” or “PO”) has asserted five patents, including the '194 patent, in *Aerin Medical Inc. v. Neurent Medical Inc.*, Case No. 1:23-cv-00756-JLH (D. Del). Three other patents owned by The Foundry LLC (“Foundry”) are also asserted against Petitioners in that litigation. Petitioners are concurrently filing *inter partes* review petitions challenging the asserted claims of the following patents:

Challenged Patent	Patent Owner	Case No.
9,072,597	Aerin	IPR2024-00275
11,241,271	Aerin	IPR2024-00277
11,033,318	Aerin	IPR2024-00278
10,610,675	Foundry	IPR2024-00279

Challenged Patent	Patent Owner	Case No.
10,894,011	Foundry	IPR2024-00280
11,679,077	Foundry	IPR2024-00281
11,766,286	Aerin	IPR2024-00282

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III. CERTIFICATION OF GROUNDS FOR STANDING

Petitioners certify under 37 C.F.R. § 42.104(a) that the '194 patent is available for IPR and that Petitioners are not barred or estopped from requesting IPR on the grounds identified herein.

IV. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED

Petitioners request cancellation of claims 1-3, 6, 12, 14, 16, 18, and 19 (“challenged claims”) of the '194 patent.

A. Prior Art

The '194 patent was filed on March 31, 2015, and claims a priority date of June 14, 2011.¹ Ex.1001-USP194, Cover. Petitioners rely upon the documents in the Table of Exhibits, including:

1. **WO Publication No. 2010/077980** (“Baker”), Ex.1013-Baker, published on July 8, 2010, and filed on December 16, 2009, as §§102(a)(1) and 102(a)(2) prior art.²
2. **USP 6,517,535** (“Edwards-’535”), Ex.1010-Edwards-’535, published February 11, 2003, and filed November 9, 1999, as §§102(a)(1) and 102(a)(2) prior art.
3. **Chen et al.**, “Radiofrequency treatment of nasal posterior-under nerve, ethmoidal nerve and infratubinal for perennial allergic rhinitis under nasal endoscope,” 11:3 China J. Endoscopy 239 (March 2005) (English translation)

¹ Petitioners assume for purposes of this Petition that the '194 patent is entitled to the claimed priority date but reserve the right to argue in the parallel litigation that it is not.

² The '194 patent was examined under the provisions of the AIA, but the relied-upon references also qualify as prior art under the corresponding pre-AIA provisions.

(“Chen”), Ex.1017-Chen, published March 2005, as §102(a)(1) prior art. *See* Ex.1070-Munford-Decl.; Ex.1071-Chen-Decl.; Ex.1075-Chen-Appx, *Telefonaktiebolaget LM Ericsson v. TCL Corp.*, 941 F.3d 1341, 1346-67 (Fed. Cir. 2019).

B. Discretionary Denial Is Not Warranted

Discretionary denial is inappropriate under 35 U.S.C. §§ 314(a) and 325(d). *First*, no *Fintiv* factor favors denial. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 (P.T.A.B. May 13, 2020). The parallel litigation has not progressed past the pleadings, and there is no current case schedule or trial date. The Final Written Decision here would be expected well before the approximately 3 year median time to trial in the District of Delaware. *See* Ex.1006. And the Petition presents compelling merits underlying three Grounds.

Second, none of the references in the grounds presented in this Petition were previously applied to the claims during the prosecution of the ’194 patent, as neither Baker, nor Edwards-’535, nor Chen were before the examiner during prosecution. Moreover, even if it could be argued that the examiner considered the same or similar teachings to those of Baker, Edwards-’535, or Chen during prosecution of the ’194 patent, the lack of any record demonstrating that the examiner applied those teachings to the challenged claims demonstrates material error. Discretionary denial

is not warranted under such circumstances. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, 10 (P.T.A.B. Feb. 13, 2020) (“[I]f the record of the Office’s previous consideration of the art is not well-developed or **silent**, then a petitioner may show the Office erred by overlooking something persuasive.”)³; *Edwards Lifesciences Corp. v. Boston Scientific Scimed, Inc.*, IPR2017-01295, Paper 9, 27 (P.T.A.B. Oct. 25, 2017) (declining to exercise discretion to deny institution where the examiner “did not consider whether [the claims] may have been obvious, under 35 U.S.C. § 103(a), over [a reference of record] in combination with additional prior art”).

C. Grounds for Challenge

The challenged claims are unpatentable under 35 U.S.C. §§102 and 103 as follows:

Ground	35 U.S.C. §	Claims	References
I	102	1-3, 12, 14, 16, 18, 19	Baker
II	103	1-3, 12, 14, 16, 18, 19	Baker
III	103	1-3, 6, 12, 14, 16, 18, 19	Baker, Edwards-’535, Chen

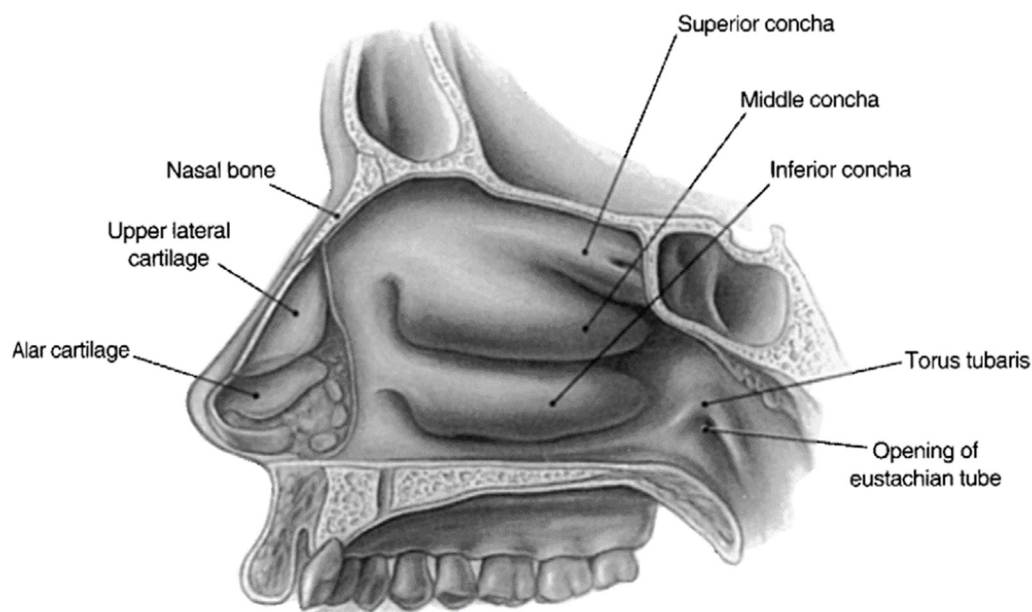
³ All emphasis added unless otherwise noted.

This Petition, supported by the declaration of Dr. DelGaudio (Ex.1002-Decl.), demonstrates that each challenged claim is unpatentable.

V. TECHNOLOGY BACKGROUND

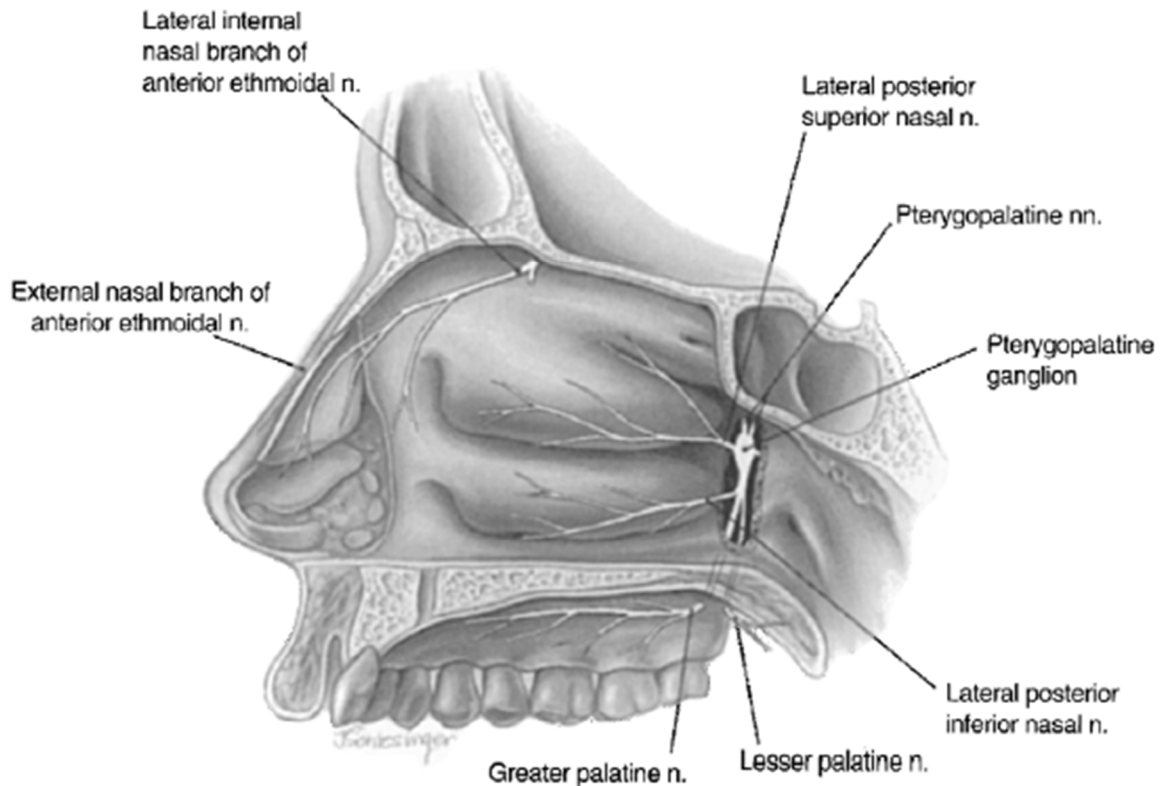
A. Anatomy of the Nose

Certain anatomical features of the nose and upper airways are generally depicted below. The nose has right and left nostrils that lead into separate right and left nasal cavities. Ex.1021-Makower, [0131]. The nasal cavity includes three nasal turbinates, inferior, middle, and superior, lined with mucosal tissue, which increase the interior surface area of the nose and help transfer moisture to inhaled air. *Id.*, [0004]. Posterior to the turbinates, the nasal passages open into the nasopharynx. *Id.*, [0002].



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

A network of nerves branches out through the various anatomical structures of the nose. For example, as illustrated below, the inferior turbinate is innervated by the lateral posterior inferior nasal nerve.



Ex.1060-Lane, FIG.4. Ex.1002-Decl., ¶¶31-32.

B. Post Nasal Drip and Chronic Cough

By the 2010s, many conditions of the nose and upper airways and their symptoms were well understood in the art. The '194 patent claims recite two such conditions, post nasal drip and chronic cough:

- **Post nasal drip** is the presence of excess mucus secretion from the nose in the back of the throat, causing discomfort and frequent throat-clearing. Ex.1037-Chung, 5, 86, 286.
- **Chronic cough** is a persistent cough that lasts longer than a predetermined amount of time, such as 8 weeks. *Id.*, 11, 285.

Ex.1002-Decl., ¶¶34-36.

Like many upper airway conditions, post nasal drip and chronic cough are interrelated and arise from shared underlying causes. For example, one of the shared underlying causes is rhinitis, a condition characterized by inflammation of mucosal tissue. Ex.1037-Chung, 110-111. Rhinitis is a common cause of post nasal drip, which in turn has been cited as “the most common cause of chronic cough in adults.” *Id.*, 247 (“Multiple studies have demonstrated PNDS [post nasal drip syndrome] to be the most common cause of chronic cough in adults. PNDS may be the result of various processes, including seasonal and perennial allergic rhinitis, perennial non-allergic rhinitis, vasomotor rhinitis, postinfectious (postviral) rhinitis and chronic bacterial sinusitis.”); *see also id.* 5, 28, 61, 107, 285. Ex.1002-Decl., ¶¶34-36.

The symptoms of rhinitis, in turn, were known to be triggered by sensory nerve stimulation or parasympathetic nerve stimulation in the nose. Ex.1049-Konno, 108, 111; Ex.1048-Nomura, 493. Ex.1002-Decl., ¶33.

C. Treating Post Nasal Drip and Chronic Cough

A known strategy for treating chronic cough was to treat its underlying causes, which, as explained above, include allergic rhinitis and post nasal drip.

Table 27.5 Treatments for cough.

1 Treating the specific underlying cause(s)

Asthma, cough-variant asthma	Bronchodilators and inhaled corticosteroids
Eosinophilic bronchitis	Inhaled corticosteroids; leukotriene inhibitors
Allergic rhinitis and postnasal drip	Topical nasal steroids and antihistamines Topical nasal anticholinergics (with antibiotics, if indicated)
Gastro-oesophageal reflux	Conservative measures Histamine H ₂ -antagonist or proton pump inhibitor
Angiotensin-converting enzyme inhibitor	Discontinue and replace with alternative drug such as angiotensin II receptor antagonist
Chronic bronchitis/chronic obstructive pulmonary disease (COPD)	Smoking cessation Treat for COPD
Bronchiectasis	Postural drainage. Treat infective exacerbation and airflow obstruction
Infective tracheobronchitis	Appropriate antibiotic therapy Treat any postnasal drip

Ex.1037-Chung, 292.⁴ Ex.1002-Decl., ¶38.

Other known techniques for treating rhinitis and its symptoms included delivering treatment to nerves within the nose, including a “posterior nasal neurectomy” (i.e., cutting/removal of posterior nasal nerves), as such treatments were known to provide “superb clinical effectiveness.” Ex.1049-Konno, 110, Abstract; *see also* Ex.1056-Liang, Abstract (targeting the ethmoidal nerve to treat allergic rhinitis); Ex.1017-Chen, Abstract. Ex.1002-Decl., ¶37.

⁴ All annotations added unless otherwise noted.

D. Energy Based Therapy

By 2011, many techniques for treating upper airway conditions had been developed. Certain well-known techniques used energy (e.g., electrical, electromagnetic, or acoustic energy) to treat tissues within the nasal cavity. *E.g.*, Ex.1038-Thapliyal, 7:56-8:15 (electrical energy); Ex.1019-Gertner, [0013] (light energy), Ex.1039-Banhiran, 950 (radiofrequency energy); Ex.1013-Baker, 7:18-21 (acoustic energy). These energy based therapies achieve clinical results by ablating, removing, disrupting, or otherwise treating the nasal tissues. Ex.1013-Baker, 8:17-24 (energy-based therapies for “**treatment, disruption, ablation and/or removal** of undesired tissue or obstructions, and the like, are known in the art.”). Ex.1002-Decl., ¶¶39-41.

VI. THE '194 PATENT

A. Alleged Invention

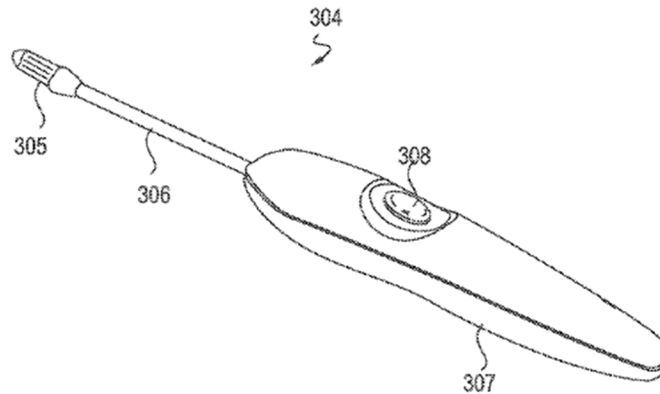
The '194 patent is directed to techniques that purportedly “alleviate the discomfort of post nasal drip” and/or “chronic cough.” Ex.1001-USP194, 1:23-28, Abstract. Ex.1002-Decl., ¶42.

The '194 patent concedes that post nasal drip and chronic cough were well understood by the patent’s filing date. Ex.1001-USP194, 1:32-45. For example, the '194 patent acknowledges that post nasal drip and chronic cough were known to

be caused by upper airway conditions, such as allergic rhinitis, and summarizes known methods that treat these conditions by targeting their underlying causes. *Id.*, 2:4-7, 2:20-22 (describing known techniques “for controlling the symptoms of moderate-to-severe allergic rhinitis”). Ex.1002-Decl., ¶43.

However, the ’194 patent alleges that prior art treatments failed to provide “a long lasting, single-treatment or low frequency treatment for PNDS caused by allergies, anatomical causes or other causes.” Ex.1001-USP194, 2:40-42. To address this purported need, the ’194 patent claims the use of an “energy-based therapy device” to deliver treatment to nasal tissue. *Id.*, Clm.1. According to the specification, the energy-based therapy device can deliver energy in any number of different forms, *id.*, 9:55-63, and “may have any of a number of different effects on the treated tissue,” *id.*, 2:48-55. Apart from applying energy based therapy to nasal tissue, the ’194 patent does not disclose any specific parameters regarding how post nasal drip or chronic cough can be treated (e.g., any necessary tissue temperature, therapy time, or specific target tissue). Ex.1002-Decl., ¶44.

Figure 18, reproduced below, depicts one embodiment of an energy-based therapy device, although the challenged claims do not limit the structure or design to this (or any other) embodiment.



Ex.1001-USP194, FIG.18. Ex.1002-Decl., ¶45.

The '194 patent also contends that it would be desirable to have a treatment that alleviates symptoms of post nasal drip “without producing severe and/or chronic side effects.” Ex.1001-USP194, 2:42-44. To address this purported need, the challenged claims recite that the claimed method is performed “without piercing the mucosal tissue” (claim 1), “without forming an incision in the mucosal tissue and without delivering an implant” (claim 2), and/or “without changing a shape of the mucosal tissue” (claim 16). *Id.*, Claims 1, 2, 16. Ex.1002-Decl., ¶46.

B. Prosecution History

The '194 patent was subject to an abbreviated examination in which the challenged claims received no substantive rejections based on prior art. The only rejection was based on double patenting over the issued claims of the grandparent patent, Ex.1003-US194FH, 433-34 (Non-Final Office Action), which PO overcame

by filing a terminal disclaimer, *id.*, 456-57.⁵ The subsequent notice of allowance did not identify examiner’s reasons for allowance. *Id.*, 524. Ex.1002-Decl., ¶¶47-49.

During prosecution of the grandparent patent application, the examiner rejected claims similar to the challenged claims of the ’194 patent as being anticipated by USPA 2007/0219600 (“Gertner”). Ex.1018-US594FH, 246-47 (Non-Final Office Action); *see also* Ex.1003-US194FH, 433-34 (double patenting rejection identifying challenged claims as being “obvious variations” of the grandparent patent’s claims). In response, PO amended those claims to require “*applying [a] treatment surface to the nasal tissue with sufficient force to alter a shape of the nasal tissue*” and argued that Gertner failed to teach “chang[ing] the shape of nasal tissue.” Ex.1018-US594FH, 262, 267-68. PO did not otherwise contest the examiner’s reliance on Gertner. *Id.*, 266-70. The examiner subsequently allowed the grandparent’s claims without stating the reasons for allowance. Ex.1018-US594FH, 273-77. Ex.1002-Decl., ¶50.

⁵ The office action also identified USP 6,416,491 as being “pertinent” to the claims but did not explain why the reference was believed to be “pertinent” and did not rely on the reference as the basis for any rejection. Ex.1003-US194FH, 434.

The challenged claims of the '194 patent, however, do not recite any limitations corresponding to “*applying [a] treatment surface to the nasal tissue with sufficient force to alter a shape of the nasal tissue.*” Without addressing the key limitation PO argued was missing in Gertner in order to obtain allowance of the grandparent application, the sparse record of the '194 patent's examination provides no insight into why the challenged claims were found allowable. Ex.1003-US194FH, 524. Moreover, as demonstrated in the grounds below, multiple references that were not addressed during prosecution—including Baker, alone or in combination with Edwards-'535 and Chen—render the challenged claims unpatentable. Ex.1002-Decl., ¶¶51-52.

VII. PERSON OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art (“POSITA”) at relevant times (2005-2015) would have had (1) a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline and (2) at least three years of experience in the clinical use, design, development, and/or testing of medical devices, including medical devices that deliver energy to tissue. A higher level of education may compensate for less work experience, and vice versa. Ex.1002-Decl., ¶29.

VIII. CLAIM CONSTRUCTION

For the purposes of this IPR, the Board need not construe any terms because the challenged claims are invalid under any reasonable interpretation. Ex.1002-Decl., ¶62.⁶

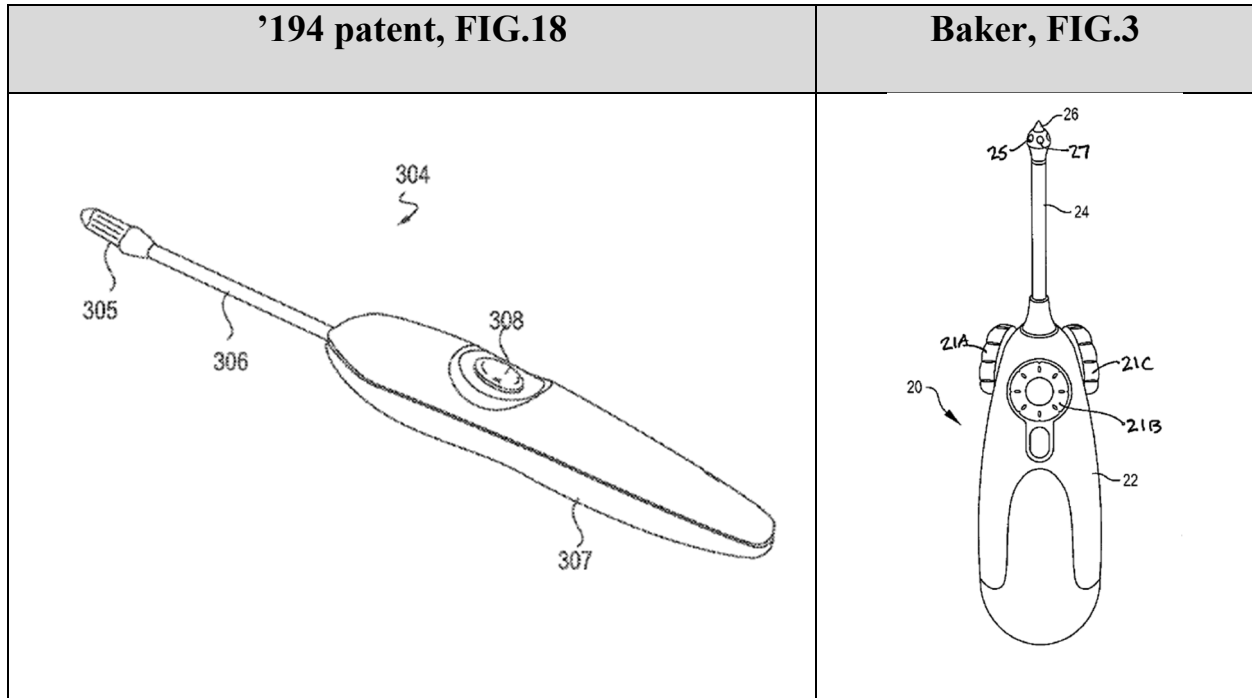
IX. OVERVIEW OF THE ASSERTED PRIOR ART

A. Baker

Like the '194 patent, Baker is directed to techniques for treating rhinitis and its symptoms, including post nasal drip. Ex.1013-Baker, 26:7-11, 1:25-29. Ex.1002-Decl., ¶53.

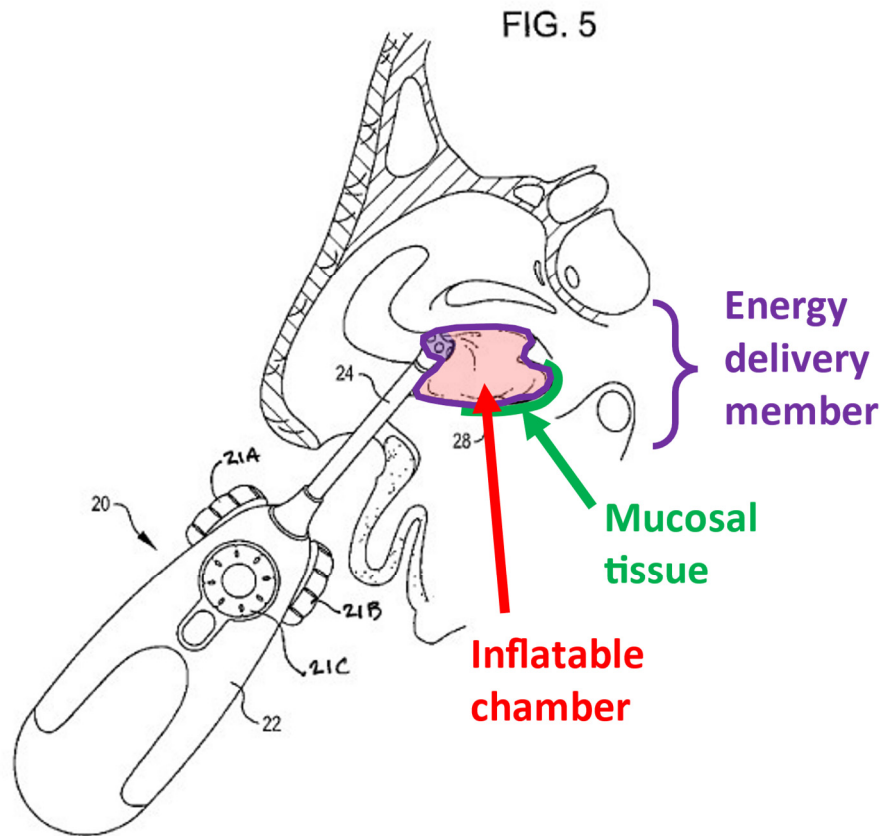
Baker discloses treatment techniques that include energy-based therapy. For example, Baker discloses inserting a device into a patient's nostril to "deliver...acoustic energy...directly to tissue surfaces...in nasal passages." Ex.1013-Baker, 7:18-21. Figure 3 of Baker, reproduced below side-by-side with Figure 18 of the '194 patent, depicts an embodiment of the acoustic energy delivery device.

⁶ Petitioners reserve the right to propose constructions for claim terms in the parallel litigation and respond to any claim construction arguments advanced by PO in this proceeding and the parallel litigation.



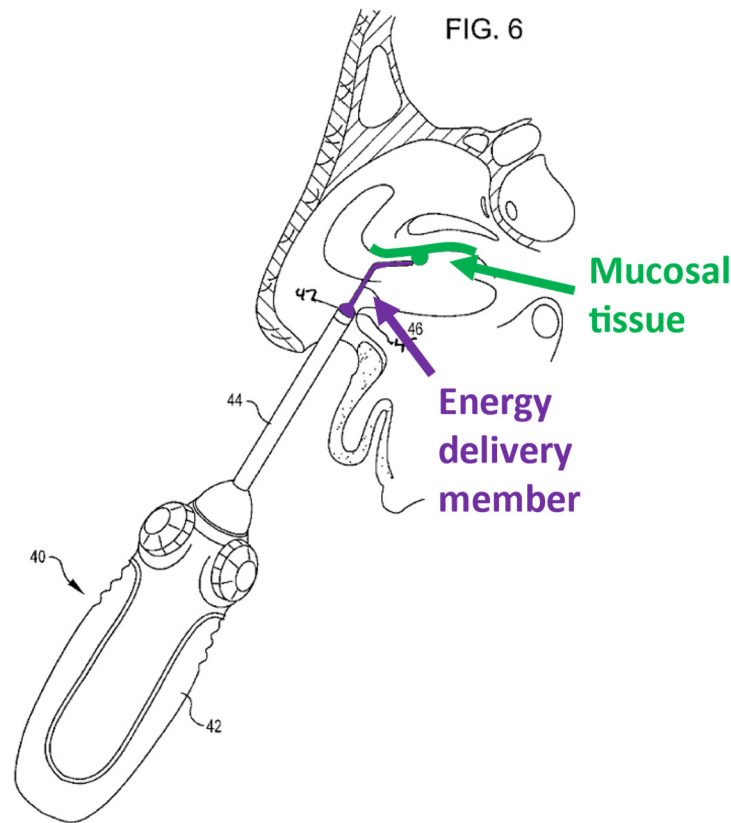
See also Ex.1013-Baker, FIGs. 4-7. Ex.1002-Decl., ¶54.

As detailed in the Grounds, Baker discloses multiple embodiments of acoustic energy delivery devices that independently satisfy the challenged claims. For example, Figure 5 of Baker (reproduced below) depicts a device 20, which includes an energy delivery member with an inflatable chamber 28 that conforms to tissue lining the nasal passages.



Ex.1013-Baker, FIG.5; *see also id.*, 17:22-32. Ex.1002-Decl., ¶55.

Additionally, Figure 6 of Baker (reproduced below) depicts a device 40, which includes an energy delivery member 46 that extends from the end of insertion member 44 to contact target tissue.

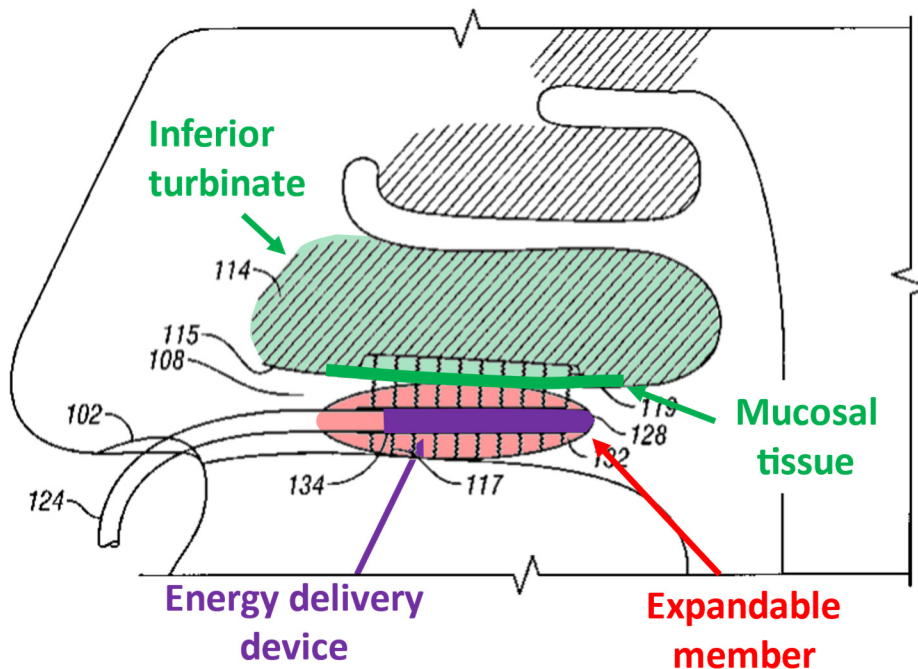


Ex.1013-Baker, FIG.6; *see also id.*, 22:10-25. Ex.1002-Decl., ¶56.

B. Edwards-'535

Edwards-'535 is also directed to techniques for treating upper airway conditions and, like Baker and the '194 patent, discloses devices and methods that deliver energy based therapies. Ex.1010-Edwards-'535, 1:22-26, 6:66-7:17. Referring to Figure 3B, reproduced below, Edwards-'535 discloses an apparatus 134 that includes an RF energy delivery device and an expandable member at its distal end. *Id.*, 5:18-35. For example, Edwards-'535 teaches arrangements of apparatus 134 in which the RF energy delivery device is positioned “on the surface 147 of the

expandable member.” *Id.*, 8:8-33. The RF energy delivery device is “introduced through a nostril” and delivers “RF energy which ablates [nasal tissue such as that of the inferior turbinate] by heat and cell destruction.” Ex.1010-Edwards-’535, 5:18-45, 8:18-25, 8:51-53.



Ex.1010-Edwards-’535, FIG.3B. Ex.1002-Decl., ¶57.

C. Chen

Chen discloses results of a clinical study showing that applying RF energy to the upper airways is a promising technique for treating allergic rhinitis. Ex.1017-Chen, Abstract, 243 (in the study, “a new method for perennial allergic rhinitis” by treating patients with “radiofrequency [energy] under nasal endoscope,” was found

to be “highly effective” and “easy to perform” while mitigating the risk of complications). Chen explains that such techniques can advantageously “reduce the sensitivity of the nasal mucosa to external stimuli,...reduce the gland secretion, and...alleviate or eliminate symptoms such as nasal itching, sneezing, nasal congestion, and runny nose in patients, achieving the objective of treating [allergic rhinitis].” Ex.1017-Chen, 240, 243. Ex.1002-Decl., ¶58.

X. SPECIFIC GROUNDS FOR UNPATENTABILITY

A. Ground I: Baker Anticipates Claims 1-3, 12, 14, 16, and 18

As set forth below, Baker discloses multiple embodiments that independently anticipate claims 1-3, 12, 14, 16, and 18, including: (1) a method for using a device 20, which has an expandable balloon at its distal end; and (2) a method for using a similar device 40, which has a flexible, steerable structure at its distal end. Ex.1002-Decl., ¶64.

1. Claim 1

- a. Element 1[pre]: A method for reducing mucus secretion in an upper airway of a patient to treat at**

least one of post nasal drip or chronic cough, the method comprising:

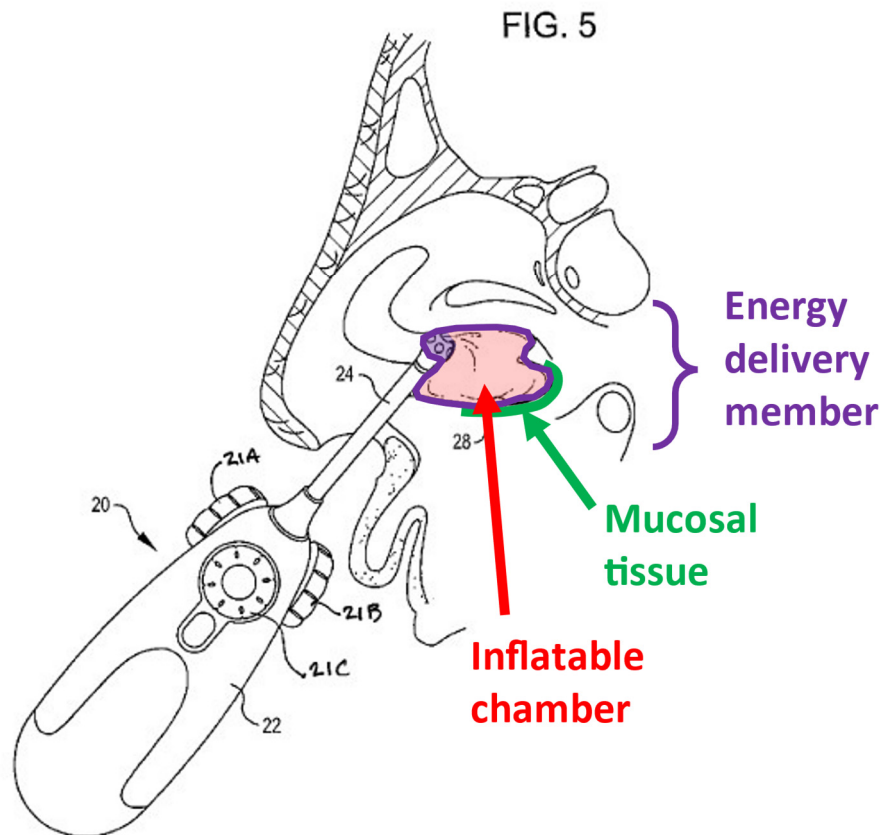
If the preamble is limiting, Baker discloses a *method for reducing mucus secretion in an upper airway* (e.g., nasal passages) *of a patient to treat at least one of post nasal drip or chronic cough.*⁷ Ex.1002-Decl., ¶65.

i. Device 20

First, as explained in further detail below (*see* limitations 1[a]-1[c]), Baker discloses a *method* of using a device 20 to treat various upper airway conditions, including “common colds, nasal congestion and allergic rhinitis, as well as sinusitis and other nasal conditions.” Ex.1013-Baker, 26:7-11. A POSITA would have understood that these conditions are each associated with excessive mucous secretion, such that by treating these conditions, Baker’s method *reduces mucus secretion*. *See id.*, 1:25-32, 5:5-12 (Baker’s methods aim to achieve “[e]ffective and long-lasting **reduction of mucus**...within the nasal passages, sinuses and their drainage systems.”). Ex.1002-Decl., ¶¶66-67.

⁷ Apart from citations, italicized text corresponds to claim language unless otherwise noted.

Second, Baker’s method is applied to “tissue sites such as **nasal passages**,” Ex.1013-Baker, 16:19-22, which are locations in the *upper airway of a patient*. For example, Figure 5, reproduced below, depicts device 20 being inserted through a patient’s nostril to treat the *upper airway of a patient*.



Id., FIG.5; *see also id.*, FIG.4. Ex.1002-Decl., ¶67.

Third, to the extent the intended result of the claimed method is limiting,⁸ Baker also teaches that its techniques are used to *treat at least one of post nasal drip or chronic cough*. For example, Baker discloses embodiments in which the method

⁸ Limitations 1[pre] and 1[c] each recite that the intended result of the claimed method is “to treat” post nasal drip or chronic cough. The Board and Federal Circuit have routinely found such claim language, whether in the preamble or body of the claim, to have no patentable weight. *See, e.g., Bristol Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1375-76 (Fed. Cir. 2001) (construing the preamble expression “[a] method for treating a cancer patient **to effect regression of a taxol-sensitive tumor...**” as a mere “statement of purpose and intended result [because it] **does not result in a manipulative difference** in the steps of the claim”); *Minton v. Nat’l Ass’n. of Sec. Dealers*, 336 F.3d 1373, 1381 (Fed. Cir. 2003); *Baxter Healthcare Corp. v. Millenium Biologix, LLC*, IPR2013-00590, Paper 49 (Final Written Decision), 10 (P.T.A.B. March 18, 2015) (giving preamble “wherein” clauses “**no patentable weight beyond** requiring that the recited biomaterial compound be **capable of producing the recited intended results** when implanted”); *FedEx Corp. v. Intellectual Ventures II LLC*, IPR2017-00729, Paper 41, 40 (P.T.A.B. July 20, 2018).

is used for “*treating...allergic rhinitis*,” symptoms of which include “*post-nasal drip*.” Ex.1013-Baker, 26:7-11; 1:25-29. Accordingly, a POSITA would have understood that by treating allergic rhinitis, Baker’s method also treats the symptoms of allergic rhinitis including *post nasal drip*. Ex.1002-Decl., ¶68.

Moreover, by the 2010s it was textbook knowledge that *chronic cough* is caused by *post nasal drip*, Ex.1037-Chung, 247, and that by treating *post nasal drip*, one also treats *chronic cough*, *id.*, 292. Therefore, because Baker’s method treats allergic rhinitis and *post nasal drip*, as explained above, a POSITA would have understood that Baker’s method also treats *chronic cough*. Ex.1002-Decl., ¶69.

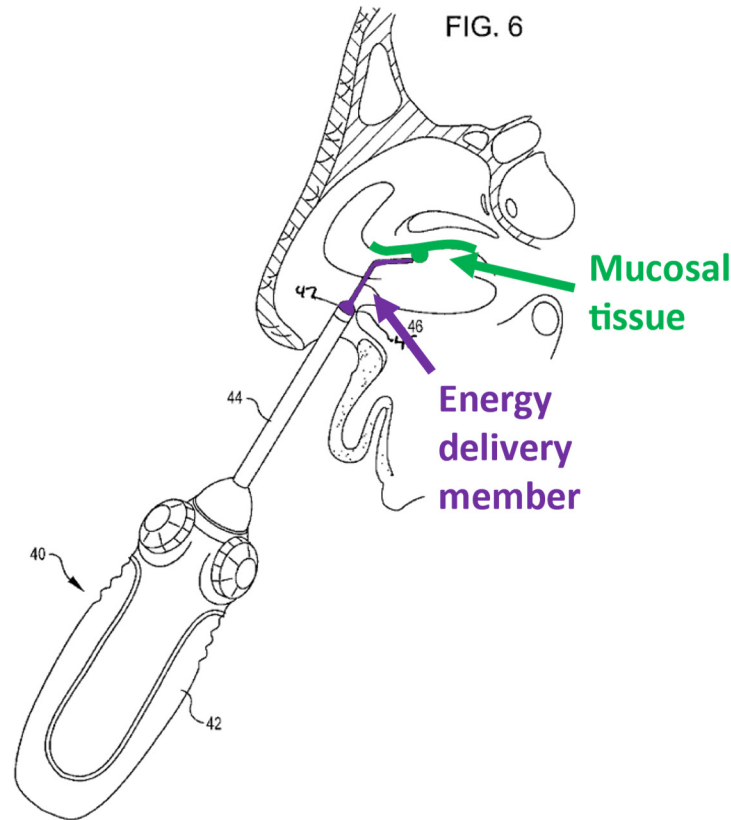
ii. Device 40

Additionally or alternatively, Baker’s teachings in connection with device 40 satisfy the preamble. Ex.1002-Decl., ¶70.

First, Baker also discloses a method of using a device 40, which treats the same upper airway conditions as Baker’s method of using device 20, discussed above, and thereby *reduces mucus secretion* for the same reasons. Ex.1013-Baker, 26:7-11. Ex.1002-Decl., ¶¶71-72.

Second, like device 20, Baker discloses that device 40 is used to deliver treatment to “nasal passages,” Ex.1013-Baker, 21:21-22, which are locations in the

upper airway of a patient. For example, Figure 6, reproduced below, depicts device 40 being inserted through a patient's nostril to treat the *upper airway of a patient.*



Id., FIG.6; *see also id.*, FIGs. 7-8D. Ex.1002-Decl., ¶72.

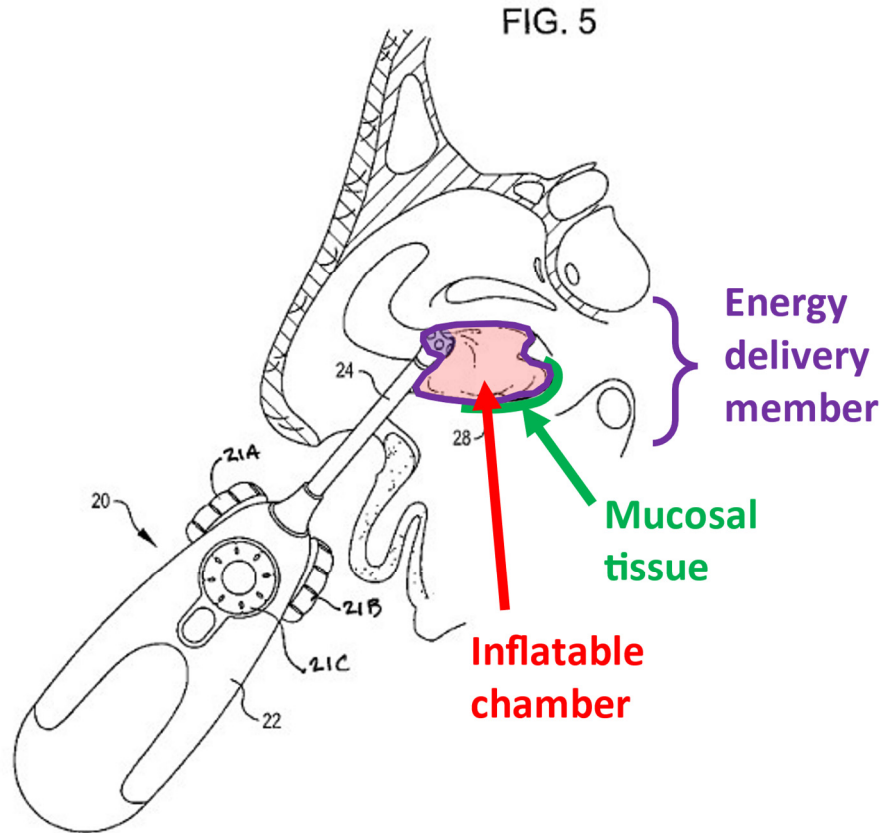
Third, because device 40 is used to treat the same upper airway conditions as device 20, it is also used to *treat at least one of post nasal drip or chronic cough* for the same reasons as provided above for device 20. Ex.1002-Decl., ¶73.

- b. Element 1[a]: advancing a treatment delivery portion of an energy-based treatment device into a nostril of the patient;**

Baker discloses *advancing a treatment delivery portion* (e.g., **energy delivery member**) *of an energy-based treatment device* (e.g., device 20/40) *into a nostril of the patient*. Ex.1002-Decl., ¶74.

i. Device 20

Referring to Figure 5 below, Baker’s method of using device 20 includes “insert[ing]” (i.e., *advancing*) an insertion wand 24 “through a nostril opening” (i.e., *nostril of a patient*). Ex.1013-Baker, 16:19-26. An **energy delivery member** including an **inflatable chamber 28** is located at the distal tip of insertion wand 24 and is likewise *advanced into the nostril of the patient*. *Id.*, 17:22-32, 20:35-39 (“[T]he **insertion wand and energy delivery member are positioned in a nasal cavity**, with the **energy delivery member** contacting...**tissue** desired to be treated.”).



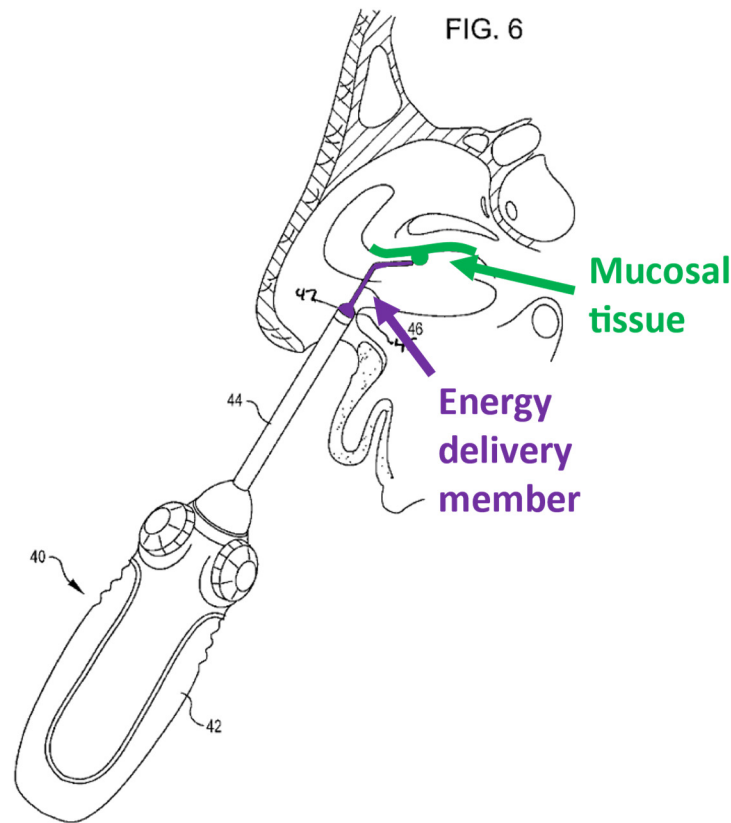
Id., FIG.5. Ex.1002-Decl., ¶75.

A POSITA would have understood the energy delivery member to be a *treatment delivery portion* of device 20, as it delivers acoustic energy (e.g., ultrasound) to treat tissue surfaces in contact with the chamber wall. Ex.1013-Baker, 17:22-32. In turn, device 20 would have been understood as an *energy based treatment device* given that its purpose is to deliver energy to treat upper airway tissue. Ex.1002-Decl., ¶76.

Baker describes another embodiment of device 20, depicted in Figure 4, which does not include **chamber 28**, but which is otherwise used in the same manner – e.g., by advancing an **energy delivery member 26** into a patient’s nostril to deliver energy-based treatment – and therefore satisfies limitation 1[a] for the same reasons provided above. Ex.1013-Baker, 17:11-21 (“**Energy delivery member 26** may be provided at the tip of the insertion wand and configured for...contacting blockages **within nasal passages, mucous membranes and nasal turbinates...for delivery of high frequency acoustic energy.**”), FIG. 4. Ex.1002-Decl., ¶77.

ii. Device 40

Additionally or alternatively, Baker’s teachings in connection with device 40 satisfy limitation 1[a]. Referring to Figure 6 below, Baker’s method of using device 40 includes a step of “insert[ing]” (i.e., *advancing*) an insertion member 44 “through a nostril opening” (i.e., *nostril of a patient*). Ex.1013-Baker, 21:21-25. An **energy delivery member 46**, which extends from the end of insertion member 44, is likewise *advanced into the nostril of the patient*. Ex.1013-Baker, 22:10-25.



Id., FIG.6; *see also id.*, FIGs.8A-8D. Ex.1002-Decl., ¶78.

Like the energy delivery member of device 20, **energy delivery member 46** is a *treatment delivery portion* of device 40, as it delivers acoustic energy (e.g., ultrasound) to treat **tissue surfaces** in contact with **energy delivery member 46**. Ex.1013-Baker, 22:16-21 (“**[E]nergy delivery member 46** comprises a generally rigid or semi-rigid wire-like structure capable of conveying, and **delivering, high frequency acoustic energy...by contact with tissue** or obstructive material along its length and/or at a distal end of the **delivery member.**”). In turn, device 40 would

have been understood as an *energy based treatment device* given that its purpose is to deliver energy to treat upper airway tissue. Ex.1002-Decl., ¶79.

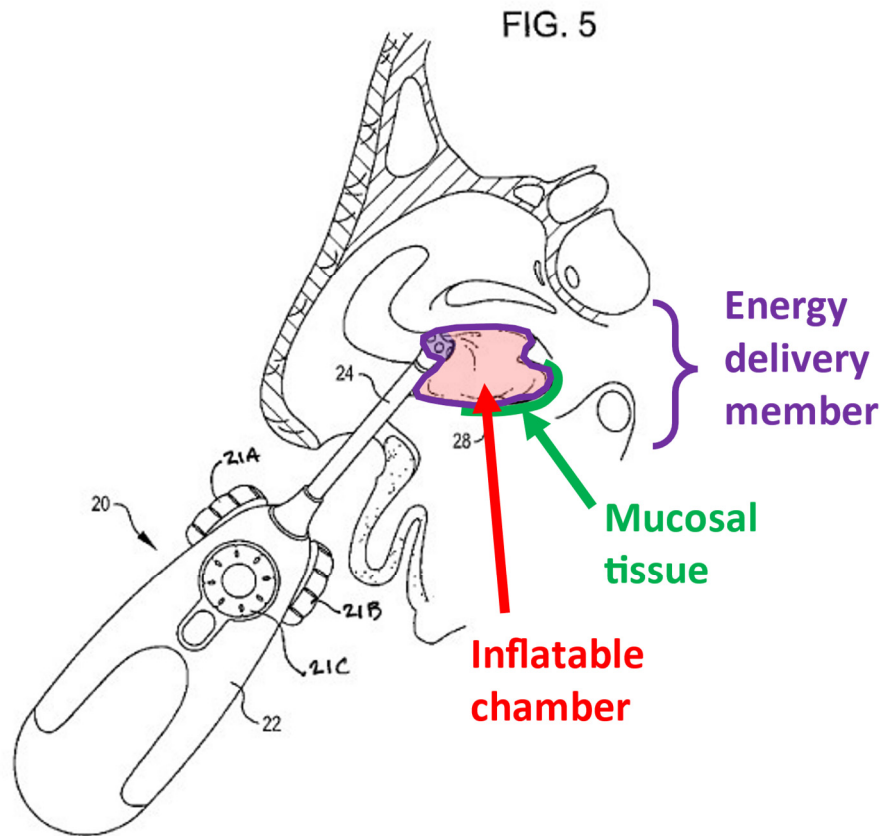
Baker describes another embodiment of device 40, depicted in Figure 7, in which **energy delivery member 46** includes an additional flexible steering structure 48, but which is otherwise used in the same manner—e.g., by advancing **energy delivery member 46** into a patient’s nostril to deliver energy-based treatment—and therefore satisfies limitation 1[a] for the same reasons provided above. Ex.1013-Baker, 22:21-29, FIG.7. Ex.1002-Decl., ¶80.

c. Element 1[b]: contacting mucosal tissue of the upper airway with the treatment delivery portion, without piercing the mucosal tissue; and

Baker discloses *contacting mucosal tissue of the upper airway with the treatment delivery portion* (e.g., **energy delivery member**), *without piercing the mucosal tissue*. Ex.1002-Decl., ¶81.

i. Device 20

First, referring to Figure 5 below, Baker’s method of using device 20 includes “*contact[ing] a tissue site*” with the **energy delivery member** (i.e., *treatment delivery portion*; see limitation 1[a]), including **expandable chamber 28**. Ex.1013-Baker, 17:22-32; 20:35-39.



Id., FIG.5. Ex.1002-Decl., ¶82.

As explained for limitation 1[pre], Baker’s method applies treatment to “tissue sites such as **nasal passages**,” Ex.1013-Baker, 16:19-22. It was well-understood that nasal passages are lined with mucosal tissue. Ex.1021-Makower, [0004] (“The nasal turbinates [(i.e., part of the nasal passages)]...extend inwardly from the lateral walls of the nose and are covered with mucosal tissues”); Ex.1060-Lane, 392. Accordingly, a POSITA would have understood that the tissue contacted by the **energy delivery member**, as described above, includes the tissue lining the nasal

passages, i.e., *mucosal tissue of the upper airway*. Ex.1013-Baker, 20:35-39.
Ex.1002-Decl., ¶83.

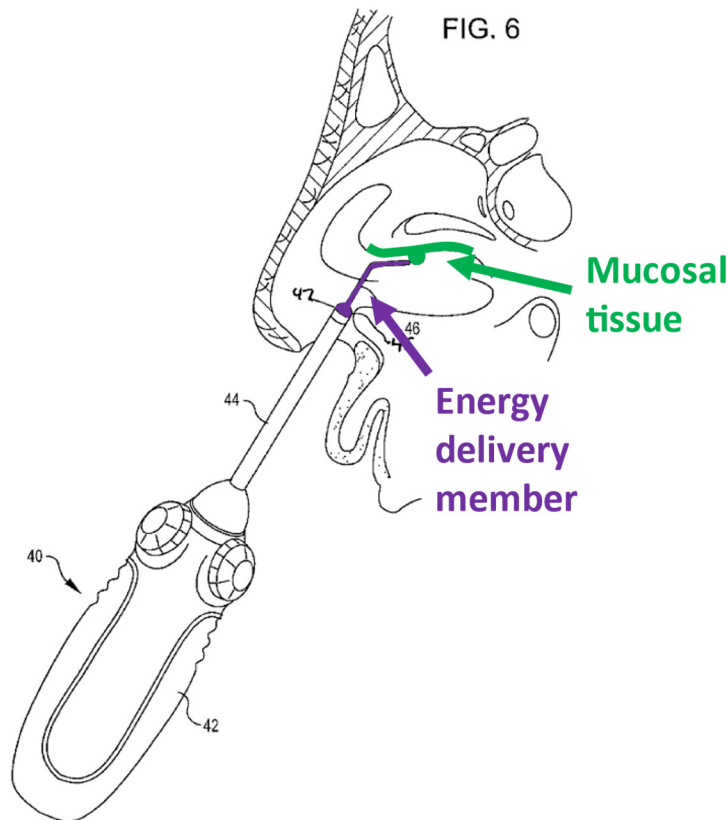
Second, Baker discloses that the **energy delivery member** (i.e., *treatment delivery portion*) contacts the mucosal tissue *without piercing the mucosal tissue*. For example, Baker discloses that treatment is “applied to the tissue **surfaces**,” i.e., portions of the tissue that are accessible without piercing the tissue. Ex.1013-Baker, 17:22-32. In fact, Baker discloses that **inflatable chamber 28** is “flexible” and “deformable” such that it does not pierce tissue but rather “**conform[s] to contours of...intranasal passages**.” Ex.1013-Baker, 17:22-36. Consistent with these descriptions, Figure 5 (reproduced above) depicts the **energy delivery member** and **chamber 28** contacting mucosal tissue without piercing the mucosal tissue. Ex.1002-Decl., ¶84.

Baker describes another embodiment of device 20, depicted in Figure 4, which does not include **chamber 28**, but which is otherwise used in the same manner by—e.g., placing the “**energy delivery member in contact with...tissues**” without piercing the tissue—and therefore satisfies limitation 1[b] for the same reasons provided above. Ex.1013-Baker, 17:11-21; *see also id.* 18:10-15, FIG.4. Ex.1002-Decl., ¶85.

ii. Device 40

Additionally or alternatively, Baker's teachings in connection with device 40 satisfy limitation 1[b]. Ex.1002-Decl., ¶86.

First, referring to Figure 6 below, Baker's method of using device 40 includes “*contacting a tissue surface such as mucous membranes...within cavities such as nasal passages [(i.e., mucosal tissue of the upper airways)]*” with **energy delivery member 46** (i.e., *treatment delivery portion*; see limitation 1[a]). Ex.1013-Baker, 22:12-16.



Id., FIG.6; *see also id.*, FIGs.8A-8D. Ex.1002-Decl., ¶86.

Second, Baker discloses that **energy delivery member 46** (i.e., *treatment delivery portion*) contacts the mucosal tissue *without piercing the mucosal tissue*. For example, Baker discloses that **energy delivery member 46** “contact[s] a tissue **surface**,” i.e., the portion of the tissue that are accessible without piercing the tissue. Ex.1013-Baker, 22:12-16. Consistent with this description, Figure 6 (reproduced above) depicts **energy delivery member 46** contacting mucosal tissue without piercing the mucosal tissue. *Id.*, FIG.6; *see also id.*, FIGs.8A-8D. Ex.1002-Decl., ¶87.

Baker describes another embodiment of device 40, depicted in Figure 7, in which **energy delivery member 46** includes an additional flexible steering structure 48, but which is otherwise used in the same manner, e.g., by “positioning...the **energy delivery member** in **contact with...tissues**” without piercing the tissue, and therefore satisfies limitation 1[b] for the same reasons provided above. Ex.1013-Baker, 22:21-29, FIG.7. Ex.1002-Decl., ¶88.

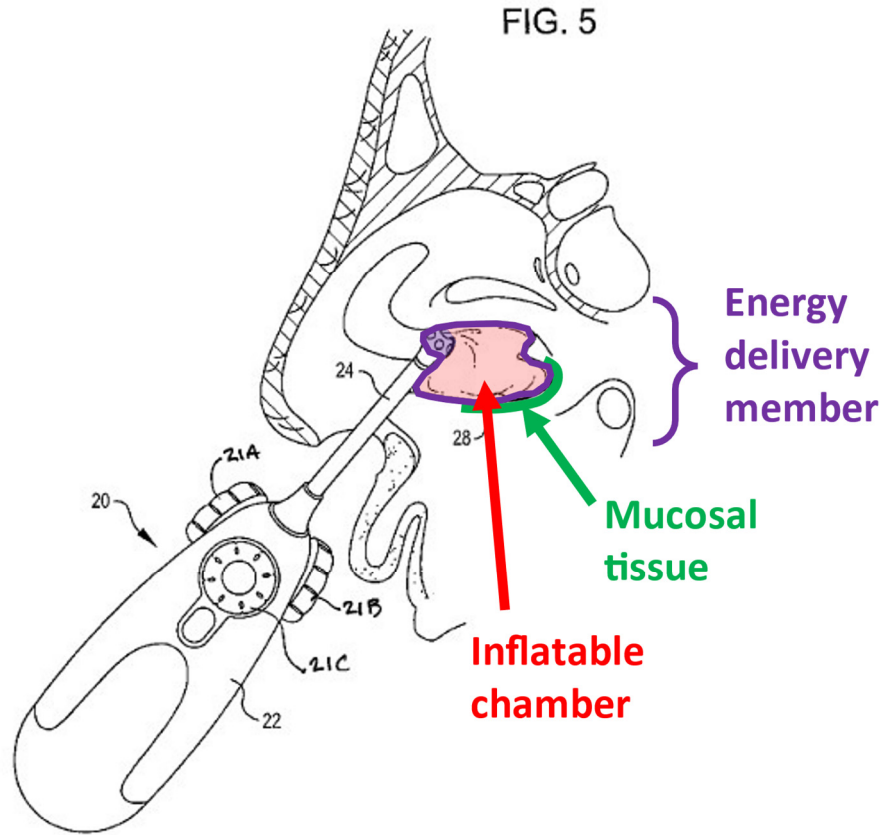
- d. **Element 1[c]: delivering a treatment from the treatment delivery portion to at least one tissue selected from the group of the mucosal tissue and another tissue underlying the mucosal tissue to modify a property of the at least one tissue and thus treat at**

least one of post nasal drip or chronic cough in the patient.

Baker discloses *delivering a treatment* (e.g., energy-based therapy) *from the treatment delivery portion* (e.g., **energy delivery member**) *to at least one tissue selected from the claimed group* (e.g., *mucosal tissue*) *to modify a property of* (e.g., *treat*) *the at least one tissue and thus treat at least one of post nasal drip or chronic cough in the patient.* Ex.1002-Decl., ¶89.

i. Device 20

First, referring to Figure 5 below, Baker’s method of using device 20 includes “*deliver[ing]...ultrasound energy [(i.e., treatment)] to tissue surfaces*” from the **energy delivery member** (i.e., *treatment delivery portion*; see limitation 1[a]). Ex.1013-Baker, 18:6-9, 17:22-24, 16:19-23.



Id., FIG.5. Ex.1002-Decl., ¶90.

Second, as explained for limitation 1[b], the energy delivery member delivers acoustic energy (i.e., *treatment*) to mucosal tissue that is in contact with the energy delivery member. Ex.1013-Baker, 17:22-32, 20:35-39, 16:19-22. Ex.1002-Decl., ¶91.

Third, by delivering acoustic energy to mucosal tissue, the energy delivery member modifies a property of the mucosal tissue. For example, Baker discloses embodiments in which the energy delivered from the energy delivery member is

“sufficient to ablate tissue” (i.e., it modifies a property of the tissue by removing all or a portion of the tissue). Ex.1013-Baker, 18:35-37. Ex.1002-Decl., ¶92.

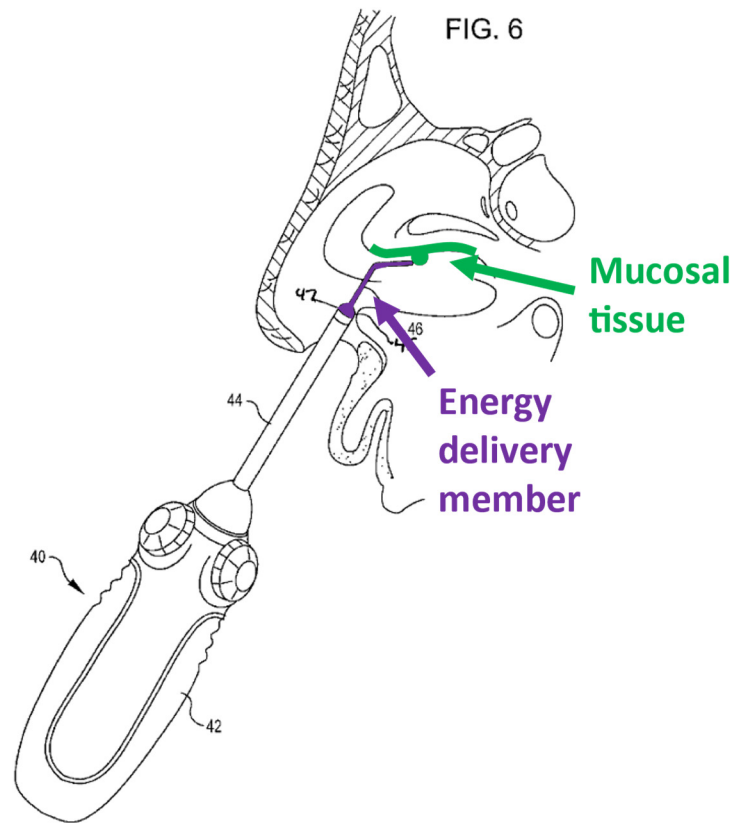
Fourth, to the extent the intended result of limitation 1[c] is limiting, Baker also teaches that its method of delivering treatment is used to *treat at least one of post nasal drip or chronic cough* for the same reasons provided above for limitation 1[pre]. Ex.1002-Decl., ¶93.

Baker describes another embodiment of device 20, depicted in Figure 4, which does not include **chamber 28**, but which is otherwise used in the same manner – e.g., by “deliver[ing] high frequency acoustic energy” to mucosal tissue – and therefore satisfies limitation 1[c] for the same reasons provided above. Ex.1013-Baker, 17:11-21, FIG.4. Ex.1002-Decl., ¶94.

ii. Device 40

Additionally or alternatively, Baker’s teachings in connection with device 40 satisfy limitation 1[c]. Ex.1002-Decl., ¶95.

First, referring to Figure 6 below, Baker’s method of using device 40 includes “*delivering[] high frequency acoustic energy [(i.e., treatment)]...by contact with tissue*” from **energy delivery member 46** (i.e., *treatment delivery portion*; see limitation 1[a]). Ex.1013-Baker, 22:10-25, 21:21-24, 23:5-8.



Id., FIG.6; *see also id.*, FIGs.8A-8D. Ex.1002-Decl., ¶95.

Second, as explained for limitation 1[b], **energy delivery member 46** delivers acoustic energy (i.e., *treatment*) to **mucosal tissue** that is in contact with the **energy delivery member 46**. Ex.1013-Baker, 22:10-25 (“**Energy delivery member 46** is configured such that a distal end may be...**contacting a tissue surface such as mucous membranes and nasal turbinates [(i.e., mucosal tissue)]**...within cavities such as nasal passages. In one embodiment, illustrated in Fig. 6, **energy delivery member 46** [is]...capable of conveying, and *delivering*, high frequency acoustic energy [(i.e., *treatment*)]...by contact with tissue.”). Ex.1002-Decl., ¶96.

Third, by delivering acoustic energy to mucosal tissue, energy delivery member 46 modifies a property of the mucosal tissue. For example, Baker discloses embodiments in which the energy delivered from energy delivery member 46 is “sufficient to ablate tissue” (i.e., it modifies a property of the tissue by destroying all or a portion of the tissue). Ex.1013-Baker, 23:29-33. Ex.1002-Decl., ¶97.

Fourth, Baker also teaches that delivering treatment is used to *treat at least one of post nasal drip or chronic cough* for the same reasons provided above for limitation 1[pre]. Ex.1002-Decl., ¶98.

Baker discloses another embodiment of device 40, depicted in Figure 7, in which energy delivery member 46 includes an additional flexible steering structure 48, but which is otherwise used in the same manner – by “deliver[ing]...high frequency acoustic energy” to mucosal tissue – and therefore satisfies limitation 1[c] for the same reasons provided above. Ex.1013-Baker, 22:21-29, FIG.7. Ex.1002-Decl., ¶99.

2. Claim 2: The method of claim 1, wherein the treatment is delivered without forming an incision in the mucosal tissue and without delivering an implant.

Baker discloses that the *treatment* (e.g., energy) is *delivered without forming an incision in the mucosal tissue and without delivering an implant*. Ex.1002-Decl., ¶100.

a. Device 20

As explained above for limitation 1[b], Baker’s method of using device 20 delivers treatment *without piercing the mucosal tissue* and therefore does so *without forming an incision and delivering an implant*, which are predicated on piercing tissue. In fact, Baker draws a contrast between its disclosed methods and prior art techniques that involved forming an incision to deliver an implant. Ex.1013-Baker, 4:38-39 (describing “[p]lacement of stents and other implantable devices in sinus passageways” as a prior art technique). Ex.1002-Decl., ¶101.

b. Device 40

Additionally or alternatively, as explained above for limitation 1[b], Baker’s method of using device 40 delivers treatment *without piercing the mucosal tissue* and therefore does so *without forming an incision and without delivering an implant* for the same reasons provided above for device 20. Ex.1002-Decl., ¶102.

3. Claim 3: The method of claim 1, wherein delivering the treatment comprises delivering energy from the delivery treatment portion⁹ in a form selected from the group

⁹ For the purposes of this proceeding, Petitioners interpret the “delivery treatment portion” as referring to the “treatment delivery portion” of claim 1.

consisting of ultrasound, microwave, heat, radiofrequency, electrical, light and laser energy.

Baker discloses that *delivering the treatment* (e.g., energy) *comprises delivering energy from the [treatment delivery] portion* (e.g., energy delivery member) *in a form selected from the claimed group* (e.g., ultrasound energy). Ex.1002-Decl., ¶103.

a. Device 20

As explained above for limitation 1[c], Baker’s method of using device 20 includes “*deliver[ing]...ultrasound energy to tissue surfaces*” from the energy delivery member (i.e., *treatment delivery portion*; see limitation 1[a]). Ex.1013-Baker, 18:6-9, 17:11-24, 16:19-23. Ex.1002-Decl., ¶104.

b. Device 40

Additionally or alternatively, as explained above for limitation 1[c], Baker’s method of using device 40 includes “*delivering...ultrasound energy*” to tissue from energy delivery member 46 (i.e., *treatment delivery portion*; see limitation 1[a]). Ex.1013-Baker, 22:10-25, 21:21-24, 23:5-8. Ex.1002-Decl., ¶105.

4. Claim 12: The method of claim 1, wherein delivering the treatment comprises injuring the at least one tissue.

Baker discloses that *delivering the treatment* (e.g., energy) *comprises injuring the at least one tissue* (e.g., mucosal tissue). Ex.1002-Decl., ¶106.

a. Device 20

As explained above for limitation 1[c], Baker's method of using device 20 includes delivering treatment by "ablat[ing] tissue." Ex.1013-Baker, 18:35-37. A POSITA would have understood that ablation results in an injury that impairs the tissue's normal structure and function, and as such would have understood Baker's delivery of treatment to include *injuring the mucosal tissue*. Ex.1002-Decl., ¶107.

b. Device 40

Additionally or alternatively, as explained above for limitation 1[c], Baker's method of using device 40 includes delivering treatment by "ablat[ing] tissue," Ex.1013-Baker, 23:29-33, and therefore *injures the mucosal tissue* for the same reasons provided above for device 20. Ex.1002-Decl., ¶108.

- 5. Claim 14: The method of claim 12, wherein the at least one tissues is selected from the group consisting of cilia, goblet cells, nerves, submucosal tissue, muscle, ligaments, cartilage, tendon, and skin.**

Baker discloses that *the at least one tissue* (e.g., *mucosal tissue*) is selected from the claimed group (e.g., *skin*). Ex.1002-Decl., ¶109.

a. Device 20

As explained above for limitations 1[b]-1[c] and claim 12, Baker's method of using device 20 includes delivering treatment by injuring *at least one tissue*. Ex.1013-Baker, 16:19-22, 18:35-37 (explaining that treatment includes "ablat[ing]

tissue”), 20:35-39. Moreover, Baker discloses embodiments in which the target tissue includes *skin*. *Id.*, 5:19-23 (“Methods and systems of the present invention may be applied for the treatment of **tissue sites such as skin surfaces**...for the disruption and/or removal of the obstruction(s).”). Ex.1002-Decl., ¶110.

b. Device 40

Additionally or alternatively, as explained above for limitations 1[pre], 1[b], 1[c], and claim 12, Baker’s method of using device 40 includes delivering treatment to *skin*. Ex.1013-Baker, 5:19-23. Ex.1002-Decl., ¶111.

- 6. Claim 16: The method of claim 1, wherein delivering the treatment comprises modifying the at least one tissue in a manner that decreases a volumetric rate of mucus production of the mucosal tissue without changing a shape of the mucosal tissue.**

Baker discloses that *delivering the treatment* (e.g., energy) *comprises modifying the at least one tissue in a manner that decreases a volumetric rate of mucus production of the mucosal tissue without changing a shape of the mucosal tissue*. Ex.1002-Decl., ¶112.

a. Device 20

First, as explained above for limitation 1[c], Baker’s method of using device 20 includes *delivering treatment* by “ablat[ing] tissue.” Ex.1013-Baker, 18:35-37. In doing so, Baker’s method *modifies the mucosal tissue* (see limitation 1[c]) in a

manner that achieves “[e]ffective and long-lasting **reduction of mucus**...within the nasal passages” (i.e., *in a manner that decreases a volumetric rate of mucus production of the mucosal tissue*). Ex.1013-Baker, 5:5-12; *see also* limitation 1[pre]. Ex.1002-Decl., ¶113.

Second, a POSITA would have understood that when mucosal tissue is ablated (and not reshaped), as disclosed by Baker, the tissue is modified *without changing its shape*. In fact, Baker’s disclosure is similar to the ’194 patent’s embodiments where tissue is not reshaped. *Compare* Ex.1013-Baker, 18:35-37 (Energy delivered by device 20 is “sufficient to...ablate tissue and/or cellular structures.) *with* Ex.1001-USP194, 13:14-19 (“[D]eliver[ing] treatment energy to **create specific localized tissue...ablation** stimulat[es] the body’s healing response to create desired conformational or structural changes that **reduces the mucus producing ability** of the mucus producing cells.”). Ex.1002-Decl., ¶114.

Where the ’194 patent describes embodiments involving reshaping tissue, it explains that in those embodiments the treatment portion is “rigid or minimally elastic” such that the tissue conforms to the shape of the treatment device. Ex.1001-USP194, 11:55-58. Here, unlike those embodiments, Baker discloses an **inflatable chamber** that is flexible and deformable. Ex.1013-Baker, 17:22-32. Ex.1002-Decl., ¶115.

b. Device 40

Additionally or alternatively, as explained above for limitation 1[c], Baker's method of using device 40 includes delivering treatment by "ablat[ing] tissue," Ex.1013-Baker, 23:29-31, and does so with the same goal of reducing mucus production, *id.*, 5:5-12; limitation 1[pre], using an energy delivery member that is "flexible or conformable," *id.*, 22:33-45, and therefore *delivers treatment by modifying the at least one tissue in a manner that decreases a volumetric rate of mucus production of the mucosal tissue without changing a shape of the mucosal tissue* for the same reasons provided above for device 20. Ex.1002-Decl., ¶116.

7. Claim 18: The method of claim 1, wherein delivering the treatment comprises delivering the treatment to at least one turbinate of the upper airway.

Baker discloses that *delivering the treatment* (e.g., energy) *comprises delivering the treatment to at least one turbinate of the upper airway*. Ex.1002-Decl., ¶117.

a. Device 20

As explained above for limitations 1[b] and 1[c], Baker's method of using device 20 includes *delivering treatment* to "tissue sites such as nasal passages," Ex.1013-Baker, 16:19-22, which includes the "**nasal turbinates**" (i.e., *at least one turbinate of the upper airway*). *Id.*, 17:11-13 ("Energy delivery member 26 may

be...configured for positioning in proximity to and/or contacting blockages within nasal passages, mucous membranes and **nasal turbinates**, or pathological or undesired tissue.”).¹⁰ Ex.1002-Decl., ¶118.

b. Device 40

Additionally or alternatively, as explained above for limitations 1[pre], 1[b], and 1[c], Baker’s method of using device 40 includes delivering treatment to a “tissue surface such as...**nasal turbinates**” (i.e., *at least one turbinate of the upper airway*). Ex. 1013-Baker, 22:10-25. Ex.1002-Decl., ¶119.

Therefore, the challenged claims in Ground I are anticipated because Baker discloses all their elements arranged as in the claims. *See Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1341 (Fed. Cir. 2016).

¹⁰ Where not otherwise specified, a POSITA would have understood that Baker’s description of energy delivery member 26 (as shown in Figures 3 and 4) applies equally to the energy delivery member (without a reference numeral) shown in Figure 5. Ex.1013-Baker, 9:35-10:10; *compare id.*, FIG.4 *with id.*, FIG.5 (each depicting an embodiment of an energy delivery member of device 20 delivering treatment to the same or similar structures within the nose). Ex.1002-Decl., ¶118.

B. Ground II: Baker Renders Obvious Claims 1-3, 12, 14, 16, 18, and 19

1. Claims 1-3, 12, 14, 16, and 18

As set forth below, Baker renders claims 1-3, 12, 14, 16, and 18 obvious. Because Baker also anticipates each of these claims (*see* Ground I), any limitation not specifically addressed below is disclosed by Baker for the reasons provided in Ground I. Ex.1002-Decl., ¶120.

a. Treating post nasal drip or chronic cough

To the extent PO argues that Baker does not expressly disclose that its methods are used to treat post nasal drip or chronic cough, these limitations would have been obvious as follows. Ex.1002-Decl., ¶121.

i. Post nasal drip (limitations 1[pre] and 1[c])

As explained above for limitations 1[pre] and 1[c], Baker discloses that its methods are used to treat rhinitis, among other conditions. Ex.1013-Baker, 26:7-11. In view of Baker's teaching that *post nasal drip* is a symptom of rhinitis, Ex.1013-Baker, 1:25-32, it would have been obvious to a POSITA to use Baker's methods to treat post nasal drip. Doing so would have been a matter of using a known technique (i.e., Baker's methods for treating rhinitis) to treat a related condition (i.e., post nasal drip) in the same way. A POSITA would have had a reasonable expectation of success given that it was well known that an effective way to treat upper airway

conditions (i.e., post nasal drip) was to treat their underlying causes (i.e., allergic rhinitis). *See* Ex.1037-Chung, 292 (explaining that a known technique for treating upper airway conditions was to “[t]reat[] the specific underlying cause(s)”), 107 (“A number of conditions can cause **PNDS [post nasal drip syndrome]**. The differential diagnosis includes...perennial **allergic rhinitis.**”); Ex.1049-Konno, 107 (explaining that treating “allergic rhinitis can produce dramatic relief of hyperreactive nasal symptoms, particularly hyperrhinorrhea [(i.e., post nasal drip)]”). Ex.1002-Decl., ¶¶122-123.

ii. Chronic cough (limitations 1[pre] and 1[c])

For the same reasons provided above for post nasal drip, it would have been obvious to a POSITA to use Baker’s methods for treating allergic rhinitis to treat *chronic cough*, because just as post nasal drip was known to be caused by rhinitis, chronic cough was known to be caused by post nasal drip (and, in turn, by allergic rhinitis). Ex.1037-Chung, 247 (“**Multiple studies have demonstrated PNDS [post nasal drip syndrome] to be the most common cause of chronic cough in adults.** **PNDS may be the result of** various processes, including seasonal and perennial **allergic rhinitis**, perennial non-allergic rhinitis, vasomotor rhinitis, postinfectious (postviral) rhinitis and chronic bacterial sinusitis.”). Accordingly, a POSITA would have readily applied textbook knowledge of upper airway conditions (including the

well-known causal interactions among rhinitis, post nasal drip, and chronic cough) to Baker’s teachings, and this would have resulted in the POSITA using a known technique (i.e., Baker’s method for treating rhinitis) to treat a related condition (i.e., chronic cough) in the same way. A POSITA would have had a reasonable expectation of success for the same reasons provided above for post nasal drip. Ex.1037-Chung, 292 (explaining that a known technique for treating cough was to “[t]reat[] the specific underlying cause(s)” including “[a]llergic rhinitis and postnasal drip”). Ex.1002-Decl., ¶124.

b. Treating at least one turbinate

As explained above for claim 18, a POSITA would have understood that the energy delivery device shown in Baker’s Figure 5 *delivers treatment to at least one turbinate* because Baker expressly states that energy device 26 (as shown in Figures 3 and 4) delivers treatment to turbinates and a POSITA would have understood that description to apply equally to Figure 5. Ex.1002-Decl., ¶125.

To the extent that PO contends Baker does not disclose using the device shown in Figure 5 to *deliver treatment to at least one turbinate*, such a use would have been obvious. Baker discloses an express motivation for a POSITA to deliver such treatment. For example, in its background section, Baker explains that prior art techniques were able to improve nasal congestion (e.g., by increasing nasal

ventilation) by delivering ultrasound energy to mucosal tissue of the “nasal turbinates.” Ex.1013-Baker, 4:13-16. In view of these background teachings, a POSITA would have been motivated to use Baker’s method for using device 20 as shown in Figure 5 to apply ultrasound energy to the turbinates. Doing so would have been a matter of using a known technique (i.e., Baker’s method of delivering ultrasound energy to the nasal passages) to treat a similar structure (i.e., nasal turbinates) in the same way. A POSITA would have had a reasonable expectation of success given that delivering ultrasound energy to nasal turbinates had been reported to improve nasal ventilation. Ex.1002-Decl., ¶126.

2. Claim 19: The method of claim 18, wherein the at least one turbinate comprises an inferior turbinate, and contacting the mucosal tissue comprises contacting a posterior aspect of the inferior turbinate.

In its scant disclosure supporting claim 19, the ’194 patent does not identify any clinical significance to treating the “inferior turbinate” or contacting the “posterior aspect of the inferior turbinate,” as claimed. To the contrary, the patent asserts that its techniques are generally applicable to “the tissue of the nose and throat, including but not limited to skin, muscle, mucosa, submucosa and nasal turbinate,” Ex.1001-USP194, 3:1-10, and states merely by way of example, without elaboration, that a clinician may “apply energy to the posterior aspect of the inferior turbinate,” *id.*, 23:32-35. Ex.1002-Decl., ¶127.

Baker's teachings are similarly applicable to tissue located throughout the upper airways – which encompasses the claimed portions of the inferior turbinate – and therefore renders claim 19 obvious. Ex.1013-Baker, 16:19-23, 17:11-13, 22:12-16. *See In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994) (lack of disclosure in patent supports finding that POSITA could have implemented prior art). Namely, as explained above for Ground I, Baker discloses delivering treatment to *at least one turbinate* (claim 18) and *contacting mucosal tissue* (limitation 1[b]). However, Baker does not specify which turbinate is treated and/or which aspect of the turbinate is contacted. Instead, like the '194 patent, Baker leaves it to the knowledge and skill of a POSITA to select among the limited number of known turbinates (e.g., inferior, middle, or superior) and aspects of turbinates (e.g., posterior or anterior), such that the claimed posterior aspect of the inferior turbinate would have been—at minimum—obvious to try. Ex.1002-Decl., ¶128.

A POSITA would have been motivated to apply Baker's methods to the claimed anatomical structures, as described above, with a reasonable expectation of success given that Baker's methods are intended to contact and treat tissue (e.g., mucosal tissue) that is found on or within the inferior turbinate and runs the length of the turbinate from the back (posterior) to the front (anterior), per textbook knowledge of nasal anatomy. *See supra*, § V.A. Accordingly, a POSITA would

have reasonably expected to successfully use Baker's methods to deliver treatment to tissue of the *inferior turbinate* by *contacting a posterior aspect of the inferior turbinate*, and in doing so treat post nasal drip and chronic cough. *See supra*, § X.A.1.a; Ex.1017-Chen, 240 (treating inferior turbinate was known to improve symptoms of allergic rhinitis); Ex.1040-Kong (same). Ex.1002-Decl., ¶129.

C. Ground III: Baker in view of Edwards-'535 and Chen Renders Obvious Claims 1-3, 6, 12, 14, 16, 18, and 19

As set forth below, Baker in view of Edwards and Chen renders obvious the subject matter of claim 6, which is not addressed in Grounds I or II. The combination further discloses each of the remaining challenged claims as an additional or alternative mapping to Baker alone. Ex.1002-Decl., ¶130.

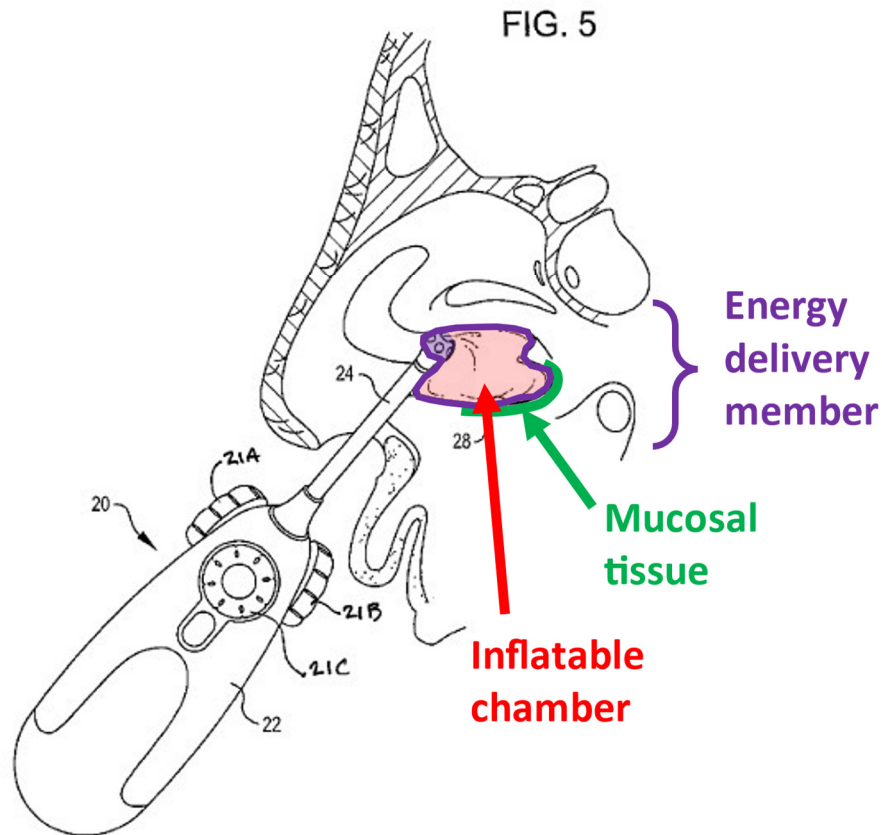
1. Claim 1

- a. Element 1[pre]: A method for reducing mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough, the method comprising:**

If the preamble is limiting, Baker in view of Edwards-'535 and Chen discloses *a method for reducing mucus secretion in an upper airway* (e.g., nasal passages) *of a patient to treat at least one of post nasal drip or chronic cough*. Ex.1002-Decl., ¶131.

i. Baker

As explained above for Grounds I-II, Baker discloses multiple *methods*, one of which uses an embodiment of device 20 having an **inflatable chamber 28** at its distal end, as depicted in Figure 5. *See supra*, §§X.A.1.a.i, X.A.1.b.i. **Chamber 28** is part of an **energy delivery member** that delivers “**acoustic energy**...to tissue sites such as nasal passages.” Ex.1013-Baker, 16:19-22, 17:22-36.



Id., FIG.5. Ex.1002-Decl., ¶132.

Baker further discloses that its methods and systems can be used to deliver acoustic energy “in combination with another treatment modality such as...application of...**radio frequency energy**.” Ex.1013-Baker, 5:28-33; *see also id.*, 9:15-18. However, Baker does not provide further details of such embodiments. Ex.1002-Decl., ¶133.

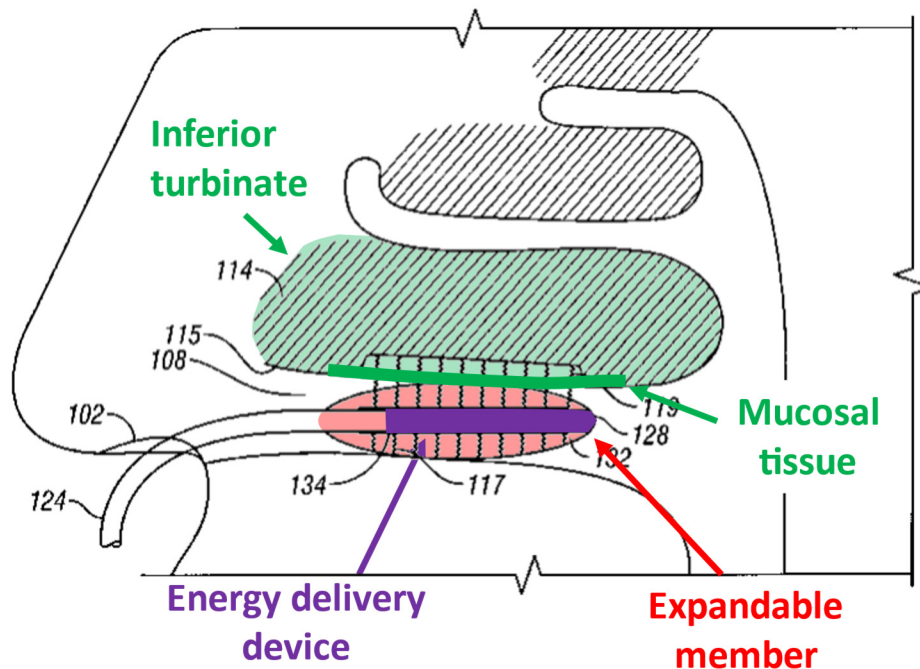
ii. Edwards-’535

Edwards-’535 discloses an apparatus 124 that, like Baker’s device 20, is “introduced through a nostril” of a patient and is used for “treating airway obstructions,” such as those associated with the “turbinates.” Ex.1010-Edwards-’535, 1:22-26, 5:18-26. Ex.1002-Decl., ¶134.

Referring to Figure 3B, reproduced below, apparatus 124 includes an **energy delivery device 134** that delivers “**RF energy** to at least a portion of the **nasal [turbinates]¹¹** being treated.” Ex.1010-Edwards-’535, 5:31-35, 5:46-51. The RF energy “caus[es] the ablation of tissue by heating at least a portion of the **nasal**

¹¹ Edwards-’535 uses the terms “concha” and “turbinates” interchangeably. Ex.1010-Edwards-’535, 4:19-20, 4:41-43 (“the nasal concha, also referred to as the turbinates”). For clarity and consistency, this Petition refers to the structures as “turbinates.”

[turbينات] being treated.” *Id.*, 5:35-45. Apparatus 124 further includes an expandable member 132 that – like Baker’s inflatable chamber 28 – “conforms to the surface of the nasal [turbينات] to be ablated” and does not penetrate mucosal tissue. *Id.*, 5:27-31, 7:33-40.



Ex.1010-Edwards-’535, FIG.3B. Although Figure 3B depicts RF energy delivery device 134 as being located within expandable member 132, Edwards-’535 also discloses arrangements in which RF energy delivery device 134 is located “on the surface 147 of the expandable member.” *Id.*, 8:8-32. Ex.1002-Decl., ¶¶135-136.

iii. Chen

Chen discloses results of a clinical study showing that applying RF energy to specified tissues in the upper airways, including those of the inferior turbinate, is a promising, highly effective and easy to perform, technique for treating allergic rhinitis. Ex.1017-Chen, Abstract, 243. Chen explains that such techniques can “reduce the sensitivity of the nasal mucosa to external stimuli,...reduce the gland secretion, and...alleviate or eliminate symptoms such as nasal itching, sneezing, nasal congestion, and runny nose in patients, achieving the objective of treating [allergic rhinitis].” *Id.*, 240, 243. Ex.1002-Decl., ¶137.

For example, Chen discloses that significant therapeutic benefits were observed in patients where RF energy was used to ablate mucosal tissue lining the inferior turbinate and/or nerves within the inferior turbinate (e.g., “posterior inferior nerve,” “cholinergic nerves,” and “parasympathetic nerve plexus”). Ex.1017-Chen, 239-40 (“From September 2002 to March 2003, 40 patients with PAR [perennial allergic rhinitis] (observation group) were **treated with radiofrequency**

thermocoagulation¹² of the **posterior inferior nasal nerve**, anterior ethmoidal nerve, and **inferior turbinate** under nasal endoscopy, and comparison was made with another group (control group) of 40 patients with PAR treated with only radiofrequency thermocoagulation of the sphenopalatine nerve¹³ under nasal endoscopy in order to study the new method to improve the therapeutic effect of PAR. After six months of follow-up, **the therapeutic effect was significant.**”), 240, 240. Ex.1002-Decl., ¶139.

¹² Thermocoagulation is a form of ablation in which heat is used to ablate tissue. See Ex.1066-Cioanta, [0061] (“thermal ablation is carried out by causing the targeted tissue to thermocoagulate”). It is the same type of ablation disclosed by Edwards-’535. Ex.1010-Edwards-’535, 5:35-45 (“[A]blative energy...caus[es] the **ablation of tissue by heating** at least a portion of the nasal [turbinates] being treated.”). Ex.1002-Decl., ¶138.

¹³ The sphenopalatine nerve or sphenopalatine ganglion (SPG) is also referred to as the pterygopalantine ganglion. Ex.1002-Decl., ¶139.

Chen does not state whether the methods and devices used in the clinical study involved piercing the patients' mucosal tissue.¹⁴ See Ex.1017-Chen, 240. Even if the devices did pierce the mucosal tissue, Chen's lack of specificity—Chen never mentions puncturing tissue or the importance of using a particular RF energy delivery tool in its detailed analysis of the clinical results—would have suggested to a POSITA that Chen's teachings are applicable to other RF energy delivery methods (e.g., including known non-puncturing methods). As detailed further below, the

¹⁴ Chen's disclosure that its methods involved placing the RF energy delivery probe “**on**” the wall of the nasal cavity and produced “a strip-shaped thermocoagulation” suggests that the strips were formed by moving a non-piercing RF energy delivery device over the surface of the mucosa. Ex.1017-Chen, 240. Chen's use of non-piercing methods and devices would have been consistent with similar prior art studies (including Liang, published by the same group as Chen) that treated patients with allergic rhinitis using a non-piercing RF energy delivery device, the SHP-I. Ex.1055-Fang, 876; Ex.1056-Liang, 341 (same). A POSITA would have understood the SHP-I to be non-piercing for at least the reason that its RF electrode was spheroid/ball-shaped. Ex.1059-Liang-'227, FIG. 1 (showing that the SHP-I device uses a ball-shaped (i.e., non-piercing) RF electrode), 3. Ex.1002-Decl., ¶140.

promising clinical results would have motivated a POSITA to use Chen's treatment with nonpenetrating RF devices. Ex.1002-Decl., ¶141.

iv. Motivation to Combine

As explained above, Baker teaches a method of using device 20 that can be used to deliver RF energy to the upper airways. Ex.1013-Baker, 5:28-33; *see also id.*, 9:15-18. Edwards-'535 and Chen disclose further details of techniques for using RF energy to treat upper airway conditions, including, for example, describing specific embodiments of RF energy delivery devices and identifying specific tissues in the upper airways to which the RF energy should be applied. A POSITA would have been motivated to combine these teachings, namely, by modifying Baker's method so that its device 20 would have included an RF energy delivery device (as taught by Edwards-'535) and been used to treat allergic rhinitis by applying RF

energy to specific tissues identified by Chen, with a reasonable expectation of success for the following reasons.¹⁵ Ex.1002-Decl., ¶142.

First, Baker itself suggests modifying its method for using device 20 to deliver acoustic energy (e.g., ultrasound) “in combination with another treatment modality such as...application of...radio frequency energy” but does not disclose the details of such modifications. Ex.1013-Baker, 5:28-33; *see also id.*, 9:15-18. Baker is thus ready for improvement and expressly instructs a POSITA to seek out other teachings that disclose details regarding the use of RF energy to treat upper airway conditions, such as the teachings of Edwards-’535 and Chen. Ex.1002-Decl., ¶144.

Second, a POSITA would have had an express motivation to turn to the teachings of Edwards-’535 to fill in the details of Baker’s embodiments that use RF

¹⁵ As explained in Section IX, *supra*, Baker, Edward-’535, and Chen are in the same field as the ’194 patent and are reasonably pertinent to solving the problems addressed in the ’194 patent (e.g., treating tissue in a body cavity) with the same types of solutions (e.g., applying energy to tissue), and are therefore analogous art to the ’194 patent. *See Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1004 (Fed. Cir. 2023). Ex.1002-Decl., ¶143.

energy because Edwards-'535 specifically discloses the benefits of its RF energy delivery device (e.g., **energy delivery device 134**). For example, Edwards-'535 explains that using an **RF energy delivery device** in accordance with its teachings **“eliminates the need for surgical cutting to remove a portion of a nasal [turbinate] and the risks associated therewith”** and enables procedures to be **“performed bloodlessly and without the need to penetrate tissue, thereby significantly reducing the risk of infection.”** Ex.1010-Edwards-'535, 4:53-60; *see also id.*, 4:66-67 (“This approach should be **significantly less painful** for the patient than traditional surgical methods”). A POSITA would therefore have been motivated to modify Baker’s device 20 in view of Edwards-'535 teachings of an RF energy delivery device to obtain known benefits including the ability to deliver RF energy to nasal tissue with few side effects or risks of complications. Ex.1002-Decl., ¶145.

Third, a POSITA would have had an express motivation to turn to Chen’s teachings to fill in details of how to use Baker’s device 20 (as modified to deliver RF energy according to Edwards-'535’s teachings), given that both Baker and Chen aim to treat allergic rhinitis, and Chen discloses a promising method for treating allergic rhinitis using RF energy. For example, Chen discloses clinical data suggesting that its approach for using RF energy to treat allergic rhinitis **“is highly**

effective, easy to perform and [has] few complications” and is therefore “a **good** way to treat” allergic rhinitis. Ex.1017-Chen, Abstract; *see also id.*, 243 (“This method has the advantages of **significant therapeutic effect, simple operation, and no side effects**, and is worthy of clinical use.”). Chen also discloses advantages—including “alleviat[ing] or eliminat[ing] symptoms such as nasal itching, sneezing, nasal congestion, and runny nose,...[thereby] achieving the objective of treating [allergic rhinitis]”—of delivering RF energy to specific tissues, e.g., nerves within or proximate to the inferior turbinate. *See id.*, 240, 243. A POSITA would therefore have been motivated to modify Baker’s method (as modified according to Edwards-’535’s teachings) in view of Chen to obtain known benefits including the ability to treat allergic rhinitis effectively with few side effects or risks of complications. Ex.1002-Decl., ¶146.

Fourth, Baker, Edwards-’535, and Chen each describe similar techniques that deliver energy to upper airways to treat various conditions such that their combination would have yielded predictable results. Ex.1013-Baker, 16:19-22, 26:7-11; Ex.1010-Edwards-’535, 1:22-23, 5:36-30; Ex.1017-Chen, Abstract, 239. In fact, Baker, Edwards-’535, and Chen each disclose delivering treatment in the same way, e.g., by ablating tissue of the upper airways, such as the turbinates. Ex.1013-Baker, 18:35-37 (Baker’s method delivers energy “sufficient to **ablate**

tissue.”), 17:11-13 (energy can be applied to “nasal **turbinates**”); Ex.1010-Edwards-’535, 5:35-38 (“Sufficient energy 117 is delivered through the surface 115 of the nasal [turbinate] 114 to **ablate** at least a portion 119 of the nasal [**turbinate**] 114.”); Ex.1017-Chen, 239-40 ([P]atients were “treated with radiofrequency **thermocoagulation**,” i.e., a type of **ablation**, of structures including the “inferior **turbinate**.”). Thus, Baker, Edwards-’535, and Chen each share similar objectives and means for accomplishing those objectives, indicating that their combination would have been straightforward and yielded predictable results. Ex.1002-Decl., ¶147.

Fifth, a POSITA would have had a reasonable expectation of success in applying Edwards-’535’s and Chen’s teachings to Baker’s method given that, as explained above, Baker expressly disclosed that its methods can be combined with techniques for delivering RF energy. Moreover, in the combination, the known techniques of Edwards-’535 and Chen would have each been used to improve Baker’s similar method in the same way, for example:

- Baker discloses a device 20 having an inflatable chamber at the distal end, Ex.1013-Baker, 17:22-36, and Edwards-’535 discloses a way to deliver RF energy using such a device (e.g., by placing an RF energy delivery device on the surface of the inflatable chamber), Ex.1010-

Edwards-'535, 8:8-25. Thus, Edwards-'535's teachings would have been applied to Baker in the same way those teachings are used in Edwards-'535 itself.

- Baker's device 20 (when modified to include an RF energy delivery device as taught by Edwards-'535) delivers RF energy to ablate tissue by RF thermocoagulation, Ex.1010-Edwards-'535, 5:36-51, and Chen discloses a promising clinical application of RF thermocoagulation (e.g., treating allergic rhinitis by ablating nerve tissue and/or turbinates), Ex.1017-Chen, 239-40.¹⁶ Thus, Chen's teachings would

¹⁶Multiple other clinical studies from the same timeframe confirm that RF ablation of nasal tissue was regarded as a promising treatment for rhinitis such that a POSITA would have had a reasonable expectation of success. *See* Ex.1055-Fang, 876 (treating allergic rhinitis using "radiofrequency ablation of the sphenopalatine foramen, anterior ethmoidal nerve, and inferior nasal concha" yielded "good" results); Ex.1056-Liang, 341 (treating allergic rhinitis by radiofrequency thermocoagulation of the ethmoidal nerve had a "significant" therapeutic effect). Ex.1002-Decl., ¶148.

likewise be applied to the combination of Baker and Edwards-'535 in the same way those teachings are used in Chen itself.

Accordingly, applying Edwards-'535's and Chen's teachings to Baker would have been a matter of routine implementation well within the skill of a POSITA and would have yielded predictable results—e.g., Baker's method being used to deliver RF energy to treat allergic rhinitis, as taught by Edwards-'535 and Chen—with a reasonable expectation of success. Ex.1002-Decl., ¶148.

Finally, the '194 patent does not explain specifically how energy-based therapy can be delivered to a patient's upper airway to treat post nasal drip or chronic cough. Instead, it simply states that post nasal drip and chronic cough can be treated using energy delivery devices that deliver energy in any number of different forms, Ex.1001-USP194, 9:55-63 ("heat, radiofrequency (RF), laser, light, ultrasound (e.g. high intensity focused ultrasound), [etc.]"), that "may have any of a number of different effects on the treated tissue," *id.*, 2:48-55. Thus, the '194 patent assumes it is well within the level of ordinary skill to use a broad range of devices and techniques to treat post nasal drip and chronic cough. A POSITA would have therefore had a similar expectation of success in using Baker's method of using device 20 (as modified to include Edwards-'535' RF energy delivery device) to reduce mucus production and treat post nasal drip and/or chronic cough by treating

specific tissue as taught by Chen. *See In re Epstein*, 32 F.3d at 1568. Ex.1002-Decl., ¶150.

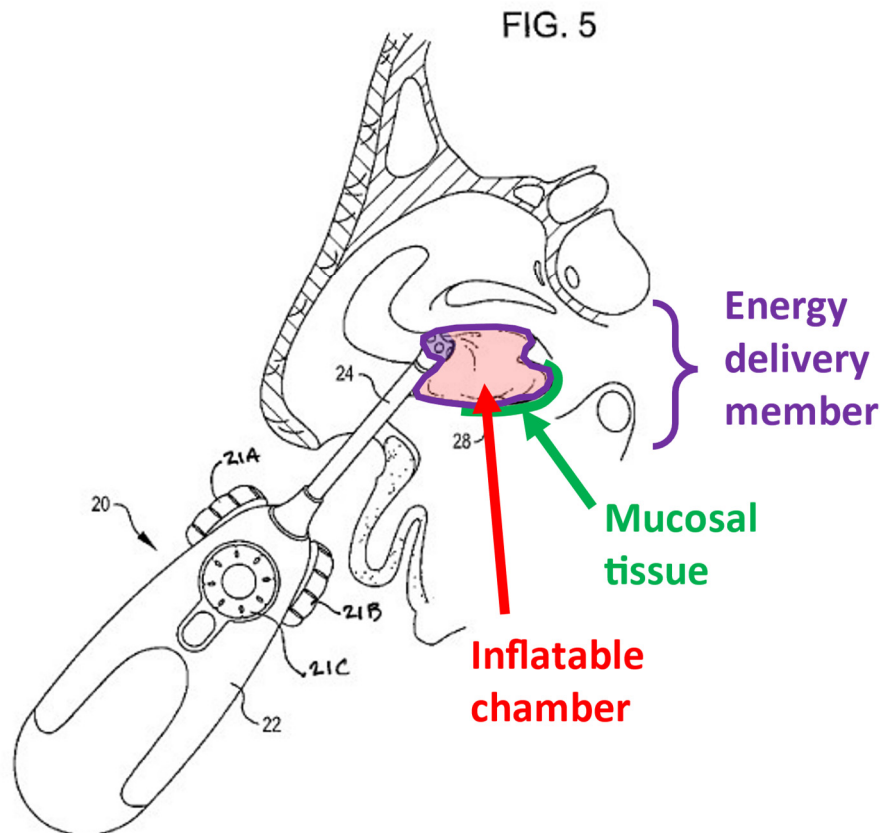
Accordingly, a POSITA would have been motivated to combine the teachings of Baker, Edwards-'535, and Chen and, as explained in further detail for limitations 1[a]-1[c] below, the combination would have resulted in a *method for reducing mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough*.¹⁷ Ex.1002-Decl., ¶151.

b. Element 1[a]: advancing a treatment delivery portion of an energy-based treatment device into a nostril of the patient;

Baker in view of Edwards-'535 and Chen discloses *advancing a treatment delivery portion* (e.g., Edwards-'535's RF energy delivery device 134) *of an energy-based treatment device* (e.g., Baker's device 20 as modified in view of Edwards-'535) *into a nostril of the patient*. Ex.1002-Decl., ¶152.

¹⁷ Given that the combined method is used to treat allergic rhinitis (as taught by Baker and Chen), a POSITA would have understood and/or found it obvious that the method also reduces mucus secretion and treats post nasal drip and/or chronic cough for the reasons provided in Grounds I and II. *See supra*, §§ X.A.1.a.i and X.B.1. Ex.1002-Decl., ¶151.

First, as explained above for Grounds I-II, Baker’s method of using device 20 includes “insert[ing]” (i.e., *advancing*) an insertion wand 24 “through a nostril opening” (i.e., *nostril of a patient*). Ex.1013-Baker, 16:19-26 (“[I]nsertion wand 24 is configured for **insertion through a nostril opening** and positioning at least partially within nasal passageways.”). An **inflatable chamber 28** is located at the distal tip of insertion wand 24 and is likewise *advanced into the nostril of the patient* and subsequently inflated to contact the walls of a patient’s upper airway. Ex.1013-Baker, 17:22-32.



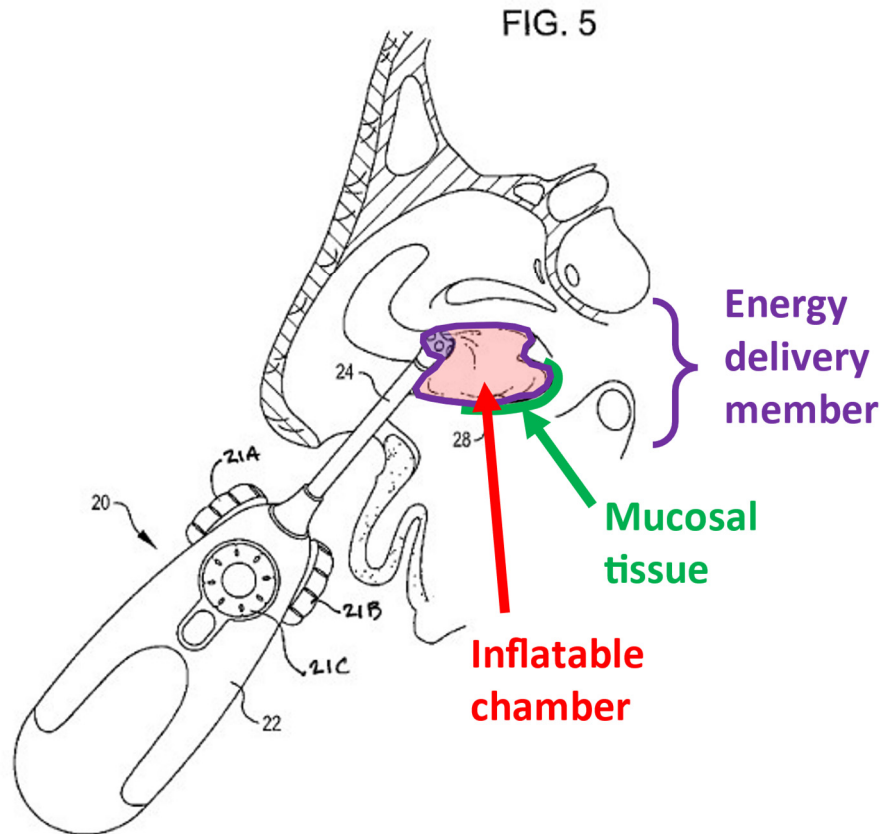
Id., FIG.5. Ex.1002-Decl., ¶153.

Second, as explained above for limitation 1[pre], the combination of Baker and Edwards-'535 would have resulted in Baker's device 20 being modified to include an RF energy delivery device (such as Edwards-'535's RF energy delivery device 134). In accordance with Edwards-'535's teachings, the RF energy delivery device would have been positioned on the surface of Baker's chamber 28. Ex.1010-Edwards-'535, 8:8-32. Therefore, the RF energy delivery device would have likewise been *advanced into the nostril of the patient*. A POSITA would have been motivated to combine Baker, Edwards-'535, and Chen in this manner, and would have done so with a reasonable expectation of success, for the same reasons provided above for limitation 1[pre]. Ex.1002-Decl., ¶154.

c. Element 1[b]: contacting mucosal tissue of the upper airway with the treatment delivery portion, without piercing the mucosal tissue; and

Baker in view of Edwards-'535 and Chen discloses *contacting mucosal tissue of the upper airway* (e.g., tissue lining the inferior turbinate as taught by Chen) *with the treatment delivery portion* (e.g., Edwards-'535's RF energy delivery device 134), *without piercing the mucosal tissue*. Ex.1002-Decl., ¶155.

First, as explained above for Grounds I-II, Baker’s method of using device 20 includes “*contact[ing]* a **tissue site**” with the **inflatable chamber 28**. Ex.1013-Baker, 17:22-32.



Id., FIG.5. Ex.1002-Decl., ¶156.

Second, as explained above for limitations 1[pre] and 1[a], the combination of Baker and Edwards-’535 would have resulted in Baker’s device 20 being modified to include an RF energy delivery device (such as Edwards-’535’s **RF energy delivery device 134**) on the surface of Baker’s **chamber 28**. Ex.1010-

Edwards, 8:8-32. Therefore, the RF energy delivery device (i.e., *treatment delivery portion*) would have likewise *contacted mucosal tissue of the upper airway*. For example, Edwards-'535 discloses embodiments in which the contacted *mucosal tissue* is on the surface of a turbinate. *Id.*, 5:28-31 (“[E]xpandable member 132 is brought into contact with the **surface 115 of the nasal [turbinate] 114** to be treated.”). Ex.1002-Decl., ¶157.

Third, as explained above for limitation 1[pre], the combination of Baker, Edwards-'535, and Chen would have resulted in Baker's method (as modified according to Edwards-'535's teachings) being applied to tissues that Chen identified as promising targets for treating allergic rhinitis, including *mucosal tissue* lining the inferior turbinate and/or nerves within and near the inferior turbinate. Ex.1017-Chen, 239-40 (“The treatment for the [posterior inferior nerve] involved placing the [RF energy] probe on the lateral wall of the nasal cavity between the posterior end of the middle and inferior turbinate, making a strip-shaped thermocoagulation from the top to the bottom with a length of about 2.5 cm, a width of 0.5 cm, and a depth up to the bone wall.... Spot-like **thermocoagulation was also performed on the anterior and medial mucosa of the inferior turbinate.**”). Accordingly, a POSITA would have understood that the tissue contacted by the RF energy delivery device includes *mucosal tissue of the upper airway*, including (a) when treatment is applied

directly to mucosal tissue lining the turbinate and (b) when treatment applied to nerves within and near the turbinate, which – as will be further explained below for limitation 1[c] – run underneath mucosal tissue such that the RF energy delivery device contacts the overlying mucosal tissue when delivering treatment to the underlying nerves. Ex.1002-Decl., ¶158.

Fourth, a POSITA would have understood that the RF energy delivery device (i.e., *treatment delivery portion*) contacts the mucosal tissue *without piercing the mucosal tissue* for the same reasons provided above for Grounds I-II. *See supra*, §§ X.A.1.c.i. A POSITA would have been further motivated not to pierce the mucosal tissue to achieve additional benefits disclosed by Edwards-’535, e.g., that by not piercing tissue, the procedure would be “bloodless[]” and have a “significantly reduc[ed] risk of infection.” Ex.1010-Edwards-’535, 4:55-60 (“The use of ablative energy eliminates the need for surgical cutting to remove a portion of a nasal concha and the risks associated therewith. As a result, the procedure can be performed bloodlessly and without the need to penetrate tissue, thereby significantly reducing the risk of infection.”). A POSITA would have been motivated to combine Baker, Edwards-’535, and Chen in this manner, and would have done so with a reasonable expectation of success, for the same reasons provided above for limitation 1[pre]. Ex.1002-Decl., ¶159.

In fact, Edwards-'535 discloses techniques that go an extra length to avoid piercing tissue by “cooling the surface of the nasal [turbinate] being ablated” such that “ablation can be performed to remove an internal section of a nasal [turbinate] without damaging the surface of the nasal [turbinate].” Ex.1010-Edwards-'535, 4:60-67, 6:10-37. Although Edwards-'535's cooling technique is just one way to avoid piercing tissue (and thus the combination satisfies limitation 1[b] with or without it), a POSITA would have been motivated to use Edwards-'535's cooling technique to achieve the additional benefits disclosed by Edwards-'535 (e.g., no damage to the surface of the turbinate) and would have done so with a reasonable expectation of success given that Edwards-'535 already discloses the use of the cooling technique in a system that is substantially similar to the combined system of Baker, Edwards-'535, and Chen, such that the use of the same technique in the combined system would have been straightforward and yielded predictable results. Ex.1002-Decl., ¶160.

- d. Element 1[c]: delivering a treatment from the treatment delivery portion to at least one tissue selected from the group of the mucosal tissue and another tissue underlying the mucosal tissue to modify a property of the at least one tissue and thus treat at**

least one of post nasal drip or chronic cough in the patient.

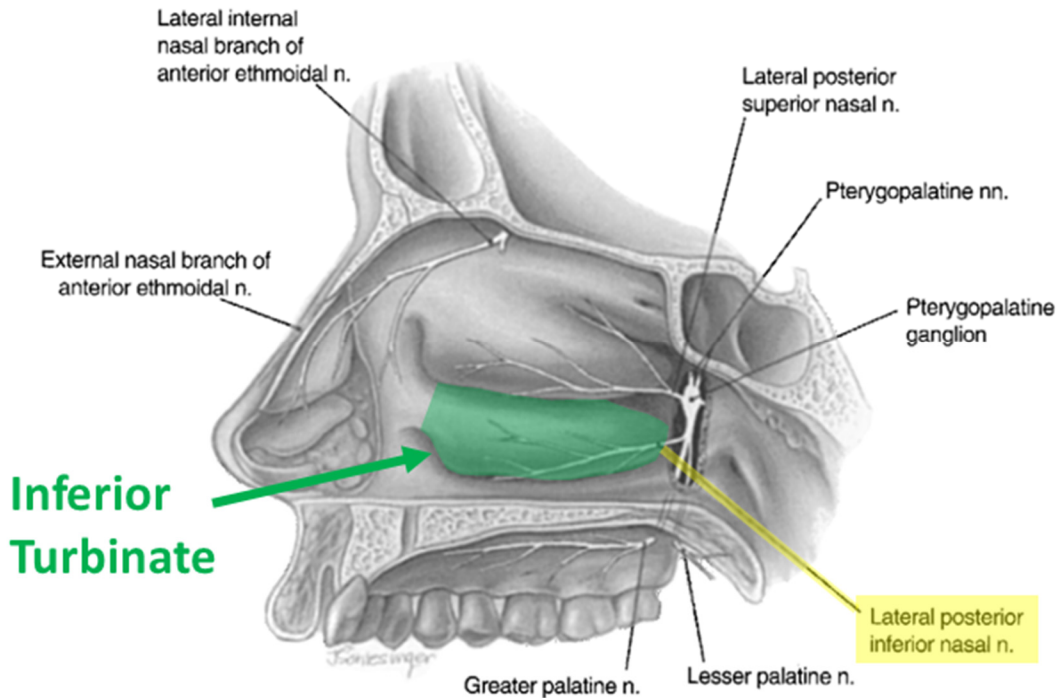
Baker in view of Edwards-'535 and Chen discloses *delivering a treatment* (e.g., ablative RF energy) *from the treatment delivery portion* (e.g., Edwards-'535's RF energy delivery device 134) *to at least one tissue selected from the group of the mucosal tissue* (e.g., mucosa of the inferior turbinate, as taught by Chen) *and another tissue underlying the mucosal tissue* (e.g., posterior inferior nasal nerve, as taught by Chen) *to modify a property of* (e.g., ablate) *the at least one tissue and thus treat at least one of post nasal drip or chronic cough in the patient.* Ex.1002-Decl., ¶161.

First, as explained above for limitations 1[pre]-1[b], the combination of Baker and Edwards-'535 would have resulted in Baker's device 20 being modified to include an RF energy delivery device (e.g., Edwards-'535's RF energy delivery device 134). Ex.1010-Edwards-'535, 8:8-32. In accordance with Edwards-'535's teachings, the RF energy delivery device would have *delivered* ablative RF energy (i.e., *treatment*) to the nasal tissue. *Id.*, 5:30-38 ("Ablative energy 117 is then delivered through the apparatus and the energy delivery device 134 to the nasal [turbinate] 114. Sufficient energy 117 is delivered through the surface 115 of the nasal [turbinate] 114 to ablate at least a portion 119 of the nasal [turbinate] 114. According to this method, the ablative energy may be any form of energy capable of

causing the ablation of tissue by heating at least a portion of the nasal [turbinate] being treated.”). Ex.1002-Decl., ¶162.

Second, as explained above for limitation 1[b], the combination of Baker, Edwards-’535, and Chen would have resulted in Baker’s method (as modified according to Edwards-’535’s teachings) delivering the ablative RF energy to tissues that Chen identified as promising targets for treating allergic rhinitis, including the *mucosal tissue* lining the inferior turbinate and/or nerves within the inferior turbinate. Ex.1017-Chen, 239-40. Ex.1002-Decl., ¶163.

When the combined teachings are used to deliver energy to the nerves within the inferior turbinate, a POSITA would have understood from textbook knowledge of nasal anatomy that the nerves are *tissue underlying the mucosal tissue*. For example, as shown below, the posterior inferior nasal nerve is located in a region of the nasal passages within and/or behind the inferior turbinate.



Ex.1060-Lane, FIG.4. A POSITA would have further understood that the posterior inferior nasal nerve, as well as other nerves of the inferior turbinate, run through the submucosa, i.e., underneath the mucosal tissue lining the inferior turbinate. *Id.*, 392 (“The **submucosa** contains ... sensory **nerves**, and immune cells”). Ex.1002-Decl., ¶164.

Third, delivering ablative RF energy to the target tissue (e.g., mucosal tissue and/or the underlying nerves) using the combined method *modifies a property* of the tissue. For example, Edwards-’535 discloses that the ablative RF energy “caus[es] the ablation of tissue [(i.e., modifying a property of the tissue by removing all or a portion of the tissue)] by heating at least a portion of the nasal [turbinate] being

treated.” Ex.1010-Edwards-’535, 5:35-39; *see also* Ex.1017-Chen, 239-40 (“The treatment for the [posterior inferior nasal nerve] involved placing the probe on the lateral wall of the nasal cavity between the posterior end of the middle and inferior turbinate, **making a strip-shaped thermocoagulation** from the top to the bottom with a length of about 2.5 cm, a width of 0.5 cm, and a depth up to the bone wall.... Repeated thermocoagulation was allowed, with the local mucosa appearing as white patches. Spot-like **thermocoagulation was also performed on the anterior and medial mucosa of the inferior turbinate.**”). Ex.1002-Decl., ¶165.

Fourth, to the extent the intended result of limitation 1[c] is limiting, Baker in view of Edwards-’535 and Chen also teaches that the combined method of delivering treatment is used to *treat at least one of post nasal drip or chronic cough* for the same reasons provided above for limitation 1[pre]. A POSITA would have been motivated to combine Baker, Edwards-’535, and Chen in the above-described manner, and would have done so with a reasonable expectation of success, for the same reasons provided above for limitation 1[pre]. Ex.1002-Decl., ¶166.

2. Claim 2: The method of claim 1, wherein the treatment is delivered without forming an incision in the mucosal tissue and without delivering an implant.

As explained above for limitation 1[b], the combined method of Baker, Edwards-’535, and Chen delivers treatment *without piercing the mucosal tissue* and

therefore does so *without forming an incision and delivering an implant*, which are predicated on piercing tissue for the same reasons provided above for Grounds I-II. *See supra*, §§ X.A.1.c.1, X.A.2.a, X.C.1.c. A POSITA would have been motivated to combine Baker, Edwards-'535, and Chen in this manner, and would have done so with a reasonable expectation of success, for the same reasons provided above for limitation 1[pre]. Ex.1002-Decl., ¶167.

3. Claim 3: The method of claim 1, wherein delivering the treatment comprises delivering energy from the delivery treatment portion in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light and laser energy.

As explained above for limitation 1[c], the combined method of Baker, Edwards-'535, and Chen delivers treatment by delivering ablative RF energy from Edwards-'535's *RF energy delivery device* (*i.e., treatment delivery portion*) and therefore delivers energy in the form of *radiofrequency energy*. Ex.1013-Baker, 5:28-33, 9:15-18 ("radio frequency energy"); Ex.1010-Edwards-'535, 5:30-38, 5:43-51 ("[T]he **energy is...preferably RF radiation.**"); Ex.1017-Chen, Abstract, 239-240 ("radiofrequency"). A POSITA would have been motivated to combine Baker, Edwards-'535, and Chen in this manner, and would have done so with a reasonable expectation of success, for the same reasons provided above for limitation 1[pre]. Ex.1002-Decl., ¶168.

4. **Claim 6: The method of claim 3, wherein the at least one tissue comprises nerve tissue underlying the mucosal tissue, and wherein delivering the energy comprises ablating the nerve tissue.**

As explained above for limitation 1[c], the combined method of Baker, Edwards-'535, and Chen discloses delivers energy to the nerve tissue within the inferior turbinate (i.e., *nerve tissue underlying the mucosal tissue*). Ex.1002-Decl., ¶169.

As further explained above for limitation 1[c] and claim 3, the combination of Baker, Edwards-'535, and Chen would have resulted in Baker's device 20 being modified to *deliver energy to ablate* the nerve tissue. Ex.1010-Edwards-'535, 5:30-38; *see also* Ex.1017-Chen, 239-240 ("The **treatment for the [posterior inferior nerve]** involved placing the [RF energy] probe on the lateral wall of the nasal cavity between the posterior end of the middle and inferior turbinate, making a strip-shaped **thermocoagulation** from the top to the bottom with a length of about 2.5 cm, a width of 0.5 cm, and a depth up to the bone wall.... Spot-like **thermocoagulation was also performed on the anterior and medial mucosa of the inferior turbinate.**"), 240 ("In the inferior turbinate, there are **cholinergic nerves and parasympathetic nerve plexus.**"). A POSITA would have been motivated to combine Baker, Edwards-'535, and Chen in this manner, and would have done so with a reasonable

expectation of success, for the same reasons provided above for limitation 1[pre].
Ex.1002-Decl., ¶170.

To further facilitate ablation of the nerve tissue underlying the mucosal tissue, as explained above for limitation 1[b], Edwards-'535 discloses “cooling the surface of the nasal [turbinate] being ablated” such that “ablation can be performed to remove an **internal section** of a nasal [turbinate] without damaging the surface of the nasal [turbinate].” Ex.1010-Edwards-'535, 4:60-67, 6:10-37. Although Edwards-'535's cooling technique would have been just one way to ablate the nerve tissue underlying the mucosal tissue (and thus the combination satisfies claim 6 with or without it), a POSITA would have been motivated to use Edwards-'535's cooling technique to achieve the additional benefits disclosed by Edwards-'535 (e.g., no damage to the surface of the turbinate) and would have done so with a reasonable expectation of success given that Edwards-'535 already discloses the use of the cooling technique in a system that is substantially similar to the combined system of Baker, Edwards-'535, and Chen, such that the use of the same technique in the combined system would have been straightforward and yielded predictable results.
Ex.1002-Decl., ¶171.

5. Claim 12: The method of claim 1, wherein delivering the treatment comprises injuring the at least one tissue.

As explained above for limitation 1[c], Baker in view of Edwards-'535 and Chen discloses ablating target tissue (i.e., *delivering the treatment*) which thereby *injures the tissue* for the same reasons provided above for Ground I-II. A POSITA would have been motivated to combine Baker, Edwards-'535, and Chen in this manner, and would have done so with a reasonable expectation of success, for the same reasons provided above for limitation 1[pre]. *See supra*, §§X.A.4.i. Ex.1002-Decl., ¶172.

6. Claim 14: The method of claim 12, wherein the at least one tissues is selected from the group consisting of cilia, goblet cells, nerves, submucosal tissue, muscle, ligaments, cartilage, tendon, and skin.

As explained for limitation 1[c], the combination of Baker, Edwards-'535, and Chen would have resulted in the combined method delivering ablative RF energy to (and thereby *injuring*; *see* claim 12) *nerves* within and near the inferior turbinate. Ex.1017-Chen, 239-40 (describing treatment using “radiofrequency thermocoagulation of the **posterior inferior nasal nerve, anterior ethmoidal nerve, and inferior turbinate** under nasal endoscopy.”), 240 (“In the inferior turbinate, there are cholinergic nerves and parasympathetic nerve plexus.”). A POSITA would have been motivated to combine Baker, Edwards-'535, and Chen in

this manner, and would have done so with a reasonable expectation of success, for the same reasons provided above for limitation 1[pre]. Ex.1002-Decl., ¶173.

7. **Claim 16: The method of claim 1, wherein delivering the treatment comprises modifying the at least one tissue in a manner that decreases a volumetric rate of mucus production of the mucosal tissue without changing a shape of the mucosal tissue.**

First, as explained above for limitations 1[pre] and 1[c], the combined method of Baker, Edwards-'535, and Chen would have delivered ablative RF energy (i.e., *treatment*) that ablates tissue (i.e., *modifies the at least one tissue*) and thereby *decreases a volumetric rate of mucus production of the mucosal tissue*. Ex.1017-Chen, 240, 243 (“The use of radiofrequency thermocoagulation of the posterior inferior nasal nerve, anterior ethmoidal nerves, and inferior turbinate...can...**reduce the gland secretion**, and...**alleviate or eliminate symptoms such as...nasal congestion[] and runny nose**”). Ex.1002-Decl., ¶174.

Second, the combined method is carried out *without changing a shape of the mucosal tissue* given that Chen’s disclosure, like that of Baker discussed in Ground I, *see supra*, § X.A.4.i, is similar to the ’194 patent’s embodiments where tissue is not reshaped. *Compare* Ex.1017-Chen, 240, 243 (“The use of **radiofrequency thermocoagulation [(i.e., a type of ablation)]** of the posterior inferior nasal nerve, anterior ethmoidal nerves, and inferior turbinate...can...**reduce the gland**

secretion.”) with Ex.1001-USP194, 13:14-19 (“[D]eliver[ing] treatment energy to create specific localized...ablation stimulat[es] the body’s healing response to create desired conformational or structural changes that **reduces the mucus producing ability of the mucus producing cells.”). A POSITA would have been motivated to combine Baker, Edwards-’535, and Chen in this manner, and would have done so with a reasonable expectation of success, for the same reasons provided above for limitation 1[pre]. Ex.1002-Decl., ¶¶175-176.**

8. Claim 18: The method of claim 1, wherein delivering the treatment comprises delivering the treatment to at least one turbinate of the upper airway.

As explained above for limitation 1[c], the combined method of Baker, Edwards-’535, Chen delivers ablative RF energy to the mucosal tissue lining the inferior turbinate and/or nerves within the inferior turbinate, as taught by Chen, and thereby *delivers treatment to at least one turbinate of the upper airway*. Ex.1017-Chen, 239-40; *see also* Ex.1010-Edwards-’535, 1:22-23, 5:18-26 (“Ablative energy 117 is then delivered through the apparatus and the energy delivery device 134 to the nasal [turbinate] 114.”). A POSITA would have been motivated to combine Baker, Edwards-’535, and Chen in this manner, and would have done so with a reasonable expectation of success, for the same reasons provided above for limitation 1[pre]. Ex.1002-Decl., ¶177.

9. **Claim 19: The method of claim 18, wherein the at least one turbinate comprises an inferior turbinate, and contacting the mucosal tissue comprises contacting a posterior aspect of the inferior turbinate.**

As explained above for limitation 1[c] and claim 18, the combined method of Baker, Edwards-'535, Chen delivers treatment to the *inferior turbinate*. Ex.1017-Chen, 239-40; *see also* Ex.1010-Edwards-'535, 1:22-23, 5:18-26, 6:40-42. Ex.1002-Decl., ¶178.

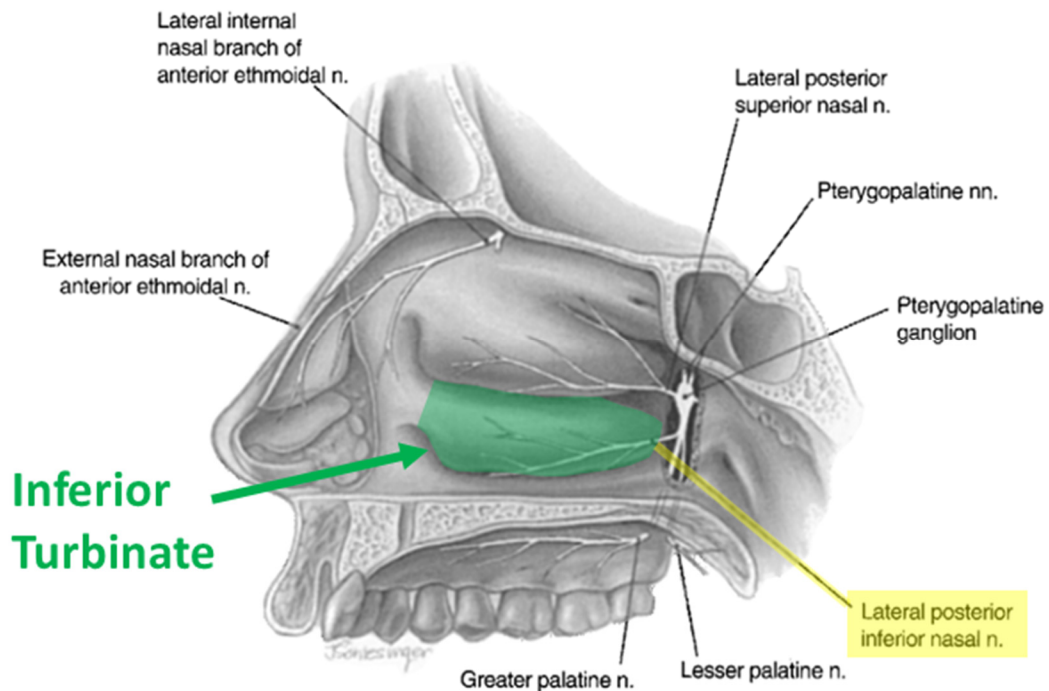
Moreover, as explained for limitation 1[b], the combination of Baker, Edwards-'535, and Chen results in the RF energy delivery device contacting mucosal issue, as the mucosal tissue either (a) is itself the target tissue or (b) overlies nerves that are the target tissue. Moreover, Edwards-'535 and Chen each disclose that the mucosal tissue being contacted is located at the *posterior aspect of the inferior turbinate*. Ex.1010-Edwards-'535, 6:42-47 (“energy may be selectively delivered to the...**posterior sections of the inferior nasal [turbinate].**”); Ex.1017-Chen, 240 (“The treatment for the [posterior inferior nasal nerve] involved placing the probe on the lateral wall of the nasal cavity **between the posterior end of the middle and inferior turbinate, making a strip-shaped thermocoagulation from**

the top to the bottom¹⁸ with a length of about 2.5 cm, a width of 0.5 cm, and a depth up to the bone wall.”). A POSITA would have been motivated to combine Baker, Edwards-’535, and Chen in this manner, and would have done so with a reasonable expectation of success, for the same reasons provided above for limitation 1[pre]. Ex.1002-Decl., ¶179.

Additionally, as explained in Ground II, it would have been obvious to try *contacting a posterior aspect of the inferior turbinate* given that the posterior aspect is one of a finite number of known alternatives (e.g., anterior, middle, and posterior). *See, e.g.*, Ex.1040-Kong, 214 (“the inferior turbinate was divided into two parts, i.e., the anterior and posterior part, or three parts, i.e., the anterior, middle, and posterior part”); Ex.1017-Chen, 240; §X.B.2. For example, a POSITA would have tried

¹⁸ A POSITA would have understood that Chen’s disclosure of delivering ablative RF energy between the posterior ends of the turbinates “from the top to the bottom” at least suggests that RF energy delivery device would have contacted the posterior aspects of the turbinates, particularly given that in the combined method of Baker, Edwards-’535, and Chen, the RF energy delivery device would have been positioned on the surface of Baker’s expandable chamber and thus contacting structures in the vicinity of the target tissue. Ex.1002-Decl., ¶180.

contacting the posterior aspect with a reasonable expectation of success given that the nerve tissue identified by Chen as a promising target for allergic rhinitis runs the length of the inferior turbinate, from the back (posterior) to the front (anterior), such that a POSITA would have reasonably expected to successfully ablate the intended target nerves by contacting the posterior aspect.



Ex.1060-Lane, FIG.4. Ex.1002-Decl., ¶181.

XI. CONCLUSION

The challenged claims of the '194 patent are anticipated and rendered obvious by the prior art grounds set forth herein. Accordingly, Petitioners request institution of an *inter partes* review to cancel these claims.

Respectfully submitted,

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Counsel for Petitioners

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing, Petition for *Inter Partes* Review, contains 13,736 words as measured by the word processing software used to prepare the document, in compliance with 37 C.F.R. § 42.24(d), excluding the parts of the Petition exempted from the word count by 37 C.F.R. § 42.24(a)(1).

/Brian J. Lambson/
Brian J. Lambson
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CERTIFICATE OF SERVICE

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

- Petition for *Inter Partes* Review of U.S. Patent No. 9,415,194
- Petitioners' Table of Exhibits
- Exhibits 1001-1003, 1006-1008, 1010, 1011, 1013, 1017-1019, 1021, 1025-1027, 1029, 1037-1040, 1046-1049, 1055, 1056, 1059, 1060, 1066, and 1070-1080
- Certificate of Compliance Regarding Word Count
- Fee Authorization
- Power of Attorney
- Appendix of Claims

to be served on the Patent Owner's correspondence address listed on Patent Center (Dorsey & Whitney LLP - PA, Intellectual Property Department, 50 South Sixth Street, Suite 1500, Minneapolis, MN 55402-1498, United States) via electronic mail to:

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Petitioners' Table of Exhibits

Exhibit	Description
1001	U.S. Patent No. 9,415,194 (“’194 patent”)
1002	Declaration of Dr. John DelGaudio
1003	File History of U.S. Patent No. 9,415,194
1004-1005	RESERVED
1006	District Court Amended Complaint
1007	Exhibit U to District Court Amended Complaint
1008	Docket Navigator District of Delaware Statistics as of January 18, 2024
1009	RESERVED
1010	U.S. Patent No. 6,517,535 (“Edwards-’535”)
1011	U.S. Patent No. 5,575,788 (“Baker”)
1012	RESERVED
1013	WO 2010/077980 (“Baker-’980”)
1014-1016	RESERVED
1017	Chen et al., “Radiofrequency treatment of nasal posterior-under nerve, ethmoidal nerve and infratubinal for perennial allergic rhinitis under nasal endoscope,” 11:3 China J. Endoscopy 239 (March 2005) (English translation) (“Chen”)
1018	File History of U.S. Patent No. 8,936,594
1019	U.S. Patent App. No. 2007/0219600 (“Gertner”)
1020	RESERVED
1021	U.S. Patent App. No. 2005/0240147 (“Makower”)
1022-1024	RESERVED
1025	U.S. Patent No. 874,178 (“De Forest”)
1026	U.S. Patent No. 3,538,919 (“Meyer”)

Exhibit	Description
1027	U.S. Patent No. 3,117,571 (“Fry”)
1028	RESERVED
1029	Arora et al., Cryodestruction of Vidian Nerve Branches, 32:3 Indian J. Otolaryngology 80 (September 1980) (“Arora”)
1030-1036	RESERVED
1037	Chung, Cough: Causes, Mechanisms and Therapy, Blackwell Publ'g Ltd (2003) (“Chung”)
1038	U.S. Patent No. 6,109,268 (“Thapliyal”)
1039	Banhiran, Quality of life in patients with chronic rhinitis after radiofrequency inferior turbinate reduction, J. Med Assoc Thai, Vol. 93 No.8 (2010) (“Banhiran”)
1040	Kong et al., “Clinical observation on radiofrequency ablation treatment in perennial allergic rhinitis” J. Clin Otorhinolaryngol (China) Vol.19, No.5 (March 2005)(English translation) (“Kong”)
1041-1045	RESERVED
1046	U.S. Patent No. 3,941,121 (“Olinger”)
1047	U.S. Patent No. 4,271,848 (“Turner”)
1048	Nomura et al., Distribution and Clinical Significance of Autonomic Nervous System in the Human Nasal Mucosa, 73 Acta Otolaryng 493 (1972). (“Nomura”)
1049	Akiyoshi Konno, Historical, Pathophysiological, and Therapeutic Aspects of Vidian Neurectomy, 10 Curr Allergy Asthma Rep 105 (2010). (“Konno”)
1050-1054	RESERVED
1055	Fang et al., Nasal endoscopy combined with multiple radiofrequency for perennial allergic rhinitis, 25:7 J. First Mil Med Univ 876 (2005) (English translation) (“Fang”)
1056	Liang et al., Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy, 13:8 J. Clin

Exhibit	Description
	Otorhinolaryngol (China) 341 (August 1999) (English translation) (“Liang”)
1057-1058	RESERVED
1059	Chinese Patent No. 2225227 (English translation) (“Liang ’227”)
1060	Andrew P. Lane, Nasal anatomy and physiology 12 Facial Plast Surg Clin N Am 387 (2004) (“Lane”)
1061-1065	RESERVED
1066	U.S. Patent App. No. 2004/0230188 (“Cioanta”)
1067-1069	RESERVED
1070	Declaration of June Munford
1071	Translator Declaration for Chen
1072	Translator Declaration for Liang
1073	Translator Declaration for Fang
1074	Translator Declaration for Kong
1075	Munford Appendices for Chen
1076	Munford Appendices for Liang
1077	Munford Appendices for Fang
1078	Munford Appendices for Kong
1079	Additional Appendices to Munford Declaration
1080	Translator Declaration for Liang ’227

Appendix of Claims

Claim 1	
Limitation	Claim Language
1[pre]	1. A method for reducing mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough, the method comprising:
1[a]	advancing a treatment delivery portion of an energy-based treatment device into a nostril of the patient;
1[b]	contacting mucosal tissue of the upper airway with the treatment delivery portion, without piercing the mucosal tissue; and
1[c]	delivering a treatment from the treatment delivery portion to at least one tissue selected from the group of the mucosal tissue and another tissue underlying the mucosal tissue to modify a property of the at least one tissue and thus treat at least one of post nasal drip or chronic cough in the patient.

Claim 2

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

Claim 3

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

Claim 2

The method of claim 1, wherein the treatment is delivered without forming an incision in the mucosal tissue and without delivering an implant.

Claim 3

The method of claim 1, wherein delivering the treatment comprises delivering energy from the delivery treatment portion in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light and laser energy.

Claim 6

The method of claim 3, wherein the at least one tissue comprises nerve tissue underlying the mucosal tissue, and wherein delivering the energy comprises ablating the nerve tissue.

Claim 12

The method of claim 1, wherein delivering the treatment comprises injuring the at least one tissue.

Claim 14

The method of claim 12, wherein the at least one tissues is selected from the group consisting of cilia, goblet cells, nerves, submucosal tissue, muscle, ligaments, cartilage, tendon, and skin.

Claim 16

The method of claim 1, wherein delivering the treatment comprises modifying the at least one tissue in a manner that decreases a volumetric rate of mucus production of the mucosal tissue without changing a shape of the mucosal tissue.

Claim 18

The method of claim 1, wherein delivering the treatment comprises delivering the treatment to at least one turbinate of the upper airway.

Claim 19

The method of claim 18, wherein the at least one turbinate comprises an inferior turbinate, and contacting the mucosal tissue comprises contacting a posterior aspect of the inferior turbinate.