

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVANOS MEDICAL, INC.,

Petitioner,

v.

STRATUS MEDICAL, LLC,

Patent Owner.

Case IPR2024-01212

Patent 10,925,664

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 10,925,664

TABLE OF CONTENTS

PETITIONER’S EXHIBIT LIST	IV
GLOSSARY	VII
I. INTRODUCTION	1
II. THE ’664 PATENT.....	6
A. Overview.....	6
B. Prosecution history	10
III. LEVEL OF ORDINARY SKILL IN THE ART	11
IV. CLAIM CONSTRUCTION	11
V. REQUIREMENTS FOR IPR UNDER 37 C.F.R. § 42.104	12
A. Standing	12
B. Identification of challenge	12
VI. GROUND A: CLAIMS 1-10, 18-26, AND 28-29 ARE OBVIOUS IN VIEW OF RACZ, FITZ, AND LEE.	13
A. Prior Art Overview	13
1. Overview of Racz	13
2. Overview of Fitz.....	15
3. Overview of Lee	17
B. Motivation to Combine Racz, Fitz, and Lee.....	21
C. Ground A: Independent Claim 1	28
1. Racz discloses the preamble [1pre] and limitations [1a], [1b], [1c], [1d], and [1e]	28
a. [1pre]	28
b. [1a].....	28
c. [1b] through [1d]	28
2. Racz as modified in view of Fitz and Lee discloses limitations [1e] through [1h]	30
a. [1e]—needle comprises “a filament”	30

b. [1e] and [1f]—“moving the filament” from “a retracted position” to “a deployed position”.....	38
c. [1g] – “inserting a radiofrequency probe...”	41
d. [1h] – “operating the radiofrequency probe, the tip, and the filament as a monopolar electrode...”	46
D. Ground A: Dependent Claims 2-10 and 20	48
1. Claim 2	48
2. Claims 3-5.....	49
3. Claims 6 and 7	51
4. Claim 8	54
5. Claims 9 and 20	54
6. Claim 10	55
E. Ground A: Independent Claim 21 and dependent Claims 22-26	56
F. Ground A: Claims 18-19 and 28-29	59
VII. GROUND B: CLAIMS 1-10, 18-26, AND 28-29 ARE OBVIOUS IN VIEW OF RACZ, FITZ, LEE, AND YOUNG ’965	62
A. Overview of Young ’965	62
B. Ground B: Claim 1.....	64
C. Ground B: Claim 2.....	66
D. Ground B: Claims 8, 9, 20, and 23	66
VIII. GROUNDS C AND D: CLAIMS 1-10, 18-26, AND 28-29 ARE OBVIOUS OVER ANY OF THE PREVIOUS COMBINATIONS IN FUTURE VIEW OF SCHEIBE.....	67
A. Overview of Scheibe.....	67
B. Ground C: Claims 1 and 21	69
C. Ground D: Claims 1 and 21	71
IX. GROUNDS E-H: CLAIMS 11-17, 19, 27, AND 29 ARE OBVIOUS IN FURTHER VIEW OF GODARA.....	72
A. Overview of Godara	72
B. Claims 12, 14-17, and 27	73

C. Claims 11 and 13	74
D. Claims 19 and 29	75
X. GROUND I-L: CLAIMS 18 AND 28 ARE OBVIOUS IN FURTHER VIEW OF COHEN	76
XI. CONCLUSION.....	78
XII. MANDATORY NOTICES	79
A. Real parties-in-interest.....	79
B. Related matters	79
C. Counsel and service information	79
XIII. CLAIMS LISTING.....	80

PETITIONER'S EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 10,966,782 to Wright et al. (issued April 6, 2021) (“’782 Patent”)
1002	U.S. Patent No. 10,736,688 to Wright et al. (issued August 11, 2020) (“’688 Patent”)
1003	U.S. Patent No. 10,925,664 to Wright et al. (issued February 23, 2021) (“’664 Patent”)
1004	U.S. Patent No. 11,806,070 to Wright et al. (issued November 7, 2023) (“’070 Patent”)
1005	U.S. Patent No. 10,716,618 to Wright et al. (issued July 21, 2020) (“’618 Patent”)
1006	The Complete File History of the ’782 Patent, U.S. Patent App. No. 16/933,811 (filed July 20, 2020) (the ’811 application)
1007	The Complete File History of the ’688 Patent, U.S. Patent App. No. 15/098,673 (filed April 14, 2016) (the ’673 application)
1008	The Complete File History of the ’664 Patent, U.S. Patent App. No. 16/933,995 (filed July 20, 2020) (the ’995 application)
1009	U.S. Patent No. 6,146,380 to Racz et al. (issued November 14, 2000) (“Racz”)
1010	U.S. Publication No. 2007/0016183 to Lee et al. (published January 18, 2007) (“Lee”)
1011	U.S. Publication No. 2005/0059964 to Fitz (published March 15, 2005) (“Fitz”)
1012	U.S. Publication No. 2006/0084965 to Young (published April 20, 2006) (“Young ’965”)
1013	U.S. Publication No. 2007/0260223 to Scheibe et al. (published November 8, 2007) (“Scheibe”)
1014	U.S. Patent No. 7,976,542 to Cosman et al. (filed on March 2, 2006 and issued on July 12, 2011) (“Cosman ’542”)
1015	U.S. Publication No. 2007/0027449 to Godara et al. (published on February 1, 2007) (“Godara”)
1016	U.S. Publication No. 2009/0112201 to Young (published April 30, 2009) (“Young ’201”)

Exhibit No.	Description
1017	U.S. Patent No. 6,652,516 to Gough (filed November 19, 1999 and issued on November 25, 2003) (“Gough ’516”).
1018	U.S. Patent No. 5,728,143 to Gough (filed February 14, 1996 and issued on March 17, 1998) (“Gough ’143”)
1019	Cohen et al., Randomized Placebo-controlled Study Evaluating Lateral Branch Radiofrequency Denervation for Sacroiliac Joint Pain, Anesthesiology, Vol. 109, Issue 2, 279-288 (2008) (“Cohen”)
1020	U.S. Patent No. 6,551,302 to Rosinko (filed on October 26, 2000 and issued on April 22, 2003) (“Rosinko”)
1021	U.S. Patent No. 5,855,576 to LeVeen et al. (filed on December 12, 1996 and issued on January 5, 1999) (“LeVeen”)
1022	U.S. Patent No. 7,918,852 to Tullis et al. (filed May 1, 2006 and published January 18, 2007) (“Tullis”)
1023	U.S. Patent No. 4,411,266 to Cosman (issued October 25, 1983) (“Cosman ’266”)
1024	U.S. Patent No. 7,195,629 to Behl et al. (filed August 18, 2003 and issued March 27, 2007) (“Behl”)
1025	U.S. Patent No. 5,782,827 to Gough et al. (filed December 19, 1995 and issued July 21, 1998) (“Gough ’827”)
1026	U.S. Patent No. 5,928,229 to Gough et al. (filed October 30, 1997 and issued July 27, 1999) (“Gough ’229”)
1027	U.S. Patent No. 9,078,678 to Zerfas et al. (filed March 21, 2013 and issued July 14, 2015) (“Zerfas”)
1028	U.S. Patent App. Pub. No. 2007/0203486 to Young (published August 30, 2007) (“Young ’486”)
1029	U.S. Patent App. Pub. No. 2005/0159797 to Chandran et al. (published July 21, 2005) (“Chandran”)
1030	U.S. Patent App. Pub. No. 2008/0269774 to Garcia et al. (published October 30, 2008) (“Garcia”)
1031	Reserved
1032	Reserved
1033	Reserved

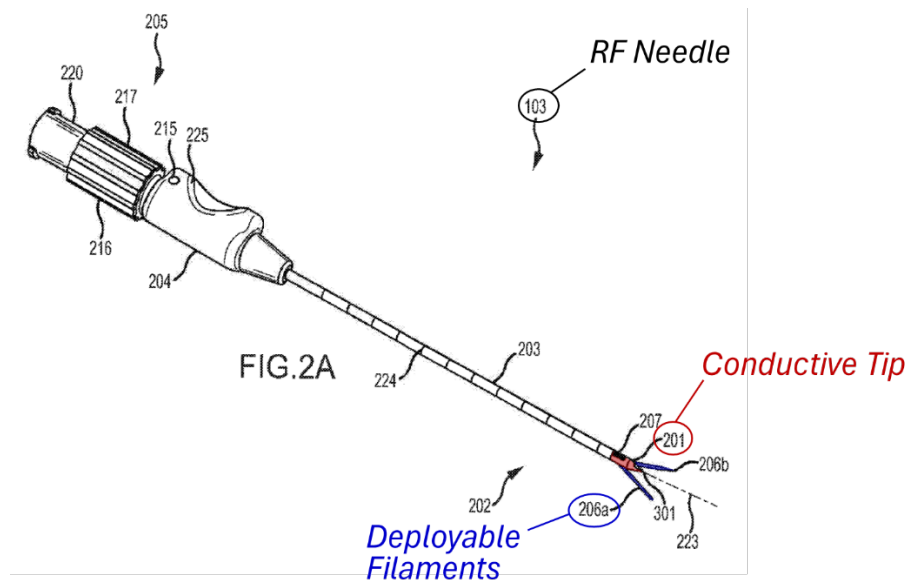
Exhibit No.	Description
1034	Declaration of Dr. Robert D. Tucker (July 26, 2024)

GLOSSARY

Term	Meaning
“’664 Patent” or “Challenged Patent”	U.S. Patent No. 10,925,664 to Wright et al. (issued Feb. 23, 2021)
“Challenged Claims”	Claims 1-29 of the ’664 Patent
“Board”	USPTO Patent Trial and Appeal Board
POSA	Person of ordinary skill in the art at the time of the ’664 Patent’s alleged invention
RF	Radiofrequency
“Racz’s modified device”	Racz’s cannula (10/33) modified by a POSA to include deployable filaments as disclosed in Fitz and Lee.

I. INTRODUCTION

Radiofrequency (RF) ablation is a procedure in which an electrical needle is inserted into targeted patient tissue and activated with RF energy. The RF energy transmitted from the needle's electrode heats the surrounding tissue and generates a lesion, thereby ablating (or destroying) the tissue. Using RF energy to ablate tissue is effective for a variety of treatments. For example, RF ablation may be used to ablate nerve tissue to disrupt the transmission of pain signals (these procedures are also referred to as RF neurotomy). Similarly, RF ablation may be used to destroy liver tumors, uterine fibroids, and other undesirable tissue to treat various conditions.



'664 Patent – Figure 2A (annotated)

The '664 Patent is directed to a method of using an RF neurotomy needle (103) that includes a conductive tip (201) (**shaded red**) and deployable electrode

filaments (206a-b) (**shaded blue**) (*see e.g.*, Figs. 2D and 3D). The tip (201) and filaments (206a-b) (when deployed) transmit RF energy and heat tissue in the area near the tip and filaments.

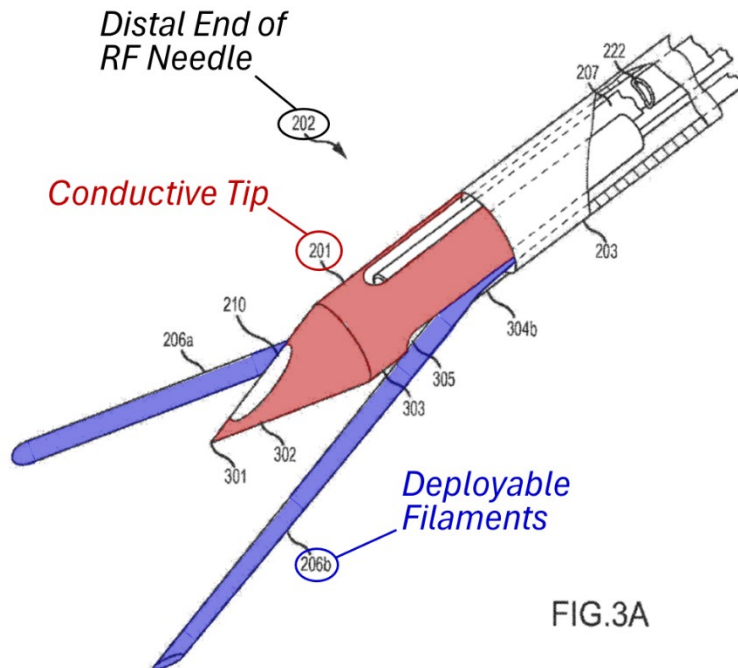


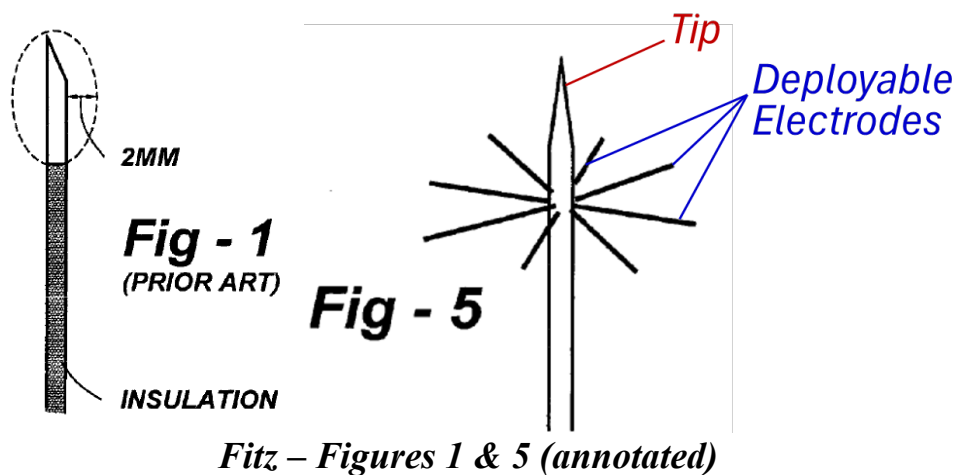
FIG.3A

'664 Patent – Figure 3A (annotated)

According to the '664 Patent, the needle (103) solves a problem associated with single-tip needles (i.e., RF needles having only one electrode tip). Because single-tip needles emanate RF energy from just one location, “the size of a radiofrequency lesion using conventional single needle technology is thus practically limited.” Ex-1003, 6:7-10. Thus, the '664 Patent describes “[a] needle 103 with deployable filaments 206a, 206b [that] overcomes this obstacle and expands the effective area of RF energy delivery by providing multiple locations

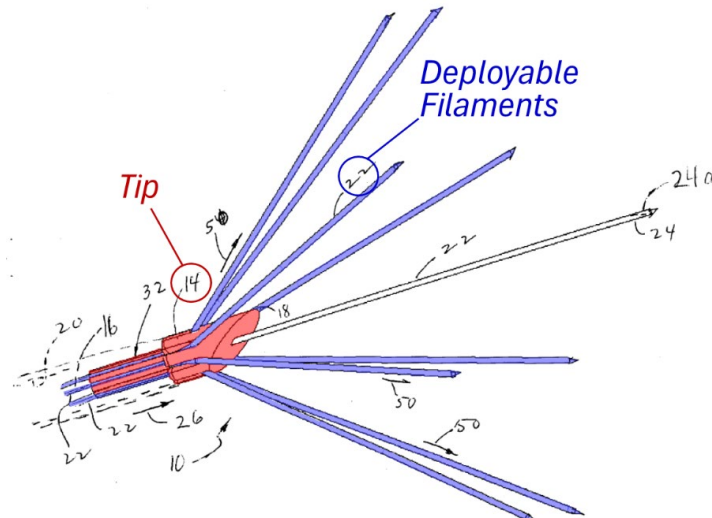
(e.g., tip 201 and filaments 206a, 206b) from which the RF energy emanates.” Ex-1003, 6:11-17.

This solution, however, was nothing new. Five years earlier, U.S. Publication No. 2005/0059964 to Fitz disclosed that “[a] problem with current [RF neurotomy needles] is that they do not allow for adequate coverage of the target area” and produce spherical lesions that “extend[] only a few millimeters.” Ex-1011, ¶0002, 0004, Fig. 1. To solve this problem, Fitz proposed an “improved-coverage RF neurotomy instrumentation” configured “to deploy a set of electrodes to an area to be treated.” Ex-1011, ¶0009, Fig. 5. According to Fitz, the deployable electrodes “enhance the energy coverage area” of RF neurotomy devices compared to single-tip electrodes. *Id.*

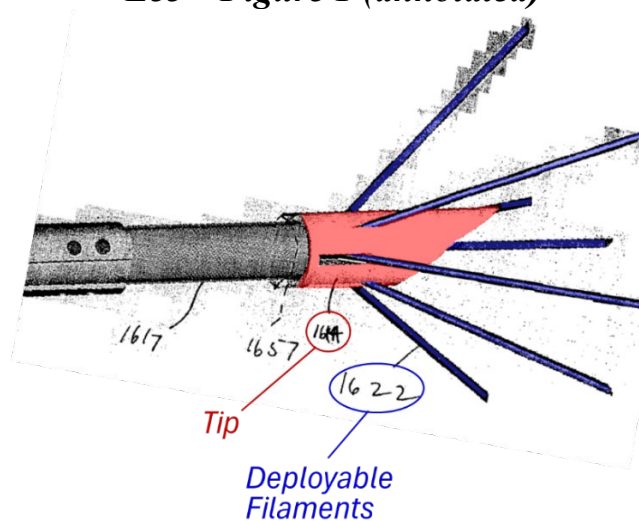


In fact, by the time of the '664 Patent's alleged invention, deployable filaments were commonly used in RF ablation devices. U.S. Publication No. 2007/0016183 to Lee discloses RF ablation needles that—like the '664 Patent—

use channels to guide deployable filaments (**shaded blue**) outwardly around a needle's tip (**shaded red**). Ex-1010, Figs 1, 48. Lee also notes that the number, pattern, direction, size, and/or length of the filaments can all be varied to generate any desired ablation volume. Ex-1010, ¶0123-0131, 0084, 0012, 0103.



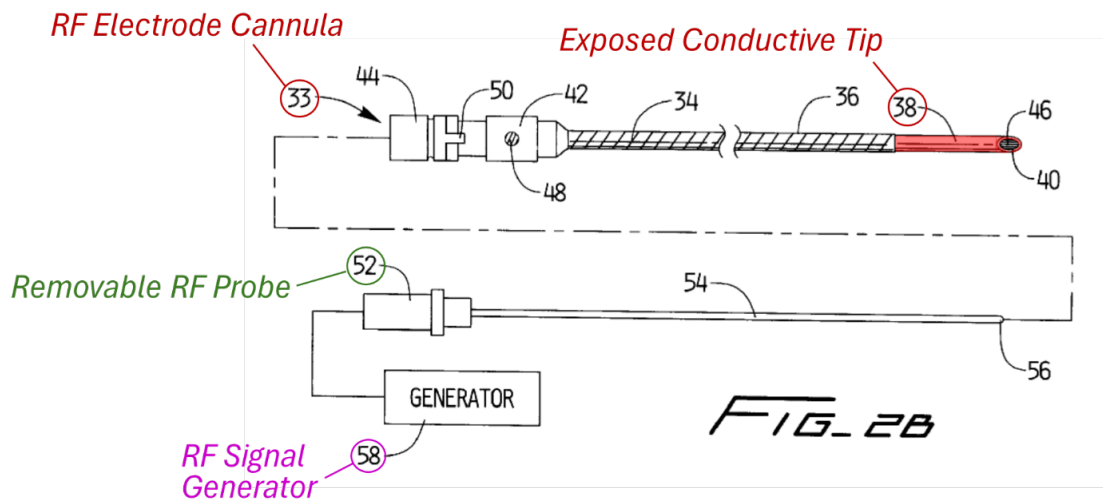
Lee – Figure 1 (annotated)



Lee – Figure 48 (annotated)

Although the '664 Patent's claims are directed to methods, the recited steps are merely a conventional use of an RF needle comprised of well-known features

(the obviousness of which is established by the references combined herein). Most 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 U.S. Patent No. 6,146,380 to Racz. As shown below, Racz describes a typical RF neurotomy needle (without deployable filaments).



Racz – Figure 2B

The claimed features relating to deployable filaments—which were well-known at the time of the invention—are rendered obvious by at least Fitz and Lee (combined with Racz). Fitz discloses that Racz’s single-tip device would produce limited ablation volumes and would have motivated a POSA to solve this problem by adding deployable filaments. Lee would have provided further guidance, motivating a POSA to implement deployable filaments on the tip of Racz’s device using channels within the cannula. Lee also shows how the filaments can extend

outwardly around the needle's tip to advantageously expand and control the ablation volume.

As explained herein, a POSA would have found it obvious to modify Racz's device to include the well-known deployable filaments described in Fitz and Lee. This would have been a matter of routine engineering with entirely predictable results. The combination and the use of the resulting RF needle to perform routine RF neurotomy procedures was obvious—so too are the Challenged Claims.

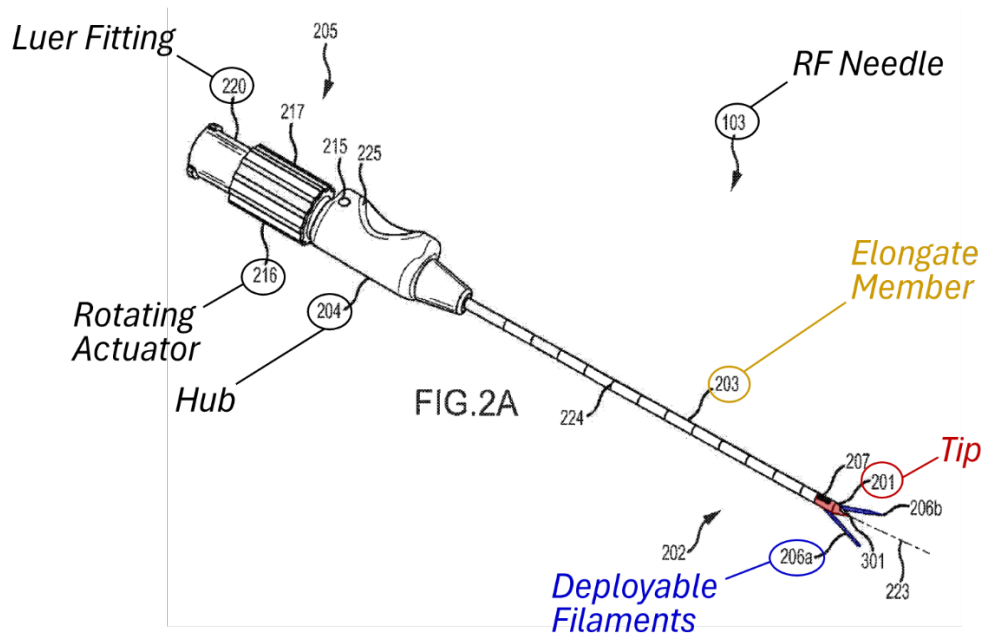
II. THE '664 PATENT

A. Overview

The '664 Patent describes embodiments of an RF needle (103) that can be used for RF neurotomy or “adapted ... for use in other medical procedures” using RF energy. Ex-1003, 4:42-64, 31:6-24.¹ In Fig. 2A, the needle (103) includes an elongate member (203) having a conductive tip (201) (**shaded red**) and deployable filaments (206a-b) (**shaded blue**). Ex-1003, 5:33-55, 6:45-51; Ex-1034, ¶89-90. The elongate member (203) “may be constructed from an insulative material” while the tip (201) and filaments (206a-b) are conductive and electrically active. Ex-1003, 5:33-41, 8:22-31. A Luer fitting (220) at the proximal end of the needle

¹ The '664 Patent includes 21 figures (labeled 1-15) showing various needle configurations. One example is described herein for context and brevity.

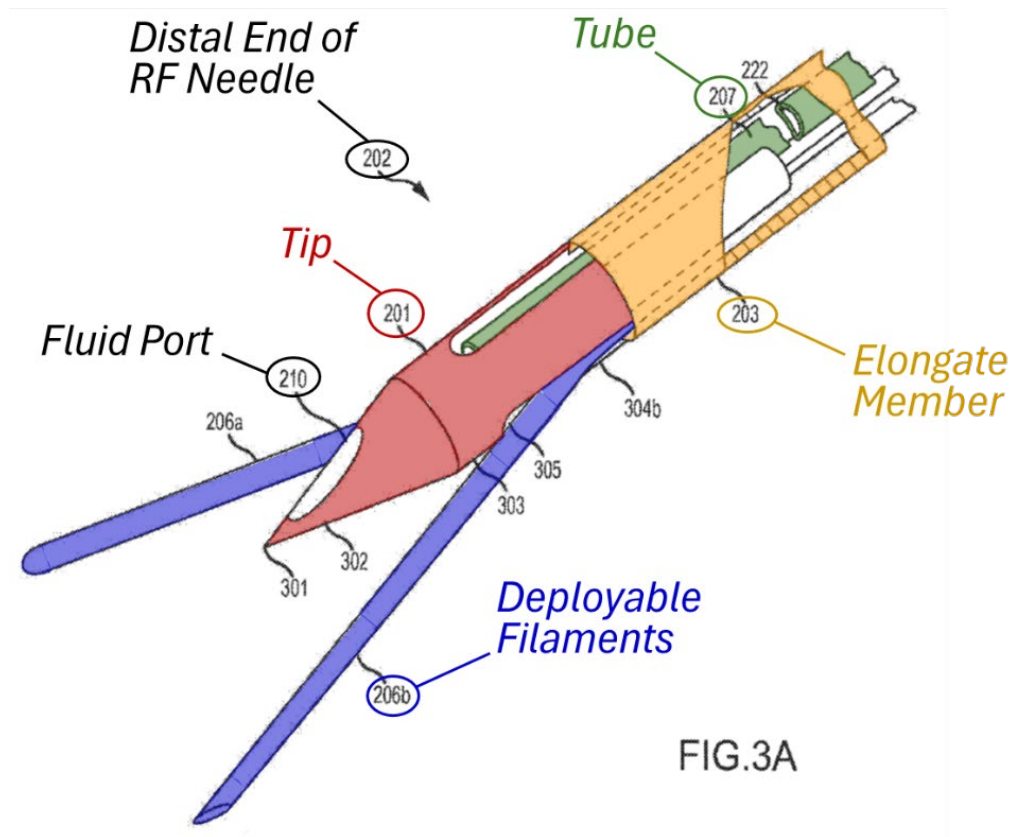
(103) is configured for receiving (i) a removable RF probe (401) (which is inserted into a tube (207) in the elongate member) and (ii) fluid delivered through the lumen (when the probe (401) is removed). Ex-1003, 5:7-15, 5:56-67, 17:56-63.



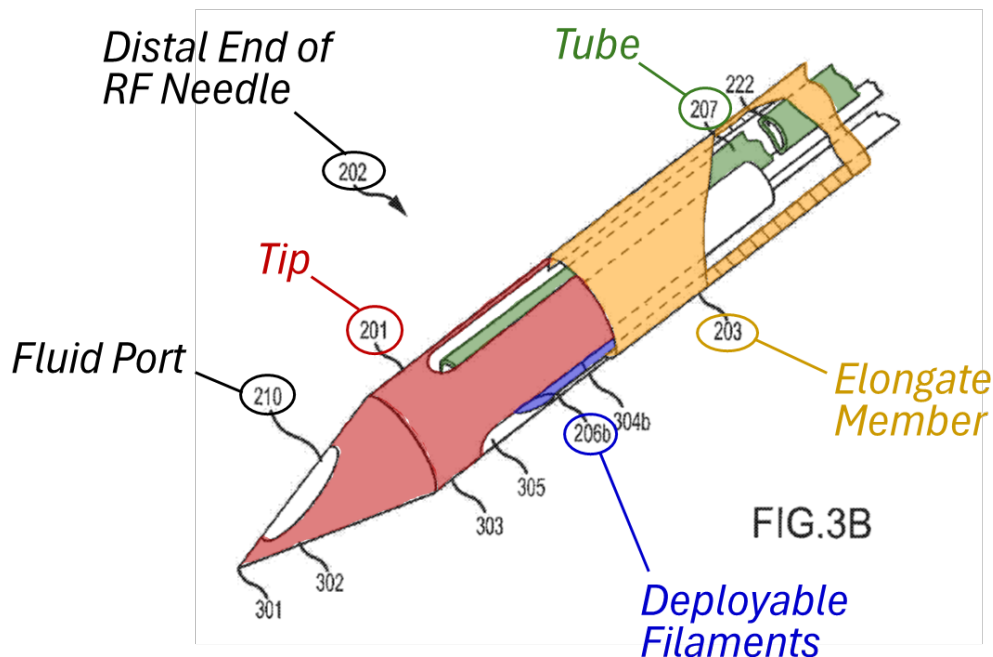
'664 Patent - Fig. 2A

The filaments (206a-b) are deployed/retracted by a rotating actuator (216). Ex-1003, 5:53-55, 17:17-18:40. When deployed, the filaments (206a-b) “expand the volume of effective RF energy delivery as compared to known single-electrode RF probes.” Ex-1003, 5:42-49; Ex-1034, ¶91. Additionally, “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). Ex-1003, 11:19-31, 11:65-12:42, 13:44-14:12.

As shown in Figs. 3A-3B, the needle's tip (201) is positioned at the elongate member's distal end. Ex-1003, 5:33-39; 6:33-44; Ex-1034, 92. The tip (201) includes a fluid port (210) (e.g., for delivering anesthetic via the Luer fitting (220) when the probe (401) is removed) and a pointed end (301) for “piercing the skin of a patient.” Ex-1003, 5:33-36, 7:41-57, 17:56-63.



'664 Patent - Fig. 3A



'664 Patent - Fig. 3B

Although the tip (201) and elongate member (203) may be a “unitary structure,” Figs. 3A and 3B show a configuration where the tip (201) is a separate member “fixedly interconnected” to the elongate member (203). Ex-1003, 8:46-56; Ex-1034, ¶93. The tip (201) defines “filament slots” (304a-b) (e.g., channels) that guide the filaments (206a-b) in and out of the tip (201) when the filaments (206a-b) are deployed/retracted by the actuator (216). Ex-1003, 6:52-7:40.

In some embodiments, the elongate member (203) includes a tube (207). Ex-1003, 5:56-67. To transmit RF energy to the tip (201) and filaments (206a-b), “the tube 207 may be constructed from a 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.” Ex-1003, 8:58-63. When the filaments are deployed, “RF energy passes from the RF probe 401 to tip 201 and filaments 206a, 206b, and into a target volume within the patient 101.” Ex-1003, 9:51-55. In this way, the tip (201) and filaments (206a-b) operate together as an electrode. Ex-1003, 9:55-61; Ex-1034, ¶94.

B. Prosecution history

The '664 Patent issued from U.S. Patent Application No. 16/933,995 (the '995 Application”) filed on July 20, 2020. The '995 Application claims priority through a chain of continuation applications to two US Provisional Applications (61/347,351 filed May 21, 2010, and 61/280,557 filed November 5, 2009).

Following a Track One Request and an interview, the Examiner issued a first-action allowance on October 15, 2020. Ex-1008, 16, 100, 227, 237-238. Although the Examiner’s Reasons for Allowance discussed four references submitted in an IDS, the Examiner appeared persuaded that the claimed “monopolar electrode” distinguished over the “bipolar configuration[s]” of most of the cited art. Ex-1008, 233-35; Ex-1034, ¶95-103.

As explained herein, the features of the allowed claims were all well-known and obvious. Ex-1034, ¶104. Among the references in the Petition’s Grounds, only Young '965 was discussed at all during prosecution. None of the remaining references in the Petition’s Grounds were discussed. Moreover, because the

Examiner was burdened with *more than 500 cited references*, it is unsurprising that the relevance of the cited references was not appreciated.

III. LEVEL OF ORDINARY SKILL IN THE ART

The '664 patent identifies its technical field as relating to “thermal ablation systems and methods,” which includes “methods for performing Radio Frequency (RF) neurotomy”. Ex-1003, 1:24-27. A POSA 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. Ex-1034, ¶105.

IV. CLAIM CONSTRUCTION

Petitioner does not believe that any terms in the Challenged Claims require express construction for purposes of this IPR and does not believe it is necessary to construe any term according to § 112(f). *See* Trial Practice Guide at 44-49; Ex-1034, ¶106. The '664 Patent claims have not been previously construed in any proceeding. Petitioner reserves the right to respond to any claim construction positions offered by Patent Owner.

V. REQUIREMENTS FOR IPR UNDER 37 C.F.R. § 42.104

A. Standing

Petitioner certifies that the '664 patent is available for IPR and that Petitioner is not barred or estopped from challenging the claims in this Petition.

B. Identification of challenge

The Challenged Claims are invalid under the following Grounds:

	Claims	Statute	Prior Art
A	1-10, 18-26, 28-29	§ 103(a)	Racz, Fitz, and Lee
B	1-10, 18-26, 28-29	§ 103(a)	Racz, Fitz, Lee, and Young '965
C	1-10, 18-26, 28-29	§ 103(a)	Racz, Fitz, Lee, and Scheibe
D	1-10, 18-26, 28-29	§ 103(a)	Racz, Fitz, Lee, Scheibe, and Young '965
E	11-17, 19, 27, and 29	§ 103(a)	Racz, Fitz, Lee, and Godara
F	11-17, 19, 27, and 29	§ 103(a)	Racz, Fitz, Lee, Godara, and Young '965
G	11-17, 19, 27, and 29	§ 103(a)	Racz, Fitz, Lee, Godara, and Scheibe
H	11-17, 19, 27, and 29	§ 103(a)	Racz, Fitz, Lee, Godara, Young '965, and Scheibe
I	18 and 28	§ 103(a)	Racz, Fitz, Lee and Cohen
J	18 and 28	§ 103(a)	Racz, Fitz, Lee, Cohen, and Young '965
K	18 and 28	§ 103(a)	Racz, Fitz, Lee, Cohen, and Scheibe
L	18 and 28	§ 103(a)	Racz, Fitz, Lee, Cohen, Young '965, and Scheibe

Each of the above references were issued/published more than one year before the '664 Patent's earliest claimed priority date (November 5, 2009) and are therefore prior art under § 102(b). The only non-patent reference, Cohen, was published in August of 2008 in the medical journal *Anesthesiology* and would have been readily accessible to a POSA more than a year before the earliest claimed priority date. Ex-1019, 279 (indicating issue and publication month).

VI. GROUND A: CLAIMS 1-10, 18-26, AND 28-29 ARE OBVIOUS IN VIEW OF RACZ, FITZ, AND LEE.

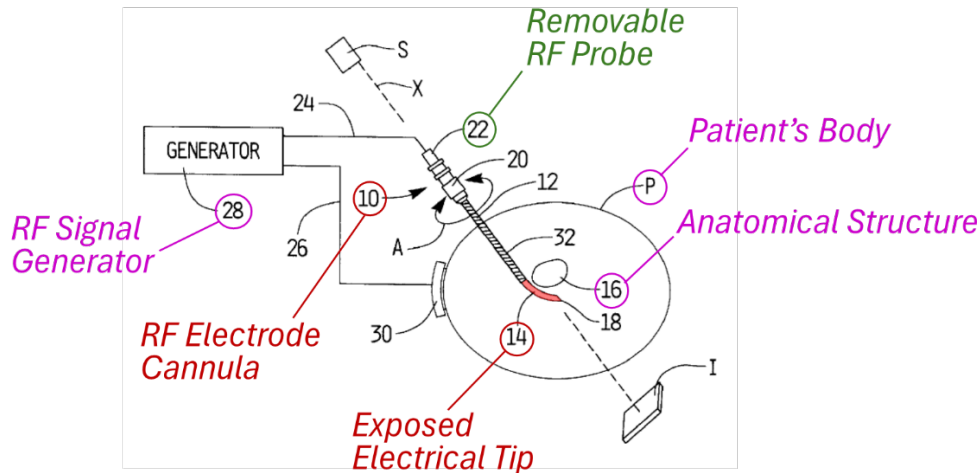
A. Prior Art Overview

1. Overview of Racz

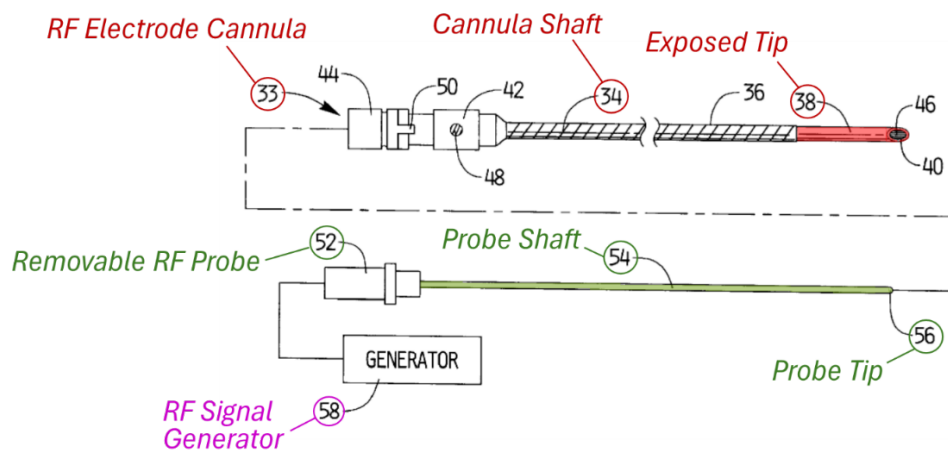
Racz discloses an “apparatus for pain relief that delivers electrical stimulation pulses or high-frequency signals to the vicinity of a neural structure via an electrical needle or cannula.” Ex-1009, 1:4-9. Thus, Racz is directed to the same field as the ’664 Patent (“thermal ablation systems and methods”). *See* Ex-1003, 1:24-27; Ex-1034, ¶110.

As shown in Figure 1, Racz’s system includes a “radio-frequency electrode cannula 10” (aka “electrical needle”) that is “inserted directly through the skin of [a] body portion P to locate the [cannula’s] tip 14 in a target position within the body.” Ex-1009, 3:42-45. Racz shows a “specific embodiment” of the Figure 1 system in Figures 2A/B, which illustrate an electrode cannula (33). Ex-1009, 4:59-62, 5:7-51, Fig. 2A/2B. The cannula (33) corresponds to the cannula (10) and so Petitioner refers to common features in Figures 1 and 2A/2B using the convention “cannula (10/33).” Ex-1009, 4:59 to 5:6; Ex-1034, ¶111-113, 117.²

² Racz’s Figs. 3A/B show another specific embodiment that corresponds to the Figure 1 system. For simplicity, Racz’s Figs. 3A/B are only referred to herein when necessary.



Racz – Fig. 1 (annotated)



Racz – Fig. 2B (annotated)

The cannula (10/33) includes a shaft (12/34) defining an internal lumen. Ex-1009, 5:41-45. The shaft is covered with insulation (36) but includes an uncovered, exposed distal tip (14/38) (**shaded red**). Ex-1009, 4:62-65. The tip (14/38) includes a pointed end (40), which allows the cannula (33) to “penetrat[e] tough tissue.” Ex-1009, 5:3-5; Ex-1034, ¶114.

RF energy is conveyed to the cannula's exposed tip (14/38) via a removable electrical probe (22/52), which is connected to a signal generator (28/58). Ex-1009, 3:60-63, 4:18-23, 4:18-20. The electrical probe (22/52) includes a probe shaft (54) (**shaded green**) having a probe tip (56), which may include a temperature sensor. Ex-1009, 5:26-30, Fig. 2B. When the probe (22/52) is fully inserted into the cannula (10/33), "physical contact" between the probe (22/52) and the cannula's tip (14/38) conducts the RF energy to the tip (14/38). Ex-1009, 3:60-65, 4:18-23, 5:41-48, Fig. 2B; Ex-1034, ¶115.

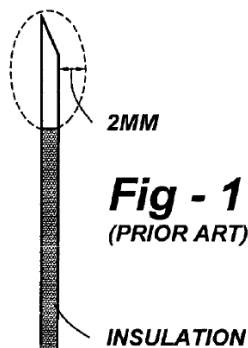
In this way, Racz's cannula (10/33) provides "electrical stimulation or high-frequency heating of tissue near the exposed electrical tip 14." Ex-1009, 3:60 to 4:23, 5:41-51, Fig. 1. Additionally, a reference electrode (30) is placed on the patient's body (P), allowing the tip (14/38) to function as a monopolar electrode. Ex-1009, 4:3-23; Ex-1034, ¶116-117.

2. Overview of Fitz

Fitz is directed to an "improved-coverage" RF neurotomy device. Ex-1011, ¶0001-0002, 0009, Abstract, Claim 1. Thus, Fitz is also directed to the Challenged Patent's field. *See* Ex-1003, 1:24-27; Ex-1034, ¶118.

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." Ex-1011, ¶0004. As Fitz illustrates in Figure 1, single-tip neurotomy needles (like Racz's

device) produce lesions that “extend[] only a few millimeters” from the exposed needle tip. Ex-1011, ¶0004-0005. As a result, multiple lesions may be needed to achieve adequate energy coverage. Ex-1011, ¶0004-0005; Ex-1034, ¶119.

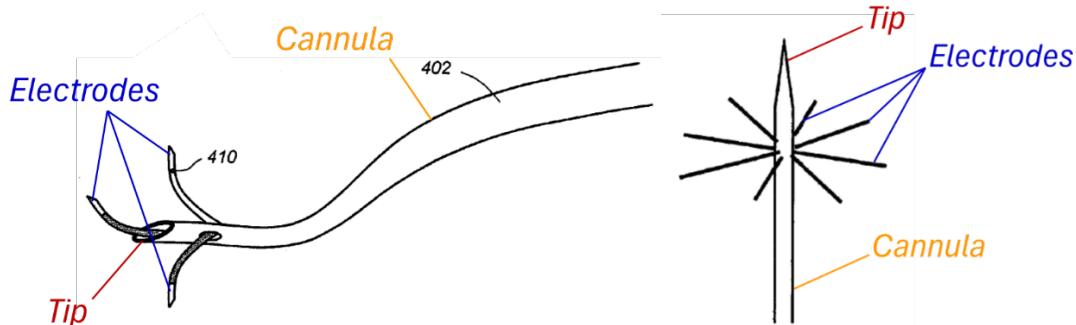


Fitz – Fig. 1

To solve the problem of inadequate coverage in single-tip neurotomy devices, Fitz suggests providing a deployable “set of electrodes” that extend outwardly from the “exposed distal tip” of an RF neurotomy cannula. Ex-1011, ¶0009, Abstract, Claim 1; Ex-1034, ¶120. The deployable electrodes may be made from a “shape-memory alloy” and configured to “deliver [RF] energy to a localized region.” Ex-1011, ¶0009-0010. By deploying outwardly “to an area to be treated,” the deployable electrodes “enhance the energy coverage area” of the neurotomy cannula. Ex-1011, ¶0009, Abstract, Claim 1.

Fitz describes several versions of its deployable electrode neurotomy device. In one example (Fig. 4), an introducer (402) (aka “cannula”) includes “a plurality of electrodes ... deployed through the tip and/or multiple side ports.” Ex-1011, ¶0020, Fig. 4. In another example (Fig. 5), Fitz describes “an introducer having a

tip and sufficient side ports to form an array of electrodes once deployed.” Ex-1011, ¶0021, Fig. 5. In each example, the electrodes are deployed outwardly from the cannula’s distal tip to enhance the device’s energy coverage area. Ex-1034, , ¶121-123.



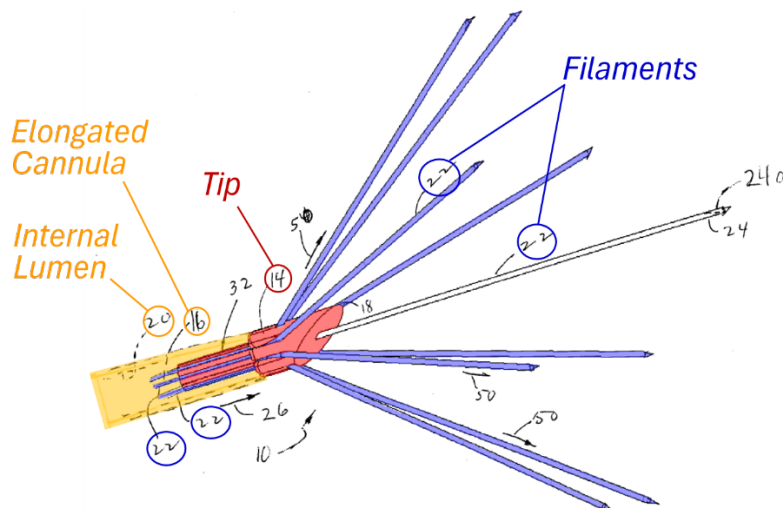
Fitz – Fig. 4 (annotated at left) & Fig. 5 (annotated at right)

3. Overview of Lee

Lee discloses various techniques for deploying electrodes from the tip of an RF ablation device. *See e.g.*, Ex-1010, ¶0012, 0107. Thus, Lee is also directed to the '664 Patent's field. *See* Ex-1003, 1:24-27; Ex-1034, ¶138, 30-33.

Like Fitz, Lee discloses that a deployable-electrode technique can be used to deliver RF energy to a targeted area of tissue. Ex-1010, ¶0084, 0032, Title. In Figure 1, Lee shows a “multiple antenna ablation device” (also referred to as an “ablation trocar” (10)). Ex-1010, ¶0032. The ablation trocar (10) includes a “trocar point” (14) (a tip) (**shaded red**) that is mounted on a cannula (16) (**shaded orange**) and includes a piercing surface (18). Ex-1010, ¶0032, 0091-0092, Fig. 1. A “plurality of stylets 22” (**shaded blue**) are housed within the cannula’s internal

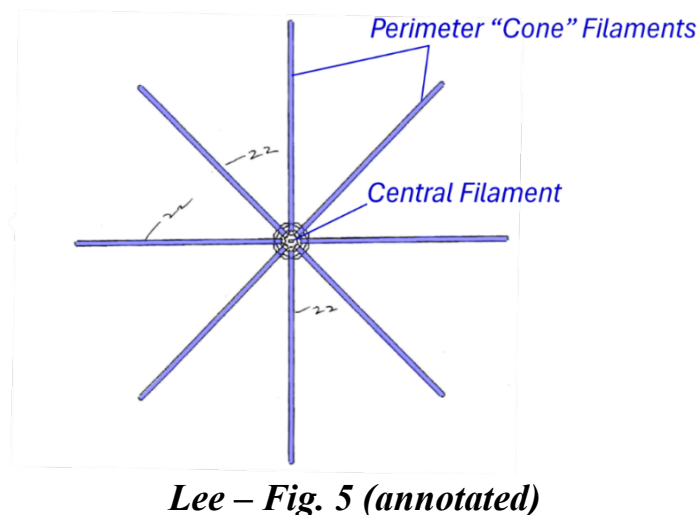
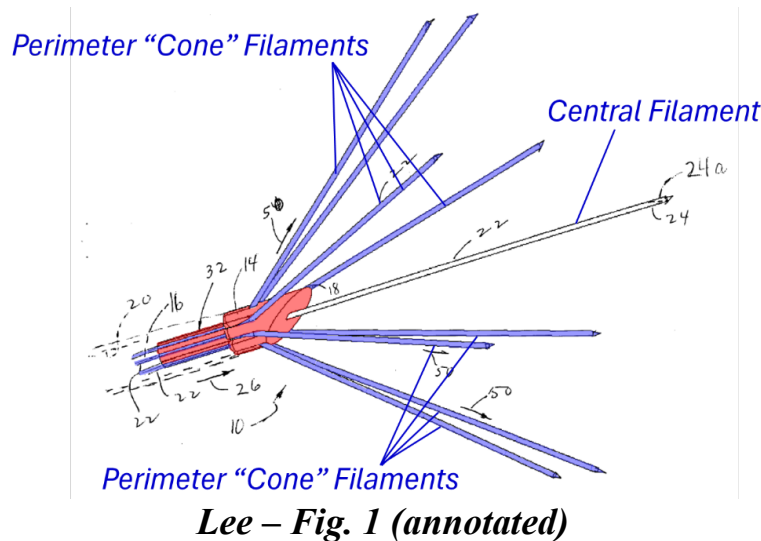
lumen (20) (when retracted). Ex-1010, ¶0092. The stylets (22) are conductive electrodes and deployed outwardly from the tip (14) to apply RF energy for ablation of a targeted area. Ex-1010, ¶0092, 0107. Lee notes that the stylets (22) may be “springy wire-like members” constructed from a nickel titanium alloy. Ex-1010, ¶0092, 0087. In other words, the stylets (22) are filaments. Ex-1034, ¶125-126.



Lee – Fig. 1 (annotated)

Figure 1 shows Lee’s filaments (22) in a deployed position. Ex-1010, ¶0092, 0093, 0099, 0102. The tip (14) includes delivery mandrel surfaces (12) (or “deflection surfaces”) comprising channels and ramps positioned in the cannula (16). Ex-1010, ¶0016, 0018, Claims 8, 10. The filaments (22) are positioned around the tip (14) and, when deployed, are guided outwardly by the deflection surface channels/ramps (12). Ex-1010, ¶0091, 0102, Abstract; Ex-1034, ¶127.

Lee's filaments (22) are positioned around the perimeter of the tip (14) and extend outwardly in a "cone" orientation. Ex-1010, ¶0103. An exception is a central filament (22) (unshaded), which is surrounded by the perimeter filaments (22) and deployed through the center of the trocar point (14). Ex-1010, ¶0092, ¶0102, Figs. 1-3; Ex-1034, ¶128.

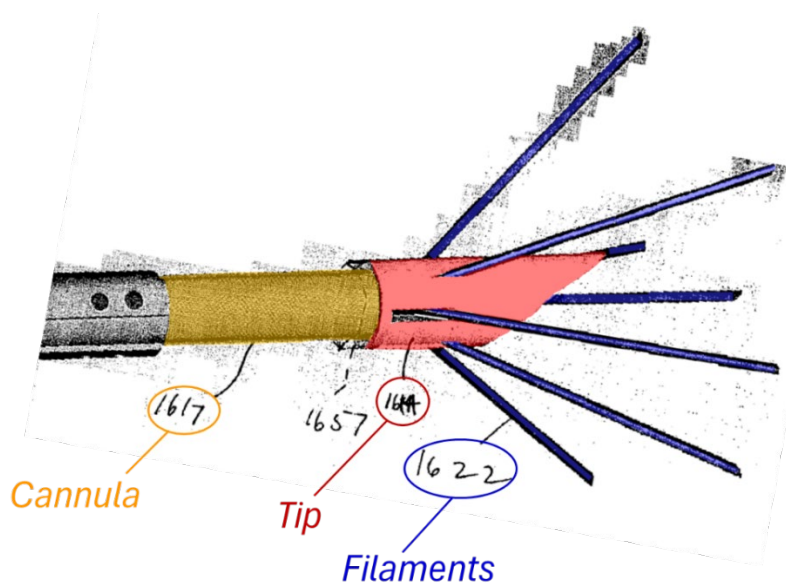


Lee discloses that the filaments “define an ablation volume in the target tissue.” Ex-1010, ¶0012. Thus, “the destruction of target tissue [occurs] at the site

where the electrodes are located.” Ex-1010, ¶0084. The ablation volume may be varied by adjusting the filaments’ length, direction, arrangement, and/or pattern.

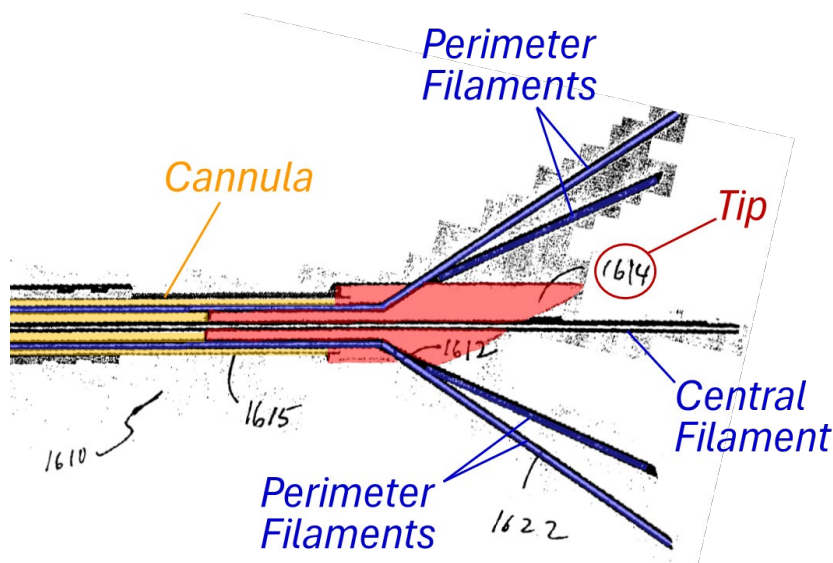
See Ex-1010, ¶0123-0131, 0084; Ex-1034, ¶129.

Lee provides additional detail regarding filament deployment with reference to a trocar (1610) (Figs. 48-49). The device’s cannula (1615) (**shaded orange**) may be a metal tube coated with an insulative material (1617). Ex-1010, ¶0142. The cannula (1615) (aka “hypotube”) houses a plurality of metal stylets (1622) (**shaded blue**) (i.e., filaments). Ex-1010, ¶0143; Ex-1034, ¶130. A tip or “trocar point” (1614) (**shaded red**) is secured to the end of the cannula (1615) and includes deflection surfaces (1612) to deflect the filaments (1622) when they are extended outwardly from the tip (1614). Ex-1010, ¶0142-0146. The filaments (1622) transmit RF energy to define an ablation volume. Ex-1010, ¶0146.



Lee – Fig. 48 (cropped and annotated)

Figure 49 shows a cross-sectional view of the device (1610), which illustrates how the filaments (1622) extend through the cannula (1615) and are guided outwardly by the tip's deflection surfaces (1612). Ex-1010, ¶0142, 0146. As illustrated, the deployed filaments (1622) extend outwardly around the tip (14). Ex-1010, ¶0142, 0146; Ex-1034, ¶131. The perimeter filaments (1622) again define a cone shape, while a central filament extends through a passage in the center of the tip (1614) such that the perimeter filaments are positioned around the central filament. Ex-1010, ¶0103, 0146, Figs. 1-3, 48-49.



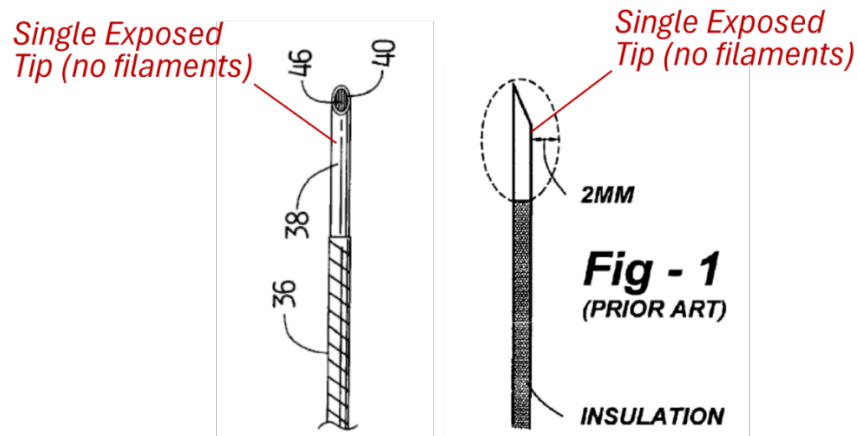
Lee – Fig. 49 (cropped and annotated)

B. Motivation to Combine Racz, Fitz, and Lee.

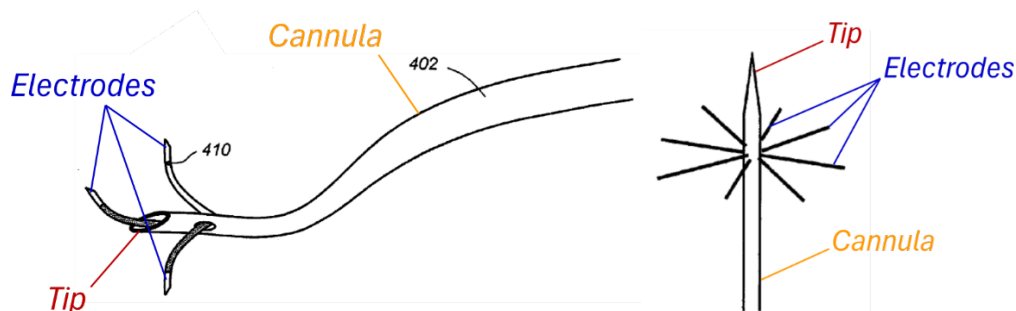
Considering Racz, Fitz, and Lee together, a POSA would have been motivated to implement deployable filaments on the distal tip (14/38) of Racz's electrode cannula (10/33). "[I]f there's a known technique to address a known problem using 'prior art elements according to the established functions,' then

there is a motivation to combine.” *Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1380 (Fed. Cir. 2023) (internal citations omitted). 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. Ex-1011, ¶¶0009-0010, Abstract; Ex-1010, ¶¶0012, 0084, 0123-0131; Ex-1034, ¶¶132, 60-65, 69-72. Thus, a POSA would have recognized that the Fitz/Lee technique would improve the energy coverage area of Racz’s single-tip device. *Id.*

Several factors would have motivated a POSA to combine the references. Four years after Racz’s publication, Fitz disclosed 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 also would have confirmed to a POSA that this limited coverage problem would be present in Racz’s device due to its single-tip configuration (see comparison below). Ex-1011, ¶¶0004, 0012, 0017; Ex-1034, ¶¶133-135.

*Racz – Fig. 2B**Fitz – Fig. 1*

To solve the limited energy coverage problem in Racz’s device, Fitz would have motivated a POSA to provide deployable electrodes on Racz’s exposed tip (14/38). Ex-1011, ¶0009, Abstract; Ex-1034, ¶136. Fitz instructs that the electrodes may be made from a “shape-memory alloy” and be deployed outwardly from the distal tip “to an area to be treated.” Ex-1011, ¶0009-0010, 0018-0021, Abstract, Figs. 4-5. Fitz discloses that this deployable-electrode technique “deliver[s] [RF] energy to a localized region” and solves the inadequate coverage problem of single-tip RF neurotomy needles by “enhanc[ing] the energy coverage area” of the device. Ex-1011, ¶0009-0010.

*Fitz – Fig. 4 (annotated at left) & Fig. 5 (annotated at right)*

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); **(iii)** 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). Thus, Fitz would have motivated a POSA to add deployable electrodes to the distal tip (14/38) of Racz's cannula (10/33). Ex-1034, ¶137. As Fitz's device is also an RF neurotomy needle, a POSA would have understood that Fitz's deployable electrodes could be easily implemented onto Racz's tip (14/38). *Id.*

Nearly two years after Fitz's publication, Lee disclosed a further refinement of the deployable-electrode technique that would have provided additional motivation and guidance to a POSA. 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

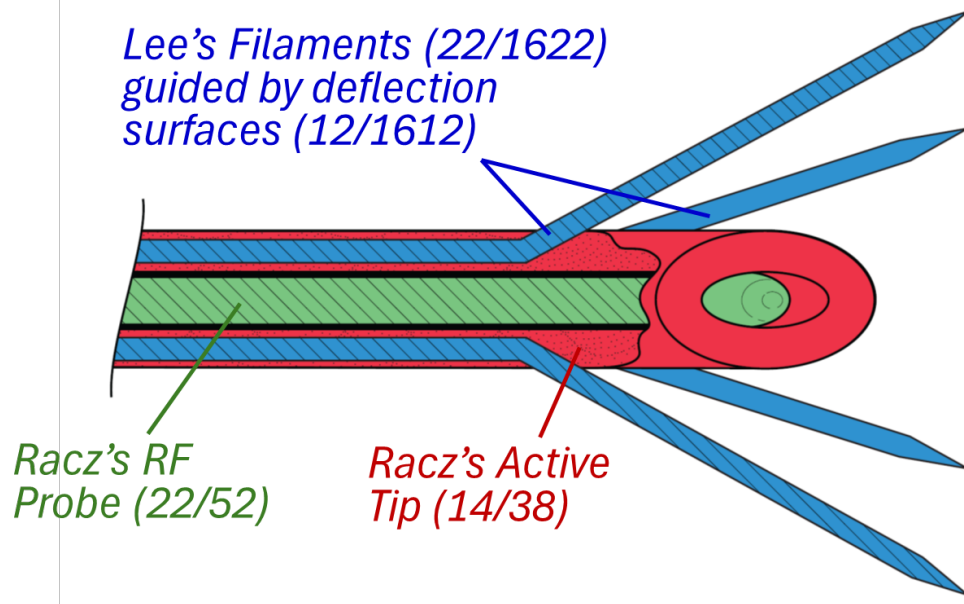
desired pattern” (Ex-1010, ¶0103) and the precision and control offered by the filaments (22/1622) allows “the operator [to] deliver the [radiofrequency] treatment safely and effectively” (Ex-1010, ¶0084). For at least these reasons, a POSA would have been further motivated by Lee to add deployable filaments 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. Ex-1034, ¶138.

Lee also would have confirmed to a POSA that its deployable filaments (22/1622) would be easily implemented on the distal tip (14/38) of Racz’s cannula (10/33). As explained for Claim 1 (*infra* § VI.C.2.a, element [1e]), Lee’s 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. *See* Ex-1010, ¶0094, 0099, 0125, Figs. 1, 23, 49. This would have confirmed to a POSA that Lee’s deployable filaments (22/1622) would be easily arranged to accommodate Racz’s centrally located removable probe (22/52). Ex-1034, ¶139-140.

Furthermore, Lee discloses that deflection surfaces (12/1612) (internal channels and ramps) located in the cannula’s tip can engage and guide those perimeter filaments (22/1622). Ex-1010, ¶0016, 0018, 0091, 0102, Abstract, claims 8, 10. Thus, a POSA would understand that providing deflection surfaces in Racz’s tip (14/38) would result in Lee’s perimeter filaments (22/1622) both physically

contacting Racz's active tip (14/38) and be deployed outwardly around Racz's active tip (14/38). Ex-1034, ¶141. In this way, Lee's perimeter filaments (22/1622) would join Racz's existing monopolar tip (14/38) to function together as a single monopolar electrode. *Id.*

Petitioner's expert—Dr. Tucker—illustrates in his declaration one example of how a POSA (motivated by both Fitz and Lee) would have incorporated Lee's deployable filaments (22/1622) as monopolar electrodes at Racz's distal tip (14/38). Ex-1034, ¶143. Dr. Tucker opines that a POSA would have been motivated to implement Lee's deployable filaments (22/1622) while preserving the functionality of Racz's cannula (10/33), active tip (14/38), and removable probe (22/52). Ex-1034, ¶144-147. According to Dr. Tucker, this implementation 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. *Id.*



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

“If a technique has been used to improve one device, and a [POSA] 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.” *Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1380 (Fed. Cir. 2023) (internal citations omitted). As explained below for Claim 1, a POSA would have found implementing Lee’s deployable filaments (22/1622) on Racz’s tip (14/38) to be a matter of routine engineering, well within the level of ordinary skill in the art, and executable with a reasonable expectation of success. Ex-1034, ¶148-149. The resulting device would include every limitation of the needle recited in claims 1 and 21 (and the structural limitations of Claims 1-10 and 20-26).

C. Ground A: Independent Claim 1**1. Racz discloses the preamble [1pre] and limitations [1a], [1b], [1c], [1d], and [1e]***a. [1pre]*

Claim 1's preamble recites "a method" ([1pre]). Racz is "directed to a system and method for ... pain relief" and therefore discloses [1pre]. Ex-1009, 2:46-47; Ex-1034, ¶150.³

b. [1a]

Element [1a] recites "inserting a needle into a patient." Racz discloses a "curved tip needle electrode." Ex-1009, 2:46-48; *id.* at 3:24-26, Abstract (referring to the "electrical needle or cannula"). Racz's cannula (10/33) (aka "electrical needle") is "inserted directly through the skin." Ex-1009, 3:42-45; *see also id.* at 8:45-57, 9:49-51 (claim 3). Thus, Racz discloses the step, "inserting a needle into a patient" [1a]. Ex-1034, ¶151.

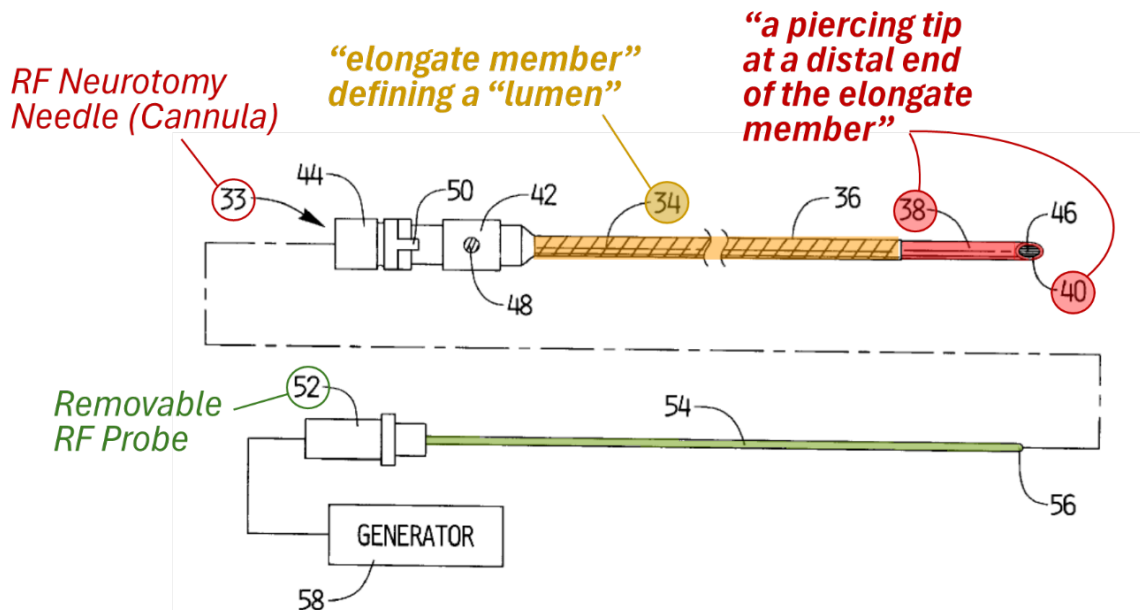
c. [1b] through [1d]

Elements [1b] through [1d] recite features of the "needle" that is inserted into the patent, each of which are disclosed in Racz.

Racz discloses that its electrode cannula (10/33) comprises "an elongated shaft" (12/34) defining "an internal lumen." Ex-1009, 1:33-36, 2:48-51, 5:41-48,

³ All emphasis in quotations in this Petition is added unless otherwise indicated.

Claim 1, Claim 11. In one example, the shaft (12/34) is a “metal tubular shaft” (i.e., a tube defining an internal lumen). Ex-1009, 2:48-51, Claim 8. Racz discloses 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.” Ex-1009, 9:44-48, 3:38-42, 3:60-65, 5:26-28, 5:37-51. Thus, Racz’s shaft (12/34) is “an elongate member” [1b] (**shaded orange**) and defines a “lumen within” it [1d]. Ex-1034, ¶152-153.



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

Further, the Racz’s exposed electrical tip (14/38) is positioned at a distal end of the shaft (12/34) and defines a “self-penetrating point” (18/40). Ex-1009, 3:47-51, 1:28-30, 5:3-5. This allows the cannula (10/33) to be “inserted directly through the skin.” Ex-1009, 3:42-45; *id.* at 8:45-57, 9:49-51 (claim 3: “the distal tip portion defines a sharp end to facilitate insertion into the patient[.]”). Thus, Racz discloses

a “piercing tip at a distal end of the elongate member” [1c] (**shaded red**). *See also* Ex-1034, ¶154.

2. Racz as modified in view of Fitz and Lee discloses limitations [1e] through [1h]

For the reasons explained above, a POSA would have been motivated to implement Lee’s perimeter deployable filaments (22/1622) 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. *Supra* § VI.B (“Motivation to Combine”). Furthermore, a POSA would have found implementing Lee’s deployable filaments (22/1622) on Racz’s cannula (10/33) to be a matter of routine engineering, well within the level of ordinary skill in the art, and executable with a reasonable expectation of success. *Infra* § VI.C.2.a; Ex-1034, ¶155. Implementing Lee’s perimeter deployable filaments (22/1622) on the distal tip (14/38) of Racz’s cannula (10/33) would have resulted in a device having the features recited in [1e] through [1h] (and, as described above, the features recited in limitations [1a] to [1d]).

a. [1e]—needle comprises “a filament”

Claim 1 recites that its needle comprises “a filament in a retracted position in which the filament is at least partially disposed within the elongate member” [1e]. Lee’s deployable “stylets” (22/1622) are each a “filament” as in [1e] (and steps [1f]-[1h]).

Although Lee uses the terms “stylet” and “electrode,” Lee discloses that these stylets/electrodes (22/1622) 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). Ex-1010, ¶¶0092, 0087. Thus, each of Lee’s stylets/electrodes (22/1622) is “a filament” (as recited in element [1e]) and are therefore referred to herein as “filaments (22/1622).” Ex-1034, ¶¶156-157; *cf.* Ex-1003, 9:62-64 (“filaments” may be “constructed from a material operable to conduct RF energy, e.g., a metal such as ... Nitinol, or shape memory alloy”).

Motivated by Fitz/Lee to implement Lee’s deployable filaments (22/1622) on the distal tip (14/38) of Racz’s cannula (10/33), a POSA would have considered at least the following teachings from both Racz and Lee (Ex-1034, ¶158):

(i) Racz’s distal tip (14/38) is electrically active via “physical contact” between the removable probe (22/52) and tip portion (14/38) of the cannula (10/33) (Ex-1009, 5:41-51; *supra* § VI.A.1);

(ii) Racz discloses that physical contact is an effective method of transmitting RF energy because the probe (22/52) and tip (14/38) are constructed from conductive materials (Ex-1009, 4:62 to 5:5, 5:45-58);

(iii) Lee’s filaments (22/1622) are “springy wire-like member[s]” made from a conductive material (e.g., Nitinol) (Ex-1010, ¶¶0087, 0092, 0017);

(iv) Lee's filaments (22/1622) "may be housed wholly within lumen 20 of cannula 16" (Ex-1010, ¶0092);

(v) Lee's filaments (22/1622) physically contact and are guided by "deflection surfaces" (channels and ramps) at the tip of Lee's RF cannula (Ex-1010, ¶0016, 0018, 0087, 0092, 0102, Claims 8, 10);

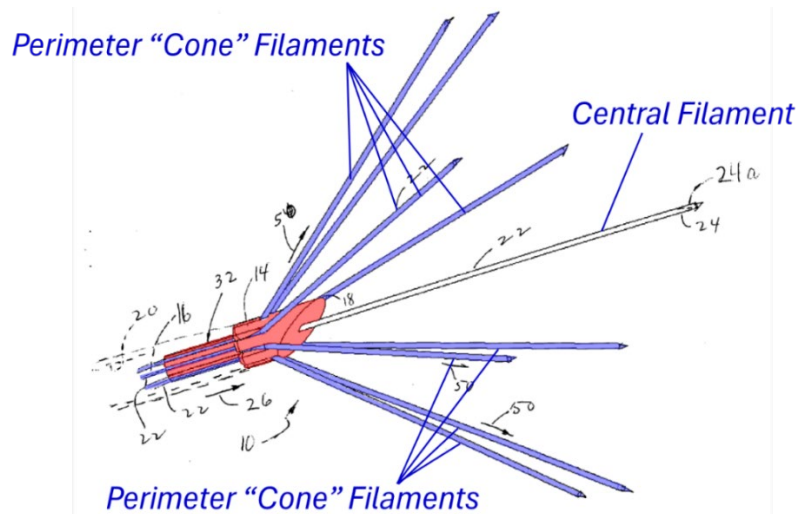
(vi) Lee's device includes perimeter filaments (22/1622) arranged around the inner perimeter of the cannula such that they surround and provide space for a central element (a central filament (22/1622) that extends in a straight-forward direction out of the center of the cannula's tip) (Ex-1010, ¶0092, 0102, 0146, Figs. 1-3, 48-49; *supra* § VI.A.3);

(vii) when deployed, Lee's perimeter filaments (22/1622) extend outwardly and around the cannula's tip in a "cone" shape (Ex-1010, ¶0103, Figs. 1, 5, 48-49);

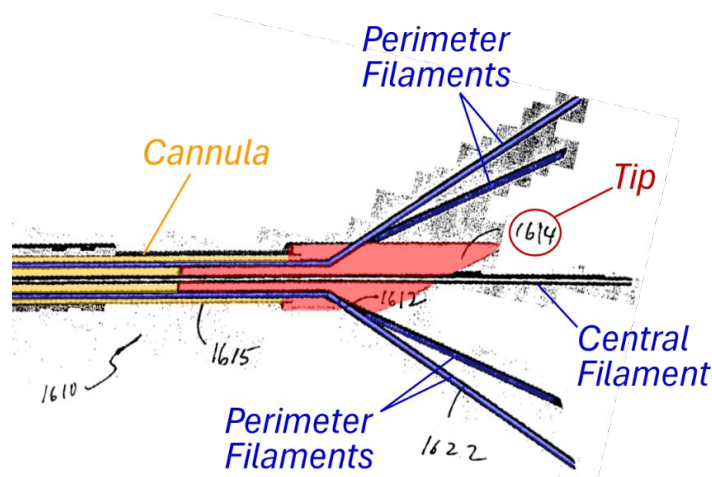
(viii) Lee's filaments (22/1622) are electrically active and—like Racz's tip (14/38)—transmit RF energy to "define an ablation volume in the target tissue" (Ex-1010, ¶0012, *see also* ¶0084); and

(ix) "variations in ablation volume may be achieved by varying the extent to which [filaments] are extended from the distal end of the trocar and the direction in which [filaments] extend" and that "the arrangement of [filaments] may ... form any desired pattern" (Ex-1010, ¶0123-0131, 0084, 0103).

In view of these teachings in Racz and Lee, a POSA would have found implementing Lee's perimeter filaments (22/1622) on Racz's distal tip (14/38) to be a routine engineering task. Ex-1034, ¶159. A POSA would have recognized that it would be appropriate to implement Lee's perimeter filaments (22/1622) without including Lee's central filament. *See* §VI.A.3 (discussing Lee's perimeter/central filaments). Lee discloses that any number and arrangement of filaments may be implemented to provide a desired ablation volume (i.e., the centrally located filament is not always needed). Ex-1010, ¶0103 ("the arrangement of stylets may ... form any desired pattern"), ¶0105 (filaments may be used "singly, in combination or in any desired pattern"), ¶0106 ("the patterns of ... electrode deployment may be varied to achieve any desired effect"). Additionally, as Racz's exposed distal tip (14/38) is already active, a POSA would have recognized that Lee's central filament would not be necessary (shown below unshaded in Lee's Fig. 1 and 49). Ex-1009, 3:60-63, 4:18-23; Ex-1034, ¶159. Thus, a POSA 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. Ex-1034, ¶159, 73-75, 79-83. As Lee (and Fitz) confirm, this would improve Racz's device by providing an expanded and controlled energy coverage area. Ex-1011, ¶0009-0010, Abstract; Ex-1010, ¶0012, 0084, 0123-0131; Ex-1034, ¶159.



Lee – Fig. 1 (annotated to show perimeter filaments)



Lee – Fig. 49 (annotated to show perimeter filaments)

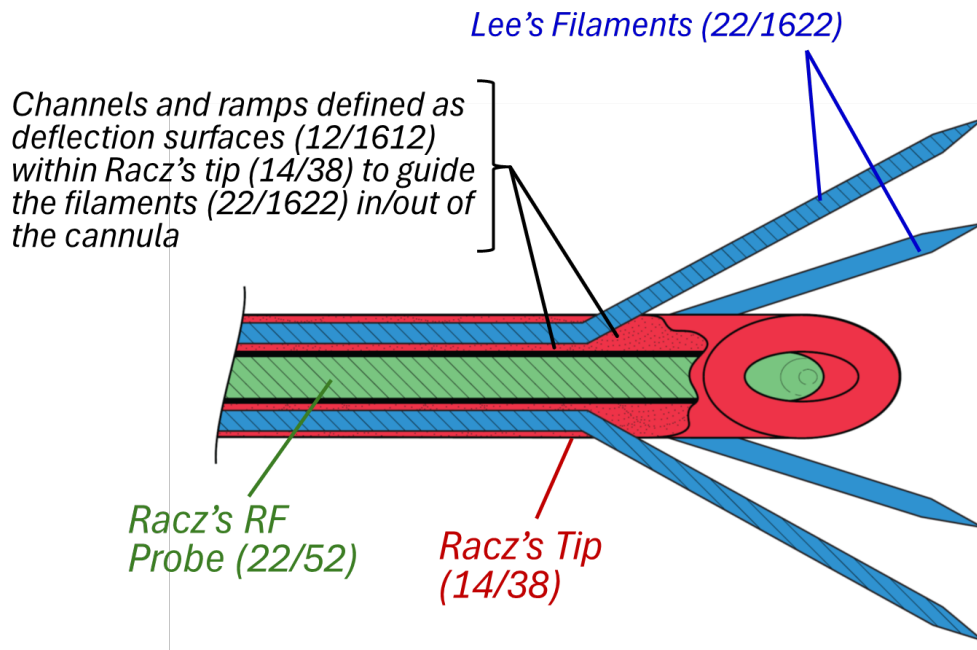
To implement Lee's perimeter filaments (22/1622) on Racz's distal tip (14/38), a POSA would have found it obvious to modify Racz's tip (14/38) to include internal deflection surfaces (12/1612) (e.g., channels and ramps as disclosed in Lee) to guide the perimeter filaments (22/1622) outwardly around Racz's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

To preserve the functionality of Racz's removable electrical probe (22/52) and active tip (14/38)—and consistent with Lee's teachings—a POSA would have arranged the perimeter filaments, channels, and ramps around the internal perimeter of Racz's cannula (10/33). Ex-1010, ¶¶0091, 0092, 0098, 0102; Ex-1034, ¶161. As discussed above, Racz's electrical probe (22/52) is configured to extend the full length of the cannula's shaft (12/34) to supply RF energy to the tip (14/38) and measure tissue temperature. *Supra* § VI.A.1. By omitting Lee's central filament (which would not be needed) and arranging the perimeter filaments, channels, and ramps around the inner perimeter of Racz's cannula (10/33), a POSA would have easily implemented Lee's perimeter filaments (22/1622) without obstructing Racz's cannula (10/33). This would preserve the functionality of Racz's electrical probe (22/52), which is needed to transmit RF energy. Ex-1034, ¶161.

Although the filaments (22/1622) could be implemented in a variety of ways, Petitioner's expert (Dr. Tucker) shows in his declaration one example of how a POSA would have implemented Lee's perimeter filaments (22/1622) and deflection surfaces (12/1612) around the inner perimeter of Racz's distal tip (14/38) (such that Racz's probe (22/52) would still be received into the cannula's

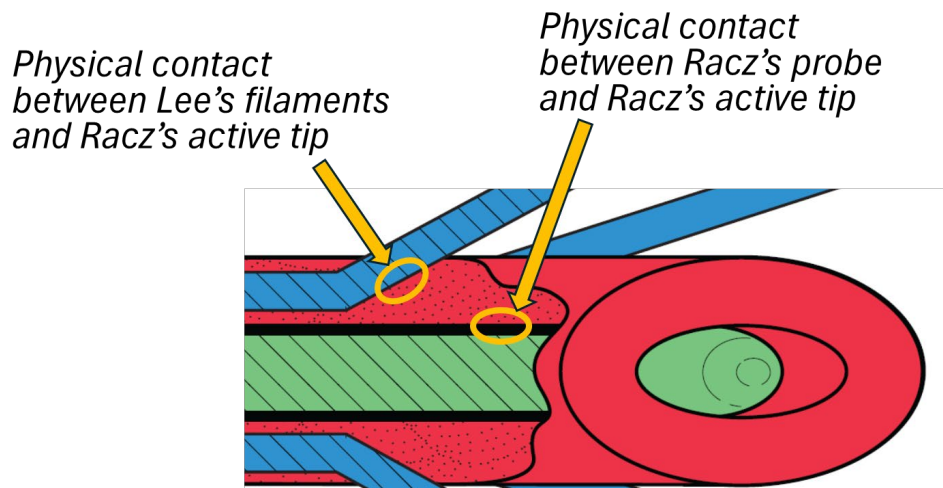
central lumen). Ex-1034, ¶162. According to Dr. Tucker, Lee's deflection surfaces (channels and ramps) would be easily formed as an integral portion of Racz's distal tip (14/38) (e.g., by defining internal channels and ramps as a unitary part of the cannula's shaft (12/34)). Ex-1034, ¶162. Dr. Tucker notes that, alternatively, the deflection surfaces would be defined on a separate, electrically conductive mandrel secured to the end of Racz's shaft (12/34) and provided with a lumen to receive a distal portion of the electrical probe (22/52) (the mandrel thereby defining both the tip (14/38) and deflection surfaces). Ex-1034, ¶162, 39-40.



Dr. Tucker Declaration at ¶162

With respect to conveying RF energy, Racz discloses that “physical contact” between the electrical probe (52) and the cannula's distal tip (14/38) is an effective method of transmitting RF energy to the distal tip (14/38). Ex-1009, 5:35-45. As discussed above, Lee discloses that its perimeter filaments (22/1622) are

electrically active and, when deployed, are guided out of the cannula's distal tip (14/1614) by physical contact with the deflection surfaces (themselves defined at the cannula's active tip (14/38)). Ex-1010, ¶¶0016, 0018, 0087, 0091, 0102, Claims 8, 10. As shown in the example illustration provided by Dr. Tucker above, when Racz's exposed distal tip (14/38) is modified to include deflection surfaces (channels and ramps), the tip's deflection surfaces will physically contact the filaments (22/1622) to guide them as they are deployed and *retracted* from Racz's cannula. Ex-1034, ¶163.



Dr. Tucker Declaration at ¶163

As Racz's electrical probe (52), Racz's distal tip (14/38), and Lee's filaments (22/1622) are all constructed from conductive materials, the RF energy from Racz's electrical probe (52) would necessarily be transmitted to the modified device's distal tip (14/38) and perimeter filaments (22/1622). Ex-1009, 4:60 to 5:1, 5:38-48, 7:43-50; Ex-1010, ¶¶0087, 0092, 0017; Ex-1034, ¶164, 42. Specifically,

RF energy from the electrical probe (52) would be transmitted by physical contact to the distal tip (14/38), and the distal tip (14/38)—which defines the deflection surfaces—would transmit RF energy by physical contact to the perimeter filaments (22/1622). Ex-1034, ¶164.

For at least these reasons, Racz’s cannula (10/33)—as modified by a POSA to include Lee’s perimeter filaments (22/1622)—would include “a filament” [1e]. As explained in the next subsection, the filament would also be provided “in a retracted position in which the filament is at least partially disposed within the elongate member” as further recited in [1e]. Ex-1034, ¶165.

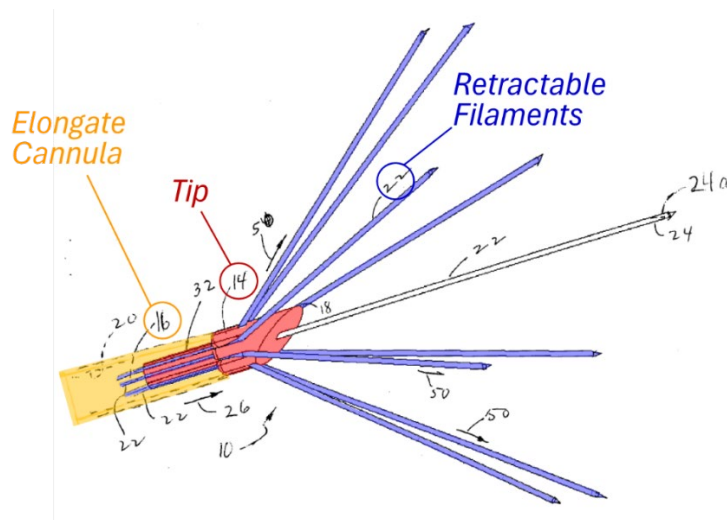
b. [1e] and [1f]—“moving the filament” from “a retracted position” to “a deployed position”

Element [1e] further recites that the filament is “in a retracted position ... at least partially disposed within the elongate member,” and element [1f] recites the step, “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.” These features are likewise obvious. Ex-1034, ¶166.

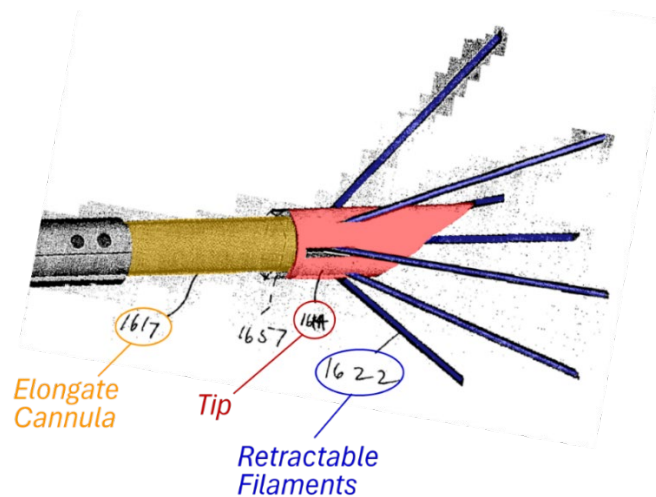
Lee discloses that its perimeter filaments (22/1622) are configured to be adjusted between deployed and withdrawn positions. In the withdrawn position, the filaments are “housed wholly within lumen 20 of cannula 16” during insertion and withdrawal of the device. Ex-1010, ¶0092, 0098-0099, 0106, 0107, Figs. 1-3. In the deployed position, the filaments (22/1622) extend outwardly from the

cannula (and distally beyond the cannula's tip) to define the ablation volume. *Id.*

Indeed, Lee discloses 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.” Ex-1010, ¶0129 (emphasis added). As shown below, Lee illustrates how its filaments (22/1622) extend beyond the tip of its device. See e.g., Ex-1010, Figs. 1, 48, 49; Ex-1034, ¶167.



Lee – Fig. 1 (annotated)



Lee – Figure 48 (annotated)

Thus, a POSA implementing Lee's filaments (22/1622) on the tip (14/38) of Racz's device would have been motivated to configure the filaments (22/1622) to be positioned such that "at least a distal end of the filament is out of the elongate member and disposed away from the tip" (14/38) in a deployed configuration (e.g., to expand the ablation volume of Racz's device), as recited in claim element [1f], and to be positioned within the shaft (12/34) in a "retracted position" (e.g., to enable effective withdrawal and insertion of Racz's modified device), as in claim element [1e] (i.e., "at least partially disposed within the elongate member"). Ex-1034, ¶168.

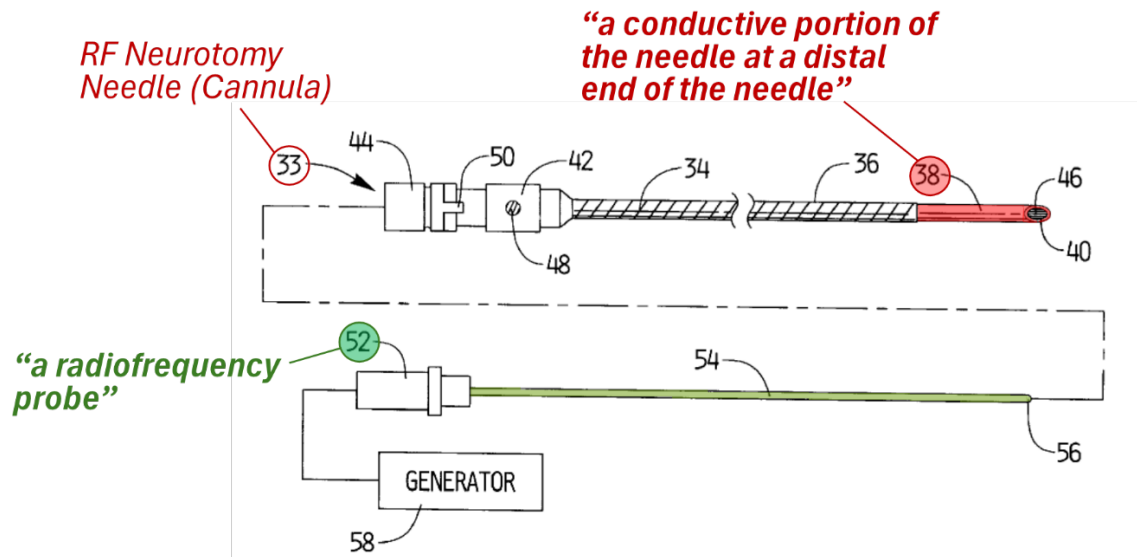
Further, "moving" the filament between retracted and deployed positions is also taught by the proposed combination (and within a POSA's skill). Ex-1034, ¶169. Lee discloses that its perimeter filaments (22/1622) "may be connected to *suitable advancement and retraction mechanisms*" (i.e., an actuator) for adjusting the filaments (22/1622) between the deployed position and the withdrawn position. Ex-1010, ¶0106. Lee teaches that "[s]uch mechanisms may be of a conventional design." Ex-1010, ¶0106. Fitz likewise teaches its filaments are "deployed" from the introducer by a "slid[ing] movement." Ex-1011, ¶0009; *see also id.*, ¶0007 (describing prior art reference where deployable electrical lead "may be actuated with various mechanisms").

As confirmed by Dr. Tucker, a POSA 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). Ex-1034, ¶170-172, 77-78. Further, Lee discloses that the filaments (22/1622) should be moved from the retracted position to the deployed position once the needle is positioned inside a patient and in a position for the filaments (22/1622) to be deployed into targeted tissue for ablation. *See* Ex-1010, ¶0087, 0091-0092, 0098-0099, 0102, 0107. 0121. Accordingly, in view of Lee's teachings, a POSA would have found it obvious to move the filament from the "retracted position" (as in element [1e]) to the "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" (as in element [1f]). Ex-1034, ¶172.

c. [1g] – "inserting a radiofrequency probe..."

Racz discloses that its electrode cannula (10/33) comprises "an elongated shaft" (12/34) defining "an internal lumen." Ex-1009, 1:33-36, 2:48-51, 5:41-48, Claim 1, Claim 11. In one example, the shaft (12/34) is a "metal tubular shaft" (i.e., a tube defining an internal lumen). Ex-1009, 2:48-51, Claim 8. Racz discloses that the shaft's lumen accepts the radiofrequency probe (22/52) (**shaded green**) to conduct RF energy to the tip (14/38). Ex-1009, 3:38-42, 3:60-65, 5:26-28, 5:37-51.

Thus, Racz discloses “inserting a radiofrequency probe into the lumen of the needle” as required in [1g]. Ex-1034, ¶173.



Racz – Fig. 2B (annotated)

When 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. In other words, the probe (22/52) is electrically connected to the tip (14/38) by “*physical contact* between the probe shaft 54 and the electrode shaft 34.” Ex-1009, 5:41-48; Ex-1034, ¶174.

When inserted into the lumen at the interior of the cannula’s shaft (12/34), the probe’s shaft (54) is configured to extend the full length of the cannula shaft

(12/34) such that the probe's tip (56) is positioned at the cannula's tip (14/38). *See* Ex-1009, FIG. 2B, Ex-1034, ¶175. Indeed, Racz discloses that the probe's tip (56) may include a temperature sensor (Ex-1009, 5:28-30) and a POSA would have understood that the temperature sensor is for measuring the tissue temperature at the tip (14/38) during ablation. Ex-1009, 8:58-62; Ex-1034, ¶175, 50.⁴ The probe's temperature sensor could not accurately measure the tissue temperature during ablation if the probe's tip (56) were not positioned at the cannula's tip (14/38) when the probe (22/52) is inserted. *Id.*

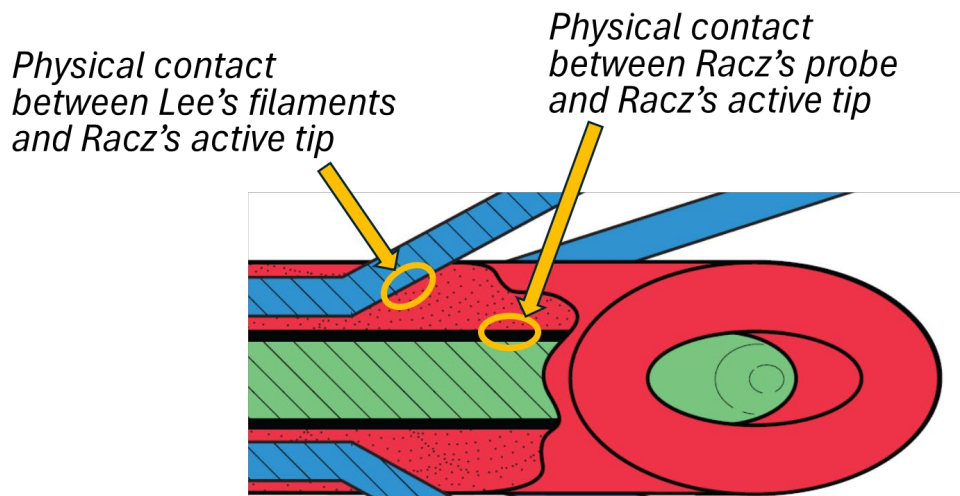
As Racz's probe shaft (54) extends the full length of the cannula's internal lumen, a POSA would recognize that the “physical contact between the probe shaft 54 and the electrode shaft 34” would occur at least at the conductive tip (14/38) of the cannula (10/33). Ex-1009, 5:45-48; Ex-1034, ¶176. As the electrical probe's shaft (54) has a uniform profile and extends the full length of the cannula shaft (12/34), the probe (22/52) would necessarily contact the shaft (12/34) along its full length—including the tip (14/38). *Id.*

⁴ *See also* Ex-1011, ¶0003 (noting that RF neurotomy devices include “a thermocouple temperature sensor [at the] distal uninsulated tip” and provide “very close proximity of the thermocouple sensor to the tissue the temperature of which must be measured, and very accurate and rapid temperature response”).

Racz also discloses that the cannula's tip (14/38) conducts electrical signals for "high-frequency heating" (e.g., generating radio-frequency heat lesions). Ex-1009, 4:18-23, 4:52-58, 3:41-59, 5:38-45, 7:43-50. The tip (14/38) is made of a conductive material (e.g., where the cannula's "shaft (34) comprises a hollow metal tube," the exposed tip (14/38) may be "an extension of the metal tube"). Ex-1009, 4:60 to 5:1, 5:45-48. As such, physical contact with the probe (22/52) transmits RF energy to the tip (14/38) and into patient tissue. Ex-1009, 3:60-65, 4:18-23 (describing "practice" of "electrical stimulation" by "exposed electrical tip" as "well known" in the art), 5:41-48, Fig. 2B; Ex-1034, ¶177. Thus, Racz's "probe contacts a conductive portion [14/38] of the needle at a distal end of the needle" [1g] and "establish[es] an electrically conductive path" from the probe (22/52) to the conductive portion (14/38) of the needle as recited. Ex-1034, ¶177.⁵

⁵ Racz's exposed electrical tip (14/38)—including its pointed end (18/40)—can serve as *both* the "conductive portion of the needle at a distal end the needle" [1g] *and* the "piercing tip at a distal end of the elongate member" [1c]. Dependent Claim 23 confirms that the "conductive portion" and the "piercing tip" can be the same portion of the claimed "needle." Ex-1003, 33:16-19 ("physically contacting the radiofrequency probe to the *conductive portion of the needle* at the distal end ... comprises physically contacting the radiofrequency probe to *the tip*.").

Furthermore, implementing Lee's filaments (22/1622) in Racz's device would provide a conductive path to the "to the filament." As discussed above at pages 3636-38, Racz's electrical probe (52), Racz's distal tip (14/38), and Lee's filaments (22/1622) are all constructed from conductive materials, so that the (modified) tip's deflections surfaces will physically contact the filaments. Thus, RF energy would be transmitted from the probe (52) to the tip (14/38) and to the perimeter filaments (22/1622) by physical contact. Ex-1034, ¶178.



Dr. Tucker Declaration at ¶178

Accordingly, when the RF probe (22/52) is inserted into the lumen of Racz's electrode cannula (10/33)—as modified to include Lee's perimeter filaments (22/1622)—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” as recited in [1g]. Ex-1034, ¶179.

d. [1h] – “operating the radiofrequency probe, the tip, and the filament as a monopolar electrode...”

As described immediately above, “radiofrequency energy from the radiofrequency probe being conducted to the filament through the electrically conductive path and transmitted by the filament” as required by [1h]. Ex-1034, ¶180; *see also supra* § VI.C.2.a, VI.C.2.c.

The additional limitations in [1h] recite “operating the radiofrequency probe, the tip, and the filament as a monopolar electrode.” This step also would have been obvious. In Racz’s modified device, a POSA would have configured the active tip (14/38) and perimeter filaments (22/1622) to operate together as a single electrode in a monopolar mode. Ex-1034, ¶181, 84-88. 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.” Ex-1009, 4:3-23, Fig. 1. In other words, Racz’s distal tip (14/38) would already have been configured as a monopolar electrode. Ex-1034, ¶181. Lee discloses that 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.” Ex-1010, ¶0024.

A POSA would have understood that 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. Ex-1034, ¶182, 84-88. In other words, when the filaments (22/1622) are deployed and the probe (22/52) is inserted into the cannula (10/33), the filaments (22/1622) and tip (14/38) will transmit RF energy together and operate as a single monopolar electrode. Ex-1034, ¶182.

A POSA also 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. Ex-1009, 4:3-23, Fig. 1; Ex-1010, ¶0024; Ex-1034, ¶183. In implementing Lee's filaments (22/1622) to expand and control the ablation volume of Racz's device, a POSA 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.*

Thus, Racz's device—as modified by a POSA in view of Fitz and Lee—would be configured to “operat[e] the radiofrequency probe, the tip, and the filament as a monopolar electrode” as recited in [1h]. Ex-1034, ¶184.

For at least these reasons, Claim 1 is obvious in view of Racz, Fitz, and Lee. Ex-1034, ¶184.

D. Ground A: Dependent Claims 2-10 and 20**1. Claim 2**

Lee teaches that its device should first be positioned in a target area within a patient (prior to its filaments (22/1622) being deployed). Ex-1010, ¶¶0087, 0091-0092, 0098-0099, 0102, 0107. 0121. 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.” Ex-1010, ¶¶0085. Lee also teaches that “*after* the [filaments] 22 have been successfully deployed in the tumor mass to be ablated, *RF energy ... is applied* to the [filaments].” Ex-1010, ¶¶0107, 0099, 0087.

Additionally, Racz explains that its needle (10/33) “can be inserted directly through the skin of the body portion P to locate the tip 14.” Ex-1009, 3:42–44. 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. Ex-1009, 1:43-52, 5:31-51. And, *after* the RF probe is inserted, its tip (14/38) is activated with RF energy to ablate targeted tissue. Ex-1009, 2:53-56, 4:18-23, 5:29-51.

Accordingly, following the teachings of Racz and Lee, a POSA would have found it obvious 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. Ex-1034, ¶185-187.

Thus, it would have been obvious to a POSA to “mov[e] the filament to a deployed position within the patient ... prior to said inserting the radiofrequency probe into the lumen of the needle.” Ex-1034, ¶187. Claim 2 is therefore obvious under §103(a) in view of Racz, Fitz, and Lee.

2. Claims 3-5

The proximal hub (20/42/70) of Racz’s cannula may be “a standard hypodermic needle or luer type hub, capable of connection to stylets, electrical probes, syringes, or injection tubes.” Ex-1009, 5:66-6:7. Racz’s 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). Ex-1009, 5:14-18, 8:54-57, 5:66-6:8, 6:9-12, 1:29-33, Abstract. The hub allows “diagnostic or therapeutic liquids” to be dispensed through the cannula’s shaft (12/34) and out of the pointed end (40). Ex-1009, 5:14-18, 6:9-12, 1:29-33. Moreover, Racz’s proximal hub (20/42/70) is also configured to receive the probe (22/52) (for transmitting RF energy during ablation) in addition to receiving fluid from a fluid source (e.g., from a syringe or injection tube when the probe (22/52) is not inserted). Ex-1009, 3:59-65, 5:66-6:12, 9:30-39, 10:8-10. In other words, the fluid source can necessarily be disconnected from the hub (20/42/70) to allow for insertion of the RF probe (22/52) through the hub/fitting. Ex-1034, ¶188.

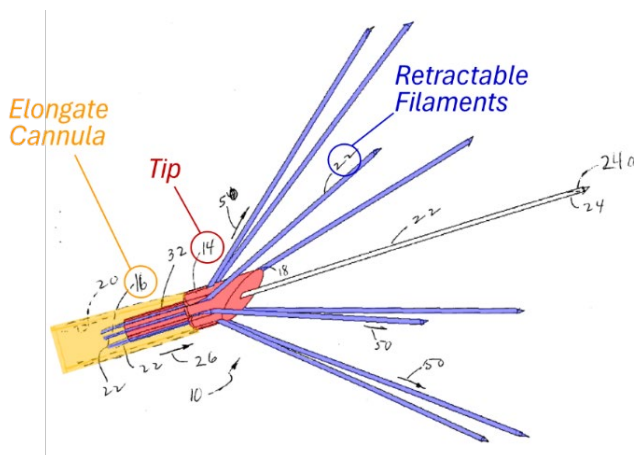
Thus, Racz's hub (20/42/70) is "a fitting in fluid communication with the lumen" ([3a]), which allows "connecting a fluid source to the fitting" ([3b]), "transporting fluid through the lumen of the needle to a target volume within the patient" ([3c]), and then "disconnecting the fluid source from the fitting" ([3d]). Ex-1034, ¶189. Furthermore, Racz teaches "inserting the radiofrequency probe into the lumen is achieved by passing the radiofrequency probe through the fitting" [4]. Ex-1034, ¶189.

Racz also 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." Ex-1009, 5:66-6:7; *see also id.* at 1:55-63 (describing "routine[]" procedure where "[a]nesthetic or diagnostic localization agents" are injected through needles before "stimulation testing" and ablation "can then be performed"); Ex-1022, 5:46-57. It was therefore obvious, in view of the teaching to dispense fluid before applying RF energy, to "insert[] the radiofrequency probe into the lumen ... after said disconnecting the fluid source from the fitting" [5]. Ex-1034, ¶190-191.

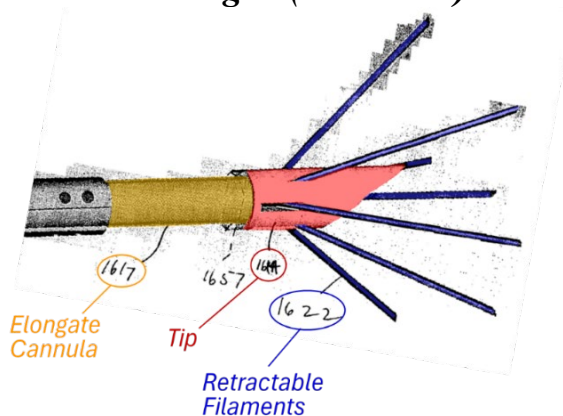
For at least the foregoing reasons, Claims 3, 4, and 5 are each obvious in view of Racz, Fitz, and Lee.

3. Claims 6 and 7

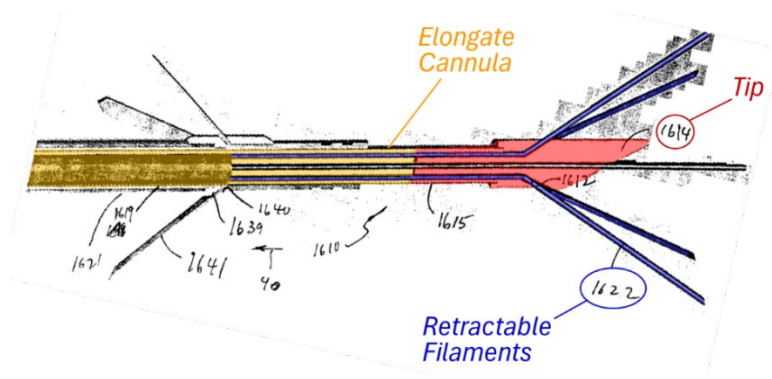
As explained for element [1f] above, in the deployed position, the filaments (22/1622) are positioned such that their tips are located “distally beyond the tip of the needle” [6]. Ex-1010, ¶¶0092, 0098-0099, 0106, 0107, Figs. 1-3. Lee teaches that “variations in ablation volume may be achieved by varying *the extent to which stylets are extended from the distal end* of the trocar and the direction in which stylets extend.” Ex-1010, ¶¶0129. And Lee illustrates its filaments (22/1622) extending beyond the tip of its device. *See e.g.*, Ex-1010, Figs. 1, 48, 49; Ex-1034, ¶192.



Lee – Fig. 1 (annotated)

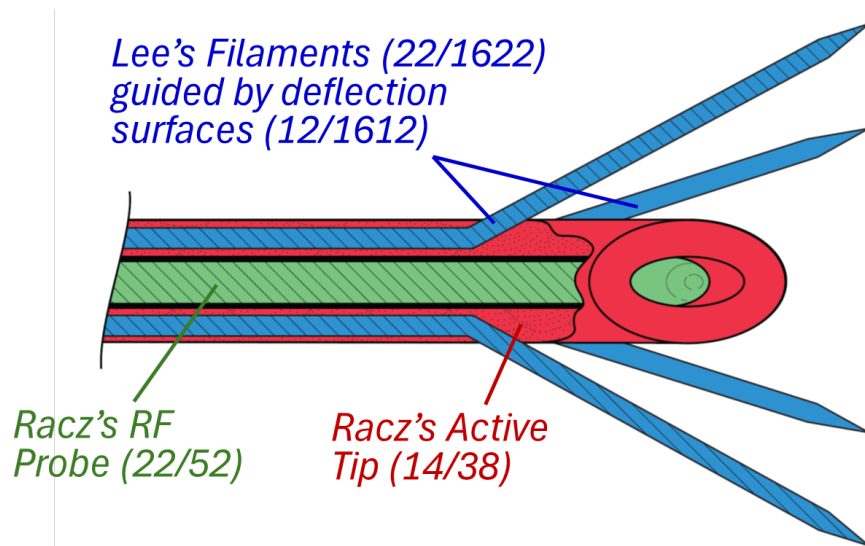


Lee – Figure 48 (annotated)



Lee – Figure 49 (annotated)

Thus, 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's device. *Supra* § VI.A.2. As Dr. Tucker has explained and illustrated, Lee's deployable filaments (22/1622) would be configured to extend beyond the tip (14/38) of Racz's device. Ex-1034, ¶193.



Dr. Tucker Declaration at ¶193

Thus, a POSA would have found it obvious to operate Racz's modified device by "moving the filament to the deployed position comprises positioning the distal end of the filament distally beyond the tip of the needle" [6]. Ex-1034, ¶194.

As is readily apparent from each of the figures from Lee above, Lee teaches the tips of the filaments (22/1622) are spaced apart from the cannula's central longitudinal axis by a distance that is greater than the radius of the elongate member. Ex-1034, ¶195; Ex-1010, Figs. 1, 5, 48, 49 and ¶0138 ("other sizes and shapes of [filaments] may be used"). Indeed, 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. Ex-1034, ¶195. Moreover, 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." Ex-1010, ¶0129. Thus, it would have been obvious to extend the filaments (22/1622) 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.*

Thus, a POSA would have found it obvious to move the filaments (22/1622) to a deployed position that "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” [7]. Ex-1034, ¶196. Accordingly, Claims 6 and 7 are each obvious in view of Racz, Fitz, and Lee.

4. Claim 8

As discussed above for element [1g], Racz’s modified device operates with its tip (14/38) and filaments (22/1622) functioning as a monopolar electrode. *Supra* § VI.C.2.c. Racz discloses that its system includes an “a reference electrode 30 in contact with the patient’s body.” Ex-1009, 4:1-5. And 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.” Ex-1010, ¶0024. Thus, a POSA would have found it obvious to “attach[] a return electrode pad to the patient prior to said operating the radiofrequency probe, the tip, and the filament as the monopolar electrode” [8]. *See also* Ex-1034, ¶197. Accordingly, Claim 8 is obvious in view of Racz, Fitz, and Lee.

5. Claims 9 and 20

As discussed above at pages 36-38 (element [1e]) and Sections VI.C.2.c-VI.C.2.d (elements [1g]-[1h]), Racz’s electrical probe (52), 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 transmit the RF energy. *See also* Ex-1034, ¶198. Specifically, when the RF probe

(22/52) is inserted, a distal end of the probe's conductive shaft (54) physically contacts the conductive tip (14/38). Ex-1034, ¶198; *see also supra* § VI.C.2.c (discussing [1g]'s "contact" limitation).

Thus, as recited in Claim 9, the "conductive portion" at the end the needle further "comprises a conductive material in the tip" (14/38) and inserting the RF probe results in "contacting a distal end of the [RF] probe to the conductive material" in the tip (14/38). Ex-1034, ¶199-200. Likewise, as recited in Claim 20, "the probe directly contacts the tip during said operating the radiofrequency probe, the tip, and the filament as the monopolar electrode." *Id.*; *supra* § VI.C.2.d ([1h], tip and filaments operate as monopolar electrode).

Accordingly, Claims 9 and 20 are obvious in view of Racz, Fitz, and Lee.

6. Claim 10

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. Ex-1009, 1:4-10 ("The invention relates to ... an apparatus for pain relief that delivers electrical stimulation pulses or high-frequency signals to the vicinity of a neural structure via an electrical needle or cannula."); *see also id.* at 3:42-45 ("The cannula 10 can be inserted directly through the skin of the body ... to locate the tip 14 in a target position within the body."), 4:49-58 ("the clinician may desire to

modify or coagulate those nerves by electrical signals sent from the tip 14 by the signal generator 28”), 7:43-50 (“radio-frequency heat lesion is to be made on the neural structures”); Ex-1011, ¶0007; Ex-1034, ¶201. Thus, it would have been obvious to use Racz’s modified device and, “after said inserting the needle into the patient, mov[e] the needle to a target volume within the patient that includes a nerve” and “ablat[e] the nerve to relieve pain of the patient” [10]. Accordingly, Claim 10 is obvious in view of Racz, Fitz, and Lee.

E. Ground A: Independent Claim 21 and dependent Claims 22-26

Independent Claim 21 and dependent Claims 22-26 are comprised of limitations substantially the same as those discussed for Claims 1, 2, 3, and 10. The following claim chart shows where the obviousness of each feature in Claims 21-26 is explained above. Claims 21-26 are therefore obvious in view of Racz, Fitz, and Lee. Ex-1034, ¶202.

	Claim Language	Analysis
[21pre]	21. A method comprising:	<i>Supra</i> §VI.C.1.a [1pre]
[21a]	introducing a needle into a patient, the needle comprising:	<i>Supra</i> § VI.C.1.b [1a]
[21b]	an elongate member;	<i>Supra</i> § VI.C.1.c [1b]
[21c]	a lumen within the elongate member; and	<i>Supra</i> § VI.C.1.c [1d]
[21d]	a filament in a retracted position relative to the elongate member;	<i>Supra</i> § VI.C.2.a [1e]
[21e]	moving the filament to a deployed position within the patient;	<i>Supra</i> § VI.C.2.b [1f]

	Claim Language	Analysis
[21f]	inserting a radiofrequency probe into the lumen of the needle;	<i>Supra</i> § VI.C.2.c [1g]
[21g]	physically contacting the radiofrequency probe to a conductive portion of the needle at a distal end of the needle; and	<i>Supra</i> § VI.C.2.c [1g] (including discussion of “physical contact” from probe to tip of needle); <i>see also</i> Ex-1009, 3:60-65 (“This physical relationship between the probe 22 and the shaft 12 facilitates electrical contact between the two elements.”).
[21h]	operating the radiofrequency probe and the filament as a monopolar electrode while the radiofrequency probe contacts the conductive portion of the needle, such that radiofrequency energy from the radiofrequency probe passes through the conductive portion of the needle and is transmitted by the filament.	<i>Supra</i> § VI.C.2.d [1h]
[22]	The method of claim 21, wherein the needle further comprises a piercing tip at a distal end of the elongate member, and wherein said operating the radiofrequency probe and the filament the monopolar electrode further	<i>Supra</i> § VI.C.1.c [1c] (piercing tip) and VI.C.2.c [1h] (operating the radiofrequency probe, the tip, and the filament as a monopolar electrode) ⁶

⁶ Claim 22 contains grammatical errors that potentially render it indefinite. For the purpose of this proceeding only and reserving all rights, Petitioner asserts the claim is obvious assuming the phrase “filament *the* monopolar electrode” instead reads, “filament *as a* monopolar electrode.”

	Claim Language	Analysis
	comprises operating the tip together with the radiofrequency probe and the filament as the monopolar electrode.	
[23]	The method of claim 22, wherein said physically contacting the radiofrequency probe to the conductive portion of the needle at the distal end of the needle comprises physically contacting the radiofrequency probe to the tip.	<i>Supra</i> § VI.C.2.c [1g] and [21g] (in this table)
[24]	The method of claim 21, 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.	<i>Supra</i> § VI.D.1 [2]
[25a]	The method of claim 21, wherein the needle further comprises a fitting in fluid communication with the lumen, the method further comprising:	<i>Supra</i> § VI.D.2 [3]
[25b]	connecting a fluid source to the fitting;	
[25c]	transporting fluid through the lumen of the needle to a target volume within the patient; and	
[25d]	disconnecting the fluid source from the fitting.	

	Claim Language	Analysis
[26]	The method of claim 21, further comprising: 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.	<i>Supra</i> § VI.D.6 [10]

F. Ground A: Claims 18-19 and 28-29

Claims 18-19 and 28-29 each recite the step of “forming a lesion” of specific sizes that includes a nerve. Claims 18 and 28 recite the lesion “has a maximum cross dimension that is 10 millimeters or larger,” while claims 19 and 29 recite the lesion “has a volume of about 500 mm³.” The claims otherwise differ only in the base claim from which they depend (Claim 1 or Claim 21).

Using Racz’s modified device, a POSA would have found it obvious to form a lesion of various sizes and shapes, including the claimed sizes. Ex-1034, ¶203-204, 79-83. Fitz teaches that a “problem” with single-tip neurotomy devices was they did “not allow for adequate coverage of the target area,” sometimes requiring *multiple* lesions to meet the therapeutic need. Ex-1011, ¶0004-0005. So, Fitz disclosed an “improved-coverage RF neurotomy” device using multiple electrodes (i.e., filaments). Ex-1011, ¶0009.

Lee also taught that it was known that “[v]arious shape ablation volumes may be defined by varying the configuration of ... various springy antennae [i.e.,

filaments]” Ex-1010 ¶0007. And Lee’s disclosed device with its multiple filaments (22/1622) “extending in different directions ... may be used to define the shapes of [] various ablation volumes.” Ex-1010, ¶0123. According to Lee, this can be accomplished by varying the number, pattern, direction, size, and/or length of the filaments (22/1622) implemented. Ex-1010, ¶0012, 0084, 0103, 0123-0131, 0106 (“the patterns of ... electrode deployment may be varied to achieve any desired effect”); 0129 (“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”).

Other prior art RF ablation devices with multiple filaments or electrodes *also* show that a POSA knew how to arrange the filaments to control the target lesion size. Ex-1034, ¶205-206, 79-83. For example, Gough ’143, which was cited by Lee, disclosed that “[a]ny number of different ablation geometries can be achieved” depending on several “selectable and controllable” factors, including the number and size of deployable filaments. Ex-1018, 6:52-59. Young ’965 taught an RF ablation device with an “array” of deployable electrodes that “define[d] a volume” with a radius in the range of 5-40mm, and that a POSA would “appreciate[] that a wide variety of particular patterns can be provided to uniformly cover the region to be treated.” Ex-1012, ¶¶0026, 0028.

The '664 Patent merely follows these teachings and employs ordinary skill to achieve the claimed lesion sizes. ¶Ex-1034, 207. The '664 Patent notes the same problem as Fitz—of limited lesion size from “conventional single needle technology”—and it proposes the same solution as Fitz (and Lee)—it “overcomes” that problem and “*expands the effective area* of RF energy delivery” by using multiple filaments. Ex-1003, 3:18-27, 6:11-22; *cf.* Fitz. ¶¶0004-0005. And like Lee, the '664 Patent explains that “[t]he size, shape and location of a lesion” can be “established by the quantity, location and orientation of the filaments.” 664Patent, 6:17-22. But Fitz, Lee, and the other cited evidence show these variations of configuration to achieve various lesion sizes were known and within the level of skill in the art. *Cf. In re Rose*, 220 F.2d 459, 463 (C.C.P.A. 1955); *In re Kirke*, 40 F.2d 765, 767 (C.C.P.A. 1930) (“[T]here is nothing patentable in making a machine or apparatus larger or smaller, if it produces the same result in the same manner.”). *Compare* 664Patent 11:19-14:29 (describing various configurations to “to achieve particular lesion sizes, positions and/or shapes”), *with* Ex-1010, ¶0123-0131 (same); *see also* Ex-1015, ¶0104 (describing ability to “create[e] a lesion having a desired shape, size and location”); Ex-1034, ¶207.

Thus, by dictating these characteristics of the filaments (22/1622)—and the size and/or shape of Racz’s tip (14/38)—a POSA would be capable of configuring Racz’s modified device to produce lesions of any desired volume. Ex-1034, ¶208.

And the claimed sizes—a “cross-dimension” of 10 mm or “a volume of about 500 mm³”—are ones that was already known, desired, and used in the field. Ex-1019, 282 (creating lesion size of “10 mm”); Ex-1015, ¶0133 (describing forming lesion with volume up to 500 mm³ as “useful for lesioning of the nerves of the medial branch of the dorsal ramus at the thoracic region of the spine”). The claimed ablation sizes were thus well-within the level of skill in the art. Ex-1034, ¶208.

Thus, using Racz’s modified device, a POSA would have found it obvious to “form[] a lesion that includes the nerve and has a maximum cross dimension that is 10 millimeters or larger” (**Claims 18 and 28**) or “has a volume of about 500 mm³” (**Claims 19 and 29**). Ex-1034, ¶209. Claims 18-19 and 28-29 are therefore obvious in view of Racz, Fitz, and Lee.

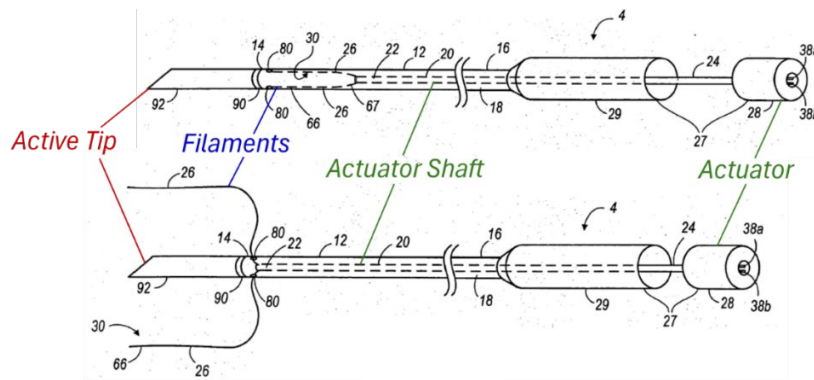
VII. GROUND B: CLAIMS 1-10, 18-26, AND 28-29 ARE OBVIOUS IN VIEW OF RACZ, FITZ, LEE, AND YOUNG ’965

A. Overview of Young ’965

Young ’965 discloses a “tissue ablation system” having “a probe assembly 4 configured for introduction into the body of a patient for ablative treatment of target tissue, and a radio frequency (RF) generator 6 configured for supplying RF energy to the probe assembly 4.” Ex-1012, ¶0022. Thus, Young ’965 is directed to the same field as the ’664 Patent. *See* Ex-1003, 1:24-28; Ex-1034, ¶210.

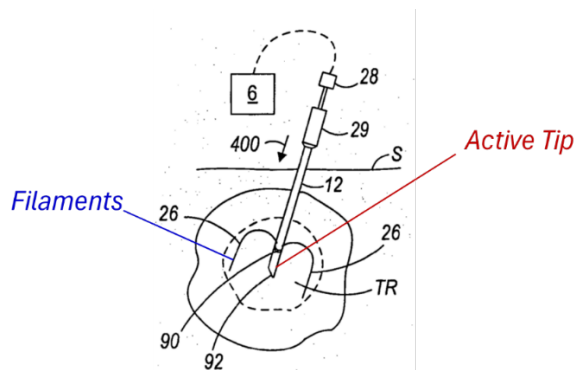
Young ’965’s device (4) includes a cannula (12) housing an “array 30” of deployable “electrodes 26.” Ex-1012, ¶0023, Figs. 2-3. Like Lee’s filaments,

Young '965's electrodes (26) are small diameter "electrode tines" or "wires" (i.e., filaments) made from a shape memory alloy (e.g., Nitinol). Ex-1012, ¶0024-25, 0029. The filaments (26) are coupled to an actuator (a shaft (20)) moved within the cannula (12) by a handle assembly (27). Ex-1012, ¶0034-0035. The deployed filaments (26) extend outwardly from and around the device's electrode tip (92). Ex-1012, ¶0031, Figs. 2-3; Ex-1034, ¶211.



Young '965 – Figs. 2 and 3 (annotated)

When activated with RF energy, “[t]he electrode 92 is in conjunction with the array 30 to deliver energy to tissue.” Ex-1012, ¶0031, 0022, 0033. As shown below, the filaments (26) and electrode tip (92) create a lesion spanning a treatment region (TR). Ex-1012, ¶0039-0042; Ex-1034, ¶212.



Young '965 – Fig. 7C (annotated)

Young '965's teachings would have *further motivated* a POSA to implement Lee's filaments (22/1622) on Racz's tip (14/38) in the manner recited in Claims 1 and 21. Ex-1034, ¶213.

B. Ground B: Claim 1

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. Ex-1012, ¶0033. "[T]he 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.*

Thus, Young '965 would have confirmed to a POSA that configuring an RF ablation device to have an active tip and deployable filaments operating together as a single monopolar electrode is effective for tissue ablation. Ex-1034, ¶214-215. Considered in combination with Racz, Fitz, and Lee, a POSA would have been further motivated by Young '965 to modify Racz's device and thereby perform the step of: "operating the radiofrequency probe, the tip [14/38], and the filament [22/1622] 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." as recited in [1h]. Ex-1034, ¶215.

Young '965's filaments (26) are interconnected to an actuator shaft (20) and handle assembly (27) to retract and deploy the filaments (26). Ex-1012, ¶0023-0024, 0034-0035, 0037-0038. A POSA 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 (e.g., the shaft (20) could be hollowed and dimensioned to accommodate Racz's RF probe (22/52)). Ex-1034, ¶216. Thus, a POSA would have been further motivated by Young '965 to modify Racz's device to perform the step of "moving" a retracted filament in the device to a "deployed position within the patient" as recited in [1f]. *Id.*

Young '965's filaments (26) are as small as 0.2mm (wide) and 0.05mm (thick). Ex-1012, ¶0030. By comparison, Racz discloses that its neurotomy cannula may be as large as 10 gauge (i.e., up to 3.404mm outer diameter and 2.692 mm inner diameter). Ex-1009, 8;9-15; Ex-1034, ¶217. Thus, Young '965 would have confirmed to a POSA 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.*

Accordingly, Claim 1 (and its dependent claims 2-20) are obvious in view of Racz, Fitz, Lee, and Young '965.⁷ Ex-1034, ¶218.

C. Ground B: Claim 2

Young '965 describes an example “operation of the tissue ablation system 2.” Ex-1012, ¶0039. In the example operation, “[a]fter the cannula 12 is properly placed, the electrode array 30 is deployed out of the lumen 18 of the cannula 12.” Ex-1012, ¶0040. Once the electrode array 30 is deployed, “[n]ext, the RF generator 6 is then connected to the probe assembly 4 via the electrical connectors.” Ex-1012, ¶0041. As described in § VI.B, the filaments in the modified Racz are energized by a removable RF probe. Accordingly, a POSA would understand that, when operating the modified Racz, the step of “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-1034, ¶219. Claim 2 is therefore obvious in view of Racz, Fitz, Lee, and Young '965.

D. Ground B: Claims 8, 9, 20, and 23

The teachings in Young '965 identified above for Claim 1 also renders the limitations in certain dependent claims further obvious in combination with Racz,

⁷ The cited teachings of Young '965 are also evidence of a POSA's skill level to have a reasonable expectation of success in these modifications.

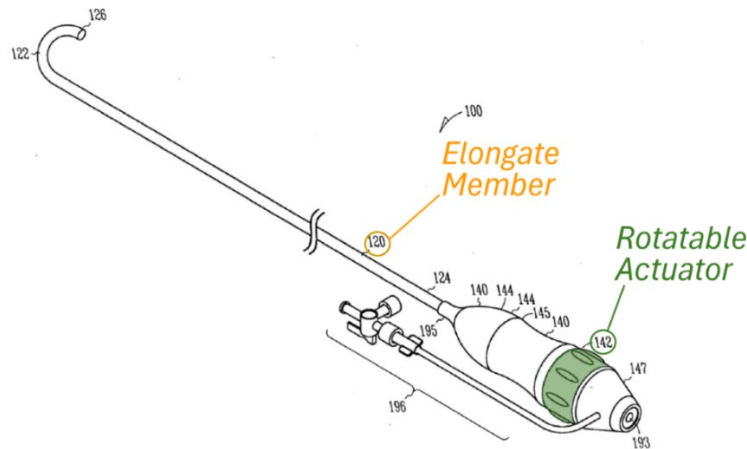
Fitz, and Lee: [8] (in monopolar mode “attaching a return electrode pad to the patient prior to said operating the radiofrequency probe, the tip, and the filament as the monopolar electrode.”); [9] (filament and tip “wherein the conductive portion comprises a conductive material in the tip, and wherein 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”); [20] (“wherein the probe directly contacts the tip during said operating the radiofrequency probe, the tip, and the filament as the monopolar electrode”); and [23] (“physically contacting the radiofrequency probe to the conductive portion of the needle at the distal end of the needle comprises physically contacting the radiofrequency probe to the tip”). *Supra* § VI.C.2.a, VI.C.2.c; Ex-1034, ¶220.

VIII. GROUNDS C AND D: CLAIMS 1-10, 18-26, AND 28-29 ARE OBVIOUS OVER ANY OF THE PREVIOUS COMBINATIONS IN FURTHER VIEW OF SCHEIBE

A. Overview of Scheibe

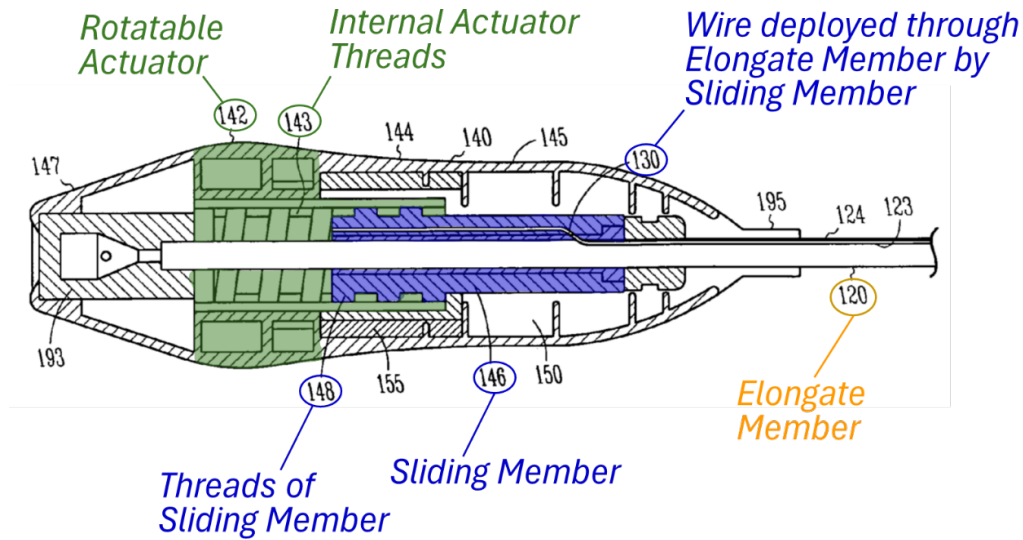
Scheibe discloses a rotational actuator (142) for linearly translating a “sliding member” (146) within a medical device. Ex-1013, ¶¶0019, 0021, 0024-0029, 0032-0035. Scheibe’s actuator (142) is adapted for linear translation of a pullwire (130) through the lumen of an elongate body (120), so it is analogous to the ’664 patent. *Id.*; Ex-1034, ¶221.

Scheibe's actuator (142) is shown in a deflectable catheter (or sheath), which includes an elongate, deflectable body (120), a handle assembly (140), and a pullwire (130). Ex-1013, ¶0016, Fig. 1. The device's pullwire (130) extends "through a lumen" of the body (120) and "translates longitudinally through the lumen" to deflect a distal end of the body (120). Ex-1013, ¶0017-0018.



Scheibe – Fig. 1 (annotated)

The rotatable actuator (142) (**shaded green**) rotates about the longitudinal axis of Schiebe's device but is otherwise fixed in place. Ex-1013, ¶0025; Ex-1034, ¶222-223. The rotatable actuator (142) includes internal threads (143) that engage outer threads (148) of a sliding member (146) (**shaded blue**). Ex-1013, ¶0021-0022. When the actuator (142) is rotated, the sliding member (146) moves linearly (without rotating) within the device's housing (144) and around the elongate body (120). Ex-1013, ¶0024-0025, 0029. As the pullwire (130) is secured to the sliding member (146), rotating the actuator (142) causes the pullwire (130) to move linearly within the elongate body (120). Ex-1013, ¶0018-0019, 0035.



Scheibe – Fig. 2 (annotated)

B. Ground C: Claims 1 and 21

A POSA 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). Ex-1034, ¶224. As Scheibe’s pullwire (130) is secured to its sliding member (146), a POSA would appreciate that proximal ends of Lee’s filaments (22/1622) are securable to the sliding member (146) in the same manner. Ex-1013, ¶0018-0019, 0035; Ex-1034, ¶224. Because Scheibe’s pullwire (130) is moved through its elongate body (120), a POSA also would appreciate that the rotatable actuator (142) would retract and deploy Lee’s filaments (22/1622) through Racz’s shaft (12/34). Ex-1034, ¶224, 77-78. Scheibe’s actuator (142)—by rotating—would move relative to Racz’s hub (20/42/70) to deploy/withdraw the filaments (22/1622). Ex-1034, ¶224. As the

sliding member (146) does not rotate, rotation of the actuator (142) would also not twist the filaments (22/1622). *Id.*

A POSA would also understand that Scheibe's rotatable actuator (142) and sliding member (146) are adapted to avoid interference with the lumen of the elongate body (120). This allows the actuator (142) and sliding member (146) to be easily implemented in Racz's device without obstructing Racz's central lumen (which receives the probe (22/52)). Ex-1013, ¶0034-0035, Figs. 2, 5, 7, 9, 10; Ex-1034, ¶225. Indeed, Scheibe's disclosure of a Luer fitting at the distal end of its device confirms that the actuator (142) and sliding member (146) would not obstruct the elongate body (120). Ex-1013, ¶0031. By avoiding interference with the internal lumen of the shaft (12/34), Scheibe's actuator would enable deployment and withdrawal of Lee's filaments (22/1622) regardless of whether the probe (22/52) is inserted. Ex-1034, ¶225. Finally, Scheibe notes that its teachings are not limited to catheters and are relevant to "other types of body stimulating systems." Ex-1013, ¶0037.

A POSA would have easily implemented Scheibe's actuator (142) and sliding member (146) into Racz's modified device. Ex-1034, ¶226. As one example, a POSA would have recognized that Racz's hub (20/42/70) can be replaced with Scheibe's handle assembly (140). Scheibe's handle assembly (140) provides a hub for Racz's shaft (12/34). Ex-1013, ¶0019-0020, Fig. 1; Ex-1034,

¶226. Additionally, like Racz's hub (20/42/70), Scheibe's handle assembly (140) includes a "luer fitting [that] allows a variety of external components with a mating luer fitting to be attached to the proximal end of the [assembly]" and "allows other devices to be passed into and through the passage of the [device]." Ex-1013, ¶0031; Ex-1009, 5:66 to 6:7.

Accordingly, a POSA would have recognized that Scheibe's rotating actuator (142) and sliding member (146) would be a suitable actuator to implement into Racz's device for deployment/retraction of Lee's filaments (22/1622). Ex-1010, ¶0106; Ex-1034, ¶227. Thus, in combination with Racz, Fitz, and Lee, Scheibe would have further motivated a POSA to perform "moving the filament to a deployed position within the patient" as recited in Claims 1 and 21 ([1f] and [21e]), as well as suggesting a suitable mechanism to do so. Ex-1034, ¶227. Claims 1-10, 18-26, and 28-29 are therefore obvious in view of Racz, Fitz, Lee, and Scheibe (Ground C).

C. Ground D: Claims 1 and 21

Scheibe may also be considered (optionally) in combination with Young '965, which discloses that rotational actuators can be used to retract and deploy filaments. Ex-1012, ¶0038; Ex-1034, ¶228. Thus, a POSA 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. Ex-1034, ¶239. Claims 1-10, 18-26,

and 28-29 are therefore obvious in view of Racz, Fitz, Lee, Young '965, and Scheibe (Ground D).

IX. GROUNDS E-H: CLAIMS 11-17, 19, 27, AND 29 ARE OBVIOUS IN FURTHER VIEW OF GODARA

A. Overview of Godara

Godara is directed to an electrosurgical device “for the treatment of pain” having “an elongate member” with “electrically exposed conductive portions for delivering energy substantially distal to the elongate member.” Ex-1015, Abstract, ¶0002. Thus, Godara is directed to the same field as the '664 Patent. *See* Ex-1003, 1:24-28; Ex-1034, ¶229.

As described in § VI.F, a POSA would be motivated to combine Racz, Fitz, and Lee to expand and control lesion sizes in an RF ablation device using the known technique of deployable electrodes at a distal tip. Like Racz and Fitz, Godara’s device is configured for generating lesions at a target tissue site, “for example a nerve” (or “neural tissue”). Ex-1015, ¶0098-0100, 0096, 0003; Ex-1009, 1:4-10, 3:42-45, 4:49-58, 7:43-50; Ex-1011, ¶0002-0005, 0007, 0009. Godara discloses that lesions “between about 150 mm³ and about 500 mm³ in volume ... may be particularly useful for lesioning of [spinal] nerves.” Ex-1015, ¶00133. Thus, a POSA would have been motivated to consider Godara’s disclosure in using Racz’s modified device. Ex-1034, ¶230.

B. Claims 12, 14-17, and 27

These claims merely recite specific types and locations of a target “nerve” to be ablated (of claim 10, from which they depend):

- “a medial branch nerve proximate a lumbar facet joint” [12], which is one “example” of “an afferent nociceptive nerve,” [17], *see* Ex-1003, 21:2-5;
- “a medial branch nerve positioned in an intertransverse space between adjacent thoracic vertebrae” [14];
- “proximate a cervical zygapophyseal joint” [15]; and
- “a posterior ramus of a sacroiliac joint” [16]; and

Claim 27 recites the same types and locations of the target “nerve” as claims 12 and 14-16, but as alternative targets within a single claim.

As a general matter, Fitz teaches that RF neurotomy “can be used on *any area* of the spine, be it cervical, thoracic, or lumbar” (Ex-1011 ¶0002), so there is nothing inventive about the specific locations recited in these claims. Ex-1034, ¶231-232. Godara further 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, “sites within one or more intervertebral discs,” and other sites “within a patient’s body.” Ex-1015 ¶0114. And Godara specifically teaches use in or around the claimed areas:

- medial branch nerves in the “lumbar region” including “the nerves innervating the facet joint, [12], Ex-1015 ¶¶0124-25 and claim 37, and the “thoracic region,” where the medial branches may “remain suspended within the intertransverse space” thoracic vertebrae [14], Ex-1015, ¶¶0128-0130 and claim 36;
- the “cervical region” and specifically the “zygapophyseal ... joints” [15]. Ex-1015, ¶¶0119-0120;
- the sacroiliac joint, and “posterior primary [or “dorsal”] rami” [16], Ex-1015, ¶¶0134, 0119, claim 38; *see also* Ex-1034, ¶233 (explaining equivalent use of “posterior” and “dorsal” ramus).

Therefore, Godara would have motivated a POSA to use the modified Racz anywhere Godara’s device was appropriate, such that Claims 12, 14-17, and 27 are obvious. *See* Ex-1015, ¶0119; Ex-1034, ¶232-233. Moreover, as Racz’s cannula is adapted for RF neurotomy—and modified using known deployable filaments—a POSA would have had a reasonable expectation of success in using Racz’s modified device in these locations. *See* Ex-1009, 1:4-10, 3:42-45, 4:49-58, 7:43-50; Ex-1011, ¶0002-0005, 0007, 0009; Ex-1034, ¶233.

C. Claims 11 and 13

Claims 11 and 13 recite “inserting the needle within 30 degrees of perpendicular to a surface of the patient,” with the only difference being the claim from which they depend.

Godara teaches, “the probe may be inserted and positioned *substantially perpendicular* or generally upstanding to the surface, including “between about 60° and 120°.” Ex-1015 ¶0094; *see also id.* ¶0006 (a “more perpendicular approach” would be “advantageous”), ¶0126 (treatment of lumbar facet joints can include inserting the probe “from a number of angles and positioned at a wide variety of locations”). Godara also discloses that this technique is applicable when using devices configured—like Racz’s modified device—to create “a lesion that is located primarily distally with respect to the distal end of a probe, thus allowing a probe that has been inserted substantially perpendicularly ... to effectively treat the target site by delivering energy to form a lesion distal to the probe.” Ex-1015 ¶0094; *supra* § VI.D.3 (discussing filament tips positioned beyond the needle tip). Thus, a POSA 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. Ex-1034, ¶234-235.

D. Claims 19 and 29

Claims 19 and 29 each recite “forming a lesion that includes the nerve and has a volume of about 500 mm³”; they differ only in the base claim from which they depend.

Godara’s device is configured for generating lesions at a target tissue site, “for example a nerve” (or “neural tissue”). Ex-1015, ¶0098-0100, 0096, 0003.

Godara discloses that lesions “formed at the target site may be of a variety of shapes and sizes,” including “between about 150 mm³ and about 500 mm³,” which “may be particularly useful for lesioning of [spinal] nerves.” Ex-1015, ¶00133. Thus, considered in combination with Lee’s disclosure that its filaments can be adjusted to provide any desired ablation volume (*supra* § VI.F), Godara would have further motivated a POSA to configure Racz’s modified device to “form[] a lesion that includes the nerve and has a volume of about 500 mm³” as recited in **Claims 19 and 29**. Ex-1034, ¶236-237.

For the foregoing reasons, Claims 11-17, 19, 27, and 29 are each further obvious in view of Racz, Fitz, Lee, and Godara (Ground E). For the same reasons, Claims 11-17, 19, 27, and 29 are obvious in view of Racz, Fitz, Lee, Godara, and: Young ’965 (Ground F; *supra* § VII) or Scheibe (Ground G; *supra* § VIII.B) or Young ’965 and Scheibe (Ground H; *supra* § VIII.C); Ex-1034, ¶238.

X. GROUND I-L: CLAIMS 18 AND 28 ARE OBVIOUS IN FURTHER VIEW OF COHEN

Cohen describes the techniques and results of a “randomized placebo-controlled study” to evaluate the “lateral branch radiofrequency lesioning” in patients with sacroiliac joint pain. Ex- Cohen, 279. Cohen’s study employed commercially available “cooled” and “conventional” (non-cooled) RF probes to create the lesions. Ex- Cohen, 279, 281-282. Thus, Cohen is directed to the same

field as the '664 Patent (“thermal ablation systems and methods”), though its focus is the clinical use of the devices. *See* Ex-1003, 1:24-27; Ex-1034, ¶239.

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”; they differ only in the base claim from which they depend.

Like Racz and Fitz, Cohen discusses techniques for RF neurotomy. Ex-1009, 1:4-10, 3:42-45, 4:49-58, 7:43-50; Ex-1011, ¶¶0002-0005, 0007, 0009; Ex-1034, ¶240-241. In particular, Cohen expressly describes creating a “lesion diameter ranging between 8 and 10 mm” in procedures for denervation of the sacroiliac joint. Ex- Cohen, 282 (including Fig. 3). Considered in combination with Lee’s disclosure that its filaments can be adjusted to provide any desired ablation volume (Ex-1010, ¶¶0123-0124, 0129-0130), Cohen would have motivated a POSA to configure and/or use Racz’s device modified to include Lee’s filaments (22/1622)—as described in Grounds A-D—to form lesions of various sizes, specifically including lesions with maximum cross dimension that is 10 millimeters or larger. Ex-1034, ¶241.

The steps recited in **Claims 18 and 28** are therefore obvious in further view of Cohen. Accordingly, Claims 18 and 28 are obvious in view of Racz, Fitz, Lee, and Cohen (Ground I). For the same reasons, Claims 11-17, 19, 27, and 29 are obvious in view of Racz, Fitz, Lee, Cohen, and: Young '965 (Ground J; *supra* §

VII) or Scheibe (Ground K; *supra* § VIII.B) or Young '965 and Scheibe (Ground L; *supra* § VIII.C); Ex-1034, ¶242.

XI. CONCLUSION

For at least the foregoing reasons, Petitioner requests that the Board institute an *Inter Partes* Review and cancel Claims 1-29 of the '664 patent.

Respectfully submitted,

/Christopher B. Kelly/
Christopher B. Kelly (Reg. No. 62,573)

XII. MANDATORY NOTICES

Petitioner Avanos Medical, Inc. submits the following mandatory notices pursuant to 37 C.F.R. § 42.8(a)(2).

A. Real parties-in-interest

Petitioner contends the sole real “party-in-interest” in this Petition is Avanos Medical, Inc. However, in the interest of transparency, Avanos further states that Diros Technology, Inc. of Markham, Ontario, Canada is a wholly owned subsidiary of Avanos Medical, Inc.

B. Related matters

Petitioner is not aware of any other judicial or administrative matters that would affect, or be affected by, a decision in this IPR proceeding.

C. Counsel and service information

Under 37 C.F.R. §§ 42.8(b)(3) and 42.10(a), Petitioner identifies Christopher B. Kelly (Reg. No. 62,573) as lead counsel and the following back-up counsel: Gregory Carlin (Reg. No. 45,607), Warren Thomas (Reg. No. 70,581), and Lee Hamilton (Reg. No. 80,413). All counsel can be reached by mail at Meunier Carlin & Curfman LLC, 999 Peachtree St, NE, Suite 1300, Atlanta, GA 30309; and by phone at 404-645-7700. Petitioner consents to electronic service by email to the counsel above.

XIII. CLAIMS LISTING

Claim Element	Challenged Claims
[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.
[2]	The method of claim 1, 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.
[3a]	The method of claim 1, wherein the needle further comprises a fitting in fluid communication with the lumen, the method further comprising:
[3b]	connecting a fluid source to the fitting;
[3c]	transporting fluid through the lumen of the needle to a target volume within the patient; and
[3d]	disconnecting the fluid source from the fitting.

Claim Element	Challenged Claims
[4]	The method of claim 3, wherein said inserting the radiofrequency probe into the lumen is achieved by passing the radiofrequency probe through the fitting.
[5]	The method of claim 3, wherein said inserting the radiofrequency probe into the lumen takes place after said disconnecting the fluid source from the fitting.
[6]	The method of claim 1, wherein said moving the filament to the deployed position comprises positioning the distal end of the filament distally beyond the tip of the needle.
[7]	The method of claim 1, 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.
[8]	The method of claim 1, 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.
[9]	The method of claim 1, 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.
[10]	The method of claim 1, further comprising: 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.
[11]	The method of claim 10, wherein said inserting the needle into the patient comprises inserting the needle within 30 degrees of perpendicular to a surface of the patient.

Claim Element	Challenged Claims
[12]	The method of claim 10, wherein the nerve comprises a medial branch nerve proximate a lumbar facet joint of the patient.
[13]	The method of claim 12, wherein said inserting the needle into the patient comprises inserting the needle within 30 degrees of perpendicular to a surface of the patient.
[14]	The method of claim 10, wherein the nerve comprises a medial branch nerve positioned in an intertransverse space between adjacent thoracic vertebrae of the patient.
[15]	The method of claim 10, wherein the nerve is proximate a cervical zygapophyseal joint of the patient.
[16]	The method of claim 10, wherein the nerve comprises a posterior ramus of a sacroiliac joint of the patient.
[17]	The method of claim 10, wherein the nerve comprises an afferent nociceptive nerve.
[18]	The method of claim 10, wherein said ablating comprises forming a lesion that includes the nerve and has a maximum cross dimension that is 10 millimeters or larger.
[19]	The method of claim 10, wherein said ablating comprises forming a lesion that includes the nerve and has a volume of about 500 mm ³ .
[20]	The method of claim 1, wherein the probe directly contacts the tip during said operating the radiofrequency probe, the tip, and the filament as the monopolar electrode.
[21pre]	A method comprising:
[21a]	introducing a needle into a patient, the needle comprising:
[21b]	an elongate member;
[21c]	a lumen within the elongate member; and

Claim Element	Challenged Claims
[21d]	a filament in a retracted position relative to the elongate member;
[21e]	moving the filament to a deployed position within the patient;
[21f]	inserting a radiofrequency probe into the lumen of the needle;
[21g]	physically contacting the radiofrequency probe to a conductive portion of the needle at a distal end of the needle; and
[21h]	operating the radiofrequency probe and the filament as a monopolar electrode while the radiofrequency probe contacts the conductive portion of the needle, such that radiofrequency energy from the radiofrequency probe passes through the conductive portion of the needle and is transmitted by the filament.
[22]	The method of claim 21, wherein the needle further comprises a piercing tip at a distal end of the elongate member, and wherein said operating the radiofrequency probe and the filament the monopolar electrode further comprises operating the tip together with the radiofrequency probe and the filament as the monopolar electrode.
[23]	The method of claim 22, wherein said physically contacting the radiofrequency probe to the conductive portion of the needle at the distal end of the needle comprises physically contacting the radiofrequency probe to the tip.
[24]	The method of claim 21, 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.
[25a]	The method of claim 21, wherein the needle further comprises a fitting in fluid communication with the lumen, the method further comprising:
[25b]	connecting a fluid source to the fitting;
[25c]	transporting fluid through the lumen of the needle to a target volume within the patient; and
[25d]	disconnecting the fluid source from the fitting.

Claim Element	Challenged Claims
[26]	The method of claim 21, further comprising: 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.
[27]	The method of claim 26, wherein the nerve is a medial branch nerve proximate a lumbar facet joint of the patient, a medial branch nerve positioned in an intertransverse space between adjacent thoracic vertebrae of the patient, a cervical zygapophyseal joint of the patient, or a posterior ramus of a sacroiliac joint of the patient.
[28]	The method of claim 26, wherein said ablating comprises forming a lesion that includes the nerve and has a maximum cross dimension that is 10 millimeters or larger.
[29]	The method of claim 26, wherein said ablating comprises forming a lesion that includes the nerve and has a volume of about 500 mm ³ .

CERTIFICATION UNDER 37 C.F.R. § 42.24(d)

Pursuant to 37 C.F.R. § 42.24(d), Petitioner certifies that the foregoing Petition for *Inter Partes* Review contains 13,986 words, excluding the portions as permitted by § 42.24(a).

/Christopher B. Kelly/
Christopher B. Kelly (Reg. No. 62,573)

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), the undersigned certifies that on July 26, 2024, a copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 10,925,664, the associated Power of Attorney, and Exhibits 1001-1030 and 1034 and were served by FedEx Priority Overnight on the correspondence address of record indicated in the Patent Office's public Patent Center system for U.S. Patent No. 10,925,664:

Daniel Higgs
MED VENTURE MANAGEMENT, LLC
299 S. MAIN STREET
SUITE 2300
SALT LAKE CITY, UT 84111

/Felice M. Ernst/
Felice M. Ernst, Paralegal
Meunier Carlin & Curfman LLC
999 Peachtree St, NE
Suite 1300
Atlanta, GA 30309