Filed: April 25, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

AERIN MEDICAL INC.,
Patent Owner.

_____

Case IPR2024-00276
Patent No. 9,415,194

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I. Introduction

U.S. Patent No. 9,415,194 ("the '194 patent") is directed to novel methods and devices for reducing mucus secretion in an upper airway of a patient to treat at least one of postnasal drip or chronic cough. Petitioner challenges claims 1-3, 6, 12, 14, 16, 18, and 19 of the '194 patent.

In Ground 1, Petitioner fails to meet its burden to show that Baker anticipates the challenged claims. Petitioner combines different embodiments of Baker into one improper anticipation argument. Further, Ground 2, an obviousness ground based on Baker, fails to cure the deficiencies of Petitioner's improper anticipation argument. In Ground 3, Petitioner relies on the combination of Baker, Edwards-535, and Chen. But this combination does not result in the claimed invention because it does not teach "contacting mucosal tissue of the upper airway with the treatment delivery portion, without piercing the mucosal tissue."

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

II. The '194 Patent

The '194 patent is directed to "systems, devices and methods for treating structures within the upper airway to reduce and/or prevent overproduction and/or flow of mucus." Ex. 1001-'194 patent, 1:24-28. According to the '194 patent, "the energy-application mechanisms may be used to re-shape, remodel, or change the mechanical or physiologic properties of structures in order to cause mucus to

divert." *Id.*, 10:4-7. Figure 6 illustrates an embodiment of a "mucus reduction treatment device 30" which may include a treatment element that may "be placed inside the nasal cavity, nasal passage, nasal airway and/or throat to deliver the desired treatment." *Id.*, 10:54-59. The mucus reduction treatment device may also include a handle section 34 that may "be sized and configured for easy handheld operation by a clinician," an electronic control system 42 that may control "energy or other treatment applied to targeted regions of a nasal passageway," and a power supply 44 that may "deliver power to the handle section 23 and/or the treatment element 32." *Id.*, 10:59-61, 11:17-21, 11:35-37.

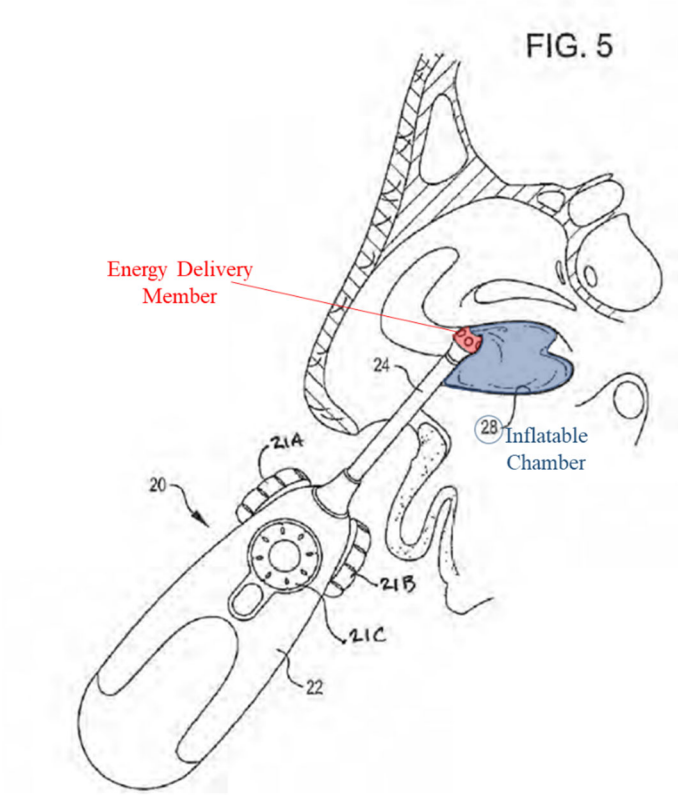
According to the '194 patent, "the treatment element 32 may be configured to deliver energy (e.g. heat, RF, ultrasound, microwave) or cryo-therapy uniformly over an entire outer surface of the treatment element thereby treating all nasal and/or upper airway tissues in contact with the treatment element 32." *Id.*, 11:63-67. 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.*, 12:9-12. In some embodiments, "RF electrodes may be positioned adjacent to and in contact with a targeted tissue region." *Id.*, 12:63-65. The "upper airway tissue that is in contact with the treatment element may receive sufficient energy to treat the tissue." *Id.* 18:5-7.

The '194 patent further discloses a method for reducing mucus secretion in an upper airway of a patient. The method may include "advancing a treatment delivery portion of an energy-based treatment device into a nostril," "contacting mucosal tissue of the upper airway with the treatment delivery portion," and "delivering a treatment from the treatment delivery portion to the mucosal tissue." *Id.*, 4:32-42.

III. The Asserted Art

A. 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.

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.

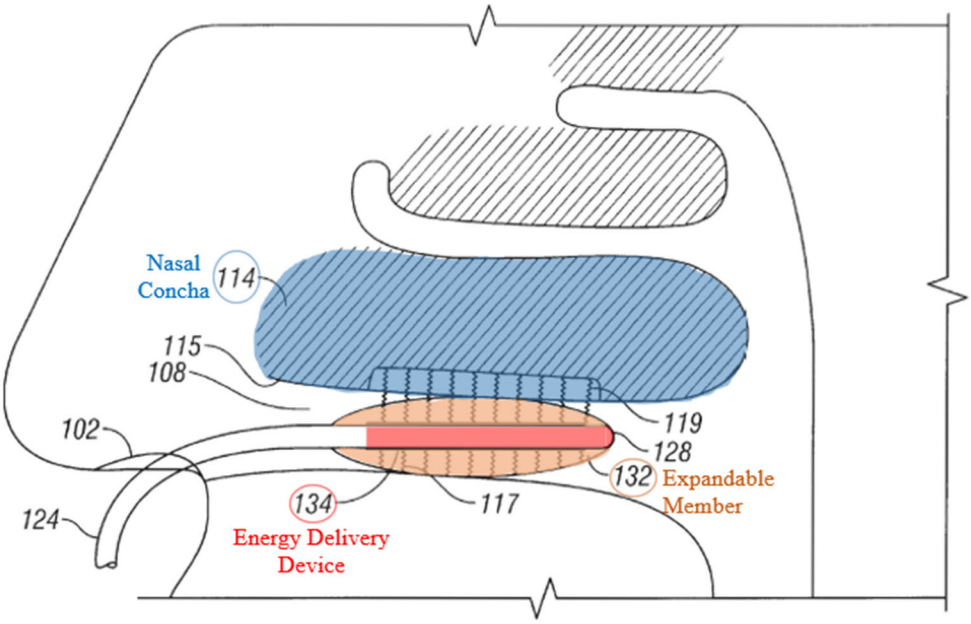


FIG. 3B

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. Chen

Chen is a clinical study that discusses methods for treating perennial allergic rhinitis. Ex. 1017-Chen, 239. The study's authors describe a surgical technique involving "making a strip-shaped thermocoagulation" on a "lateral wall of the nasal cavity." *Id.*, 240. The authors noted that "[r]epeated thermocoagulation" and "[s]pot-like thermocoagulation [were] also performed." *Id.* The authors found that, after the surgery, "symptoms were milder than those before the surgery." *Id.*

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

Petitioner failed to carry its burden of showing anticipation of the claims challenged in Ground 1 by Baker.

A. Petitioner Has the Burden of Proving Anticipation

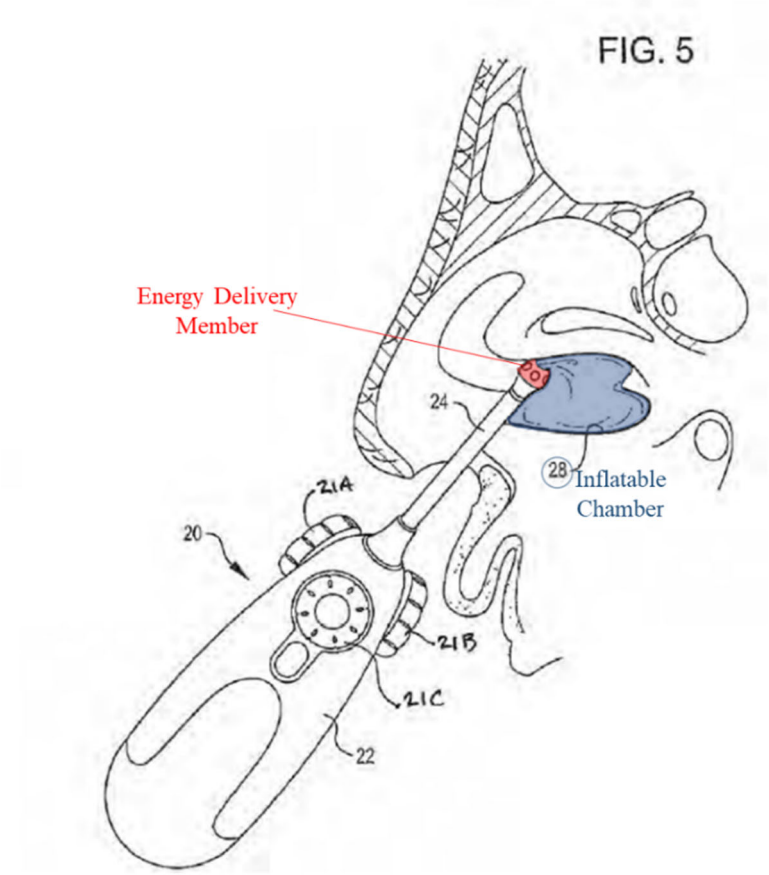
"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). "[D]ifferences between the prior art reference and 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)).

B. Baker Fails to Disclose "Contacting Mucosal Tissue of the Upper Airway with the Treatment Delivery Portion," as Required by Claim Element [1.b] of the '194 Patent

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.

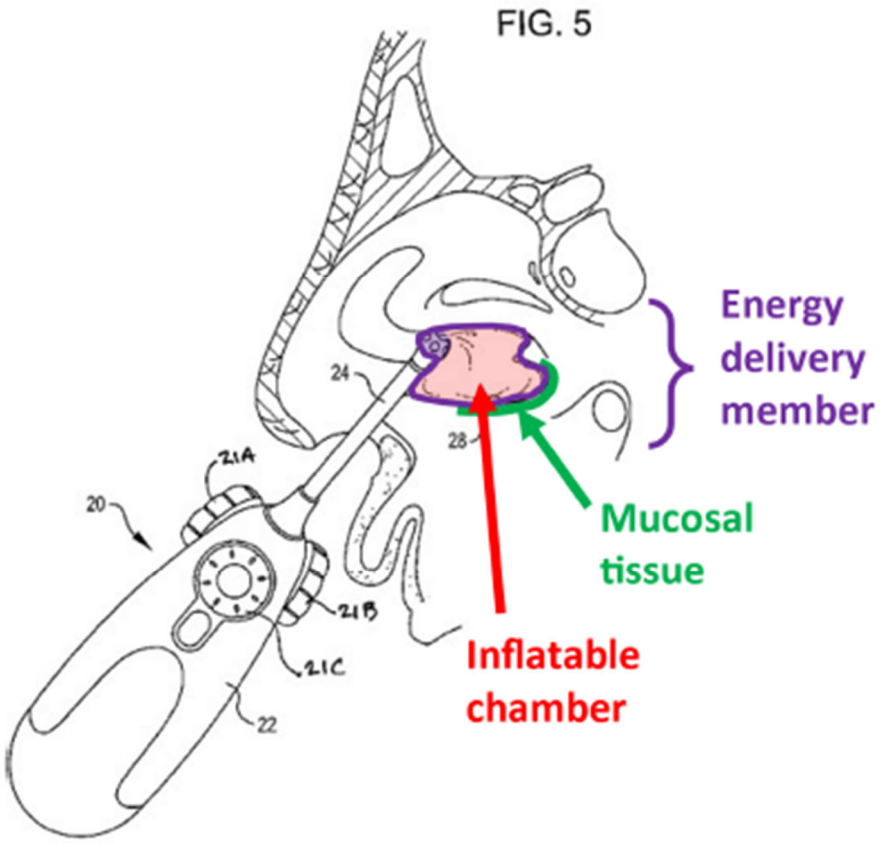
Petitioner presents Ground 1 as an anticipation ground in which it contends "multiple embodiments" of Baker—namely, Device 20 and Device 40—"*independently* anticipate [the] claims." Pet., 22 (emphasis added). But the Device 20 embodiment of Baker does not anticipate at least element [1.b] of the '194 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 element [1.b] of the '194 patent. Petitioner relies on Device 20, as depicted below in annotated Figure 5 of Baker, as disclosing element [1.b].



Ex. 1013-Baker, Fig. 5 (annotated).

In the Petition, Petitioner provides the following annotated version of Figure 5.



Pet., 33 (Petitioner's annotations of Fig. 5 of Baker). Petitioner asserts that a person of ordinary skill in the art "would have understood the energy delivery member to be a treatment delivery portion of device 20." *Id.*, 29. Petitioner also identifies the "inflatable chamber 28" that it contends contacts a tissue site. *Id.*, 34 However, the inflatable chamber 28 is not a "treatment delivery portion" as required by claim 1.

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 delivery portion."

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. 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.").

For example, for limitation [1.a], Petitioner asserts that "Baker discloses advancing a treatment delivery portion (e.g., energy delivery member) of an energy-based treatment device (*e.g., device 20/40*) into a nostril of the patient." Pet., 28 (emphasis added). For the same limitation, Petitioner asserts that "Baker's method of using device 20 includes 'insert[ing]' (i.e., advancing) an insertion wand 24 'through a nostril opening'" while also asserting "*[a]dditionally or alternatively*, Baker's teachings in connection with Device 40 satisfy limitation 1[a]." *Id.*, 28, 30 (emphasis added). Petitioner uses "[a]dditionally or alternatively" when introducing its Device 40 argument for every limitation of claim 1. *See id.*,

26-39. Petitioner's repeated use of "*[a]dditionally* or alternatively" reveals that the Device 40 part of Ground 1 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 6-8D of Baker when asserting that Device 40 discloses the elements of the challenged claims. Pet., 27, 31-32, 35-36, 39-41. 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.

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

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

In Ground 2, Petitioner first argues that claims 1-3, 12, 14, 16, and 18—the same claims that Petitioner contends Baker anticipates—would have been obvious over Baker. Pet., 49. Petitioner argues that "[t]o the extent . . . Baker does not expressly disclose that its methods are used to treat post nasal drip or chronic cough, these limitations would have been obvious . . . ." *Id.* Petitioner then addresses those limitations of claim 1 and treating at least one turbinate of claim 18, arguing why they are allegedly obvious over Baker. *See id.*, 49-51. For all other limitations, Petitioner simply refers back to the anticipation arguments in Ground 1. *See id.*, 49 ("[A]ny limitation not specifically addressed . . . is disclosed by Baker for the reasons provided in Ground 1.").

Petitioner does not cure the deficiencies regarding claim 1 noted above in Ground 1, including Baker's failure to teach limitation [1.b] with Device 20,

discussed in Section IV. *Id.*, 49-52. Further, Petitioner does not cure the deficiencies of the Petition's improper interchangeable use of Device 20 and Device 40 in the purported anticipation argument regarding Device 40, discussed in Section IV. *Id.* Instead, Petitioner's reliance on and incorporation of its improper anticipation arguments from Ground 1, without more, are fatal to Ground 2 for the same reasons.

Petitioner also argues that dependent claim 19 would have been obvious over Baker. *Id.*, 52-54. But claim 19 depends from claim 18, which depends from claim 1, and Petitioner does not allege that the modification it advances for dependent claim 19 based on alleged "textbook knowledge of nasal anatomy" would cure the deficiencies regarding claim 1 noted above in Ground 1, including Baker's failure to teach limitation [1.b] with Device 20, discussed in Section IV. *Id.* Further, this ground does not cure the deficiencies of the Petition's improper interchangeable use of Device 20 and Device 40 in the purported anticipation argument regarding Device 40, as discussed in Section IV. *Id.*

For these reasons, Petitioner has not carried its burden of proving a reasonable likelihood of prevailing on the challenged claims of Ground 2.

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

The combination of Baker, Edwards-535, and Chen does not disclose each and every limitation of the challenged claims. Specifically, the combination fails to satisfy at least element [1.b], "contacting mucosal tissue of the upper airway with the treatment delivery portion, without piercing the mucosal tissue."

The Petition relies on the combination of Baker, Edwards-535, and Chen for limitation [1.b]. Pet., 70-74. The Petition specifically relies on Baker in combination with Edwards-535 in an attempt to satisfy the "contacting mucosal tissue of the upper airway . . . with the treatment delivery portion" of the limitation. *Id.*, 71-72.

First, Petitioner contends that "Baker's method of using device 20 includes 'contact[ing] a tissue site' with the inflatable chamber." *Id.*, 70. Baker comprises an energy delivery member and an inflatable chamber. However, as discussed in Section IV, the energy delivery member does *not* contact the mucosal tissue. Instead, as disclosed in Baker, inflatable chamber 28 "may be enlarged . . . until the *walls of the chamber contact a tissue site*." Ex. 1013-Baker, 17:27-29 (emphasis added). The inflatable chamber, not the energy delivery member, contacts the mucosal tissue. *See id.*, Fig. 5. Therefore, this configuration of Baker

does not satisfy limitation [1.b], "contacting mucosal tissue of the upper airway with the treatment delivery portion, without piercing the mucosal tissue."

Second, the combination of Baker and Edwards-535 does not disclose at least element [1.b]. Petitioner contends that "the combination of Baker and Edwards-535 would have resulted in Baker's device 20 being modified to include an RF energy device (such as Edwards-'535's RF energy delivery device 134) on the surface of Baker's chamber 28." Pet., 71. In this combination, Petitioner asserts that the RF energy delivery device of Edwards-535 is the claimed "treatment delivery portion." *Id.*, 71-72. But Edwards-535 does not disclose a treatment delivery portion on an *outside* surface of an inflatable chamber.

Figure 5 of Edwards-535, as shown below, shows the energy delivery device 134 *inside* the expandable member 132. Further, Edwards-535 explains that "the energy delivery device 134 may be positioned *within* the expandable member." Ex. 1010-Edwards-535, 8:8-9 (emphasis added).

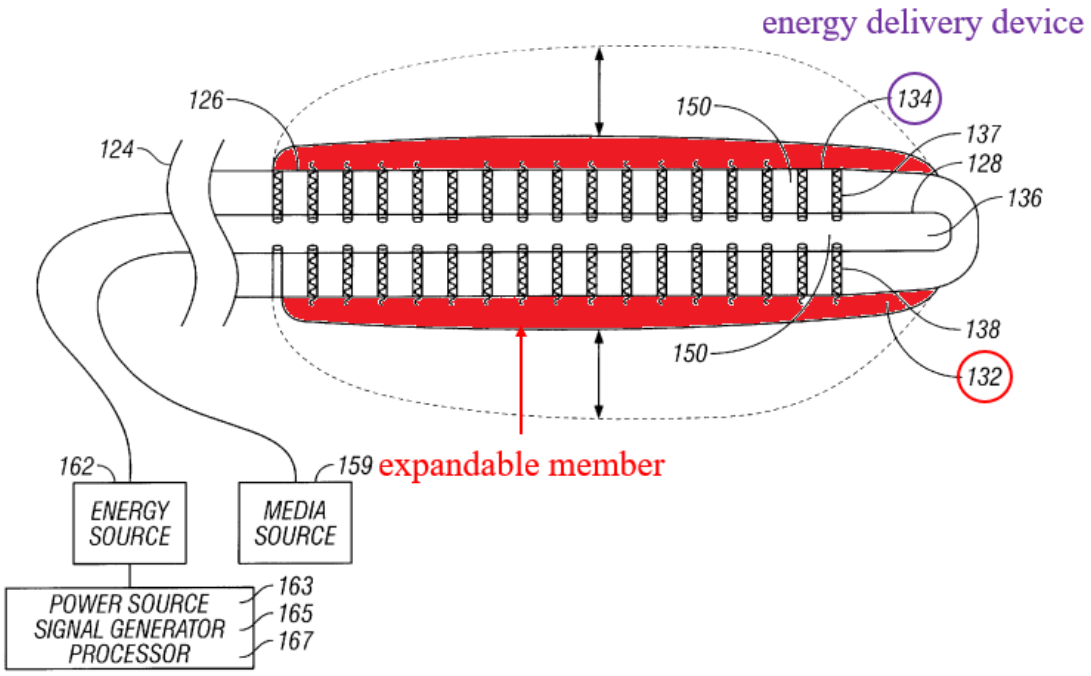


FIG. 5

Id., Fig. 5 (annotated). Accordingly, the energy delivery device shown above does not contact the mucosal tissue.

Edwards-535 then states "[a]lternatively, the energy delivery device may be positioned on a surface 147 of the expandable member." *Id.*, 8:12-14. "Surface 147" is not annotated on Figure 5 of Edwards-535. *Id.*, Fig. 5. The Petition seems to assume, though does not expressly contend, that "surface 147" is referring to the *outside* surface of the expandable member. But there is no indication in Edwards-535 that "surface 147" in this single sentence is the *outside* surface of the expandable member. To the contrary, and as explained in greater detail below, the way that Edwards-535 describes what it means to have an electrode on the surface

of the expandable member demonstrates that Edwards-535 is referring to the *inside* surface of the expandable member.

Figure 6 of Edwards-535, shown below, also shows the energy delivery device 134 *inside* the expandable member 132.

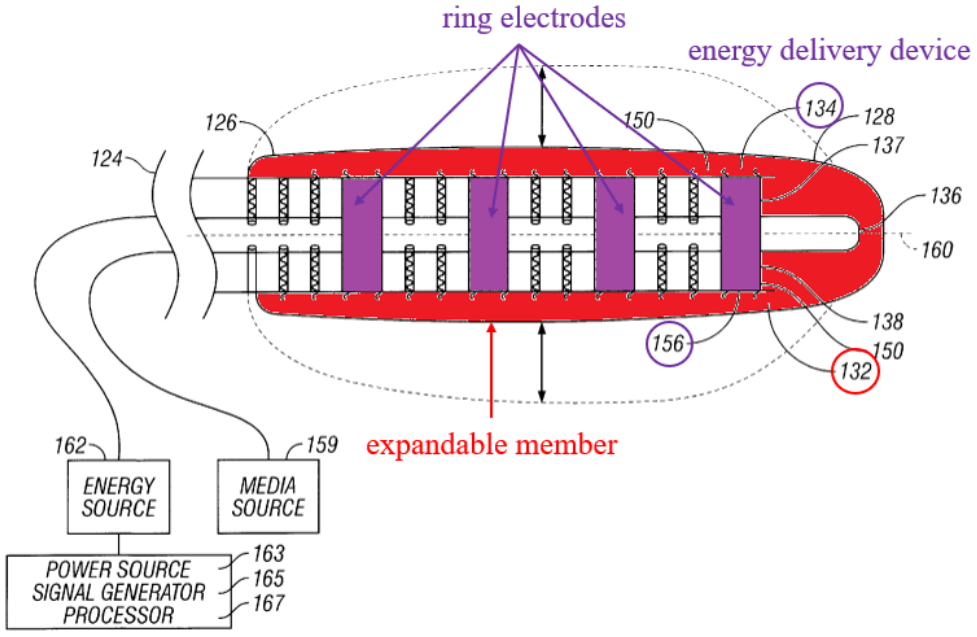


FIG. 6

Id., Fig. 6 (annotated). Edwards-535 states that "the energy delivery device includes one or more ring electrodes 156 disposed on the surface of the expandable member 132." *Id.,* 8:18-20. The Petition again seems to assume that "the surface" is referring to the *outside* surface of the expandable member 132. But, yet again, this assumption is not supported by Edwards-535. Figure 6, shown above, depicts electrodes 156 *inside* the expandable member 132. *Id.*, Fig. 6. It plainly does not show "one or more ring electrodes 156 disposed on" the *outside* surface of the

expandable member 132, and Edwards-535 nowhere states that the ring electrodes are disposed on the outside surface. *Id.*, Fig. 6. Indeed, Figure 6 shows that when Edwards-535 discusses an electrode being disposed on the "surface" of an expandable member, it is referring to the *inside* surface of that member. Thus, the unlabeled "surface" of the expandable member 132 that Edwards-535 describes the ring electrodes as being "disposed on" must be the *inside* surface of the expandable member 132, which does not contact the nasal mucosa.

Edwards-535 then explains how "a plurality of energy delivery devices are positioned on a surface of the expandable member" by pointing to Application Serial No. 08/319,373, which issued as U.S. Patent No. 5,575,788 to Baker (Ex. 1011). *Id.*, 8:26-31. Baker describes sealing electrodes 28 between layers 20(a) and 20(b) of conformable member 20. Ex. 1011-Baker, 7:66-8:8. And Figure 4 of Baker, which is a cross-section of the ablative end of the device, shows that electrode 28 is *inside* of conforming member 20, not on the outside of it. *Id.*, Fig. 4. Likewise, Figure 8 of Baker, which also illustrates a cross-section, shows zones for electrodes that are not on the outer surface of conforming member 20. *Id.*, Fig. 8.

Thus, every time Edwards-535 describes what it means to have an electrode disposed on the surface of the expandable member, Edwards-535 is referring to it being either on the *inside* surface of the expandable member or *within* the

expandable member. Edwards-535 *never* shows an electrode disposed on the *outer* surface of the expandable member, whether through the specification itself or by reference to Baker. And, notably, Edwards-535 *never* shows or discloses that the energy delivery device is *outside* of the expandable member. The single sentence cited by Petitioner is insufficient to teach an energy delivery device that contacts the nasal mucosa, particularly in view of the full description in Edwards-535. This combination, therefore, fails to teach the "contacting mucosal tissue of the upper airway with the treatment delivery portion, without piercing the mucosal tissue" limitation. Petitioner has not carried its burden of proving a reasonable likelihood of prevailing on any challenged claim in Ground 3.

VII. 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

By: /Kathleen A. Daley/
Kathleen A. Daley, Reg. No. 36,116
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP

Lead Counsel for Patent Owner
Aerin Medical Inc.

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Kathleen A. Daley, certify that **PATENT OWNER'S PRELIMINARY RESPONSE** contains 3,449 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 **PATENT OWNER'S PRELIMINARY RESPONSE** was served upon the below-listed counsel by electronic mail:

David Cavanaugh
david.cavanaugh@wilmerhale.com

Gregory Lantier
Gregory.Lantier@wilmerhale.com

Alexis Cohen
alexis.cohen@wilmerhale.com

Joshua Stern
Joshua.Stern@wilmerhale.com

Alexander Nemtzow
alex.nemtzow@wilmerhale.com

Brian Lambson
brian.lambson@wilmerhale.com

WHNeurentIPRService@wilmerhale.com

Dated: April 25, 2024

By: /Lisa C. Hines/
Lisa C. Hines
Case Manager
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP