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Paper 68
Date: March 5, 2026

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AVANOS MEDICAL, INC.,
Petitioner,

v.

STRATUS MEDICAL, LLC,
Patent Owner.

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IPR2024-01212
Patent 10,925,664 B2

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

PESLAK, *Administrative Patent Judge*.

# JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Dismissing the Parties' Motions to Exclude (Papers 47, 49)
*35 U.S.C. § 318(a)*

# I. INTRODUCTION

Avanos Medical, Inc. ("Petitioner") filed a Petition for an *inter partes* review of claims 1–29 ("the Challenged Claims") of U.S. Patent No. 10,925,664 B2 ("the '664 patent," Ex. 1003). Paper 1 ("Pet."). Petitioner filed a Declaration of Dr. Robert Tucker in support of the Petition. Ex. 1034. Stratus Medical, LLC ("Patent Owner") did not file a Preliminary Response. On February 6, 2025, we instituted this *inter partes* review as to all Challenged Claims and all grounds presented in the Petition. Paper 8 ("Dec.").

After institution, Patent Owner filed a Response to the Petition ("PO Resp."). Paper 65.[1] In support of the Patent Owner Response, Patent Owner filed a Declaration of Professor Marc Andrew Russo (Ex. 2001), a Declaration of Peter Crosby (Ex. 2006), and a Declaration of Cody Jorgenson (Ex. 2015). Petitioner filed a Reply ("Pet. Reply"). Paper 30. In support of the Reply, Petitioner filed a Reply Declaration of Dr. Robert Tucker (Ex. 1042), a Declaration of Mark A. Konno (Ex. 1043), and a Declaration of Dennis Johnson (Ex. 1044). Patent Owner filed a Sur-reply ("Sur-reply"). Paper 40. An oral hearing was held on November 6, 2025, and the transcript is entered into the record. Paper 60 ("Tr.").

[1] The Patent Owner Response was originally filed under seal as Paper 13 and publicly with redactions as Paper 14. 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 59; Ex. 3[add Trials email of Jan. 15, 2026, 1:12PM]. Patent Owner has represented that Paper 65 is identical to the now expunged Paper 13. Ex. [same exhibit, probably numbered 3004].

Patent Owner filed a Motion to Exclude Evidence. Paper 47 ("PO MTE"). Petitioner filed an Opposition. Paper 51 ("Pet. MTE Opp."). Patent Owner filed a Reply. Paper 53 ("PO MTE Reply").

Petitioner filed a Motion to Exclude Evidence. Paper 49 ("Pet. MTE"). Patent Owner filed an Opposition. Paper 50 ("PO MTE Opp."). Petitioner filed a Reply. Paper 53 ("Pet. MTE Reply").

We have jurisdiction under 35 U.S.C. § 6. This is a Final Written Decision under 35 U.S.C. § 318(a) as to the patentability of the Challenged Claims. For the reasons discussed below, we determine Petitioner establishes by a preponderance of the evidence that all Challenged Claims are unpatentable.

A. Real Parties-in-Interest

Petitioner identifies itself, Avanos Medical, Inc., as the real party-in-interest. Pet. 79. Petitioner explains that "Diros Technology, Inc. of Markham, Ontario, Canada is a wholly owned subsidiary of Avanos Medical, Inc." *Id.*

Patent Owner identifies itself, Stratus Medical, LLC, as the real party-in-interest. Paper 4, 2.

B. Related Matters

Patent Owner identifies *Stratus Med., LLC v. Avanos Med., Inc.*, No. 1:25-cv-00546 (D. Del.) as a related matter. Paper 44, 2.

Petitioner filed four Petitions challenging claims of Stratus Medical's Patents. IPR2024-01212 involving the '664 patent at issue here; IPR2024-01210 and IPR2024-01211, both involving U.S. Patent No. 10,736,688 B2 ("the '688 patent," Ex. 1002); and IPR2024-01209, involving U.S. Patent No. 10,966,782 B2 ("the '782 patent," Ex. 1001). Paper 44, 2.

C. The '664 Specification

The '664 patent for "Methods for Radio Frequency Neurotomy," is assigned on its face to Stratus Medical, LLC, and issued to Robert E. Wright and Scott A. Brandt on February 23, 2021. Ex. 1003, codes (54), (72), (73). The '644 patent claims the benefit of Provisional Application Nos. 61/280,557 and 61/347,351, both filed on May 21, 2010. *Id.* at codes (10), (12), (60), (73).

The '664 patent discloses systems and methods for performing thermal tissue ablation using radiofrequency [RF] energy. *See generally*, Ex. 1003, 1:24–28, 8:26–41. "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" which "causes the temperature in the area surrounding the electrode tip to rise," thereby ablating the target tissue. *Id.* at 1:31–49. The term "RF neurotomy" applies when the target tissue is a nerve, such as a spinal nerve. *See, e.g.*, *id.* at 1:50–52, 2:54–64, 4:26–41. *See also id.* at 31:6–24. (describing further applications in ablating blood vessels, cardiac tissue, and vertebral discs). Ablation (cauterization) of the target nerve disrupts the ability of the nerve to transmit pain signals to the central nervous system. *Id.* at 1:50–52, 4:36–40.

The Specification discloses an embodiment directed to a neurotomy system 100 for use in performing RF neurotomy on a patient. *See* Ex. 1003, 3:44–45, 4:42–5:6, 5:16–32, Fig. 1. "[S]ystem 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 4:48–57; 5:16–21.

> 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 4:57–61.

As illustrated in Figure 2A, reproduced below, RF neurotomy 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." Ex. 1003, 5:42–45, Fig. 2A.

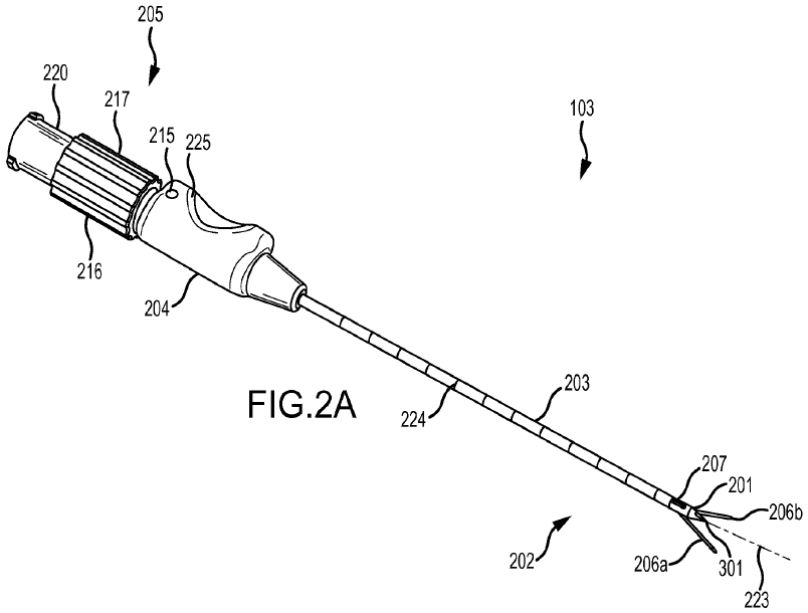



FIG.2A

Figure 2A shows a perspective view of an RF neurotomy needle 103 comprising elongate member 203 having a tip 201 and deployable filaments 206a-b. *Id.* at 3:33–55. Filaments 206a-b are deployed/retracted by a rotating actuator 216. *Id.* at 5:53–55, 17:17–18:40. 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 206a-b. *See id.* at 11:19–31, 11:65–12:42, 13:44–14:12.

With reference to Figure 2B (not shown), actuator 216 may be fitted with a Luer fitting 220 at the proximal end of the needle 103, and configured for inserting (i) a removable RF probe 401 through the lumen 222 of elongate member 203, and (ii) fluid delivered through the lumen (when the probe 401 is removed). *See* Ex. 1003, 2:15–20, 5:7–15, 5:56–67, 17:56–63; *see also id.* at 2:20–23 ("In another implementation, an RF probe may be integrated into the needle structure for communication of an RF signal to the tip and plurality of filaments.").

Figures 3A and 3B are reproduced below:

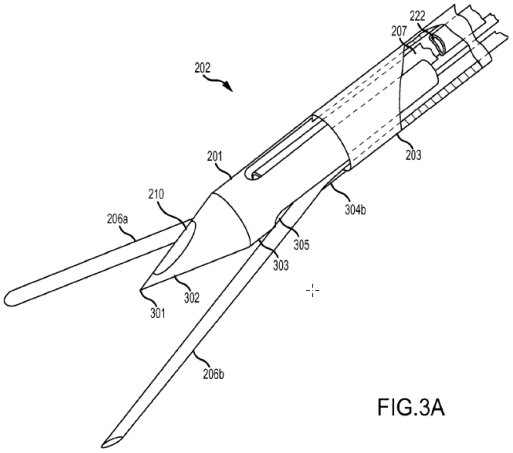



FIG.3A

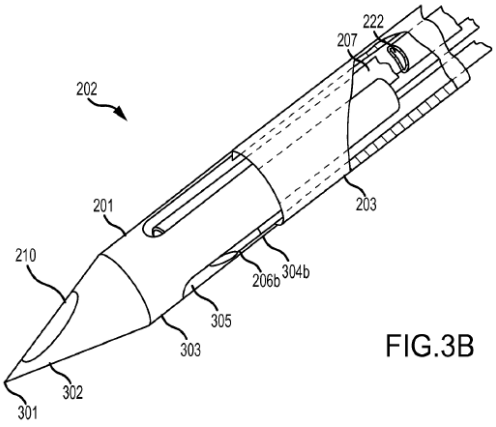



FIG.3B

Figures 3A and 3B are cut-away views of the distal end 202 of needle 103 with filaments 206a-b in fully deployed and retracted configurations, respectively. Ex. 1003, 3:53–56, 6:33–34. Figures 3A and 3B also show tip (201) including a fluid port 210 (e.g., for delivering anesthetic and/or image enhancing dye during an RF neurotomy procedure) via Luer fitting 220

when probe 401 is removed, and a sharpened point 301 "for piercing the skin of a patient and facilitating advancement through tissue." *Id.* at 5:33–36, 6:33–36, 7:40–57, 17:55–62.

According to the Specification, 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 within the 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. Ex. 1003, 6:45–47, 9:61–64, 10:57–63, 14:65–15:1. The "RF energy emanating from the tip and filaments may generate heat that ablates the target nerve." *Id.* at 24:35–36.

D. Challenged Claims

Petitioner challenges claims 1–29, of which claims 1 and 21 are independent. *See* Pet. 12–13, 80–84 (claims listing). Claim 1 is reproduced below with Petitioner's formatting and element annotations:

[1pre] A method comprising:

[1a] inserting a needle into a patient, the needle comprising:

[1b] an elongate member;

[1c] a piercing tip at a distal end of the elongate member;

[1d] a lumen within the elongate member; and

[1e] a filament in a retracted position in which the filament is at least partially disposed within the elongate member;

[1f] moving the filament to a deployed position within the patient in which at least a distal end of the filament is out of the elongate member and disposed away from the tip;

[1g] inserting a radiofrequency probe into the lumen of the needle such that the radiofrequency probe

contacts a conductive portion of the needle at a distal end of the needle to thereby establish an electrically conductive path from the radiofrequency probe to the filament; and

[1h] operating the radiofrequency probe, the tip, and the filament as a monopolar electrode, with radiofrequency energy from the radiofrequency probe being conducted to the filament through the electrically conductive path and transmitted by the filament.

Ex. 1003, 31:32–53.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following twelve grounds of unpatentability (Pet. 12):

| Ground | Claims | 35 U.S.C. § | References |
|---|---|---|---|
| A | 1–10, 18–26, 28, 29 | 103(a)[2] | Racz,[3] Fitz,[4] Lee[5] |
| B | 1–10, 18–26, 28, 29 | 103(a) | Racz, Fitz, Lee, Young '965[6] |
| C | 1–10, 18–26, 28, 29 | 103(a) | Racz, Fitz, Lee, Scheibe[7] |
| D | 1–10, 18–26, 28, 29 | 103(a) | Racz, Fitz, Lee, Young '965, Scheibe |
| E | 11–17, 19, 27, 29 | 103(a) | Racz, Fitz, Lee, Godara[8] |
| F | 11–17, 19, 27, 29 | 103(a) | Racz, Fitz, Lee, Godara, Young '965 |
| G | 11–17, 19, 27, 29 | 103(a) | Racz, Fitz, Lee, Godara, Scheibe |
| H | 11–17, 19, 27, 29 | 103(a) | Racz, Fitz, Lee Godara, Young '965, Scheibe |

[2] We apply the pre-AIA version of 35 U.S.C. § 102 and 35 U.S.C. § 103 because the claims at issue have an effective filing date prior to March 16, 2013, the effective date of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"). *See* Ex. 1001, code (22).

[3] Ex. 1009, Racz et al., US 6,146,380, issued Nov. 14, 2000.
[4] Ex. 1011, Fitz, US 2005/0059964 A1, pub. March 17, 2005.
[5] Ex. 1010, Lee et al., US 2007/0016183 A1, pub. Jan. 18, 2007.
[6] Ex. 1012, Young, US 2006/0084965 A1, pub. April 20, 2006.
[7] Ex. 1013, Scheibe et al., US 2007/0260223 A1, pub. Nov. 8, 2007.
[8] Ex. 1015, Godara et al., US 2007/0027449 A1, pub. Feb. 1, 2007.

| Ground | Claims | 35 U.S.C. § | References |
|---|---|---|---|
| I | 18, 28 | 103(a) | Racz, Fitz, Lee, Cohen[9] |
| J | 18, 28 | 103(a) | Racz, Fitz, Lee, Cohen, Young '965 |
| K | 18, 28 | 103(a) | Racz, Fitz, Lee, Cohen, Scheibe |
| L | 18, 28 | 103(a) | Racz, Fitz, Lee, Cohen, Young '965, Scheibe |

## II. ANALYSIS

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

A claim is unpatentable under § 103(a) if the differences between the claimed subject matter 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. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of

[9] Ex. 1019, Cohen et al., *Randomized Placebo-controlled Study Evaluating Lateral Branch Radiofrequency Denervation for Sacroiliac Joint Pain*, 109(2) Anesthesiology, 279–288 (2008).

obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) when in evidence, objective indicia of non-obviousness (i.e., secondary considerations). *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

The Supreme Court explained in *KSR International Co. v. Teleflex Inc.* that

> [o]ften, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.

550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." (alteration in original)). Further, for motivation to combine, it is enough to show that there was a known problem in the art, that a prior art reference "helped address that issue" and that combining the teachings of the references "wasn't beyond the skill of an ordinary artisan." *Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1381 (Fed. Cir. 2023).

"Whether an ordinarily skilled artisan would have been motivated to modify the teachings of a reference is a question of fact." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1327 (Fed. Cir. 2016). "[W]here a party argues

a skilled artisan would have been motivated to combine references, it must show the artisan 'would have had a reasonable expectation of success from doing so.'" *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1360–61 (Fed. Cir. 2017) (quoting *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1068–69 (Fed. Cir. 2012)).

Reasonable expectation of success of the proposed combination is also a question of fact. *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F. 3d 1359, 1366 (Fed. Cir. 2016). "The reasonable expectation of success requirement refers to the likelihood of success in combining references to meet the limitations of the claimed invention." *Id.* at 1367. In evaluating reasonable expectation of success, we must consider the appropriate scope of the "claimed invention." *Id.* (emphasis omitted).

A. Level of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *See Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *see also Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

According to Petitioner, the relevant technical field is "'thermal ablation systems and methods,' which includes 'methods for performing Radio Frequency (RF) neurotomy.'" Pet. 11 (citing Ex. 1003, 1:24–27). Relying on the testimony of Dr. Tucker, Petitioner contends that the ordinarily skilled artisan in this field 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 and methods; or
>
> (ii) an advanced degree in the same areas of academic study with at least 1 year[] of experience with thermal ablation systems and methods.

*Id.* (citing Ex. 1034 ¶ 105).

Patent Owner argues that Petitioner's "assert[ion] that the relevant field is 'thermal ablation systems and methods'" . . . diverts attention to unrelated and inappropriate fields of RF ablation." PO Resp. 26. According to Patent Owner, "the central focus of the '664 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." *Id.* In support of this argument, Patent Owner quotes, with added emphasis, the description in the '664 patent Specification that "[t]he 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." *Id.* (quoting Ex. 1003, 1:24–27).

Patent Owner next argues that "RF ablation broadly encompasses many diverse, non-overlapping subfields involving different physicians treating different conditions in different parts of the body for different clinical purposes using different devices." PO Resp. 27 (citing Ex. 2001 ¶ 177; Ex. 2006 ¶¶ 47–49). Citing Dr. Russo's testimony, Patent Owner further argues that there are no medical practitioners who are generalists in RF ablation and likewise RF medical devices are not usable in all RF

ablation procedures. *Id.* (citing Ex. 2001 ¶ 76). According to Patent Owner, "there has historically been little to no cross-talk or cross-pollination of the various fields in which RF ablations are performed." *Id.* (quoting Ex. 2001 ¶ 76).

Patent Owner next offers various criticisms of Petitioner's proposed level of skill in the art. PO Resp. 29–30. Patent Owner then proffers the following level of ordinary skill in the art:

> [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.

*Id.* at 30 (citing Ex. 2006 ¶ 58) (alteration in original).

Petitioner responds that "the patent claims are not limited to neurotomy" and directs us to Mr. Crosby's testimony confirming this. Pet. Reply 2 (citing Ex. 1003, 31:32–34:23; Ex. 1045, 257:1–22).[10] Petitioner contends that "the intrinsic evidence is unequivocal: '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.'" *Id.* (quoting Ex. 1003, 31:6–

[10] Although many of the claims, including both independent claims, are not limited to neurotomy, some of the dependent claims, namely claims 10–19 and 26–29, are arguably limited to RF neurotomy.

10 (emphasis added by Petitioner); Ex. 1054, 30). Petitioner further contends that "[t]he specification describes using RF needles for 'cauterize[ing] 'feeder vessels'" in ulcers and for 'cardiac ablation' generally—*not RF neurotomy*." *Id.* (citing Ex. 1003, 31:10–22; Ex. 1046, 34:7–10, 142:9–145:8) (alterations in original). Petitioner contends that the '622 patent "expressly stat[es] the target volume can be a 'nerve or a tumor.'" *Id.* (citing Ex. 1003, 1:34–35).

Petitioner next contends that Dr. Russo "agreed that cooled-tip technology (providing 'enlarged lesions') was originally developed for cardiac and tumor RF ablation needles and then *adapted* for RF neurotomy." Pet. Reply 3 (citing Ex. 1015; Ex. 1046, 69:24–70:23, 125:10–25; Ex. 1055; Ex. 2001 ¶ 107; Ex. 2004, 3902–03, 3906). According to Petitioner, Patent Owner's "lead inventor (Wright) was working with cooled-tip neurotomy needles . . . *immediately before* the alleged invention" and "the claimed invention was developed by benchmarking a needle with cooled-tip technology adopted from cardiac/tumor ablation." *Id.* at 4 (citing Ex. 1046, 58:4–60:11, 72:12–73:19, 75:1–24, 90:3–93:10; Ex. 1051, 5, 8; Ex. 1055; Ex. 2004, 3902).

Petitioner next provides several criticisms of Patent Owner's proposed level of skill in the art. Petitioner first argues that Patent Owner "errs by requiring 'significant experience performing RF neurotomy procedures' when the patent's field is not limited to neurotomy" and "the claims are not limited to neurotomy at all." Pet. Reply 5 (citing Ex. 1003, 31:32–34:23; Ex. 1045, 211:7–213:18). Next, Petitioner argues that Patent Owner's declarants Dr. Russo and Mr. Crosby testified that "they never relied on one another for their testimony." *Id.* (emphasis omitted) (citing Ex. 1045, 21:7–

23:20, Ex. 1046, 26:2–27:11). According to Petitioner, "Crosby is not a physician but didn't need Russo to form his opinions" yet "believed himself competent to offer testimony on *all aspects* of the Stratus patents and the prior art, including operating the devices." *Id.* (citing Ex. 1045, 98:5–101:10, 105:1–107:2; Ex. 2006 ¶ 21). Lastly, Petitioner argues that Patent Owner's level of skill "requires 'experience in the design and development of devices and methods for applying electromagnetic energy to nerves" but this would encompass an ordinarily skilled artisan with "experience only with stimulating nerves—*but no experience in RF ablation*." *Id.* at 6 (citing Ex. 1045, 30:1–5).

In the Sur-reply, Patent Owner argues that "RF neurotomy is the almost exclusive focus of the patent." Sur-reply 20. Patent Owner concedes that the '664 "patent mentions some non-neurotomy ablation applications, it merely says the invention can be 'adapted,' 'modified,' 'scaled,' or 'tailored' for other RF ablation procedures," but argues these descriptions mean "the invention itself is not directed to those procedures." *Id.*

We first address the field of the invention and then the parties' respective contentions concerning the level of ordinary skill in the art.

In determining a patent's field of invention, we are guided by the following Federal Circuit precedent:

> 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).

The '664 patent describes the invention as "relat[ing] to thermal ablation systems and methods and more specifically to improved systems for performing Radio Frequency (RF) neurotomy" and "is particularly apt for spinal RF neurotomy procedures." Ex. 1003, 1:24–28. The '664 patent next describes that "[t]he target volume" for a thermal ablation procedure "may be, for example, *a nerve or tumor*." *Id.* at 1:32–35 (emphasis added). The '664 patent further describes that

> 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 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 electrical rhythm in the hart [sic].

*Id.* at 31:6–16.

Of the Challenged Claims, only dependent claims 10–19 and 26–29 are arguably limited to RF neurotomy. Independent claims 1 and 21 are not so limited.

Based on the foregoing, we find that the field of invention is "thermal ablation systems" and is not limited to RF neurotomy as Patent Owner argues. This accords with the Specification which states under the heading "Field of Invention" that "[t]he present invention relates to thermal ablation systems and methods." Ex. 1003, 1:24–25. The fact that the Specification describes that the needles "may be adapted (modified or scaled) for use in in other medical procedures" does not, as Patent Owner asserts, mean that the field of the claimed invention is limited to RF neurotomy. The import of

this statement is that it would be within the knowledge of a person of ordinary skill in the art to determine how to modify the disclosed embodiments to accommodate "other medical procedures" in order to practice the invention recited in claims 1 and 21 for example. In sum, Patent Owner asks us, in essence, to find that the field of the invention is "limited to the specific point of novelty, the narrowest possible conception of the field, or the particular focus within a given field" in contravention of the Federal Circuit's holding in *Netflix*. We do not so find.

We now turn to the level of ordinary skill in the art.

Patent Owner's proposal set forth above suffers from two defects. First, it mandates certain education and experience in RF neurotomy specifically. This is too narrow as neither the field of the invention nor independent claims 1 and 21 are limited to RF neurotomy. Second, it requires the ordinarily skilled artisan to be both a physician who performs RF ablation (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 also too narrow because it excludes physicians and other advanced degree holders that research and design devices and methods for performing RF ablation, but do not actually operate on patients. For these reasons, we do not adopt Patent Owner's proffered level of skill in the art.

We apply Petitioner's proffered level of skill in the art set forth on page 11 of the Petition and set forth above because it is consistent with the problems addressed in the '664 patent and the prior art.

B. Claim Construction

Petitioner contends that no claim term requires express construction. Pet. 11 (citing Ex. 1034 ¶ 106 (Dr. Tucker's 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")).

Patent Owner does not address claim construction in the Patent Owner Response. *See generally* PO Resp.

After review of the parties' evidence and arguments, we determine that we need not expressly construe any claim terms to resolve the controversy before us. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) ("The Board is required to construe 'only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

C. Overview of Asserted References for Ground A

Petitioner relies on Racz, Fitz, and Lee for Ground A. Pet. 12.

1. Overview of Racz (Ex. 1009)

Racz discloses a "Bent Tip Electrical Surgical Probe" comprising a "medical needle or canula for stimulation or ablation." Ex. 1009, Abstract.

> The device is partially insulated and has a tip that is at least partially electrically exposed; a connection to an external signal generator provides electrical stimulation or high-frequency heating of the patient's tissue proximal to the exposed tip. The device includes a longitudinal passage to facilitate the injection of fluids or the insertion of instruments through the cannula or needle.

*Id.*

Racz's Figure 1 is reproduced below:

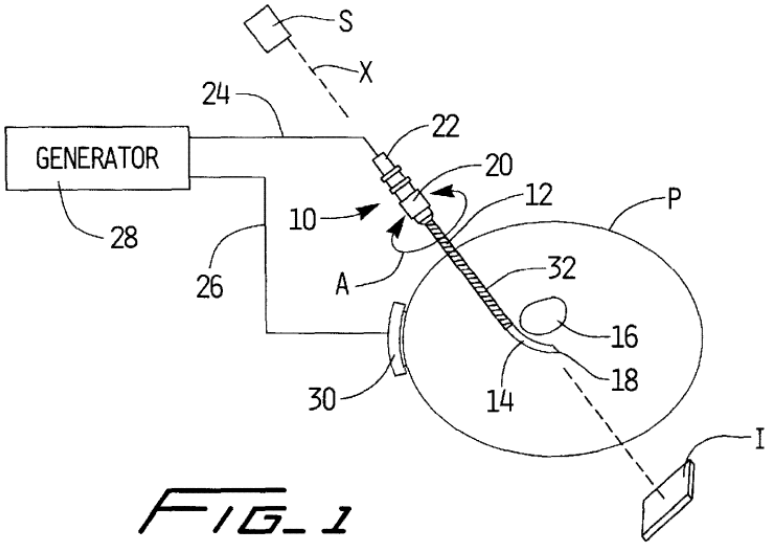



FIG. 1

Figure 1 is 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." Ex. 1009, 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." Ex. 1009, 3:42–44. RF "cannula 10 further comprises a hub 20. 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's Figure 2B, reproduced below, shows a specific embodiment of the system illustrated in Figure 1:

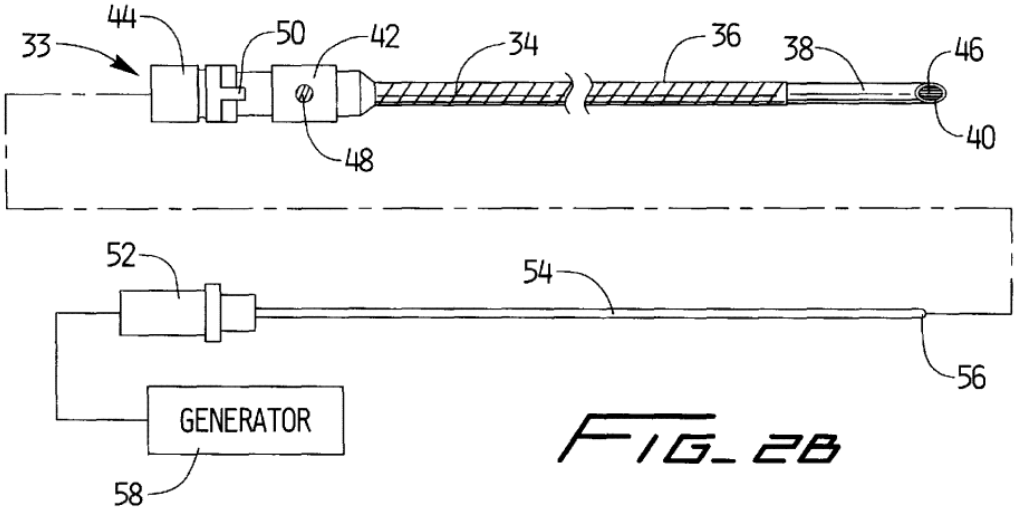



Fig. 2B is a "schematic side elevation and orthogonal view of" Racz's device. Ex. 1009, 3:27–30.

The cannula, 33 in this embodiment,[11] includes a shaft 34 defining an internal lumen. Ex. 1009, 5:41–45. Shaft 34 "comprises a hollow metal tube with an insulated portion 36 illustrated by hatched lines," and an exposed distal tip 38. *Id.* at 4:62–65. The distal tip 38 includes a pointed end (40), which "can be useful in penetrating tough tissue." *Id.* at 5:3–5.

In operation, cannula 33, "with a stylet positioned in the shaft 34, is inserted into the patient's body portion P." Ex. 1009, 5:31–33. "The stylet is

[11] According to Petitioner, Racz uses a different numbering system for the corresponding elements of its figures such that, for example, cannula 10 of Figure 1 corresponds to cannula 33 of Figures 2A. In discussing the specific embodiment of Figure 2b, Petitioner references both sets of numbers, as, e.g., "cannula (10/33)." *See, e.g.*, Pet. 13. Petitioner applies the same convention to Lee, e.g., referencing "filaments (22/1622)," to indicate that a corresponding structure is differently labeled 22 in Figure 1 and 1622 in Figure 48 of that reference. *See id.* at 24–27. Patent Owner does not dispute this approach by Petitioner. *See generally* PO Resp.

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. Electrical probe 52 includes probe shaft 54 having probe tip 56, which may include a temperature sensor. *Id.* at 5:26–30, Fig. 2B. When probe 52 is fully inserted into the cannula 33, "physical contact" between probe 52 and cannula's tip 38 conducts the RF energy to 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 14." *Id.* at 3:60–4:23, 5:41–51, Fig. 1.

2. Overview of Fitz (Ex. 1011)

Fitz is directed to "[i]mproved-coverage RF neurotomy instrumentation" comprising a multiplicity of electrically conductive electrodes. Ex. 1011, Abstract; claim 1.

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. Ex. 1011 ¶ 4. "Although multiple lesions may be created in order to enhance coverage, this is more time-consuming and usually more painful to 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." Ex. 1011, Abstract. Fitz's

> introducer features a plurality of elongated, co-extensive cannula, each including an insulated, electrically conductive electrode. Each electrode has a proximal end configured for attachment to a source of energy, and 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.* ¶ 9. According to Fitz, at least some of the "electrodes [may be] constructed of a shape-memory material to control deployment. The cannula 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's Figure 4 is reproduced below:

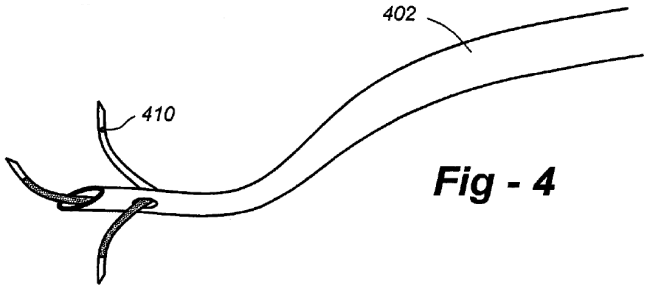



Fig - 4

Figure 4 represents an embodiment of Fitz's invention having a side port inducer. Ex. 1011 ¶ 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.

Fitz's Figure 5 is reproduced below:

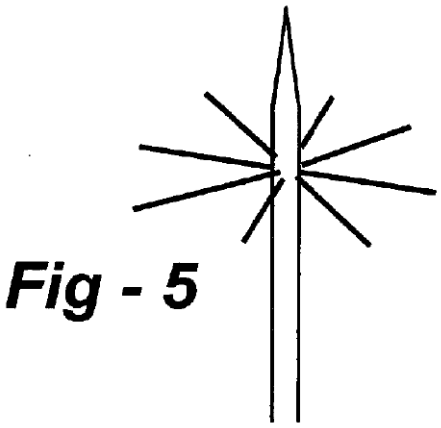



Figure 5 shows an embodiment of Fitz's invention "in the form of a radial array." Ex. 1011 ¶ 16. In this embodiment the "inducer ha[s] a tip and sufficient side ports to form an array of electrodes once deployed. Although the side electrodes are shown as emanating from more or less the same distance from the tip, this is not necessary, in that a helix or spiral of apertures may alternative[ly] be used." *Id.* ¶ 21

3. Overview of Lee (Ex. 1010)

Lee discloses a radio frequency ablation device having a plurality of deployable electrodes or "ablation antennae." *See, e.g.*, Ex. 1010, Abstract, ¶ 8. Figure 1 of Lee is reproduced below:

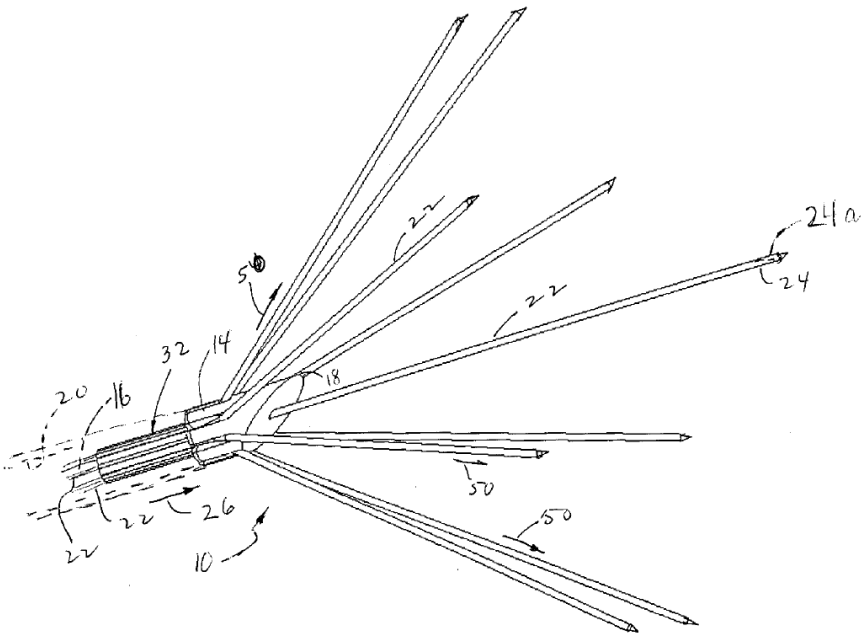



Figure 1 is a perspective view of the distal portion of Lee's "multiple antenna ablation device" or "ablation trocar." *Id.* ¶¶ 32, 91.

Ablation trocar 10 includes trocar point 14 having "a forward piercing edge surface 18." Ex. 1010 ¶ 91. "[T]rocar point 14 is mounted on a cannula 16[, which] . . . may be made of . . . metal covered with a plastic insulating layer, to prevent ablative energy from leaking out of the device along the length of the cannula." *Id.* "Cannula 16 defines an internal lumen 20 which carries a plurality of stylets 22" each of which "comprises a long and straight springy wire-like member" and is "made of a springy conductive material such as a springy nickel titanium alloy." *Id.* ¶ 92.[12] "[S]tylets 22 . . . may be housed wholly within lumen 20 of cannula 16." *Id.* (referencing Fig. 2). But in the deployed configuration shown in Figure 1,

[12] Petitioner refers to Lee's conductive stylets/electrodes as "filaments." *See, e.g.*, Pet. 19, 37 (citing Ex. 1034 ¶¶ 125–126, 162–163). Patent Owner does not dispute this characterization. *See generally* PO Resp.

"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, 93, 99, 102. "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 of 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 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 trocar point 14. Ex. 1010 ¶¶ 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, Abstract, claims 8, 10. The ends of the exposed stylets transmit RF energy to define an ablation volume. *See, e.g.*, *id.* ¶¶ 7, 12, 123, 129, claims 1, 2.

D. Ground A: Obviousness in view of Racz, Fitz, and Lee

For Ground A, Petitioner challenges claims 1–10, 18–26, 28, and 29 as obvious in view of Racz, Fitz, and Lee. Pet. 13–62.

Patent Owner contends that Lee is not analogous art, none of the references teach a deployable filament energized at the distal end by an insertable RF probe, Petitioner's proposed modification of Racz's device is

too vague, Petitioner has not established reasonable expectation of success, Petitioner's proposed modification of Racz's device "is not enabled," the references teach away from Racz's modified device, Petitioner fails to establish motivation to combine, and the teachings of the prior art would not have a led an ordinarily skilled artisan to Racz's modified device. PO Resp. 34–59. Further, Patent Owner submits that objective indicia of non-obviousness support the patentability of the challenged claims. *Id.* at 61–74.

1. Claim 1

a) Petitioner's Contentions

Petitioner provides limitation-by-limitation contentions for claim 1 detailing how the combination of Racz, Fitz, and Lee teaches each of the elements of claim 1. Pet. 28–47. Supported by the testimony of Dr. Tucker, Petitioner contends that an ordinarily skill artisan would have been motivated to combine the teachings of Racz, Fitz, and Lee with a reasonable expectation of success of arriving at the claimed invention. *Id.* at 1–6, 21–27; Ex. 1034 ¶¶ 132–149.

We begin with motivation to combine and reasonable expectation of success and then address Petitioner's mapping of the prior art to the claim limitations.

i. Motivation to Combine/Reasonable Expectation of Success

Petitioner contends that "[c]onsidering Racz, Fitz, and Lee together, a [person of ordinary skill in the art] would have been motivated to implement deployable filaments on the distal tip (14/38) of Racz's electrode cannula (10/33)." Pet. 21. According to Petitioner, "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" leading an ordinarily skilled artisan to "recognize[] that the Fitz/Lee technique would improve the energy coverage area of Racz's single-tip device." *Id.* at 22 (citing Ex. 1010 ¶¶ 84, 123–131; Ex. 1011 ¶¶ 9–10, Abstract; Ex. 1034 ¶¶ 60–65, 69–72, 132).

Petitioner next contends that because Fitz discloses a known problem with single-tip RF neurotomy devices, an ordinarily skilled artisan would have understood that Racz's single-tip device would also suffer from inadequate coverage of the target area. Pet. 22 (citing Ex. 1011 ¶¶ 4, 12, 17; Ex. 1034 ¶¶ 133–135; *see also id.* at 23 (reproducing a side-by-side comparison of Racz's Figure 2B and Fitz's Figure 1). Petitioner further contends that Fitz would have motivated the ordinarily skilled artisan "to provide deployable electrodes on Racz's exposed tip" in order to "[t]o solve the limited energy coverage problem in Racz's device." *Id.* at 23 (citing Ex. 1011 ¶ 9, Abstract; Ex. 1034 ¶ 136). In support of this contention, Petitioner points to Fitz's disclosure that its "electrodes may be made from a 'shape-memory alloy' and be deployed outwardly from the distal tip 'to an area to be treated.'" *Id.* (citing Ex. 1011 ¶¶ 9–10, 18–21, Abstract, Figs. 4, 5).

Petitioner next contends that Fitz's deployable electrodes implemented in Racz's distal tip would have numerous benefits including "reducing instances where a target nerve 'is not lesioned at all,'" "reducing the need to create multiple lesions," "providing greater flexibility in lesion size/placement as 'anatomy differs from patient to patient,'" and "expanding the energy coverage area without compromising the device's ability to be

'readily deployable through muscle tissue.'" Pet. 24 (citing Ex. 1011 ¶¶ 4–8). According to Petitioner, for these reasons, "Fitz would have motivated a [person of ordinary skill in the art] to add deployable electrodes to the distal tip (14/38) of Racz's cannula (10/33)" and the deployment of Fitz's electrodes in Racz's tip "could be easily implemented." *Id.* (citing Ex. 1034 ¶ 137).

Petitioner next contends that Lee "disclose[s] a further refinement of the deployable-electrode technique." Pet. 24. Petitioner argues that Lee's "filaments (22/1622) 'define an ablation volume in the target tissue' as 'the destruction of target tissue [occurs] at the site where the electrodes are located" allowing "variations in ablation volume" to "be achieved by controlling the number of filaments (22/1622) used as well as their length, direction, and arrangement." *Id.* (citing Ex. 1010 ¶¶ 12, 84, 123–131). According to Petitioner, Lee would have motivated an ordinarily skilled artisan "to add deployable filaments to the distal tip (14/38) of Racz's cannula (10/33) to not just expand—*but also to control*—the ablation volume generated by Racz's device." *Id.* at 25 (citing Ex. 1034 ¶ 138).

Petitioner next contends that Lee discloses that its "deployable filaments (22/1622) can be arranged around the inner perimeter of a cannula such that they surround and provide space for a central element." Pet. 25 (citing Ex. 1010 ¶¶ 94, 99, 125, Figs 1, 23, 49). According to Petitioner, Lee's disclosure "would have confirmed to a [person of ordinary skill in the art] that Lee's deployable filaments (22/1622) would be easily arranged to accommodate Racz's centrally located removable probe" and would "be a matter of routine engineering, well within the level of ordinary skill in the

art, and executable with a reasonable expectation of success." *Id.* at 25, 27 (citing Ex. 1034 ¶¶ 139–140, 148–149).

Patent Owner interposes numerous arguments that are relevant to Petitioner's contentions on motivation to combine which we address below and determine are unavailing.

We now set forth our findings and legal conclusions in light of the legal principles underlying motivation to combine.

We start with the premise that, "if 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." *KSR*, 550 U.S. at 417. In this case, we must determine whether one of ordinary skill in the art would recognize that applying the teachings of Fitz and Lee of deploying multiple filaments to increase and control the ablation volume to Racz's distal tip would improve Racz's device in the same way. For us to resolve this question in Petitioner's favor, Petitioner must provide "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.* at 418 (citing *In re Kahn*, 441 F.3d at 988). However, bodily incorporation, i.e., "an actual physical substitution of" Lee's filaments into Racz is not required. *See In re Mouttet*, 686 F.3d 1322, 1332 (Fed. Cir. 2012) ("It is well-established that a determination of obviousness based on teachings from multiple references does not require an actual, physical substitution of elements."); *In re Nievelt*, 482 F.2d 965, 968 (CCPA 1973) ("Combining the *teachings* of references does not involve an ability to combine their specific structures.").

The Federal Circuit holds that that

> motivation to combine may be found explicitly or implicitly in market forces; design incentives; the 'interrelated teachings of multiple patents'; 'any need or problem known in the field of endeavor at the time of invention and addressed by the patent'; and the background knowledge, creativity, and common sense of the person of ordinary skill.

*Zup, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365, 1371 (Fed. Cir. 2018); *see also Intel*, 61 F.4th at 1381 (explaining that it is sufficient for motivation to combine "that there was a known problem . . . in the art, that Bauman[] . . . helped address that issue, and that combining the teachings of Kabemoto and Bauman wasn't beyond the skill of an ordinary artisan. Nothing more is required to show a motivation to combine under *KSR*").

Fitz is directed to RF neurotomy. Ex. 1011 ¶ 2. Fitz explains that the then current designs consisted of "a straight needle . . . used to cover a small nerve on a rounded bony surface." *Id.* ¶ 4. Fitz describes that a problem with those designs "is that they do not allow for adequate coverage of the target area." *Id.* This may require "multiple lesions . . . to enhance coverage" but "this is more time-consuming and usually more painful to the patient." *Id.* ¶ 5. Fitz's purported invention is an "improved coverage RF neurotomy instrumentation, including an introducer used to deploy a set of electrodes to an area to be treated. *Id.* ¶ 9. Figure 2 of Fitz shows an embodiment deploying a plurality of electrodes 206. *Id.* ¶ 17, Fig. 2.

Lee discloses "utilizing radio frequency heating of tissues for ablation or shrinkage by the application of the energy to the tissues through specialized delivery devices." Ex. 1010 ¶ 83. Lee discloses deploying a plurality of stylets (electrodes) 22 through its distal tip. *Id.* ¶ 92, Fig. 1. Lee discloses that extending the electrodes in different directions and in differing

lengths defines and controls the shape and volume of ablation. *See id.* ¶¶ 123–130.

These and other disclosures in Fitz and Lee support Dr. Tucker's testimony that a person of ordinary skill in the art would have been motivated to combine the teachings of Racz, Fitz, and Lee. In particular, Dr. Tucker testifies that an ordinarily skilled artisan:

> would have been motivated to implement deployable filaments on the distal tip (14/38) of Racz's electrode cannula (10/33). . . . Fitz and Lee disclose a technique for solving the problem of inadequate coverage in single-tip 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. Ex-1011, ¶ 0009-10, Abstract; Ex-1010, ¶ 0012, 0084, 0123-131. Thus, a [person of ordinary skill in the art] would have recognized that the Fitz/Lee technique would improve the energy coverage area of Racz's single tip device.

Ex. 1034 ¶ 132.

> 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 extending "only a few millimeters" from the exposed tip. Ex-1011, ¶ 0004-0005. . . . Fitz therefore teaches a [person of ordinary skill in the art] that this limited coverage problem would be present in Racz's device due to its single-tip configuration . . . Ex.-1011, ¶ 0004, 0012, 0017.

*Id.* ¶ 134.

> Fitz also teaches a solution to this problem: providing a deployable set of electrodes on the exposed distal tip. Ex-1011, ¶ 9, Abstract. The deployable electrodes may be made from a "shape-memory alloy" and can be configured to be deployed outwardly from the distal tip of a cannula "to an area to be treated." Ex-1011, ¶ 0009-0010, 0018-0021, Abstract.

*Id.* ¶ 135.

> Fitz would have accordingly motivated a [person of ordinary skill in the art] to solve the limited energy coverage problem in Racz's device by providing deployable electrodes on Racz's exposed tip (14/38). Ex. 1011, ¶ 0009.

*Id.* ¶ 136.

> A POSA would have understood from Fitz that implementing deployable electrodes at Racz's distal tip (14/38) has numerous benefits: (i) reducing instances where a target nerve "is not lesioned at all" (Ex-1011, ¶0004); (ii) reducing the need to create multiple lesions, which is "time-consuming and usually more painful to the patient" (Ex-1011, ¶0005); providing greater flexibility in lesion size/placement as "anatomy differs from patient to patient" (Ex-1011, ¶0004); and (iv) expanding the energy coverage area without compromising the device's ability to be "readily deployable through muscle tissue"(Ex-1011, ¶0006-0008).

*Id.* ¶ 137.

> Lee disclosed a further refinement of the deployable-electrode technique that would have provided additional motivation and guidance to a POSA to combine the references. For example, Lee discloses that its filaments (22/1622) "define an ablation volume in the target tissue" as "the destruction of target tissue [occurs] at the site where the electrodes are located." Ex-1010, ¶0012, 0084. As a result, "variations in ablation volume" may be achieved by controlling the number of filaments (22/1622) used as well as their length, direction, and arrangement. Ex-1010, ¶0123-0131, 0084. Indeed, the "arrangement of [filaments] may … form any desired pattern" (Ex1010, ¶0103) and the precision and control offered by the filaments (22/1622) allows "the operator [to] deliver the [radiofrequency] treatment safely and effectively" (Ex-1010, ¶0084). Thus, a POSA would understand from Lee the relationship between the configuration of the filaments and the shape/size lesion created. From this relationship a POSA would be motivated to use filaments in radiofrequency ablation devices to control the shape and/or size of the lesions created by the device.

*Id.* ¶ 138.

> Lee would have confirmed to a POSA that providing deployable filaments (e.g., stylets (22/1622)) at the distal tip of an ablation device

> can be used to not only to expand the ablation volume but to precisely control the size and shape of the ablation volume. For at least these reasons, a POSA would have been further motivated by Lee to add deployable filaments to the distal tip (14/38) of Racz's cannula (10/33) to not just expand—*but also control*—the ablation volume generated by Racz's device.

*Id.* ¶ 139.

We accord substantial weight to this testimony of Dr. Tucker because it is supported by the cited disclosure from Racz, Fitz, and Lee.

Based on the foregoing disclosures in Racz, Fitz, and Lee and the testimony of Dr. Tucker, we find that Petitioner has shown that Racz's single tip electrode suffered from a known problem of inadequate energy coverage and that Fitz and Lee addressed that problem by deploying multiple electrodes to increase and control the ablation volume. Consequently, an ordinarily skilled artisan would have been motivated to combine Racz with the interrelated teachings of Fitz and Lee. *Intel*, 61 F.4th at 1381; *Zup*, 896 F.3d at1371.

We address the question of reasonable expectation of success in connection with our analysis of Patent Owner's contentions set forth below.

ii. Petitioner's Claim Limitation Contentions

[1pre][13] "A method comprising:"

Petitioner contends that Racz discloses that it is "directed to a system and *method* for . . . pain relief." Pet. 28 (underlining omitted) (citing Ex. 1009, 2:46–47; Ex. 1034 ¶ 150).

Patent Owner does not address the preamble. *See generally* PO Resp.

[13] We use Petitioner's claim limitation annotations for ease of reference.

We have reviewed Petitioner's contentions and evidence and find that Racz discloses the subject matter of the preamble. Moreover, the preamble here clearly is not limiting.

> [1a] "inserting a needle into a patient, the needle comprising:"

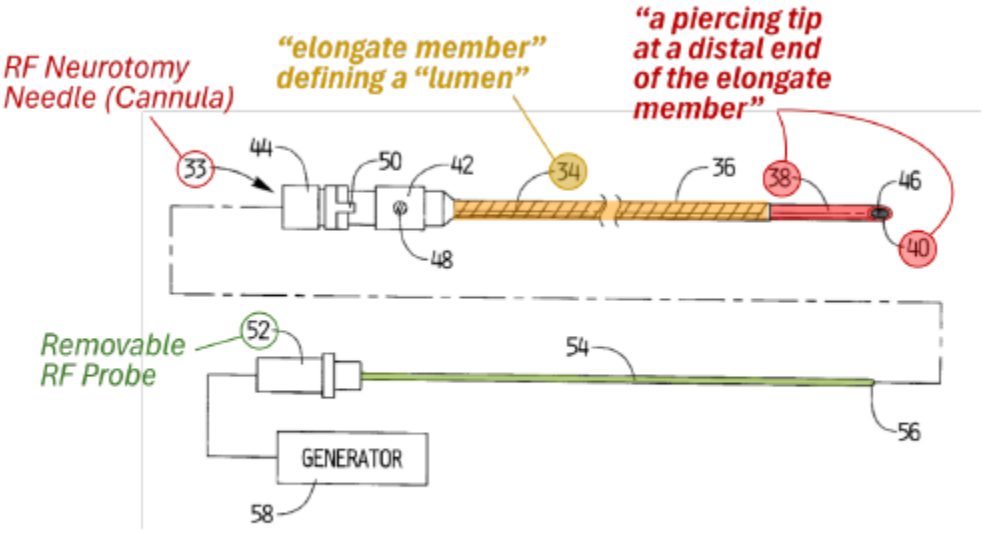
Petitioner contends that Racz discloses a "curved tip needle electrode" or cannula, that may be "inserted directly through the skin." Pet. 28 (citing Ex. 1009, 2:46–48, 3:24–45, 8:45–57, 9:49–51; Ex. 1034 ¶ 151).

Patent Owner does not address this limitation. *See generally* PO Resp.

We have reviewed Petitioner's contentions and evidence and find that Racz discloses this limitation.

> [1b] "an elongate member;"; [1d] "a lumen within the elongate member; and"

In support of its contentions for limitations [1b] and [1d], Petitioner provides the following annotated version of Racz's Figure 2B:




***Racz – Fig. 2B (annotated to show [1b]-[1d])***

Pet. 29. Figure 2B is a "schematic side elevation and orthogonal view" of Racz's device. Ex. 1009, 3:27–28. Petitioner annotates Figure 2B with green highlighting of element 54, a green circle around element number 52 and green text "Removable RF probe"; orange highlighting of element number 34 and element 34 and orange text "'elongate member' defining a 'lumen'"; red highlighting of element numbers 38 and 40 and element 38 with red text "a piercing tip at distal end of elongate member"; and a red circle around element number 33 with red text "RF Neurotomy Needle (Cannula)." Pet. 29.

For limitations [1b] and[1d], Petitioner contends that Racz discloses an "electrode cannula (10/33) compris[ing] 'an elongated shaft' (12/34) defining 'an internal lumen.'" Pet. 28–29 (citing Ex. 1009, 1:33–36, 2:48–51, 5:41–48, claims 1, 8, 11). Petitioner further contends that the "shaft's lumen accepts the radiofrequency probe (22/52) via the hub (20/42/70), which is 'mounted at a proximal end of the shaft.'" *Id.* at 29 (citing Ex. 1009, 3:38–42, 3:60–65, 5:26–28, 5:37–51, 9:44–48, Fig. 2B (annotated); Ex. 1034 ¶¶ 152–153).

Patent Owner does not address these limitations. *See generally* PO Resp.

We have reviewed Petitioner's contentions and evidence and find that Racz discloses these limitations.

> [1c] "a piercing tip at a distal end of the elongate member;"

With reference to its annotated reproduction of Racz's Figure 2B, Petitioner contends that "exposed electrical tip (14/38) . . . positioned at a distal end of the shaft (12/34) . . . defines a 'self-penetrating point' (18/40),"

which "allows the cannula (10/33) to be 'inserted directly through the skin.'" Pet. 29–30 (underlining omitted) (citing Ex. 1009, 3:42–45, 3:47–51, 1:28–30, 5:3–5, 8:45–57, 9:49–51, claim 3; Ex. 1034 ¶ 154).

Patent Owner does not address this limitation. *See generally* PO Resp.

We have reviewed Petitioner's contentions and evidence and find that Racz discloses this limitation.

> [1e] "a filament in a retracted position in which the filament is at least partially disposed within the elongate member"; [1f] "moving the filament to a deployed position within the patient in which at least a distal end of the filament is out of the elongate member and disposed away from the tip"

Petitioner contends that Lee's deployable stylets/electrodes (22/1622) correspond to the recited "filament" and that Lee's stylets/electrodes "are each 'a long and straight springy wire-like member' and may be 'made of a springy conductive material such as a springy nickel titanium alloy' (i.e., Nitinol)." Pet. 30–31 (citing Ex. 1010 ¶¶ 87, 92; Ex. 1034 ¶¶ 156–157).

Relying on its contentions for motivation to combine discussed above, Petitioner contends that one of ordinary skill in the art would have been motivated to implement Lee's perimeter filaments "on the distal tip (14/38) of Racz's cannula (10/33) for the purpose of expanding and controlling the energy coverage area of Racz's device." Pet. 30, 33 ("a [person of ordinary skill in the art would have been motivated to implement Lee's perimeter filaments (22/1622) around Racz's tip (14/38) to provide a desired ablation volume (e.g., in a full or partial cone shape) and omit Lee's central filament." (citing Ex. 1034 ¶¶ 73–75, 79–83. 159)). According to Petitioner, a person of ordinary skill in the art would have been further motivated to

omit Lee's central filament as unnecessary because "Racz's exposed distal tip (14/38) is already active," and omitting the central filament would have the benefit of not obstructing Racz's cannula (10/33). *Id.* at 33, 35 (citing Ex. 1009, 3:60–63, 4:18–23; Ex. 1034 ¶¶ 159, 161).

Petitioner next contends that an ordinarily skilled artisan seeking to implement Lee's perimeter filaments (22/1622) on Racz's distal tip (14/38)

> would have found it obvious to modify Racz's tip (14/38) to include internal deflection surfaces (12/1612) (e.g., channels and ramps as disclosed in Lee) to guide the perimeter filaments (22/1622) outwardly around Racz's tip (14/38). Ex-1010, ¶0016, 0018, 0092, 0102, Claim 8, Claim 10; Ex-1034, ¶160. It would have been further obvious to provide openings in Racz's distal tip (14/38) (e.g., in communication with the internal deflection surfaces as disclosed in Lee) such that Lee's perimeter filaments (22/1622) can—when deployed—exit Racz's distal tip (14/38). Ex-1010, ¶0092, 0102; Ex-1034, ¶160.

Pet. 34–35; *see also id.* at 35–38 (citing Ex. 1034 ¶¶ 162–165 (summarizing Dr. Tucker's testimony regarding an example of how one of ordinary skill in the art would have implemented Lee's filaments and deflection surfaces to guide them as they are deployed and retracted from Racz's cannula)).

Petitioner contends that limitations [1e] and [1f] would have been obvious in light of Lee's disclosure that "perimeter filaments (22/1622) are configured to be adjusted between deployed and withdrawn positions," and thus, extend beyond the tip of the device when in the deployed position "to define the ablation volume." Pet. 38–39 (citing Ex. 1010 ¶¶ 92, 98–99, 106–107, Figs. 1–3; Ex. 1034 ¶¶ 166–168). In support of this contention, Petitioner argues that Lee teaches "variations in ablation volume may be achieved by varying the extent to which stylets are extended from the distal

end of the trocar and the direction in which stylets extend." *Id.* at 39 (emphasis omitted) (citing Ex. 1010 ¶ 129, Figs. 1, 48, 49; Ex. 1034 ¶ 167).

Petitioner further contends one of ordinary skill in the art "would have been motivated (and found it obvious) to connect Lee's perimeter filaments (22/1622) to an actuator that would not obstruct Racz's central lumen for the purpose of preserving the functionality of Racz's electrical probe (22/52) (e.g., a rotating actuator configured to rotate around Racz's central lumen)." Pet. 41 (citing Ex. 1034 ¶¶ 77–78, 170–172). In support of this contention, Petitioner references Lee's disclosure that "perimeter filaments (22/1622) 'may be connected to suitable advancement and retraction mechanisms' (i.e., an actuator) for adjusting the filaments (22/1622) between the deployed position and the withdrawn position'" and that "[s]uch mechanisms may be of a conventional design." *Id.* at 40 (emphasis omitted, alteration in original) (citing Ex. 1010 ¶ 106). Petitioner similarly relies on Fitz's disclosure of "filaments . . . 'deployed' from the introducer by a 'slid[ing] movement," and its reference to a prior art deployable electrical lead that "may be actuated with various mechanisms." *Id.* (citing Ex. 1011 ¶¶ 7, 9) (second alteration in original).

Patent Owner does not address these limitations. *See generally* PO Resp.

We have reviewed Petitioner's contentions and evidence and find that the combination of Racz, Fitz, and Lee teaches these limitations.

> [1g] "inserting a radiofrequency probe into the lumen of the needle such that the radiofrequency probe contacts a conductive portion of the needle at a distal end of the needle to thereby establish an electrically conductive path from the radiofrequency probe to the filament; and"

Petitioner contends that Racz's electrode cannula (10/33) comprises a "metal tubular shaft" defining an internal lumen that "accepts the radiofrequency probe (22/52) . . . to conduct RF energy to the tip (14/38)." Pet. 41 (citing Ex. 1009, 1:33–36, 2:48–51, 3;38–42, 3:60–65, 5:26–28, 5:37–51, claims 1, 11). With reference to its annotated reproduction of Racz's Figure 2B (*id.* at 42), Petitioner reasons that,

> [w]hen the probe 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." Ex-1009, 3:60-65. Thus, "electrical signals from the signal generator 58 are communicated to the exposed distal tip 38 by way of *contact between* the probe shaft 54 and [the] internal lumen defined by the electrode shaft 34." Ex-1009, 5:41-48, 4:18-23.

*Id.* (citing Ex. 1034 ¶ 174) (second alteration in original). With respect to the conduction of RF energy to the filament(s), Petitioner asserts that because Racz's electrical probe (52)/ distal tip (14/38) and Lee's filaments (22/1622) "are all constructed from conductive materials, . . . the (modified) tip's deflection surfaces will physically contact the filaments [such that] . . . energy would be transmitted from the probe (52) to the tip (14/38) and to the perimeter filaments (22/1622) by physical contact." *Id.* at 45 (citing Ex. 1034 ¶¶ 178–179).

Patent Owner concedes that "Racz teaches an insertable RF probe to energize a needle at its distal tip" but argues that Racz does not teach or

suggest a deployable filament." PO Resp. 36. Patent Owner further argues that "[a]lthough Fitz and Lee each teach deployable filaments, neither Fitz nor Lee teaches energizing those filaments at a distal end using an insertable RF probe" and "[w]hat is missing from all three references is a deployable filament that is energized at the distal end by an insertable RF probe." *Id.* This contention is unavailing because it attacks the references individually while Petitioner relies on the combination of the teachings of Racz, Fitz, and Lee for this limitation. *See Bradium Techs. LLC v. Iancu*, 923 F.3d 1032, 1050 (Fed. Cir. 2019) ("A finding of obviousness . . . cannot be overcome 'by attacking references individually where the rejection is based upon the teachings of a combination of references.'" (quoting *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986)); *In re Mouttet*, 686 F.3d at 1333 (Fed. Cir. 2012) (holding that the test for obviousness is "what the combined teachings of the references would have suggested to those having ordinary skill in the art").

We have reviewed Petitioner's contentions and evidence in light of Patent Owner's contention and find that the combination of Racz, Fitz, and Lee teaches this limitation.

> [1h] "operating the radiofrequency probe, the tip, and the filament as a monopolar electrode, with radiofrequency energy from the radiofrequency probe being conducted to the filament through the electrically conductive path and transmitted by the filament."

Petitioner contends that Racz's "tip (14/38) is configured to operate in a conventional monopolar mode by providing a 'reference electrode 30' that is electrically connected to a signal generator (28) and 'in contact with the patient's body portion P.'" Pet. 46 (citing Ex. 1009, 4:3–23, Fig. 1;

Ex. 1034 ¶ 181). As such, Petitioner argues, "implementing Lee's perimeter filaments (22/1622) at Racz's tip (14/38)—and electrically connecting the monopolar tip (14/38) and perimeter filaments (22/1622) by physical contact using internal deflection surfaces discussed above—would naturally result in the active tip (14/38) and perimeter filaments (22/1622) functioning together as a single monopolar electrode" for transmitting RF energy suitable for RF ablation procedures. *Id.* at 46–47 (citing Ex. 1009, 4:3–23, Fig 1; Ex. 1010 ¶ 24; Ex. 1034 ¶¶ 84–88, 182). Relying on the testimony of Dr. Tucker, Petitioner contends that the ordinarily skilled artisan "would have had no reason to deviate from Racz's monopolar configuration and would have been motivated to electrically connect Lee's filaments (22/1622) to function as a single monopolar electrode with Racz's tip (14/38)." *Id.* at 47 (citing Ex. 1034 ¶¶ 183–184). Petitioner further contends that an ordinarily skilled artisan "would have had a reasonable expectation of success in implementing this configuration as both Racz and Lee disclose that a monopolar configuration is suitable for RF ablation procedures." *Id.* (citing Ex. 1009, 4:3–23, Fig. 1; Ex. 1010 ¶ 24; Ex. 1034 ¶ 183).

For all the foregoing reasons, Petitioner has shown that the combination of Racz, Fitz, and Lee teaches all the limitations of claim 1.

2. Claim 2

Claim 2 depends from claim 1 and recites "wherein said moving the filament to a deployed position within the patient takes place prior to said inserting the radiofrequency probe into the lumen of the needle." Ex. 1003, 31:54–57.

Petitioner first contends that "Lee teaches it 'is important for the physician operator to carefully place the ablation [filaments] (for example

radiofrequency electrodes in the correct positions . . . *prior to* applying ablative energy'" and "that '*after* the [filaments] 22 have been successfully deployed in the tumor mass to be ablated, *RF energy … is applied* to the [filaments].'" Pet. 48 (citing Ex. 1010 ¶¶ 85, 87, 99, 107) (alterations in original). Petitioner next contends that "Racz also discloses that the RF probe (22/52) can be inserted into the cannula (10/33) *after* the cannula (10/33) has been inserted into the patient" and "*after* the RF probe is inserted, its tip (14/38) is activated with RF energy to ablate targeted tissue." *Id.* (citing Ex. 1009, 1:43–52, 2:53–56, 4:18–23, 5:29–51). Based on the cited disclosure of Lee and Racz, Petitioner contends it would have been obvious to an ordinarily skilled artisan "to insert Racz's modified cannula (10/33) into a patient, then insert Racz's RF probe (22/52) into the cannula, then deploy Lee's filaments (22/1622) from the tip (14/38), and then activate the filaments (22/1622) and tip (14/38) with RF energy to ablate a targeted volume of tissue." *Id.* at 48–49 (citing Ex. 1034 ¶¶ 185–187).

Petitioner's contentions are not persuasive. Claim 2 requires inserting deploying the filaments prior to inserting the radiofrequency probe. Petitioner's contentions are the opposite, i.e., the radiofrequency probe is first inserted and then the filaments are deployed. Consequently, Petitioner fails to show that that the combination of Racz, Fitz, and Lee teaches the limitations of claim 2.

3. Claims 3, 4, 5

Claim 3 depends from claim 1 and recites "wherein the needle further comprises a fitting in fluid communication with the lumen, the method further comprising: connecting a fluid source to the fitting; transporting fluid

through the lumen of the needle to a target volume within the patient; and disconnecting the fluid source from the fitting." Ex. 1003, 31:58–64.

Claim 4 depends from claim 3 and recites "wherein said inserting the radiofrequency probe into the lumen is achieved by passing the radiofrequency probe through the fitting." Ex. 1003, 31:65–67.

Claim 5 depends from claim 3 and recites "wherein said inserting the radiofrequency probe into the lumen takes place after said disconnecting the fluid source from the fitting." Ex. 1003, 32:1–3.

Petitioner contends that Racz's proximal hub (20/42/70) "may be a standard hypodermic needle or luer type hub capable of connection to stylets, electrical probes, syringes, or injection tubes" and its "tip (14/38) includes 'an opening 46 that is capable . . . of dispensing diagnostic or therapeutic liquids' that are injected *via the hub* (20/42/70) and through the lumen of the shaft (12/34)." Pet. 49 (citing Ex. 1009, 1:29–33, 5:14–18, 5:66–6:8, 6:9–12, 8:54–57). In addition to receiving fluid, "Racz's proximal hub (20/42/70) is also configured to receive the probe (22/52) (for transmitting RF energy during ablation)." *Id.* (citing Ex. 1009, 3:59–65, 5:66–6:12, 9:30–39; 10:8–10). According to Petitioner, "the fluid source can necessarily be disconnected from the hub (20/42/20) to allow for insertion of the RF probe (22/52) through the hub/fitting," and therefore discloses the limitations of claims 3 and 4. *Id.* at 49–50 (citing Ex. 1034 ¶¶ 188–189).

For claim 5, Petitioner contends that Racz "teaches that 'injection of a local anesthetic' through the hub 'can be used to confirm the exact *position* of a target' which 'may be a *precursor* to other options such as stimulation [and] radio frequency heating.'" Pet. 50 (citing Ex. 1009, 1:55–63, 5:66–

6:7; Ex. 1022, 5:46–57) (alteration in original). Petitioner further contends that this disclosure renders the subject matter of claim 5 obvious to a person of ordinary skill in the art. *Id.* (citing Ex. 1034 ¶¶ 190–191).

Patent Owner does not dispute Petitioner's contentions for claims 3–5. *See generally* PO Resp.

We have reviewed Petitioner's evidence and contentions and find the combination of Racz, Fitz, and Lee teaches the limitations of claims 3, 4, and 5.

4. Claims 6 and 7

Claim 6 depends from claim 1 and recites "wherein said moving the filament to the deployed position comprises positioning the distal end of the filament distally beyond the tip of the needle." Ex. 1003, 32:4–7.

Claim 7 depends from claim 1 and recites "wherein said moving the filament to the deployed position places the distal end of the filament at a position that is spaced from a central longitudinal axis of the needle by a distance greater than a radius of the elongate member." Ex. 1003, 32:8–12.

Petitioner contends that "Lee teaches that 'variations in ablation volume may be achieved by varying *the extent to which stylets are extended from the distal end* of the trocar and the direction in which stylets extend" and "illustrates its filaments (22/1622) extending beyond the tip of its device." Pet. 51 (citing Ex. 1010 ¶ 129, Figs. 1, 48, 49; Ex. 1034 ¶ 192). Petitioner further contends that "in the proposed combination, configuring the filaments (22/1622) to extend beyond the distal tip would be an obvious way to expand the device's achievable ablation volume (in comparison to Racz unmodified), which is the problem Fitz identifies as being present in Racz." *Id.* at 52. According to Petitioner, it would have been obvious to an

ordinarily skilled artisan to operate Racz's modified device to position "the distal end of the filament distally beyond the tip of the needle" which corresponds to the limitations of claim 6. *Id.* at 53 (citing Ex. 1034 ¶ 194).

Petitioner next contends that, "in each of Lee's figures, the filament tips extend well outside of the cannula, which means the filament tips are spaced from the cannula's central longitudinal axis by a distance greater than the cannula's radius." Pet. 53 (citing Ex. 1010, Figs. 1, 5, 48, 49; Ex. 1034 ¶ 195). Petitioner further contends that "Lee emphasizes that 'variations in ablation volume may be achieved by varying *the extent to which stylets are extended from the distal end* of the trocar and the direction in which stylets extend." *Id.* (citing Ex. 1010 ¶ 129). According to Petitioner, this disclosure teaches the limitations of claim 7 because one of ordinary skill in the art would understand the filaments (22/1622) would be extended "to any position necessary to produce a desired ablation volume (including where 'the distal end of the filament [is] at a position that is spaced from a central longitudinal axis of the needle by a distance greater than a radius of the elongate member.')." *Id.* (alteration in original).

Patent Owner does not dispute Petitioner's contentions for claims 6 and 7. *See generally* PO Resp.

We have reviewed Petitioner's evidence and contentions and find that the combination of Racz, Fitz, and Lee teaches the limitations of claims 6 and 7.

5. Claim 8

Claim 8 depends from claim 1 and recites "further comprising attaching a return electrode pad to the patient prior to said operating the

radiofrequency probe, the tip, and the filament as the monopolar electrode." Ex. 1003, 32:14–17.

Petitioner first refers to it contentions for limitation 1[g] that "Racz's modified device operates with its tip (14/38) and filaments (22/1622) functioning as a monopolar electrode." Pet. 54. Petitioner contends that "Lee teaches its filaments (22/1622) 'may be used in a monopolar fashion with . . . a return electrode being applied usually in the form a conductive pad in contact with a remote surface on the patient." *Id.* (citing Ex. 1010 ¶ 24) (alteration in original). According to Petitioner, based on this disclosure, an ordinarily skilled artisan would have found it obvious "to attach a return electrode pad to the patient" as required by claim 8. *Id.* (citing Ex. 1034 ¶ 197).

Patent Owner does not dispute Petitioner's contentions for claim 8. *See generally* PO Resp.

We have reviewed Petitioner's evidence and contentions and find that the combination of Racz, Fitz, and Lee teaches the limitations of claim 8.

6. Claims 9 and 20

Claim 9 depends from claim 1 and recites

> wherein the conductive portion comprises a conductive material in the tip, and wherein said inserting the radiofrequency probe into the lumen of the needle such that the radiofrequency probe contacts the conductive portion of the needle comprises contacting a distal end of the radiofrequency probe to the conductive material of the tip.

Ex. 1003, 32:18–24.

Claim 20 depends from claim1 and recites "wherein the probe directly contacts the tip during said operating the radiofrequency probe, the tip, and the filament as the monopolar electrode." Ex. 1003, 32:55–57.

Referring to its contentions for limitations [1e], [1g], and [1h], Petitioner contends that "Racz's distal tip (14/38), and Lee's filaments (22/1622) are all constructed from conductive materials and direct physical contact between them allows the device to operate to transmits the RF energy" and when "RF probe (22/52) is inserted, a distal end of the probe's conductive shaft (54) physically contacts the conductive tip (14/38)." Pet. 54–55 (citing Ex. 1034 ¶ 198). Petitioner further contends that this disclosure corresponds to the limitations of claim 9 that the needle "comprises a conductive material in the tip" and inserting the RF probe results in "contacting a distal end of the probe to the conductive material" in the tip. *Id.* at 55 (citing Ex. 1034 ¶¶ 199–200). Petitioner further contends that this disclosure corresponds to the limitation of claim 20 that "the probe directly contacts the tip during said operating the radiofrequency probe, the tip, and the filament as the monopolar electrode." *Id.*

Patent Owner does not dispute Petitioner's contentions for claims 9 and 20. *See generally* PO Resp.

We have reviewed Petitioner's evidence and contentions and find that the combination of Racz, Fitz, and Lee teaches the limitations of claims 9 and 20.

7. Claim 10

Claim 10 depends from claim 1 and recites "after said inserting the needle into the patient, moving the needle to a target volume within the patient that includes a nerve; and ablating the nerve to relieve pain of the patient." Ex. 1003, 32:25–29.

Petitioner contends that "Racz expressly teaches its device is used for nerve ablation to relieve pain, and to do so necessarily involves inserting the

needle into the patient, moving the device proximate to a target nerve, and ablating the nerve to relieve pain." Pet. 55–56 (citing Ex. 1009, 1:4–10, 3:42–45, 4:49–58, 7:43–50; Ex. 1011 ¶ 7; Ex. 1034 ¶ 201).

Patent Owner does not dispute Petitioner's contentions for claim 10. *See generally* PO Resp.

We have reviewed Petitioner's evidence and contentions and find that the combination of Racz, Fitz, and Lee teaches the limitations of claim 10.

8. Claim 21

For independent claim 21, Petitioner relies on its contentions and evidence for corresponding elements of claim 1. Pet. 56–57.

Patent Owner does not dispute Petitioner's contentions for claim 21. *See generally* PO Resp.

We have reviewed Petitioner's evidence and contentions and find that the combination of Racz, Fitz, and Lee teaches the limitations of claim 21.

9. Claims 18, 19, 28, and 29

Claim 18 depends from claim 10 and recites "wherein said ablating comprises forming a lesion that includes the nerve and has a maximum cross dimension that is 10 millimeters or larger." Ex. 1003, 32:49–51. Claim 28 depends from claim 21 and recites the same limitations. *Id.* at 34:18–20.

Claim 19 depends from claim 10 and recites "wherein said ablating comprises forming a lesion that includes the nerve and has a volume of about 500 $mm^3$." Ex. 1003, 32:52–54. Claim 29 depends from claim 21 and recites the same limitations. *Id.* at 34:30–32.

Petitioner contends that the combination of Racz, Fitz, and Lee teaches the limitations of claims 18, 19, 28, and 29. Pet. 62. Specifically, Petitioner argues that Fitz "disclose[s] an 'improved-coverage RF

neurotomy' device using multiple electrodes (i.e., filaments)" to solve "a 'problem' with single-tip neurotomy devices," such as Racz, which "did not allow for adequate coverage of the target area." *Id.* at 59 (citing Ex. 1011 ¶¶ 4–5, 9). Petitioner next argues that Lee discloses "varying the number, pattern, direction, size, and/or length of the filaments (22/1622)" in order to "define the shapes of [] various ablation volumes." *Id.* at 60 (citing Ex. 1010 ¶¶ 12, 84, 106, 123–131) (alteration in original). Petitioner further argues that the '664 patent follows the teachings of the prior art "and employs ordinary skill to achieve the claimed lesion sizes." *Id.* at 61 (citing Ex. 1034 ¶ 207). According to Petitioner, "by dictating the[] characteristics of the filaments (22/1622)—and the size and/or shape of Racz's tip (14/38)––a [person of ordinary skill in the art] would be capable of configuring Racz' modified device to produce lesion of any desired volume" including those recited in claims 18, 19, 28, and 29. *Id.* at 61–62 (citing Ex. 1015 ¶ 133; Ex. 1019, 282; Ex. 1034 ¶ 208).

Patent Owner does not dispute Petitioner's contentions for claims 18, 19, 28, and 29. *See generally* PO Resp.

We have reviewed Petitioner's evidence and contentions and find that the combination of Racz, Fitz, and Lee teaches the limitations of claims 18, 19, 28, and 29.

10. Claims 22–26

For claims 22–26, which depend from claim 21, Petitioner relies on its contentions for substantially similar limitations from claims 1, 2, 3, and 10. Pet. 56–59.

Patent Owner does not dispute Petitioner's contentions for claims 22–26. *See generally* PO Resp.

We have reviewed Petitioner's evidence and contentions and find that the combination of Racz, Fitz, and Lee teaches the limitations of claims 22–26.

b) Patent Owner's Contentions

i. Adequacy of Motivation to Combine

Patent Owner argues 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." PO Resp. 57 (citing Ex. 2006 ¶¶ 161–167). Patent Owner further argues that, "[i]n the RF neurotomy field specifically, the two approaches were considered mutually exclusive because of the very limited space available at the tip of a small RF neurotomy needle." *Id.* (citing Ex. 2006 ¶ 164). According to Patent Owner, the Petition is flawed because it incorrectly treats the two approaches "as complementary rather than alternatives." *Id.*

For the following reasons, this argument is unavailing.

Patent Owner is arguing that an ordinarily skilled artisan would not have combined Racz's "tine-less device" with "probe-less tined devices" such as Fitz and Lee, because of size limitations at the tip of Racz's device. In other words, Patent Owner is arguing that a device with deployable filaments such as Lee could not be bodily incorporated into Racz's device because of the limited size of Racz's tip. This argument is, thus, unavailing. *In re Mouttet*, 686 F.3d at 1332. Further, the argument does not directly address Petitioner's evidence and reasons for combining the teachings of Racz, Fitz, and Lee, which as discussed above, we find to be persuasive.

ii. Dr. Tucker

Patent Owner asserts that Petitioner's declarant, Dr. Tucker, does not satisfy its definition of a person of ordinary skill in the art. PO Resp. 30. Based on this, Patent Owner argues that we should give little weight to his testimony.

For the following reasons, we disagree with Patent Owner's assertion.

First, the argument is unavailing because we do not adopt Patent Owner's definition of the level of ordinary skill in the art. Contrary to Patent Owner's argument, 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. 1034 ¶ 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 Owner[14]). *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. 30–31. 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:

> I have a Ph.D. in engineering and had no intention of doing pathology on patient samples day-to-day. I wanted to combine

[14] *See* PO Resp. 31 (citing Ex. 2020, 10:19–12:20).

> 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, as explained elsewhere in this Decision, his testimony adequately supports motivation to combine and a reasonable expectation of success.

iii. Lee is not Analogous Art

Patent Owner contends that Lee is not analogous art. PO Resp. 34. According to Patent Owner, "the pertinent field must include RF neurotomy." Patent Owner argues that "Lee does not relate to neurotomy at all" and would qualify as prior art only if "reasonably pertinent" to the problem with which the inventors of the '664 patent were concerned. *Id.* at 34–35.

Patent Owner next contends that Lee is not reasonably pertinent because it "pertains to a different non-overlapping field of RF ablation involving much larger structures, different target tissue, different physician users, different devices, different scale of devices" and sought to solve a problem of "sufficiently ablating uterine fibroid tumors, several orders of magnitude larger than nerves." PO Resp. 35 (citing Ex. 2001 ¶¶ 172–181; Ex. 2006 ¶¶ 153, 222). According to Patent Owner, "[t]he sufficiency-of-ablation problem in Lee is not reasonably pertinent to the miss-the-nerve problem solved by the" '664 patent. *Id.*

Petitioner responds that "Lee is within the patent's field of 'thermal ablation systems and methods" because "Lee discloses an RF ablation needle" and its "needle shares a similar structure and function to the ['664]

patent's needle." Pet. Reply 8–9 (citing Pet. 17–21, 36–41; PO Resp. 22; Ex. 1003, 1:32–62, 5:33–6:22, 24:35–38; Ex. 2006 ¶ 34).

Petitioner alternately argues that Lee is "'reasonably pertinent' to the inventors' problem: expanding the needle's ablation volume." Pet. Reply 9 (citing Pet. 2, 7; PO Resp. 5; Ex. 1003, 5:42–45, 6:11–22; Ex. 2001 ¶¶ 121–122; Ex. 2006 ¶ 91). According to Petitioner, Patent Owner "conflates the field of endeavor and reasonable pertinence inquiries, 'effectively exclude[ing] consideration of any references outside [the patent's] field." *Id.* (citing *Donner Tech., LLC v. Pro Stage Gear, LLC*, 979 F.3d 1353, 1360 (Fed. Cir. 2020)) (alterations in original).

For the following reasons, we find that Lee qualifies as analogous art.

For a prior-art reference to qualify as analogous art, the reference must either be in the field of the applicant's endeavor or reasonably pertinent to the problem with which the inventor was concerned. *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992). References are selected as being reasonably pertinent to the problem based on the judgment of a person having ordinary skill in the art. *Id.* ("[I]t is necessary to consider 'the reality of the circumstances,' —in other words, common sense—in deciding in which fields a person of ordinary skill would reasonably be expected to look for a solution to the problem facing the inventor." (quoting *In re Wood*, 599 F.2d 1032, 1036 (CCPA 1979))). Furthermore, the scope of analogous art for the reasonably pertinent prong is to be construed broadly. *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1238 (Fed. Cir. 2010) ("The Supreme Court's decision in *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007), directs us to construe the scope of analogous art broadly, stating that '*familiar items may have obvious uses beyond their primary purposes*, and a

person of ordinary skill often will be able to fit the teachings of multiple patents together like pieces of a puzzle.' *Id.* at 402 (emphasis added).").

As discussed above, we find that the field of invention is thermal ablation systems or methods and is not limited to RF neurotomy systems or methods. Lee discloses methods that "utilize radio frequency heating of tissues for ablation or shrinkage by the application of energy to the tissues through specialized delivery devices" that "have electrodes or antenna that are placed into, or onto, the tissue to be treated." Ex. 1010 ¶ 83. Lee further discloses that "energy delivery devices are provided which are adapted to the destruction of target tissue at the site where the electrodes are located." *Id.* ¶ 84. Based on this disclosure in Lee, we find that Lee is in the field of RF thermal ablation systems and qualifies as analogous art.

Further, even if the field of the invention were to be limited strictly to RF neurotomy as Patent Owner asserts, Lee would qualify as reasonably pertinent art. Similar to the challenged patent, Lee teaches using RF current to shrink tissue, i.e, "a uterine fibroid" rather than nerve tissue. Ex. 1010 ¶ 84. In accordance with the Federal Circuit's direction in *Wyers* to construe the scope of analogous art broadly, Lee is reasonably pertinent to the problem facing the inventors of the '664 patent.

iv. Reasonable Expectation of Success

Patent Owner contends that an ordinarily skilled artisan would not have had a reasonable expectation of success. PO Resp. 43. Patent Owner argues that Petitioner's "sole support" for reasonable expectation of success "is Dr. Tucker's bald conclusion which is entitled to no weight." *Id.* Patent Owner offers Mr. Crosby's testimony that details alleged "impediments a [person of ordinary skill in the art] would encounter trying

to ***make*** Racz's modified device." *Id.* (citing Ex. 2006 ¶¶ 273, 221–260). According to Patent Owner, "Racz's modified device "would be either impossible to fabricate or doing so would require undue experimentation and have no reasonable expectation of success." *Id.* (citing Ex. 2006 ¶ 221; Ex. 2020, 112:5, 123:6).

Patent Owner first argues that "the channels for the filaments 'would be extremely challenging, if not impossible to fabricate. That is true even assuming the tip in Racz's modified device is straight; it would be even more difficult . . . if the tip is bent or curved, as emphatically taught by Racz." PO Resp. 43–44 (citing Ex. 2006 ¶ 225). Based on the testimony of Dr. Russo and Mr. Crosby, Patent Owner argues that "[a]t its largest an RF neurotomy needle would be 16 gauge with a 1.65-mm outer diameter and 1.19-mm inner diameter, meaning the sidewall is 0.22 mm thick." *Id.* at 45 (citing Ex. 2001 ¶¶ 158–160, 230–236; Ex. 2006 ¶ 235). According to Patent Owner, "[t]he channels must be notably smaller in diameter, and the filaments must be smaller still in diameter" and an ordinarily skilled artisan "would not reasonably expect to be able to successfully make such narrow channels of any appreciable length, as would be required to make Racz's modified device in any form." *Id.*

Patent Owner next contends that Mr. Crosby considered every way that an ordinarily skilled artisan might reasonably consider to form the channels in Racz's modified device "and concluded that a [person of ordinary skill in the art] would have no reasonable expectation of success that any such way would succeed." PO Resp. 44 (citing Ex. 2006 ¶¶ 235–245). According to Patent Owner, Mr. Crosby testifies that "drilling, including laser drilling", "casting or sintering", "injection molding",

"extrusion", or "3D printing" would all present a "challenge that would be too great for a [person of ordinary skill in the art]" to have a reasonable expectation of success." *Id.* at 44–45 (citing Ex. 2006 ¶¶ 246, 248–252); *id.* at 45 (arguing that Mr. Crosby testifies that the alleged challenges would be "considerably more difficult for a curved tip, as required by Racz" (citing Ex. 2006 ¶¶ 244, 247)); *id.* at 46 (arguing that Mr. Crosby "considers the possibility that Racz's modified device is made of conductive plastic rather than metal" and reaches a similar conclusion (citing Ex. 2006 ¶ 254)).

Patent Owner next argues that filaments for use with a 16-gauge needle for neurotomy "would be so fragile that the risk of bending unpredictably, permanently deforming, or possibly breaking within the patient's body would defeat any reasonable expectation of success." PO Resp. 48 (citing Ex. 2006 ¶¶ 277–282). Patent Owner also points to testimony by Dr. Russo that filaments "within the sidewall of a 16-to-22 gauge needle . . . present significant risks of being damaged or deflected." *Id.* (citing Ex. 2001 ¶ 215).

Petitioner, in turn argues that the '664 patent "describes an elongate cannula, RF probe, deployable filaments, actuator, and a filament-guiding tip (separately attached or formed as a 'single unitary structure' with the cannula)." Pet. Reply 16 (citing Ex. 1003, 5:33–6:22, 8:46–53). According to Petitioner, "[t]he patent is *silent* on how to make these components . . . demonstrat[ing] that the 'purported novelty' was not in *manufacturing* the claimed invention—that was within the level of ordinary skill." *Id.* (case citations omitted). Petitioner further contends that Mr. Crosby "testified that a [person of ordinary skill in the art] would have been able to make the disclosed RF needles in the '688 patent (which shares the '664 patent's

specification)" and that "the prior art is silent on manufacturing techniques, further reflecting that making RF needles is within the level of ordinary skill." *Id.* (citing Ex. 1045, 272:9–279:15, 280:6–12, 284:8–285:17, 295:7–22).

Petitioner next contends that "Lee provides a blueprint for how to implement deployable filaments." Pet. Reply 17 (citing Pet. 31–38). According to Petitioner, "Lee illustrates how the filaments can be arranged around the cannula's inner perimeter and deployed around the tip" which "is an ideal configuration to preserve the functionality of Racz's probe." *Id.* (citing Ex. 1034 ¶¶ 125–131, 140–148, 161). Petitioner further contends that an ordinarily skilled artisan "would have known that Lee's device would produce an ablation volume having a nearly identical shape to the claimed invention." *Id.* at 18 (citing Ex. 1045, 161:15–162:19, 175:19–176:5; Ex. 1051, 1, Ex. 2006 ¶¶ 230–232; Ex. 2010, 21–22).

Petitioner next contends that Patent Owner's "reasonable expectation of success arguments depend on its experts' unsupported—and false—testimony that neurotomy needles cannot be larger than 16–gauge." Pet. Reply 19 (citing PO Resp. 4, 43–44, 48, 50; Ex. 2001 ¶¶ 47, 155–169, 210–215; Ex. 2006 ¶¶ 158, 228–253, 267). Petitioner contends that Patent Owner "agree[s] that Racz discloses an RF neurotomy needle" and "Racz expressly teaches that its needle comes in 'many variations,' including from *10- to 30-gauge*." *Id.* (citing PO Resp. 19; Ex. 1009, 8:10–15). Petitioner argues that "[t]here are other examples of RF neurotomy needles larger than 16-gauge too." *Id.* (citing Ex. 1015 ¶ 40; Ex. 1056, 160). Petitioner further argues that Patent Owner's "only 'evidence' of its assertion are its expert declarations . . . neither Crosby nor Russo point to *any evidence* that

neurotomy needles must be 16-gauge or smaller." *Id.* (citing Ex. 1003, 8:10–15).

Petitioner also takes issue with Patent Owner's argument that "0.2 mm nitinol filaments don't work." Pet. Reply 20 (citing Ex. 2006 ¶¶ 276–282). According to Petitioner, "the patents say [0.2 mm filaments] do" work. *Id.* (citing Ex. 1001, 21:49–52, 22:37–49; Ex. 1003, 9:62–64).

In the Sur-reply, Patent Owner argues that Petitioner's reliance on the failure of the Specification to address how to manufacture the disclosed invention should be discounted because Patent Owner's "invention is ***different*** from RMD and does ***not*** have the unique enablement flaws that RMD has." Sur-reply 5–6. According to Patent Owner, "[t]hose flaws relate to having ***long narrow channels in the sidewall of a needle***" and the "evidence establishes that the those long narrow channels in the sidewall of a needle cannot be made." *Id.* at 6 (citing PO Resp. 43–46).

Patent Owner next argues that "Lee's filaments extend down the ***internal lumen*** of a cannula 1615 and then through short grooves in an external surface of a tip 1614" but "Lee does not teach how to implement his deployable filaments in impossible-to-make long narrow channels fully ***within the sidewall*** of that cannula (let alone a smaller cannula)." Sur-reply 6.

With respect to Racz's disclosure of a needle larger than 16-gauge, Patent Owner argues that the passage relied on by Petitioner (Ex. 1009, 8:10–15) is "vague" and "does not actually say that a ***neurotomy*** needle could be as big as 10-gauge." Sur-reply 9. According to Patent Owner, the passage "suggests that a larger (or smaller) needle may be associated with one of 'many variations" but "Racz explains that those 'many variations'

include 'other medical and surgical procedures' apart from neurotomy." *Id.* (citing Ex. 1009, 9:12–18).

Patent Owner next argues that Dr. Russo "is a peer-recognized worldwide leader in the field of RF neurotomy" and performs RF neurotomy procedures "a dozen times per day." Sur-reply 9. Patent Owner further argues that Dr. Russo "cogently explained why neurotomy needles are between 16- and 22- gauge." *Id.* (citing Ex. 2001 ¶¶ 157–169).

Patent Owner does not dispute that its patents disclose ranges for filament sizes that encompass filaments with a diameter of 0.2 mm. Sur-reply 15 (citing Pet. Reply 20). Patent Owner argues, however, that its "commercial embodiments have considerably thicker filaments." *Id.*

Analysis

"[A] conclusion of obviousness requires a reasonable expectation of success." *Intelligent Bio-Sys.*, 821 F.3d at 1365 (citing *KSR*, 550 U.S. at 421) (alteration in original). "The reasonable expectation of success requirement refers to the likelihood of success in combining references *to meet the limitations of the claimed invention*." *Id.* at 1367 (emphasis added). In evaluating reasonable expectation of success, we must consider the appropriate scope of the "claimed invention." *Id.* (emphasis omitted). "Obviousness does not require absolute predictability of success . . . all that is required is a reasonable expectation of success." *In re O'Farrell*, 853 F.2d 894, 903–04 (Fed. Cir. 1988) (citations omitted). With these principles in mind, we evaluate the parties' respective contentions.

We start by determining the appropriate scope of the claimed invention so that we can evaluate the parties' respective contentions.

Independent claims 1 and 21 recite a "method" for "inserting" or "introducing a needle" into a patient. Ex. 1003, 31:32–53, 32:58–33:10. Neither claim 1 nor claim 11 contains any limitations concerning RF neurotomy or requiring ablation of any tissue at all let alone nerve tissue. *See id.* Further, neither claim 1 nor claim 11 nor any claim depending from either claim recites any limitation concerning needle size or filament size. *See id.* at 31:32–34:29. Claims 10–19 and 26–29 recite limitations relating to thermal ablation of nerve tissue but do not recite any limitation concerning needle size or filament size. *Id.* at 32:25–54, 34:8–23. Consequently, the issues raised by Patent Owner relating to needle size and filament size appear to be inapposite because no claim of the '664 patent requires a particular needle or filament size.

The Specification of the '664 patent provides the following relevant disclosure:

> The filaments 206a, 206b may be at least partially disposed within the elongate member 203 and may be operable to emerge through a side wall of the needle 103 proximate to the distal end of the needle 103.

Ex. 1003, 5:46–49; Fig. 2A.

> The elongate member 203 may be of any appropriate size and internal configuration to allow insertion into the patient 101 and to house componentry therein. In an exemplary embodiment, the elongate member may, for example, be a 16 gauge round tube or smaller. For example, the elongate member 203 may be 18 or 20 gauge. For example, the elongate member may have a maximum cross dimension of at most 1.7 mm. In another example, the elongate member may have a maximum cross dimension of at most 1 mm.

*Id.* at 8:10–19.

> The filaments 206a, 206b may be constructed from a material operable to conduct RF energy, e.g., a metal such as stainless steel, Nitinol or shape memory alloy.

*Id.* at 10:62–64.

> *The filaments discussed herein may be encased within lumens sized to help prevent buckling or bending of the filaments within the elongate member 203. Such lumens may be part of the elongate members (e.g., tubes within the elongate member).* Such lumens may be formed by an inner member (not shown) within the elongate member where the inner member includes channels along its periphery in which the filaments may lie with the elongate member forming a portion of the lumens.

*Id.* at 16:53–63 (emphasis added).

In its related '782 patent,[15] Patent Owner discloses filament diameters in the range of between approximately 0.06mm and about 1mm. Ex. 1001, 22:28–31; Tr. 69:8–16. Patent Owner does not dispute that this range is disclosed but argues, based on the testimony of Dr. Russo and Mr. Crosby, that filaments within at least part of this range would be inappropriate for use in RF neurotomy procedures. PO Resp. 48 (citing Ex. 2001 ¶¶ 215, 217, 218, 220; Ex. 2006 277–282); Tr. 69:7–11 ("the lower end [of the range in the patents] would not be suitable").[16] Given the disclosure in the related '782 patent of a range of filament sizes with no indication that the entire range is not suitable for RF neurotomy, the testimony of Dr. Russo and Mr. Crosby concerning reasonable expectation of success of the "claimed

[15] The application for the '782 patent was filed on the same day as the application for the '664 patent and claims priority to the same prior applications as does the application for the '664 patent. Ex. 1001, codes (22), (63); Ex. 1003, codes (22), (63).

[16] Young '965 discloses filaments "in the range from 0.05 mm to 0.3 mm, preferably from 0.1 mm to 0.2 mm. Ex. 1012 ¶ 30; *see also* Pet. 65 (arguing that "Young '965 would have confirmed to a [person of ordinary skill in the art] that Lee's filaments (22/1622) would be implemented in sizes as small as 0.2 mm wide and easily implemented into Racz's cannula (10/33)").

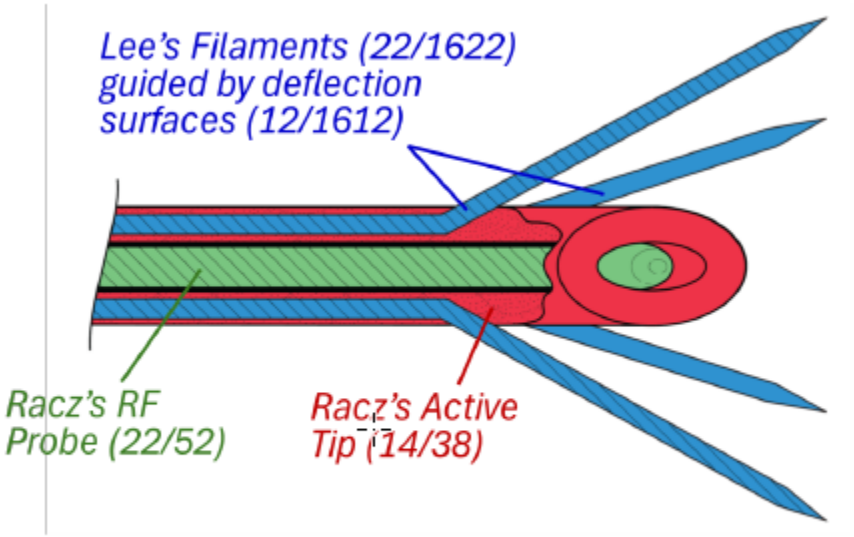
invention" based on filament size for RF neurotomy is entitled to little weight because it does not align with the disclosure of '664 patent and/or the '782 patent.

Patent Owner does not direct us to any part of the '664 patent Specification describing a technique for forming the lumens with channels in the sidewalls of the elongate member described in the Specification. Our review of the Specification of the '664 patent does not reveal any such description. This lack of description of how to form internal lumens in both Lee and the '664 patent supports a finding that one of ordinary skill in the art would have had a reasonable expectation of success in modifying Racz as proposed by Petitioner because the techniques for making lumens either in the tip or along the length of the elongate member in the proposed combination would have been within the knowledge of an ordinarily skilled artisan.

We now turn to the relevance of RF neurotomy needle size and filament size to reasonable expectation of success. Claims 1–9 and 20–26 are not limited to ablating nerve tissue, do not recite any filament size, and do not recite any needle size. Consequently, even if we accept Patent Owner's position that RF neurotomy needles can be no larger than 16 gauge, the question of needle size and filament size is irrelevant to reasonable expectation of success for claims 1–9 and 20–26.

Claims 10–19 and 27–29, are directed to ablating nerve tissue, but do not recite any needle size or filament size. For the reasons discussed below, we determine that Patent Owner's arguments are unavailing for these claims as well.

We reproduce below an example offered by Petitioner of the proposed combination of Racz and Lee:




*Dr. Tucker Declaration at ¶143 (showing one example of how a POSA would modify Racz to include Lee's filaments)*

Pet. 27. The above drawing shows Racz's active tip (14/38) in red, Racz's RF probe (22/52) in green, and Lee's filaments (22/1622) guided by deflection surfaces (12/612) in blue near the left end of Racz's active tip. Ex. 1034 ¶¶ 143–144.

Patent Owner interposes a series of arguments based on Mr. Crosby's testimony that "the channels for the filaments 'would be extremely challenging, if not impossible to fabricate." PO Resp. 43–47. These arguments are premised on a needle no larger than 16 gauge for RF neurotomy procedures. *Id.* at 44. Based on a 16-gauge needle, Patent Owner provides calculations of wall thickness of the tip and filament size for Petitioner's example. *Id.*; Sur-reply 16 (providing drawing illustrating wall thicknesses based on Mr. Crosby's calculations). These arguments are unavailing for several reasons.

Racz discloses a needle size as large as 10 gauge. Ex. 1009, 8:10–15. The parties, however, dispute whether or not Racz's disclosure of needles larger than 16 gauge could be used for RF neurotomy or whether it refers to other type of tissue ablation procedures. Pet. Reply 19; Sur-reply 8–9. As discussed above, the '664 patent discloses example embodiments that are 16 gauge or smaller but does not describe that 16 gauge is the maximum diameter for use in RF neurotomy. *See* Ex. 1003, 8:8–19.

Patent Owner does not ask us to construe these claims as limited to needles of 16-gauge and smaller. *See generally* PO Resp. Nor do we view the examples of needle size in the Specification as either lexicographical definitions or disclaimer of claim scope. Patent Owner's reasonable expectation of success arguments, therefore, are premised on an inappropriate incorporation of an exemplary embodiment in the Specification of a maximum 16-gauge needle into the claims and some undefined minimum filament size. Consequently, Patent Owner's arguments are unavailing and do not undercut Petitioner's showing.

Petitioner provides several arguments in support of motivation to combine including that "implementing Lee's deployable filaments (26/1622) while preserving the functionality of Racz's cannula (10/33), active tip (14/38), and removable probe (22/52)" "would involve nothing more than using prior art elements according to their established functions and combining them in a way that would achieve an expected improvement." Pet. 26 (citing Ex. 1034 ¶¶ 144–147). As discussed above, we agree with Petitioner and find that an ordinarily skilled artisan would have been motivated to combine Racz, Fitz, and Lee. In a case such as this, where motivation to combine arguments are intertwined with reasonable

expectation of success, a finding of motivation to combine also implicates, and therefore, supports a finding of reasonable expectation of success. *See Elekta Ltd. v. ZAP Surgical Sys., Inc.*, 81 F.4th 1368, 1376 (Fed. Cir. 2023).

After considering the parties' respective contentions and all of the evidence of record, given our finding that the proposed combination is a simple substitution of known components performing known functions to achieve an expected result, we find that Petitioner has shown that a person of ordinary skill in the art would have had a reasonable expectation of success in the proposed combination.

v. Vagueness of the Proposed Combination

Patent Owner next contends that the Petition fails to satisfy the "particularity' requirement of 35 U.S.C. § 312 because the Petition's description of Racz, as modified by Fitz and Lee, suffers from "numerous omissions, ambiguities, and confusing aspects." PO Resp. 38 (citing Ex. 2001 ¶¶ 182–201).

Patent Owner provides the following criticisms of the Petition:

1) "[T]he petition and Dr. Tucker present just one partial view of Racz's modified device, from just one perspective." PO Resp. 38. Patent Owner argues that no side views, perspective/isometric views are presented, the Petition does not depict or describe the structure in the proximal direction, or how many filaments are included and where the filaments are located. *Id.* at 39 (citing Ex. 2006 ¶¶ 182, 184).
2) No dimensions are provided on the drawing. *Id.* at 39 (citing Ex. 2006 ¶ 190).

3) "[T]here is uncertainty regarding the filaments and their channels." *Id.* at 40 (citing Ex. 2006 ¶ 187). Patent Owner argues that "there is no description of how those channels are made." *Id.*
4) "[I]t is unknown whether the tip remains bent, as taught by Racz, or has been straightened to accommodate the filaments in Racz's modified device." *Id.* (citing Ex. 2006 ¶ 191).
5) "[I]t 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." *Id.* at 41 (citing Ex. 2006 ¶ 184).
6) "[I]t is also unknown . . . 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." *Id.* (citing Ex. 2006 ¶ 188).
7) "[I]t appears that no features of Fitz are incorporated into this modified device, but that it not clear." *Id.* (citing Ex. 2006 ¶ 193).
8) "Dr. Tucker refers to two examples of Racz's modified device, but the differences between them are not clear" it is not "clear from the petition or Tucker's declaration if there are other (unillustrated) examples that he or the petitioner intends to rely upon." *Id.* (citing Ex. 2006 ¶¶ 195–197; Ex. 2020, 112:9–113:5).

Petitioner, in turn, argues that "obviousness does not require the art be 'physically combinable,' must less in the exacting detail" that Patent Owner suggests. Pet. Reply 12. Petitioner further argues that "there is evidence of a known problem, known solution, and that combining the art was within the skill of a [person of ordinary skill in the art]—'nothing more is required to

show motivation to combine." *Id.* According to Petitioner, "[t]he detail in the Petition and Dr. Tucker's declaration, which provided 'Racz's modified device' as a helpful example, went beyond what is required." *Id.* (citing Pet. 23–27, 35–45; Ex. 1034 ¶¶ 143–148, 157–179).

For the following reasons, Patent Owner's arguments are unavailing.

We first note that Patent Owner is not "disputing the presence of any particular claim limitation in the prior art collectively." Tr. 61:12–18. Consequently, these allegedly "numerous omissions, ambiguities, and confusing aspects" in the Petition have no relevance to whether the Petition has established that the combination of Racz, Fitz, and Lee teaches each and every limitation of the Challenged Claims.

Patent Owner's arguments that Petitioner must provide multiple detailed views of the entire exemplary device from distal to proximal end with dimensions is far beyond what is required to show motivation to combine or reasonable expectation of success. *See Intel*, 61 F.4th at 1381. Further, Patent Owner does not tie these allegedly missing items to the claimed invention, but rather they are directed to unclaimed structural elements such as filament size, number of filaments, size of the needle, whether the probe is curved or straight at its tip, and whether Lee's anchors and RF signal source are included or not.

Petitioner is required to show a motivation to combine the *teachings* of Racz, Fitz, and Lee, not show that the structures of Fitz and/or Lee can be bodily incorporated into Racz. *In re Mouttet*, 686 F.3d at 1332. As discussed above, Petitioner has shown that the combination teaches each and every claim limitation and that an ordinarily skilled artisan would have been

motivated to combine Racz. Fitz, and Lee with a reasonable expectation of success.

vi. Modified Device not Enabled

Patent Owner next repackages its lack of reasonable expectation of success argument as a failure by Petitioner to satisfy the "enablement requirement." PO Resp. 49–51. According to Patent Owner, "[t]he references in an obviousness challenge must collectively teach a [person of ordinary skill in the art] how to make the claimed invention" and that "Racz, Fitz, and Lee do not, collectively, enable a [person of ordinary skill in the art] to make Racz's modified device." *Id.* at 49. Patent Owner then directs us to Mr. Crosby's testimony, referenced above in connection with reasonable expectation of success, that "it is not possible to construct Racz's modified device without undue experimentation, if at all." *Id.* (citing Ex. 2006 ¶¶ 261–271).

Patent Owner's arguments are inapposite. The law does not impose an "enablement" requirement in regards to a *combination* of references in an obviousness challenge.

Patent Owner cites to several cases, none of which support its arguments. First, it cites to *Beckman Instruments, Inc. v. LKB Produktor AB*, 892 F.2d 1547 (Fed. Cir. 1989). *Beckman* involved anticipation and the Federal Circuit merely explained that "[e]ven if a reference discloses an inoperative device, it is prior art for all that it teaches." *Id.* at 1551. Second, it cites to *Bristol-Myers Squibb v. Ben Venue Labs, Inc.*, 246 F.3d 1368, 1374 (Fed. Cir. 2001). This case also involved anticipation and the Federal Circuit explained that "[t]o anticipate, the reference must also enable

one of skill in the art to make and use the claimed invention." *Id.* at 1374. Neither case supports Patent Owner's position.

Patent Owner next cites to *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). *Wands* is an appeal from our predecessor, the Board of Patent Appeals and Interferences, in which the Board affirmed an examiner's rejection of a patent application as failing to satisfy the enablement requirement set forth in 35 U.S.C. § 112, first paragraph. *Id.* at 733. This case does not support Patent Owner's position.

For the foregoing reasons, Patent Owner's enablement argument is unsupported and unavailing.

vii. Teaching Away

Patent Owner contends that in Petitioner's proposed combination, "the filaments would need to be extraordinarily thin or narrow" and "so flexible as to be bent by tissue in unpredictable manners as they exit the needle or possibly not even be able to pass through the tissue." PO Resp. 51 (citing Ex. 2001 ¶¶ 217–218; Ex. 2006 ¶ 282). According to Patent Owner, "Racz expressly teaches away from deploying a flexible electrode from a cannula in the context of neurotomy for these exact reasons." *Id.* at 52. Patent Owner cites to Racz's disclosure that "flexible off-axis electrodes have a limitation that their tips cannot penetrate tough tissue or encounter hard bone without being damaged or diverted." *Id.* (citing Ex. 1009, 2:26–37) (emphasis omitted).

Patent Owner argues that Racz teaches away from using a straight tip. PO Resp. 53. Patent Owner argues that "Racz repeatedly and clearly says the tip 14 should be curved to go around anatomical obstacles, such as the structure 16 illustrated in Figure 1." *Id.* at 53–54 (reproducing Ex. 1009,

Fig. 1). Patent Owner contends that "Racz is emphatic in teaching a curved tip" and identifies straight needles as problematic." *Id.* at 54 (citing Ex. 1009, 1:63–2:15, 2:30–42, 2:57–3:17, 4:49–5, 9:40, 10:31, 10:42). According to Patent Owner, an ordinarily skilled artisan "would interpret Racz as teaching that a curved or bent tip is an ***essential*** feature of Racz's probe" and "Racz's devices, and any variations thereof, require a permanently bent tip." *Id.* (citing Ex. 2001 ¶ 151; Ex. 2006 ¶ 203).

Patent Owner next contends that Lee's "anchors are a necessity to prevent movement of the needle when Lee's stylets are deployed unless, the stylets are deployed 'one at a time.'" PO Resp. 56 (citing Ex. 1010 ¶¶ 89, 110). According to Patent Owner, "[i]t is unclear how the filaments (Lee's stylets) are deployed in Racz's modified device, but neither the petition nor Dr. Tucker has indicated that they would be deployed one at a time," and Lee would teach away from Racz's modified device if "the filaments in Racz's modified device are deployed all at once and Racz's modified device does not have anchors." *Id.* (citing Ex. 2006 ¶ 289).

Petitioner, in turn, replies "Racz indicated that 90's-era electrodes having flexible curved tips . . . were effective 'in certain neural regions such as the trigeminal ganglion or the pituitary gland." Pet. Reply 13 (citing Ex. 1009, 2:26–35). Petitioner argues that "Racz suggests a preference for a bent tip in limited scenarios but never requires it." *Id.* at 14 (citing Ex. 1045, 129:15–131:2, 133:17–134:10). Petitioner further argues that "Lee is unequivocal that its anchors are optional." *Id.* (citing Ex. 1010 ¶¶ 90, 114).

Petitioner next argues that "the curved-tip electrodes Racz mentions bear no resemblance to the deployable filament in Fitz/Lee." Pet. Reply 13 (citing Ex. 1010, Fig. 48; Ex. 1058). Petitioner contends that "Lee teaches

'straight electrodes . . . have superior mechanical advantages over curved,' allowing them to 'push[] into and through . . . 'tough fibroid tumor[s].'" *Id.* at 13–14 (citing Ex. 1010 ¶ 87) (alterations in original). Based on this disclosure, a person of ordinary skill in the art "would not be dissuaded from using Lee's filaments to expand Racz's ablation volume." *Id.* at 14.

With respect to Patent Owner's reliance on Racz's requirement of a curved or bent tip and Lee's requirements for anchors, Petitioner argues "[t]he claims do not require a straight (or bent) tip or anchors" and its "arguments do not turn on them either." Pet. Reply 14 (citing Ex. 1003, 31:32–34:23; Ex. 2020, 46:16–48:3, 68:17–69:13).

For the following reasons, we are not persuaded by Patent Owner's teaching away arguments.

A reference must be considered for all it discloses, both disclosure that teaches away from the invention at issue as well as disclosure that points toward and teaches the invention. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 296 (Fed. Cir. 1985). A reference does not teach away "if it merely expresses a general preference for an alternative invention but does not 'criticize, discredit, or otherwise discourage' investigation into the invention claimed." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009). "The degree of teaching away will of course depend on the particular facts; in general a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994).

We initially note that Patent Owner frames its teaching away arguments as "teaching away from Racz's modified device." PO Resp. 51.

However, the pertinent question is whether Racz and/or Lee teach away from the claimed invention.

With respect to Racz, as discussed above, none of the challenged claims recites any particular filament size. Further, none of the challenged claims requires that the tip of the recited needle be straight or bent. For example, claim 1 merely recites "a piecing tip at a distal end of the elongate member." Ex. 1003, 31:35. Consequently, the scope of claim 1 is broad enough to encompass both a curved piercing tip or a straight piercing tip.

There is no dispute that Racz is directed to RF neurotomy. Ex. 1009, 1:55–2:15; *see* Pet. 5. We agree with Petitioner that Racz describes flexible electrodes as useful in RF neurotomy procedures. Pet. Reply 13. Racz discloses that flexible electrodes with curved tips 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, 2:32–35. Because the claimed invention does not require any filament size or a straight tip, we do not perceive how Racz can be said to teach away from the invention as claimed. Rather, it discloses a device used to ablate nerves including a piercing tip at its distal end, albeit a curved tip. These disclosures suggest the claimed invention. Consequently, we find that Racz, when considered in its entirety, does not teach away from the claimed invention.

Lee discloses that "[i]t is also contemplated in accordance with the invention that there are circumstances where anchors might not be applied at all." Ex. 1010 ¶ 90. Further, Lee discloses that "if desired, anchors may not be deployed. An implementation of a use of the inventive trocar 10 without anchors would be promoted by advancing the ends of stylets 22 one at a

time." *Id.* ¶ 104. Lee clearly contemplates circumstances where anchors may not be used and gives an example of a circumstance where anchors are not required. Based on this, we find that Lee does not teach away from using anchors or not using anchors. While Lee can be interpreted as stating a preference for using anchors, Lee does not discourage a person of ordinary skill in the art from using or not using anchors. More pertinently, none of Challenged Claims recites the use of anchors or preclude the use of anchors so Lee does not teach away from any aspect of the claimed invention.[17]

viii. There is a simpler way to combine the references

Patent Owner contends that, "[s]etting aside whether a [person of ordinary skill in the art] would have had sufficient motivation to do so, the teachings of Racz and Fitz could be combined in a much simpler way to achieve the expanded-ablation-volume objective stated in the petition." PO Resp. 58 (citing Ex. 2006 ¶¶ 168–175). The fact that there may be a better way to combine the references is not determinative of whether or not Petitioner has shown a motivation to combine. *In re Mouttet*, 686 F.3d at 1334 ("This court has further explained that just because better alternatives exist in the prior art does not mean that an inferior combination is inapt for obviousness purposes."). Consequently, Patent Owner's contention is unavailing.

[17] With respect to Patent Owner's argument that Lee's anchors are needed to prevent needle movement "when Lee's stylets are deployed, unless the stylets are deployed 'one at a time'" (PO Resp. 56), claim 1 requires only one stylet to be deployed. Ex. 1003, 31:37–40.

ix. Objective Indicia of Non-Obviousness

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. 61.

Objective indicia evidence "must always 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 (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. 74. According to Patent Owner, this is because the "Nimbus devices embody at least challenged claim 1 and are coextensive with claim 1." *Id.* at 73 (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 '664 patent and the two related patents that are the subject of *inter partes* reviews No. IPR2024-

01209, No. IPR2024-01210, and No. IPR2024-01211. Ex. 2006 ¶¶ 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, what the claim chart compares to claim 1 of the '664 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.

Patent Owner describes the "Nimbus device" as "includ[ing] all components recited in the claim and little else." PO Resp. 73. The "little else" apparently refers to the recited "radiofrequency probe." *Id.* at 14 ("Stratus *additionally* sells both reusable and disposable varieties of RF probes") (emphasis added). Thus, there is a clear disconnect between Patent Owner's position that "the Nimbus *devices* embody at least challenged claim 1 and are coextensive with claim 1" (PO Resp. 72) and its evidence. The testimony of Mr. Crosby cited by Patent Owner refers only to the Nimbus *device* (without the RF probe).

In Mr. Crosby's testimony quoted above, he relies on Exhibit 2008. Ex. 2006 ¶21. Exhibit 2008, however, does not support his testimony. For limitation 1[g] (i.e., "a radio frequency probe"), the claim chart fails to map limitation 1[g] to any portion of the Nimbus device. Instead, the claim chart maps limitation [1g] to one of two additional Nimbus products: "Stratus offers two types of RF probes, reusable and disposable, for use with its needle." Ex. 2008, 9. As Petitioner correctly points out, "[i]t is undisputed that all claims require an RF probe." Pet. Reply 25 (citing Ex. 1003, claim 1; Ex. 1045, 95:22–96:9).

In its Sur-reply, Patent Owner argues that, for presumption of nexus, "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, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (quoting *Demaco*, 851 F.2d at 1392). Patent Owner failed to do this.

Thus, Patent Owner has failed to show that its objective indicia evidence bears a nexus to the claimed invention and its evidence is entitled to little, if any, weight.

11. Balancing the *Graham* Factors

After weighing all the evidence submitted by the parties in light of the *Graham* factors, we determine Petitioner has demonstrated by a preponderance of the evidence that the claims 1, 3–10, 18–26, 28, and 29 would have been obvious over Racz, Fitz, and Lee. As discussed above, Petitioner's evidence establishes that the combination of Racz, Fitz, and Lee teaches every limitation of claims 1, 3–10, 18–26, 28, and 29 and that an ordinarily skilled artisan would have been motivated to combine Racz, Fitz, and Lee with a reasonable expectation of success. Further, as discussed above, Patent Owner's evidence of secondary considerations is entitled to little, if any, weight because Patent Owner fails to establish nexus. Consequently, after considering all the evidence in the record both for and against patentability, we determine that Petitioner has shown by a

preponderance of the evidence that claims 1, 3–10, 18–26, 28, and 29 would have been obvious over Racz, Fitz, and Lee.

E. Ground B: Obviousness in view of Racz, Fitz, Lee and Young '965

Petitioner contends that claims 1–10, 18–26, and 28–29 are also obvious over Racz, Fitz, Lee, and Young '965. Pet. 62–67.

Patent Owner argues that Young '965 does not cure the alleged deficiencies in Ground 1, is directed to tumor ablation not neurotomy, would require a substantial redesign of Racz's modified device, and there is no motivation to combine. PO Resp. 59–60.

We start with a brief overview of Young '965 and address the parties' respective contentions.

1. Overview of Young '965 (Ex. 1012)

Young '965 is directed "to radio frequency (RF) electrosurgical probes for the treatment of tissue, and more particularly, to electrosurgical probes having multiple tissue-penetrating electrodes that are deployed in an array." Ex. 1012 ¶ 1. An ablation device disclosed in Young '965 "includes a cannula having a distal end and a lumen, an array of electrodes deployable from within the lumen, each of the electrodes having a first configuration when inside the lumen, and a second configuration when outside the lumen." *Id.* ¶ 8.

Figure 2 of Young '365 is reproduced below:

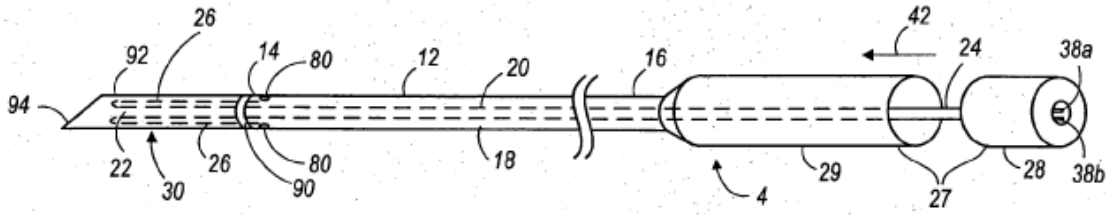



FIG. 2

Figure 2 is a perspective view of Young '965's ablation probe with the electrode array retracted. Ex. 1012 ¶ 16.

The probe illustrated in Figure 2 "includes an elongate cannula 12, a shaft 20 slidably disposed within the cannula 12, and an array 30 of electrodes 26 carried by the shaft 20." Ex. 1012 ¶ 23. Cannula 12 "has a distal end 14, a proximal end 16, and a central lumen 18 extending through the cannula 12 between the distal end 14 and the proximal end 16." *Id.*

"[E]ach electrode takes the form of an electrode tine, which resembles the shape of a needle or wire" and "is in the form of a small diameter metal element, which can penetrate into tissue as it is advanced from a target site within the target region." Ex. 1012 ¶ 25. The electrodes will have "a thickness (in the radial direction) in the range of 0.05 mm to 0.3 mm, and preferably from 0.1 mm to 0.2 mm." *Id.* ¶ 30.

2. Claim 1

Petitioner contends that "Young '965's electrode tip (92) is configured 'for delivering ablation energy in a monopolar configuration,' where a dispersive electrode is attached to the patient." Pet. 64 (citing Ex. 1012 ¶ 33). Petitioner further contends that Young '965's "array 30 of electrodes 26 and the operative electrode 92 are monopolar electrodes, and current will pass from the electrodes 26 and the electrode 92 to the dispersive electrode to thereby deliver ablation energy in a monopolar configuration." *Id.* Petitioner argues that an ordinarily skilled artisan would have been further motivated "by Young '965 to modify Racz's device and thereby perform the step" recited in limitation [1.h] "of operating the radio frequency probe, the tip [14/38], and the filament [22/1622] as a monopolar electrode . . ." *Id.* (citing Ex. 1034 ¶ 215) (emphasis omitted).

Petitioner next contends that "Young '965's filaments (26) are interconnected to an actuator shaft (20) and handle assembly (27) to retract and deploy the filaments (26)." Pet. 65 (citing Ex. 1012 ¶¶ 23–24, 34–35, 37–38). According to Petitioner, an ordinarily skilled artisan "would have recognized that Young '965's shaft (20) could be adapted to deploy and retract Lee's filaments (22/1622) from Racz's device" and would have been further motivated "to modify Racz's device to perform that step of '<u>moving</u>' a retracted filament in the device to a '<u>deployed position within the patient</u>'" as recited in limitation [1.f]. *Id.* (citing Ex. 1034 ¶ 216).

Petitioner next contends that "Young '965's filaments (26) are as small as 0.2mm (wide) and 0.05mm (thick)." Pet. 65 (citing Ex. 1012 ¶ 30). According to Petitioner, "Young '965 would have confirmed to a [person of ordinary skill in the art that Lee's filaments (22/1622) would be

implemented in sizes as small as 0.2mm wide and easily implemented into Racz's cannula (10/33)." *Id.* (citing Ex. 1034 ¶ 217).

Petitioner, thus, argues that claim 1–10, 18–26, and 28–29 are obvious in view of Racz, Fitz, Lee, and Young '965). Pet. 66 (citing Ex. 1034 ¶ 218). Below, we address the subset of these claims for which Petitioner provides separate and additional contentions.

3. Claim 2

Petitioner provides separate and additional contentions for claim 2. Pet. 66. Petitioner contends that Young '965 discloses that "[a]fter the cannula 12 is properly placed the electrode array 30 is deployed out of the lumen 18 of the cannula 12" and "[n]ext, the RF generator 6 is then connected to the probe assembly 4 via the electrical connectors." *Id.* (citing Ex. 1012 ¶¶ 40–41). Referring to its contentions from Ground 1, Petitioner notes that "the filaments in the modified Racz are energized by a removable RF probe" and contentions that an ordinarily skilled artisan "would understand that, when operating modified Racz," the step recited in claims 2 of "moving the filament to a deployed position within the patient takes place prior to inserting the radiofrequency probe into the lumen of the needle." *Id.* (citing Ex. 1034 ¶ 219) (emphasis omitted).

Patent Owner does not dispute Petitioner's contentions for claim 2 beyond those already discussed in Ground A. *See generally* PO Resp.

We find that the combination of Racz, Fitz, Lee, and Young '965[18] teaches the limitations of claim 2.

[18] This cited disclosure in Young '965 cures the deficiency in Petitioner's Ground A challenge to claim 2 discussed above.

4. Claims 8, 9, 20, and 23

Petitioner provides separate contentions for claims 8, 9, 20, and 23. Pet. 66–67. According to Petitioner, "[t]he teachings in Young '965 identified above for claim 1 also renders the limitations in certain dependent claims further obvious in combination with Racz, Fitz, and Lee." *Id.*

5. Patent Owner's Contentions

Patent Owner contends that "Young '965 does not cure the deficiencies in Racz's modified device and introduces further complications." PO Resp. 59.

Patent Owner first argues that "Young '965 is generally directed to tumor ablation and not neurotomy" and "lacks relevance to Racz and Fitz in many of the same ways as Lee." PO Resp. 59 (citing Ex. 2001 ¶¶ 182–184; Ex. 2006 ¶ 295).

Patent Owner next argues that "the petition's proposal to adapt Young '965's shaft 20 to deploy and retract Lee's filaments would require a substantial redesign of Racz's modified device, yet the petition provides no details of how this redesign could be implemented." PO Resp. 59–60 (citing Ex. 2006 ¶ 296). According to Patent Owner "shaft 20 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)." *Id.* at 60 (citing Ex. 2006 ¶ 297).

Patent Owner next argues that an ordinarily skilled artisan would not have found it obvious to incorporate Racz's RF probe 52 into a hollowed-out shaft 20 for two reasons. PO Resp. 60. Petitioner argues that "(1) the petitioner has identified no motivation to do so and (2) this would position

the RF probe's temperature sensor away from the ablation zone, thus comprising its performance." *Id.* (citing Ex. 2001 ¶¶ 186–189).

6. Petitioner's Reply

Petitioner argues that Patent Owner "vaguely suggests that Young '965 'lacks relevance' but does not assert that it is non-analogous art" and that a non-analogous art argument is waived. Pet. Reply 10 (citing PO Resp. 59–60; Paper 9, 10). Notwithstanding the waiver argument, Petitioner contends that "Young '965 is directed to an RF ablation needle with deployable filaments (Pet. 62–65) and is analogous art for the same reasons discussed above for Lee." *Id.*

7. Analysis

First, as discussed above in Ground A, we determine, after considering Patent Owner's arguments that there are no deficiencies in Racz's modified device as proposed by Petitioner, except for claim 2. Consequently, this ground would succeed even if there are issues with Young '965.

Regardless of whether Patent Owner waived arguing that Young '965 is non-analogous art, the parties rely on substantially the same arguments as they did in Ground A regarding whether Lee is non-analogous art. PO Resp. 59. Consequently, for the same reasons discussed above for Lee, we find that Young '965 qualifies as analogous art.

Patent Owner's last two arguments, that adding Young '965 would require a substantial redesign of Racz's tip and would result in positioning the temperature sensor away from the ablation zone, are bodily incorporation arguments and, consequently, unavailing.

8. Conclusion

For the foregoing reasons and after considering all the evidence in the record both for and against patentability, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–10, 18–26, 28, and 29 would have been obvious over Racz, Fitz, Lee, and Young '965.

F. Grounds C and D: Obviousness in view of Racz, Fitz, Lee, and Scheibe with or without Young '365

Petitioner contends that claims 1–10, 18–26, and 28–29 are also obvious over Racz, Fitz, Lee, and Scheibe with or without Young '965. Pet. 67–72.

Patent Owner argues that Scheibe does not cure the alleged deficiencies in Ground 1, is directed to a deflectable catheter assembly, and is not analogous art. PO Resp. 60–61.

We start with a brief overview of Scheibe and address the parties' respective contentions.

1. Overview of Scheibe (Ex. 1013)

Scheibe is directed to "a deflectable catheter that allows for more ease positioning of the distal end of the deflectable catheter." Ex. 1013 ¶ 3. Figure 1 of Scheibe is reproduced below:

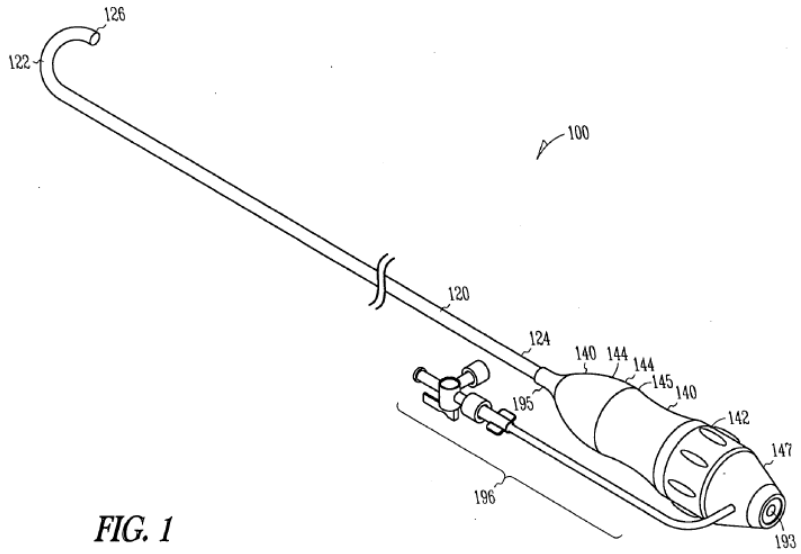



*FIG. 1*

Figure 1 is a perspective view of Scheibe's deflectable catheter 100. *Id.* ¶ 4.

Figure 2 of Scheibe is reproduced below:

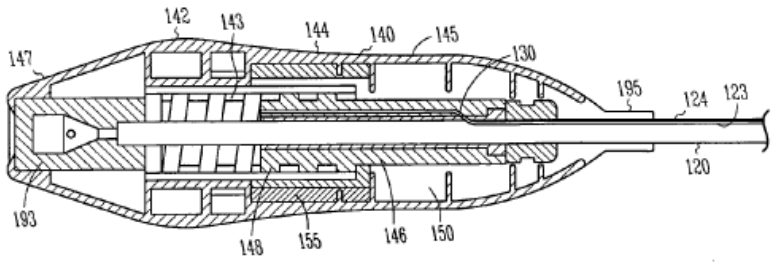



*FIG. 2*

Figure 2 is a cross-sectional view of a proximal portion of a deflectable catheter. Ex. 1013 ¶ 5.

Deflectable catheter 100 comprises deflectable body 120, housing 140 and pullwire 130. Ex. 1013 ¶ 16. As shown in Figure 2 of Scheibe, pullwire 130 is coupled with catheter body 120 and is disposed through a lumen in deflectable body 120. *Id.* ¶¶ 17–18. Deflectable body 120 further comprises handle assembly 140 which allows displacement of pullwire 130 relative to deflectable body 120 by rotating knob 142. *Id.* ¶ 19; *id.* ¶ 35 ("sliding member 146 is fixed to an inner tube 164 and moves axially when the knob

is rotated . . . causing the pullwire to translate longitudinally along the deflectable body 120.").

2. Claims 1 and 21

Petitioner contends that an ordinarily skilled artisan "would have been motivated to provide Scheibe's rotatable actuator (142) and sliding member (146) in Racz's device for the purpose of 'moving' Lee's filaments (22/1622) between their retracted and deployed positions without compromising the functionality of Racz's probe (22/52)." Pet. 69 (citing Ex. 1034 ¶ 224). Petitioner further contends that an ordinarily skilled artisan would understand "that proximal ends of Lee's filaments (22/16[]2) are securable to the sliding member (146)" in a similar manner to how Scheibe's pullwire 130 is secured to sliding member 146. *Id.* (citing Ex. 1013 ¶¶ 18–19, 35; Ex. 1034 ¶ 224). Petitioner also contends that an ordinarily skilled artisan would understand "that the rotatable actuator (142) would retract and deploy Lee's filaments (22/162) through Racz's shaft (12/34)" by rotating Scheibe's actuator (142). *Id.* (citing Ex. 1034 ¶ 224).

Petitioner next contends that Scheibe may be optionally considered in combination with Young '965, which discloses that rotational actuators "can be used to retract and deploy filaments." Pet. 71 (citing Ex. 1012 ¶ 38; Ex. 1034 ¶ 228). According to Petitioner, an ordinarily skilled artisan "would be further motivated to select a suitable rotational actuator (such as Scheibe's) for deploying Lee's filaments (22/1622) from Racz's device." *Id.* (citng Ex. 1034 ¶ 239).

Patent Owner argues that Scheibe's "deflectable catheter assembly is not in the same field as RF neurotomy needles" and "[n]o amount of reliance by the petitioner and Dr. Tucker on a clearly erroneous statement in Scheibe

that mischaracterizes 'deflectable catheter assemblies' as implantable leads for cardiac stimulation systems can render Scheibe analogous to RF neurotomy devices." PO Resp. 60–61 (citing Ex. 2001 ¶¶ 191–193).

Patent Owner further argues that Scheibe is not reasonably pertinent. PO Resp. 61. Patent Owner quotes Dr. Russo's declaration that Scheibe's "pullwire" is not reasonably pertinent "to the objective of pushing tines out of a distal end of a stiff cannula." *Id.* (citing Ex. 2001 ¶ 194) (emphasis omitted).

Petitioner, in turn, contends Scheibe qualifies as analogous art under the reasonably pertinent prong. Pet. Reply 10–11. Petitioner argues that Patent Owner "conflates the patent's field with the reasonable pertinence inquiry, improperly excluding all non-neurotomy art." *Id.* (citing PO Resp. 61–62). Petitioner points to disclosure in the Specification of the '664 patent of "an actuator to deploy/retract filaments" and further describes a rotatable Luer fitting that results in linear motion of an advancing hub. *Id.* (citing Ex. 1003, 5:53–55, 17:34–35, 17:45–55). Petitioner argues that Scheibe's disclosure of a luer fitting and a rotatable actuator causing linear movement addresses the same problems as the '664 patent. *Id.* (citing Ex. 1013 ¶¶ 24–25, 29–37).

Petitioner has shown that Scheibe is analogous art under the reasonably pertinent test because it addresses the same problems as did the inventors of the '664 patent of moving a filament from a retracted to a deployed position as recited in claim elements [1e], [1f], [21d], and [21e]. Consequently, Petitioner has shown by a preponderance of the evidence that claims 1–10, 18–26, and 28–29 would have been obvious over the combination of Racz, Fitz, Lee, Scheibe, and Young '965.

G. Grounds E–H: Obviousness over Godara in Combination with Racz, Fitz, Lee, Young '965, and Scheibe

Petitioner contends that claims 11–17, 19, 27, and 29 are obvious over Godara in various combinations with Racz, Fitz, Lee, Young '965, and/or Scheibe. Pet. 72–76. Patent Owner does not address these grounds. *See generally* PO Response.

We begin with a brief overview of Godara and then address Petitioner's contentions.

1. Overview of Godara (Ex. 1015)

Godara is directed to electrosurgical devices and methods of treatment of pain. Ex. 1015 ¶ 2. Godara explains that "[e]lectrosurgical procedures typically rely on the application of high frequency, for example radiofrequency (RF) energy to treat, cut, ablate or coagulate tissue structures such as, for example neural tissue." *Id.* ¶ 3.

Godara discloses that

> Embodiments of the method aspect of the present invention may be useful for creating a lesion having a desired shape, size, and/or location with various tissues of a human or animal. More specifically, some embodiments of the present invention may comprise treatment procedures for treating one or more target tissue sites associated with a patient's vertebral column. For example, treatment procedures may be performed at various locations external to the vertebrae, including, but not limited to target sites at the cervical, thoracic, lumbar and sacral regions of the spine. In addition, treatment procedures may be performed at target sites within the vertebrae themselves, referred to as an intraosseous procedure. Furthermore, treatment procedures may be performed at target sites within one or more intervertebral discs.

*Id.* ¶ 114.

2. Claims 12, 14–17, and 29

Petitioner contends that "[t]hese [dependent] claims merely recite specific types and locations of a target 'nerve' to be ablated." Pet. 73 (citing Ex. 1001, claims 12, 14–17, and 27). Petitioner further contends that "Fitz teaches that RF neurotomy 'can be used on *any area* of the spine, be it cervical, thoracic, or lumbar . . . so there is nothing inventive about the specific locations recited in these claims." *Id.* (citing Ex. 1011 ¶ 2; Ex. 1034 ¶¶ 231–232). Petitioner next contends that Godara "teaches treatment by ablation 'at various locations,' including 'target sites at the cervical, thoracic, lumbar and sacral regions of the spine,' 'sites within the vertebrae themselves,[']  [and] 'sites within one or more intervertebral discs.'" *Id.* (citing Ex. 1015 ¶ 114). Petitioner also contends that Godara teaches use in the areas recited in these claims. *Id.* at 73–74 (citing Ex. 1015 ¶¶ 119–120, 124–125, 128–130, 134, claims 36–38). According to Petitioner, "Godara would have motivated a [person of ordinary skill in the art] to use the modified Racz anywhere Godara's device was appropriate such that claims 12, 14–17, and 27 are obvious." *Id.* at 74 (citing Ex. 1015 ¶2 119; Ex. 1034 ¶¶ 232–233).

We have reviewed Petitioner's undisputed contentions and evidence regarding Godara and find that the combination of Racz, Fitz, Lee, and Godara with or without Young '965 and/or Scheibe teaches the limitation of claims 12, 14–17, and 29.

3. Claims 11 and 13

Claims 11 and 13 both recite "inserting the needle within 30 degrees of perpendicular to a surface of the patient." Ex. 1003, 32:31–33, 32:37–39. Petitioner contends that "Godara teaches, 'the probe may be inserted and

positioned *substantially perpendicular* or generally upstanding to the surface, including 'between about 60° and 120°." Pet. 75 (citing Ex. 1015 ¶¶ 6, 94, 126). According to Petitioner, an ordinarily skilled artisan "would have found it obvious to perform the step of **Claims 11 and 13** (which Godara confirms is a known technique) using Racz's modified device." *Id.* (citing Ex. 1034 ¶¶ 234–235).

We have reviewed Petitioner's undisputed contentions and evidence regarding Godara and find that the combination of Racz, Fitz, Lee, and Godara with or without Young '965 and/or Scheibe teaches the limitation of claims 11 and 13.

4. Claims 19 and 29

Claims 19 and 29 both recite "forming a lesion that includes the nerve and has a volume of about 500 $mm^3$." Ex. 1003, 32:52–54, 34:21–23.

Petitioner contends that "Godara's device is configured for generating lesions at a target tissue site, 'for example a nerve' (or 'neural tissue')." Pet. 75 (citing Ex. 1015 ¶¶ 3, 96, 98–100). Petitioner further contends that Godara discloses forming lesions at target sites "including 'between about 150 $mm^3$ and about 500 $mm^3$,' which 'may be particularly useful for lesioning of [spinal] nerves.'" *Id.* at 76 (citing Ex. 1015 ¶ 133). According to Petitioner, "considered in combination with Lee's disclosure that its filaments can be adjusted to provide any desired ablation volume . . . Godara would have further motivated a [person of ordinary skill in the art] to configure Racz's modified device" to form a lesion with the volume recited in claims 19 and 29. *Id.*

We have reviewed Petitioner's undisputed contentions and evidence regarding Godara and find that the combination of Racz, Fitz, Lee, and

Godara with or without Young '965 and/or Scheibe teaches the limitation of claims 19 and 29.

For the foregoing reasons, Petitioner has shown by a preponderance of the evidence that claims 11–17, 19, 27, and 29 would have been obvious over the combination of Racz, Fitz, Lee, and Godara with or without Young '965 and/or Scheibe.

### H. Grounds I–L: Obviousness over Cohen in Combination with Racz, Fitz, Lee, Young '965, and Scheibe

Petitioner contends that claims 18 and 28 are obvious over Cohen in various combinations with Racz, Fitz, Lee, Young '965, and/or Scheibe. Pet. 76–79. Patent Owner does not address these grounds. *See generally* PO Resp.

We begin with a brief overview of Cohen and then address Petitioner's contentions.

#### 1. Overview of Cohen (Ex. 1019)

Cohen is a scientific paper published by the American Society of Anesthesiologists. Ex. 1019, 279.[19] The title of the paper is "Randomized Placebo-controlled Study Evaluating Lateral Branch Radiofrequency Denervation for Sacroiliac Joint Pain." *Id.*

#### 2. Claims 18 and 28

Claims 18 and 28 each recite "forming a lesion that includes the nerve and has a maximum cross dimension that is 10 millimeters or larger." Ex. 1003, 32:49–51, 34:18–20.

Petitioner contends that "Cohen discusses techniques for RF neurotomy" and "expressly describes creating a 'lesion diameter ranging

[19] For Exhibit 1019, we refer to the original page numbers in the document.

between 8 and 10 mm' in procedures for denervation of the sacroiliac joint." Pet. 77 (citing Ex. 1019, 282, Fig. 3; Ex. 1034 ¶¶ 240–241). Petitioner further contends that when "[c]onsidered in combination with Lee's disclosure that its filaments can be adjusted to provide any desired ablation volume", an ordinarily skilled artisan would have been motivated "to configure and/or use Racz's device modified to include Lee's filaments (22/1622) . . . to form lesions of various sizes specifically including lesions with maximum cross dimension that is 10 millimeters or larger." *Id.* (citing Ex. 1034 ¶ 241).

We have reviewed Petitioner's undisputed contentions and evidence regarding Cohen and find that the combination of Racz, Fitz, Lee, and Cohen with or without Young '965 and/or Scheibe teaches the limitation of claims 18 and 28.

I. Motions to Exclude Evidence

Each of the parties filed a motion to exclude. Papers 47, 49.

Petitioner's Motion seeks to exclude (1) paragraphs 16–27, and 47 from a declaration of Cody Jorgensen (Exhibits 2015, 2016, 2039, and 1037[20]) and (2) Exhibits 2021–2026 in their entireties. Pet. MTE, 1.

Patent Owner's Motion seeks to exclude Petitioner's Exhibit 1063 if Patent Owner's Exhibits 2044 and 2045 are excluded or otherwise not

[20] 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 27, 5.

considered.[21] *See* PO MTE, 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.").

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

[21] Exhibits 2044 and 2045 were filed by Patent Owner with its Sur-reply contrary to 37 C.F.R. § 42.23(b). *See* Papers 49, 52. We do not rely on either of these exhibits.

## III. CONCLUSION[22]

In summary:

| Claim(s) | 35 U.SC. § | Reference(s)/ Basis | Claim(s) Shown Unpatentable | Claim(s) Not Shown Unpatentable |
|---|---|---|---|---|
| 1–10, 18–26, 28, 29 | 103(a) | Racz, Fitz, Lee | 1, 3–10, 18–26, 28, 29 | 2 |
| 1–10, 18–26, 28, 29 | 103(a) | Racz, Fitz, Lee, Young '965 | 1–10, 18–26, 28, 29 | |
| 1–10, 18–26, 28, 29 | 103(a) | Racz, Fitz, Lee, Scheibe | 1–10, 18–26, 28, 29 | |
| 1–10, 18–26, 28, 29 | 103(a) | Racz, Fitz, Lee, Scheibe, Young 965' | 1–10, 18–26, 28, 29 | |
| 11–17, 19, 27, 29 | 103(a) | Racz, Fitz, Lee, Godara | 11–17, 19, 27, 29 | |
| 11–17, 19, 27, 29 | 103(a) | Racz, Fitz, Lee, Godara, Young '965 | 11–17, 19, 27, 29 | |
| 11–17, 19, 27, 29 | 103(a) | Racz, Fitz, Lee, Godara, Scheibe | 11–17, 19, 27, 29 | |
| 11–17, 19, 27, 29 | 103(a) | Racz, Fitz, Lee, Godara, | 11–17, 19, 27, 29 | |

[22] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

| Claim(s) | 35 U.SC. § | Reference(s)/ Basis | Claim(s) Shown Unpatentable | Claim(s) Not Shown Unpatentable |
|---|---|---|---|---|
| | | Young'965, Scheibe, | | |
| 18, 28 | 103(a) | Racz, Fitz, Lee, Cohen | 18, 28 | |
| 18, 28 | 103(a) | Racz, Fitz, Lee, Cohen, Young '965 | 18, 28 | |
| 18, 28 | 103(a) | Racz, Fitz, Lee, Cohen, Scheibe | 18, 28 | |
| 18, 28 | 103(a) | Racz, Fitz, Lee, Cohen, Young '965, Scheibe | 18, 28 | |
| **Overall Outcome** | | | 1–29 | |

## IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–29 of the '664 patent have been shown by a preponderance of the evidence to be unpatentable;

FURTHER ORDERED that the parties Motions to Exclude Evidence, Papers 47 and 49 are dismissed as moot; and

FURTHER ORDERED that any party seeking judicial review must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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