

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVANOS MEDICAL, INC.,
Petitioner,

v.

STRATUS MEDICAL, LLC,
Patent Owner.

IPR2024-01212
Patent 10,925,664 B2

Before MICHAEL J. FITZPATRICK, JOHN G. NEW, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

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

I. INTRODUCTION

Avanos Medical, Inc. (“Petitioner,” “Avanos”) filed a Petition for an *inter partes* review of claims 1–29 of U.S. Patent No. 10,925,664 B2 (“the ’664 patent,” Ex. 1003). Paper 1 (“Pet.”). Stratus Medical, LLC (“Patent Owner,” “Stratus Medical”) did not file a Preliminary Response.

We review the Petition and accompanying evidence under 35 U.S.C. § 314. An *inter partes* review may not be instituted unless “the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Further, a decision to institute may not do so on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); 37 C.F.R. § 42.108(a).

After considering the evidence and arguments presented in the Petition, we determine that Petitioner demonstrates a reasonable likelihood of prevailing in showing that at least one of the challenged claims of the ’664 patent is unpatentable. Accordingly, we institute an *inter partes* review as to all the challenged claims of the ’664 patent on all the grounds of unpatentability set forth in the Petition.

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

B. Background and Related Proceedings

Petitioner maintains 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).

The '644, '688, and '782 patents all claim benefit of priority to Provisional application No. 61/347,351, filed on May 21, 2010. Exs. 1001–1003, code (60). The '664 patent issued from a continuation application that matured into the '688 patent such that the two patents share a common specification. *See* Ex. 1003, Code (63). The '782 patent at issue in IPR2024-01209, however, further claims benefit of priority to Provisional application No. 61/357,894, filed on June 23, 2010, that is not common to the '644 and '688 patents. *See* Exs. 1001–1003, code (60).

Other than the four Petitions before the Board, the parties identify no past or present controversies involving the '782, '664, or '688 patents. *See* Pet. 79, Paper 4, 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. The '644 patent claims the benefit of Provisional Application Nos. 61/280,557 and 61/347,351, both filed on May 21, 2010. Ex. 1003, 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.

Ex. 1003, 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 a neurotomy system 100 for use in performing RF neurotomy on a patient. *See id.* at 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.

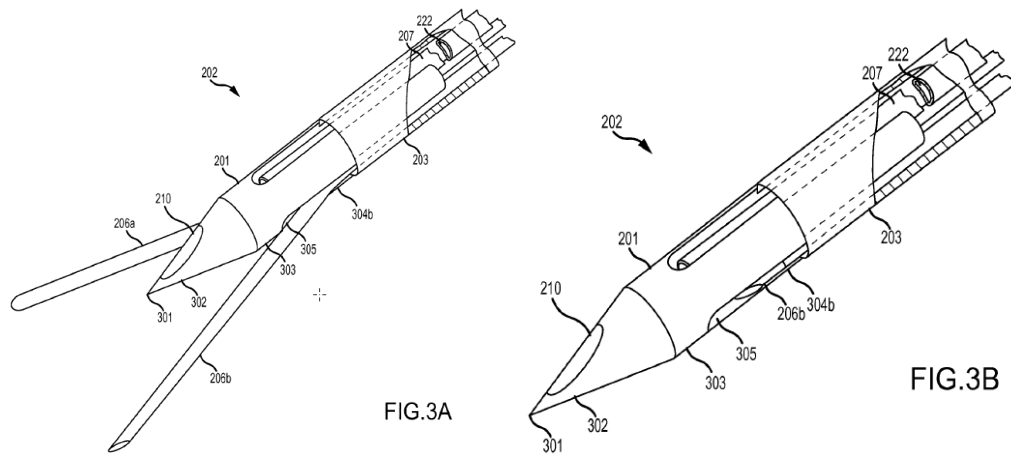
As illustrated in Figure 2A, reproduced below, RF neurotomy needle 103 may include “a self-contained mechanical mechanism, in the form of deployable filaments 206a, 206b, operable to expand the volume of effective



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 id.* at 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, reproduced below, provide cut away views of the distal end 202 of needle 103. *Id.* at 3:53–56, 6:33–34.



Figures 3A and 3B show filaments 206a-b in fully deployed and retracted configurations, respectively. *Id.* at 3:53–56. 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 the Luer fitting 220 when the 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 the RF probe 401 is inserted within the tube 207, the RF energy emitted by the RF probe 401 may be conducted through the tube 207 and into and through the tip 201 and filaments 206A, 206b. *Id.* at 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.” 24:35–36.

D. Challenged Claims

Petitioner challenges claims 1–29 in this proceeding, of which claims 1 and 21 are independent. *See* Pet. 12–13, 80–84 (claims listing).

Reproduced below with Petitioner’s formatting and element designations, representative claim 1 recites:

[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
1	1–10, 18–26, 28, 29	103(a)	Racz, ¹ Fitz, ² Lee ³
2	1–10, 18–26, 28, 29	103(a)	Racz, Fitz, Lee, Young '965 ⁴
3	1–10, 18–26, 28, 29	103(a)	Racz, Fitz, Lee, Scheibe ⁵
4	1–10, 18–26, 28, 29	103(a)	Racz, Fitz, Lee, Young '965, Scheibe
5	11–17, 19, 27, 29	103(a)	Racz, Fitz, Lee, Godara ⁶
6	11–17, 19, 27, 29	103(a)	Racz, Fitz, Lee, Godara, Young '965
7	11–17, 19, 27, 29	103(a)	Racz, Fitz, Lee, Godara, Scheibe
8	11–17, 19, 27, 29	103(a)	Racz, Fitz, Lee Godara, Young '965, Scheibe

¹ Ex. 1009, Racz et al., US 6,146,380, issued Nov. 14, 2000.

² Ex. 1011, Fitz, US 2005/0059964 A1, pub. March 17, 2005.

³ Ex. 1010, Lee et al., US 2007/0016183 A1, pub. Jan. 18, 2007.

⁴ Ex. 1012, Young, US 2006/0084965 A1, pub. April 20, 2006.

⁵ Ex. 1013, Scheibe et al., US 2007/0260223 A1, pub. Nov. 8, 2007.

⁶ Ex. 1015, Godara et a., US 2007/0027449 A1, pub. Feb. 1, 2007.

Ground	Claims	35 U.S.C. §	References
9	18, 28	103(a)	Racz, Fitz, Lee, Cohen ⁷
10	18, 28	103(a)	Racz, Fitz, Lee, Cohen, Young '965
11	18, 28	103(a)	Racz, Fitz, Lee, Cohen, Scheibe
12	18, 28	103(a)	Racz, Fitz, Lee, Cohen, Young '965, Scheibe

In support of its patentability challenges, Petitioner relies on the Declaration of Robert Tucker, Ph.D., M.D. (Ex. 1034). In light of the level of ordinary skill in the art provisionally adopted in section II.A, below, we find Dr. Tucker qualified to provide expert testimony in this proceeding. *See* Ex. 1034 ¶¶ 1–14, Appendix A.

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).

⁷ Ex. 1019, Cohen et al., *Randomized Placebo-controlled Study Evaluating Lateral Branch Radiofrequency Denervation for Sacroiliac Joint Pain*, 109(2) *Anesthesiology*, 279–288 (2008).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which that subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of 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 ordinary skill in the art; and (4) objective evidence of non-obviousness, if present. *KSR*, 550 U.S. at 406.

“[W]hen a patent ‘simply arranges old elements with each performing the same function it had been known to perform’ and yields no more than one would expect from such an arrangement, the combination is obvious.” *Id.* at 417 (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)). But in analyzing the obviousness of a combination of prior art elements, it can also be important to identify a reason that would have prompted one of skill in the art “to combine . . . known elements in the fashion claimed by the patent at issue.” *Id.* at 418.

“[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.” *In re Preda*, 401 F.2d 825, 826 (CCPA 1968). Moreover, a precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *KSR*, 550 U.S. at 418. Rather, “any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in

the manner claimed.” *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness over a combination of references must show that “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (quotations and citations omitted).

A. Person 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 years of experience with thermal ablation systems and methods.

Id. (citing Ex. 1034 ¶ 105) (paragraphing added).

Absent evidence or argument to the contrary, we apply Petitioner’s proposed definition, as it appears consistent with the prior art and is supported by the presently unopposed testimony of Dr. Tucker. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355, (Fed. Cir. 2001) (the level of ordinary skill in the art may be reflected in the prior art itself). We note, however, that Petitioner’s open-ended language “at least” expands the ranges of education and experience indefinitely with no upper bound, thereby encompassing those of extraordinary skill. Therefore, we do not adopt this aspect of Petitioner’s formulation.

B. Claim Construction

The Board interprets claim terms in an *inter partes* review using the same claim construction standard that is used to construe claims in a civil action in federal district court. *See* 37 C.F.R. § 42.100(b)). In construing claims, district courts give claims their ordinary and customary meaning, which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

With respect to the challenged claims, 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”)). On the presents record, we agree with Petitioner that no term requires express construction.

C. Overview of Asserted References

As discussed in Section I.E., above, Petitioner relies on Racz, Fitz, and Lee for Ground 1. Grounds 2–12 further combine Racz, Fitz, and Lee

with one or more of Cohen, Scheibe, Godara, and Young '965. For the purpose of institution, we find it sufficient to address Ground 1 and its supporting references.

1. Overview of Racz (Ex. 1009)

Racz discloses a “Bent Tip Electrical Surgical Probe” comprising a “medical needle or cannula 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 Figure 1 is reproduced below.

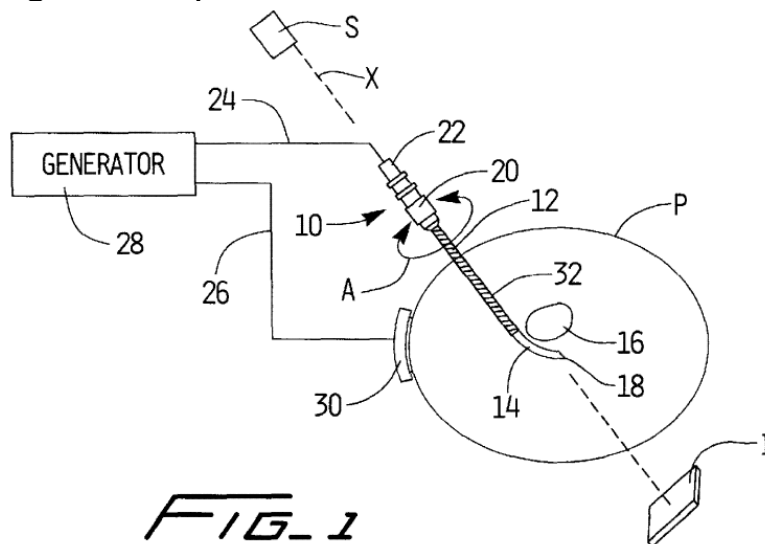
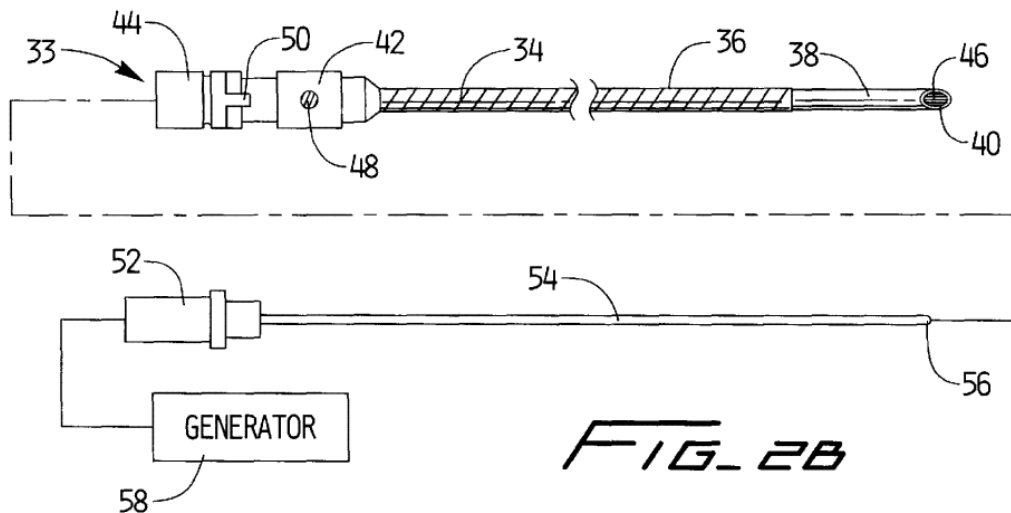


Figure 1 is a schematic diagram of Racz's system comprising “a radio-frequency electrode cannula 10 having a shaft 12 inserted into a portion P of a patient's body.” *Id.* at 3:24–26, 38–40. “The cannula 10 can be inserted directly through the skin of the body portion P to locate the tip 14 in a target

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

Racz’s Figure 2B, reproduced below, shows a specific embodiment of the system diagrammed in Figure 1.



Id. at 3:27–30; 4:59–62, 5:7–51. The cannula, 33 in this embodiment,⁸ includes a shaft 34 defining an internal lumen. *Id.* at 5:41–45. Shaft 34

⁸ According to Petitioner, Racz uses 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

“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.” *Id.* at 5:31–33. “The stylet is then removed, and the probe 52 is inserted into the shaft 34.” *Id.* at 5:37–38. “The probe 52 is connected to the signal generator 58” in order to generate high-frequency heating, or other electrical stimulation. *Id.* at 3:60–63, 4:18–23, 4:18–20. The electrical probe 52 includes a probe shaft 54 having a probe tip 56, which may include a temperature sensor. *Id.* at 5:26–30, Fig. 2B. When the probe 52 is fully inserted into the cannula 33, “physical contact” between the probe 52 and the cannula’s tip 38 conducts the RF energy to the tip 38. *Id.* at 3:60–65, 4:18–23, 5:41–48. Racz’s cannula 33 thus provides “electrical stimulation or high frequency heating of tissue near the exposed electrical tip 14.” *Id.* at 3:60 to 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.

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. Absent evidence to the contrary, we find Petitioner’s labeling convention acceptable.

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

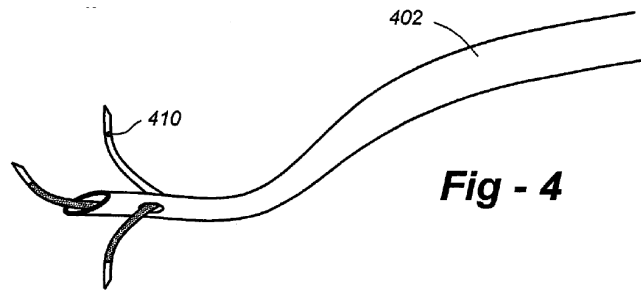


Figure 4 represents an embodiment of Fitz’s invention having a side port inducer. *Id.* ¶ 15. In this embodiment, “introducer 402 is curved, and a plurality of electrodes are deployed through the tip and/or multiple side ports.” *Id.* ¶ 20.

Fitz’s Figure 5 is reproduced below.

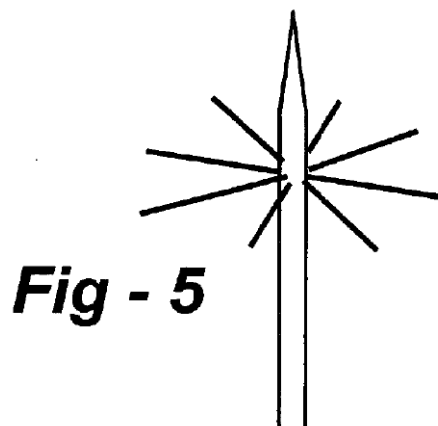


Figure 5 shows an embodiment of Fitz’s invention “in the form of a radial array.” *Id.* ¶ 16. In this embodiment the “inducer ha[s] a tip and sufficient side ports to form an array of electrodes once deployed. Although the side electrodes are shown as emanating from more or less the same distance from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

conductive material such as a springy nickel titanium alloy.” *Id.* ¶ 92.⁹ “[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, “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 a conductive pad in contact with a remote surface on the patient.” *Id.* at ¶ 24.

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

⁹ Petitioner reasonably refers to Lee’s conductive stylets/electrodes as “filaments.” *See, e.g.,* Pet. 19, 37 (citing Ex. 1034 ¶¶ 125–126, 162–163).

D. Ground 1: Asserted Obviousness in view of Racz, Fitz, and Lee

For Ground 1, Petitioner challenges claims 1–10, 18–26, 28, and 29 as obvious in view of Racz, Fitz, and Lee. Pet. 13–62. For the purpose of institution, we focus on independent claim 1. As noted above, Patent Owner did not file a Preliminary Response. Accordingly, Petitioner’s assertions—and the testimony of its declarant—are presently unopposed.

1. Overview of Petitioner’s Contentions

Petitioner relies on the teachings of Racz for claim elements [1pre] through [1e]. Pet. 28–30. Petitioner further relies on “Racz as modified in view of Fitz and Lee,” with respect to elements [1e] through [1h]. *See generally, id.* at 30–47. Supported by the testimony of Dr. Tucker, Petitioner contends that one of ordinary skill in the art 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.

In short, Petitioner contends that “[m]ost of the recited RF needle features—including an elongate cannula, a removable RF probe, a conductive tip, and a monopolar configuration—are conventional features disclosed in . . . Racz,” whereas Fitz discloses that a single-tip device, such as disclosed in Racz, “would produce limited ablation volumes and would have motivated a POSA to solve this problem by adding deployable filaments,” as recited in claim elements [1e] and [1f]. *Id.* at 4–5, 21–22. In addition to its reliance on the multiple electrode tips disclosed in Fitz, Petitioner contends that Lee would have “motivate[ed] a POSA to implement deployable filaments on the tip of Racz’s device using channels within the cannula,” and “also shows how the filaments can extend

outwardly around the needle's tip to advantageously expand and control the ablation volume.” *Id.* at 5–6. Accordingly, Petitioner contends, one of ordinary skill in the art “would have found it obvious to modify Racz’s device to include the well-known deployable filaments described in Fitz and Lee,” and would have implemented this combination as “a matter of routine engineering.” *Id.* at 6, 27.

2. [1pre]

To the extent the preamble is limiting, Petitioner points to Racz’s disclosure 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).

3. [1a]

Element [1a] recites the step of “inserting a needle into a patient.” With respect to this step, Petitioner points to Racz’s disclosure of a “curved tip needle electrode” or cannula, that may be “inserted directly through the skin.” Pet. 28 (underlining omitted) (citing Ex. 1009, 2:46–48, 3:24–45, 8:45–57, 9:49–51; Ex. 1034 ¶ 151).

4. [1b] and [1d]

Elements [1b] and [1d] require that the needle of step [1a] include an elongate member and a lumen within the elongate member. For these features, Petitioner points to Racz’s disclosure of 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). Further emphasizing that Racz’s elongate member includes a lumen, Petitioner asserts that Racz’s “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).

5. [1c]

Element [1c] recites “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.’” *Id.* at 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).

6. [1e]

Element [1e] requires that the needle recited in step [1a] further comprise “a filament in a retracted position in which the filament is at least partially disposed within the elongate member.” Equating Lee’s deployable stylets/electrodes (22/1622) with the filament of element [1e], Petitioner contends that one of ordinary skill in the art would have been motivated to implement a plurality of Lee’s perimeter filaments on the distal tip (14/38) of Racz’s cannula (10/33) to provide a desired ablation volume. *See generally* Pet. 30–38 (citations and underlining omitted). According to Petitioner, a person of ordinary skill in the art would have been 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 (citing, e.g., Ex. 1009, 3:60–63, 4:18–23; Ex. 1034 ¶ 159).

According to Petitioner, a POSA 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 e.g., Ex. 1034 ¶¶ 162–165 (additional testimony from Dr. Tucker regarding 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”)).

7. [1e] and [1f]

As noted above, element [1e] recites “a filament in a retracted position . . . at least partially disposed within the elongate member.” Element [1f] recites the step of “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 these elements 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. Pet. 38–41 (underlining omitted) (citing e.g., Ex. 1010 ¶¶ 92, 98–99, 106–107, Figs. 1, 48; Ex. 1034 ¶¶ 166–168). In this respect, Petitioner points, for example, to Lee's teaching 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.* at 39 (emphasis omitted) (citing Ex. 1010 ¶ 1029, 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).” *Id.* at 41 (citing Ex. 1034 ¶¶ 77–78, 170–172). In support of such a mechanism, Petitioner further 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) (citing Ex. 1010 ¶ 106). Petitioner similarly points to 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).

8. [1g]

Element [1g] recites the step of “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.” According to Petitioner, the electrode cannula (10/33) disclosed in Racz encompasses a “metal tubular shaft” defining an internal

lumen that “accepts the radiofrequency probe (22/52) . . . to conduct RF energy to 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, 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. at 42 (citing Ex. 1034 ¶ 174). With respect to the further conduction of RF energy to the filament(s), Petitioner asserts that because “Racz’s electrical probe (52), Racz’s distal tip (14/38), and Lee’s filaments (22/1622) are all constructed from conductive materials, . . . the (modified) tip’s deflections 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).

9. [1h]

Element [1h] recites the step of “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.”

According to Petitioner, “Racz discloses that its 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).

III. CONCLUSION

After considering the evidence and arguments presented in the Petition, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least one challenged claim of the ’664 patent is unpatentable. In particular, because Petitioner has demonstrated a reasonable likelihood that at least one claim is rendered obvious by the combination of Racz, Fitz, and Lee, as argued in Ground 1, we institute *inter partes* review as to all claims and all Grounds.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or the construction of any claim term. Thus, our view with regard to any

conclusion reached in the foregoing could change upon consideration of Patent Owner's merits response and completion of the record.

In keeping with our mission of resolving patentability disputes in a just, speedy, and inexpensive manner, we exercise our discretion to institute *inter partes* review as set forth in the following Order.

IV. ORDER

Accordingly, it is

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–27 of the '664 patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of the '664 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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