

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. IPR2024-00275

U.S. Patent No. 9,072,597

**PETITION FOR *INTER PARTES* REVIEW
OF CLAIMS 9, 14, 16, 18, 20, 22-24, 44 and 46 OF
U.S. PATENT NO. 9,072,597
UNDER 35 U.S.C. §312 AND 37 C.F.R. §42.104**

Table of Contents

I.	INTRODUCTION	1
II.	MANDATORY NOTICES	2
	A. Real Parties in Interest.....	2
	B. Related Matter	2
	C. Counsel	3
	D. Service Information	3
III.	CERTIFICATION OF GROUNDS FOR STANDING	4
IV.	OVERVIEW OF CHALLENGE AND RELIEF REQUESTED	4
	A. Prior Art.....	5
	B. Discretionary Denial Is Not Warranted.....	6
	C. Grounds for Challenge	11
V.	TECHNOLOGY BACKGROUND.....	12
	A. Anatomy of the Nose.....	12
	B. Energy Based Therapy	13
	C. Applying Energy To The Nose	13
	D. Energy Delivery Devices	13
VI.	THE '597 PATENT.....	15
	A. Brief Description	15
	B. Prosecution History	17
VII.	PERSON OF ORDINARY SKILL IN THE ART	19
VIII.	CLAIM CONSTRUCTION	20
IX.	OVERVIEW OF THE ASSERTED PRIOR ART	20
	A. Gertner	20
	B. Edwards-'535	21
	C. Baker.....	22
X.	SPECIFIC GROUNDS FOR UNPATENTABILITY	25
	A. Ground I: Claims 9, 14, 18, 20, 22-24, 44, and 46 Are Anticipated by Gertner	25

B.	Ground II: Claims 9, 14, 16, 18, 20, 22, 23, 44, and 46 Are Anticipated by Edwards-'535.....	43
C.	Ground III: Claim 16 Is Obvious Over Edwards-'535	61
D.	Ground IV: Claims 9, 14, 16, 18, 20, 22-24, 44, and 46 Are Anticipated by Baker.....	64
E.	Ground V: Claim 14 Is Obvious Over Baker.....	91
XI.	CONCLUSION.....	93

TABLE OF AUTHORITIES

CASES

	Page(s)
<i>Advanced Bionics v. MED-EL</i> , IPR2019-01469 (P.T.A.B. Feb. 13, 2020)	7, 9, 10
<i>Amazon.com, Inc., v. M2M Solutions LLC</i> , IPR2019-01205, 2020 WL 44835 (P.T.A.B. Jan. 27, 2020)	9
<i>Apple Inc. v. Fintiv, Inc.</i> , IPR2020-00019 (P.T.A.B. May 13, 2020)	6
<i>Blue Calypso, LLC v. Groupon, Inc.</i> , 815 F.3d 1331 (Fed. Cir. 2016)	43, 61, 91
<i>Mylan Pharm. Inc., v. Merck Sharp & Dohme Corp.</i> , No. IPR2020-00040, 2020 WL 2478503 (P.T.A.B. May 12, 2020)	10
<i>Peloton Interactive, Inc. v. iFIT Inc. f/k/a ICON Health & Fitness, Inc.</i> IPR2022-00030, Paper 12 (P.T.A.B. April 22, 2020)	8
<i>Sonos, Inc. v. Google LLC f/k/a Google Inc.</i> , IPR2023-00118, Paper 9 (P.T.A.B. May 19, 2023)	8

STATUTES AND REGULATIONS

37 C.F.R.	
§42.8	2
§42.104	4
35 U.S.C.	
§102	5, 11
§103	11
§314(a)	6
§325(d)	6, 9

I. INTRODUCTION

Claims 9, 14, 16, 18, 20, 22-24, 44 and 46 (“challenged claims”) of U.S. Patent No. 9,072,597 (“’597 patent”) are directed to “treating a patient’s nasal airway” using the following steps: (1) “adjusting a shape of...[a] treatment device,” (2) “contacting...tissue” with part of the device, (3) “delivering an energy based therapy,” and (4) “removing” the device. Ex.1001-USP597, Clm.9. The challenged claims recite only simple, well-known steps. They omit limitations that Aerin Medical Inc. (“Patent Owner,” “PO,” or “Aerin”) had previously relied upon to distinguish similar claims of the ’597 patent’s parent application from Gertner, one of the anticipation references in this Petition. Despite these omissions, the challenged claims were never rejected over Gertner or any other prior art, and no reasons for allowance were provided. In short, the challenged claims do not recite any limitations identified by Aerin or the examiner as having purported novelty. Accordingly, as detailed in Ground I, the challenged claims are anticipated by the same reference, Gertner, that the examiner had initially identified as anticipating the claims of the parent application.

More generally, the claimed “energy based therapy”—which can include any of light, ultrasound, and or radiofrequency energy therapy, among others (*see* Claim 18)—was well known. As set forth in this Petition, multiple prior art references

disclose the claimed energy based therapy as well as each of the remaining claim limitations, rendering the challenged claims unpatentable.

II. MANDATORY NOTICES

A. Real Parties in Interest

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

B. Related Matter

Pursuant to 37 C.F.R. §42.8(b)(2), Petitioners submit that Patent Owner has asserted five patents, including the '597 patent, in *Aerin Medical Inc. and The Foundry LLC v. Neurent Medical Inc. and Neurent Medical Ltd.*, Case No. 1:23-cv-00756-JLH (D. Del). Three other patents owned by The Foundry LLC 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.
9,415,194	Aerin Medical Inc.	IPR2024-00276
11,241,271	Aerin Medical Inc.	IPR2024-00277
11,033,318	Aerin Medical Inc.	IPR2024-00278
10,610,675	The Foundry LLC	IPR2024-00279
10,894,011	The Foundry LLC	IPR2024-00280
11,679,077	The Foundry LLC	IPR2024-00281

Challenged Patent	Patent Owner	Case No.
11,766,286	Aerin Medical Inc.	IPR2024-00282

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III. CERTIFICATION OF GROUNDS FOR STANDING

Petitioners certify under 37 C.F.R. §42.104(a) that the '597 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 9, 14, 16, 18, 20, 22-24, 44, 46 (“challenged claims”) of the '597 patent.

A. Prior Art

The '597 patent was filed on June 30, 2014, and claims a priority date of June 14, 2011.¹ Ex.1001-USP597, Cover. Petitioners rely upon the documents in the Table of Exhibits, including:

1. **USPA 2007/0219600** (“Gertner”), Ex.1019-Gertner, published September 20, 2007, and filed August 24, 2006, 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. **WO Publication No. 2010/077980** (“Baker”), Ex.1013-Baker, published July 8, 2010, and filed December 16, 2009, as §§102(a)(1) and 102(a)(2) prior art.

¹ Petitioners assume for purposes of this Petition that the '597 patent is entitled to the claimed priority date but reserve the right to argue in the parallel litigation that it is not.

² The '597 patent was examined under the provisions of the AIA, but each of the relied-upon references qualifies as prior art regardless of whether the AIA or pre-AIA provisions apply.

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 five Grounds.

Second, as detailed below, none of references in the Grounds presented in this petition have been previously applied to the claims during the prosecution of the '597 patent. One reference, Gertner, was applied during prosecution of the **parent** application, but PO argued patentability based on a limitation which is not present in the allowed claims of the '597 patent and the record is devoid of any indication why challenged claims of the '597 patent are patentable over Gertner.

1. Gertner

Gertner is of record, having been cited during prosecution of the continuation-in-part parent of the '597 patent. However, the examiner committed a material error by allowing the challenged claims over Gertner, and therefore discretionary denial

is not warranted. *See Advanced Bionics, LLC v. MED-EL Elektromedizinische Gerate GmbH*, IPR2019-01469, 2020 WL 740292, at *4 (Feb. 13, 2020).

As explained in Section VI.B, *infra*, the examiner relied on Gertner to reject certain claims of the parent of the '597 patent. PO distinguished Gertner solely on the basis of a specific limitation of the parent's claims—"applying [a] treatment surface to the nasal tissue with sufficient force to alter a shape of the nasal tissue"—that is **not** recited in the '597 patent's claims. Ex.1018-US594FH, 262. No further discussion of Gertner appears in the '597 prosecution history, and no reasons for allowance were provided in either the parent's or the '597 patent's respective notices of allowance. Ex.1018-US594FH, 273-277; Ex.1003-US597FH, 276-281.

Moreover, as further explained in Section VI.B, *infra*, the examiner cited a different embodiment of Gertner (Figure 2A) than the one Petitioners rely on in Ground I (Figure 4A). One difference between these embodiments is the use of an "expandable balloon," which is depicted in Figure 4A but not in Figure 2A. As explained in Ground I, Gertner's teachings in connection with Figure 4A's expandable balloon disclose the limitation of "*adjusting a shape of a treatment device*," as recited by challenged claim 9. However, the parent application's claims did not recite the limitation of "*adjusting a shape of a treatment device*." The examiner found that those claims were anticipated solely in view of Gertner's Figure

2A embodiment and has not otherwise relied on the Figure 4A embodiment as the basis for any rejection during prosecution. Accordingly, the examiner's silence regarding Gertner's Figure 4A embodiment, including its relevance to the new limitation of "*adjusting a shape of a treatment device*," further demonstrates material error.

Thus, neither the '597 patent's prosecution history nor that of its parent articulate the examiner's basis for allowing the challenged claims over Gertner. The Board has routinely found material error under these circumstances. *See Peloton Interactive, Inc. v. iFIT Inc. f/k/a ICON Health & Fitness, Inc.* IPR2022-00030, Paper 12 at 14 (P.T.A.B. April 22, 2020) (finding material error where "the apparent reason for allowing the [parent application's claims] does not apply to the [challenged] claims"); *Sonos, Inc. v. Google LLC f/k/a Google Inc.*, IPR2023-00118, Paper 9 at 28 (P.T.A.B. May 19, 2023) (finding material error where a reference that had a "prominent role" during prosecution of the parent application was not applied to the challenged claims). Additionally, the other references applied in the Grounds demonstrate ample basis to merit institution.

2. Edwards-'535

Edwards-'535 is not of record in the '597 patent. Further, no reference containing the relied upon teachings of Edwards-'535 was applied to the challenged claims during prosecution.

a. USP 5,800,429

Edwards-'535 is a continuation-in-part of USP 5,800,429, which was cited in an IDS during prosecution but was buried among 85 other references and was not discussed in any meaningful regard on the record. *See infra* §VI.B. Therefore, even if PO argues that Edwards-'535 is substantially the same as its CIP parent, the Board has made clear that “[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....” *Advanced Bionics* at *4 (emphasis added); *see also Amazon.com, Inc., v. M2M Solutions LLC*, IPR2019-01205, 2020 WL 44835, at *7 (P.T.A.B. Jan. 27, 2020).

Moreover, as presented herein, Edwards-'535 discloses the limitations of each of the challenged claims. *See infra* §X.B. To the extent the same teachings exist in USP 5,800,429, the examiner committed a material error by overlooking those teachings, even if it could be argued that USP 5,800,429 was considered. 35 U.S.C. §325(d); *Advanced Bionics* at *3.

The Board has previously instituted review under these circumstances, and Petitioners respectfully request that it do so again here. *See, e.g., Mylan Pharm. Inc., v. Merck Sharp & Dohme Corp.*, No. IPR2020-00040, 2020 WL 2478503, at *7 (P.T.A.B. May 12, 2020) (instituting review even though “WO ’498 was presented to the Examiner” because the “Examiner never discussed WO ’498 or made a rejection based on it” and “gave no reasons for allowance” even though the “disclosure meets the claimed invention” and “[t]he likeliest explanation ... is that the Examiner simply overlooked [its] teachings”); *see also Advanced Bionics*, 2020 WL 740292, at *3 n.9 (“An example of a material error may include misapprehending or overlooking specific teachings of the relevant prior art where those teachings impact patentability of the challenged claims.”).

b. Other Cited References

Edwards-’535 shares a named inventor with many other references that were cited (but not discussed) during prosecution. Ex.1003-US597FH, 164-169 (IDS citing over 20 references with first inventor named Edwards-’535). Edwards-’535 also shares a named inventor with USP 6,416,491, which the examiner relied upon to reject only certain non-challenged claims during prosecution. However, these other references are in different patent families from Edwards-’535 and contain distinct teachings. Moreover, with the exception of USP 6,416,491, they were not

discussed during prosecution, so even if PO argues that they contain the same or similar teachings, the record's silence as to these references demonstrates material error. *See supra* §§IV.B.2.a.

C. Grounds for Challenge

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

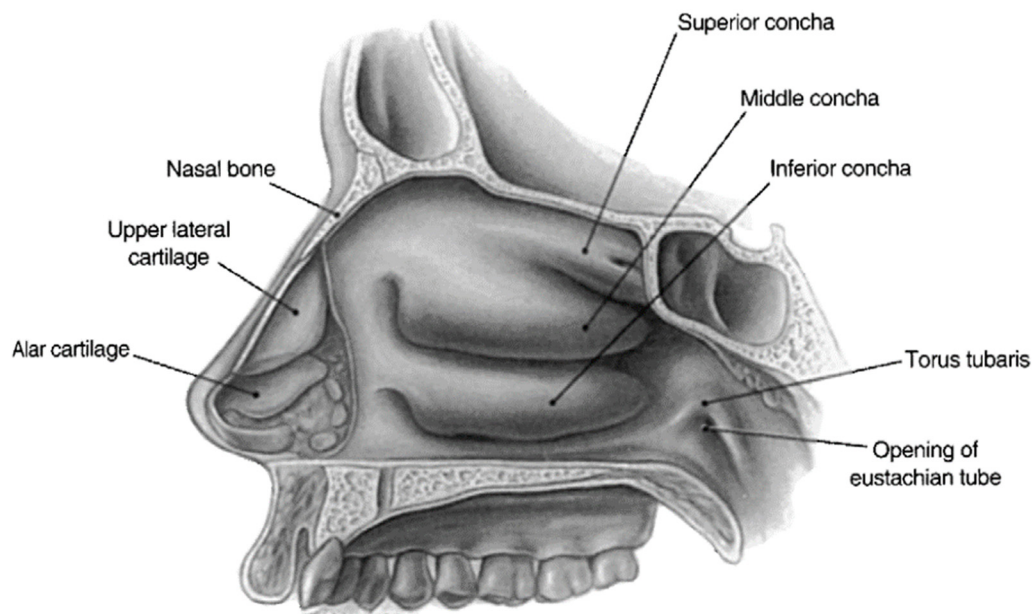
Ground	35 U.S.C. §	Claims	References
I	102	9, 14, 16, 18, 20, 22-24, 44, 46	Gertner
II	102	9, 14, 18, 20, 22, 23, 44, 46	Edwards-'535
III	103	16	Edwards-'535
IV	102	9, 14, 16, 18, 20, 22-24, 44, 46	Baker
V	103	14	Baker

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., ¶¶30-31.

B. Energy Based Therapy

Applying energy to tissue to treat a medical condition has been known for over a century. *E.g.*, Ex.1025-De Forest, 1:14-23 (patent issued in 1907 disclosing the use of “high frequency electrical current passing into a [human] body” for cauterization). Other known energy based therapies used light energy, Ex.1026-Meyer, 1:35-40, sound energy, Ex.1027-Fry, 1:67-70, radiofrequency energy, Ex.1046-Olinger, 3:32-40, and microwave energy, Ex.1047-Turner, 5:55-6, to treat various tissues. Ex.1002-Decl., ¶32.

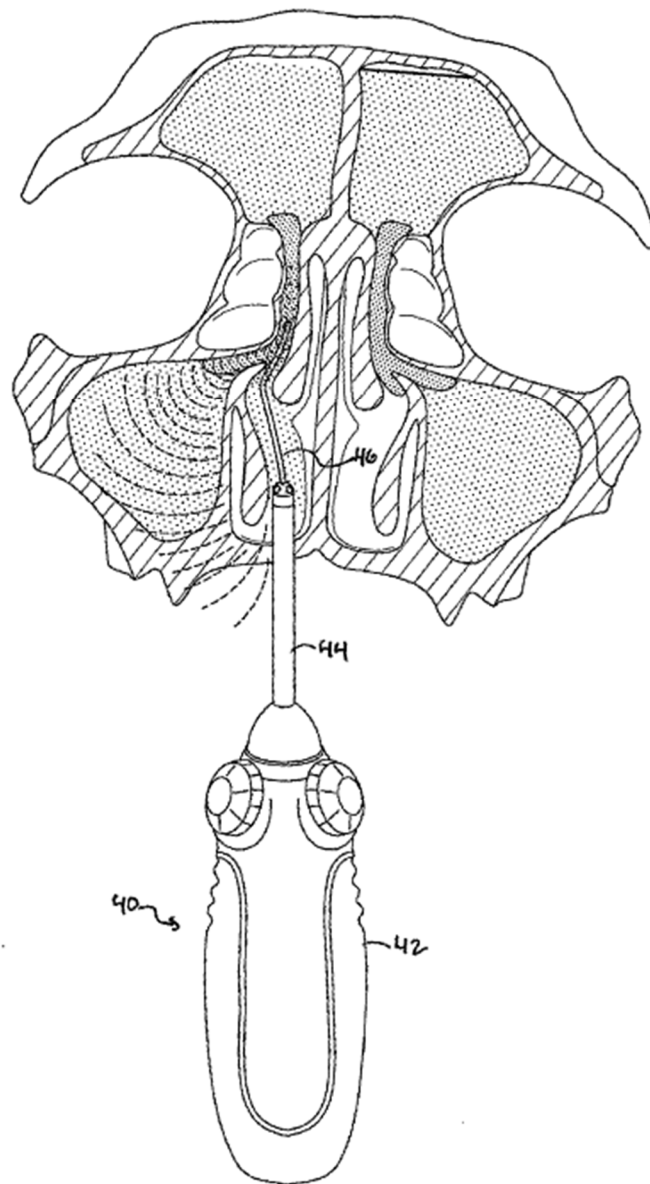
C. Applying Energy To The Nose

Applying energy to the nose was also well-known long before 2011, having been used to treat a wide range of conditions including sinusitis, Ex.1021-Makower, Abstract, rhinitis, Ex.1017-Chen, 239-40, and other airway obstructions, Ex.1010-Edwards-’535, 4:19-32, 5:33-35. Not only was applying energy inside the nose to treat different conditions known before 2011, it was also known to apply energy to specific structures within the nose including “mucous membranes and nasal turbinates” to treat such conditions. Ex.1013-Baker, 17:11-13. Ex.1002-Decl., ¶33.

D. Energy Delivery Devices

By 2011, a wide variety of designs for energy based treatment devices were well known. For example, it was well known that flexible/articulate shafts could

be used to position the energy delivery device, especially inside the nose. *See, e.g.*, Ex.1021-Makower, [0186]; Ex.1013-Baker, Abstract, 16:19-32, 22:10-25. One illustration, Figure 8C of Baker, reproduced below, depicts an energy delivery member 46 being extended to deliver acoustic energy to an obstruction within nasal passages.



Ex.1013-Baker, FIG.8C; *see also id.* 25:5-12. Ex.1002-Decl., ¶34.

Likewise, the use of inflatable balloons to hold the energy delivery device in place, focus energy on target tissue, extrude fluid, and/or cool tissue was also well known. Ex.1010-Edwards-'535, 5:18-34, 6:10-37, FIGs.3A-3B; Ex.1019-Gertner, [0107], [0109], [0111], FIG.10. Ex.1002-Decl., ¶35.

VI. THE '597 PATENT

A. Brief Description

The '597 patent is directed to “treating structures within the nose and upper airway” to “improve airflow.” Ex.1001-USP597, 1:26-32. Figure 3 depicts a treatment device 30 with “a treatment element 32...to be placed inside the nasal cavity.” *Id.*, 15:45-49.

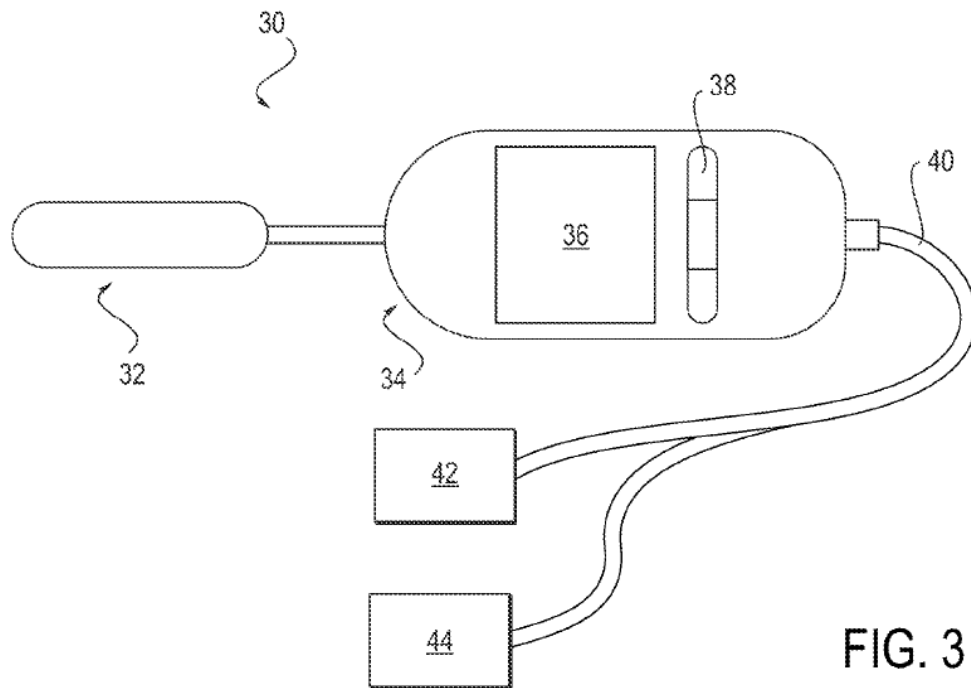


FIG. 3

Id., FIG.3. Ex.1002-Decl., ¶36.

The '597 patent discloses various configurations for the treatment element, including those that include a flexible shaft, Ex.1001-USP597, 28:66-67, or an inflatable balloon, shown in Figure 4B below, *id.*, 14:4-10.

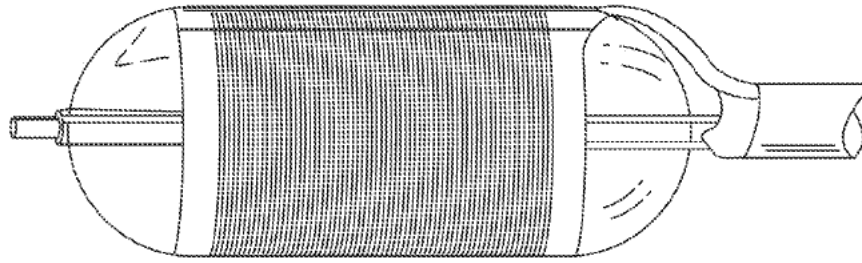


FIG. 4B

Id., FIG.4B. Ex.1002-Decl., ¶37.

According to the '597 patent, applying energy can modify tissue without changing its shape. Ex.1001-USP597, 20:65-21:2. The '597 patent discloses many types of energy that can be used (e.g., radiofrequency, light, or ultrasound), and does not express a preference for one over another. Ex.1001-USP597, 14:53-67. The challenged independent claims likewise do not specify any particular type of energy. Ex.1002-Decl., ¶¶38-39.

B. Prosecution History

The '597 patent was subject to an abbreviated examination in which the challenged claims received no substantive rejection based on prior art. The only rejection was based on double patenting over the allowed claims of a parent

application, Ex.1003-US597FH, 238-239, which PO overcame by filing a terminal disclaimer, *id.*, 258-268.³ The subsequent notice of allowance did not identify examiner's reasons for allowance. *Id.*, 276-281. Ex.1002-Decl., ¶¶40-42.

During prosecution of the **parent** patent application, the examiner rejected claims substantially similar to the challenged claims of the '597 patent as being anticipated by Gertner. Ex.1018-US594FH, 246-247; *see also* Ex.1003-US597FH, 238-239 (double patenting rejection identifying challenged claims as being an obvious variation of the parent'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, 267-268. PO did not otherwise

³ The examiner also initially rejected certain device claims (not challenged here) of the as-filed application over USP 6,416,491. Ex.1003-US597FH, 240-241. However, PO overcame the rejection without making any arguments, instead amending the rejected independent claims to recite subject matter of dependent claims that the examiner deemed allowable. *Id.*, 262-263, 265-266. As such, the record is also limited as to the examiner's application of USP 6,416,491 to the '597 patent claims. Ex.1002-Decl., ¶¶40-42.

contest the examiner's reliance on Gertner. *Id.*, 266-270. The examiner subsequently allowed the parent's claims without stating the reasons for allowance. *Id.*, 273-277. Ex.1002-Decl., ¶43.

The challenged claims of the '597 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 to obtain allowance of the parent application, the sparse record of the '597 patent's examination provides no insight into why the challenged claims were allowed over Gertner. Moreover, as demonstrated in the grounds below, Gertner anticipates each of the challenged claims, and two other references that were not addressed during prosecution, Edwards-'535 and Baker, also render the challenged claims unpatentable. Ex.1002-Decl., ¶¶44-45.

VII. PERSON OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art (“POSITA”) at relevant times (2005-2014) 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., ¶54.⁴

IX. OVERVIEW OF THE ASSERTED PRIOR ART

A. Gertner

Gertner discloses techniques for “providing therapeutic light to a target region of tissue within a nasal cavity.” Ex.1019-Gertner, Abstract, [0003] (describing light as a type of “energy”). Referring to Figure 4A, reproduced below, Gertner discloses a therapy device 200 with a distal end 216 that applies light energy through an expandable component 218 to the nasal cavity 10. *Id.*, [0106], [0107].

⁴ 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.

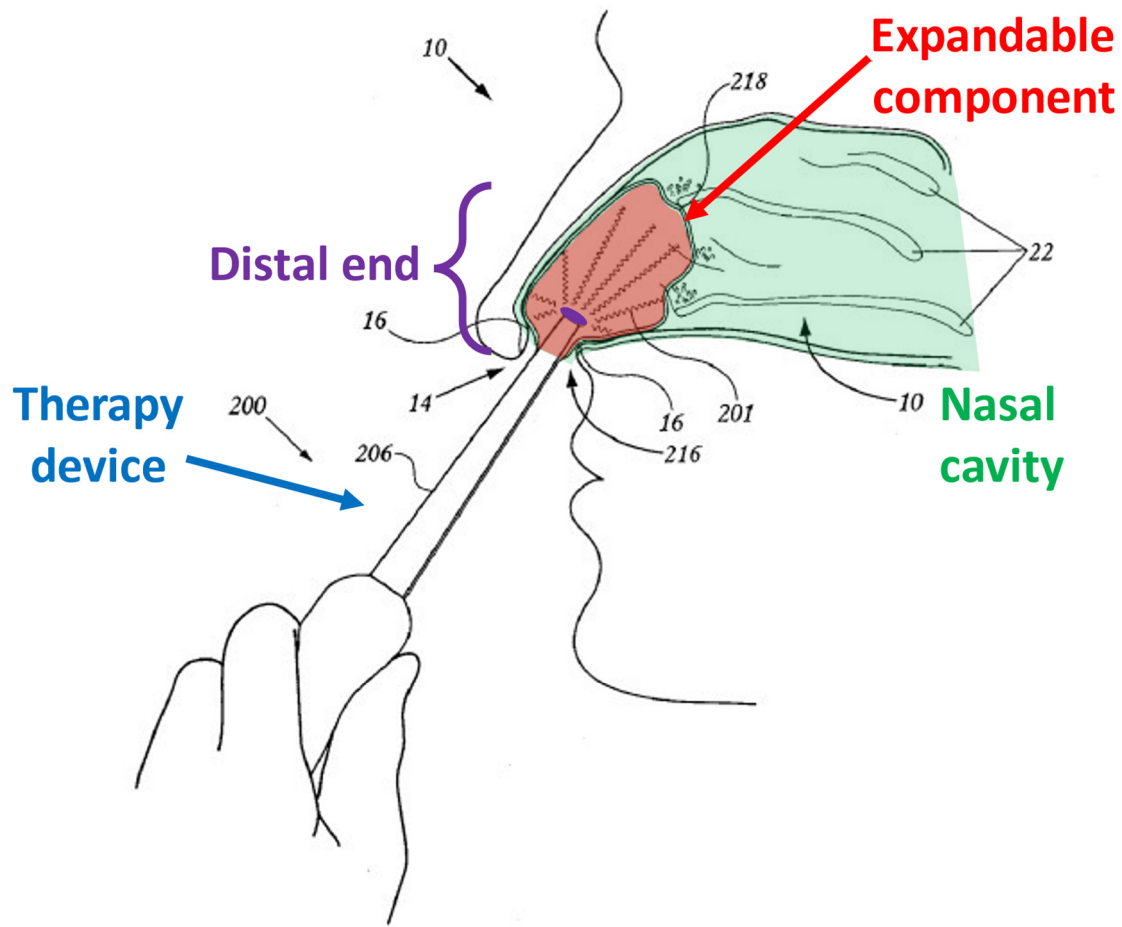


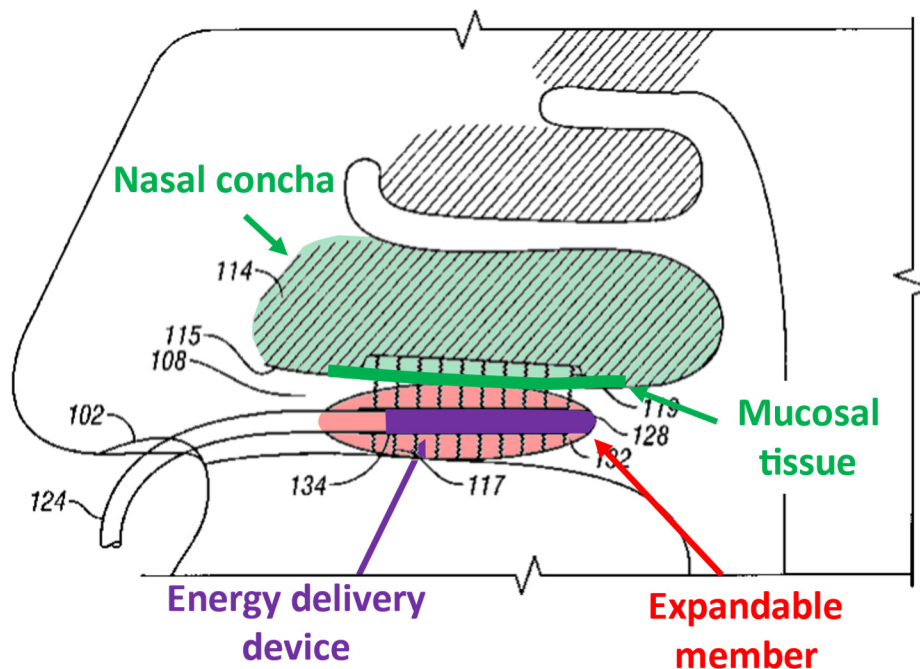
FIG. 4A

Id., FIG.4A. Ex.1002-Decl., ¶46.

B. Edwards-'535

Edwards-'535 discloses techniques for treating upper airway conditions using devices and methods that deliver RF energy to tissue within the nasal passages. 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.” *Id.*, 5:18-45, 8:18-25, 8:51-53.



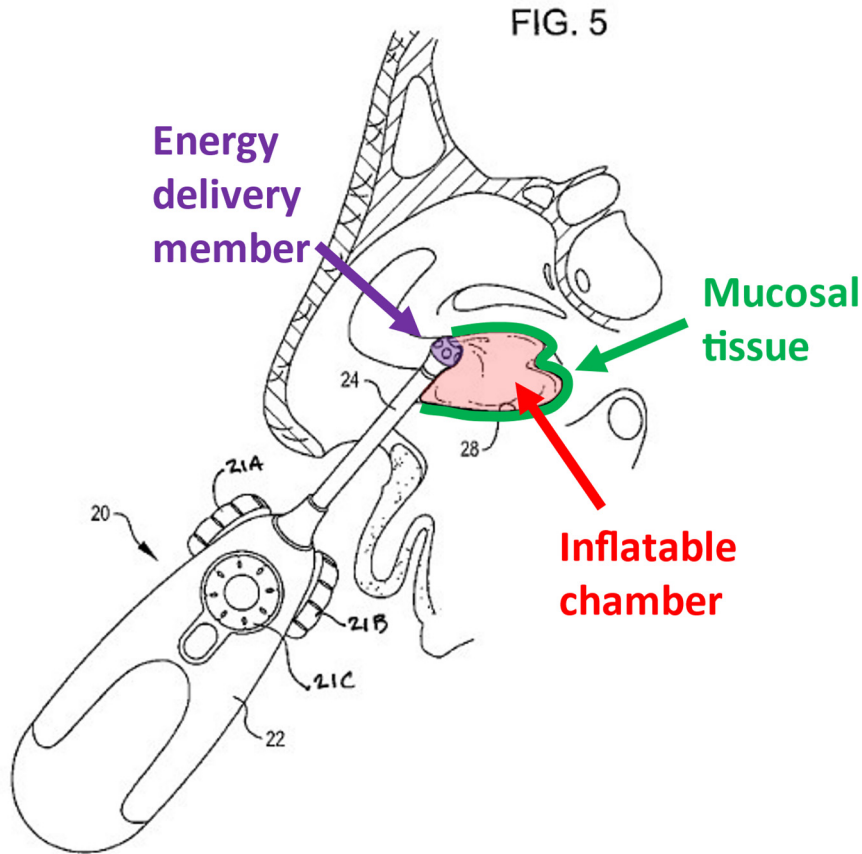
Id., FIG. 3B. Ex.1002-Decl., ¶47.

C. Baker

Baker is directed to techniques for treating upper airway conditions, such as allergic rhinitis, and their symptoms. Ex.1013-Baker, 26:7-11 (“The methods and

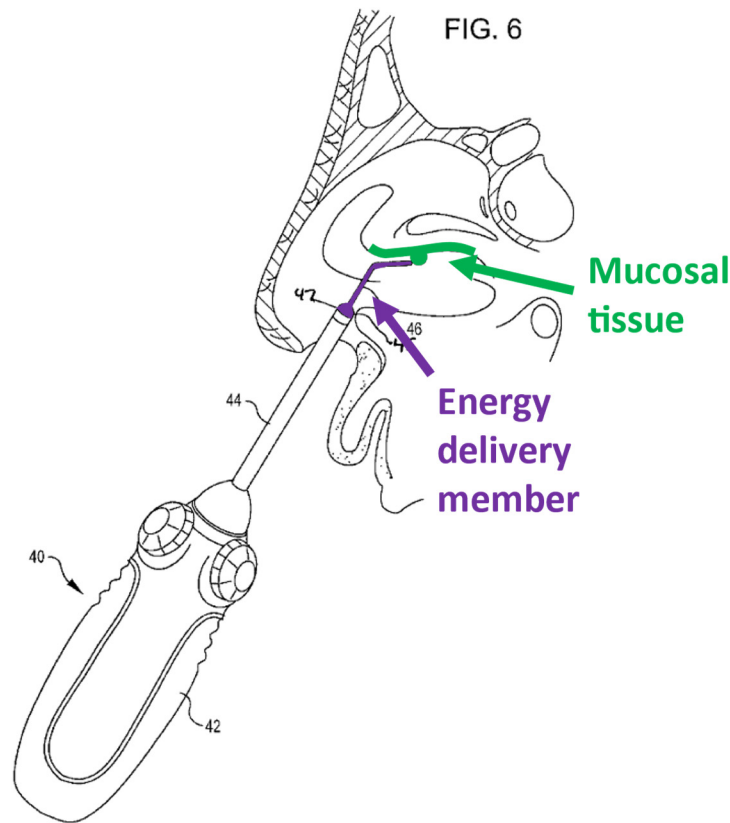
devices may be used for treating common colds, nasal congestion and allergic rhinitis, as well as sinusitis and other nasal conditions”), 1:25-29 (“Symptoms of rhinitis include runny nose, nasal congestion and post-nasal drip”). Baker’s treatment techniques include delivering forms of energy based therapy. For example, Baker discloses inserting a device into a patient’s nostril to “deliver ... acoustic energy ... directly to tissue surfaces ... in nasal passages.” *Id.*, 7:18-21. Ex.1002-Decl., ¶48.

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 (“an **energy delivery member** may comprise a flexible, **deformable bladder or inflatable chamber 28** adapted for retaining an acoustically transmissive material.... The bladder or inflatable member(s) ... provides a flexible surface that is expandable and deformable to conform to contours of ... intranasal passages”). Ex.1002-Decl., ¶49.

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 (“The **energy delivery member** may be extendible and/or retractable with respect to handle 42 and/or insertion member 44 to provide desired positioning of the **energy delivery member** in contact with obstructions and/or **tissues** for delivery of high frequency acoustic energy.”).

Ex.1002-Decl., ¶50.

X. SPECIFIC GROUNDS FOR UNPATENTABILITY

A. Ground I: Claims 9, 14, 18, 20, 22-24, 44, and 46 Are Anticipated by Gertner

As explained in Section VI.B, PO and the patent office have already recognized that Gertner is highly relevant to the challenged claims, and although PO

distinguished Gertner’s teachings during prosecution of the ’597 patent’s parent application, the challenged claims do not recite the limitations that PO identified as being distinct. Ex.1018-US594FH, 261-270. Without those limitations, the challenged claims are anticipated by Gertner, as set forth below. Ex.1002-Decl., ¶56.

1. Claim 9

**a. Element 9

```
[pre]: A method of treating a patient’s nasal airway
```**

If the preamble is limiting, Gertner discloses *a method of treating a patient’s nasal airway*⁵ (e.g., a nasal cavity). Ex.1002-Decl., ¶57.

Gertner discloses a method for using a therapy device 200 to “provide therapeutic light to a target region of tissue within a nasal cavity.” Ex.1019-Gertner, [0103]; *see also id.*, [0003] (describing light as a form of “energy”), [0013]-[0018], FIG.4A. The light therapy is used to treat medical conditions in the patient’s nasal airway such as, for example, rhinitis. *Id.*, Abstract, [0007]-[0010], [0042], [0066], [0103]. Ex.1002-Decl., ¶58.

⁵ Apart from citations, italicized text corresponds to claim language unless otherwise noted.

b. Element 9[a]: adjusting a shape of a nasal airway treatment device

Gertner discloses *adjusting a shape* (e.g., expanding **expandable component 218**) of a nasal airway treatment device (e.g., therapy device 200). Ex.1002-Decl., ¶59.

Gertner discloses that therapy device 200 has a **distal end 216** used to apply the light therapy to a portion of a **nasal cavity 10**. Ex.1019-Gertner, [0106], [0109], FIG.4A. As discussed above for limitation 9[pre], Gertner discloses that the therapeutic light is for treatment of a nasal airway, and accordingly, therapy device 200 would have been understood as a *nasal airway treatment device*. Ex.1002-Decl., ¶60.

Gertner further discloses that an **expandable component 218** (e.g., a fillable balloon) is positioned at the **distal end 216** and helps “hold[] the therapy device in place...while the phototherapy is being delivered.” Ex.1019-Gertner, [0103], [0106], [0107], [0111] (“the balloon is placed at the region of the limen nasi and then expanded with a fluid” such that “the balloon conforms to the anterior portion of the nasal cavity.”), FIG.4A. The use of **expandable component 218** allows the user to make further adjustments to the shape of treatment device to facilitate delivery of light therapy. *Id.*, [0103] (“When expended [*sic*: expanded], the expandable component...facilitate[s] positioning of the distal end....Because the

expandable component 218 grips the walls of the nasal cavity, the therapy device can pivot and deliver light to various parts of the nasal cavity 10.”), [0107]. In fact, Gertner’s disclosure of an expandable balloon that can adjust the shape of the device is identical to one of the ’597 patent’s corresponding embodiments. *E.g.*, Ex.1001-USP597, 7:5-8 (“[A]djusting the shape may involve inflating the treatment element to increase a surface area of the treatment element.”). Thus, Gertner discloses *adjusting a shape* of the therapy device by expanding the **expandable component 218**.

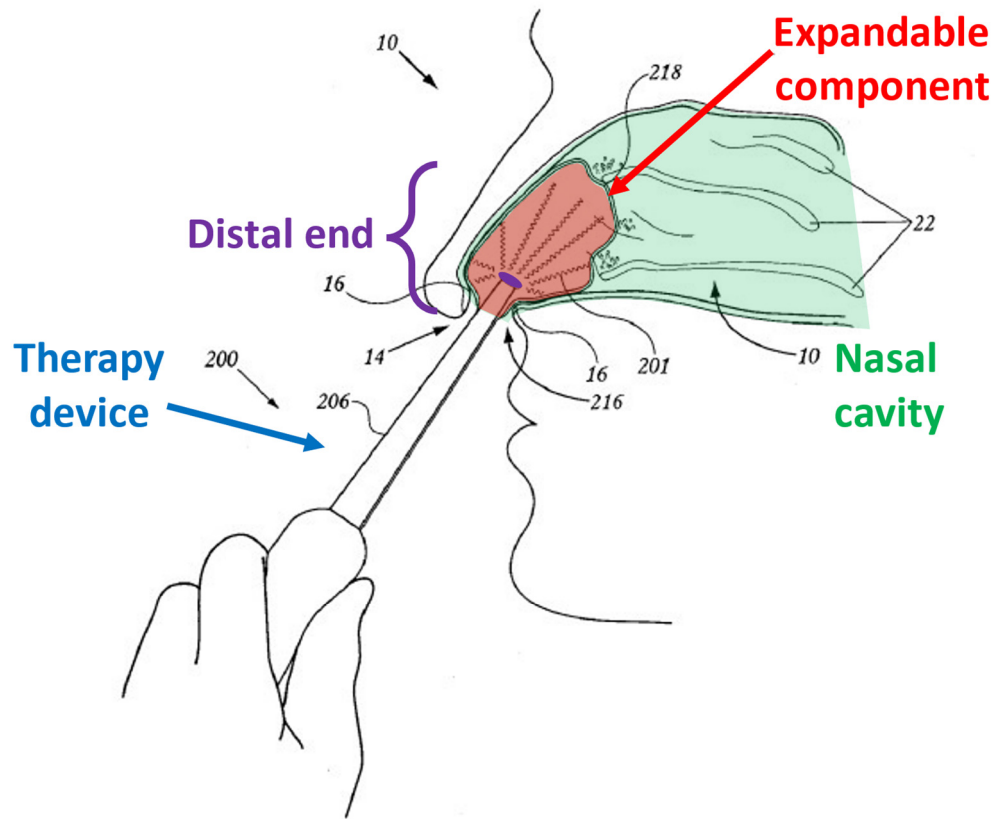


FIG. 4A

Ex.1019-Gertner, FIG.4A. Ex.1002-Decl., ¶¶61-62.

- c. **Element 9[b]: contacting a treatment element of the treatment device with mucosal tissue in the patient's nasal airway;**

Gertner discloses *contacting a treatment element* (e.g., distal end 216 of therapy device 200, including a light emitter and expandable component 218) of the treatment device (e.g., therapy device 200) with mucosal tissue (e.g., tissue within a nasal cavity 10) in the patient's nasal airway. Ex.1002-Decl., ¶63.

As explained above for limitations 9[pre] and 9[a], Gertner discloses a *treatment device* (e.g., therapy device 200) with a **distal end 216** that emits light and includes an **expandable component 218**. Gertner further discloses the **distal end 216** emits light from “within” the **expandable component 218**, such that the light emitter and **expandable component 218** (which together constitute **distal end 216**) act as a *treatment element*. Ex.1019-Gertner, [0103], [0106]-[0107]. Ex.1002-Decl., ¶64.

As shown in Figure 4A, reproduced below, **expandable component 218** (i.e., part of the *treatment element*) *contacts mucosal tissue* lining the nasal passages, including when it “holds the therapy device in place in a space between a nasal septum and a lateral wall of the nasal cavity,” “grips the walls of the nasal cavity,” and/or “expand[s] the limen nasi 16 or other portions of the nasal cavity by either an expanding or wedging action.” Ex.1019-Gertner, [0037], [0103], FIGs.1A, 4A. Similarly, Gertner discloses that “light reaches the turbinates 22,” which, as shown in Figure 4A, are also contacted by the **expandable component 218**. *Id.*, [0108], FIG.4A; *see also id.*, [0037] (describing turbinates lined with “overlying mucosa”). Thus, as shown in Figure 4A, the **expandable component 218** *contacts mucosal tissue* of the **limen nasi 16**, the **nasal cavity**, and the **turbinates 22**, as well as the nasal septum (which forms the wall of the nasal cavity opposite **turbinates 22**), all of which are in the patient’s nasal airway.

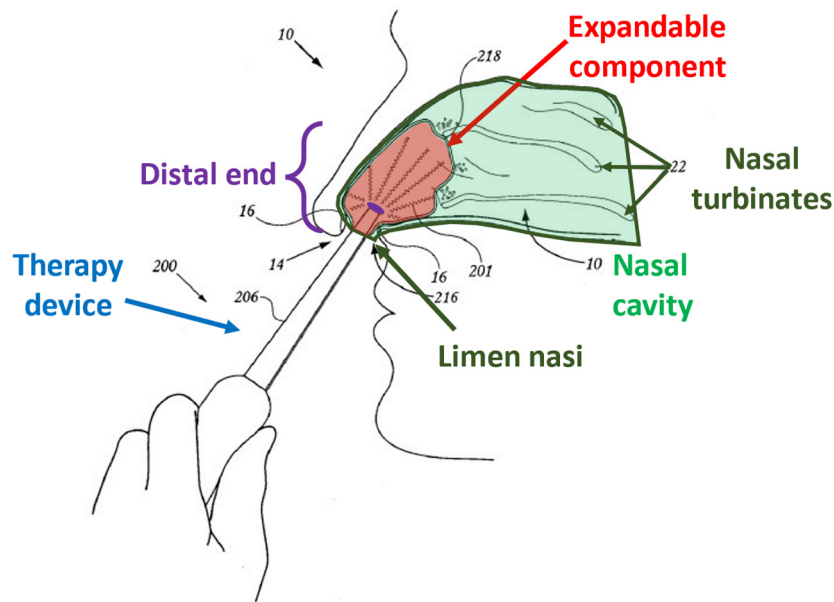


FIG. 4A

Ex.1019-Gertner, FIG.4A. Ex.1002-Decl., ¶¶65-66.

- d. **Element 9[c]: delivering an energy based therapy to at least one of the mucosal tissue or an underlying tissue beneath the mucosal tissue, using the treatment element; and**

Gertner discloses *delivering an energy based therapy* (e.g., therapeutic light) *to...the mucosal tissue* (e.g., tissue within a nasal cavity 10) *using the treatment element* (e.g., distal end 216). Ex.1002-Decl., ¶67.

Gertner discloses that therapeutic “light 201 is emitted” from distal end 216 (i.e., *treatment element*) “into the nasal cavity.” Ex.1019-Gertner, [0103]-[0104], [0106]-[0109]. As discussed above for limitation 9[pre], such light energy is applied

for treatment, for example to treat rhinitis, and is therefore an *energy based therapy*.

Ex.1002-Decl., ¶68.

Further, Gertner discloses that the **expandable component 218** (i.e., part of the *treatment element*) contacts tissue within a **nasal cavity 10** – including mucosal tissue that is lining the turbinates, posterior to the limen nasi, and/or lining the nasal septum, *see supra* §X.A.1.c – such that “the therapeutic light is delivered to the tissue through the wall” of **expandable component 218**, thereby *delivering an energy based therapy to mucosal tissue*. Ex.1019-Gertner, [0107]; *see also id.*, [0067], [0103], [0106], [0108], [0109] (“A distal portion of the expandable component transmits the therapeutic light 201 through the wall of the **expandable component** and to the tissue of the **nasal cavity 10**.”).

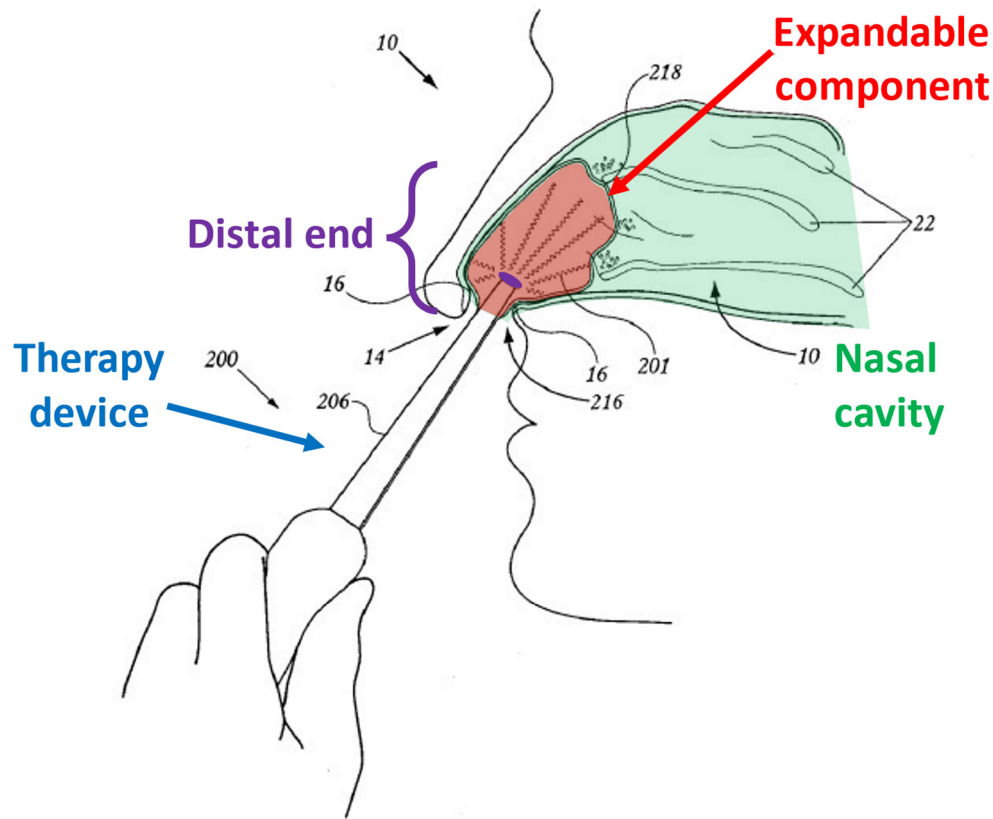


FIG. 4A

Ex.1019-Gertner, FIG.4A. Ex.1002-Decl., ¶69.

- e. **Element 9[d]: removing the treatment element from the nasal airway.**

Gertner discloses *removing the treatment element* (e.g., **distal end 216**) *from a patient's nasal airway* (e.g., **nasal cavity 10**). For example, Gertner discloses advancing the therapy device 200 into **nasal cavity 10** and then “withdrawing the device from the **nasal cavity**.” Ex.1019-Gertner, [0112]. Ex.1002-Decl., ¶70.

2. **Claim 14: A method as in claim 9, wherein adjusting the shape comprises manipulating a secondary component of the treatment element to increase a surface area of the treatment element.**

Gertner discloses that *adjusting the shape comprises manipulating (e.g., expanding) a secondary component (e.g., expandable component 218) of the treatment element (e.g., distal end 216) to increase a surface area of the treatment element (e.g., expanding the expandable component 218).* As discussed above for limitation 9[a], Gertner discloses expanding **expandable component 218**, for example by filling it with fluid. As shown in Figure 4A below, this expansion *increases the exposed surface area of expandable component 218 (i.e., a secondary component).*

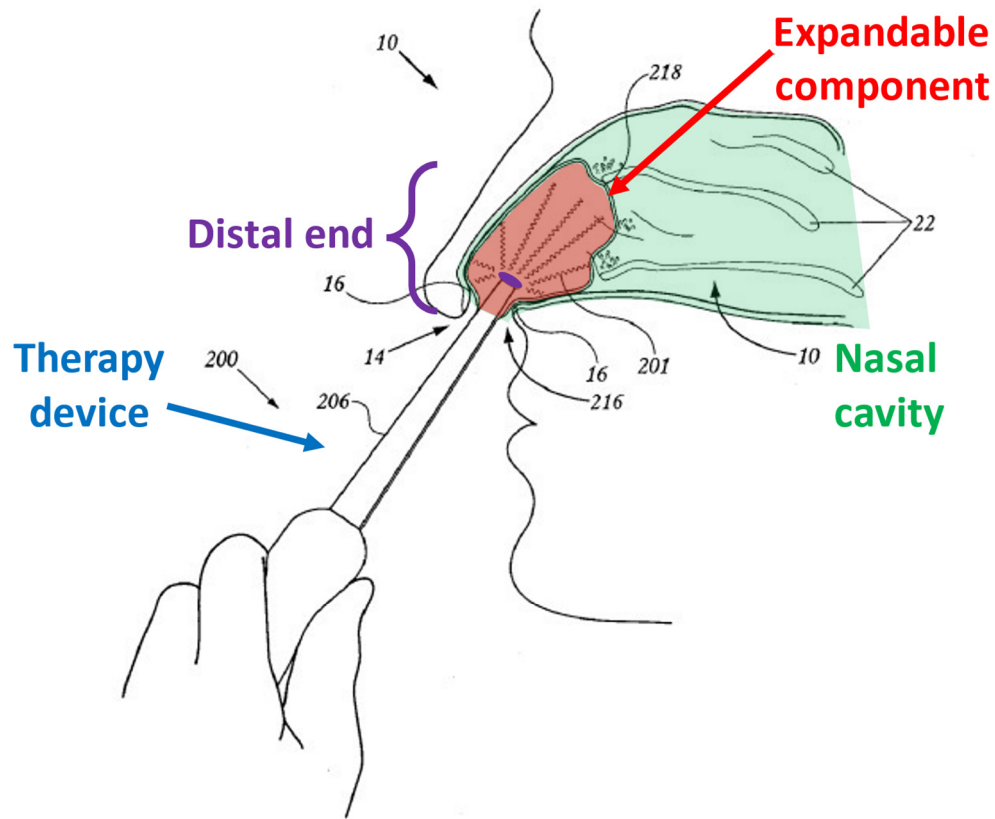


FIG. 4A

Ex.1019-Gertner, FIG.4A; *see also id.*, [0103], [0106]-[0109], [0111].. Ex.1002-Decl., ¶¶71-73.

3. **Claim 16:** A method as in claim 9, wherein adjusting the shape comprises forming at least one bend in a shaft of the treatment device.

Gertner discloses that *adjusting the shape comprises forming at least one bend in a shaft* (e.g., elongate body 208) *of the treatment device*. Ex.1002-Decl., ¶74.

As shown in Figure 4A, reproduced below, Gertner depicts a therapy device 200 (i.e., *treatment device*) with an elongate body 208 (i.e., *shaft*) inserted into a patient's nostril.

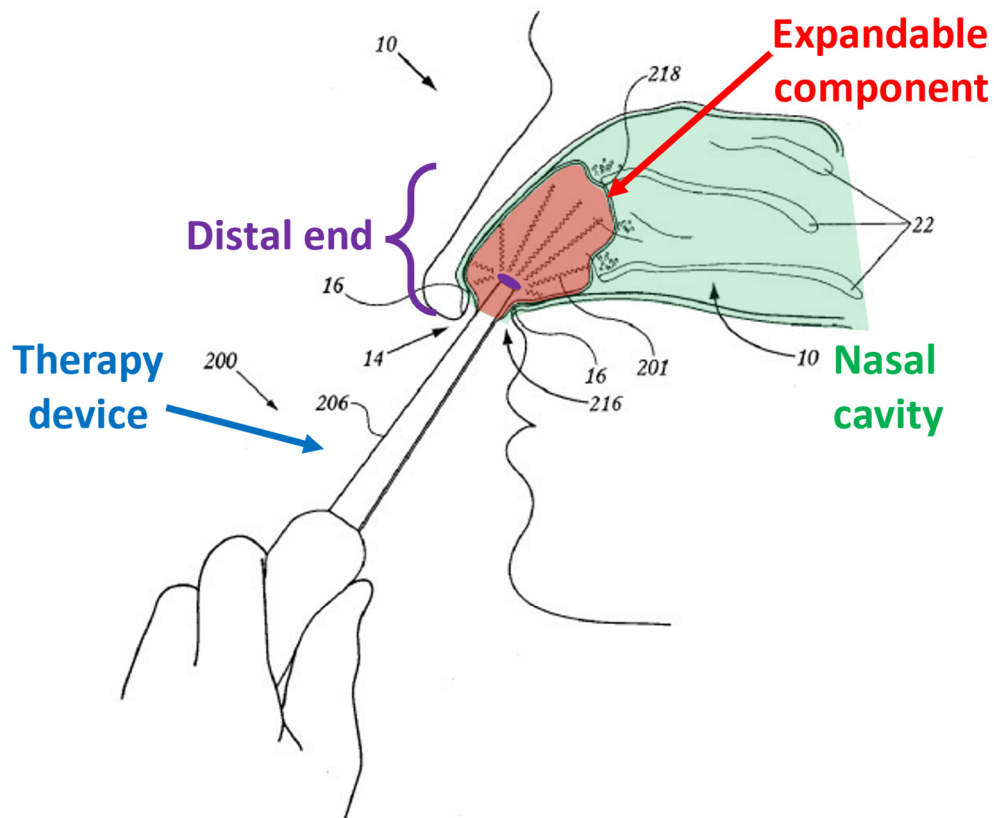


FIG. 4A

Ex.1019-Gertner, FIG.4A. Gertner discloses that the elongate insertion members used in its treatment devices can be made of “flexible materials so that [they] can bend, or be steered around corners, or conform to the shape of the cavity, as

required.” *Id.*, [0077]; *see also id.*, [0072].⁶ Accordingly, a POSITA would have understood that bending or steering a flexible body (i.e., *shaft*) as taught by Gertner results in *forming at least one bend in a shaft*. Ex.1002-Decl., ¶¶75-77.

4. **Claim 18: A method as in claim 9, wherein delivering the energy based therapy comprises delivering energy in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light, laser and quantic molecular resonance.**

Gertner discloses that *delivering the energy based therapy comprises delivering energy in a form selected from the claimed group* (e.g., *light*). As discussed above for limitations 9[pre] and 9[c], Gertner discloses *delivering energy* from **distal end 216** “in the form of rays or waves, including *light*, [delivered] into the nasal cavity.” Ex.1019-Gertner, [0003]; *see also id.*, [0103]-[0104], [0106]-[0109]. Ex.1002-Decl., ¶78.

⁶ Where not otherwise specified, a POSITA would have understood that Gertner’s description of the elongate insertion member 106 shown in Figure 2A applies equally to elongate body 206 shown in Figure 4A. *Compare* Ex.1019-Gertner, FIG.2A (depicting a therapy device 100 with an elongate insertion member 106) *with id.*, FIG.4A. (depicting a therapy device 200 having a modified distal end but with a similar elongate body 206 to that of therapy device 100). Ex.1002-Decl., ¶76.

5. Claim 20: A method as in claim 9, wherein the mucosal tissue is located in a part of the nasal airway other than an internal nasal valve of the airway.

Gertner discloses that *the mucosal tissue* (e.g., tissue within a **nasal cavity 10**) *is located in a part of the nasal airway other than an internal nasal valve of the airway* (e.g., limen nasi, nasal turbinates 22, and/or nasal septum). As discussed above for limitations 9[b] and 9[c], Gertner discloses delivering energy to *mucosal tissue* lining the nasal turbinates, posterior to the limen nasi, and/or lining the nasal septum. As Dr. DelGaudio explains, a POSITA would have understood that none of these locations are located in an internal nasal valve, and therefore the mucosal tissue lining these structures is *located in a part of the nasal airway other than an internal nasal valve*. See also Ex.1019-Gertner, [0038] (“[T]he nasal valve tissue is limited to the lateral aspect of the nasal vestibule 14.”), [0103]-[0104] (disclosing delivery of light posterior to the limen nasi but not to the “*nasal valve*”), FIGs.1A, 4A. Ex.1002-Decl., ¶¶79-81.

6. Claim 22: A method as in claim 20, wherein the wherein [sic] mucosal tissue includes tissue selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum within the nasal valve, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll,

**a floor of the nasal cavity, a piriform area, and swell bodies
on a floor of the nasal cavity.**

Gertner discloses that *the mucosal tissue* (e.g., tissue within a **nasal cavity 10**) *includes tissue selected from the claimed group* (e.g., *nasal septum within the nasal valve and/or nasal septum outside of the nasal valve*). As discussed above for limitations 9[b] and 9[c] and claim 20, Gertner discloses delivering energy to *mucosal tissue* of the nasal septum. As Dr. DelGaudio explains, a POSITA would have understood that the portion of the nasal septum contacted using Gertner's method is positioned either *within* or *outside of the nasal valve* (or both). Ex.1002-Decl., ¶82.

**7. Claim 23: A method as in claim 9, further comprising
applying force to the mucosal tissue with the treatment
element at least one of before, during or after delivering the
energy based therapy to deform the mucosal tissue.**

Gertner discloses *applying force to the mucosal tissue* (e.g., tissue within a **nasal cavity 10**) *with the treatment element* (e.g., **distal end 216**) *at least one of before, during or after delivering the energy based therapy* (e.g., therapeutic light) *to deform the mucosal tissue*. Ex.1002-Decl., ¶83.

As explained above for limitations 9[a]-9[b], Gertner discloses expanding an **expandable component 218** to contact *mucosal tissue*, which thereby *applies force to the mucosal tissue to deform the mucosal tissue*. For example, **expandable**

component 218 “wedge[s] open” (i.e., *deforms*) portions of the nasal cavity 10 and thereby deforms the *mucosal tissue* lining those portions. Ex.1019-Gertner, [0108].

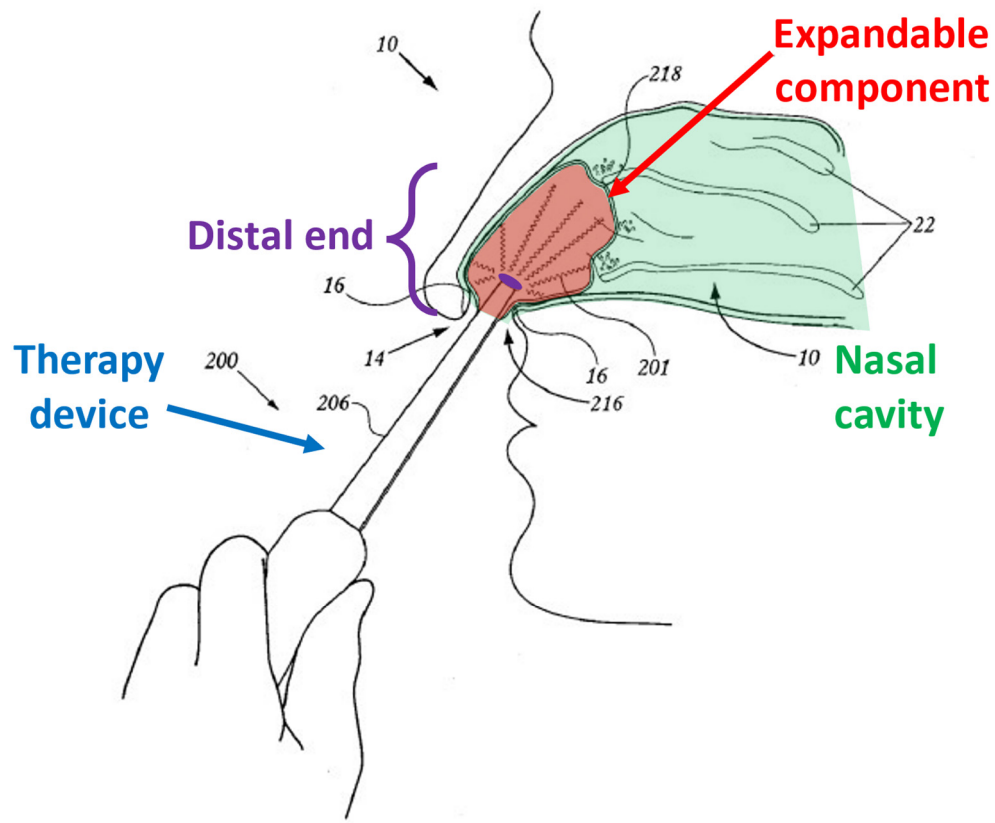


FIG. 4A

Ex.1019-Gertner, FIG.4A. Ex.1002-Decl., ¶¶84-85.

Gertner further discloses that the force is applied *before* and/or *during* delivering the energy based therapy. For example, Gertner teaches that in order to “deliver a more relatively uniform distribution of light,” fluid pressure within expandable component 218 (and the associated application of force on surrounding

tissue) is maintained *during* the delivery of light energy. *Id.*, [0107]. In addition, Gertner discloses “[t]he **expandable component 218** can be filled or expanded” – which causes application of force – “*prior* to placement in the nose or *after insertion* into the nasal cavity 10.” *Id.*, [0108]. Furthermore, because keeping **expandable component 218** expanded during light therapy delivery controls such delivery to particular portions of the nasal cavity, Gertner further discloses maintaining force on mucosal tissue *during delivery of the energy*. *Id.*, [0103], [0106]-[0109]. Ex.1002-Decl., ¶86.

8. Claim 24: A method as in claim 9, wherein delivering the energy based therapy modifies at least one property of the mucosal tissue or the underlying tissue without reshaping the tissue.

Gertner discloses that *delivering the energy based therapy* (e.g., therapeutic light) *modifies at least one property of the mucosal tissue or the underlying tissue* (e.g., tissue within a **nasal cavity 10**) *without reshaping the tissue*. Ex.1002-Decl., ¶87.

Gertner discloses that applying therapeutic light to tissue is associated with clinical outcomes such as eliminating infections, reducing effects or symptoms of diseases caused by atopy (e.g., rhinitis, asthma), treating psoriasis or vertigo, minimizing lesions or marks, reducing mucus production (e.g., “dryness”), and “histologic transformation from respiratory epithelium to squamous epithelium.”

Ex.1019-Gertner, [0005]-[0011], [0040], [0157]. As Dr. DelGaudio explains, a POSITA would have understood these clinical outcomes to arise from the therapeutic light modifying mucosal tissue. A POSITA would have further understood that applying therapeutic light does not reshape tissue, but instead merely modifies at least one property of the tissue in a manner sufficient to achieve the desired clinical outcome. In fact, during prosecution of the parent patent of the '597 patent, Aerin expressly argued that Gertner's light energy delivery device does not reshape tissue. Ex.1018-US594FH, 266-268 (arguing that Gertner contains "no teaching that the therapeutic light changes the shape of nasal tissue"). Ex.1002-Decl., ¶¶88-89.

9. Claim 44

a. Element 44[pre]: A method of treating a patient's nasal airway

As described above for limitation 9[pre], Gertner discloses the preamble. Ex.1002-Decl., ¶90.

b. Element 44[a]: contacting a treatment element of a treatment device with a first mucosal tissue located in a part of the nasal airway other than an internal nasal valve of the airway

As described above for limitation 9[b] and claim 20, Gertner discloses this limitation. Ex.1002-Decl., ¶91.

- c. Element 44[b]: delivering an energy based therapy to at least one of the first mucosal tissue or an underlying tissue beneath the first mucosal tissue, using the treatment element**

As described above for limitation 9[c], Gertner discloses this limitation.

Ex.1002-Decl., ¶92.

- d. Element 44[c]: removing the treatment element from the nasal airway.**

As described above for limitation 9[d], Gertner discloses this limitation.

Ex.1002-Decl., ¶93.

- 10. Claim 46: A method as in claim 44, wherein the wherein mucosal tissue includes tissue selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity.**

As described above for claim 22, Gertner discloses this limitation. Ex.1002-Decl., ¶94.

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

B. Ground II: Claims 9, 14, 16, 18, 20, 22, 23, 44, and 46 Are Anticipated by Edwards-'535

Edwards-'535 anticipates the challenged claims. Ex.1002-Decl., ¶95.

1. Claim 9

a. Element 9[pre]: A method of treating a patient's nasal airway

If limiting, Edwards-'535 discloses *a method of treating a patient's nasal airway* (e.g., **nasal concha**). Ex.1002-Decl., ¶96.

Edwards-'535 discloses “a method...for *treating* airway obstructions,” which can be used to treat sleep apnea and improve air flow through the nasal passages. Ex.1010-Edwards-'535, 1:22-50, 1:60-66, 4:19-32, 6:66-7:4, 7:12-25, Clm.1, FIGs.3A-3D, 4A-4C. To remove the obstruction, Edwards-'535 discloses “ablating at least a portion of a **nasal concha** (turbinate)” to reduce its size. *Id.*, 4:19-32; *see also id.*, Abstract, 1:22-41, 4:63-67, 5:9-15, 6:59-7:4, 7:12-25, Clm.1, FIGs.4A-4C.

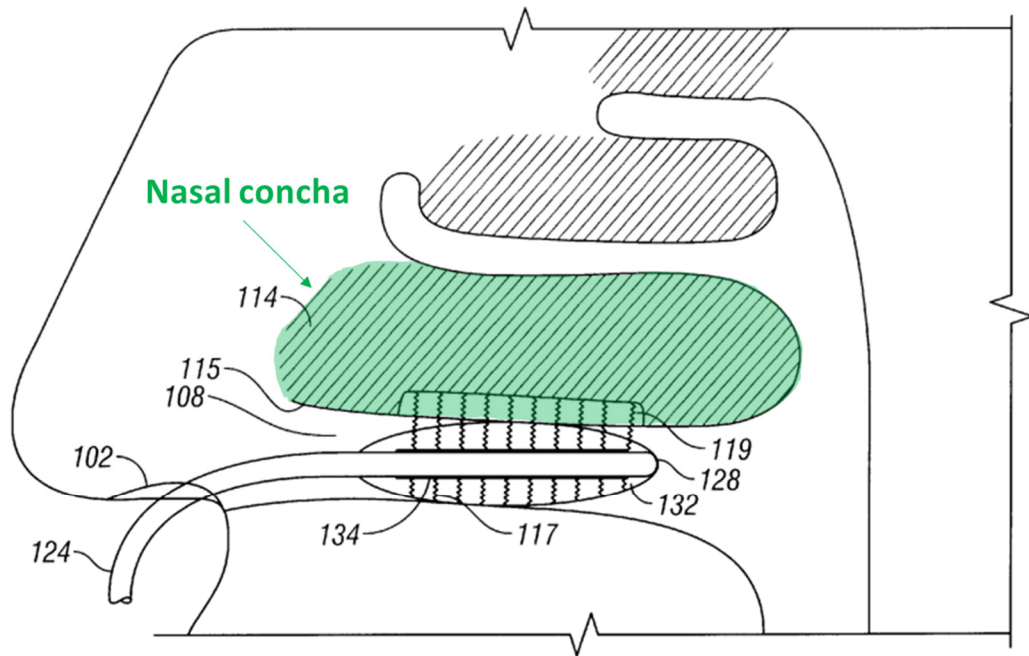


FIG. 3B

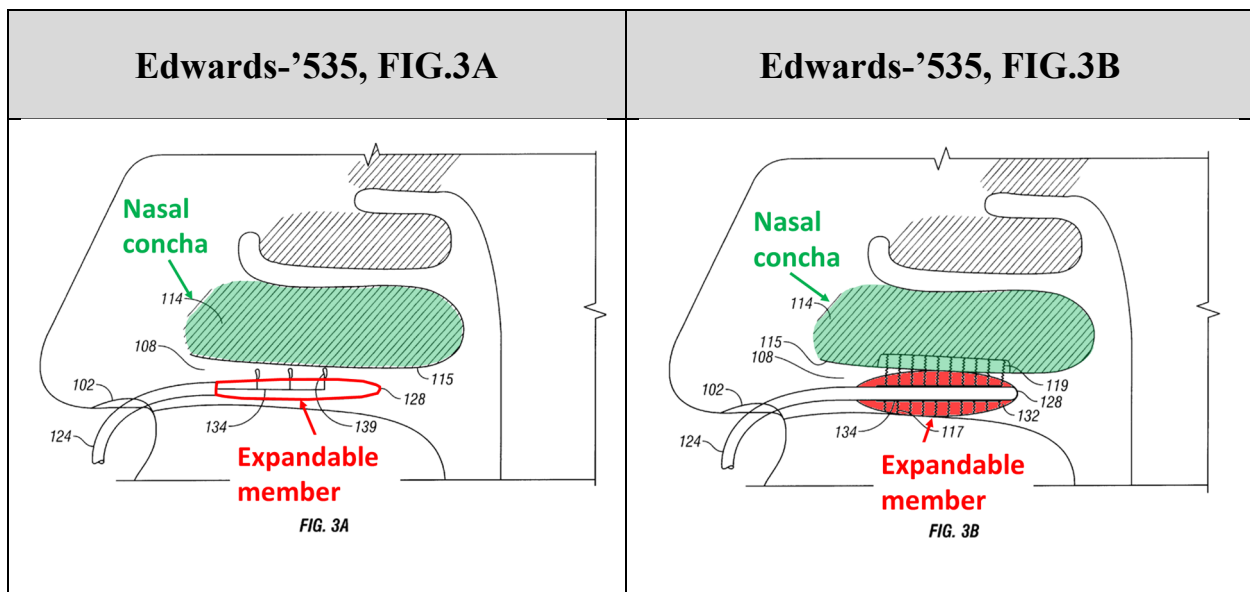
Ex.1010-Edwards-'535, FIG.3B. Ex.1002-Decl., ¶97.

b. Element 9[a]: adjusting a shape of a nasal airway treatment device

Edwards-'535 discloses *adjusting a shape* (e.g., inflating) of a nasal airway treatment device (e.g., apparatus 124). Ex.1002-Decl., ¶98.

Edwards-'535 discloses “an apparatus 124 having a distal portion 128 with an **expandable member 132**” that is used to treat **nasal concha** (i.e., part of the *nasal airway*). Ex.1010-Edwards-'535, 5:20-26; *see also id.*, 5:27-35 (contacting **expandable member 132** with a “**nasal concha 114** to be treated”), 5:51-61, 7:37-53, FIGs.3A-3C. Ex.1002-Decl., ¶XX.

When expanded, “**expandable member 132** is brought into contact with the surface 115 of the **nasal concha 114**.” Ex.1010-Edwards-’535, 5:27-35. As shown in Figures 3A-3B reproduced below, expansion of “**expandable member 132**” is achieved by “delivering a medium into the **expandable member**,” causing the *shape* of the **expandable member** to be *adjusted*. *Id.*, 5:18-35, 5:51-61, FIG.3B. Similar to Gertner, Edwards-’535’s use of an expandable member to satisfy this limitation matches one of the corresponding embodiments (expandable balloon) disclosed in the ’597 patent. *See* Ex.1001-USP597, 17:4-7.



Ex.1002-Decl., ¶99.

- c. **Element 9[b]: contacting a treatment element of the treatment device with mucosal tissue in the patient’s nasal airway;**

Edwards-’535 discloses *contacting a treatment element* (e.g., distal portion 128, including **energy delivery device 134** and **expandable member 132**) of the

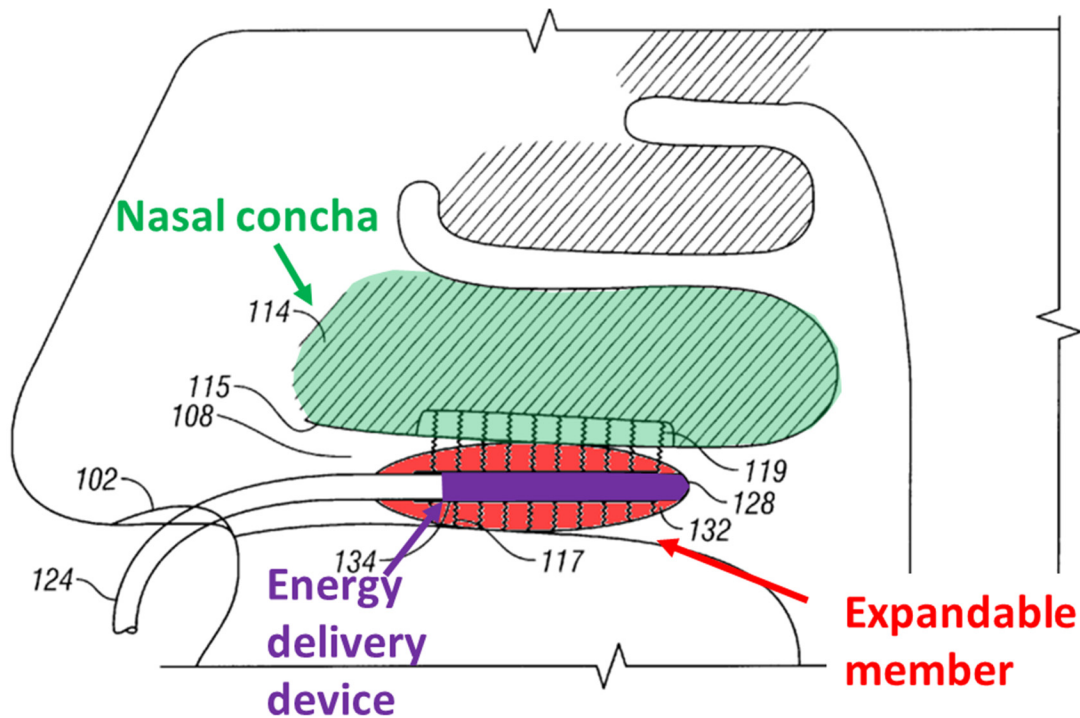
treatment device (e.g., apparatus 124) with *mucosal tissue* (e.g., **nasal concha 114**) in the patient's nasal airway. Ex.1002-Decl., ¶100.

First, Edwards-'535 discloses that a distal portion 128 of apparatus 124 includes an **energy delivery device 134** and an **expandable member 132** that together deliver “ablative energy” to a *nasal airway* (**nasal concha**). Ex.1010-Edwards-'535, 5:18-27, FIGs.3A-3D. As discussed above for limitation 9[pre], delivery of such energy is used for treatment (e.g., ablation of tissue), and accordingly, distal portion 128 would have been understood as a *treatment element of the treatment device*. Ex.1002-Decl., ¶101.

Second, Edwards-'535 discloses multiple configurations of distal portion 128 (i.e., *treatment element*), including positioning **energy delivery device 134** within **expandable member 132** or on its surface. In each case, the treatment element *contacts mucosal tissue in the patient's nasal airway*. Ex.1002-Decl., ¶100.

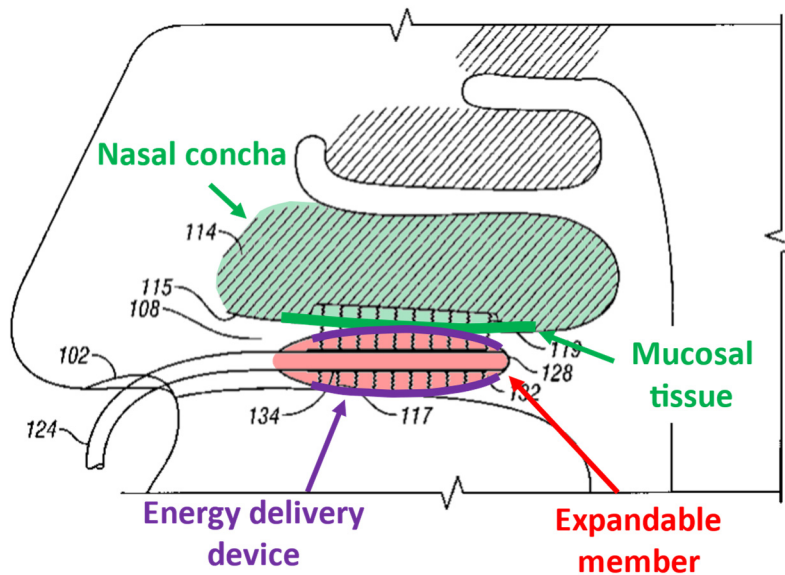
In one configuration of distal portion 128, **energy delivery device 134** is positioned within **expandable member 132**. Ex.1010-Edwards-'535, 4:53-67, 5:18-35, 8:8-17, Clm.1, FIGs.3A-3C. In this configuration, “the **expandable member 132** is expanded [and] brought into *contact* with the surface 115 of the **nasal concha 114** to be treated.” Ex.1010-Edwards-'535, 5:27-35; *see also id.*, 4:53-67, 5:46-61, 7:18-25, 8:18-25, Clm.1, FIG.3B. The surface 115 of the **nasal concha 114** comprises

mucosal tissue. Id., 7:18-25; *see also* 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.



Ex.1010-Edwards-'535, FIG.3B. Ex.1002-Decl., ¶102.

In another configuration of distal portion 128, energy delivery device 134 is “positioned on a surface” of expandable member 132, rather than on the inside thereof. *Id.*, 8:8-33, FIGs.3A-3D, 5-6. In this configuration, energy delivery device 134 as well as expandable member 132 *contacts mucosal tissue*, as illustrated in Figure 3B below.



Ex.1010-Edwards-'535, FIG.3B. Ex.1002-Decl., ¶¶103-104.

- d. **Element 9[c]: delivering an energy based therapy to at least one of the mucosal tissue or an underlying tissue beneath the mucosal tissue, using the treatment element; and**

Edwards-'535 discloses *delivering an energy based therapy* (e.g., ablative energy) *to at least one of the mucosal tissue* (e.g., surface 115 of nasal concha 114) *or an underlying tissue beneath the mucosal tissue* (e.g., tissue within nasal concha 114), *using the treatment element* (e.g., distal portion 128). Ex.1002-Decl., ¶105.

First, as discussed above for limitation 9[b], Edwards-'535 discloses that the *treatment element* (e.g., distal portion 128) delivers ablative energy for reducing the size of the nasal concha 114, and therefore delivers an *energy based therapy*. Ex.1002-Decl., ¶106.

Second, Edwards-’535 further teaches that after “expandable member 132 is brought into contact with the surface 115 of the nasal concha 114 to be treated,” “[s]ufficient [ablative] energy 117 is delivered through the surface 115 of the nasal concha 114 to ablate at least a portion 119 of the nasal concha 114.” Ex.1010-Edwards-’535, 5:27-35. By applying energy “through the surface 115 of the nasal concha 114,” which comprises *mucosal tissue*, Edwards-’535 teaches applying the ablative energy to *mucosal tissue*. For example, as shown in Figure 3B below, Edwards-’535 shows the “at least a portion 119 of the nasal concha 114” that receives ablative energy includes a lower surface of the inferior turbinate (which includes *mucosal tissue*), as well as area underneath that tissue (i.e., *underlying tissue beneath the mucosal tissue*). *Id.*, 5:27-35.

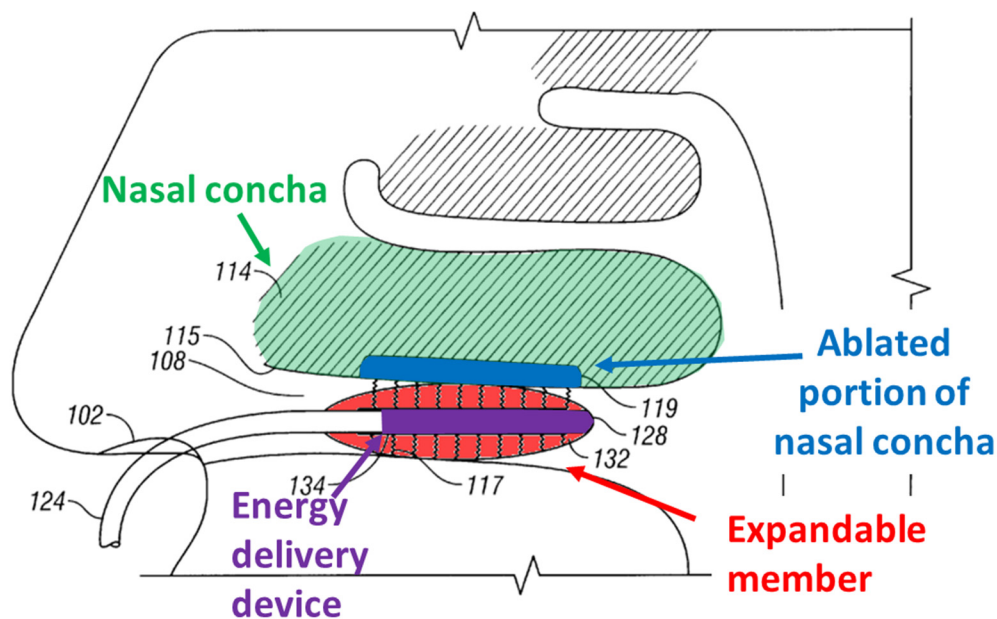
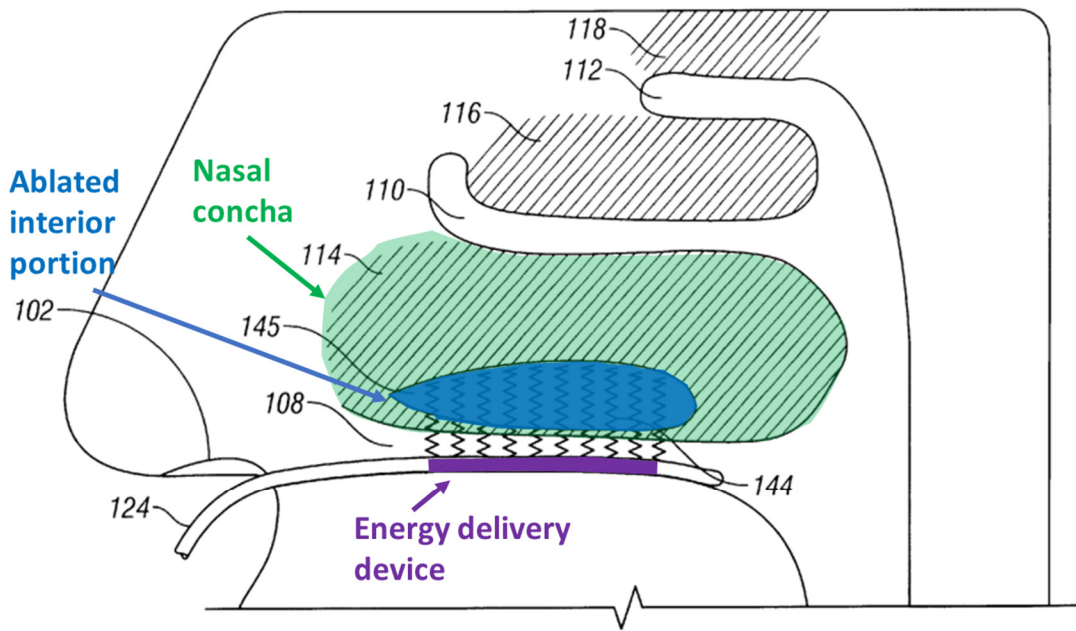


FIG. 3B

Ex.1010-Edwards-'535, FIG.3B; *see also id.*, FIG.3D (same). Ex.1002-Decl.,

¶¶107-108.

Third, to further facilitate the delivery of therapy to *underlying tissue beneath the mucosal tissue*, Edwards-'535 discloses a cooling technique in which “the surface of the nasal concha to be ablated is cooled during the delivery of energy to ablate the nasal concha...to prevent the **nasal concha** surface from being ablated.” Ex.1010-Edwards-'535, 6:9-22; *see also id.*, 4:53-67; 6:23-37. “As a result, an **interior portion** of a **nasal concha** is ablated without ablating the surface of the nasal concha.” *Id.*, 6:13-16; *see also id.*, 6:23-32. Figure 4A, reproduced below, shows the interior portion of the **nasal concha 114** to which energy is applied, which includes *underlying tissue beneath the mucosal tissue*.



Ex.1010-Edwards-'535, FIG.4A; *see also id.* 4B-4C, 3:57-64, 6:9-22, 6:66-4;

Ex.1002-Decl., ¶109.

e. Element 9[d]: removing the treatment element from the nasal airway.

Edwards-'535 discloses *removing the treatment element* (e.g., distal portion 128) *from a patient's nasal airway*. Ex.1002-Decl., ¶110.

Given that Edwards-'535's energy based therapy operates by ablating tissue, not delivering an implant, a POSITA would have understood that distal portion 128 (i.e., *treatment element*) is removed from the nasal airways. For example, Figures 4A-4C depict the insertion (Figure 4A) and subsequent removal (Figures 4B-4C) of distal portion 128 from the nasal airways. Ex.1010-Edwards-'535, 6:66-7:25.

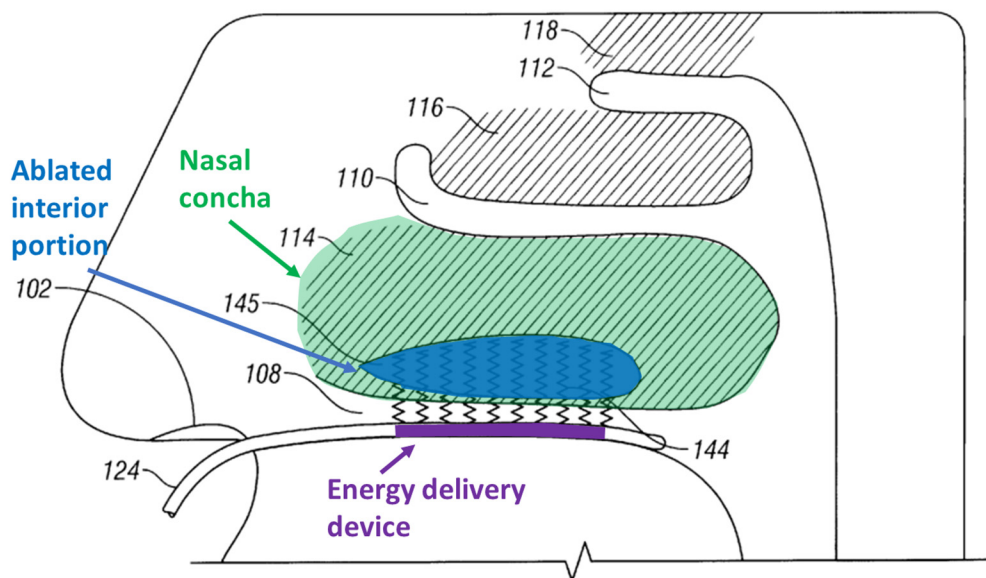


FIG. 4A

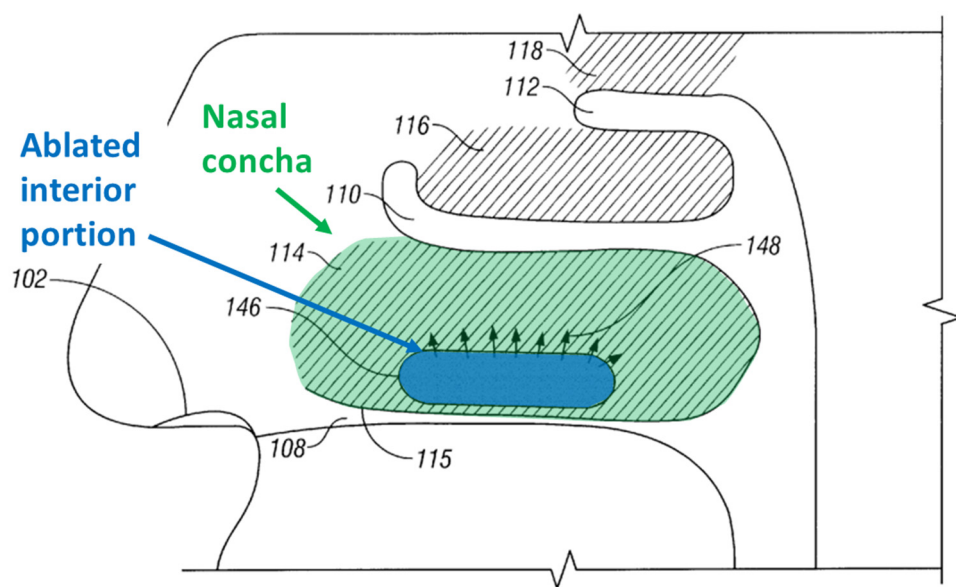


FIG. 4B

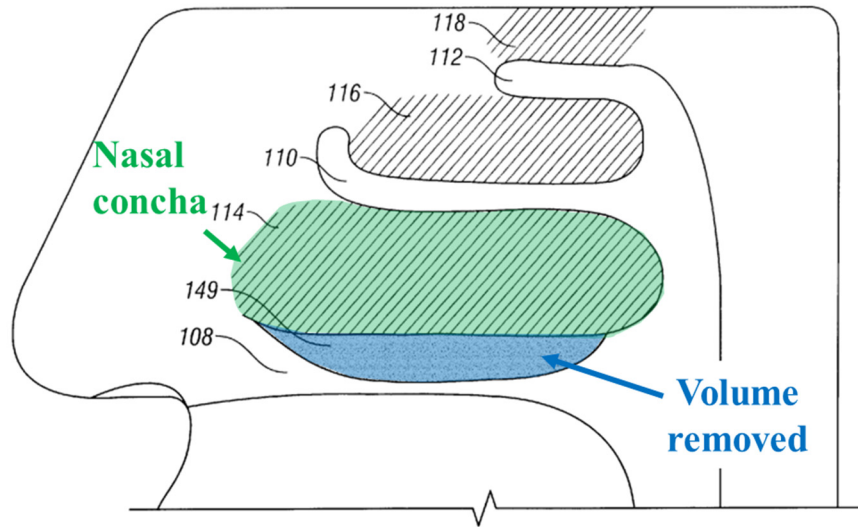
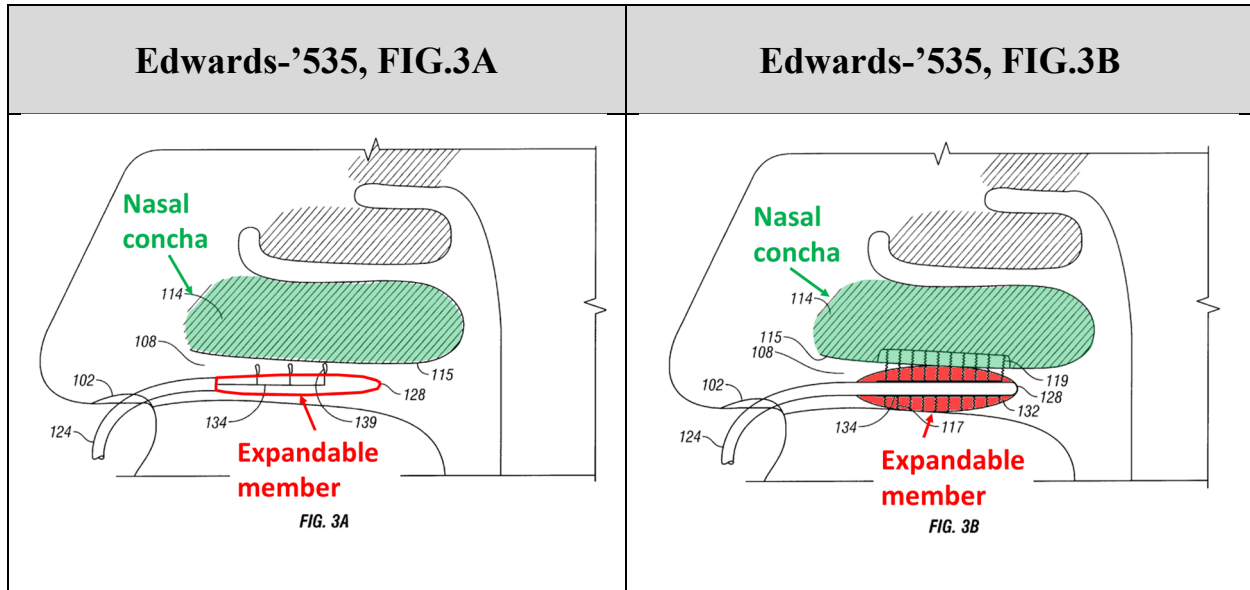


FIG. 4C

Ex.1010-Edwards-'535, FIGs.4A-4C. Ex.1002-Decl., ¶¶110-111.

2. **Claim 14:** A method as in claim 9, wherein adjusting the shape comprises manipulating a secondary component of the treatment element to increase a surface area of the treatment element.

Edwards-'535 discloses that *adjusting the shape comprises manipulating* (e.g., inflating) *a secondary component* (e.g., **expandable member 132**) *of the treatment element* (e.g., distal portion 128) *to increase a surface area of the treatment element*. As discussed above for limitation 9[a], Edwards-'535 discloses inflating **expandable member 132** (i.e., *secondary component*), which, as shown in Figures 3A-3B, causes the **expandable member 132** to become larger in multiple directions thereby increasing its surface area. *Id.*, 5:51-61, 7:37-54, FIGs.3A-3B; *see also id.*, FIG.3C (showing larger area).



Ex.1002-Decl., ¶¶112-114.

3. **Claim 18:** A method as in claim 9, wherein delivering the energy based therapy comprises delivering energy in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light, laser and quantic molecular resonance.

Edwards-'535 discloses that *delivering the energy based therapy comprises delivering energy in a form selected from the claimed group (e.g., ultrasound, microwave, radiofrequency, electrical, light, and laser)*. As discussed above for limitations 9[a]-9[c], Edwards-'535 discloses *delivering energy*, and further discloses that the energy is *in a form* of one or more of “diode laser” or “laser fiber” (i.e., *light* and/or *laser*), “microwave,” “ultrasound,” and “RF” (i.e., *radiofrequency*). Ex.1010-Edwards-'535, 5:36-51, 8:47-53, 8:61-9:13, Clm.1.

Ex.1002-Decl., ¶115.

4. **Claim 20: A method as in claim 9, wherein the mucosal tissue is located in a part of the nasal airway other than an internal nasal valve of the airway.**

Edwards-'535 discloses that *the mucosal tissue* (e.g., on the **nasal concha 114**) *is located in a part of the nasal airway other than an internal nasal valve of the airway*. As discussed above for limitations 9[b]-9[c], Edwards-'535 discloses contacting and/or applying energy to *mucosal tissue* on a **nasal concha 114** (or “turbinate”). As Dr. DelGaudio explains, a POSITA would have understood that the turbinates are not located in an internal nasal valve, and therefore the mucosal tissue lining the turbinates is *located in a part of the nasal airway other than an internal nasal valve*. Ex.1010-Edwards-'535, 1:60-2:6 (“The turbinates, also referred to as nasal concha”), 3:18-37, 5:46-51, 6:38-51, FIGs.3A-4C.

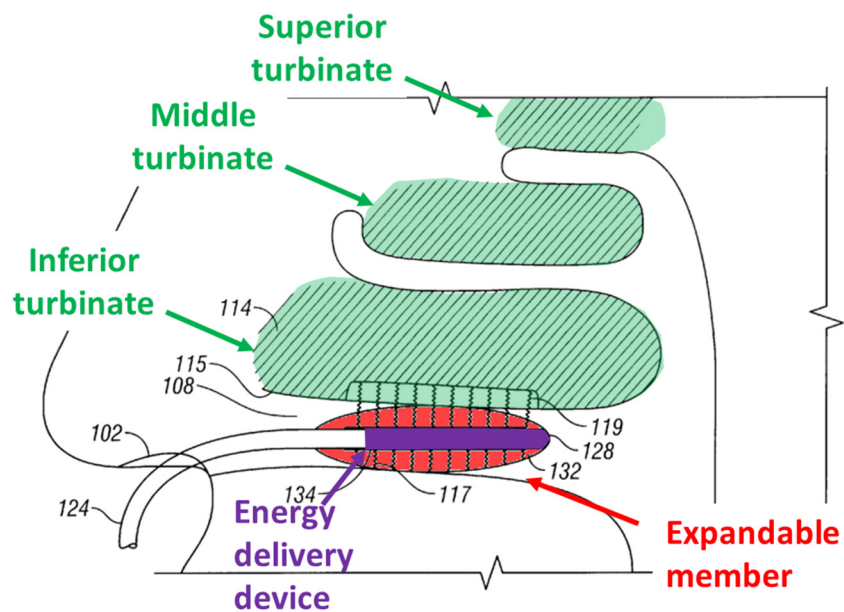
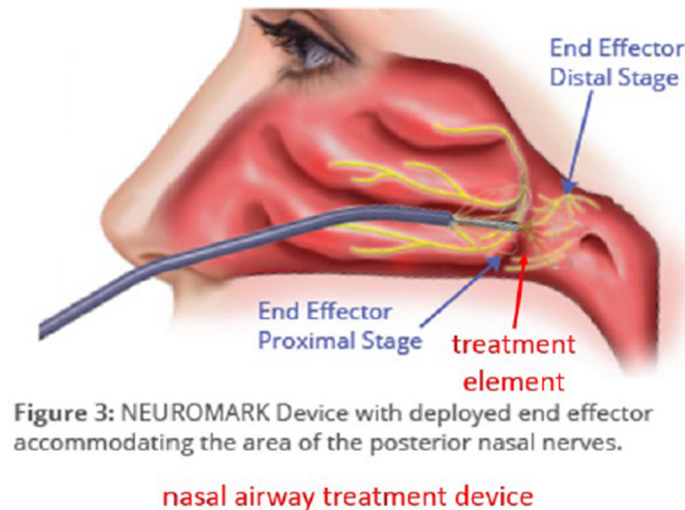


FIG. 3B

Ex.1010-Edwards-'535, FIG.3B. Ex.1002-Decl., ¶¶116-117.

5. **Claim 22:** A method as in claim 20, wherein the wherein [*sic*] mucosal tissue includes tissue selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum within the nasal valve, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity.

In the parallel litigation, PO argues that the following annotated diagram satisfies claim 22 by “show[ing] the end effector contacting mucosal tissue in at least the piriform area and floor of the nasal cavity.”



Ex.1007, 16 (annotations made by PO). Ex.1002-Decl., ¶118.

Referring to Figure 3B below, Edwards-'535 depicts distal end 128 (i.e., *treatment element*) contacting the same or similar parts of the nasal anatomy as PO's annotated diagram.

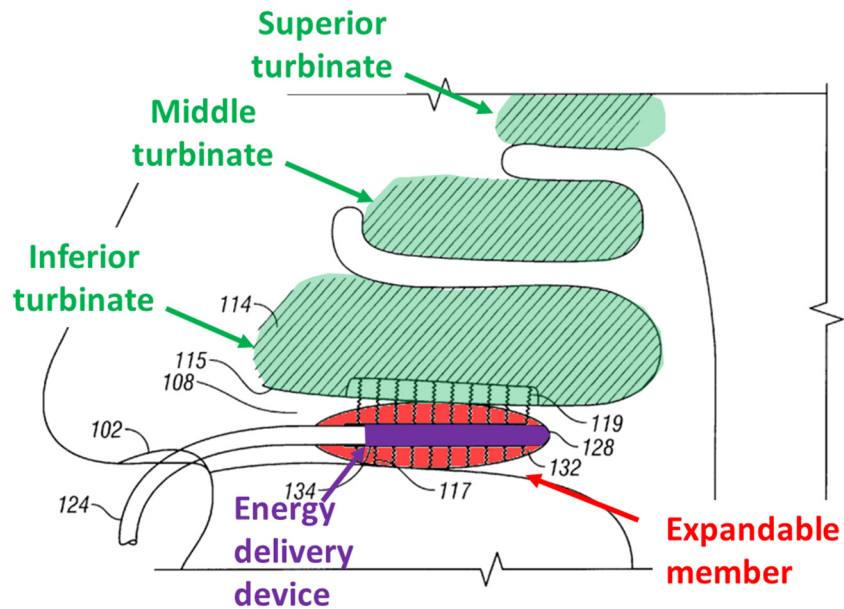


FIG. 3B

Ex.1010-Edwards-'535, FIG.3B. Accordingly, to the extent PO advances an interpretation of claim 22 consistent with its apparent interpretation in the parallel litigation,⁷ Edwards-'535 satisfies this limitation by contacting mucosal tissue in at least the *piriform area* and *floor of the nasal cavity*. Ex.1002-Decl., ¶119.

6. **Claim 23: A method as in claim 9, further comprising applying force to the mucosal tissue with the treatment**

⁷ Petitioners reserve the right to contest PO's interpretation and respond to any arguments advanced by PO in this proceeding and the parallel litigation.

element at least one of before, during or after delivering the energy based therapy to deform the mucosal tissue.

Edwards-'535 discloses *applying force to the mucosal tissue* (e.g., on the **nasal concha 114**) *with the treatment element* (e.g., distal portion 128) *at least one of before, during or after delivering the energy based therapy* (e.g., ablative energy) *to deform the mucosal tissue*. Ex.1002-Decl., ¶120.

As explained above for limitations 9[b]-9[c], Edwards-'535 discloses expanding the **expandable member 132** such that it “**contact[s]**...the surface 115 of the **nasal concha 114** to be treated.” Ex.1010-Edwards-'535, 5:27-35, 5:51-61. A POSITA would have understood that contacting surface 115 of **nasal concha 114** results in *applying force to the mucosal tissue* lining **nasal concha 114** and in turn, as Dr. DelGaudio explains, the applied force would *deform the mucosal tissue*, at least temporarily, given that the mucosal tissue lining **nasal concha 114** is soft and malleable. Moreover, the expansion is performed *before delivering* ablative energy and is maintained *during delivering* of ablative energy. Ex.1010-Edwards-'535, 4:53-67, 5:27-35, 5:46-51, 7:18-25, 8:18-25, Clm.1, FIGs.3A (showing unexpanded **expandable member 132** before application of ablative energy), 3B-3D (showing expanded **expandable member 132** during application of ablative energy). Ex.1002-Decl., ¶¶121-122.

7. Claim 44

- a. Element 44[pre]: A method of treating a patient's nasal airway**

As described above for limitation 9[pre], Edwards-'535 discloses the preamble. Ex.1002-Decl., ¶123.

- b. Element 44[a]: contacting a treatment element of a treatment device with a first mucosal tissue located in a part of the nasal airway other than an internal nasal valve of the airway**

As described above for limitation 9[b] and claim 20, Edwards-'535 discloses this limitation. Ex.1002-Decl., ¶124.

- c. Element 44[b]: delivering an energy based therapy to at least one of the first mucosal tissue or an underlying tissue beneath the first mucosal tissue, using the treatment element**

As described above for limitation 9[c], Edwards-'535 discloses this limitation. Ex.1002-Decl., ¶125.

- d. Element 44[c]: removing the treatment element from the nasal airway.**

As described above for limitation 9[d], Edwards-'535 discloses this limitation. Ex.1002-Decl., ¶126.

- 8. Claim 46: A method as in claim 44, wherein the wherein mucosal tissue includes tissue selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal**

septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity.

As explained above for claim 22, Edwards-'535 discloses this limitation. Ex.1002-Decl., ¶127.

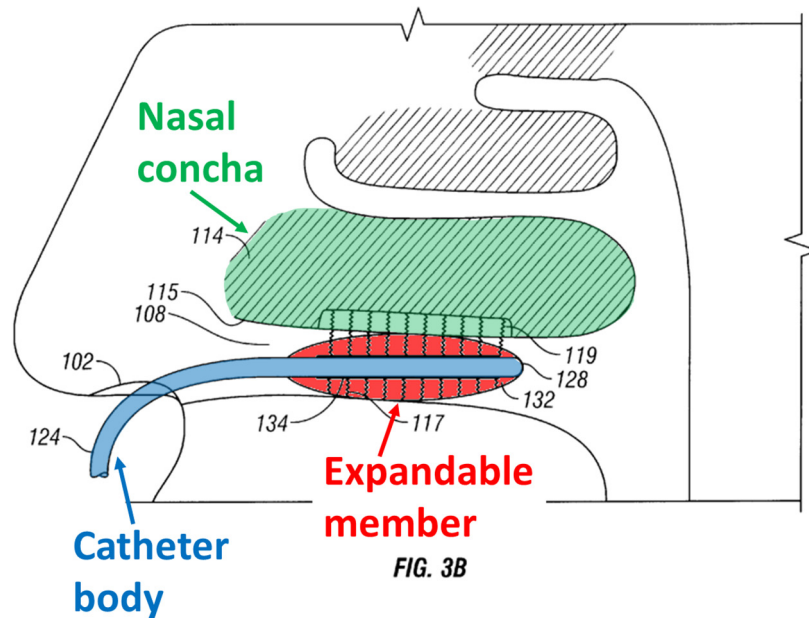
Therefore, the challenged claims in Ground II are anticipated because Edwards-'535 discloses all their elements arranged as in the claims. *See Blue Calypso*, 815 F.3d at 1341.

C. Ground III: Claim 16 Is Obvious Over Edwards-'535

- 1. Claim 16: A method as in claim 9, wherein adjusting the shape comprises forming at least one bend in a shaft of the treatment device.**

Edwards-'535 renders obvious *adjusting the shape comprises forming at least one bend in a shaft* (e.g., catheter body) *of the treatment device* (e.g., apparatus 124). Ex.1002-Decl., ¶128.

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



Ex.1010-Edwards-'535, FIG.3B; *see also id.*, 2:63-3:6 (“the apparatus includes a catheter having a distal portion with a dimension configured for positioning the catheter distal portion through a nostril of a patient”). A POSITA would have understood that a bend in a catheter shaft, such as the one illustrated in Figure 3B, is necessarily *formed*, such that the method includes *forming at least one bend in a shaft of the treatment device*. Ex.1002-Decl., ¶129.

However, to the extent PO argues that claim 16 requires, and Edwards-'535 does not disclose, a particular mechanism for forming the bend shown in Figure 3B, a POSITA would have found it obvious to implement Edwards-'535 teachings using any number of well-known mechanisms for forming bends in catheter shafts. For example, as Dr. DelGaudio explains, bendable catheter shafts that facilitate inserting

a device into a patient's nose were commonplace by 2011 such that they would have been background knowledge to a POSITA. Therefore, a POSITA would have been motivated to apply background knowledge of bendable catheter shafts to Edwards-'535, as doing so would have amounted merely to using a known technique (i.e., one or more techniques for forming a bend in a catheter shaft) to improve a similar device (Edwards-'535' apparatus 124, which includes a bent catheter shaft) in the same way. Ex.1002-Decl., ¶¶130-131.

Edwards-'535's lack of detailed disclosure about its catheter supports that that these features would have been considered routine and well-known. Moreover, given that Edwards-'535 does not disclose a particular mechanism for forming the bend in the catheter shaft (e.g., Edwards-'535 does not identify the material the catheter is made of), a POSITA would have recognized that Edwards-'535 is ready for the improvements provided by known techniques for forming a bend in the catheter shaft and would have been motivated to combine those known techniques with Edwards-'535's teachings. Selecting among these known techniques would have been a matter of routine implementation and yielded predictable results (i.e., the ability to form a bend in the catheter shaft). Moreover, by using these techniques, a POSITA would have had a reasonable expectation of success in achieving the goals of forming a bend in a catheter shaft, such as more accurate placement of the distal

end of Edwards-'535's catheter shaft and/or the ability to contact surfaces (e.g., the posterior of a nasal turbinate) that would otherwise be obstructed. Ex.1002-Decl., ¶132.

D. Ground IV: Claims 9, 14, 16, 18, 20, 22-24, 44, and 46 Are Anticipated by Baker

As set forth below, Baker discloses multiple embodiments that independently satisfy the claims, including: (1) a method for using a device 20, which has an expandable balloon at its distal end, to carry out the claimed steps; and (2) a method for using a similar device 40, which has a steerable structure at its distal end, to carry out the claimed steps. Ex.1002-Decl., ¶133.

1. Claim 9

a. Element 9[pre]: A method of treating a patient's nasal airway

If limiting, Baker discloses *a method of treating a patient's nasal airway* (e.g., nasal passages, mucous membranes, and/or nasal turbinates). Ex.1002-Decl., ¶134.

i. Device 20

As explained in further detail below, *see infra* limitations 9[a]-9[d], Baker discloses a method for using a device 20 to “deliver[] generally high frequency acoustic energy...to tissue sites such as nasal passages.” Ex.1013-Baker, 16:19-22; *see also id.*, 17:24-27, FIGs.3-5. The method is for “*treating* common colds, nasal congestion and allergic rhinitis, as well as sinusitis and other nasal conditions.” *Id.*,

26:7-8; *see also id.*, Abstract, 1:11-22, 5:5-12, 16:19-32, Clm.1. The method is applied “within **nasal passages, mucous membranes and nasal turbinates.**” *Id.*, 17:11-16. These locations are in the *nasal airway*. Ex.1002-Decl., ¶135.

ii. Device 40

Additionally or alternatively, Baker discloses a method for using a device 40 to “deliver[] generally high frequency acoustic energy to **nasal passages,**” Ex.1013-Baker, 21:21-24, which is likewise used for “*treating...nasal conditions,*” *id.*, 26:7-11, and is applied to “**mucous membranes[,] nasal turbinates[, and] nasal passages**” (i.e., *nasal airway*), *id.*, 22:10-16. Ex.1002-Decl., ¶136.

b. Element 9[a]: adjusting a shape of a nasal airway treatment device

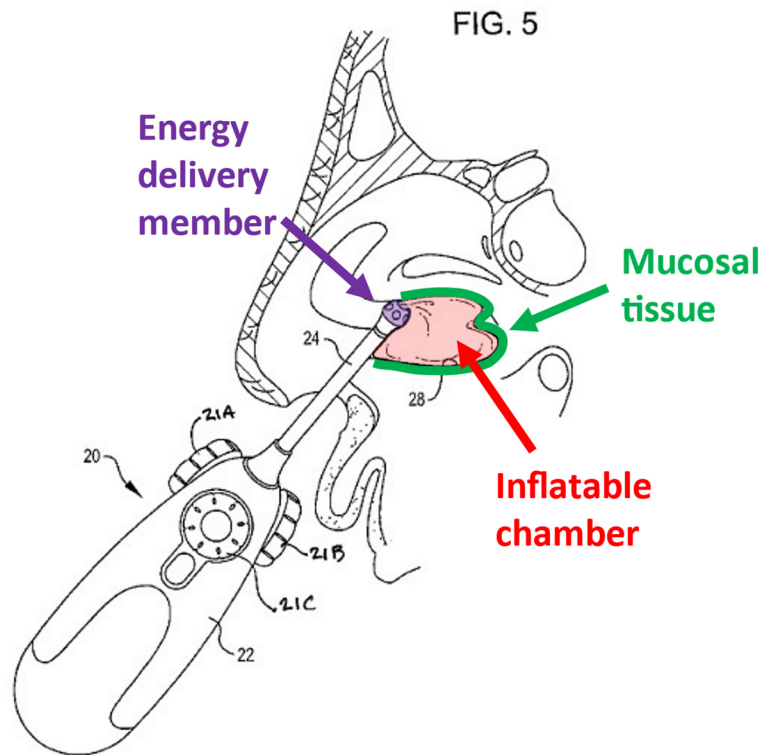
Baker discloses *adjusting a shape* (e.g., extending/retracting, bending, and/or enlarging) *of a nasal airway treatment device* (e.g., device 20 and/or 40). Ex.1013-Baker, 16:19-32, 17:11-21, 21:21-32, FIGs.4-8B. Ex.1002-Decl., ¶137.

i. Device 20

Device 20 is a *nasal airway treatment device* used “for delivery of high frequency acoustic energy to internal sites, such as nasal passageways.” Ex.1013-Baker, 16:23-26; *see also* limitation 9[pre]. The device 20 has an “insertion wand 24” having “**energy delivery member 26**” at the tip of insertion wand 24 that is used for treatment of a nasal airway (**target site on tissue surfaces** of nasal passages,

mucous membranes, and/or nasal turbinates). Ex.1013-Baker, 16:19-32, 17:11-21, FIGs.3-5. **Energy delivery member 26** includes an “extendible and/or retractable” portion “to provide desired positioning of the energy delivery member in contact with obstructions and/or tissues for delivery of...energy.” *Id.*, 17:11-21. Thus, Baker discloses *adjusting a shape* by extending and/or retracting the **energy delivery member 26**. Ex.1002-Decl., ¶138.

Baker further discloses *adjusting a shape* in embodiments where **energy delivery member 26** includes a “flexible, deformable bladder or **inflatable chamber 28**” that can “be enlarged, at a desired target site, until the walls of the chamber contact a tissue site, or the walls of a cavity or passageway or lumen.” Ex.1013-Baker, 17:22-32.



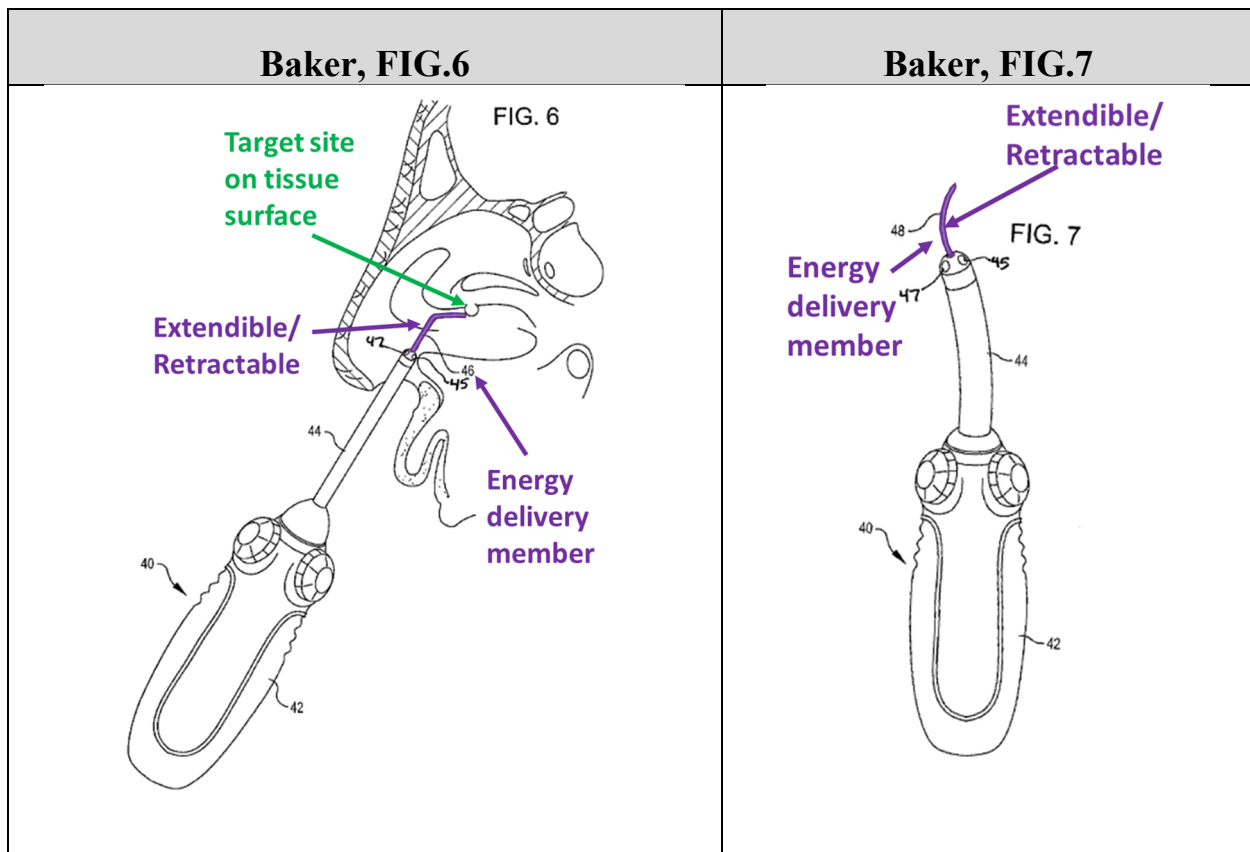
Id., FIG.5. Ex.1002-Decl., ¶139.

ii. Device 40

Additionally or alternatively, Baker’s teachings in connection with device 40 satisfy limitation 9[a]. Ex.1002-Decl., ¶140.

Like device 20, device 40 is a *nasal airway treatment device* “for delivery of generally high frequency acoustic energy to nasal passages.” Ex.1013-Baker, 21:21-24. Many components of device 40 (e.g., an insertion member 44 and **energy delivery member 46**) are analogous to those of device 20 described above. *Id.*, 21:21-32; *see also id.*, FIGs.6-7. **Energy delivery member 46** includes an

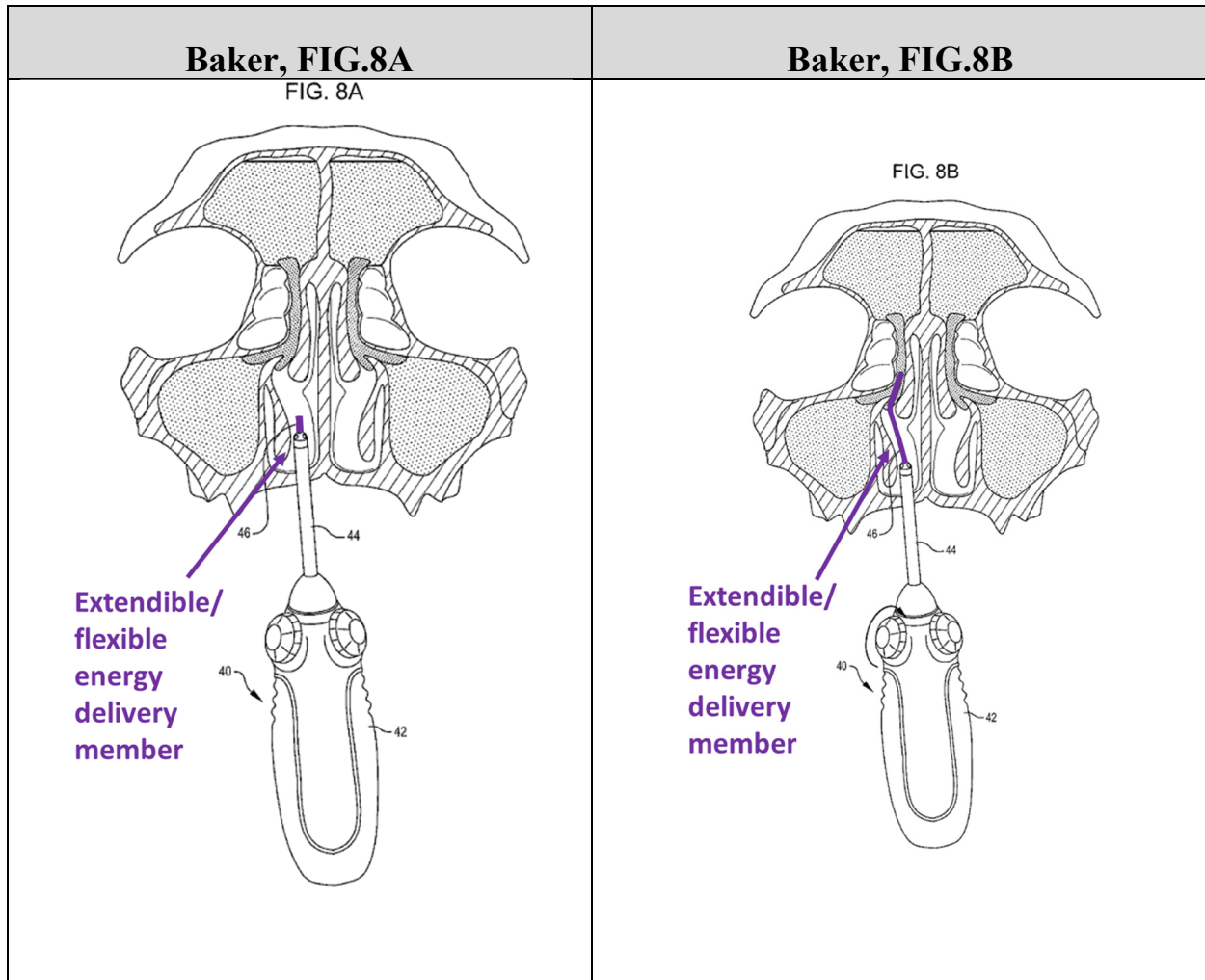
“extendible and/or retractable” portion “to provide desired positioning of the energy delivery member in contact with obstructions and/or tissues for delivery of...energy.” *Id.*, 22:16-40. Thus, Baker discloses *adjusting a shape* by extending and/or retracting the **energy delivery members 46**, as illustrated below.



Ex.1002-Decl., ¶141.

Baker discloses further configurations of device 40 in which the shape of device 40 (i.e., *treatment device*) is adjusted by articulating a “a **flexible, steerable** structure 48” of insertion member 44. Ex.1013-Baker, 21:21-22:40, FIGs.6-7; *see*

also id., FIGs.8A-8B (illustrating the progression of the flexible steerable structure 48). Thus, Baker further discloses *adjusting a shape* by steering a flexible element.



Ex.1002-Decl., ¶142.

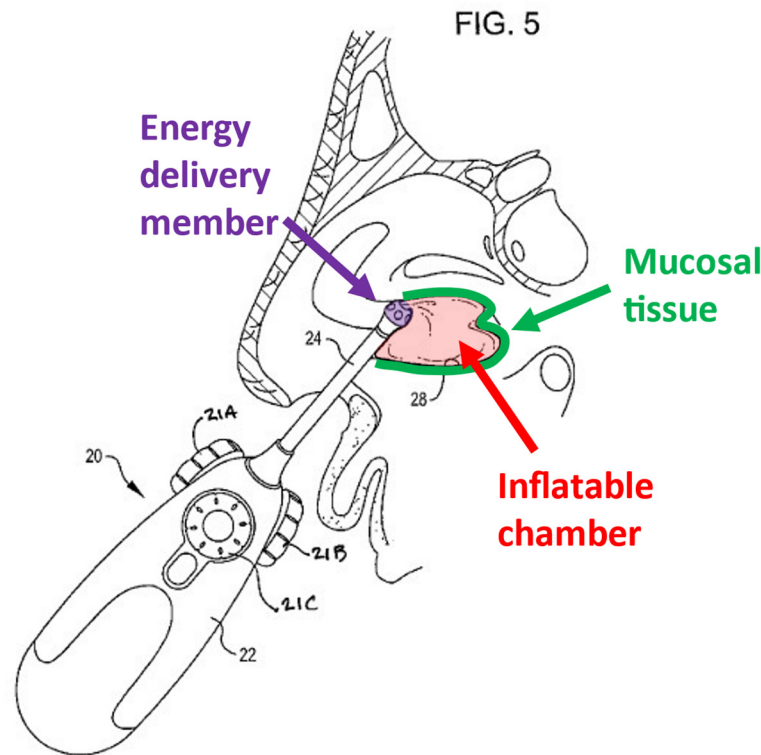
- c. **Element 9[b]: contacting a treatment element of the treatment device with mucosal tissue in the patient's nasal airway;**

Baker discloses *contacting a treatment element* (e.g., *energy delivery member 26/46/48, chamber 28*) of the treatment device (device 20/40) with mucosal tissue

(e.g., **target site on tissue surfaces** of nasal passages, mucous membranes, and/or nasal turbinates) *in the patient's nasal airway*. Ex.1002-Decl., ¶143.

i. Device 20

Energy delivery member 26 of device 20 is a *treatment element* that delivers high frequency energy to a *patient's nasal airway* (**tissue surfaces** of nasal passages, mucous membranes, and/or nasal turbinates). Ex.1013-Baker, 17:11-21; *see also id.*, Abstract, 1:11-22, 5:5-12, 16:19-32, 26:7-11, Clm.1, FIGs.3-5. Baker discloses that the “**energy delivery member**...may be extendible and/or retractable...to provide desired positioning of the energy delivery member in *contact* with...tissues.” *Id.*, 17:11-21, FIG.4. Baker also discloses embodiments in which “**energy delivery member** may comprise a flexible, deformable bladder or **inflatable chamber 28**” that can “be enlarged, at a desired target site, until the walls of the chamber *contact* a tissue site, or the walls of a cavity or passageway or lumen,” including “nasal passages, mucous membranes and nasal turbinates, or pathological or undesired tissue.” *Id.*, 17:11-32; *see also id.*, 17:33-18:9 (describing similar contact), 20:35-21:10 (same).

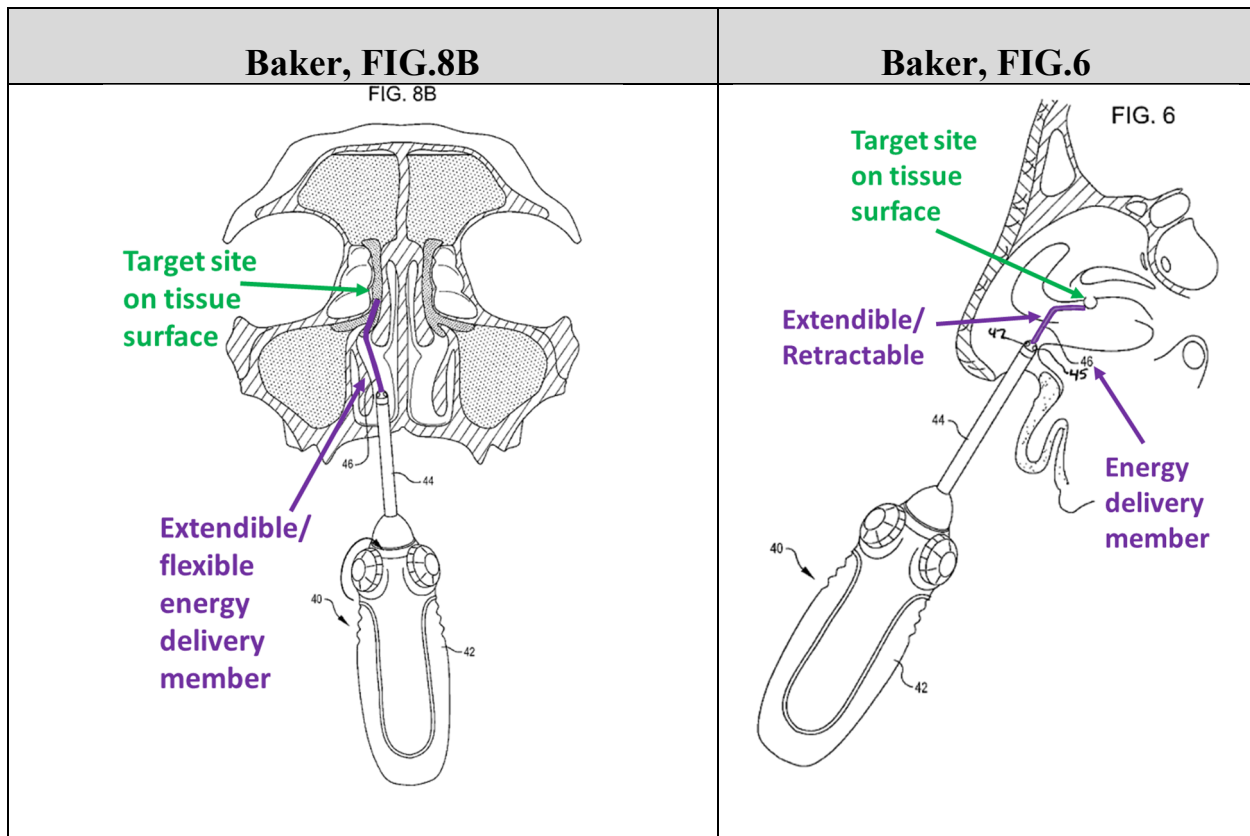


Ex.1013-Baker, FIG.5. Ex.1002-Decl., ¶¶144-145.

ii. Device 40

Additionally or alternatively, **energy delivery member 46** of device 40 is a *treatment element* that delivers high frequency energy to a *nasal airway* (**target site on tissue surfaces** of nasal passages, mucous membranes, and/or nasal turbinates). *Id.*, 21:21-32, FIGs.6-8C. Baker discloses that the distal end of the **energy delivery member 46** is “positioned...contacting a **tissue surface** such as *mucous* membranes and nasal turbinates or polyps,...or accumulations or blockages within cavities such as nasal passages.” *Id.*, 22:10-25; *see also id.*, 7:18-34, 16:33-17:10, 21:21-32, 25:5-

15, 25:37-26:6 (describing sterile use covers), FIGs.6-8B. For example, “[e]nergy delivery member 46 may be extended, as shown in Fig. 8B, to *contacting mucus* and/or debris forming an obstruction within nasal passageways.” *Id.*, 25:5-10.



Ex.1002-Decl., ¶¶146-147.

- d. **Element 9[c]: delivering an energy based therapy to at least one of the mucosal tissue or an underlying tissue beneath the mucosal tissue, using the treatment element; and**

Baker discloses *delivering an energy based therapy* (e.g., high frequency acoustic energy) to...*the mucosal tissue* (e.g., **target site on tissue surface**, including

mucous membranes, nasal turbinates, or pathological undesired tissue), *using the treatment element* (e.g., **energy delivery member 26/46/48**). Ex.1002-Decl., ¶148.

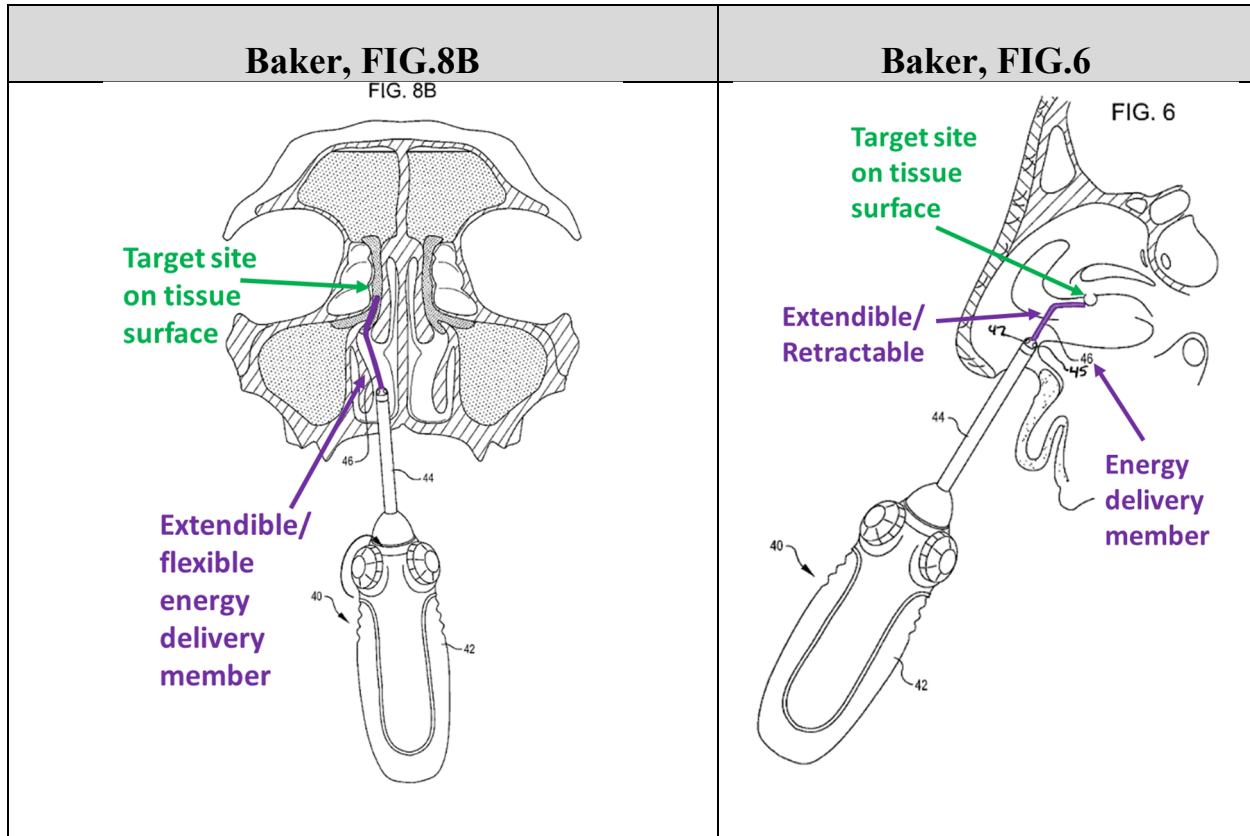
i. Device 20

Baker discloses that the *treatment element* (e.g., distal end of insertion wand 24 having **energy delivery member 26**) delivers energy to treat, disrupt, and/or remove obstructions or undesired materials. Ex.1013-Baker, 8:10-24, 16:19-32, FIGs.3-5. The delivered energy is therefore an *energy based therapy*. Ex.1002-Decl., ¶149.

For example, when the distal end and/or **chamber 28** of the **energy delivery member 26** is brought into contact with **tissue surfaces** of nasal passages, mucous membranes, and/or nasal turbinates, *see supra* limitation 9[b], energy is applied to that **tissue**. *See, e.g.*, Ex.1013-Baker, 1:11-22, 10:11-25, 17:22-18:9, 19:10-13, 20:17-20, FIGs.3-5. Baker discloses embodiments in which the delivered energy is “sufficient to ablate tissue and/or cellular structures or debris,” and other embodiments where the delivered energy is “at a sub-ablation intensity that is sufficient to disrupt tissue and/or cellular structures or debris but not ablate.” *Id.*, 18:35-37. Moreover, by applying energy to the tissue sites, Baker teaches applying energy to *mucosal tissue* as described above. Ex.1002-Decl., ¶150.

ii. Device 40

Additionally or alternatively, Baker's teachings in connection with device 40 satisfy limitation 9[c]. Once brought into contact with **tissue surfaces** of nasal passages, mucous membranes, and/or nasal turbinates, *see supra* limitation 9[b], Baker discloses that **energy delivery member 46** is used in a manner similar to **energy delivery member 26** to deliver an *energy based therapy* that treats, disrupts, and/or removes obstructions or undesired materials. Ex.1013-Baker, 21:33-22:29, 23:29-33, 23:39-24:6, 24:22-25, 25:8-20, FIGs.6-8B. For example, Baker discloses embodiments in which the delivered energy is "sufficient to ablate tissue and/or cellular structures or debris," and other embodiments in which the delivered energy is "at a sub-ablation intensity that is sufficient to disrupt tissue and/or cellular structures or debris but not ablate." *Id.*, 23:29-31.



Ex.1002-Decl., ¶¶151-152.

e. Element 9[d]: removing the treatment element from the nasal airway.

Baker discloses *removing the treatment element* (e.g., **energy delivery member 26/46**) *from a patient's nasal airway*. Ex.1002-Decl., ¶153.

i. Device 20

A POSITA would have readily understood that, after delivering the energy based therapy, *see supra* limitation 9[c], **energy delivery member 26** is removed from the patient's *nasal airway*, lest the airway be permanently obstructed by **energy delivery member 26**. Ex.1002-Decl., ¶154.

ii. Device 40

Additionally or alternatively, a POSITA would have recognized that **energy delivery member 46** is removed from the patient's *nasal airway* after treatment for the same reasons. See Ex.1013-Baker, FIG.8E (depicting nasal airways after treatment has been delivered). Ex.1002-Decl., ¶155.

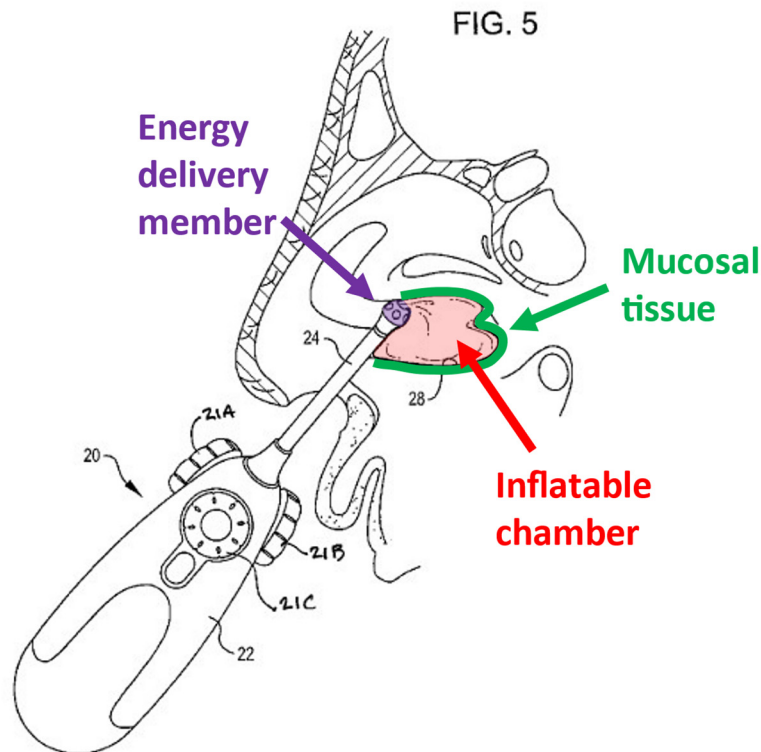
2. **Claim 14: A method as in claim 9, wherein adjusting the shape comprises manipulating a secondary component of the treatment element to increase a surface area of the treatment element.**

Baker discloses that *adjusting the shape comprises manipulating* (e.g., inflating and/or extending/retracting) *a secondary component* (e.g., **flexible, deformable bladder or inflatable chamber 28**, extendible and/or retractable portion of **energy delivery member 26/46/48**) *of the treatment element* (e.g., **energy delivery member 26/48**) *to increase a surface area of the treatment element* (e.g., **forming a bladder or inflating a chamber 28**/exposing more surface area from **energy delivery member 26/46/48**). Ex.1002-Decl., ¶156.

i. Device 20

As explained above for limitation 9[a], Baker discloses extending **energy delivery member 26** from within device 20, which *increases* the exposed *surface area* of the **energy delivery member 26**, including portions that are used for energy delivery (i.e., a *primary component*, such as ultrasound transducers) and others that

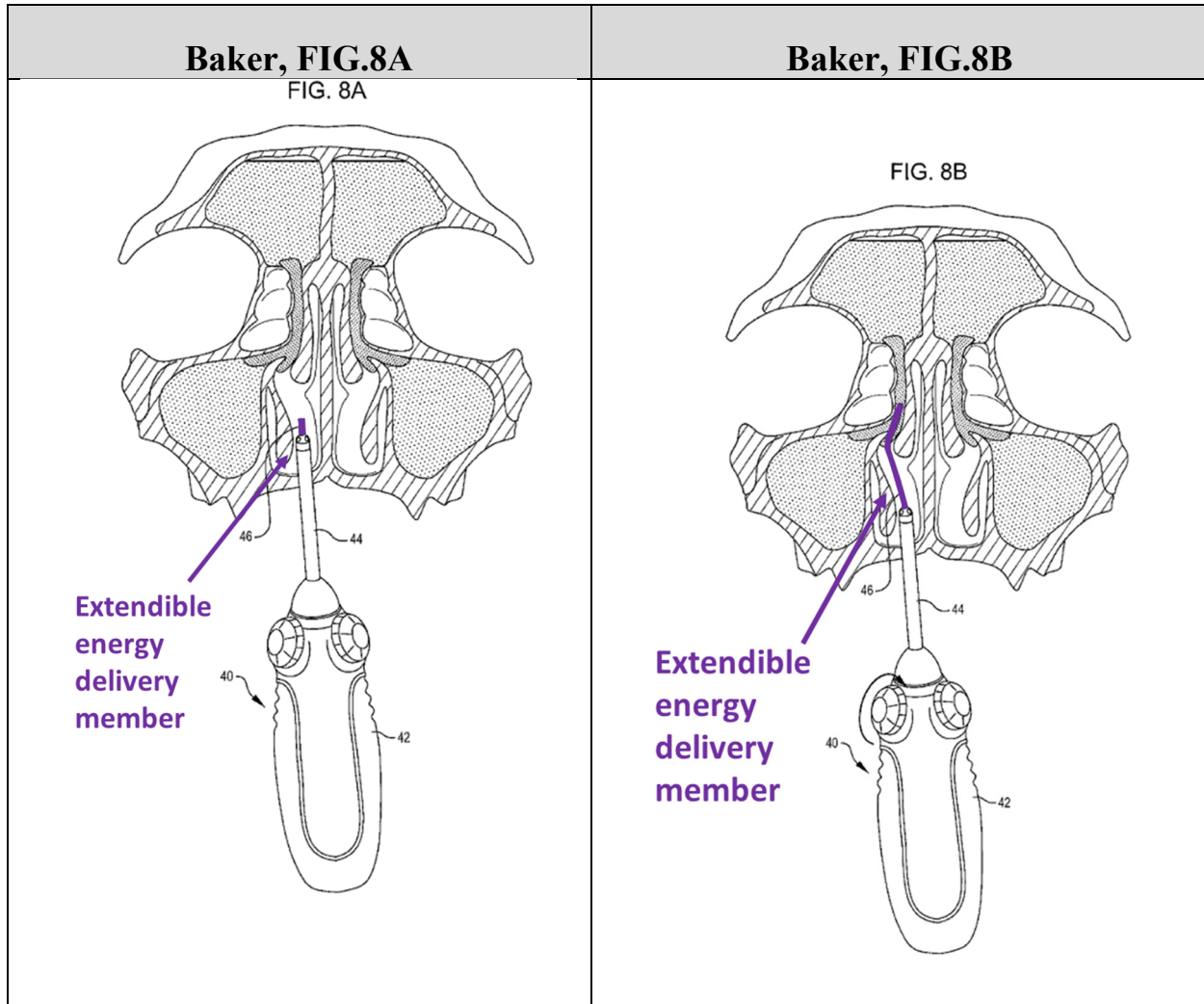
are not used for energy delivery such as mechanical support structures (i.e., a *secondary component*). Ex.1013-Baker, 17:11-18:9, 18:15-19. Likewise, in embodiments of device 20 that include bladder or **inflating chamber 28**, inflating **chamber 28** *increases the surface area* of the **chamber 28** (i.e., a *secondary component*), which is different from the transducer or other component that provides energy (i.e., primary component). *Id.*, 17:11-18:9.



Ex.1013-Baker, FIG.5. Ex.1002-Decl., ¶¶157-158.

ii. Device 40

Additionally or alternatively, Baker discloses extending **energy delivery member 46** from within device 40, *see supra* limitation 9[a], which *increases* the exposed *surface area* of the **energy delivery member 46**, including portions that are used for energy delivery (i.e., a primary component, such as ultrasound transducers) and others that are not used for energy delivery such as the flexible, steerable structure 48 (i.e., a *secondary component*). Ex.1013-Baker, 17:11-18:9, 18:15-19, 21:21-22:9, 22:21-40, 23:5-8, FIGs.8A-8B. Figures 8A and 8B, reproduced below, illustrates the process of extending **energy delivery member 46**, thereby increasing its exposed surface area.



Ex.1002-Decl., ¶¶159-160.

3. **Claim 16:** A method as in claim 9, wherein adjusting the shape comprises forming at least one bend in a shaft of the treatment device.

Baker discloses that *adjusting the shape comprises forming at least one bend in a shaft* (e.g., flexible, catheter-like structure of insertion wand/member 24/44 and/or flexible, steerable structure 48) *of the treatment device* (e.g., device 20/40).

Ex.1002-Decl., ¶161.

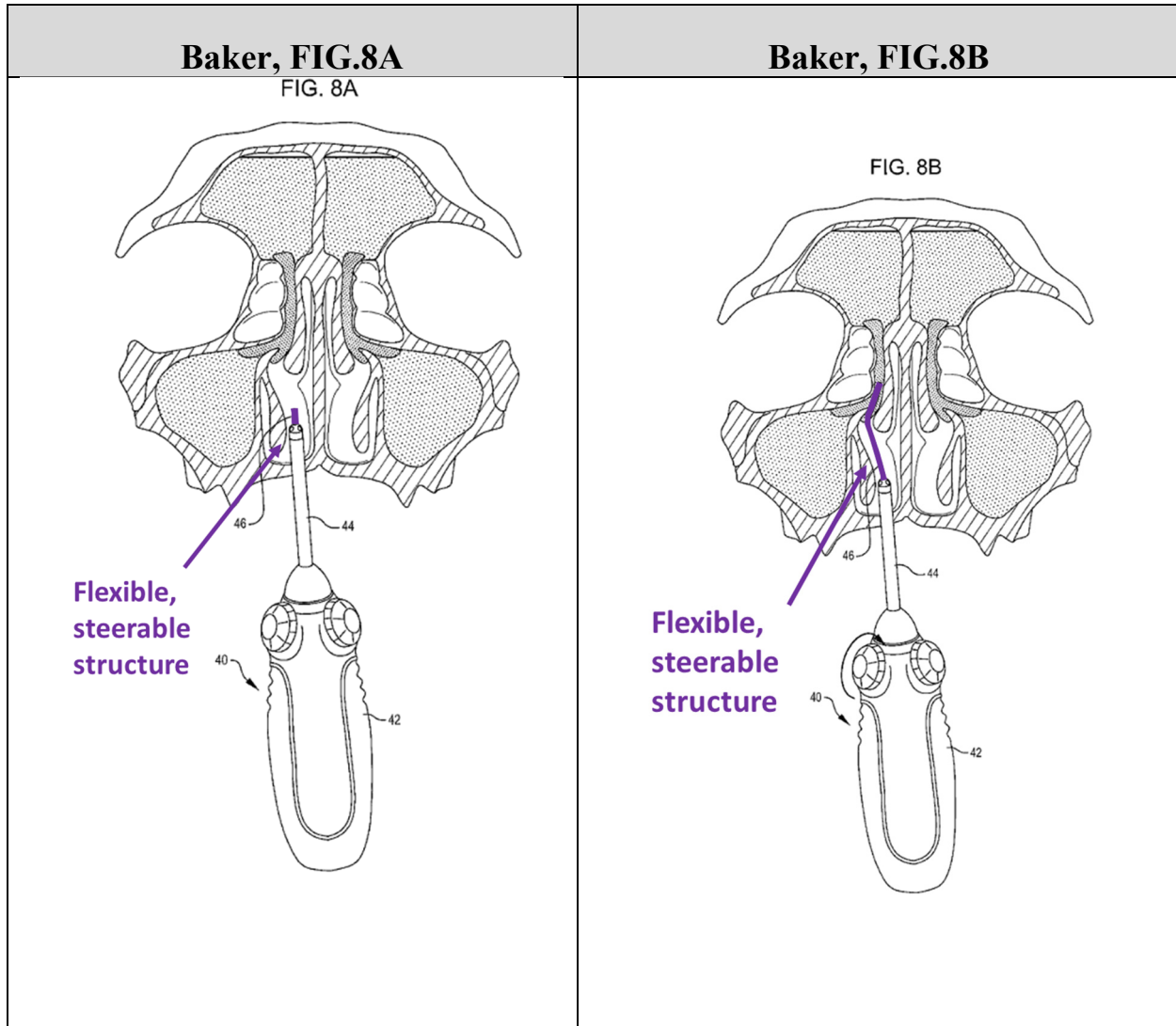
i. Device 20

Baker discloses that the device 20 includes an insertion wand 24 that has a “flexible, catheter-like structure” (i.e., *a shaft*) for insertion through nasal passageways. Ex.1013-Baker, 16:23-28, FIGs.3-5. Flexing of the catheter-like structure during insertion through nasal passageways would result in bending the catheter-like structure. Ex.1002-Decl., ¶162.

ii. Device 40

Additionally or alternatively, Baker discloses that device 40 includes an insertion member 44 with a “flexible, catheter-like structure” (i.e., *a shaft*) that meets the limitations of claim 16 for the same reasons provided above for device 20. Ex.1013-Baker, 16:23-28, 21:24-27. Ex.1002-Decl., ¶163.

Moreover, Baker discloses embodiments of **energy delivery member 46** that include a “flexible, steerable structure 48.” Ex.1013-Baker, 22:21-26, 22:31-40 (describing various forms of flexible structures 48), FIGs.7-8C. As illustrated in Figures 8A-8B, reproduced below, the *shape* of the insertion of the flexible, steerable structure 48 (i.e., *a shaft*) / energy delivery member 46 *bends*, and therefore is adjustable as it is steered to a target site. *Id.*, 22:21-22, 22:26-40, FIGs.7-8C.



Ex.1002-Decl., ¶164.

4. **Claim 18:** A method as in claim 9, wherein delivering the energy based therapy comprises delivering energy in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light, laser and quantic molecular resonance.

Baker discloses that *delivering the energy based therapy* (e.g., high frequency acoustic energy) *comprises delivering energy in a form selected from the claimed group* (e.g., *ultrasound*). Ex.1002-Decl., ¶165.

i. Device 20

Baker discloses embodiments in which device 20 delivers treatment in the form of “*ultrasound energy*.” Ex.1013-Baker, 16:19-22. Ex.1002-Decl., ¶165.

ii. Device 40

Baker likewise discloses that device 40 delivers treatment in the form of “*ultrasound energy*.” Ex.1013-Baker, 22:16-22. Ex.1002-Decl., ¶165.

5. Claim 20: A method as in claim 9, wherein the mucosal tissue is located in a part of the nasal airway other than an internal nasal valve of the airway.

Baker discloses that *the mucosal tissue* (e.g., *target site on tissue surfaces*) *is located in a part of the nasal airway* (e.g., nasal turbinates) *other than an internal nasal valve of the airway*. Ex.1002-Decl., ¶166.

i. Device 20

Baker discloses using device 20 to contact and apply energy to mucosal tissue of the “nasal turbinates.” Ex.1013-Baker, 17:11-21, FIGs.5-6. A POSITA would have understood that the turbinates are *located in a part of the nasal airway other than an internal nasal valve*. In fact, the ’597 patent acknowledges that the “septal turbinate” – i.e., a nasal turbinate – is “a part of the nasal airway other than an internal nasal valve of the airway.” Ex.1001-USP597, Clm.46. Ex.1002-Decl., ¶166.

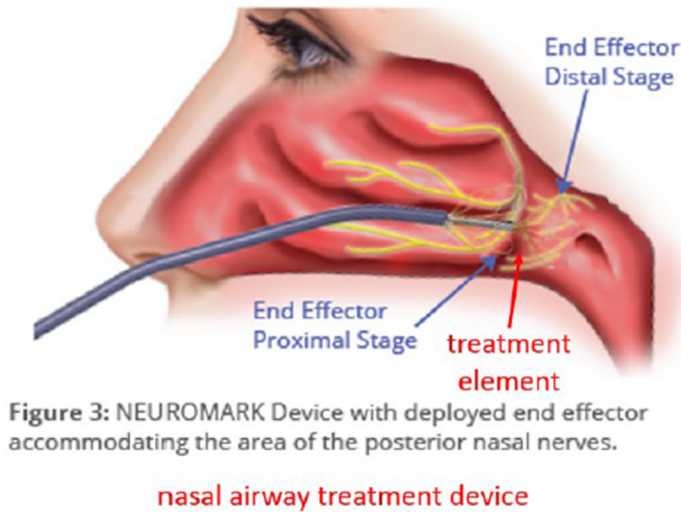
ii. Device 40

Additionally or alternatively, Baker discloses using device 40 to contact and apply energy to mucosal tissue of the “nasal turbinates,” and therefore satisfies the limitations of claim 20 for the same reasons provided above for device 20. Ex.1013-Baker, 22:12-16, FIGs.8A-E. Ex.1002-Decl., ¶166.

6. **Claim 22: A method as in claim 20, wherein the wherein [sic] mucosal tissue includes tissue selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum within the nasal valve, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity.**

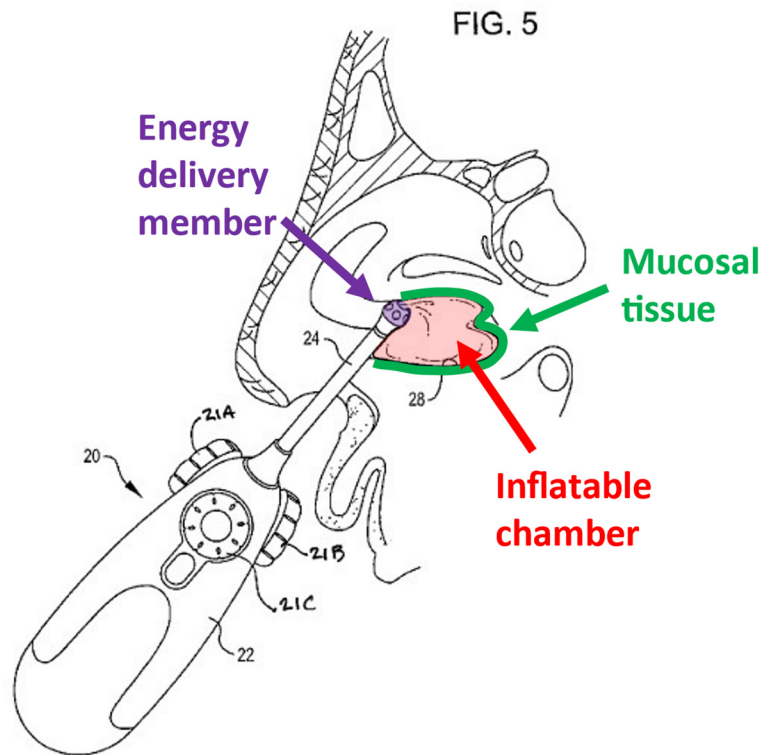
i. Device 20

As explained in Section X.B.5, *supra*, PO argues in the parallel litigation that the following annotated diagram satisfies claim 22 by “show[ing] the end effector contacting mucosal tissue in at least the piriform area and floor of the nasal cavity.”



Ex.1007, 16 (annotations made by PO). Ex.1002-Decl., ¶167.

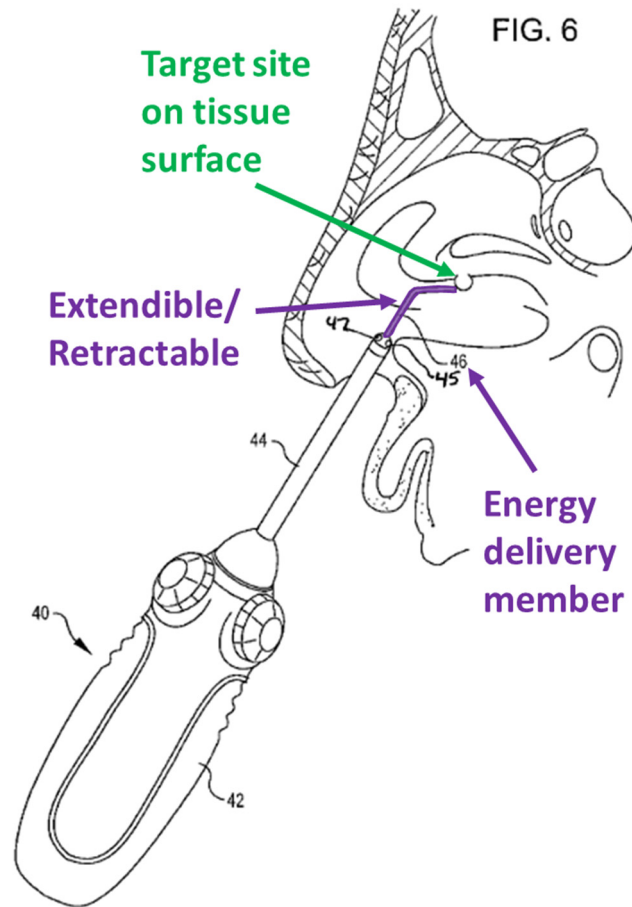
Referring to Figure 5 below, Baker depicts the *energy delivery member* (i.e., *treatment element*) of device 20 contacting the same or similar parts of the nasal anatomy as PO's annotated diagram.



Ex.1013-Baker, FIG.5. Accordingly, to the extent PO advances an interpretation of claim 22 consistent with its apparent interpretation in the parallel litigation, Baker satisfies this limitation by contacting mucosal tissue in at least the *piriform area and floor of the nasal cavity*. Ex.1002-Decl., ¶168.

ii. Device 40

Additionally or alternatively, Figure 6 of Baker, reproduced below, depicts **energy delivery member 46** (i.e. *treatment element*) of device 40 contacting the same or similar parts of the nasal anatomy, such that Baker's method of using device 40 satisfies claim 22 for the same reasons provided above for device 20.



Ex.1013-Baker, FIG.6. Ex.1002-Decl., ¶169.

7. **Claim 23:** A method as in claim 9, further comprising applying force to the mucosal tissue with the treatment element at least one of before, during or after delivering the energy based therapy to deform the mucosal tissue.

Baker discloses *applying force to the mucosal tissue* (e.g., on a **tissue site on tissue surface**, including mucous membranes, nasal turbinates, or pathological undesired tissue) *with the treatment element* (e.g., **energy delivery member 26/46/48**) *at least one of before, during or after delivering the energy based therapy*

(e.g., energy from **energy delivery member 26/46/48**) *to deform the mucosal tissue*.

Ex.1002-Decl., ¶170.

i. Device 20

As explained above for limitations 9[a]-9[c], Baker discloses embodiments in which **energy delivery member 24** is brought into contact with a nasal turbinate or other *mucosal tissue* via extension and/or flex of a catheter-like and/or steerable structure. Such contact is achieved *before delivering* energy and maintained *during delivering* of energy. Moreover, as explained for Gertner and Edwards which use similar devices to contact mucosal tissue, a POSITA would understand that the contact *applies a force to deform the mucosal tissue*. Ex.1002-Decl., ¶171.

Baker also discloses embodiments in which a **flexible, deformable bladder or inflatable chamber 28** of the **energy delivery member 26** can “be enlarged, at a desired target site, until the walls of the chamber **contact**” a **tissue site on tissue surface**, which can include nasal turbinates and other mucosal tissue. *See* Ex.1013-Baker, 16:11-18, 17:11-32, FIG.5; *supra* §§X.D.1.a-c. Such enlargement is performed *before delivering* energy, and the **bladder or chamber 28** is maintained in an enlarged state *during delivering* of energy. Ex.1013-Baker, 16:11-18, 17:11-32, FIG.5; *supra* §§X.D.1.a-c. Moreover, a POSITA would understand that expanding

the **chamber 28** when in contact with the mucosal tissue *applies force to deform the mucosal tissue*. Ex.1002-Decl., ¶171.

ii. Device 40

Additionally or alternatively, Baker discloses that **energy delivery member 46** is brought into contact with a nasal turbinate or other *mucosal tissue* via extension and/or flex of a catheter-like and/or steerable structure, and therefore discloses the limitations of claim 23 for the same reasons as provided above for device 20. *See* Ex.1013-Baker, FIGs.8A-8D. Ex.1002-Decl., ¶172.

8. Claim 24: A method as in claim 9, wherein delivering the energy based therapy modifies at least one property of the mucosal tissue or the underlying tissue without reshaping the tissue.

Baker discloses delivering the *energy based therapy* (e.g., delivering energy from **energy delivery member 26/48** for treatment, disruption, ablation and/or removal of undesired tissue or obstructions) *modifies at least one property of the mucosal tissue or the underlying tissue* (e.g., **tissue site on tissue surface**, including mucous membranes, nasal turbinates, or pathological undesired tissue) *without reshaping the tissue*. Ex.1002-Decl., ¶173.

i. Device 20

As explained above, *see supra* limitation 9[c], Baker discloses using device 20 to deliver energy “sufficient to ablate tissue and/or cellular structures or debris,”

or alternatively to deliver energy “at a sub-ablation intensity that is sufficient to disrupt tissue and/or cellular structures or debris but not ablate.” Ex.1013-Baker, 18:35-37. A POSITA would have understood that when mucosal tissue is ablated or disrupted (and not reshaped), as disclosed by Baker, the tissue is modified *without changing its shape*. In fact, Baker’s disclosure is similar to the ’597 patent’s embodiments where tissue is not reshaped. *Compare* Ex.1013-Baker, 18:35-37 (energy delivered by device 20 is “sufficient to disrupt tissue and/or cellular structures” or to “ablate tissue and/or cellular structures) *with* Ex.1001-USP194, 20:65-21:2 (“deliver[ing] treatment energy to create specific localized tissue damage [(i.e., disrupt tissue and/or cellular structures)] or ablation [(i.e., ablate tissue and/or cellular structures)] stimulat[es] the body’s healing response to create desired conformational or structural changes in the nasal valve tissue”). Ex.1002-Decl., ¶174.

Where the ’597 patent describes embodiments involving reshaping tissue, it explains that the treatment portion is rigid and inelastic such that the tissue conforms to the shape of the treatment device. Ex.1001-USP597, 16:44-48 (“the treatment element 32 may have a substantially rigid or minimally elastic shape sized and shaped such that it substantially conforms to an ideal shape and size of a patient’s nasal passageway, including the internal and external nasal valves”). Here, unlike

those embodiments, Baker discloses an **inflatable chamber** that is flexible and deformable. Ex.1013-Baker, 17:22-32. Ex.1002-Decl., ¶175.

ii. Device 40

Additionally or alternatively, Baker discloses embodiments of device 40 that disrupt or ablate tissue, *see supra* limitation 9[c], and therefore satisfies the limitations of claim 24 for the same reasons provided above for device 20. *See* Ex.1013-Baker, 25:5-20, FIGs.8A-8E. Ex.1002-Decl., ¶176.

9. Claim 44

a. Element 44[pre]: A method of treating a patient's nasal airway

As described above for limitation 9[pre], Baker discloses the preamble. Ex.1002-Decl., ¶177.

b. Element 44[a]: contacting a treatment element of a treatment device with a first mucosal tissue located in a part of the nasal airway other than an internal nasal valve of the airway

As described above for limitation 9[b] and claim 20, Baker discloses this limitation. Ex.1002-Decl., ¶178.

c. Element 44[b]: delivering an energy based therapy to at least one of the first mucosal tissue or an underlying

tissue beneath the first mucosal tissue, using the treatment element

As described above for limitation 9[c], Baker discloses this limitation.

Ex.1002-Decl., ¶179.

d. Element 44[c]: removing the treatment element from the nasal airway.

As described above for limitation 9[d], Baker discloses this limitation.

Ex.1002-Decl., ¶180.

10. Claim 46: A method as in claim 44, wherein the wherein mucosal tissue includes tissue selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity.

As discussed above for claim 22, Baker discloses this limitation. Ex.1002-Decl., ¶181.

Therefore, the challenged claims in Ground IV are anticipated because Baker discloses all their elements arranged as in the claims. *See Blue Calypso*, 815 F.3d at 1341.

E. Ground V: Claim 14 Is Obvious Over Baker

1. Claim 14

As discussed above, Baker anticipates claim 14. Moreover, in the parallel district court litigation, Aerin appears to allege that *manipulating a secondary*

component is satisfied by “operating a slider” on the device handle “to deploy the end effector.” Ex.1007-Complaint-Ex.T, 10-11. Consistent with this interpretation,⁸ Baker discloses a “[h]andle 22” that “house[s] control mechanisms, such as mechanical knobs [that] may provide user operable control of...delivery of generally high frequency acoustic energy.” Ex.1013-Baker, 19:24-29, FIGs.4-8B. A POSITA would have been motivated to control the inflating of **inflatable chamber 28** and/or extending/retracting of extendible and/or retractable portion of **energy delivery member 26/46/48** using such control mechanisms (e.g., knobs) of Baker. Baker expressly directs a POSITA to use the control mechanisms for “other operating modalities,” including inflating **chamber 28** and/or extending/retracting **energy delivery member 26/46/48**. *Id.*, 19:25-29. A POSITA would recognize that inflating of **chamber 28** and/or extending/retracting the extendible and/or retractable portion of **energy delivery member 26/46/48** would require a control mechanism, and thus would be motivated to use controls disclosed within Baker itself (e.g., knobs). Ex.1002-Decl., ¶182.

⁸ Petitioners reserve the right to contest PO’s interpretation and respond to any arguments advanced by PO in this proceeding and the parallel litigation.

XI. CONCLUSION

The challenged claims of the '597 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,

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

Counsel for Petitioners

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing, Petition for *Inter Partes* Review, contains 12,229 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
Registration No. 72,570

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. 9,075,597
- Petitioners' Table of Exhibits
- Exhibits 1001-1003, 1006-1008, 1010, 1011, 1013, 1017-1019, 1021, 1025-1027, 1040, 1046, 1047, 1056, 1060, 1071, 1072, and 1074
- 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. 9,072,597 (“’597 patent”) |
| 1002 | Declaration of Dr. John DelGaudio |
| 1003 | File History of U.S. Patent No. 9,072,597 |
| 1004-1005 | RESERVED |
| 1006 | District Court Amended Complaint |
| 1007 | Exhibit T 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”) |
| 1028-1039 | RESERVED |
| 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”) |
| 1048-1055 | RESERVED |
| 1056 | Liang et al., Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy, 13:8 J. Clin Otorhinolaryngol (China) 341 (August 1999) (English translation) (“Liang”) |
| 1057-1059 | RESERVED |
| 1060 | Andrew P. Lane, Nasal anatomy and physiology 12 Facial Plast Surg Clin N Am 387 (2004) (“Lane”) |
| 1061-1070 | RESERVED |
| 1071 | Translator Declaration for Chen |
| 1072 | Translator Declaration for Liang |
| 1073 | RESERVED |
| 1074 | Translator Declaration for Kong |

Appendix of Claims

| Claim 9 | |
|-------------------|---|
| Limitation | Claim Language |
| 9[pre] | 9. A method of treating a patient's nasal airway, the method comprising: |
| 9[a] | adjusting a shape of a nasal airway treatment device; |
| 9[b] | contacting a treatment element of the treatment device with mucosal tissue in the patient's nasal airway; |
| 9[c] | delivering an energy based therapy to at least one of the mucosal tissue or an underlying tissue beneath the mucosal tissue, using the treatment element; and |
| 9[d] | removing the treatment element from the nasal airway. |

| Claim 14 |
|--|
| A method as in claim 9, wherein adjusting the shape comprises manipulating a secondary component of the treatment element to increase a surface area of the treatment element. |

Claim 16

A method as in claim 9, wherein adjusting the shape comprises forming at least one bend in a shaft of the treatment device.

Claim 18

A method as in claim 9, wherein delivering the energy based therapy comprises delivering energy in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light, laser and quantic molecular resonance.

Claim 20

A method as in claim 9, wherein the mucosal tissue is located in a part of the nasal airway other than an internal nasal valve of the airway.

Claim 22

A method as in claim 20, wherein the wherein mucosal tissue includes tissue selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum within the nasal valve, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity.

Claim 23

A method as in claim 9, further comprising applying force to the mucosal tissue with the treatment element at least one of before, during or after delivering the energy based therapy to deform the mucosal tissue.

Claim 24

A method as in claim 9, wherein delivering the energy based therapy modifies at least one property of the mucosal tissue or the underlying tissue without reshaping the tissue.

| Claim 44 | |
|------------|---|
| Limitation | Claim Language |
| 44[pre] | A method of treating a patient's nasal airway, the method comprising: |
| 44[a] | contacting a treatment element of a treatment device with a first mucosal tissue located in a part of the nasal airway other than an internal nasal valve of the airway; |
| 44[b] | delivering an energy based therapy to at least one of the first mucosal tissue or an underlying tissue beneath the first mucosal tissue, using the treatment element; and |
| 44[c] | removing the treatment element from the nasal airway. |

| Claim 46 |
|---|
| A method as in claim 44, wherein the wherein mucosal tissue includes tissue selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity. |