

Filed: April 25, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.,
Petitioner,

v.

AERIN MEDICAL INC.,
Patent Owner.

Case IPR2024-00275
Patent No. 9,072,597

PATENT OWNER'S PRELIMINARY RESPONSE

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I. Introduction

U.S. Patent No. 9,072,597 (“the ’597 patent”) is directed to novel methods for treating a nasal airway to improve airflow. Petitioner challenges claims 9, 14, 16, 18, 20, 22-24, 44, and 46 of the ’597 patent.

Institution of Ground 1 should be denied under 35 U.S.C. § 325(d) because Gertner was presented to the Office during prosecution and Petitioner fails to show that the Examiner erred in a manner material to the patentability of the challenged claims. Petitioner’s analysis falls short because the Examiner considered Gertner when allowing the claims of the ’597 patent, the Examiner used Gertner to reject the claims of the ’597 patent’s parent, and the Examiner issued a double patenting rejection over the ’597 patent’s parent.

Grounds 1 and 2 of the Petition are anticipation grounds based on Gertner and Edwards-535, respectively. In each of these grounds, Petitioner fails to carry its burden of showing anticipation of the claims. In each of the anticipation grounds, Petitioner provides inconsistent mapping of the claimed elements in the independent and dependent claims that undermines its arguments that the cited references anticipate the challenged claims. This inconsistent mapping further violates the particularity requirement for petitions set forth in 35 U.S.C. § 312(a)(3) and the specificity requirements of 37 C.F.R. §§ 42.104(b)(4), 42.104(b)(5), and 42.22(a)(2).

Ground 3, an obviousness ground based on Edwards-535, fails to cure the deficiencies of Petitioner's improper anticipation arguments. Moreover, even if Petitioner did not provide inconsistent and contradictory mapping of the claims, Gertner and Edwards-535 do not teach the claimed features because they do not teach "contacting a treatment element of the treatment device with mucosal tissue in the patient's nasal airway" and "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."

In Ground 4, Petitioner also fails to meet its burden to show that Baker anticipates the challenged claims. Petitioner combines different embodiments of Baker into one improper anticipation argument. In addition to combining distinct embodiments of Baker, Petitioner presents an obviousness argument in the guise of an anticipation argument. Further, Ground 5, an obviousness ground based on Baker, fails to cure the deficiencies of Petitioner's improper anticipation arguments.

As a result, institution of the Petition should be denied.

II. The '597 Patent

The '597 patent is directed to "[m]ethods and devices for treating nasal airways" using "mechanical re-shaping, energy application and other treatments to ...an internal nasal valve, an external nasal valve or other nasal airways."

Ex. 1001-'597 patent, Abstract. The disclosed embodiments may be used “to improve breathing by decreasing airflow resistance and/or improving nasal airflow or perceived airflow resistance in the nasal airways.” *Id.*, 4:10-14. Figure 3 illustrates an embodiment of a nasal treatment device comprising a “treatment element 32 which may be configured to be placed inside the nasal cavity ...to deliver the desired treatment.” *Id.*, 15:45-49. The nasal treatment device may further include a handle section 34 which may be “sized and configured for easy handheld operation by a clinician,” an electronic control system 42 to control “characteristics of energy or other treatment applied to target regions of a nasal passageway,” and a power supply 44 that may be used for “driving a specific energy delivery technology in treatment element 32.” *Id.*, 15:49-51, 16:7-11, 16:32-34.

According to the '597 patent, “the treatment element 32 may be configured to deliver energy (e.g. heat, RF, ultrasound, microwave) or cryo-therapy uniformly over an entire outer surface of the treatment element 32, thereby treating all nasal tissues in contact with the treatment element 32.” *Id.*, 19:59-63. The “treatment element 32 may be configured with energy-delivery (or removal) elements distributed over an entire outer surface of the treatment element 32.” *Id.*, 20:4-7. In some embodiments, “RF electrodes may be positioned adjacent to and in contact with a targeted tissue region.” *Id.*, 20:42-44. “The nasal tissue that is in contact

with the treatment element may receive sufficient energy to treat the tissue.” *Id.*, 24:31-34. The treatment element may “deliver treatment energy to create specific localized tissue damage or ablation, stimulating the body’s healing response to create desired conformational or structural changes in the nasal valve tissue.” *Id.*, 20:65-21:2.

III. The Asserted Art

A. Gertner

Gertner discloses “therapy devices for providing therapeutic light to a target region of tissue within a nasal cavity.” Ex. 1019-Gertner, Abstract. Figure 4A of Gertner, as shown below, shows the therapy device, including an expandable component 218 and a distal end 216.

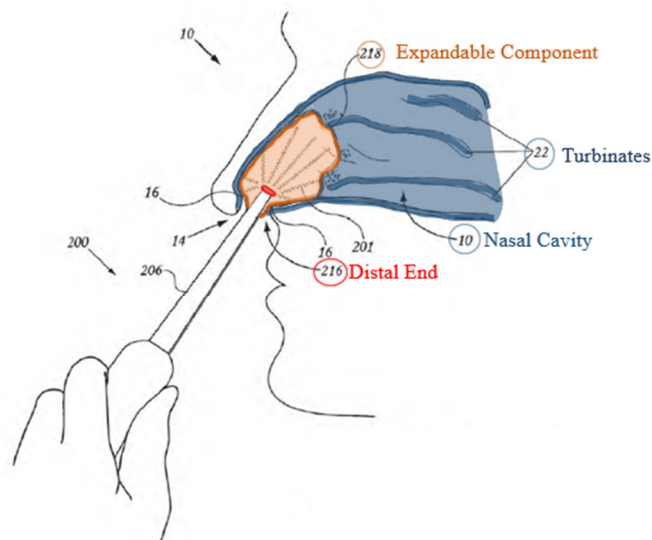


FIG. 4A

Id., Fig. 4A (annotated).

The optical therapy device of Gertner includes an expandable component that “holds the therapy device in place in a space between the nasal septum and a lateral wall of a nasal cavity while the phototherapy is being delivered posterior to the limen nasi.” *Id.*, [0103]. The insertion member of Gertner’s therapy device is “adapted to deliver therapeutic light from a light source to a region of the nasal cavity.” *Id.*, [0104]. According to Gertner, when “the expandable component 218 is a balloon, the therapeutic light is delivered to the tissue through the wall of the balloon.” *Id.*, [0107].

B. Edwards-535

Edwards-535 discloses “a method and apparatus for treating airway obstructions” by “reducing the volume of the turbinates in order [to] reduce nasal airway obstructions.” Ex. 1010-Edwards-535, 1:22-26. In all embodiments of Edwards-535, “the . . . invention provides a method for reducing the size of a nasal concha without the formation of a wound on the surface of the nasal concha.” *Id.*, 4:63-66; *see also id.*, 6:26-27 (“[A]n exposed wound site is not generated during the method.”). Figure 3B of Edwards-535, as shown below, depicts “an apparatus 124 having a distal portion 128 with an expandable member 132 and an energy delivery device 134 for delivering ablative energy.” *Id.*, 5:20-26.

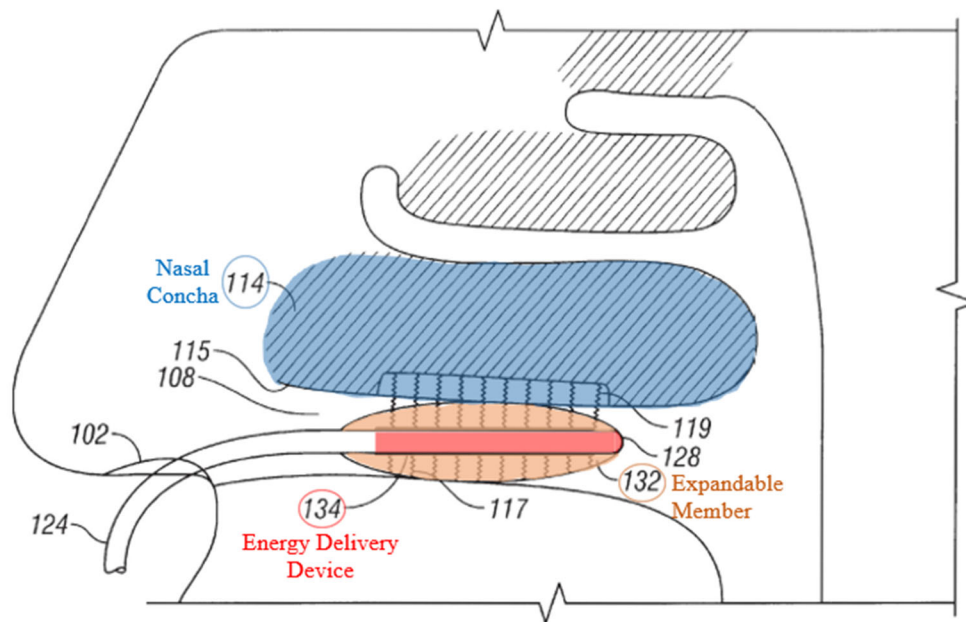


FIG. 3B

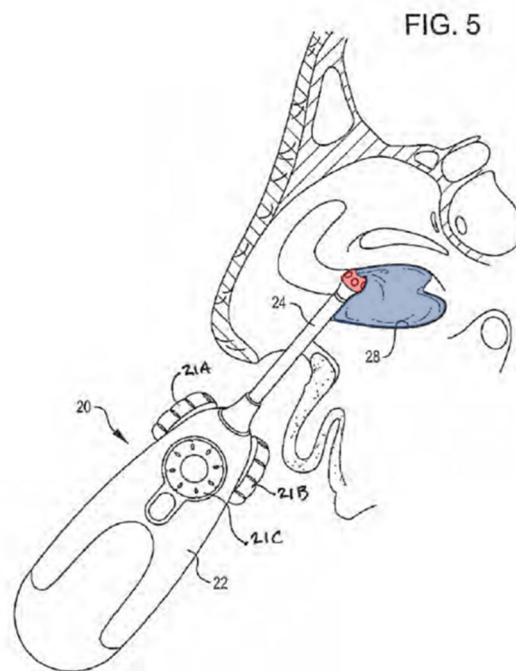
Id., Fig. 3B (annotated).

Edwards-535 describes providing cooling to the surface of the nasal concha to deliver energy to ablate the internal portion of the nasal concha while preventing ablation of the surface of the nasal concha by providing cooling to the surface. *See id.*, 4:60-63 (“By cooling the surface of the nasal concha being ablated, ablation can be performed to remove an internal section of a nasal concha without damaging the surface of the nasal concha.”); *see also id.*, 6:12-16 (“The extent of cooling provided is preferably sufficient to prevent the nasal concha surface from being ablated. As a result, an interior portion of a nasal concha is ablated without ablating the surface of the nasal concha.”); *see also id.*, 6:23-25, 7:2-4. Edwards-535 describes how its “procedure can be performed bloodlessly and without the

need to penetrate tissue” and “eliminates the need for surgical cutting.” *Id.*, 4:58-60, 4:55-56.

C. Baker

Baker discloses devices for “delivery of fluids, aerosols and ultrasound energy to tissue surfaces, cavities, and obstructed sites in passages, lumens, or cavities.” Ex. 1013-Baker, 5:5-12. Figure 5 of Baker, as shown below, shows a device 20, including an energy delivery member and an inflatable chamber.



Id., Fig. 5 (annotated).

The devices of Baker deliver “generally high frequency acoustic energy (e.g., ultrasound energy, including high intensity ultrasound (HIU) and high intensity focused ultrasound (HIFU) to tissue sites, such as nasal passages.” *Id.*,

16:19-22. In some embodiments of Baker, the “energy delivery member” is inside “a flexible, deformable bladder or inflatable chamber 28.” *Id.*, 17:22-24, Fig. 5.

IV. Petitioner Has Not Demonstrated a Reasonable Likelihood of Prevailing on Any Claim Challenged in Ground 1

A. Institution Should Be Denied Under 35 U.S.C. § 325(d)

The Board should exercise its discretion to deny institution of Ground 1 under 35 U.S.C. § 325(d) and the *Advanced Bionics* framework at least because Petitioner (1) presents the same art previously considered by the Office, and (2) fails to demonstrate that the Office erred in a manner material to the patentability of the challenged claims. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GMBH*, IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020) (precedential); *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (P.T.A.B. Dec. 15, 2017) (“*Becton Dickinson*”) (precedential as to § III.C.5, first paragraph).

1. Legal Standard for Application of § 325(d)

The Board has discretion to deny review when “the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d). The Board has explained that under § 325(d) the Director may elect not to institute a proceeding if the challenge to the patent is based on matters previously presented to the Office. *Advanced Bionics*, IPR2019-01469, Paper 6 at 7.

In evaluating matters under § 325(d), the Board uses the following two-part framework: (1) determining whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of the first part of the framework is satisfied, determining whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of the challenged claims. *Id.* at 8.

In applying this framework, the Board considers the following non-exclusive factors:

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
- (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;
- (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and
- (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

Becton Dickinson, IPR2017-01586, Paper 8 at 17-18.

Factors (a), (b), and (d) relate to whether the art or arguments presented in the petition are the same or substantially the same as those previously presented to the Office. *Advanced Bionics*, IPR2019-01469, Paper 6 at 10. Factors (c), (e), and (f) “relate to whether the petitioner has demonstrated a material error by the Office” in its prior consideration of that art or arguments. *Id.* If, after review of factors (a), (b), and (d), the Board determines that the same or substantially the same art or arguments previously were presented to the Office, then the Board considers factors (c), (e), and (f) to determine whether the petitioner demonstrated that the Office erred in a manner material to the patentability of the challenged claims. *Id.*

2. Gertner Was Considered During Prosecution of the '597 Patent, Satisfying Part One

Part one of the Board's two-part framework under *Advanced Bionics* is satisfied because Gertner was considered during prosecution of the '597 patent. In fact, Petitioner concedes that the exact same Gertner reference used in the Petition was previously presented to the Office. *See* Pet., 6-7 (conceding that “Gertner is of record, having been cited during prosecution of the continuation-in-part parent of the '597 patent”). However, not only was Gertner cited during prosecution of the parent of the '597 patent, as Petitioner admits, but Gertner was also cited in an Information Disclosure Statement (“IDS”) during examination of the application

for the '597 patent. During prosecution of the '597 patent, the Examiner entered a list of references cited by the Applicant and considered by the Examiner, in which the Examiner acknowledged the Applicant's IDS and indicated that the Examiner had considered Gertner, among other references. Ex. 1003, 251.

In addition to considering Gertner based on the Applicant's IDS, the Examiner also provisionally rejected independent claims 9 and 45 (which issued as independent claims 9 and 44, respectively) on the ground of non-statutory double patenting over certain claims of the co-pending parent application, U.S. Patent Application No. 13/495,844 ("the '844 application"). Ex. 1003, 238-39. The '844 application was examined by the same Examiner as the '597 patent, and during prosecution of the '844 application, the Examiner rejected the claims of the '844 application based on Gertner alone and Gertner in combination with additional references. This demonstrates that the Examiner considered Gertner during prosecution of the '597 patent's parent application and during the continued prosecution of the '597 patent.

Under *Becton Dickinson* factor (a), Petitioner's asserted art under Ground 1 and the prior art involved during examination are not merely similar, they are identical, i.e., there are no material differences. Similarly, under *Becton Dickinson* factor (b), Petitioner's asserted art under Ground 1 and the prior art involved during examination are not merely cumulative of each other; they are identical.

Finally, because Petitioner's asserted art under Ground 1 and the prior art involved during examination are identical, "the first part of the framework is satisfied" and *Becton Dickinson* factor (d) does not need to be analyzed. See *Advanced Bionics*, IPR2019-01469, Paper 6 at 20.

3. Petitioner Fails to Show a Material Error Under Part Two

With respect to part two of the *Advanced Bionics* framework, Petitioner has not explained how the Examiner erred in allowing the claims to issue, let alone erred in a way material to the patentability of the challenged claims. Petitioner simply walks through the prosecution history of the '597 patent and the '597 patent's parent application, noting that the Examiner cited a different embodiment of Gertner and that the claim of the '597 patent's parent contains a different element than the claims of the '597 patent. Pet., 7-8. This approach is inadequate under *Becton Dickinson* factors (c), (e), and (f), which Petitioner does not even mention, much less evaluate or satisfy. *Advanced Bionics*, IPR2019-01469, Paper 6 at 21 ("Petitioner must demonstrate that the Examiner erred in the evaluation of the prior art, for example, by showing that the Examiner misapprehended or overlooked specific teachings in the relevant prior art such that the error by the Office was material to the patentability of the challenged claims."). In fact, factors (c), (e), and (f) weigh in favor of denying institution.

With respect to *Becton Dickinson* factor (c), the '597 patent's examination record shows that the Examiner evaluated Gertner and (correctly) determined that it was not material to the patentability of the '597 patent's challenged claims. The Examiner expressly stated in the list of references cited by the Applicant and considered by the Examiner, that "ALL REFERENCES [WERE] CONSIDERED EXCEPT WHERE LINED THROUGH." Ex. 1003, 251. Gertner was not lined through on the IDS, indicating that the Examiner considered this reference in evaluating the challenged claims. *See Google LLC v. Valtrus Innovations Ltd.*, IPR2022-01197, Paper 18, 15-16, 18-19 (P.T.A.B. June 13, 2023) (finding "[e]ven though the Examiner did not discuss [the cited reference] in detail, e.g., in a rejection, the Examiner indicated that [the cited reference] was 'considered'" by initialing an IDS form including the cited reference).

As explained above with respect to part one of the *Advanced Bionics* framework, not only did the Examiner consider Gertner based on the Applicant's IDS, the Examiner also provisionally rejected independent claims 9 and 45 (which issued as independent claims 9 and 44, respectively) on the ground of non-statutory double patenting over certain claims of the '844 application. Ex. 1003, 238-39. The '844 application was examined by the same Examiner as the '597 patent, and during prosecution of the '844 application, the Examiner rejected the claims of the

'844 application based on Gertner alone and Gertner in combination with additional references.

Although the claims of the '597 patent and the parent of the '597 patent contain different claim elements, by provisionally rejecting what became claims 9 and 44 of the '597 patent under non-statutory double patenting based on the '844 application, the Examiner indicated that the claims “are not patentably distinct from each other.” Ex. 1003, 239. The Board has previously held that an Examiner's rejection of claims based on a double patenting rejection indicates that the Examiner appreciated the relevant scope of prior art applied in the parent application. *See Gator Bio, Inc. v. Sartorius Bioanalytical Instruments, Inc.*, IPR2023-00215, Paper 19 at 19-20 (P.T.A.B. June 20, 2023) (denying institution and finding that the Examiner appreciated the relevant scope of a prior art reference applied in the parent application when the claims of the challenged patent were rejected based on non-statutory double patenting).

With respect to *Becton Dickinson* factors (e) and (f), Petitioner fails to point out with specificity how the Examiner erred in evaluating Gertner. *See Advanced Bionics*, IPR2019-01469, Paper 6 at 21 (“Petitioner must demonstrate that the Examiner erred in the evaluation of the prior art, for example, by showing that the Examiner misapprehended or overlooked specific teachings in the relevant prior art such that the error by the Office was material to the patentability of the challenged

claims.”). Petitioner argues that the Examiner cited a different embodiment of Gertner (Figure 2A) than the one that Petitioner relies on in Ground 1 (Figure 4A). Pet., 7-8. But Petitioner does not assert that the Examiner “misapprehended or overlooked” the teachings of Figure 4A of Gertner as required under *Advanced Bionics*. *See id.*

Petitioner also suggests that the strength of its ground based on Gertner demonstrates that the Examiner committed material error. *See id.*, 7-8. But, as the Board has explained: “Petitioner’s alleged grounds of unpatentability cannot establish material error per se under our binding precedent. ... Otherwise, the reasonable likelihood standard of § 314(a) and the second part of the *Advanced Bionics* framework (‘material error’) would collapse into one.” *Vital Connect, Inc. v. Bardy Diagnostics, Inc.*, IPR2023-00381, Paper 7 at 20 (P.T.A.B. July 11, 2023). To satisfy its burden under *Becton Dickinson* factor (e), it is not sufficient for Petitioner to merely point to its ground’s proposed mapping of claim limitations to applied references. *See Advanced Bionics*, IPR2019-01469, Paper 6 at 9 (“If reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability. At bottom, this framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.”).

At best, Petitioner simply disagrees with the Examiner's ultimate conclusion. But mere disagreement is not sufficient to support the allegation that there was an error in a manner material to the patentability of the claims. For at least these reasons, the Board should deny institution of Ground 1.

B. Petitioner Has the Burden of Proving Anticipation

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). “[D]ifferences between the prior art reference and a claimed invention, however slight, invoke the question of obviousness, not anticipation.” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008). “[I]t is not enough that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make the whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention.” *Id.*; *see also Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1069 (Fed. Cir. 2017). Rather, the reference must “clearly and unequivocally disclose the claimed [invention] or direct those skilled in the art to the [invention] without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.” *Net*

MoneyIN, 545 F.3d at 1371 (quoting *In re Arkley*, 455 F.2d 586, 587 (C.C.P.A. 1972)).

C. Gertner Fails to Disclose “Contacting a Treatment Element” with “Mucosal Tissue” as Required by Claim Elements [9.b] and [44.a] of the ’597 Patent

Petitioner failed to carry its burden of showing anticipation of the claims challenged in Ground 1 by Gertner. Gertner does not disclose or suggest each and every limitation of the challenged claims. Specifically, Gertner fails to satisfy at least limitation [9.b], “contacting a treatment element of the treatment device with mucosal tissue in the patient’s nasal airway,” and limitation [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 depicted below in annotated Figure 4A of Gertner, therapy device 200 includes a distal end 216 and an “expandable component 218 [that] can be positioned at the distal end 216 of the elongate body 206.” Ex. 1019-Gertner, [0106]. According to Gertner, “therapeutic light [is] emitted from distal end 216,” *id.*, [0109], and the “expandable component 218 holds the therapy device in place in a space between a nasal septum and a lateral wall of the nasal cavity while the phototherapy is being delivered.” *Id.*, [0103]. According to Gertner, the “therapeutic light is delivered to the tissue through the wall of the balloon.” *Id.*, [0107].

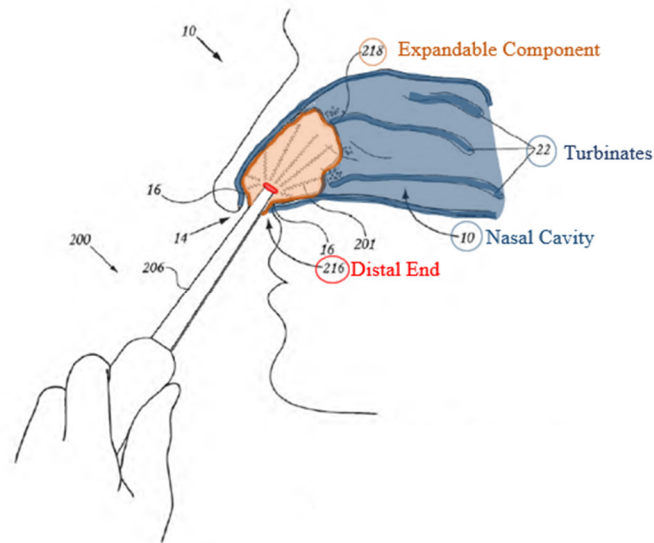


FIG. 4A

Id., Fig. 4A (annotated).

Petitioner identifies that the “expandable component 218 ... contacts mucosal tissue lining the nasal passages.” Pet., 30. In its analysis of limitation [9.b], Petitioner contends that “distal end 216 of therapy device 200, including a light emitter and expandable component 218” constitutes the claimed “treatment element.” *Id.*, 29-30. However, the expandable component 218 of Gertner, the only component that Petitioner contends “contacts mucosal tissue,” is not a “treatment element” as required by claims 9 and 44, and Petitioner’s mapping is internally inconsistent.

First, Gertner does not anticipate at least elements [9.b] and [44.a] of the ’597 patent. Petitioner identifies a single component, the “expandable component 218,” that it contends “contacts mucosal tissue lining the nasal passages.” Pet., 30.

However, the expandable component 218 of Gertner is not a “treatment element” as required by claims 9 and 44.

Gertner discloses that “therapeutic light [is] emitted from distal end 216” and merely “travels through the expandable component 218.” Ex. 1019-Gertner, [0109]. As disclosed in Gertner, expandable component 218 “holds the therapy device in place in a space between a nasal septum and a lateral wall of the nasal cavity while the phototherapy is being delivered posterior to the limen nasi.” *Id.*, [0103]. Gertner further explains that “expandable component 218 grips the walls of the nasal cavity” so that “the therapy device can pivot and deliver light to various parts of the nasal cavity 10 without delivery [of] light to other regions of the nasal cavity.” *Id.*, [0103]. According to the disclosure of Gertner, expandable component 218 merely holds the therapy device in place within the nasal cavity to facilitate the treatment but is not a “treatment element.” *See id.*

Further, in Petitioner's analysis of claim 14 in another ground, it distinguishes between portions of the treatment device, such as “portions that are used for energy delivery (i.e., a primary component...)” and portions “that are not used for energy delivery such as mechanical support structures (i.e., a secondary component ...).” Pet., 76-77. Under Petitioner's own analysis, Gertner's expandable component 218 is a component that is *not* used for energy delivery, but rather “holds the therapy device in place” while “therapeutic light [is] emitted from

distal end 216” and therefore is not a “treatment element.” Ex.1019-Gertner, [0103], [0109]. The Petition fails to show that Gertner discloses limitation [9.b], “contacting a treatment element of the treatment device with mucosal tissue in the patient’s nasal airway” and, therefore, fails to show that Gertner anticipates claim 9.

Second, the Petition’s mapping of the claimed “treatment element” between the independent and dependent claims is inconsistent with and undermines its argument that the expandable component 218 of Gertner is the claimed “treatment element.” In its analysis of claim element [9.b], Petitioner contends that the distal end 216, including both a light emitter and expandable component 218 constitutes the claimed “treatment element.” Pet., 29-30. In its analysis of claim 14, however, Petitioner characterizes only the distal end 216 as the “treatment element,” and characterizes the expandable component 218 as a separate “secondary component.” *Id.*, 34-35.

Petitioner’s mapping of the “treatment element” across these limitations is inconsistent and contradictory. *Compare id.*, 29 (identifying Gertner’s light emitter *and* expandable component 218 as the claimed “treatment element” in limitation [9.b]), *with id.*, 34 (identifying only Gertner’s distal end 216 as the claimed “treatment element” and identifying Gertner’s expandable component 218 as the separately claimed “secondary component” in claim 14). The Petition’s ambiguous

and inconsistent mapping of the “treatment element” is fatal to Petitioner’s anticipation argument. The Board has denied institution in similar situations where the Petition suffered from inconsistent mapping between the independent claims and the dependent claims. *See, e.g., Facebook, Inc. v. Uniloc USA, Inc.*, IPR2017-01523, Paper 7 at 9-19 (P.T.A.B. Dec. 4, 2017) (denying institution because “Petitioner inconsistently maps the recited ‘instant voice message’ to different elements of Zydney within its proffered analysis of independent claims 1 and 40, and across the challenged dependent claims, in the Petition”).

Moreover, this inconsistent mapping of the “treatment element” violates the particularity requirement for petitions set forth in 35 U.S.C. § 312(a)(3) that petitions “may be considered only if ... the petition identifies, in writing and with particularity, ... the grounds on which the challenge to each claim is based, and the evidence that supports the grounds,” as well as the specificity requirements of 37 C.F.R. §§ 42.104(b)(4), 42.104(b)(5), and 42.22(a)(2) that a petition must “specify where each element of the claim is found in the prior art,” “identify[] specific portions of the evidence that support the challenge,” and provide a “full statement of the reasons for the relief requested, including a detailed explanation of the significance of the evidence.” This is yet another independent reason to deny institution. *See, e.g., Facebook*, IPR2017-01523, Paper 7 at 9-19 (denying institution “for two independent reasons,” including petitioner’s inconsistent

mapping and because the “Petition’s arguments and supporting evidence ... violate[d] the statutory and regulatory requirements for a petition” under 35 U.S.C. § 312(a)(3) and 37 C.F.R. §§ 42.104(b)(4), 42.104(b)(5), and 42.22(a)(2)).

Limitation [44.a] is similar to limitation [9.b]. Petitioner’s analysis of limitation [44.a] merely cites to its analysis of limitation [9.b]. Pet., 42. Therefore, Petitioner fails to show that Gertner anticipates claim 44 for the same reasons it fails to do so for claim 9.

V. Petitioner Has Not Demonstrated a Reasonable Likelihood of Prevailing on Any Claim Challenged in Ground 2

Petitioner also failed to carry its burden of showing anticipation of the claims challenged in Ground 2 by Edwards-535. Specifically, Petitioner failed to show that Edwards-535 teaches or suggests at least limitation [9.b], “contacting a treatment element of the treatment device with mucosal tissue in the patient’s nasal airway” and limitation [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 depicted below in annotated Figure 3B of Edwards-535, the apparatus 124 has “a distal portion 128 with an expandable member 132 and an energy delivery device 134 for delivering ablative energy.” Ex. 1010-Edwards-535, 5:20-26. The expandable member 132 “is expanded within the nasal meatus 108 so that

the expandable member 132 is brought into contact with the surface 115 of the nasal concha 114.” *Id.*, 5:27-30. According to Edwards-535, “[a]blative energy 117 is ... delivered through the apparatus and the energy delivery device 134 to the nasal concha 114.” *Id.*, 5:32-35.

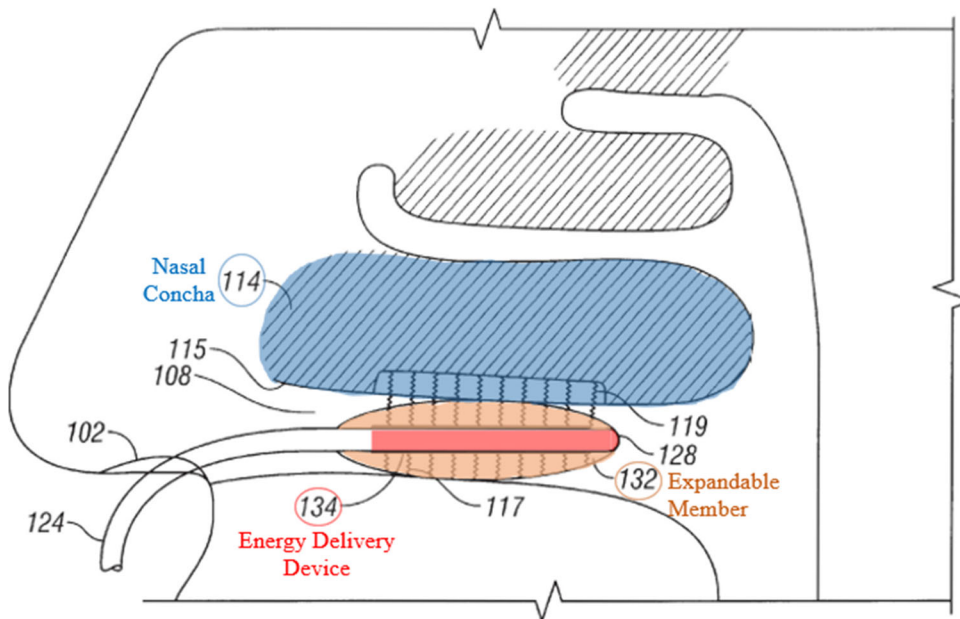


FIG. 3B

Id., Fig. 3B (annotated).

Petitioner identifies that the expandable member 132 is expanded and brought into contact with the nasal concha. Pet., 47. In its analysis of limitation [9.b], Petitioner contends that a distal portion 128 of apparatus 124 includes an energy delivery device 134 and expandable member 132 that “together deliver ‘ablative energy’ to a nasal airway.” *Id.* However, just like Petitioner’s mapping of Gertner in Ground 1, Petitioner’s mapping of Edwards-535 in Ground 2 is

internally inconsistent, and the expandable member 132 of Edwards-535 is not a “treatment element,” as required by claims 9 and 44.

First, the Petition’s mapping of the claimed “treatment element” in the independent claim and in dependent claims is inconsistent with and undermines its argument that the expandable member 132 of Edwards-535 is the claimed “treatment element.” In its analysis of claim element [9.b], Petitioner contends that the expandable member 132 *and* the energy delivery portion 134 constitute the claimed “treatment element.” Pet., 46-47. However, in its analysis of claim 14, Petitioner characterizes only the distal portion 128 as the “treatment element,” and characterizes the expandable member 132 as a separate “secondary component” of the treatment element. *Compare id.*, 45 (identifying the energy delivery device 134 *and* expandable member 132 as the claimed “treatment element” in limitation [9.b]), *with id.*, 54-55 (identifying only the distal portion 128 as the claimed “treatment element” and identifying expandable member 132 as the separately claimed “secondary component”). The Petition’s ambiguous and inconsistent mapping of the “treatment element,” both within the independent claims and across dependent claims, is fatal to its anticipation argument and warrants denial of institution. *See, e.g., Facebook, Inc.*, IPR2017-01523, Paper 7 at 9-19 (denying institution because “Petitioner inconsistently maps the recited ‘instant voice message’ to different elements of Zydney within its proffered analysis of

independent claims 1 and 40, and across the challenged dependent claims, in the Petition”).

Moreover, as discussed above in Ground 1, this inconsistent mapping of the “treatment element” violates the particularity requirement for petitions set forth in 35 U.S.C. § 312(a)(3) as well as the specificity requirements of 37 C.F.R. §§ 42.104(b)(4), 42.104(b)(5), and 42.22(a)(2). This is yet another, independent reason to deny institution. *See, e.g., Facebook*, IPR2017-01523, Paper 7 at 9-19 (denying institution “for two independent reasons,” including petitioner’s inconsistent mapping and because the “Petition’s arguments and supporting evidence ... violate[d] the statutory and regulatory requirements for a petition” under 35 U.S.C. § 312(a)(3) and 37 C.F.R. §§ 42.104(b)(4), 42.104(b)(5), and 42.22(a)(2)).

Second, Petitioner contends that “multiple configurations” of Edwards-535 “each” demonstrate anticipation of the limitations of claim elements [9.b] and [44.a]. But none of these multiple configurations do.

Petitioner first relies on an embodiment of the apparatus 124 where the “energy delivery device 134 is positioned within expandable member 132.” Pet., 47-48. That configuration is shown in Petitioner’s annotated version of Figure 3B below.

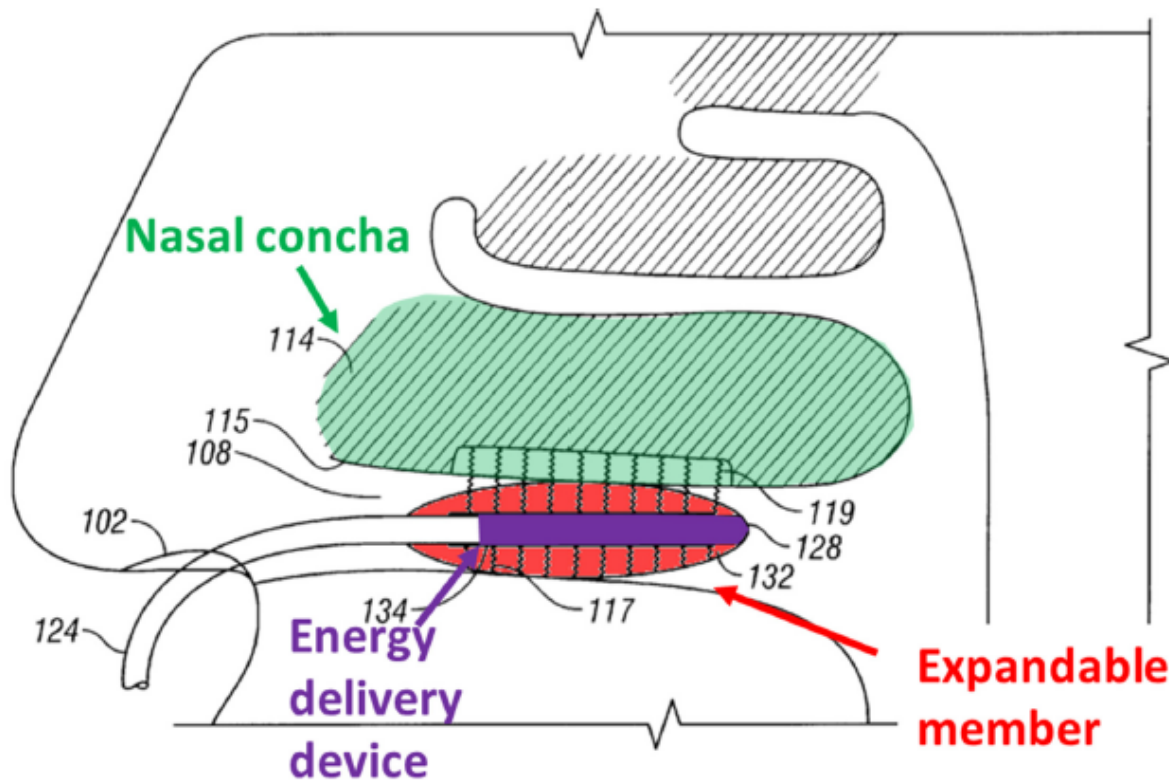


FIG. 3B

Id., 48 (Petitioner's annotations of Fig. 3B of Edwards-535).

This configuration of Edwards-535 does not anticipate limitations [9.b] and [44.a]. Petitioner concedes that the “energy delivery device 134 [is] *positioned within* expandable member 132.” *Id.*, 36 (emphasis added). As is clear from the annotated figure above, energy delivery device 134 does *not* directly contact the nasal mucosa. *See* Ex. 1010-Edwards-535, Fig. 3B. Instead, as the Petition also concedes, 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.” *Pet.*, 47 (quoting Ex. 1010-Edwards-535, 5:27-30). As disclosed in Edwards-535,

“[a]blative energy 117 is then delivered *through . . . the energy delivery device 134* to the nasal concha 114.” Ex. 1010-Edwards-535, 5:27-34 (emphasis added). The expandable member 132 contacts the nasal mucosa, and the energy delivery device 134 does not contact the nasal mucosa *See id.*, Fig. 3B, 5:27-30. Therefore, this configuration of Edwards-535 does not satisfy limitation [9.b], “contacting a treatment element of the treatment device with mucosal tissue in the patient’s nasal airway” and, therefore, fails to show that Edwards-535 anticipates claim 9.

Petitioner next relies on a second alleged “configuration” of Edwards-535 that it contends discloses “energy delivery device 134 ... ‘positioned on a surface’ of expandable member 132, rather than on the inside thereof.” Pet., 48. Petitioner cites Figures 3A-3D and Figures 5 and 6 as allegedly showing this “configuration.” *Id.*, 48-49. But as shown above, and as admitted by Petitioner, Figure 3 clearly shows the energy delivery device 134 *inside* the expandable member, not on its surface. *See, e.g.*, Ex. 1010-Edwards-535, Fig. 3B. Figures 5 and 6 of Edwards-535 both also show the energy delivery device 134 *inside* the expandable member 132.

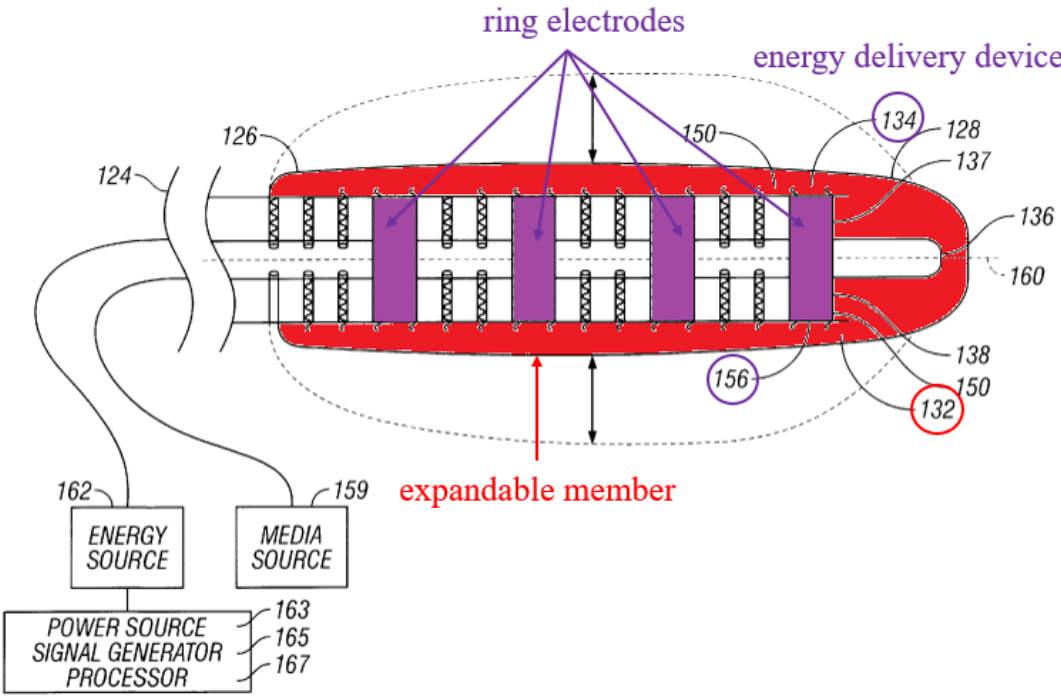


FIG. 6

Id., Fig. 6 (annotated).

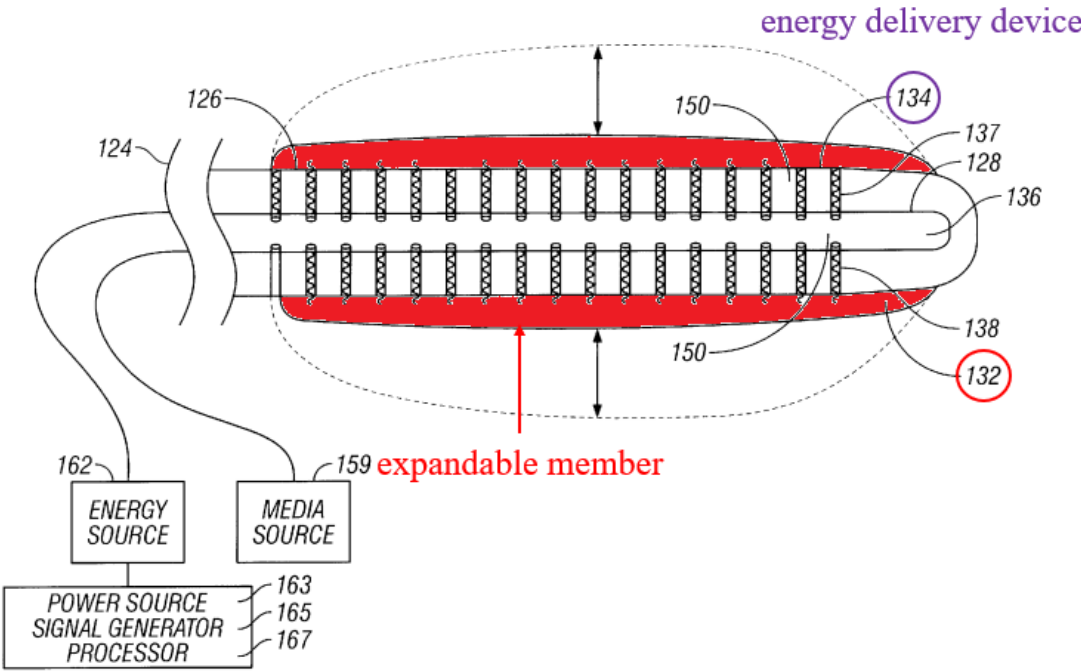


FIG. 5

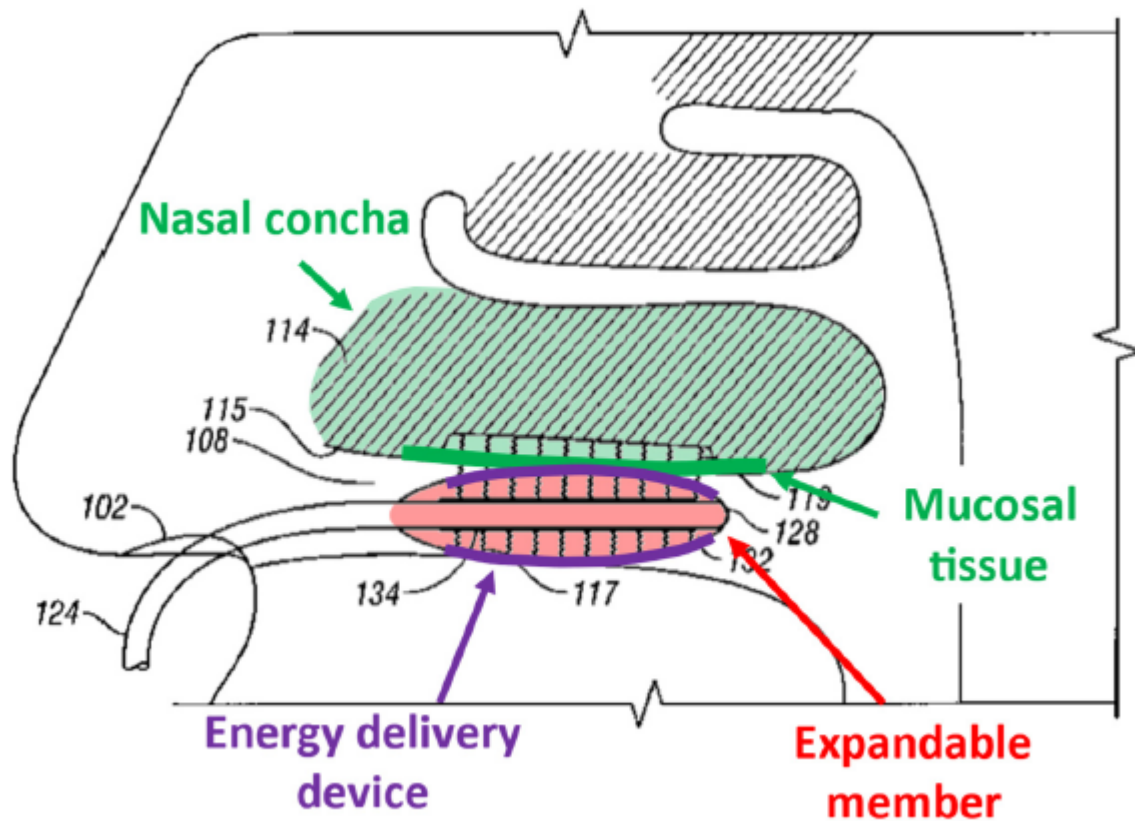
Id., Fig. 5 (annotated). As shown in Figures 5 and 6, the energy delivery device 134 is *inside* the expandable member 132 and does not contact the nasal mucosa.

Id., Figs. 5 and 6. Therefore, neither Figure 5 nor Figure 6 satisfies element [9.b].

None of Figures 3, 5, or 6 support Petitioner's argument. So Petitioner resorts to creating a new version of Figure 3B where it modifies the embodiment shown in Figure 3B to show the energy delivery device 134 on the outside surface of the expandable member when, in reality, the specification describes the energy delivery device of Figure 3B to be *inside* the expandable member. *Id.*, 5:27-35.

This modified Figure 3B is reproduced below with Petitioner's annotations.

Tellingly, Petitioner's expert does not include Petitioner's annotated Figure 3B in the expert declaration. *See* Ex. 1002, ¶¶ 103-104. So this concocted figure is nothing more than attorney argument. *See Icon Health and Fitness, Inc. v. Strava, Inc.*, 849 F.3d 1034 (Fed. Cir. 2017) ("Attorney argument is not evidence.").



Pet., 49 (Petitioner's annotations of Fig. 3B of Edwards-535).

As shown above, Petitioner has added curved purple lines labeled "energy delivery device" to a different location than where energy delivery device 134 is plainly shown in Figure 3B. In other words, Petitioner has *modified* Figure 3B, based on some alleged other "configuration" of Edwards-535, in an attempt to satisfy this limitation.

In addition, in his declaration explaining this purported other "configuration" of Edwards-535, Petitioner's expert relies not only on multiple distinct embodiments in Edwards-535 (Figures 3B, 5, and 6), but also on

embodiments disclosed in another patent, Baker-788, incorporated by reference in Edwards-535. Ex. 1002 at 64-68. But this is not a legally proper anticipation analysis. *Fujian Sanan Grp. Co. v. Epistar Co.*, IPR2018-00970, Paper 9 at 8 (P.T.A.B. Nov. 20, 2018) (“[A] patent challenger cannot rely on portions from different embodiments in a prior-art document to demonstrate anticipation.”); *Microsoft*, 878 F.3d at 1069 (“[A]nticipation is not proven by ‘multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention.’” (citation omitted)). Petitioner impermissibly stretches Edwards-535 beyond any single embodiment to support its anticipation theory.

Limitation [44.a] is similar to limitation [9.b]. Petitioner's analysis of limitation [44.a] merely cites to its analysis of limitation [9.b]. Pet., 60. Therefore, Petitioner fails to show that Edwards-535 anticipates claim 44 for the same reasons it fails to do so for claim 9.

VI. Petitioner Has Not Demonstrated a Reasonable Likelihood of Prevailing on Any Claim Challenged in Ground 3

In Ground 3, Petitioner argues that dependent claim 16, which recites “[a] method as in claim 9, wherein adjusting the shape comprises forming at least one bend in a shaft of the treatment device” would have been obvious over Edwards-535. Pet., 61-64. But claim 16 depends from independent claim 9, and Petitioner does not allege that the modification it advances for dependent claim 16 would

cure the deficiencies regarding claim 9 noted above in Ground 2, including the lack of a teaching in Edwards-535 of limitation [9.b], as discussed in Section IV.C. *See id.*, 61-64. Because claim 16 depends from claim 9, and because Ground 3 fails to cure the deficiencies regarding claim 9, Ground 3 fails to render claim 16 invalid.

VII. Petitioner Has Not Demonstrated a Reasonable Likelihood of Prevailing on Any Claim Challenged in Ground 4

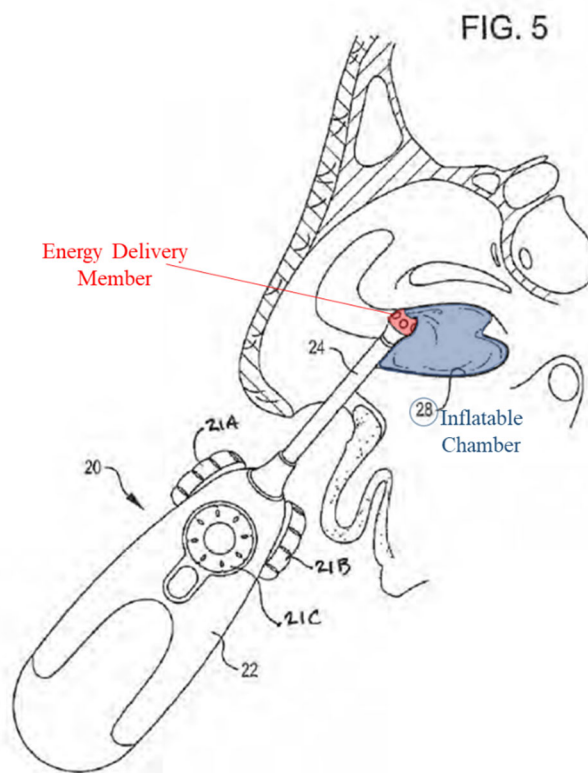
Petitioner has failed to meet its burden to show that Baker anticipates independent claims 9 and 44.

To anticipate a claim, a prior art reference “must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’” *Net MoneyIN, Inc.*, 545 F. 3d at 1369. “Thus, it is not enough that the prior art reference ... includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention.” *Id.* at 1371.

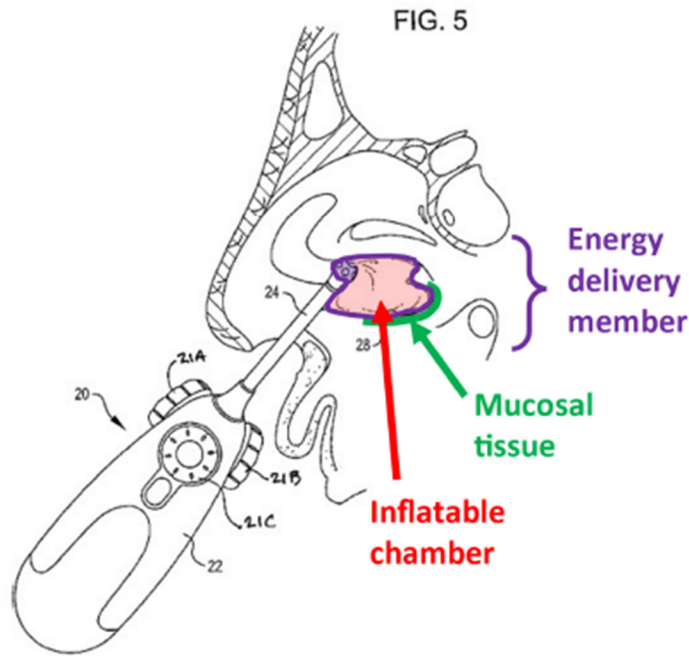
Petitioner presents Ground 4 as an anticipation ground in which it contends “multiple embodiments” of Baker—namely, Device 20 and Device 40—“*independently* satisfy the claims.” Pet., 64 (emphasis added). But the Device 20 embodiment of Baker does not anticipate at least elements [9.b] and [44.a] of the ’597 patent. And when Petitioner purports to rely on the Device 40 embodiment as

an “independent” anticipation argument, Petitioner is actually relying on *both* Device 20 and Device 40, which is legally improper.

First, Device 20 of Baker does not anticipate at least elements [9.b] and [44.a] of the '597 patent. Petitioner relies on Device 20, as depicted below in annotated Figure 5 of Baker, as disclosing elements [9.b] and [44.a].



Ex. 1013-Baker, Fig. 5 (annotated). In the Petition, Petitioner provides the following annotated version of Figure 5.



Pet., 71 (Petitioner's annotations of Fig. 5 of Baker). Petitioner asserts that "energy delivery member 26 of device 20 is a treatment element." *Id.*, 70. Petitioner also identifies a single component, "inflatable chamber 28," that it contends contacts a tissue site. *Id.* However, the inflatable chamber 28 is not a "treatment element" as required by claims 9 and 44.

Baker discloses an inflatable chamber 28. Ex. 1013-Baker, 17:22-24. According to Baker, inflatable chamber 28 "may be enlarged at a desired target site, *until the walls of the chamber contact a tissue site*, or the walls of a cavity." *Id.*, 17:27-29 (emphasis added). Further, "high frequency acoustic energy . . . or ultrasound energy may be applied, through the energy delivery member." *Id.*, 19:5-

8. According to the disclosure of Baker, inflatable chamber 28 contacts the tissue site but is not the claimed “treatment element.”

Additionally, in Petitioner's analysis of claim 14, Petitioner distinguishes between portions of Device 20, such as “portions that are used for energy delivery (i.e., a primary component . . .)” and portions “that are not used for energy delivery such as mechanical support structures (i.e., a secondary component . . .).” Pet., 76-77. Petitioner identifies energy delivery device 26 as the “primary component” used for energy delivery and identifies chamber 28 as the “secondary component” that is not used for energy delivery. Under Petitioner's own analysis, Baker's chamber 28 is a component that is *not* used for energy delivery and is therefore not a “treatment element.” *Id.* The Petition fails to show that Device 20 of Baker discloses limitation [9.b] and [44.a].

Second, when Petitioner purportedly relies on the Device 40 embodiment of Baker as an independent anticipation argument, it is not actually presenting a second, independent anticipation argument, but rather is combining the Device 20 and Device 40 embodiments of Baker into one improper anticipation argument. *Fujian Sanan Grp.*, IPR2018-00970, Paper 9 at 8 (“[A] patent challenger cannot rely on portions from different embodiments in a prior-art document to demonstrate anticipation.”).

For example, for limitation [9.a], Petitioner asserts that “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*).” Pet., 65 (emphasis added). For the same limitation, Petitioner asserts that “Device 20 is a nasal airway treatment device used ‘for delivery of high frequency acoustic energy to internal sites, such as nasal passageways’” while also asserting “[a]dditionally or alternatively, Baker’s teachings in connection with Device 40 satisfy limitation 9[a].” *Id.*, 65, 67 (emphasis added). Petitioner uses “[a]dditionally or alternatively” when introducing its Device 40 argument for every limitation of claim 9. *See id.*, 64-76 (emphasis added). Petitioner’s repeated use of “[a]dditionally or alternatively” reveals that the Device 40 part of Ground 4 does not truly present an *alternative* anticipation argument based on Device 40 of Baker alone, but rather invites the Board to rely on *additional* embodiments of Baker (namely Device 20) in combination with Device 40, which is improper to show anticipation. *Fujian Sanan Grp.*, IPR2018-00970, Paper 9 at 8 (“[A] patent challenger cannot rely on portions from different embodiments in a prior-art document to demonstrate anticipation.”); *Net MoneyIN, Inc.*, 545 F. 3d at 1369 (explaining that the prior art document “must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’” (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983))).

In addition to inviting a combination of two distinct embodiments of Baker—Device 20 and Device 40—Petitioner further relies on multiple embodiments of Device 40 itself. Throughout Ground 4 of the Petition, Petitioner relies on Figures 6-8B of Baker when asserting that Device 40 discloses the elements of the challenged claims. Pet., 68, 71, 72, 74. But, as disclosed in Baker, “Figs. 6 and 7 show schematic illustrations of *two embodiments* of a device for delivery of generally high frequency acoustic energy to nasal passages.” Ex. 1013-Baker, 21:21-22 (emphasis added). Petitioner, therefore, asserts multiple different embodiments *within* the Device 40 embodiment that Petitioner contends anticipates the claims. This is not a legally proper anticipation analysis. *Microsoft*, 878 F.3d at 1069 (“[A]nticipation is not proven by ‘multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention.’” (citation omitted)). In this additional way, Petitioner impermissibly stretches Baker beyond any single embodiment to support its anticipation theory.

Moreover, for limitation [9.d], Petitioner actually presents an *obviousness* argument in the guise of an anticipation argument. Limitation [9.d] recites “removing the treatment element from the nasal airway.” Apparently recognizing that Baker lacks any express disclosure of removing the device from the patient’s airway, Petitioner contends that in the Device 20 embodiment, “[a] POSITA would have readily understood” that the device “is removed,” and that in the Device 40

embodiment, “a POSITA would have recognized” that the device “is removed.” Pet., 75-76. What a person of ordinary skill in the art (“POSITA”) would have allegedly “understood” or “recognized” about a reference falls short of what is required for anticipation, which requires that the reference “must ... disclose all elements of the claim within the four corners of the document.” *Net MoneyIN, Inc.*, 545 F. 3d at 1369. Further, Petitioner does not allege inherency in its analysis of element [9.d]. *See Par Pharma., Inc. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1195 (Fed. Cir. 2014) (“Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” (quoting *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981))).

The Petition fails to show that Baker anticipates the challenged claims.

VIII. Petitioner Has Not Demonstrated a Reasonable Likelihood of Prevailing on Any Claim Challenged in Ground 5

In Ground 5, Petitioner argues that dependent claim 14, which recites “[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” would have been obvious over Baker. Pet., 91-92. But claim 14 depends from independent claim 9, and Petitioner does not allege that the modification it advances for dependent claim 14 would cure the deficiencies

regarding claim 9 noted above in Ground 4, including Baker's failure to teach limitation [9.b] with Device 20, discussed in Section VII. *See id.*, 91-92. Further, this ground does not cure the deficiencies of the Petition's interchangeable use of both Device 20 and Device 40 (and further multiple embodiments of Device 40) in the purported anticipation argument regarding Device 40, discussed in Section VII. *See id.* Because claim 14 depends from claim 9, and because Ground 5 fails cure the deficiencies regarding claim 9, Ground 5 fails to render claim 14 invalid.

IX. Conclusion

For at least the reasons provided above, the Petition should be denied and trial should not be instituted.

Respectfully submitted,

Dated: April 25, 2024

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Lead Counsel for Patent Owner
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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Kathleen A. Daley, certify that
PATENT OWNER'S PRELIMINARY RESPONSE contains 7,300 words,
excluding those portions identified in 37 C.F.R. § 42.24(a), as measured by the
word-processing system used to prepare this paper.

Dated: April 25, 2024

By: /Kathleen A. Daley/
Kathleen A. Daley, Reg. No. 36,116

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on April 25, 2024, a copy of
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