

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.

IPR2024-00276
Patent 9,415,194 B2

Before MICHAEL J. FITZPATRICK, ZHENYU YANG, and
MICHAEL A. VALEK, *Administrative Patent Judges*.

FITZPATRICK, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Neurent Medical Inc. and Neurent Medical Ltd. (collectively “Petitioner”) filed a Petition to institute an *inter partes* review of claims 1–3, 6, 12, 14, 16, 18, and 19 of U.S. Patent No. 9,415,194 B2 (Ex. 1001, “the ’194 patent”). Paper 3 (“Pet.”). Patent Owner, Aerin Medical Inc., filed a Preliminary Response. Paper 7 (“Prelim. Resp.”).

Institution of an *inter partes* review requires that “the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Determining whether to institute has been delegated to the Board. *See* 37 C.F.R. § 42.4(a) (“The Board institutes the trial on behalf of the Director.”).

Upon consideration of the Petition and the Preliminary Response, and for the reasons explained below, we determine that there is a reasonable likelihood that Petitioner would prevail with respect to at least one claim. Accordingly, we grant the Petition.

II. BACKGROUND

A. *Real Parties in Interest*

Each party identifies itself as the sole real party in interest. Pet. 2; Paper 6, at 1.

B. *Related Matters*

The parties identify *Aerin Medical Inc. and The Foundry LLC v. Neurent Medical Inc. and Neurent Medical Ltd.*, Case No. 1:23-cv-00756 (D. Del.) (“the Delaware litigation”) as a related matter involving the ’194 patent. Pet. 2; Paper 6, 2.

The parties also identify the following IPR proceedings involving patents related to the '194 patent and asserted in the Delaware litigation: IPR2024-00275, IPR2024-00277, IPR2024-00278, and IPR2024-00282. Pet. 2–3; Paper 6, 2. In addition, Petitioner identifies three IPR proceedings involving “patents owned by The Foundry LLC” that “are also asserted against Petitioner in that litigation.” Pet. 2 (identifying IPR2024-00279, IPR2024-00280, and IPR2024-00281); Paper 8, 2–3 (updated disclosures identifying termination of IPR2024-00281 and filing of IPR2024-00669 challenging same patent).

C. The '194 Patent

The '194 patent is titled “Post Nasal Drip Treatment” and 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, code (54), 1:24–28. According to the '194 patent, “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.* at 10:4–7. “In one embodiment, the device includes a[] treatment portion, such as an energy delivery member, sized to be inserted into a nose and/or throat or delivered external to a nose and/or throat.” *Id.* at 3:12–15. The energy delivery member may be “configured to deliver energy to tissues within the nose and/or throat and change the properties of a region of the nose and/or throat to minimize mucus production and prevent mucus from causing PNDS.” *Id.* at 3:15–20.

Figure 6 of the '194 patent is reproduced below.

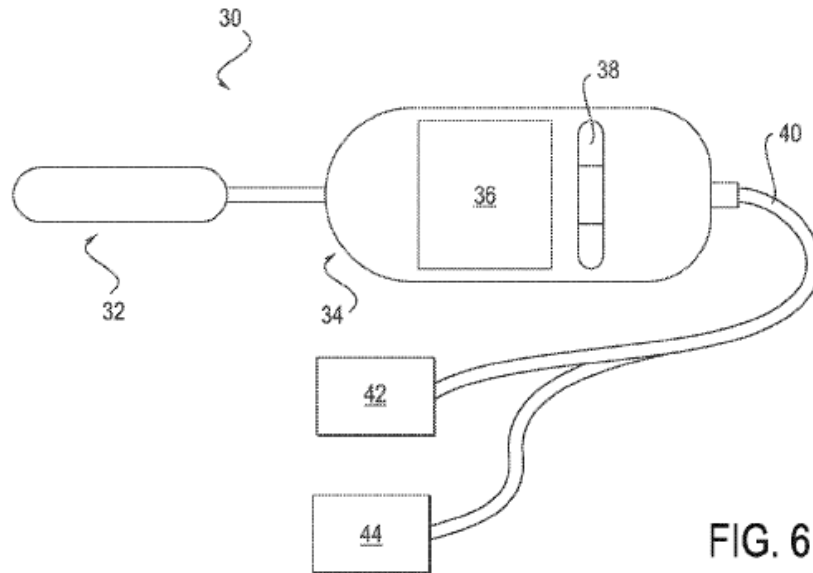


FIG. 6

Figure 6 above is a “schematic illustration of a mucus reduction treatment device 30, according to one embodiment.” Ex. 1001, 10:54–55. “The device 30 comprises a treatment element 32 which may be configured to be placed inside the nasal cavity, nasal passage, nasal airway and/or throat to deliver the desired treatment.” *Id.* at 10:56–59.

The '194 patent's filing date is March 31, 2015. *Id.* at code (22). However, it claims priority, through a string of applications, ultimately to a provisional application filed June 14, 2011. Ex. 1001, 1:5–17; *see also id.* at codes (60), (63). The Petition does not take a position as to the effective filing date of the challenged claims. *See generally* Pet.; *see also id.* at 5 n.2 (“The '194 patent was examined under the provisions of the AIA, but the relied-upon references also qualify as prior art under the corresponding pre-AIA provisions.”).

D. Challenged Claims

The Petition challenges claims 1–3, 6, 12, 14, 16, 18, and 19, all of which are method claims. Independent claim 1, the sole independent claim

being challenged, is reproduced below with its recited steps labelled consistent with the parties' identical labeling.

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

[a] advancing a treatment delivery portion of an energy-based treatment device into a nostril of the patient;

[b] contacting mucosal tissue of the upper airway with the treatment delivery portion, without piercing the mucosal tissue; and

[c] delivering a treatment from the treatment delivery portion to at least one tissue selected from the group of the mucosal tissue and another tissue underlying the mucosal tissue to modify a property of the at least one tissue and thus treat at least one of post nasal drip or chronic cough in the patient.

Ex. 1001, 29:34–47 (bracketed content added).

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Claim(s) Challenged	35 U.S.C. §¹	Reference(s)/Basis
1–3, 12, 14, 16, 18, 19	102	Baker ²

¹ The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), included revisions to 35 U.S.C. § 102 and § 103 that became effective March 16, 2013. Petitioner notes that “[t]he ’597 patent was examined under the provisions of the AIA” and cites to the AIA version of these statutes in the Petition. Pet. 5 n.2. At this stage, Patent Owner does not address whether the AIA or pre-AIA version applies, nor do we discern a reason why the differences between those versions would affect our analysis. Accordingly, we cite the AIA version herein.

² WO 2010/0779800 A1, published July 8, 2010 (Ex. 1013).

Claim(s) Challenged	35 U.S.C. § ¹	Reference(s)/Basis
1–3, 12, 14, 16, 18, 19	103	Baker
1–3, 6, 12, 14, 16, 18, 19	103	Baker, Edwards-535, ³ Chen ⁴

III. ANALYSIS OF THE ASSERTED GROUNDS

A. Level of Ordinary Skill in the Art

Petitioner contends a person of ordinary skill in the art (“POSITA”) 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.

Pet. 16 (citing Ex. 1002 ¶29).⁵ Patent Owner does not respond to Petitioner’s description of a POSITA in its Preliminary Response.

At this stage, we find Petitioner’s description of the level of ordinary skill in the art sufficiently supported by the record and apply it for purposes of this decision.

³ US 6,517,535 B2, issued Feb. 11, 2003 (Ex. 1010).

⁴ Shi-qiang Chen et al., “Preliminary study on radiofrequency thermocoagulation of the posterior inferior nerve, anterior ethmoidal nerve, and inferior turbinate under nasal endoscopy for the treatment of perennial allergic rhinitis,” 11 CHINA J. OF ENDOSCOPY 3, 239–243 (Mar. 2005) (Ex. 1017). Exhibit 1017, referred to as “Chen” herein, is a translation of the original Chinese language reference on which Petitioner relies. Exhibit 1070 is a declaration from Petitioner’s translator that attests to the accuracy of that translation and attaches the original reference.

⁵ Ex. 1002 is a declaration by John DelGaudio, M.D.

B. Claim Construction

In an *inter partes* review, claim terms “shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b).

Neither party proposes an express construction of any claim term. *See* Pet. 20 (“[T]he Board need not construe any terms because the Challenged Claims are invalid under any reasonable interpretation.”); *see generally* Prelim. Resp.

We determine that no express claim construction is necessary based on the present record.

C. The Asserted References

i. Baker

Baker is a World Intellectual Property Organization patent application publication published July 8, 2010. Ex. 1013, code (43). Petitioner asserts, and the current record supports, that Baker is prior art under 35 U.S.C. § 102(a)(1) and (2). Pet. 5.

Baker discloses “methods and systems for delivery of fluids, aerosols and ultrasound energy to tissue surfaces, cavities, and obstructed sites in passages, lumens, or cavities.” Ex. 1013, 5:9–12. Baker discloses a device 20 that may comprise handle 22, insertion wand 23, and acoustic energy delivery member 26. *Id.* at 16:22–23. Baker teaches that, for internal applications, “such as nasal passageways, insertion wand 24 is configured for insertion through a nostril opening and positioning at least partially

within nasal passageways.” *Id.* at 5:23–26. The energy deliver member “may be provided at the tip of the insertion wand and configured for positioning in proximity to and/or contacting blockages within nasal passages, mucous membranes and nasal turbinates⁶, or pathological or undesired tissue.” *Id.* at 17:11–13. For example, “[i]n one embodiment, energy delivery member 26 may comprise a tapered structure, such as a generally conical structure, for focusing and concentrating high frequency and/or high intensity acoustic energy.” *Id.* at 12:13–16. However, “[i]n another embodiment, as illustrated in Fig. 5, an energy delivery member may comprise a flexible, deformable bladder or inflatable chamber 28 adapted for retaining an acoustically transmissive material, such as a liquid or gel, within its interior volume.” *Id.* at 17:22–24. Figure 5 of Baker is reproduced below.

⁶ Dr. DelGaudio explains that turbinates are part of the anatomical structure of the nose and are also referred to as concha. Ex. 1002 ¶30.

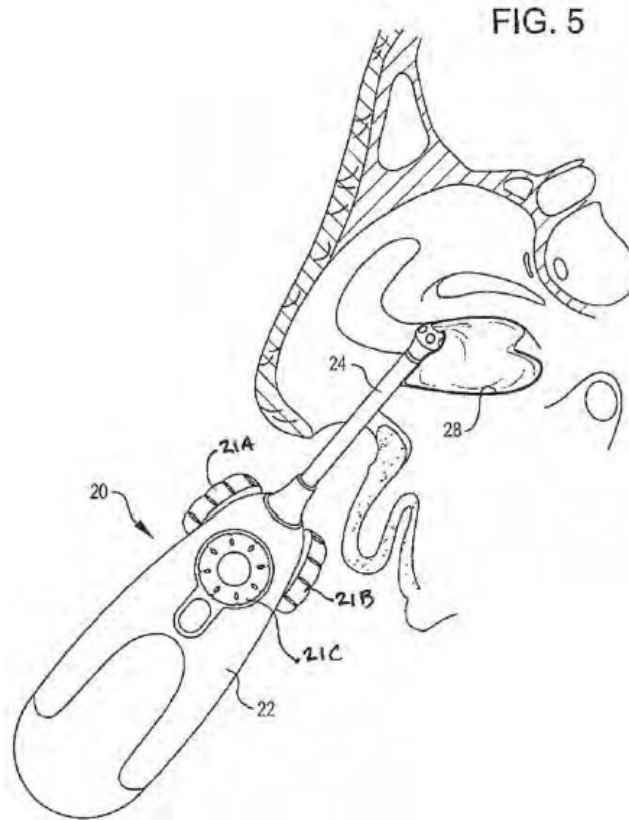


Figure 5 of Baker above shows device 20, including insertion wand 24 and deformable bladder/inflatable chamber/expandable chamber 28 at its distal end. Baker uses all three of these terms to describe the structure designated by reference numeral 28. *See* Ex. 1003, 17:22–24 (“[A]s illustrated in Fig. 5, an energy delivery member may comprise a flexible, deformable bladder or inflatable chamber 28 adapted for retaining an acoustically transmissive material, such as a liquid or gel, within its interior volume.”), *id.* at 17:27 (also referring to the structure as “[e]xpandable chamber 28.”). We hereafter refer to this structure as Baker’s “inflatable chamber.”

ii. *Edwards-535*

Edwards-535 is a United States patent issued February 11, 2003. Ex. 1010, code (45). Petitioner asserts, and the current record supports, that Edwards-535 is prior art under 35 U.S.C. § 102(a)(1) and (2). Pet. 5.

Edwards-535 discloses a method and apparatus “for ablating at least a portion of a nasal concha” to reduce its size and improve “air flow through the nasal meatus.” Ex. 1010, Abstr. Figure 3B of Edwards-535 is reproduced below.

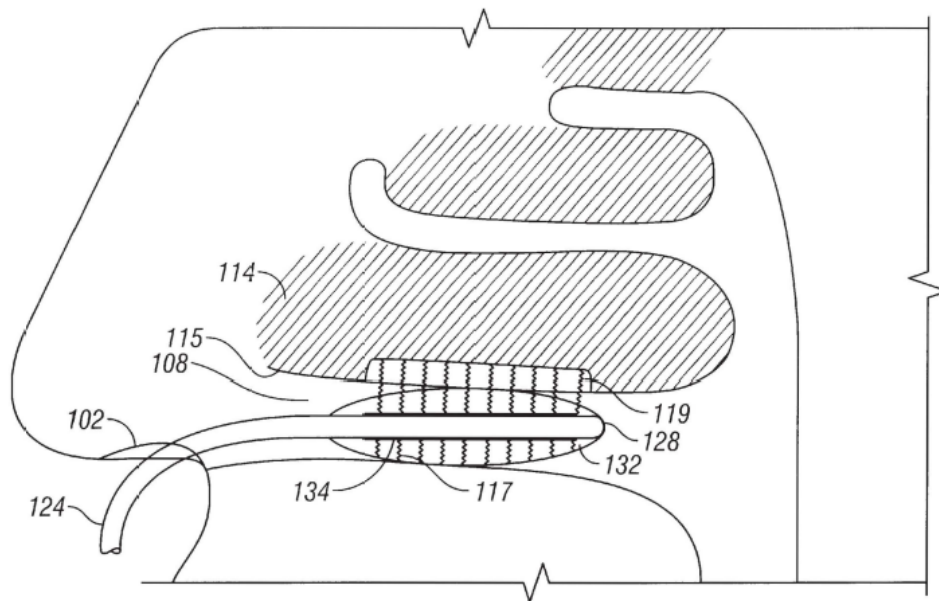


FIG. 3B

Figure 3B above shows “apparatus 124 having a distal portion 128 with an expandable member 132 and an energy delivery device 134 for delivering ablative energy” that has been “introduced through a nostril 102” into the nasal meatus 108 adjacent a surface of the nasal concha 114. *Id.* at 5:20–26. In Figure 3B, expandable member 132 has been “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 to be treated.” *Id.* at 5:27–30. “Ablative energy 117 is then delivered through the apparatus and the energy

delivery device 134 to the nasal concha 114” in order “to ablate at least a portion 119 of the nasal concha 114.” *Id.* at 5:30–34.

Edwards-535 further teaches that the surface of the nasal concha may be cooled, e.g., by “introducing cooled medium into the expandable member,” during the delivery of the ablative energy. *See* Ex. 1010, 6:9-37. According to Edwards-535:

Cooling serves at least two purposes. Cooling may be used to prevent ablation of the surface of the nasal concha by preventing the ablation of the surface of the nasal concha. As a result, an exposed wound site is not generated during the method. Cooling may also be used to control the location of the ablation site. For example, cooling the nasal concha surface enables the formation of an entirely internal ablation site. The extent of cooling can be used to control the thickness of the non-ablated tissue at the surface of the nasal concha adjacent the internal ablation site.

Id. at 6:23–32. 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.* at 4:58–60, 4:55–56.

Regarding configuration of its apparatus, Edwards-535 teaches that “the energy delivery device 134 may be positioned within the expandable member.” Ex. 1010, 8:8–9. For example, Figure 6 of Edwards-535, reproduced below, shows an embodiment of an energy delivery device comprising a plurality of “ring electrodes.” *See id.* at 4:1–2; 8:18–23.

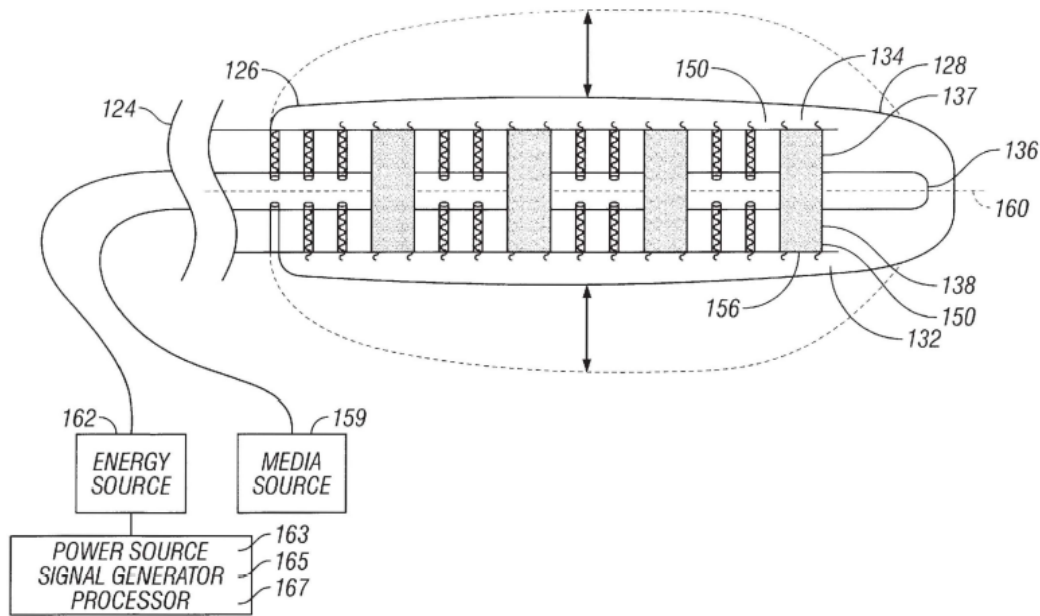


Figure 6 above depicts an embodiment comprising multiple ring electrodes 156 “disposed on the surface of the expandable member 132” in a row such that their “axes [are] aligned with a long axis 160 of the catheter body 126.” *Id.* at 8:18–23.

Edwards-535 teaches that, “[i]n another embodiment, a plurality of energy delivery devices are positioned on a surface of the expandable member.” Ex. 1010, 8:25–27; *see also id.* at 8:12–13 (“Alternatively, the energy delivery device may be positioned on a surface 147 of the expandable member.”). Edwards-535 cites another reference, U.S. patent application no. 08/319,373,⁷ as describing “[a]n example of a suitable surface for disposition on the membrane.” *Id.* at 8:27–31.

⁷ The cited application issued November 19, 1996, as US 5,575,788. Ex. 1011 (“Baker ’788”).

iii. Chen

Chen is a clinical study published March 2005 in the *China Journal of Endoscopy*. Petitioner asserts, and the current record supports, that Chen is prior art under 35 U.S.C. § 102(a)(1) and (2). Pet. 5–6.

Chen discusses methods for treating perennial allergic rhinitis (“PAR”), including the use “radiofrequency thermocoagulation.” Ex. 1017, 239. Chen observes:

The use of radiofrequency thermocoagulation of the posterior inferior nasal nerve, anterior ethmoidal nerves, and inferior turbinate under nasal endoscopy for the treatment of PAR can . . . reduce the sensitivity of the nasal mucosa to external stimuli, . . . reduce the gland secretion, and . . . alleviate or eliminate symptoms such as nasal itching, sneezing, nasal congestion, and runny nose in patients, achieving the objective of treating PAR.

Ex. 1017, 240, 243.

D. Ground 1: Anticipation by Baker

Petitioner contends that claims 1–3, 12, 14, 16, 18, and 19 are anticipated by Baker. Pet. 25–48. We begin with independent claim 1.

i. Claim 1

Claim 1 is directed to “[a] method for reducing mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough” and is reproduced in full above. Petitioner argues that Baker discloses the claimed method using either of two devices, device 20 as shown in Figure 5 of Baker (reproduced above) and device 40 as shown in Figure 6 of Baker. *See, e.g.*, Pet. 28 (“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.” (emphasis omitted)). As discussed below, we determine that Petitioner’s reliance on device 20 is sufficient and do not discuss further Petitioner’s reliance on device 40.

Patent Owner argues that Baker fails to disclose step [b], i.e., “contacting mucosal tissue of the upper airway with the treatment delivery portion, without piercing the mucosal tissue,” as recited in claim 1. Prelim. Resp. 8; *see Verdegaaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987) (“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.”).

As will become apparent from Patent Owner’s arguments, central to the dispute between the parties is Petitioner’s mapping of Baker to limitation [b] and, in particular, to the recited “treatment delivery portion” of the device. In Petitioner’s view, Baker’s inflatable chamber 28 constitutes part of the recited “treatment delivery portion.” *See* Pet. 28 (“An energy delivery member including an inflatable chamber 28 is located at the distal tip of insertion wand 24.” (citing Ex. 1013, 16:19–26, 17:22–32, 20:35–39, Fig. 5; Ex. 1002 ¶75)). Petitioner further points out, with supporting evidence, that the inflatable chamber contacts mucosal tissue without piercing it. *Id.* at 34 (citing Ex. 1013, 17:22–36, Fig. 5; Ex. 1002 ¶84).

Patent Owner does not dispute that Baker’s inflatable chamber contacts mucosal tissue without piercing it. Instead, Patent Owner contends that Baker’s inflatable chamber “is not a ‘treatment delivery portion’ as required by claim 1.” Prelim. Resp. 10. Patent Owner’s explanation for this contention is not clear. In Patent Owner’s words:

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.”

Prelim. Resp. 10–11. As best we can discern, Patent Owner argues that Baker’s inflatable chamber cannot be part of a “treatment delivery portion” because, even though radiofrequency energy travels through it and is emitted from it, the radiofrequency energy does not emanate or originate from it.

Patent Owner’s argument appears to be premised on a construction of “treatment *delivery* portion” that would render it limited to a portion of the device from which energy *emanates*, and ironically to the exclusion of a portion of the device that *delivers* energy. However, Patent Owner does not present any evidentiary basis for, let alone articulate, such a construction. Petitioner has adequately shown that Baker’s “energy deliver member[, which] may comprise a flexible, deformable bladder or inflatable chamber 28” (*see* Ex. 1001, 17:22–23) constitutes a “treatment delivery portion” within the meaning of claim 1.

There is a reasonable likelihood of Petitioner prevailing on Ground 1 as to claim 1.

ii. Claims 2, 3, 12, 14, 16, 18, and 19

Patent Owner does not present any additional arguments for any of these additionally challenged claims. Prelim. Resp. 8–13. We discern no

reason to discuss these additional claims. In *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018), the Supreme Court held the following:

Section 314(a) [of Title 35] does not require the Director to evaluate every claim individually. Instead, it simply requires him to decide whether the petitioner is likely to succeed on “at least 1” claim. Once that single claim threshold is satisfied, it doesn’t matter whether the petitioner is likely to prevail on any additional claims; the Director need not even consider any other claim before instituting review. Rather than contemplate claim-by-claim institution, then, the language anticipates a regime where a reasonable prospect of success on a single claim justifies review of all.

SAS, 138 S. Ct. at 1356; *see also* 37 C.F.R. § 42.108(a) (“When instituting *inter partes* review, the Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim.”).

E. Ground 2: Obviousness over Baker

Petitioner contends that claims 1–3, 12, 14, 16, 18, and 19 would have been obvious over Baker. Pet. 49–54. These are precisely the same claims that Petitioner contends are anticipated by Baker. *Id.* at 25–48. Because “anticipation is the epitome of obviousness,” there is a reasonable likelihood of Petitioner prevailing on Ground 2 as to claim 1. *See Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) (“[A] disclosure that anticipates under § 102 also renders the claim invalid under § 103, for ‘anticipation is the epitome of obviousness.’” (quoting *In re Fracalossi*, 681 F.2d 792, 794 (C.C.P.A. 1982))). Indeed, as to claim 1, Patent Owner merely argues that Ground 2 “does not cure the deficiencies regarding claim 1 noted above in Ground 1.” Prelim. Resp. 13. We decline, at this time, to address

the other claims challenged in Ground 2. *See SAS*, 138 S. Ct. at 1356 (“reasonable prospect of success on a single claim justifies review of all”).

F. Ground 3: Obviousness over Baker, Edwards-535, and Chen

Petitioner contends that claims 1–3, 6, 12, 14, 16, 18, and 19 would have been obvious over Baker, Edwards-535, and Chen. Pet. 54–87. We have already determined that the Petition satisfies the single-claim threshold of § 314(a) in both Grounds 1 and 2. Thus, we need not address Ground 3 at this time. *SAS*, 138 S. Ct. at 1356; 37 C.F.R. § 42.108(a).

However, Ground 3 challenges one claim of the ’194 patent that Grounds 1 and 2 do not. That claim is claim 6. Under these circumstances, we deem it prudent to discuss Ground 3 as applicable to claim 6.

Claim 6 recites that “the at least one tissue comprises nerve tissue underlying the mucosal tissue, and wherein delivering the energy comprises ablating the nerve tissue.” Ex. 1001, 29:64–67. In challenging claim 6 as obvious, Petitioner relies on Chen for teaching targeting of nerve tissue with radiofrequency energy and on Edwards-535 for teaching targeting of underlying tissue (including nerves) without harming the mucosal surface. Pet. 80–81 (citing 1017, 239–240; 1010, 4:60–67, 6:10–37; Ex. 1002 ¶171). Petitioner explains why a person of ordinary skill in the art would have combined the teachings of Baker, Edwards-535, and Chen and had a reasonable expectation of success in doing so. *Id.* at 61–68.

Patent Owner does not dispute Petitioner’s reliance on Edwards-535 and Chen to reach the additional subject matter recited in claim 6. Nor does Patent Owner dispute Petitioner’s reasons for combining Edwards-535 and Chen with Baker or that a person of ordinary skill in the art would have had a reasonable expectation of success in such an endeavor. Prelim. Resp. 15–

20. Patent Owner merely argues that the combination of Baker, Edwards-535, and Chen fails to satisfy limitation [b] of claim 1, from which claim 6 ultimately depends. Prelim. Resp. 15. However, as discussed above, we have already determined there is a reasonable likelihood that Baker alone discloses limitation [b] of claim 1.

There is a reasonable likelihood of Petitioner prevailing on Ground 3 as to both claim 1 and claim 6. We decline, at this time, to address the other claims challenged in Ground 3. *SAS*, 138 S. Ct. at 1356.

IV. CONCLUSION

For the reasons discussed above, we are persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing in establishing that at least one of the challenged claims is unpatentable. 35 U.S.C. § 314(a).

V. ORDER

Accordingly, it is:

ORDERED that the Petition is granted and an *inter partes* review is hereby instituted as to claims 1–3, 6, 12, 14, 16, 18, and 19 of U.S. Patent No. 9,415,194 B2; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this decision.

IPR2024-00276
Patent 9,415,194 B2

FOR PETITIONER:

David Cavanaugh
Alexis Cohen
Alexander Nemtzow
Sarah Murphy
WILMER CUTLER PICKERIN GHALE AND DORR LLP
david.cavanaugh@wilmerhale.com
alexis.cohen@wilmerhale.com
alex.nemtzw@wilmerhale.com
sarah.j.murphy@wilmerhale.com

FOR PATENT OWNER:

Sonja Sahlsten
Kathleen Daley
Jason Stach
Anthony Berlenbach
Christopher Howes
Kathleen Hanley
FINNEGAN, HENDERSON, FARABOW,
GARRETT, & DUNNER LLP
sonja.sahlsten@finnegan.com
kathleen.daley@finnegan.com
jason.stach@finnegan.com
anthony.berlenbach@finnegan.com
christopher.howes@finnegan.com
kathleen.hanley@finnegan.com