

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVANOS MEDICAL, INC.,
Petitioner,

v.

STRATUS MEDICAL, LLC,
Patent Owner.

IPR2024-01210
Patent 10,736,688 B2

Before MICHAEL J. FITZPATRICK, SUSAN L. C. MITCHELL, and
ARTHUR M. PESLAK, *Administrative Patent Judges*.

FITZPATRICK, *Administrative Patent Judge*.

JUDGMENT

Determining All Challenged Claims Unpatentable
Dismissing the Parties' Motions to Exclude
35 U.S.C. § 318(a)

I. INTRODUCTION

A. Background and Summary

Petitioner, Avanos Medical, Inc., filed a Petition to institute an *inter partes* review of claims 1–17 and 48–52 of U.S. Patent No. 10,736,688 B2 (Ex. 1002 (“the ’688 patent”)) pursuant to 35 U.S.C. § 311(a). Paper 1 (“Pet.”). Patent Owner, Stratus Medical, LLC, waived filing of a preliminary response pursuant to 37 C.F.R. § 42.107(b). Paper 7. We granted the Petition and instituted an *inter partes* review. Paper 9 (“Inst. Dec.”).

During the review, Patent Owner filed a Patent Owner Response to the Petition (Paper 68 (“PO Resp.”)¹), Petitioner filed a Reply (Paper 32 (“Reply”)), and Patent Owner filed a Sur-Reply (Paper 42 (“Sur-Reply”). Additionally, each party filed a motion to exclude. Paper 51 (“Pet. Mot. To Exclude”); Paper 49 (“PO Mot. To Exclude”).

An oral hearing was held November 6, 2025. A transcript of the hearing is of record in this case. Paper 63 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6, and this Final Written Decision, issued pursuant to 35 U.S.C. § 318(a), addresses issues and arguments raised during the trial. For the reasons discussed below, we

¹ The Patent Owner Response was originally filed under seal as Paper 15 and publicly with redactions as Paper 16. Those papers were later expunged and replaced with versions reflecting updates to the information considered confidential in light of the Board’s November 6, 2025, Order entering a protective order and resolving several motions to seal. *See* Paper 62; Ex. 3004. Patent Owner has represented that Paper 68 is identical to the now expunged Paper 15. Ex. 3004.

determine that Petitioner has proved, by a preponderance of the evidence, that claims 1–17 and 48–52 of the ’688 patent are unpatentable.

B. Real Parties-In-Interest

Petitioner identifies itself, Avanos Medical, Inc., as the real party-in-interest and states that “Diros Technology, Inc. of Markham, Ontario, Canada is a wholly owned subsidiary” of Petitioner. Pet. 81.

Patent Owner identifies only itself, Stratus Medical, LLC, as the real party-in-interest. Paper 5, 2.

A. Related Matters

Petitioner filed three related *inter partes* reviews: IPR2024-01209 (regarding Patent No. 10,966,782 B2); IPR2024-01211 (regarding the ’688 patent); and IPR2024-01212 (regarding Patent 10,925,664 B2). In addition, Patent Owner identifies three applications, U.S. Patent Application Nos. 17/190,224, 18/378,138, and 19/272,521, and one lawsuit, *Stratus Med., LLC v. Avanos Med., Inc.*, No. 1:25-cv-00546 (D. Del. Filed May 2, 2025). Paper 46, 2.

B. The ’688 Patent

The ’688 patent is titled “Methods and Systems for Spinal Radio Frequency Neurotomy.” Ex. 1002, code (54). The ’688 patent is directed “to thermal ablation systems and methods and, more specifically, to improved systems and methods for performing Radio Frequency (RF) neurotomy.” *Id.* at 1:16–19. The ’688 patent provides the following background for thermal ablation, RF ablation, and RF neurotomy:

Thermal ablation involves the creation of temperature changes sufficient to produce necrosis in a specific volume of tissue within a patient. The target volume may be, for example, a nerve or tumor. A significant challenge in ablation therapy is to provide adequate treatment to the targeted tissue while sparing the surrounding structures from injury.

RF ablation uses electrical energy transmitted into a target volume through an electrode to generate heat in the area of the electrode tip. The radio waves emanate from a non-insulated distal portion of the electrode tip. The introduced radiofrequency energy causes molecular strain, or ionic agitation, in the area surrounding the electrode as the current flows from the electrode tip to ground. The resulting strain causes the temperature in the area surrounding the electrode tip to rise. Temperature calibration or measurement devices, for example thermocouples, in the electrode may provide feedback and allow precise control of the temperatures produced at the electrode tip.

RF neurotomy uses RF energy to cauterize a target nerve to disrupt the ability of the nerve to transmit pain signals to the brain. Known RF neurotomy methods typically use a single RF probe generating a generally oval or oblate spheroid lesion. The RF probe is positioned in an attempt to include the target nerve within the oval or oblate spheroid lesion. In various procedures, access to a target nerve may be limited (e.g., limited to a restricted angular range), thereby raising significant challenges to medical personnel to create sufficient lesions to provide optimal clinical outcomes. Additionally, anatomical variations of the nerve location relative to anatomical landmarks provide additional challenges.

Ex. 1002, 1:24–54.

The Specification discloses neurotomy system 100 for use in performing RF neurotomy on a patient. *Id.* at 3:36–37, 4:34–65, 5:8–24, Fig. 1. “The system 100 may include an RF generator 102 capable of generating an RF energy signal sufficient to ablate target tissue,” a needle 103 capable of conducting the RF energy to the patient, and an “imaging

system 105 capable of producing internal images of the patient 101 and the needle 103 to facilitate navigation of the needle 103 during a procedure.” *Id.* at 4:40–49, 5:8–13.

Where the needle 103 is a monopolar device, a return electrode pad 104 may be attached to the patient 101 to complete a circuit from the RF generator 102, through the needle 103, through a portion of the patient 101, and back to the RF generator 102 through the return electrode pad 104.

Id. at 4:49–53.

Needle 103 may include “a self-contained mechanical mechanism, in the form of deployable filaments 206a, 206b, operable to expand the volume of effective RF energy delivery as compared to known single-electrode RF probes.” *Id.* at 5:34–37, Fig. 2A. Figure 2A is reproduced below.

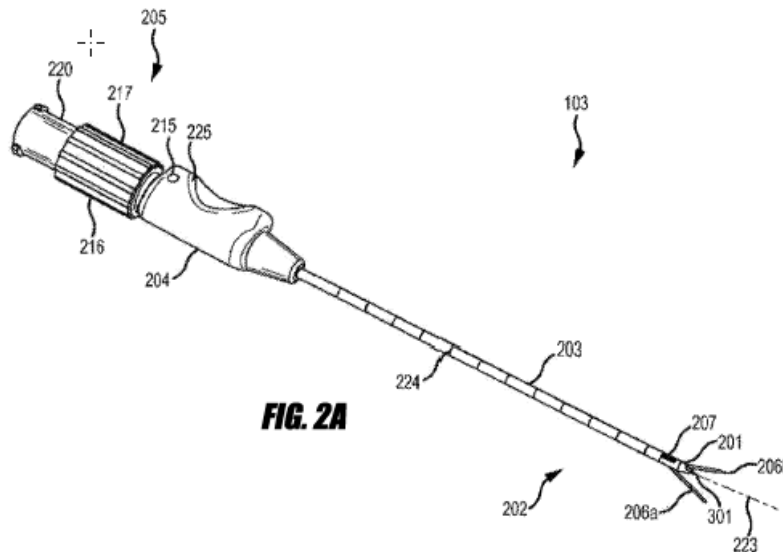


Figure 2A, reproduced above, shows the needle with elongate member 203 having tip 201 and deployable filaments 206a–b. *Id.* at 5:25–28. The filaments are deployed/retracted by a rotating actuator 216. *Id.* at 5:45–47, 29:52–53. According to the Specification, “variation in the shape, position, and/or size of lesions . . . may be achieved by different configurations of

filaments,” including varying the number, length, position, and angle of the filaments. *Id.* at 25:34–43.

With reference to Figure 2B (not shown), actuator 216 may be fitted with Luer fitting 220 at the proximal end of needle 103, and configured for inserting (i) removable RF probe 401 through lumen 222 of elongate member 203, and (ii) fluid delivered through the lumen (when probe 401 is removed). Ex. 1002, 30:12–19.

Figures 3A and 3B are reproduced below.

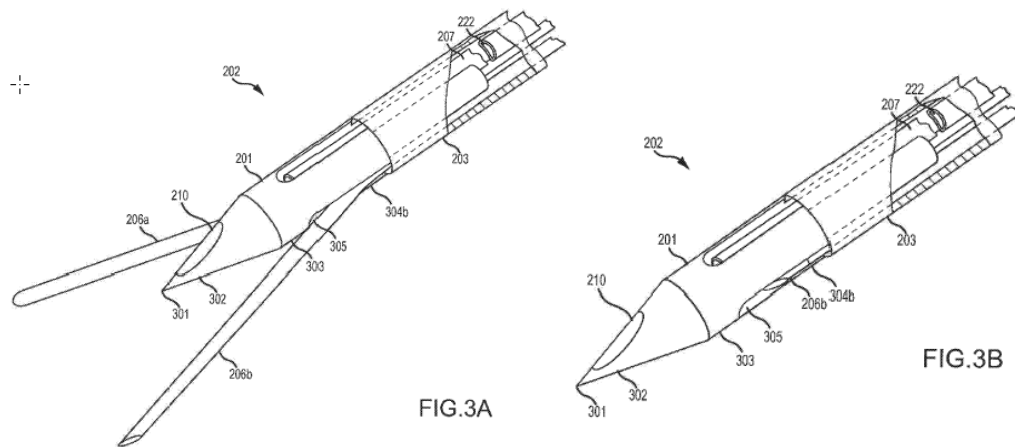


Figure 3A, reproduced above left, shows a cut away view of distal end 202 of needle 103 with filaments 206a–b deployed. *Id.* at 3:45–46. Figure 3B, reproduced above right, shows a cut away view of distal end 202 of needle 103 with filaments retracted (and thus not visible). *Id.* at 3:47–48. Figures 3A and 3B also show tip (201) including fluid port 210 (e.g., for delivering anesthetic and/or image enhancing dye during an RF neurotomy procedure) via Luer fitting 220 when the probe 401 is removed, and sharpened point 301 for piercing the skin of a patient and facilitating advancement through tissue. *Id.* at 6:25–28, 7:34–40, 17:47–53.

According to the '688 patent, tip 311 and tube 207 containing lumen 222 may be constructed from stainless steel, or other conductive material,

such that when RF probe 401 is inserted into tube 207, the RF energy emitted by RF probe 401 may be conducted through tube 207 and into and through tip 201 and filaments 206a, 206b. *Id.* at 6:37–39, 9:54–58. “[T]he filament 206a, 206b arrangement illustrated in FIGS. 2A, 3A, 3B, 5 and 6 may be operable to produce lesions that are radially offset from the central longitudinal axis 223 and distally offset from the point 301 as compared to a lesion created by the tip 201 without the filaments or a lesion created with the needle 103 with the filaments 206a, 206b in the retracted position.” *Id.* at 10:50–56.

The ’688 patent’s filing date is April 14, 2016. *Id.* at code (22). However, it claims priority back to three applications, the earliest of which was a provisional application filed on November 5, 2009. *Id.* at codes (60), (63), 1:6–12. Whether any of the challenged claims is entitled to the benefit of the filing date of any of the priority applications is not at issue. All of the asserted prior art references predate the earliest, November 5, 2009, date. *See infra* nn.2–9. Moreover, Patent Owner does not dispute that any of the asserted references is prior art to the challenged claims. *See generally* PO Resp.

C. The Challenged Claims

Petitioner challenges 1–17 and 48–52 of the ’688 patent. Of the challenged claims, only claim 1 is independent. It is reproduced below as partitioned in the Petition with Petitioner’s bracketed labels.

1. A system comprising:
[1a] an RF probe; and

[1b] a needle for insertion into a patient during an RF ablation procedure, the needle comprising:

[1c] a hub;

[1d] an elongate member fixed to the hub, the elongate member comprising a lumen at an interior thereof;

[1e] a tip fixed to the elongate member at a distal end of the needle, wherein the tip is shaped to pierce tissue of the patient;

[1f] a plurality of filaments;

[1g] an actuator interconnected to the plurality of filaments, wherein movement of the actuator in a first direction relative to the hub moves the plurality of filaments relative to the tip to a deployed position distally beyond the tip, and wherein movement of the actuator in a second direction relative to the hub retracts the plurality of filaments to a retracted position in which the plurality of filaments are disposed within at least a portion of the elongate member; and

[1h] a fitting in fluid communication with the lumen, the fitting being configured to provide a connection for injection of fluid through the fitting and through the lumen, the fitting further being configured to allow for insertion of the RF probe into the lumen through the fitting,

[1i] wherein the lumen at the interior of the elongate member is configured to accept the RF probe therein to physically contact a conductive portion of the needle and [1j] thereby electrically connect the RF probe to the tip and the plurality of filaments, such that energy emitted by the RF probe passes through the tip and the plurality of filaments, and such that the RF probe, the tip, and the plurality of filaments operate together as a single monopolar RF electrode,

[1k] wherein the conductive portion of the needle is at a distal end of the needle, and

[1l] wherein, when the RF probe is fully separated from the needle in a non-inserted state, such that none of the RF probe is within the needle, the plurality of filaments are movable via the actuator from the retracted position, in which the plurality of filaments are disposed within said at least a portion of the elongate member, to the deployed position.

Ex. 1002, 31:22–65; Pet. 82–83.

D. The Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Ground	Claims Challenged	35 U.S.C. § ²	Reference(s)/Basis
1	1, 6–9, 12–14, 17, 48–52	103(a)	Racz, ³ Fitz, ⁴ Lee ⁵
2	1, 6–9, 12–14, 17, 48–52	103(a)	Racz, Fitz, Lee, Young '965 ⁶
3	1–9, 12–14, 17, 48–52	103(a)	Racz, Fitz, Lee, Scheibe ⁷

² The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, which was enacted September 16, 2011, made amendments to 35 U.S.C. §§ 102 and 103. AIA § 3(b)–(c). Those amendments became effective eighteen months later on March 16, 2013. *Id.* § 3(n). Because the application from which the '688 patent issued was filed before March 16, 2013, any citations herein to 35 U.S.C. §§ 102 and 103 are to their pre-AIA versions. *Id.* § 3(n)(1).

³ US 6,146,380, issued November 14, 2000. Ex. 1009.

⁴ US 2005/0059964 A1, published March 17, 2005. Ex. 1011.

⁵ US 2007/0016183 A1, published January 18, 2007. Ex. 1010.

⁶ US 2006/0084965 A1, published April 20, 2006. Ex. 1012.

⁷ US 2007/0260223 A1, published November 8, 2007. Ex. 1013.

Ground	Claims Challenged	35 U.S.C. § ²	Reference(s)/Basis
4	1–9, 12–14, 17, 48–52	103(a)	Racz, Fitz, Lee, Young '965, Scheibe
5	9	103(a)	Racz, Fitz, Lee, Young '201 ⁸
6	9	103(a)	Racz, Fitz, Lee, Young '201, Young '965
7	9	103(a)	Racz, Fitz, Lee, Young '201, Scheibe
8	9	103(a)	Racz, Fitz, Lee, Young '201, Young '965, Scheibe
9	10, 11, 15	103(a)	Racz, Fitz, Lee, Gough '516 ⁹
10	10, 11, 15	103(a)	Racz, Fitz, Lee, Gough '516, Young '965
11	10, 11, 15	103(a)	Racz, Fitz, Lee, Gough '516, Scheibe
12	10, 11, 15	103(a)	Racz, Fitz, Lee, Gough '516, Young '965, Scheibe
13	16	103(a)	Racz, Fitz, Lee, Rosinko ¹⁰
14	16	103(a)	Racz, Fitz, Lee, Rosinko, Young '965
15	16	103(a)	Racz, Fitz, Lee, Rosinko, Scheibe
16	16	103(a)	Racz, Fitz, Lee, Rosinko, Young '965, Scheibe

⁸ US 2009/0112201 A1, published April 30, 2009. Ex. 1016.

⁹ US 6,652,516 B1, issued November 25, 2003. Ex. 1017.

¹⁰ US 6,551,302 B1, issued April 22, 2003. Ex. 1020.

Pet. 11–12. As noted above, each of the eighteen grounds presented relies on a combination of at least Racz, Fitz, and Lee. The vast majority of the parties’ arguments are focused heavily on the combination of Racz, Fitz, and Lee, and, as such, that will be a prime focus of the discussion below.

II. ANALYSIS

A. Claim Construction

The challenged claims should be read in light of the specification, as it would be interpreted by one of ordinary skill in the art. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010). Thus, we generally give claim terms their ordinary and customary meaning. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) (“The ordinary and customary meaning is the meaning that the term would have to a person of ordinary skill in the art in question.” (internal quotation marks omitted)); *see also* 37 C.F.R. § 42.100(b) (stating that claims are construed in IPRs according to the same standard as used in federal court).

With respect to the challenged claims, Petitioner contends that no claim term requires express construction. Pet. 11 (citing Ex. 1032 ¶120 (Dr. Robert D. Tucker’s¹¹ testimony that “the terms in the Challenged Claims would be understood by a POSA to have their plain and ordinary meaning and do not require a special construction or definition”)). In instituting the IPR, we found no need to provide an express construction of any claim term. Inst. Dec. 14. We likewise find no need to do so now, as

¹¹ Dr. Tucker has a Ph.D. in biophysics as well as a medical degree. Ex. 1032 ¶2.

neither party has proposed a construction for any claim term and none of the parties' arguments turns on a disputed meaning of any claim language.

B. Obviousness Generally

A claim is unpatentable “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103(a). “Obviousness is a question of law based on underlying facts.” *MobileMedia Ideas LLC v. Apple Inc.*, 780 F.3d 1159, 1167 (Fed. Cir. 2015). The underlying facts include (i) the scope and content of the prior art, (ii) any differences between the prior art and the claimed invention, (iii) the level of ordinary skill in the field of the invention, and (iv) any relevant objective indicia, or secondary considerations, of nonobviousness. *Id.* (citing *Graham v. John Deere of Kan. City*, 383 U.S. 1, 17–18 (1966)). Further, if all the elements of an invention are found in a combination of prior art references, then:

a proper analysis under § 103 requires, inter alia, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.

Medichem, S.A. v. Rolabo, S.L., 437 F.3d 1157, 1164 (Fed. Cir. 2006).

C. Level of Ordinary Skill in the Art

In determining whether an invention would have been obvious at the time it was made, we consider the level of ordinary skill in the pertinent art

at the time of the invention. *Graham*, 383 U.S. at 17. “The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry.” *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991). The “person having ordinary skill in the art” is a hypothetical construct, from whose vantage point obviousness is assessed. *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998).

The parties dispute the level of ordinary skill in the art, and their main point of contention in that regard is the scope of the art itself, which logically is a prerequisite to determining the level of skill therein. *See, e.g., Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986) (“The person of ordinary skill is a hypothetical person who is presumed to be aware of all the *pertinent prior art*.” (emphasis added)). Indeed, several factors for consideration are premised on the scope of the art. *See id.* (“Factors that may be considered in determining level of skill include: type of problems encountered in art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.”).

Petitioner argues that the art is “‘thermal ablation systems and methods,’ which includes RF neurotomy systems,” as set forth in the ’688 patent’s express description of the “Field of Invention.” Pet. 10 (quoting Ex. 1002, 1:16–20). Petitioner argues that a person of ordinary skill in such art:

would have had at least (i) a bachelor’s degree in biomedical engineering, or a related field, such as mechanical engineering, biomechanical engineering, or bioengineering, who also has at least 3 years of experience with thermal ablation system[s] and

methods; or (ii) an advanced degree in the same areas of academic study with at least 1 years of experience with thermal ablation systems and methods.

Id. (citing Ex. 1032 ¶119).

Patent Owner argues that the art should be limited to RF neurotomy alone—to the exclusion of other types of ablation such as tumor ablation and cardiac ablation. *See, e.g.*, PO Resp. 25 (“[T]he central focus of the ’688 Patent is RF neurotomy, which is one specialized field among many diverse and non-overlapping fields, like tumor ablation and cardiac ablation, within the broad class of RF ablation.”). Thus, according to Patent Owner, “[b]y failing to specifically include RF neurotomy, the petition’s definition [of the art] diverts attention to unrelated and inappropriate fields of RF ablation.”

Id. In support of its narrower proposal, Patent Owner quotes from the same “Field of the Invention” section of the ’688 patent to which Petitioner cites.

Id. The entirety of that section states: “The present invention relates to thermal ablation systems and methods and, more specifically, to improved systems and methods for performing Radio Frequency (RF) neurotomy. The invention is particularly apt for spinal RF neurotomy procedures.” Ex. 1002, 1:16–20.

Although it is true that the ’688 patent relates “more specifically” to RF neurotomy, it also expressly relates to “thermal ablation” generally. *Id.* And, as Petitioner points out, “[t]he target volume may be, for example, a nerve or tumor.” *Id.* at 1:26–27 (emphasis added; cited at Reply 2). As also pointed out by Petitioner, in the “Summary of the Invention” section, the ’688 patent discloses “thermal ablation in general” and “RF neurotomy” “in particular.” *See id.* at 1:58–62 (“The present invention is directed toward improved methods, systems, and related apparatuses for performing thermal

ablation in general, and in particular, improved methods, systems, and related apparatuses for performing RF neurotomy, specifically in the region of the spine of a patient.”). Further, the “Detailed Description of the Invention” concludes by emphasizing that the scope of the invention encompasses “the delivery of RF energy to tissue in the anatomy . . . for a multitude of reasons,” stating as follows:

It will be appreciated that the delivery of RF energy to tissue in the anatomy is practiced for a multitude of reasons and embodiments of needles described herein may be adapted (modified or scaled) for use in other medical procedures. For example, embodiments of needles described herein could be used to deliver RF energy as a means to cauterize “feeder vessels,” such as in bleeding ulcers and/or in orthopedic applications. Further, embodiments of needles described herein could also be adapted to procedures such as cardiac ablation, in which cardiac tissue is destroyed in an effort to restore a normal electrical rhythm in the h[e]art. This application could further benefit from the ability of embodiments of needles described herein to deliver fluid through a lumen since, for example, emerging procedures in cardiac therapy require the ability to deliver stem cells, vascular endothelial growth factor (VEGF), or other growth factors to cardiac tissue. The ability to steer embodiments of the needle (previously discussed) may provide significant benefit to the . . . field of cardiovascular drug delivery.

While various embodiments of the present invention have been described in detail, it is apparent that further modifications and adaptations of the invention will occur to those skilled in the art. However, it is to be expressly understood that such modifications and adaptations are within the spirit and scope of the present invention.

Ex. 1002, 30:63–31:20. Lastly, none of the claims of the ’688 patent recites or otherwise is limited to RF neurotomy specifically, as opposed to more generally “an RF ablation procedure,” as recited in claim 1, for example.

In the Sur-Reply, Patent Owner reasonably concedes that “the patent mentions some non-neurotomy ablation applications.” Sur-Reply 20. Patent Owner argues, however, that such non-neurotomy ablation applications are beyond the field of the invention as evidenced by the ’688 patent’s statement that “the invention can be ‘adapted,’ ‘modified,’ ‘scaled,’ or ‘tailored’ for [such] other RF ablation procedures” and, thus, “the invention itself is not directed to those procedures.” *Id.* This argument is not persuasive as it is directly at odds with the ’688 patent, which states: “it is to be expressly understood that such modifications and adaptations are within the spirit and scope of the present invention.” Ex. 1002, 31:18–20.

Further, in determining a patent’s field of invention or art, it is the patent’s broader description that controls.

We determine the field of endeavor by reference to explanations of the invention’s subject matter in the patent application, including the embodiments, function, and structure of the claimed invention. The field of endeavor is not limited to the specific point of novelty, the narrowest possible conception of the field, or the particular focus within a given field.

Netflix, Inc. v. DivX, LLC, 80 F.4th 1352, 1359 (Fed. Cir. 2023) (quotations marks and internal citations omitted).

In sum, the field of the invention is thermal ablation. It encompasses RF neurotomy, but it is not limited to RF neurotomy. With that settled, we turn now to the person of ordinary in the field/art (POSITA or POSA).

Patent Owner’s proposal is reproduced below:

[A] combination of (1) an interventional pain-specialist physician with significant experience performing RF neurotomy procedures and (2) an engineer with a degree in biomedical engineering or a related field and experience in the design and development of devices and methods for applying

electromagnetic energy to nerves. The POSITA should have either a bachelor-level degree with three years of the design/development experience noted above or an advanced degree with one year of the design/development experience noted above. Such a POSITA could be a team of two or more people working together.

PO Resp. 29. Patent Owner's proposal is too narrow in two respects. First, it mandates certain education and experience in RF neurotomy specifically. This is too narrow as neither the field of the invention nor any challenged claim is limited to RF neurotomy. Second, it requires the POSA to be both a physician who performs thermal ablation (RF neurotomy specifically) and an engineer with training and experience "in the design and development of devices and methods" for performing the same. *Id.* This is too narrow because it excludes physicians and other advanced degree holders who research and design devices and methods for performing thermal ablation but do not actually operate on patients.

We adopt the Petitioner's definition of a POSA, quoted above, as it is reflective of the level of skill in the art when viewed in light of the disclosure of the '688 patent. *Supra* (quoting Pet. 10).

D. The Racz, Fitz, Lee Combination Common to All Grounds of Unpatentability

1. The Asserted Prior Art

a) Racz

Racz is titled "Bent Tip Electrical Surgical Probe" and discloses an "apparatus for pain relief that delivers electrical stimulation pulses or high-frequency signals to the vicinity of a neural structure via an electrical needle or cannula." Ex. 1009, code (54), 1:4–9.

Racz Figure 1 is reproduced below.

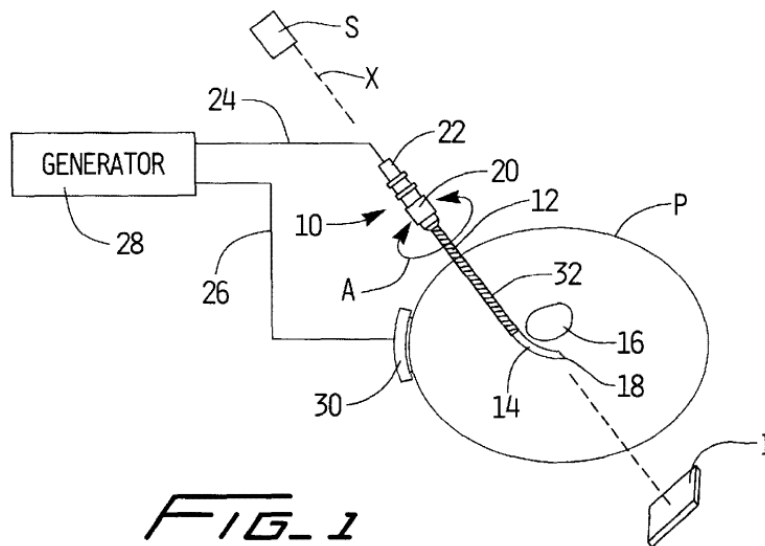


Figure 1, reproduced above, shows a schematic diagram of RacZ's system comprising "a radio-frequency electrode cannula 10 having a shaft 12 . . . inserted into a portion P of a patient's body." *Id.* at 3:24–26, 3:38–40. "The cannula 10 can be inserted directly through the skin of the body portion P to locate the tip 14 in a target position within the body." *Id.* at 3: 42–44. RF "cannula 10 further comprises a hub 20. The hub 20 is capable of accommodating an electrical probe 22, which includes a segment that is inserted into and received by the shaft 12 of the cannula 10." *Id.* at 3:60–63. "[E]lectrical connection 24 couples the cannula 10 to an external signal generator 28 by way of the hub 20 and the probe 22. A second electrical connection 26 connects the external signal generator 28 to a reference electrode 30 in contact with the patient's body portion P." *Id.* at 4:1–5. "[S]ignal generator 28 can be a source of electrical stimulation, pulsed high-frequency stimulation signals, high frequency signals, pulsed radio-frequency output, or other electrical waveforms." *Id.* at 4:6–9.

Racz Figure 2B is reproduced below.

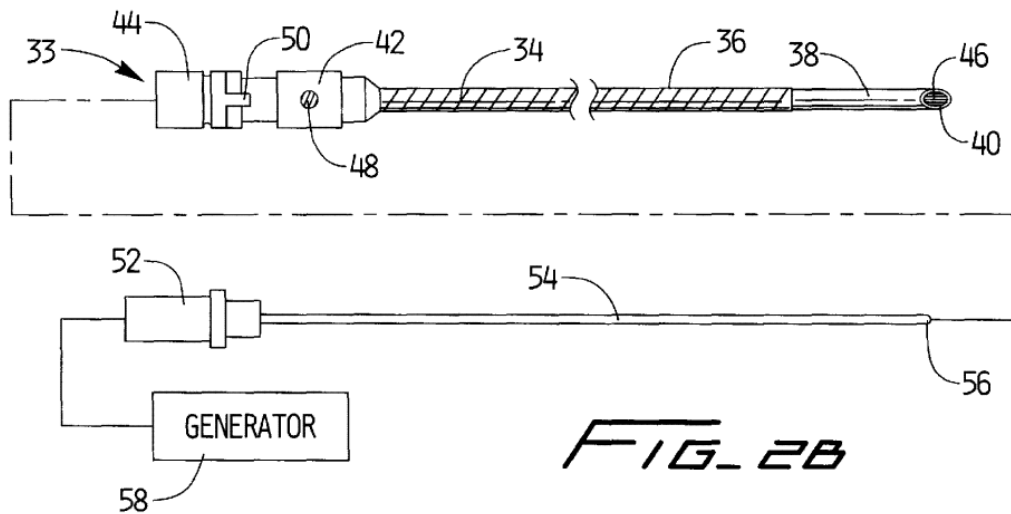


Figure 2B, reproduced above, shows a specific embodiment of the system diagramed in Figure 1. *Id.* at 3:27–30; 4:59–62, 5:7–51. The cannula, reference numeral 33 in this embodiment,¹² includes shaft 34 defining an internal lumen. *Id.* at 5:41–45. Shaft 34 “comprises a hollow metal tube with an insulated portion 36 illustrated by hatched lines,” and exposed distal tip 38. *Id.* at 4:62–65. Distal tip 38 includes a pointed end (40), which “can be useful in penetrating tough tissue.” *Id.* at 5:3–5.

¹² According to Petitioner, Racz uses different reference numerals for corresponding elements of its figures such that, for example, cannula 10 of Figure 1 corresponds to cannula 33 of Figures 2A–2B. Thus, Petitioner identifies multiple reference numerals for the same element such as, for example, “cannula (10/33).” Pet. 14–15. Patent Owner does the same thing. *See, e.g.*, PO Resp. 19 (“Racz discloses an RF neurotomy ‘needle or cannula’ 10/33 with a shaft 12/34 and curved tip 14/38, which enables it to go around anatomical structures 16. *See* Racz 4:44–58. A shaft 54 of a removable electrical probe 22/52 is insertable in the cannula 10/33. *See id.* 5:26–30. The probe 22/52 connects to a signal generator 28/58 at its proximate end.”). We follow suit.

In operation, cannula 33 “with a stylet positioned in the shaft 34 is inserted into the patient’s body portion P.” *Id.* at 5:31–33. “The stylet is then removed, and the probe 52 is inserted into the shaft 34.” *Id.* at 5:37–38. “The probe 52 is connected to the signal generator 58” in order to generate high-frequency heating, or other electrical stimulation. *Id.* at 3:60–63, 4:18–23, 4:18–20. When the probe 52 is fully inserted into the cannula 33, “physical contact” between probe 52 and the cannula’s tip 38 conducts the RF energy to the tip 38. *Id.* at 3:60–65, 4:18–23, 5:41–48. Racz’s cannula 33 thus provides “electrical stimulation or high frequency heating of tissue near the exposed electrical tip.” *Id.* at 3:60–4:23, 5:41–51, Fig. 1.

b) Fitz

Fitz discloses “improved-coverage RF neurotomy instrumentation, including an introducer used to deploy a set of electrodes to an area to be treated.” Ex. 1011 ¶9.

Fitz discloses that a known problem with single-tip RF neurotomy devices was “that they do not allow for adequate coverage of the target area,” and produce lesions that “extend[] only a few millimeters at the diameter of the midportion of the lesion” from the exposed needle tip. *Id.* ¶4. “Although multiple lesions may be created in order to enhance coverage, this is more time-consuming and usually more painful for the patient.” *Id.* ¶5. Moreover, “creation of multiple lesions also exposes the patient to more radiation, as fluoroscopy is used to place and replace the needles.” *Id.*

To address inadequate coverage in single-tip neurotomy devices, Fitz discloses “an introducer used to deploy a set of electrodes.” *Id.* ¶9. The

introducer features a plurality of elongated, co-extensive cannulae, each cannula including an insulated and electrically conductive electrode. *Id.* Each electrode has a proximal end configured for attachment to a source of energy, an exposed distal tip to deliver the energy to a localized region, and each electrode slides within its respective cannula so as to enhance the energy coverage area. *Id.* According to Fitz, “at least some of the electrodes [may be] constructed of a shape-memory material to control deployment. The cannulae are generally parallel, and may either lie in the same plane or may be arranged otherwise, including spoke-like cross-sections.” *Id.* ¶10. “At least some of the electrodes may slide independently, and at least some of the electrodes may slide in unison.” *Id.* ¶11.

Fitz Figure 4 is reproduced below.

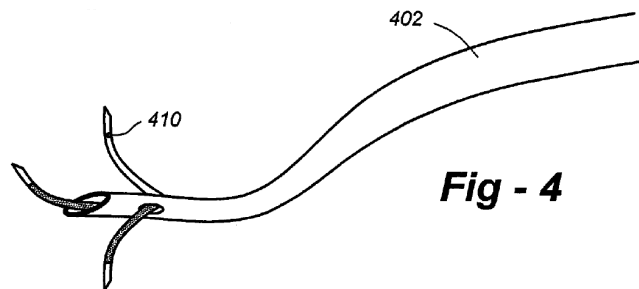


Figure 4, reproduced above, shows an embodiment of Fitz’s invention having a side port introducer. *Id.* ¶15. In this embodiment, “introducer 402 is curved, and a plurality of electrodes are deployed through the tip and/or multiple side ports.” *Id.* ¶20.

c) *Lee*

Lee discloses a radio frequency ablation device having a plurality of deployable electrodes or “ablation antennae.” *See, e.g.,* Ex. 1010, code (57), ¶8. Lee Figure 1 is reproduced below.

may be housed wholly within lumen 20 of cannula 16.” *Id.* (referencing Fig. 2). But in the deployed configuration shown in Figure 1, “the ends of the wire-like stylets 22 are exposed,” such that RF energy may be conducted from the tips of the stylets after they exit trocar 10 and “define an ablation volume in the target tissue.” *Id.* ¶¶12, 92. “The electrodes may be used in a monopolar fashion with the ablation stylets excited with RF energy and a return electrode being applied usually in the form a conductive pad in contact with a remote surface on the patient.” *Id.* ¶24.

As illustrated in Figure 1, stylets 22 are positioned around the perimeter of the tip 14 and extend outwardly in a “cone” orientation around the central stylet (labeled 24*a* to indicate a sharpened piercing point), which is deployed through the center of the trocar point 14. *Id.* ¶¶92, 102, 103, 128, Figs. 1–3. Lee discloses that stylets 22 “may be connected to suitable advancement and retraction mechanisms.” *Id.* ¶106. During deployment, the electrically conductive stylets around tip 14 are guided by “deflection surfaces,” which may comprise a plurality of channels and ramps. *Id.* ¶¶16, 18, 87 (the “electrodes are directed into the tissue at a variety of angles by a mandrel like delivery member which serves as a deflection surface”), 91, 102. The ends of the exposed stylets transmit RF energy to define an ablation volume. *Id.* ¶¶7, 12, 123, 129.

d) Whether Lee Is Analogous Art

Patent Owner argues that Lee is not analogous art. PO Resp. 2, 33–35. “Although § 103 does not, by its terms, define the ‘art to which [the] subject matter [sought to be patented] pertains,’ this determination is frequently couched in terms of whether the art is analogous or not, i.e., whether the art is ‘too remote to be treated as prior art.’” *In re Clay*, 966

F.2d 656, 658 (Fed. Cir. 1992) (quoting *In re Sovish*, 769 F.2d 738, 741 (Fed. Cir. 1985)). “Whether a reference in the prior art is ‘analogous’ is a fact question.” *Id.* at 658. “Two criteria have evolved for determining whether prior art is analogous: (1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.” *Id.* at 658–59.

Patent Owner argues that Lee is not analogous art under the first criterion because “Lee does not relate to neurotomy at all.” PO Resp. 33. However, as discussed above, the field of the invention is not limited to neurotomy. The field of the invention is thermal ablation generally, which encompasses RF neurotomy, but which is not limited to RF neurotomy. Accordingly, we are not persuaded by Patent Owner’s argument.

To the contrary, we are persuaded by Petitioner’s argument that Lee is analogous art, under at least the first *Clay* criterion, because it “discloses various techniques for deploying electrodes from the tip of an RF ablation device.” Pet. 17.

2. *The Proposed Combination—“Racz’s modified device”*

Petitioner argues that “a POSA would have been motivated to implement deployable filaments on the distal tip (14/38) of Racz’s electrode cannula (10/33),” as “Fitz and Lee disclose a known technique for solving a known problem in RF ablation devices—providing deployable filaments at a distal tip to expand and control the ablation volume compared to single-tip devices with inadequate energy coverage.” Pet. 21–22. The Petition

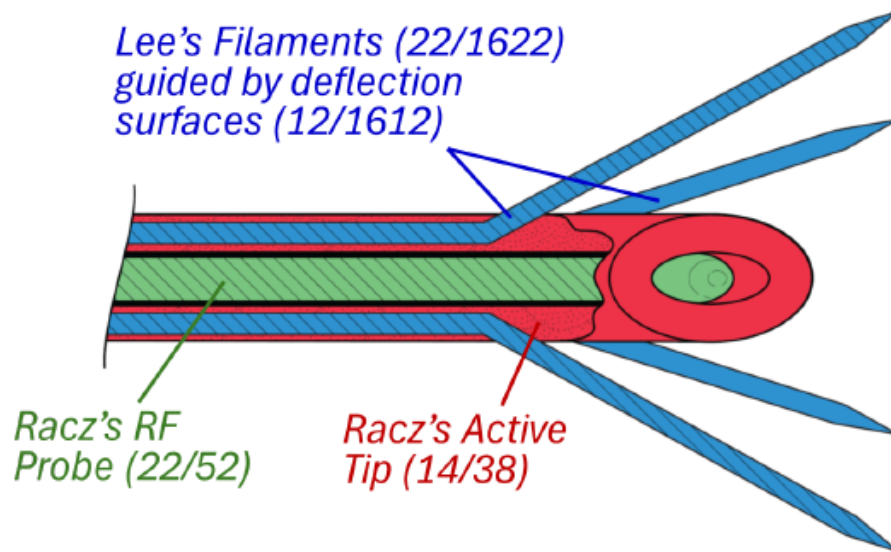
repeatedly refers to the proposed combination as “Racz’s modified device.” *See, e.g., id.* at 43, 46, 50. The Petition also provides a definition for the term, namely “Racz’s cannula (10/33) modified by a POSA to include deployable filaments as disclosed in Fitz and Lee.” *Id.* at vi. Patent Owner likewise employs the same term. *See, e.g.,* PO Resp. 22. We follow suit below.

Patent Owner asserts that the proposed combination (Racz’s modified device) is “[t]oo [v]ague” and thus the Petition fails to comply with 35 U.S.C. § 312 (“requiring petitions to set forth challenge grounds ‘with particularity’”), 37 C.F.R. § 42.104 (“requiring petitions to be ‘precise’ and ‘with specificity’”¹⁴), and 5 U.S.C. § 554(b) (“requiring timely notice of ‘the matters of fact and law asserted’”). PO Resp. 36–37.

In support of these assertions, Patent Owner lists eight criticisms purportedly demonstrating “ambiguities, omissions, and lack of clarity that frustrate Stratus’s ability to meaningfully respond to the petition.” *Id.* at 37–40. As discussed below, however, none of Patent Owner’s criticisms demonstrates a lack of compliance by the Petition with 35 U.S.C. § 312, 37 C.F.R. § 42.104, or 5 U.S.C. § 554(b).

The first such criticism is that the Petition provides “just one partial view of Racz’s modified device, from just one perspective.” PO Resp. 37–38 (reproducing an image from page 26 of the Petition). We reproduce below the illustration in question along with the related text appended to it in the Petition.

¹⁴ Contrary to Patent Owner’s argument (*see* PO Resp. 36), Rule 104 does not include the phrase “with specificity.” 37 C.F.R. § 42.104.



Dr. Tucker Declaration at ¶157 (showing one example of how a POSA would modify Racz to include Lee's filaments)

Pet. 26; *see also* Ex. 1032 ¶157. According to Petitioner what is shown above is “one example of how a POSA would modify Racz to include Lee’s filaments.” Pet. 26 (emphasis omitted). Dr. Tucker elaborates on that point, testifying:

The figure shows *one example* of how a POSA (motivated by both Fitz and Lee) would have incorporated Lee’s deployable filaments (22/1622) as monopolar electrodes at Racz’s distal tip (14/38). This figure is not intended to be limiting or represent the only way Racz’s device would have been modified, but I am providing it as a helpful illustration of how the references would be combined in one example.

Ex. 1032 ¶157.

Patent Owner does not identify any legal requirement for petitions to *illustrate* proposed combinations of prior art features. Indeed, the very statute identified by Patent Owner as “requiring petitions to set forth challenge grounds ‘with particularity’” (*see* PO Resp. 36) calls for the requisite particularity to be “in writing,” not by illustration. *See* 35 U.S.C.

§ 312(a)(3) (“A petition filed under section 311 may be considered only if . . . (3) the petition identifies, in writing and with particularity . . . the grounds on which the challenge to each claim is based.”). Simply put, there is no legal requirement to provide multiple illustrations of a proposed combination of prior art features (as Patent Owner implies), let alone a single illustration (as Petitioner has done).

The rest of the criticisms are that the Petition does not provide enough specific details. *See* PO Resp. 38 (“Second, no dimensions are provided.”), 39 (“Third, . . . it is unclear how far proximally (left as shown above) those channels continue (*i.e.*, where those channels begin on the proximal end) or how the filaments enter those channels.”), 39 (“Fourth, it is unknown whether the tip remains bent, as taught by Racz, or has been straightened to accommodate the filaments in Racz’s modified device.”), 40 (“Fifth, it is unknown whether Racz’s modified device includes anchors, which Lee says are necessary to prevent backward migration of the needle when Lee’s filaments are deployed.”), 40 (“Sixth, it is also unknown, for example, whether the filaments are electrically connected to an RF signal source, as taught by Lee, or not, as that may be unnecessary in view of Racz’s RF probe.”), 40 (“Seventh, it appears that no features of Fitz are incorporated into this modified device, but that is not clear.”), 40 (“Eighth, Dr. Tucker refers to two examples of Racz’s modified device, but the differences between them are not clear.”). None of these criticisms is persuasive.

With respect to the second through sixth criticisms set forth above, Patent Owner has not explained, nor is it apparent to us, that any such detail is necessary in light of claim requirements. For example, the challenged

claims do not specify dimensions, mandate or preclude the use of anchors, or mandate or preclude a bent tip.

As for the “[s]eventh” criticism that it is not clear whether a feature from Fitz is being utilized, we are not persuaded. Lee and Fitz are somewhat duplicative or redundant of one another as both teach the use of deployable filaments at the distal end of an ablation device. *See, e.g.*, Pet. 17 (“Like Fitz, Lee discloses that a deployable-electrode technique can be used to deliver RF energy to a targeted area of tissue.” (citing Ex. 1010 ¶¶32, 84, code (54))). It is true that the Petition illustrates “one example of how a POSA would modify Racz to include Lee’s filaments” with no mention of Fitz. *Id.* at 26. However, the Petition clearly articulates that “Racz’s modified device” is “Racz’s cannula (10/33) modified by a POSA to include deployable filaments as disclosed in Fitz and Lee.” *Id.* at vi. Thus, “Racz’s modified device” is not limited to incorporating Lee’s filaments. Further, even in the example of incorporating Lee’s deployable filaments, the cited teachings of Fitz nonetheless are relevant as they provide further support for why a POSA would have been motivated to incorporate any deployable filaments into Racz. *See id.* at 15 (“Fitz discloses that a known problem with single-tip RF neurotomy devices was ‘that they do not allow for adequate coverage of the target area.’ (quoting Ex. 1011 ¶4)), 16 (“To solve the problem of inadequate coverage in single-tip neurotomy devices, Fitz suggests providing a deployable ‘set of electrodes’ that extend outwardly from the ‘exposed distal tip’ of an RF neurotomy cannula.” (quoting Ex. 1011 ¶9, code (57))).

Patent Owner’s last criticism regarding the purported vagueness of Racz’s modified device is that “Dr. Tucker refers to two examples of Racz’s

modified device, but the differences between them are not clear.” PO Resp. 40 (citing Ex. 2006 ¶¶195–197; Ex. 2020, 112:9–113:5). What Patent Owner refers to, despite not citing to it in its brief, is Dr. Tucker’s testimony offering two examples of how deployable filaments could be implemented in Racz. *See* Ex. 1032 ¶¶159 (“As a first example, it is my opinion that a POSA would be able to define channels (as disclosed in Lee) as an integral part of Racz’s cannula and dimension the channels to accommodate Lee’s filaments.”), 161 (“As a second example, it is also my opinion that a POSA would also have been able to implement the combination of Racz and Lee using a separate tip defining channels (as disclosed in Lee).”). We are not moved by Patent Owner’s criticism. Patent Owner does not cite any legal authority that would preclude a Petitioner (or its witness) from identifying multiple examples of how a POSA could have combined the prior art.¹⁵

¹⁵ Patent Owner also states that it is not clear “if there are other (unillustrated) examples that [Dr. Tucker] or the petitioner intends to rely upon.” PO Resp. 40. To the extent this is an argument, it is not persuasive. Petitioner relies on “Racz’s cannula (10/33) modified by a POSA to include deployable filaments as disclosed in Fitz and Lee.” Pet. vi. That there may be additional permutations of how the prior art might be combined that Petitioner has not articulated does not undermine Petitioner’s obviousness challenge. In fact, the law does not require Racz to be physically combinable with Lee or Fitz for their combination to be obvious. *See Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (“Contrary to Allied’s position, it is not necessary that [Caterpillar and Ogawa] be physically combinable to render obvious the [’489 patent].” (quotes and citation omitted, alterations in original)); *In re Etter*, 756 F.2d 852, 859 (Fed. Cir. 1985) (en banc) (“Etter’s assertions that Azure cannot be incorporated in Ambrosio are basically irrelevant, the criterion being not whether the references could be physically combined but

Further, as Petitioner points out, “obviousness does not require the art be ‘physically combinable,’ much less in the exacting detail [Patent Owner] Stratus suggests.” Reply 12 (citing *Allied Erecting*, 825 F.3d at 1381). Petitioner is correct. The Federal Circuit has held:

To justify combining reference teachings in support of a rejection it is not necessary that a device shown in one reference can be physically inserted into the device shown in the other. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.

In re Keller, 642 F.2d 413, 425 (CCPA 1981) (citations omitted).

In sum, the proposed combination, which Petitioner refers to as “Racz’s modified device” and defines as “Racz’s cannula (10/33) modified by a POSA to include deployable filaments as disclosed in Fitz and Lee” (*see* Pet. vi.), is not “vague,” as Patent Owner asserts. *See* PO Resp. 36.

3. Reason To Combine

Petitioner cites *Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373 (Fed. Cir. 2023) as holding that, “if there’s a known technique to address a known problem using prior art elements according to their established functions, then there is a motivation to combine.” *Id.* at 1380 (internal quotations omitted); Pet. 21. Petitioner cites Fitz and Lee as evidence that implementing deployable filaments on the distal tip of an RF ablation device

whether the claimed inventions are rendered obvious by the teachings of the prior art as a whole.”).

was a known technique for expanding and controlling the ablation volume. Pet. 22 (citing Ex. 1011, ¶¶9–10, code (57); Ex. 1010 ¶¶12, 84, 123–131); *see also* Ex. 1032 ¶¶60–65, 69–72 (Dr. Tucker testifying, among other things, that deployable electrodes were well known in the art). In addition, Petitioner cites declaration testimony of Dr. Tucker that “a POSA would have been motivated to implement deployable filaments on the distal tip (14/38) of Racz’s electrode cannula (10/33)” of the proposed combination, as he “would have recognized that the Fitz/Lee technique would improve the energy coverage area of Racz’s single-tip device.” Ex. 1032 ¶146 (cited at Pet. 22).

Petitioner presents additional arguments and evidence to support that a POSA would have had an apparent reason to make Racz’s modified device. Pet. 22–27. We need not address these additional arguments and evidentiary citations, however, as Petitioner has demonstrated by a preponderance of the evidence that implementing deployable filaments on the distal tip of an RF ablation device was a known technique for expanding and controlling the ablation volume. Thus, so long as there would have been a reasonable expectation of success in making Racz’s modified device (addressed *infra*), the combination would have been obvious. *See Intel Corp.*, 61 F.4th at 1380 (“[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.”); *Medichem*, 437 F.3d at 1165 (“[A]n obviousness determination requires not only the existence of a motivation to combine elements from different prior art

references, but also that a skilled artisan would have perceived a reasonable expectation of success in making the invention via that combination.”).

Patent Owner argues that Petitioner presents an “[i]nadequate [m]otivation to [c]ombine Racz, Fitz, and Lee.” PO Resp. 56 (emphasis omitted). In that regard, Patent Owner summarizes testimony of Mr. Crosby as demonstrating that “the art was generally characterized by two alternative approaches: (1) tine-less devices with removable RF probes for distal energization and (2) probe-less tined devices in which deployable tines or filaments are energized at the proximal end.” *Id.* (citing Ex. 2006 ¶¶161–167). According to Patent Owner, prior to the ’688 patent, these “two distinct approaches . . . had never before been attempted together” and “were considered mutually exclusive.” *Id.* The legal significance of this line of argument is unclear. To the extent it is an attack on the references individually, it is not persuasive. *See Keller*, 642 F.2d at 426 (“But one cannot show non-obviousness by attacking references individually where, as here, the rejections are based on combinations of references.”). To the extent it is a preview of Patent Owner’s teaching away arguments, such arguments are addressed further below.

Patent Owner presents numerous additional arguments attempting to show that a POSA would not have had an adequate reason to combine the prior art as proposed by Petitioner. PO Resp. 50–56. These arguments are not persuasive, first and foremost, because they do nothing to rebut the following facts established by Petitioner: (1) it was known in the art that deployable filaments could be provided at a distal tip of an RF ablation device to expand and control the ablation volume compared to single-tip

devices, (2) a POSA would have recognized that deployable filaments similarly would improve Racz's electrode cannula in the same way.

Still, we address Patent Owner's arguments. In general, Patent Owner presents two main arguments—the asserted prior art teaches away from Racz's modified device, and a POSA would have combined the prior art in a manner outside the scope of the challenged claims. PO Resp. 50–58.

As for the teaching away argument, Patent Owner offers three explanations. First, Patent Owner argues that “Racz teaches away from the addition of filaments.” *Id.* at 50. This is so, according to Patent Owner, because, “[f]or Racz's modified device to be usable as a neurotomy needle, the filaments would need to be extraordinarily thin or narrow” such that they would be unworkable. *Id.* “Assuming they could even be constructed at all, [Patent Owner continues,] such small filaments would be so flexible as to be bent by tissue in unpredictable manners as they exit the needle or possibly not even being able to pass through the tissue.” *Id.* (citing Ex. 2006 ¶282). Patent Owner argues that Racz effectively teaches away from such filaments in the following passage.

Stimulation and high frequency electrodes having expandable and flexible curved tips are known. Examples of such electrodes are the TEW Electrode Kit and the ZHK Electrode Kit, both manufactured by Radionics. Those electrodes both have flexible, curved tips, which extend from the straight shaft of an enclosing cannula to extend off-axis in an arc. This is useful in certain neural regions such as the trigeminal ganglion or the pituitary gland, or any area where the target region is very soft or fluid filled. *Such flexible off-axis electrodes have a limitation that there [sic] tips cannot penetrate tough tissue or encounter hard bone without being damaged or diverted.*

Id. at 51 (quoting Ex. 1009, 2:26–37 (colored text converted to black)).

Petitioner replies that Racz does not teach away from flexible electrodes (or deployable filaments) because Racz endorses them in some situations, including some RF neurotomy procedures. Reply 13. Petitioner is correct. In fact, in the sentence immediately preceding the purported teaching away (in italics *supra*), Racz states that such flexible electrodes are “useful in certain neural regions such as the trigeminal ganglion or the pituitary gland, or any area where the target region is very soft or fluid filled.” Ex. 1009, 2:32–34.

Second, Patent Owner argues that, “[b]ecause Racz teaches that a curved tip is a necessity, Racz teaches away from the petition’s proposal *to the extent that Racz’s modified device would have a straight tip.*” PO Resp. 54 (emphasis added)¹⁶; *see also* Ex. 1009, codes (54) (“Bent Tip Electrical Surgical Probe”), (57) (“A medical needle or cannula for stimulation or ablation includes a rigid bent tip for simplified placement at target sites within a patient's anatomy. The curved tip or shaft is used to steer the device within the patient’s body and to avoid critical anatomical structures.”).

¹⁶ A fair reading of the Petition shows that Petitioner’s challenge is based on a modification of Racz’s improved electrode cannula, which has a bent tip, not a straight tip. *See* Pet. 21 (asserting that “a POSA would have been motivated to implement deployable filaments on the distal tip (14/38) of *Racz’s electrode cannula (10/33)*” (emphasis added)); Ex. 1009, Figs. 1 (showing Racz’s cannula 10 with a bent tip), 2A–B (showing Racz’s cannula 33 with a bent tip)). However, a fair reading of the Petition further shows that Petitioner’s challenge is not premised on Racz’s modified device having a bent tip; rather, it is indifferent as to that feature. *See, e.g.*, Pet. 12–15 (summarizing Racz’s disclosure and not even mentioning the bent tip).

Petitioner replies that, “[a]t most, Racz suggests a preference for a bent tip in limited scenarios but never requires it.” Reply 14 (citing Ex. 1009, 2:3–25, 2:39–41; Ex. 1045, 129:15–131:2, 133:17–134:10). Petitioner is correct insofar as Racz does not require a bent tip or teach away from a straight tip in all scenarios. Rather, Racz (1) substantiates that a POSA would have known about RF ablation devices with straight tips and that such devices were suitable for some applications and (2) teaches a bent tip as an improvement for other applications. *See, e.g.*, Ex. 1009, 1:32–35 (“Radiofrequency electrodes are commonly used; these typically have an insulated straight tubular metal shaft with an electrically exposed tip.”), 4:56–58 (“This procedure can be more effective when performed with the rigid bent tip 14 of the invention than with a traditional straight or flexible tip.”).

In sum, Petitioner’s proposal is not conditioned on Racz’s modified device having a straight tip. To the contrary, Petitioner proposes a modification to Racz’s device, which has a bent tip.¹⁷

¹⁷ The degree of bend or curvature of Racz’s tip can vary widely per Racz. *See* Ex. 1009, 8:58–9:1 (“Various forms and embodiments of the bent tip needle or cannula are provided herein involving various shapes, sizes, forms, and configurations of the cannula” and, within the scope of the invention, “various configurations of tip geometry, bluntness or sharpness, degree of curvature, position of fluid injection ports, and the insulation configuration may be devised.”). Dr. Tucker interpreted this to mean that it could be varied to zero, resulting in a straight tip. Ex. 2020, 48:1–3. Regardless, of whether a straight tip would be considered part of Racz’s invention, as Dr. Tucker testifies, Racz clearly shows that straight tips were known in the art.

Third, Patent Owner argues “it is unclear whether Racz’s modified device would have anchors as taught by Lee,” as the Petition does not address anchors. PO Resp. 55. Thus, according to Patent Owner, Lee teaches away from Racz’s modified device because, “[a]ccording to Lee, such anchors are a necessity to prevent movement of the needle when Lee’s [filaments] are deployed, unless the [filaments] are deployed ‘one at a time.’” *Id.* (quoting Ex. 1010 ¶104).

Petitioner replies that Lee does not teach what Patent Owner asserts it to teach. Rather, according to Petitioner, “Lee is unequivocal that its anchors are optional.” Reply 14 (citing Ex. 1010 ¶¶90, 104). Petitioner is correct. *See* Ex. 1010 ¶¶90 (“It is also contemplated in accordance with the invention that there are circumstances where anchors might not be applied at all.”), 104 (“[I]f desired, anchors may not be deployed.”).

For the reasons stated above, we are not persuaded that any of the asserted prior art teaches away from the claimed invention.

We turn now to Patent Owner’s related argument that, if a POSA would have combined the prior art, he would have done so exclusively in a manner outside the scope of the challenged claims. PO Resp. 57–58. Specifically, Patent Owner argues that a POSA would consider the use of deployable filaments in an ablation device, as taught by Fitz or Lee, only in lieu of, and not in addition to, a removable RF probe, as taught in Racz. *Id.* In other words, according to Patent Owner, if a POSA sought to improve Racz “to achieve the expanded-ablation-volume objective stated in the petition,” he “could simply replace Racz’s probe 52 with Fitz’s electrodes.” *Id.* at 57. Thus, as Patent Owner concludes, “Racz’s modified device is far more complicated and problematic than necessary.” *Id.*

This line of argument does not demonstrate that a POSA would not have combined the prior art in the manner proposed by Petitioner. It merely demonstrates that a different combination, one lacking an RF probe and thus not encompassed by the claims,¹⁸ also may have been obvious to a POSA and perhaps would have been considered superior to Petitioner's proposed combination. But "just because [allegedly] better alternatives exist in the prior art does not mean that an inferior combination is inapt for obviousness purposes." *In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012); *see also In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) ("A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use."). Thus, even if Racz's modified device were inferior to the alternative combination identified by Patent Owner, such a fact would not rebut or undermine Petitioner's reason to combine the art into Racz's modified device.

In sum, we are persuaded that a POSA would have had an adequate reason to combine the prior art as proposed by Petitioner.

4. *Reasonable Expectation of Success*

Patent Owner disputes that there would have been a reasonable expectation of success in making the proposed combination. PO Resp. 42–48. Patent Owner argues both that Petitioner's evidence does not support a reasonable expectation of success and that Patent Owner's evidence demonstrates a lack of it. *Id.* at 42.

¹⁸ Claim 1 recites "an RF probe."

As for the former point, Patent Owner argues that “[t]he sole” evidence for a reasonable expectation of success that Petitioner presents “is Dr. Tucker’s bald conclusion, which is entitled to no weight.” *Id.*

Dr. Tucker’s testimony is not a bald conclusion. His conclusion as to a reasonable expectation of success is set forth in paragraph 162 of his declaration. Ex. 1032 ¶162. It is supported extensively with testimony regarding what the prior art teaches (*see id.* ¶¶124–131 (Racz), ¶¶132–137 (Fitz), ¶¶138–145 (Lee)) and why and how a POSA would have combined the prior art teachings (*see id.* ¶¶146–161).

Dr. Tucker’s testimony clearly is entitled to weight. Since 1983, he has “been a Professor at the University of Iowa where [he] direct[s] an active research program in radiofrequency electrosurgical procedures and instrumentation.” Ex. 1032 ¶3. He has a Ph.D. in biophysics, and he is also a medical doctor (albeit he is not Board certified as pointed out by Patent Owner¹⁹). *Id.* ¶2. He also has additional training and experience that is relevant, but which is unnecessary to establish that he is qualified to offer the opinions set forth in his declaration. *Id.* ¶¶2–11.

Patent Owner argues that Dr. Tucker is not qualified to testify here because “he is not Board certified” and he is “not a pain-specialist physician and has never performed a neurotomy.” PO Resp. 29–30. Dr. Tucker explained, however, that he is not Board certified nor does he operate on patients because his work focuses on the development of instrumentation, not the use of it, explaining on cross-examination:

¹⁹ See PO Resp. 30 (citing Ex. 2020, 10:19–12:20).

I have a Ph.D. in engineering and had no intention of doing pathology on patient samples day-to-day. I wanted to combine my Ph.D. in engineering with pathology to develop instrumentation. Medical instrumentation. So I never was Board-certified. Instead of Boards, I got a Ph.D.

Ex. 2020, 11:7–13. We are persuaded that Dr. Tucker is qualified to offer testimony in this proceeding and that his testimony adequately supports Petitioner’s asserted reasonable expectation of success.

We turn now to whether there would have been a reasonable expectation of success.

It is not disputed that Racz discloses a cannula with a removable RF probe, and Lee and Fitz both disclose cannulas with deployable filaments (“electrodes” in Fitz and “stylets” in Lee). Pet. 12–21; PO Resp. 19–21. These disclosures are presumed to be enabling. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003) (“[W]e hold a presumption arises that both the claimed and unclaimed disclosures in a prior art patent are enabled.”); *Apple Inc. v. Corephotonics, Ltd.*, No. 2020-1438, 2021 WL 2577597, at *4 (Fed. Cir. June 23, 2021) (nonprecedential) (holding that in the context of AIA trial proceedings, “regardless of the forum, prior art patents and publications enjoy a presumption of enablement, and the patentee/applicant has the burden to prove nonenablement for such prior art” and that “[i]t was error for the Board to suggest otherwise”). Accordingly, it is clear that there would have been a reasonable expectation of success in making a cannula with an RF probe as well as a cannula having deployable filaments, as taught by Racz and Fitz/Lee, respectively.

The question before us is whether there would have been a reasonable expectation of success in combining the prior art features into Racz’s

modified device.²⁰ Petitioner answers that question in the affirmative, pointing to the testimony of Dr. Tucker. Pet. 27 (citing Ex. 1032 ¶162). As discussed above, Dr. Tucker’s conclusion is supported extensively with testimony regarding what the prior art teaches (*see* Ex. 1032 ¶¶124–131 (Racz), ¶¶132–137 (Fitz), ¶¶138–145 (Lee)) and why and how a POSA would have combined the prior art teachings (*see id.* ¶¶146–161). For example, Dr. Tucker explains that, because Lee discloses that deployable filaments can be arranged around the inner perimeter of a cannula such that they surround and provide space for a central element, a POSA would have understood that they could be arranged to accommodate Racz’s centrally located removable RF probe. Ex. 1032 ¶154. Dr. Tucker further testifies that a POSA could make the combination “using ordinary skill and routine engineering,” and it “would involve nothing more than using prior art elements like the filaments (22/1622), cannula (10/33), active tip (14/38), and removable probe (22/52) according to their established functions, which would have been known to a POSA.” *Id.* ¶¶157–158; *see also* Pet. 6 (“This

²⁰ Separately, Patent Owner argues that “Racz’s Modified Device is Not Enabled.” PO Resp. 48 (emphasis omitted). In particular, Patent Owner argues that the “references used in an obviousness challenge must collectively teach a POSITA how to make the claimed invention . . . without undue experimentation.” *Id.* (citing *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989); *Bristol-Myers Squibb v. Ben Venue Labs, Inc.*, 246 F.3d 1368, 1374 (Fed. Cir. 2001); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)). The cited cases, however, do not support Patent Owner’s argument. To be clear, the law does not require that a combination of prior art teachings “enable” what they render obvious. Rather, Patent Owner’s arguments in this regard appear to be a rehashing of its unpersuasive reasonable expectation of success arguments.

would have been a matter of routine engineering with entirely predictable results”). Consistent with this testimony, Petitioner accurately points out that the ’688 patent itself does not teach how to manufacture its claimed invention. *See* Reply 16 (Patent Owner “Stratus argues that the proposed combination would be too challenging to manufacture, leaving a POSA with no expectation of success. [PO Resp.] 42–50. But the specification belies Stratus’s position—nowhere does it teach how to manufacture the disclosed system or devices.”). Patent Owner does not dispute this point. Sur-Reply 5–6.²¹

Patent Owner argues there would not have been a reasonable expectation of success because of the difficulty of incorporating deployable filaments into Racz while retaining its removable RF probe given the purported size constraints applicable to neurotomy. In particular, Patent Owner argues that Racz’s modified device would have required that the deployable filaments longitudinally slide through channels extending within the sidewall of Racz’s cannula, but such narrow channels “would be extremely challenging, if not impossible, to fabricate.” PO Resp. 42 (quoting Ex. 2006 ¶221).²² According to Patent Owner:

²¹ Although Patent Owner does not dispute that the ’688 patent omits how to manufacture the claimed invention, Patent Owner argues that the omission is irrelevant because “Stratus’s invention is *different*” than Racz’s modified device. Sur-Reply 5–6. Patent Owner does not explain why the alleged differences excuse the lack of manufacturing details in the ’688 patent while a lack of manufacturing details in the Petition would be fatal to Petitioner’s challenge.

²² Patent Owner raises a related argument, that Racz’s modified device “would be even more difficult to fabricate if the tip is bent or curved, as

If reduced to a size suitable for RF neurotomy, those channels would be so long and thin that there would be no reasonable expectation of success to make them. At its largest an RF neurotomy needle would be 16 gauge, with a 1.65-mm outer diameter and 1.19-mm inner diameter, meaning that the sidewall is 0.22 mm thick.

Id. at 43 (citing Ex. 2006 ¶235; Ex. 2001 ¶¶158–160, 230–236).²³ Patent Owner’s argument is not persuasive.

As Petitioner points out, the challenged claims are not limited to a neurotomy device. *See, e.g.*, Reply 2 (“As [Patent Owner witness Mr.] Crosby confirmed, the patent claims are not limited to neurotomy.” (citing Ex. 1045, 211:7–213:18; Ex. 1002, 31:21–38:32)). Thus, even if a POSA would not have had a reasonable expectation of success in making Racz’s modified device for neurotomy applications due to the purported size

emphatically taught by Racz.” PO Resp. 42–43. However, Petitioner’s challenge is not premised on preserving Racz’s bent tip. Nor does Racz require any particular bend or curvature to the tip. Rather, Racz expressly contemplates wide variations in the geometry of the tip. *See* Ex. 1009, 8:58–9:1 (“Various forms and embodiments of the bent tip needle or cannula are provided herein involving various shapes, sizes, forms, and configurations of the cannula” and, within the scope of the invention, “various configurations of tip geometry, bluntness or sharpness, degree of curvature, position of fluid injection ports, and the insulation configuration may be devised.”). Thus, if a certain tip’s shape or curvature proved difficult to work with, a POSA would have known, based on this explicit disclosure, that the tip could be altered as needed. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (The obviousness analysis “can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.”), 421 (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”).

²³ *See* Ex. 2001 ¶99 (“Gauge refers to the inner measurement or opening of the needle, and the higher the number, the smaller the needle.”); Ex. 2006 ¶228 (“The smaller the gauge number, the bigger the needle.”).

constraints argued by Patent Owner, such a fact would not rebut the obviousness of the challenged claims. This is so because there still would be a reasonable expectation of success in making Racz's modified device of a larger size (lower wire gauge) for non-neurotomy applications encompassed by the challenged claims, which lack the purported size constraints. For this reason alone, Patent Owner's arguments about the channels being too thin to manufacture for neurotomy applications are not persuasive.

In any event, Petitioner replies with persuasive evidence that 16 gauge is *not* the maximum size for neurotomy. Reply 19. In particular, Petitioner relies on the following disclosure of Racz: "Those individuals skilled in the art will recognize that many variations of the electrode geometries depicted in FIGS. 1–3 are possible without departing from the invention. Various sized electrodes can be made, from extremely small gauges (e.g., 30 gauge) to much larger sizes (e.g., 10 gauge)." Ex. 1009, 8:10–15 (cited at Reply 19).

Patent Owner responds that Racz's teaching of 10-gauge electrodes is referring exclusively to non-neurotomy applications because it "does not actually say that a *neurotomy* needle could be as big as 10-gauge." Sur-Reply 8. Patent Owner posits that the 10-gauge teaching must be referring instead to *non-neurotomy* applications because Racz states that its "invention is not limited to use in such [previously discussed] applications, and *other medical and surgical procedures* would be apparent to a practitioner of ordinary skill." *Id.* (quoting Ex. 1009, 9:12–18).

We are not persuaded by Patent Owner's characterization of Racz. The teaching that Petitioner relies on from Racz is expressly applicable to "variations of the electrode geometries depicted in FIGS. 1–3 [that] are

possible without departing from the invention.” Ex. 1009, 8:11–13.

Notably, Patent Owner concedes that the embodiments disclosed in Racz Figures 1 and 2 are for RF *neurotomy*. See PO Resp. 19 (“Racz discloses an RF neurotomy ‘needle or cannula’ 10/33 with a shaft 12/34 and curved tip 14/38, which enables it to go around anatomical structures 16.” (citing Ex. 1009, 4:44–58)); see also Ex. 1009, Fig. 1 (labeling the cannula of Figure 1 with reference numeral “10”), Fig. 2 (labeling the cannula of Figure 2 with reference numeral “33”). Thus, Racz’s teaching that “[v]arious sized electrodes can be made, from extremely small gauges (e.g., 30 gauge) to much larger sizes (e.g., 10 gauge)” applies to RF neurotomy needles and cannulas. Ex. 1009, 8:13–15.

We are cognizant that Patent Owner cites declaration testimony that supports its contrary argument that, “[a]t its largest[,] an RF neurotomy needle would be 16 gauge.” PO Resp. 43 (citing Ex. 2006 ¶235; Ex. 2001 ¶¶158–160, 230–236). However, we find Racz—an issued patent—to be inherently more credible than witness testimony prepared specifically for litigation, and we give it more weight.

In sum, we are not persuaded by Patent Owner’s foundational argument that the needle of Racz’s modified device could not be larger than 16 gauge. According, we likewise are not persuaded by Patent Owner’s conclusion that it “would be extremely challenging, if not impossible, to fabricate” Racz’s modified device. PO Resp. 42. Instead, we are persuaded by Petitioner’s arguments and evidence showing that there would have been a reasonable expectation of success in making the proposed combination, as the prior art features were known and could have been combined through ordinary skill in the art.

E. Ground 1

Petitioner argues that claims 1, 6–9, 12–14, 17, and 48–52 would have been obvious over Racz, Fitz, and Lee. Pet. 12–61.

1. Claim 1

In mapping the prior art to claim 1, the Petition breaks the claim into thirteen portions, namely, the preamble and twelve limitations labeled [1a] through [11]. Pet. 27–48. We follow suit.

The preamble merely recites “[a] system comprising.” It is not limiting, neither party argues it is limiting, and we do not address it further. We turn now to the body of the claim and its twelve limitations as partitioned by Petitioner.

[1a] “an RF probe”

Petitioner argues that Racz’s modified device includes an RF probe (22/52), as taught by Racz and retained in the modification. Pet. 27 (citing Ex. 1009, 3:38–45, 3:60–65, 4:59–62, 5:7–51, Figs. 1, 2A–B). As discussed above, Patent Owner argues that a POSA “could simply replace Racz’s probe 52 with Fitz’s electrodes.” PO Resp. 57. However, as also discussed above, such an alternative does not rebut that it also would have been obvious to a POSA to retain Racz’s RF probe. We are persuaded that the proposed combination includes “an RF probe,” as recited in claim 1.

[1b] “a needle for insertion into a patient during an RF ablation procedure”

Petitioner argues that Racz’s modified device includes Racz’s electrode cannula (10/33), which “is an ‘electrical needle’ (or ‘spinal needle’) configured to deliver ‘electrical stimulation pulses or high-

frequency signals to the vicinity of a neural structure.” Pet. 28 (citing Ex. 1009, 1:4–10, 2:46–65, 3:24–26, 4:59–62, 5:35–45, 6:38–45, 6:59–7:10). Patent Owner does not dispute, and we are persuaded, that the proposed combination includes “a needle for insertion into a patient during an RF ablation procedure,” as recited in claim 1.

[1c] “a hub;” and [1d] “an elongate member fixed to the hub, the elongate member comprising a lumen at an interior thereof”

Petitioner argues that Racz includes these features as shown, for example, in Figure 2B, with the hub being structure 42 and the elongate member being structure 34. Pet. 29–30 (reproducing and annotating Ex. 1009, Fig. 2B); *see also id.* (reproducing and annotating Ex. 1009, Fig. 1, and showing the same features are present therein). Patent Owner does not dispute, and we are persuaded, that the proposed combination includes “a hub; and an elongate member fixed to the hub, the elongate member comprising a lumen at an interior thereof,” as recited in claim 1.

[1e] “a tip fixed to the elongate member at a distal end of the needle, wherein the tip is shaped to pierce tissue of the patient”

Petitioner argues that Racz includes this feature, directing us to its teaching of “self-penetrating point” 18/40. Pet. 30 (quoting Ex. 1009, 3:49–50); *see also* Ex. 1009, Fig. 1 (ref. 18), Fig. 2B (ref. 40). Patent Owner does not dispute, and we are persuaded, that the proposed combination includes “a tip fixed to the elongate member at a distal end of the needle, wherein the tip is shaped to pierce tissue of the patient,” as recited in claim 1.

[1f] “a plurality of filaments”

Petitioner argues that it would have been obvious to include, in Racz’s modified device, deployable filaments as taught by Fitz and Lee. Pet. 21–27, 35–44. This issue is discussed extensively above. Suffice it to say here, we are persuaded that the proposed combination includes “a plurality of filaments,” as recited in claim 1.

[1g] “an actuator interconnected to the plurality of filaments, wherein movement of the actuator in a first direction relative to the hub moves the plurality of filaments relative to the tip to a deployed position distally beyond the tip, and wherein movement of the actuator in a second direction relative to the hub retracts the plurality of filaments to a retracted position in which the plurality of filaments are disposed within at least a portion of the elongate member”

Petitioner argues that Lee teaches that its filaments are controlled in the same manner as recited in claim 1 and via an actuator interconnected thereto. Pet. 44–48. For example, Petitioner points out that “Lee’s perimeter filaments (22/1622) ‘maybe connected to suitable advancement and retraction mechanisms’ (i.e., an actuator).” *Id.* at 46 (quoting Ex. 1010 ¶106). Patent Owner does not dispute, and we are persuaded, that Lee teaches limitation [1g], and we are persuaded that it would have been obvious to include such a feature in the proposed combination.

[1h] “a fitting in fluid communication with the lumen, the fitting being configured to provide a connection for injection of fluid through the fitting and through the lumen, the fitting further being configured to allow for insertion of the RF probe into the lumen through the fitting”

Petitioner argues that the hub of Racz’s cannula “is a fitting, such as ‘a standard hypodermic needle or luer type hub, capable of connection to

stylets, electrical probes, syringes, or injection tubes.” Pet. 32 (quoting Ex. 1009, 5:66–6:2). Petitioner further argues that Racz’s hub “is also configured for receiving [the RF] probe (22/52) (for transmitting RF energy).” *Id.* at 33 (citing Ex. 1009, 3:59–65, 5:14–18, 6:9–12, 1:29–33, 5:66–6:7, 9:30–39, 10:8–10). Patent Owner does not dispute, and we are persuaded, that Racz includes limitation [1h].

Patent Owner does dispute that Racz’s modified device would retain the ability of the RF probe to be inserted into, and travel longitudinally within, the cannula/needle because, given purported size constraints for neurotomy applications, lumen space would need to be cannibalized for the addition of the deployable filaments as taught by Fitz and Lee. For example, at oral argument, counsel for Patent Owner explained as follows:

You cannot put the filaments within the lumen of Racz’s needle, as done in Lee’s figures one and 49. That wouldn’t work if you retain Racz’s probe, which fits snugly within the lumen. And in fact, they emphasize that there is physical contact at the end of the -- of the needle between the probe and the cannula. So the filaments have to go outside the lumen. Now they can’t go completely outside the needle. That means they have to be within the sidewall.

Tr. 39:3–9. As discussed above, however, the premise of these arguments—that the needle or cannula in Racz’s modified device could be no greater than 16 gauge—is not supported by the record. As further discussed above, we are persuaded that a POSA would have had a reasonable expectation of success in making Racz’s modified device, which would include preserving the removable RF probe function present in Racz’s native device. Accordingly, we are persuaded that Racz’s modified device satisfies limitation [1h].

[1i] “wherein the lumen at the interior of the elongate member is configured to accept the RF probe therein to physically contact a conductive portion of the needle”

Petitioner argues that, “[w]hen Racz’s probe (22/52) is ‘inserted into and received by the shaft 12 of the cannula 10,’ the ‘physical relationship between the probe 22 and the shaft 12 facilitates electrical contact between the two elements.’” Pet. 33 (quoting Ex. 1009, 3:60–65). Patent Owner does not dispute, and we are persuaded, that Racz includes limitation [1i].

[1j] “thereby electrically connect the RF probe to the tip and the plurality of filaments, such that energy emitted by the RF probe passes through the tip and the plurality of filaments, and such that the RF probe, the tip, and the plurality of filaments operate together as a single monopolar RF electrode”

Petitioner adequately explains how and why this feature would be present in Racz’s modified device. Pet. 39–44. For example, Petitioner includes an example illustration created by Dr. Tucker showing that, “when Racz’s exposed distal tip (14/38) is modified to include deflection surfaces (channels and ramps), the tip’s deflection surfaces will physically contact the filaments (22/1622) to guide them as they are deployed and retracted from Racz’s cannula,” and because Racz’s probe, Racz’s tip, and Lee’s filaments “are all constructed from conductive materials, the RF energy from Racz’s probe (52) would be transmitted to the modified device’s tip (14/38) and perimeter filaments (22/1622).” *Id.* at 41–42; Ex. 1032 ¶183.

Patent Owner argues: “None of Racz, Fitz, and Lee Teaches Using an Insertable RF Probe to Energize, at the Distal End, Deployable Filaments.” PO Resp. 35 (emphasis omitted). This, of course, is true as no single reference of record includes an RF probe *and* deployable filaments. Although true, Patent Owner’s argument is not persuasive. Rather, it is a

classic case of attacking references individually, which is inapposite when a prior art combination is asserted as obvious, as is the circumstance here. *Keller*, 642 F.2d at 426.

We are persuaded that Racz's modified device satisfies limitation [1j].

[1k] "wherein the conductive portion of the needle is at a distal end of the needle"

Petitioner argues that, in Racz, "[t]he tip (14/38) is made of a conductive material (e.g., where the cannula's 'shaft (34) comprises a hollow metal tube,' [and that] the exposed tip (14/38) may be 'an extension of the metal tube')." Pet. 31 (quoting Ex. 1009, 4:60–5:1 and citing *id.* at 5:45–48). Patent Owner does not dispute, and we are persuaded, that the proposed combination includes limitation [1k].

[1l] "wherein, when the RF probe is fully separated from the needle in a non-inserted state, such that none of the RF probe is within the needle, the plurality of filaments are movable via the actuator from the retracted position, in which the plurality of filaments are disposed within said at least a portion of the elongate member, to the deployed position."

For this limitation, Petitioner relies on some of the same analysis as for limitation [1g], adding that, "regardless of whether the probe (22/52) is in an inserted or non-inserted state, the filaments (22/1622) would be adjustable between their deployed position and retracted position." Pet. 47 (citing Ex. 1032 ¶195). Petitioner explains why this would be so, stating:

[A] POSA would have implemented Lee's filaments (22/1622) in Racz's device by arranging the perimeter filaments, channels, and ramps around the inner perimeter of Racz's cannula (10/33) for the purpose of not obstructing the interior lumen of Racz's shaft (12/34). *Supra* § VI.C.2.a. This would preserve the functionality of Racz's electrical probe (22/52),

which is needed to transmit RF energy to Racz's tip (14/38). *Id.* In this configuration, Racz's probe (22/52) would be insertable (and withdrawable) from the cannula (10/33) without interfering with filaments (22/1622) or their associated actuator.

Id.

We are persuaded that the proposed modification satisfies limitation [11].

Objective Indicia

Patent Owner argues that “the following objective indicia show nonobviousness: (1) long-felt-but unmet need; (2) copying by others; (3) industry praise; and (4) commercial success.” PO Resp. 60.

Objective indicia evidence “must always when present be considered when present en route to a determination of obviousness.” *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). However, “to be accorded substantial weight in the obviousness analysis, the evidence of secondary considerations must have a ‘nexus’ to the claims, i.e., there must be ‘a legally and factually sufficient connection’ between the evidence and the patented invention.” *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019). Patent Owner bears the burden of proving nexus. *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995) (“For objective evidence to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention.”); *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988) (“The burden of proof as to this connection or nexus resides with the patentee.”).

Nexus can be established in one of two ways. First, “a patentee is entitled to a rebuttable presumption of nexus between the asserted evidence

of secondary considerations and a patent claim if the patentee shows that the asserted evidence is tied to a specific product and that the product ‘is the invention disclosed and claimed.’” *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (quoting *Demaco*, 851 F.2d at 1392).

“That is, presuming nexus is appropriate ‘when the patentee shows that the asserted objective evidence is tied to a specific product and that product [1] ‘embodies the claimed features, and [2] is coextensive with them.’” *Id.* (quoting *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018)); *see also Fox Factory, Inc. v. SRAM, LLC*, 813 F. App’x 539, 542, 2020 WL 2517105 (Fed. Cir. 2020) (“[A] product is not coextensive with a claimed invention simply because it falls within the scope of the claim.”).

The second way to prove nexus is directly, by showing that the presented evidence of secondary considerations is “a direct result of the unique characteristics of the claimed invention.” *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996); *Fox Factory*, 944 F.3d at 1373–74 (In the absence of a presumption, nexus can be proved “by showing that the evidence of secondary considerations is the direct result of the unique characteristics of the claimed invention.”).

Patent Owner argues that “[t]his is a case in which a nexus should be presumed.” PO Resp. 73. This is so, according to Patent Owner because the “Nimbus devices embody at least challenged claim 1 and are coextensive with claim 1.” *Id.* at 72 (citing Ex. 2006 ¶21; Ex. 2008).

In the cited testimony, Mr. Crosby states:

I understand that Stratus makes and sells an RF neurotomy device called the “Nimbus® Multi-tined Expandable Electrode”

(Nimbus Device). I have personally inspected the Nimbus Device and compared it to the claims of the Stratus Patents. Details of that comparison are included in Exhibit 2008, which I incorporate into this declaration as part of my testimony. It is my opinion that the Nimbus Device is covered by at least some claims of each of the Stratus Patents.

Ex. 2006 ¶21.

The term “Stratus Patents” refers to the ’688 patent and the two related patents that are the subject of *inter partes* reviews No. IPR2024-01209 and No. IPR2024-01212. *Id.* ¶¶17–19. Exhibit 2008 is a claim chart purporting to map Patent Owner Stratus’s products to claim 1 of each of the three Stratus Patents. However, as pointed out by Petitioner (*see* Reply 25), what the claim chart compares to claim 1 of the ’688 patent (as well as claim 1 of the other Stratus Patents) is not the Nimbus Device but rather the Nimbus Device *in combination with a second product*, either a reusable or disposable RF Probe. Ex. 2008.

Both Mr. Crosby and Patent Owner expressly define the Nimbus Device to be the “Nimbus® Multitined Expandable Electrode” *without the RF probe*. *See* Ex. 2006 ¶21 (“I understand that Stratus makes and sells an RF neurotomy device called the ‘Nimbus® Multi-tined Expandable Electrode’ (Nimbus Device).”); PO Resp. 13 (“Stratus markets a device known as the Nimbus® Multitined Expandable Electrode (‘Nimbus device’) and RF probes usable therewith that are covered by the ’688 Patent.”). As Petitioner points out, “[i]t is undisputed that all claims require an RF probe.” Reply 25.

Patent Owner—perhaps anticipating this shortcoming—vacillates between referring to the singular “Nimbus device,” which Patent Owner defines as excluding an RF probe, and the plural “Nimbus devices,” which

Patent Owner does not define, but which it implies is a combination of the Nimbus device and one of Stratus's two RF probes. There is a clear disconnect between Patent Owner's position and its evidence. For example, Patent Owner argues that "the Nimbus *devices* embody at least challenged claim 1 and are coextensive with claim 1." PO Resp. 72 (emphasis added; citing Ex. 2006 ¶21; Ex. 2008). However, the cited testimony of Mr. Crosby refers only to the Nimbus *device* (without the RF probe).

21. I understand that Stratus makes and sells an RF neurotomy device called the "Nimbus® Multi-tined Expandable Electrode" (Nimbus Device). I have personally inspected the Nimbus Device and compared it to the claims of the Stratus Patents. Details of that comparison are included in Exhibit 2008, which I incorporate into this declaration as part of my testimony. It is my opinion that the Nimbus Device is covered by at least some claims of each of the Stratus Patents.

Ex. 2006 ¶21. Exhibit 2008 does not support Mr. Crosby's testimony. For limitation [1a] (i.e., "an RF probe"), the claim chart fails to map any portion of the Nimbus device. Instead, the claim chart maps limitation [1a] to one of two separate Nimbus products: "Stratus offers two types of RF probes, reusable and disposable, for use with its needle." Ex. 2008, 4.

In its Sur-Reply, Patent Owner argues that, for presumption of nexus purposes, "there is no legal or logical requirement that all components of the claimed invention be sold together in one transaction." Sur-Reply 25–26. Patent Owner does not cite any legal authority for this proposition. Under binding precedent, to be afforded a presumption of nexus, Patent Owner must show that its objective indicia evidence "is tied to a specific product and that the product 'is the invention disclosed and claimed.'" *Fox Factory*,

944 F.3d at 1373 (quoting *Demaco*, 851 F.2d at 1392). Patent Owner has failed to do this.

Accordingly, Patent Owner has failed to show that its objective indicia evidence bears a nexus to the claimed invention, and we give it no weight.

Conclusion as to Claim 1

Petitioner has shown by a preponderance of the evidence that claim 1 would have been obvious over Racz, Fitz, and Lee.

2. Claim 6

Claim 6 depends from claim 1 and adds “wherein the tip comprises a fluid port in fluid communication with the lumen such that an anesthetic and/or an image enhancing dye may be introduced into a region around the tip through the fluid port.” Ex. 1002, 32:14–17. For this additional feature, Petitioner directs us to Racz’s disclosure that its cannula tip includes “an opening⁴⁶ that is capable ... of dispensing diagnostic or therapeutic liquids” that are injected via the hub and through the lumen of the shaft. Pet. 48 (citing Ex. 1009, 5:15–18, 8:54–57, 5:66–6:8, 6:9–12, 1:29–33, code (57)). Patent Owner does not dispute the cited Racz disclosure. We are persuaded that claim 6 would have been obvious over Racz, Fitz, and Lee.

3. Claim 7

Claim 7 depends from claim 1 and adds “wherein each filament of the plurality of filaments has a pre-set bias such that the filament is curved when in the deployed state.” Ex. 1002, 32:18–20. For this additional feature, Petitioner directs us to Lee’s disclosure that, in some embodiments,

“deployable filaments were known to be ‘preformed with a curved configuration which they assume after exiting a sharp trocar-tipped catheter.’” Pet. 48–49 (quoting Ex. 1010 ¶7). Petitioner also directs us to Fitz’s similar disclosure of deployable filaments that “may be ‘constructed of a shape-memory material to control deployment’ and enhance directionality and navigation.” *Id.* at 49 (citing Ex. 1011 ¶¶10, 18–19). Patent Owner does not dispute these disclosures. We are persuaded that claim 7 would have been obvious over Racz, Fitz, and Lee.

4. *Claim 8*

Claim 8 depends from claim 1 and adds “wherein when each filament of the plurality of filaments is in the deployed position, the filaments extend outwardly from the tip.” Ex. 1002, 32:21–23. For this additional feature, Petitioner notes that such deployable filaments extend outwardly from the tip to expand the ablation volume. Pet. 50; *see also* Ex. 1010, Fig. 1 (Lee illustrating deployed filaments extending outward from the tip). Patent Owner does not dispute that the deployed filaments would extend outwardly from the tip. We are persuaded that claim 8 would have been obvious over Racz, Fitz, and Lee.

5. *Claim 9*

Claim 9 depends from claim 8 and adds “wherein each filament comprises a distal end, wherein the distal end of each filament defines a point when each filament is in the deployed position, and wherein an average of all the points is offset from a central longitudinal axis of the elongate member.” Ex. 1002, 32:24–28. For this additional feature, Petitioner notes that Lee teaches that “variations in ablation volume may be

achieved by varying the extent to which [filaments] are extended from the distal end of the trocar and the direction in which stylets extend.” Pet. 51 (quoting Ex. 1010 ¶129) (alteration in original). Thus, Petitioner argues, a POSA would understand that the filaments may be adjusted to define an ablation volume in any desired area relative to the tip of the needle from which they are deployed. *Id.* In addition, Petitioner notes that Racz teaches that its tip “may be configured to apply RF energy ‘only on one side of the cannula to facilitate directional stimulation or ablation’ (e.g., asymmetric relative to the cannula’s longitudinal axis).” *Id.* (quoting Ex. 1009, 8:16–22). Thus, as Patent Owner argues, a POSA would be motivated to do the same using the incorporated filaments such that “an average of all the points is offset from a central longitudinal axis of the elongate member,” as recited in claim 9. Patent Owner does not present any arguments addressing claim 9 specifically or the additional claim language it recites. We are persuaded that claim 9 would have been obvious over Racz, Fitz, and Lee.

6. *Claim 12*

Claim 12 depends from claim 1 and adds “wherein the tip tapers to a point, and wherein the elongate member and the tip comprise a single unitary structure.” Ex. 1002, 32:36–38. Petitioner shows that this feature is taught by Racz. Pet. 54 (citing Ex. 1009, 4:60–5:1, 5:3–5, 5:45–48). For example, Racz states: “The distal curved tip portion 38 is an extension of the metal tube.” Ex. 1009, 4:65–66. Patent Owner does not present any arguments addressing claim 12 specifically or the additional claim language it recites. We are persuaded that claim 12 would have been obvious over Racz, Fitz, and Lee.

7. *Claim 13*

Claim 13 depends from claim 1 and adds “wherein a proximal end of the elongate member is fixed to the hub.” Ex. 1002, 32:39–40. Petitioner shows that this feature is taught by Racz. Pet. 54 (referring back to Pet. 29–30). In that regard, Petitioner shows that Racz includes as shown, for example, in Figure 2B, a hub 42 fixed to proximal end of the elongate member 34. *Id.* at 29–30 (reproducing and annotating Ex. 1009, Fig. 2B); *see also id.* (reproducing and annotating Ex. 1009, Fig. 1, and showing the same features are present therein). Patent Owner does not present any arguments addressing claim 13 specifically or the additional claim language it recites. We are persuaded that claim 13 would have been obvious over Racz, Fitz, and Lee.

8. *Claim 14*

Claim 14 depends from claim 1 and adds “wherein the tip is asymmetrical, and wherein the hub comprises an indicator that is oriented to communicate an orientation of the asymmetrical tip.” Ex. 1002, 32:41–44. Racz clearly teaches an asymmetrical tip. *See* Ex. 1009, codes (54) (“Bent Tip Electrical Surgical Probe”), (57) (“A medical needle or cannula for stimulation or ablation includes a rigid bent tip for simplified placement at target sites within a patient's anatomy. The curved tip or shaft is used to steer the device within the patient's body and to avoid critical anatomical structures.”). As for the recited “indicator,” Petitioner shows that “Racz's hub (20/42/70) also includes a marker (48/74) to ‘indicate the orientation of the curved tip [14/38] for convenient steering or navigating of the cannula 33.’” Pet. 55 (quoting Ex. 1009, 5:18–22, 6:13–20, 7:66–8:9, 9:44–48). For

example, Racz states: “shown [in Figure 2B] is an index dot 48 on the hub which indicates the orientation of the bent tip 38.” Ex. 1009, 5:18–22. Patent Owner does not present any arguments addressing claim 14 specifically or the additional claim language it recites. We are persuaded that claim 14 would have been obvious over Racz, Fitz, and Lee.

9. *Claim 17*

Claim 17 depends from claim 1 and adds “wherein the RF probe comprises a cable for use in connecting the RF probe to a radiofrequency generator.” Ex. 1002, 32:51–53. As for this feature, Petitioner first notes that Racz discloses that the “output of the signal generator 28 is conveyed via [a] first electrical connection 24 to the probe 22.” Ex. 1009, 4:18–23 (quoted at Pet. 55). Second, Petitioner cites the testimony of Dr. Tucker that a POSA would “know that a cable is a common electrical connector between RF signal generators and RF probes” and thus it would have been obvious to use a cable in Racz as well as in Racz’s modified device. Ex. 1032 ¶214 (cited at Pet. 55). Patent Owner does not present any arguments addressing claim 17 specifically or the additional claim language it recites. We are persuaded that claim 17 would have been obvious over Racz, Fitz, and Lee.

10. *Claim 48*

Claim 48 depends from claim 1 and adds “wherein the tip comprises a conductive material and defines a channel, and wherein a distal end of the RF probe is received within the channel of the tip of the needle when the RF probe is fully inserted into the needle.” Ex. 1002, 34:50–55. Petitioner argues that this feature is taught by Racz, as already discussed above in connection with claim 1. Pet. 56 (referring back to Pet. 30–44); Ex. 1009,

4:65–5:1, 5:41–48. Patent Owner does not present any arguments addressing claim 48 specifically or the additional claim language it recites. We are persuaded that claim 48 would have been obvious over Racz, Fitz, and Lee.

11. Claim 49

Claim 49 depends from claim 48 and adds “wherein the conductive portion of the needle comprises the conductive material of the tip.” Ex. 1002, 34:56–58. Petitioner argues that this feature is taught by Racz, as already discussed above in connection with claim 1. Pet. 56 (referring back to Pet. 30–32). Patent Owner does not present any arguments addressing claim 49 specifically or the additional claim language it recites. We are persuaded that claim 49 would have been obvious over Racz, Fitz, and Lee.

12. Claim 50

Claims 50 depends from claim 1 and adds the following:

wherein the plurality of filaments extend distally beyond a distal end of the RF probe when the RF probe is fully inserted into needle and when the plurality of filaments are in the deployed position, such that when RF energy is delivered to the RF probe, the plurality of filaments conduct RF energy that emanates from the RF probe beyond the distal end of the RF probe to produce within the patient, during the RF ablation procedure, a lesion that is distally offset from the distal end of the RF probe.

Ex. 1002, 34:59–67. Petitioner argues that this feature is present in Racz’s modified device as already discussed above in connection with claims 1, 7, and 8. Pet. 56 (referring back to Pet. 44–50). Petitioner explains that, with the deployable filaments “implemented such that their tips extend beyond Racz’s tip (14/38), the lesion produced will be distally offset from Racz’s tip

(14/38)” at the distal end of the probe. *Id.* at 59 (citing Ex. 1032 ¶219). Patent Owner does not present any arguments addressing claim 50 specifically or the additional claim language it recites. We are persuaded that claim 50 would have been obvious over Racz, Fitz, and Lee.

13. Claims 51 and 52

Claim 51 recites:

A method comprising:

using the system of claim 1, wherein said using comprises:

inserting the needle into a patient;

rotating the actuator to transition the plurality of filaments from the retracted position to the deployed position; and

operating the RF probe, the tip, and the plurality of filaments as a monopolar electrode.

Ex. 1002, 35:1–9. Claim 52 depends from claim 51 and adds “wherein said using further comprises inserting the RF probe into the lumen of the needle.” *Id.* at 35:10–12.

With reference to prior art disclosures already discussed above, Petitioner shows that the prior art renders obvious the recited “using the system of claim 1,” including all of the steps recited in claims 51 and 52. Pet. 60–61. Patent Owner does not present any arguments specifically addressing either claim 51, claim 52, or the claim language either recites. We are persuaded that claims 51 and 52 would have been obvious over Racz, Fitz, and Lee.

F. Ground 2

In Ground 2, Petitioner challenges the same claims that its successfully challenges in Ground 1, namely claims 1, 6–9, 12–14, 17, and 48–52, but adds an additional reference: Young '965. Pet. 11.

Young '965 discloses “a tissue ablation system [having] a probe assembly 4 configured for introduction into the body of a patient for ablative treatment of target tissue, and a radio frequency (RF) generator 6 configured for supplying RF energy to the probe assembly 4 in a controlled manner.” Ex. 1012 ¶22.

In Ground 2, Petitioner continues to relies on Racz, Fitz, and Lee, as set forth in Ground 1, and cites Young '965 merely as “confirm[ation]” and “further motivat[ion]” with respect to certain limitations of claims 1, 7, 10, and 51. Pet. 63–67. Thus, for reasons explained above in connection with Ground 1, we are persuaded that claims 1, 6–9, 12–14, 17, and 48–52 also would have been obvious over Racz, Fitz, Lee, and Young '965.

Although Young '965 is not critical in view of Petitioner's Ground 1 challenge, we address Patent Owner's specific arguments concerning Young '965.

Patent Owner argues that, “[a]s Young '965 is generally directed to tumor ablation and not neurotomy, it lacks relevance to Racz and Fitz in many of the same ways as Lee.” PO Resp. 58. Patent Owner, however, does not identify, nor can we discern, any germane legal concept implicated by its argument. To the extent Patent Owner is challenging whether Young '965 is analogous art, it is not persuasive. *See* Reply 10 (“Stratus vaguely suggests that Young '965 ‘lacks relevance’ but does not assert that it is non-analogous art.”).

First, as discussed above, the field of the invention is not limited to RF neurotomy, but rather thermal ablation generally. Using the correct field, it is clear that Young '965 is analogous, as argued by Petitioner. *See* Reply 10 (“Young '965 is directed to an RF ablation needle with deployable filaments (Pet., 62–67) and is analogous for the same reasons discussed above for Lee.”).

Second, “[i]n evaluating whether a reference is analogous, [the Federal Circuit has] consistently held that a patent challenger must compare the reference to the challenged patent.” *Sanofi-Aventis Deutschland GmbH v. Mylan Pharms. Inc.*, 66 F.4th 1373, 1377, 1378 (Fed. Cir. 2023) (rejecting as legally erroneous a party’s argument that “it is proper to compare a reference to other references for analogous art purposes”). Thus, whether Young '965 “lacks relevance” to Racz, Fitz, and/or Lee is inapposite.

Patent Owner also argues that “Young '965’s shaft 20 [(an actuator)] could not possibly function in its original form within Racz’s modified device because there is no clear way to attach the proximal ends of Lee’s filaments to the distal end of the shaft (20).” PO Resp. 59. This bodily incorporation argument is not persuasive under case law already discussed above. *See supra* (citing *Keller*, 642 F.2d at 425).

We are persuaded that claims 1, 6–9, 12–14, 17, and 48–52 also would have been obvious over Racz, Fitz, Lee, and Young '965.

G. Ground 3

In Ground 3, Petitioner challenges the same claims that it successfully challenges in Ground 1, namely claims 1, 6–9, 12–14, 17, and 48–52, as well as claims 2–5, which we have not previously discussed. In Ground 3,

Petitioner cites the same references as in Ground 1 plus one additional reference: Scheibe. Pet. 11.

Scheibe discloses “[a] deflectable catheter assembly [that] includes a deflectable body manipulatable by a rotating actuator of a housing assembly.” Ex. 1013, code (57). Petitioner cites Scheibe for its teaching of “a rotational actuator (142) for linearly translating a ‘sliding member’ (146) within a medical device.” Pet. 67 (quoting Ex. 1013 ¶21). Petitioner argues that a POSA would have recognized that Scheibe’s teaching of a rotating actuator (142) for a longitudinally sliding member (146) could be implemented as an actuator for the deployable filaments in Racz’s modified device. *Id.* at 71–72 (citing Ex. 1010 ¶106; Ex. 1032 ¶246).

1. Claims 1, 6–9, 12–14, 17, and 48–52

For reasons explained above in connection with Ground 1, we are persuaded that claims 1, 6–9, 12–14, 17, and 48–52 would have been obvious over Racz, Fitz, Lee, and Scheibe.

2. Claims 2–5

Claim 2 depends from claim 1 and adds “wherein the actuator fits around at least a portion of the hub, and wherein the actuator is configured to rotate relative to the hub about a central longitudinal axis of the needle.” Ex. 1002, 31:66–32:2.

Claim 3 depends from claim 2 and adds “wherein the actuator is generally tubular.” *Id.* at 32:3–4.

Claim 4 depends from claim 1 and adds “wherein the needle further comprises a slide member coupled to the actuator and fixedly connected to the plurality of filaments, wherein the hub includes a cavity sized to house a

protrusion of the slide member, and wherein the slide member is limited to a linear motion relative to the hub as the actuator is rotated.” *Id.* at 32:5–10.

Claim 5 depends from claim 4 and adds “wherein the slide member is configured to axially advance and retract without rotating relative to the hub.” *Id.* at 32:11–13.

Petitioner argues that these features would have been obvious over Racz, Fitz, and Lee in view of Scheibe’s teachings regarding a rotating actuator for a longitudinally sliding member. Pet. 72–75 (citing Ex. 1013 ¶¶13, 19, 21, 24, 25, 28–30, Figs. 1–2; Ex. 1032 ¶¶149–151).

Patent Owner’s sole argument against Petitioner’s Ground 3 challenge to claims 2–5 is that Scheibe is not analogous art, but it does so under an erroneous legal standard. PO Resp. 59–60. Specifically, Patent Owner argues that “Scheibe is *even less relevant to Racz and Fitz* than are Lee and Young ’965” and “Scheibe is indeed non-analogous because it additionally *lacks reasonable pertinence to the petition’s stated objectives.*” *Id.* at 59–60 (emphasis added); *see Clay*, 966 F.2d at 658–59 (explaining that a reference is analogous if (1) it is “from the same field of endeavor” as the inventor or (2) “if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved”); *Sanofi-Aventis Deutschland*, 66 F.4th at 1377.

We are persuaded that claims 2–5 would have been obvious over Racz, Fitz, Lee, and Scheibe.

H. Ground 4

In Ground 4, Petitioner challenges the same claims that it successfully challenges in Ground 3, namely claims 1–9, 12–14, 17, and 48–52. In Ground 4, Petitioner cites one additional reference beyond those asserted in Ground 3: Young ’965. Pet. 11; *see also id.* at 75 (“Scheibe may also be considered (optionally) in combination with Young ’965, which discloses that rotational actuators can be used to retract and deploy filaments.”).

For reasons explained above in connection with Ground 3, we are persuaded that claims 1–9, 12–14, 17, and 48–52 would have been obvious over Racz, Fitz, Lee, Scheibe, and Young ’965.

I. Grounds 5–8

Each of Grounds 5 through 8 challenges a single claim—claim 9—as obvious over Racz, Fitz, Lee, and one or more of the following additional references: Young ’201, Young ’965, and Scheibe. Pet. 11. We have already determined, in connection with Ground 1, that Petitioner has shown by a preponderance of the evidence that claim 9 would have been obvious over Racz, Fitz, and Lee. Patent Owner does not present any arguments addressing claim 9 specifically or the additional claim language it recites. For reasons explained above in connection with Ground 1, we are persuaded that claim 9 would have been obvious over Racz, Fitz, Lee, and the additional reference(s) asserted in Grounds 5 through 8.

J. Ground 9

Ground 9 challenges three dependent claims—claims 10, 11, and 15—as obvious over Racz, Fitz, Lee, and Gough ’516. Pet. 12. Gough ’516

discloses a “cell necrosis apparatus [having] a flexible introducer including a lumen and a distal end sufficiently sharp to penetrate tissue,” and an “energy delivery device [that] is positionable in the introducer as the introducer is advanced through tissue.” Ex. 1017, code (57).

1. Claims 10 and 11

Claim 10 depends from claim 1 and adds “wherein the plurality of filaments comprises three filaments, and wherein an angle between each pair of adjacent filaments is 120 degrees when each filament is in the deployed position.” Ex. 1002, 32:29–32. Claim 11 depends from claim 1 and adds “wherein the plurality of filaments are configured to form a lesion having a pyramidal shape.” *Id.* at 32:33–35.

For these features, Petitioner notes that Gough ’516 discloses “deployable ‘energy delivery devices 16’ (i.e., filaments) made from shape memory alloy,” which “deliver RF energy to targeted tissue and may be provided in ‘any number of geometric configurations,’ which allows the apparatus (12) to generate lesions in which the ‘the geometry of the ablated mass is selectable and controllable.’” Pet. 77 (quoting Ex. 1017, 4:13–67, 6:19–28, 6:53–63). And, in connection with claim 11 in particular, Petitioner notes that Gough ’516 discloses an embodiment in which “three energy delivery devices are deployed” and shown as “symmetrically spaced (i.e., 120 degrees apart).” *Id.* (citing Ex. 1017, 7:66–8:11, Figs. 6B–6C, Ex. 1032 ¶258). In view of these disclosures, Petitioner argues the following:

Thus, in combination with Lee’s teachings regarding the arrangement of its filaments (22/1622) (which would extend beyond Racz’s tip (14/38)), Gough ’516’s teaching that a symmetrical three-filament configuration is effective for tissue

ablation would have further confirmed to a POSA that Racz's modified device would be effectively configured with "three filaments ... [where] an angle between each pair of adjacent filaments is 120 degrees when each filament is in the deployed position" [10]. Ex-1032, ¶259. As explained above, a POSA would have appreciated that this evenly spaced three-filament configuration would result in the filaments being "configured to form a lesion having a pyramidal shape" [11]. Ex-1032, ¶259.

Id. at 78. Patent Owner does not present any arguments specifically addressing claim 10, claim 11, or the additional claim language either recites. We are persuaded that claims 10 and 11 would have been obvious over Racz, Fitz, Lee, and Gough '516 for the reasons set forth by Petitioner as discussed above.

2. Claim 15

Claim 15 depends from claim 1 and adds "wherein the hub and/or the actuator includes markings to indicate a depth of deployment of the plurality of filaments." *Id.* at 32:45–47. For this feature, Petitioner notes that "Gough '516 also discloses that the handle of its apparatus includes 'markings to show the length of lateral deployment of energy delivery devices 16 from introducer 14.'" Pet. 78 (quoting Ex. 1017, 5:29–31). Petitioner argues that it would have been obvious to incorporate this feature into Racz's modified device so that it would include markings to indicate a depth of the deployable filaments. *Id.* (citing Ex. 1032 ¶¶260–261). Patent Owner does not present any arguments addressing claim 15 or the additional claim language it recites. We are persuaded that claim 15 would have been obvious over Racz, Fitz, Lee, and Gough '516.

K. Grounds 10–12

In each of Grounds 10 through 12, Petitioner challenges the same three claims it successfully challenges in Ground 9, namely claims 10, 11, and 15, but adds one or two additional references (i.e., Scheibe and/or Young '965). Pet. 12.

We have already determined, in connection with Ground 9, that Petitioner has shown by a preponderance of the evidence that claims 10, 11, and 15 would have been obvious over Racz, Fitz, Lee, and Gough '516. Thus, for reasons explained above in connection with Ground 9, we are persuaded that claims 10, 11, and 15 also would have been obvious over Racz, Fitz, Lee, Gough '516, and Scheibe and/or Young '965.

L. Ground 13

Ground 13 challenges claim 16 as obvious over Racz, Fitz, Lee, and Rosinko. Pet. 12. Rosinko discloses “a steerable catheter” having a rotational actuator that translates linearly. Ex. 1020, 9:57–59.

Claim 16 depends from claim 1 and adds “wherein the hub and/or the actuator includes detents to provide a tactile feedback of a position of the plurality of filaments.” For this additional feature, Petitioner directs us to Rosinko’s disclosure of “a steerable catheter having a rotational actuator (156) for linearly translating an inner deflection knob (154) secured to a pull cable,” in which the “actuator (156) engages ‘detents’ (185) as the actuator is rotated” thereby “provid[ing] an indexed mechanism, which allows a tactile response by the physician so as to control or at least be aware of the degree of deflection caused by said rotation of the actuator 156.” Pet. 79 (citing Ex. 1020, 11:1–5, 11:62–12:15, 19:26–46, Fig. 4). Petitioner argues,

with supporting testimony from Dr. Tucker, that “a POSA would have found it obvious to position detents for engagement with Scheibe’s rotating actuator(142) in order to ‘to provide a tactile feedback of a position of the plurality of filaments’ [16] in Racz’s modified device.” *Id.* (citing Ex. 1032 ¶¶263–264) (emphasis omitted). Patent Owner does not present any arguments addressing claim 16 specifically or the additional claim language it recites.

We are persuaded that claim 16 would have been obvious over Racz, Fitz, Lee, and Rosinko.

M. Grounds 14–16

In each of Grounds 14 through 16, Petitioner challenges the same claim it successfully challenges in Ground 13, namely claim 16, but adds one or two additional references (i.e., Scheibe and/or Young ’965). Pet. 12.

We have already determined, in connection with Ground 13, that Petitioner has shown by a preponderance of the evidence that claim 16 would have been obvious over Racz, Fitz, Lee, and Rosinko. Thus, for reasons explained above in connection with Ground 13, we are persuaded that claim 16 also would have been obvious over Racz, Fitz, Lee, Rosinko, and Scheibe and/or Young ’965.

III. MOTIONS TO EXCLUDE

Each of the parties filed a motion to exclude. Paper 51 (“Pet. Mot. To Exclude”); Paper 49 (“PO Mot. To Exclude”).

Petitioner's Motion seeks to exclude (1) paragraphs 16–27, 47, 54, and 55 from a declaration of Cody Jorgensen (Exhibits 2015, 2016, and 2039²⁴) and (2) Exhibits 2021–2026 in their entirety.

Patent Owner's Motion seeks to exclude Petitioner's Exhibit 1063 if Patent Owner's Exhibits 2044 and 2045 are excluded or otherwise not considered.²⁵ *See* PO Mot. To Exclude 1 (“Stratus conditionally requests that, if its Exhibits 2044 and 2045 are struck from the record or otherwise not considered by the Board, then Exhibit 1063 must be excluded under Federal Rule of Evidence (‘FRE’) 106 for violating the doctrine of completeness.”).

The instant Decision not rely on any of the evidence either party seeks to exclude. Accordingly, both Motions are dismissed as moot.

IV. CONCLUSION

We conclude, based on a preponderance of the evidence, that claims 1–17 and 48–52 are unpatentable. In summary:

²⁴ The record contains three copies of Mr. Jorgensen's declaration. Exhibit 2015 is an unredacted copy that is under seal. Exhibit 2016 is publicly filed copy with redactions of confidential information. Exhibit 2039 is a third copy of Mr. Jorgensen's declaration that Patent Owner Stratus filed, which copy “identifies the redactions that Stratus propose[d] to remove in gold highlighting and those it propose[d] to maintain in violet highlighting.” Paper 29, 5.

²⁵ Exhibits 2044 and 2045 were filed by Patent Owner with its Sur-Reply contrary to 37 C.F.R. § 42.23(b). We do not rely on either of these exhibits.

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1, 6–9, 12–14, 17, 48– 52	103(a)	Racz, Fitz, Lee	1, 6–9, 12–14, 17, 48–52	
1, 6–9, 12–14, 17, 48– 52	103(a)	Racz, Fitz, Lee, Young '965	1, 6–9, 12–14, 17, 48–52	
1–9, 12– 14, 17, 48–52	103(a)	Racz, Fitz, Lee, Scheibe	1–9, 12–14, 17, 48–52	
1–9, 12– 14, 17, 48–52	103(a)	Racz, Fitz, Lee, Young '965, Scheibe	1–9, 12–14, 17, 48–52	
9	103(a)	Racz, Fitz, Lee, Young '201	9	
9	103(a)	Racz, Fitz, Lee, Young '201, Young '965	9	
9	103(a)	Racz, Fitz, Lee, Young '201, Scheibe	9	
9	103(a)	Racz, Fitz, Lee, Young '201, Young '965, Scheibe	9	
10, 11, 15	103(a)	Racz, Fitz, Lee, Gough '516	10, 11, 15	
10, 11, 15	103(a)	Racz, Fitz, Lee, Gough '516, Young '965	10, 11, 15	
10, 11, 15	103(a)	Racz, Fitz, Lee, Gough '516, Scheibe	10, 11, 15	

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
10, 11, 15	103(a)	Racz, Fitz, Lee, Gough '516, Young '965, Scheibe	10, 11, 15	
16	103(a)	Racz, Fitz, Lee, Rosinko	16	
16	103(a)	Racz, Fitz, Lee, Rosinko, Young '965	16	
16	103(a)	Racz, Fitz, Lee, Rosinko, Scheibe	16	
16	103(a)	Racz, Fitz, Lee, Rosinko, Young '965, Scheibe	16	
Overall Outcome			1–17, 48–52	

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–17 and 48–52 of U.S. Patent No.
10,736,688 B2 are proven unpatentable;

FURTHER ORDERED that both Motions to Exclude are dismissed
as moot; and

FURTHER ORDERED that, because this Decision is final, a party to
the proceeding seeking judicial review of the Decision must comply with the
notice and service requirements of 37 C.F.R. § 90.2.

IPR2024-01210
Patent 10,736,688 B2

PETITIONER:

Christopher Kelly
Gregory Carlin
Warren Thomas
Lee Hamilton
MEUNIER CARLIN & CURFMAN LLC
ckelly@mcciplaw.com
gcarlin@mcciplaw.com
wthomas@mcciplaw.com
lhamilton@mcciplaw.com

PATENT OWNER:

Daniel Higgs
Kevin Laurence
Matthew Phillips
Derek Meeker
Joseph Hawkins
LAURENCE & PHILLIPS IP LAW
dhiggs@lpiplaw.com
klaurence@lpiplaw.com
mphillips@lpiplaw.com
dmeeker@lpiplaw.com
joe@lpiplaw.com