



AVANOS MEDICAL, INC.,

Petitioner,

v.

STRATUS MEDICAL, LLC,

Patent Owner.

IPR2024-01209 (Patent 10,966,782)

IPR2024-01210 (Patent 10,736,688)

IPR2024-01211 (Patent 10,736,688)

IPR2024-01212 (Patent 10,925,664)

Petitioner's Demonstrative Exhibit

Oral Hearing of November 6, 2025

Stratus Patents

(Slides 3-5)

Prior Art, Field, Level of Skill

(Slides 6-18)

Motivation to Combine

(Slides 19-36)

Reasonable Expectation of Success

(Slides 37-48)

Secondary Considerations

(Slides 49-58)

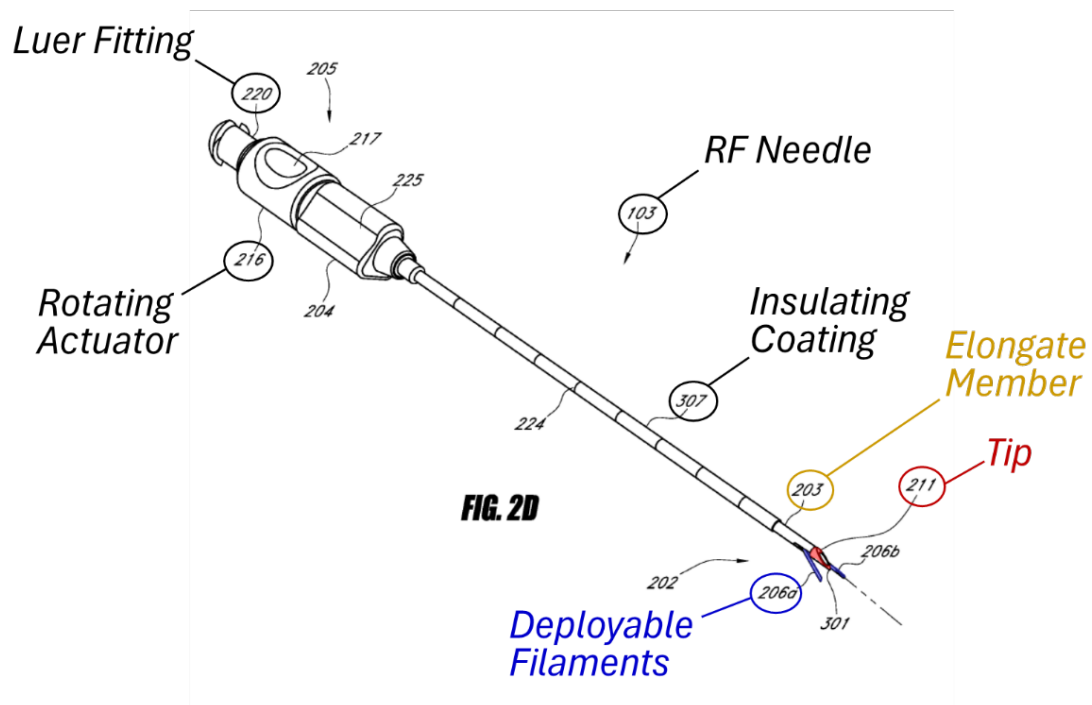
**all cites are to the record in IPR2024-01209 unless indicated otherwise*

Stratus Patents: Independent Claim Summary

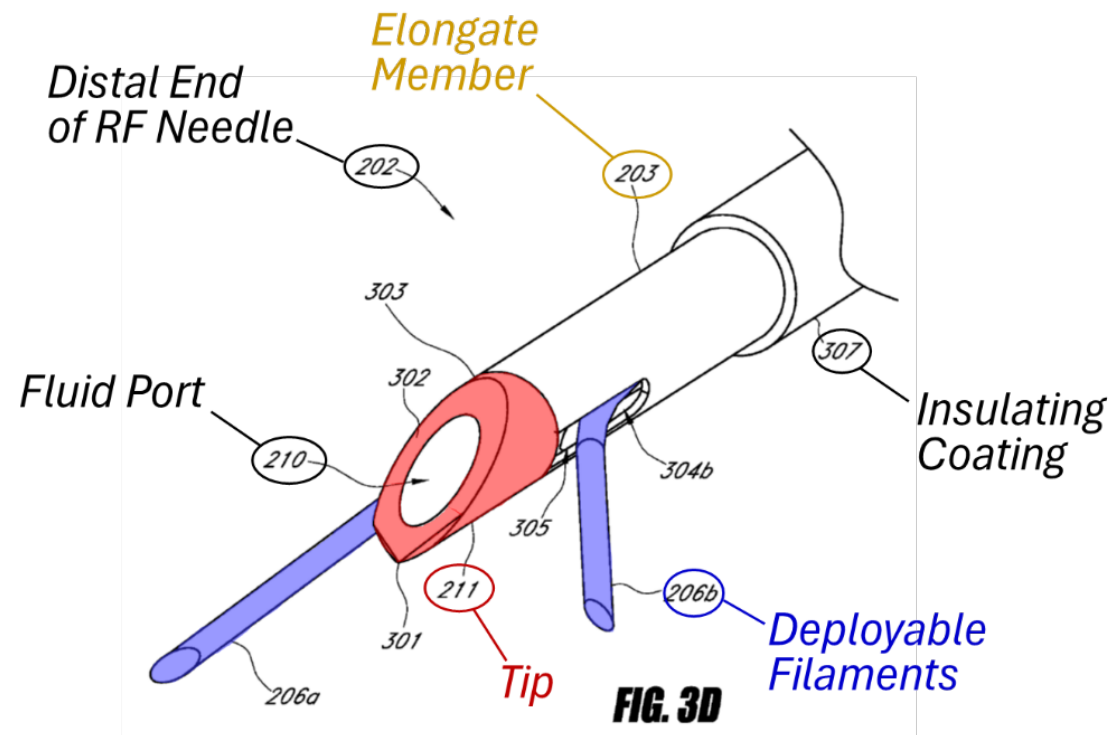
<i>Claim Features</i>	782 Patent (IPR2024-1209):	688 Patent (IPR2024-1210, -1211):	664 Patent (IPR2024-1210, -1211):
<i>Preamble</i>	System (1, 24)	System (1, 53, 56)	Method (1, 21)
<i>RF Probe</i>	Yes	Yes	Yes
<i>Needle with conductive end (tip)</i>	Yes	Yes	Yes
<i>Deployable Filament(s)</i>	Yes	Yes (“plurality”)	Yes
<i>Actuator</i>	Yes	Yes	“moving the filament”
<i>Physical Contact</i>	Yes	Yes	Yes
<i>Monopolar Electrode</i>	Yes	Yes	Yes
<i>Other</i>		“fitting in fluid communication”	

Stratus Patents: Figures

'782 Patent:



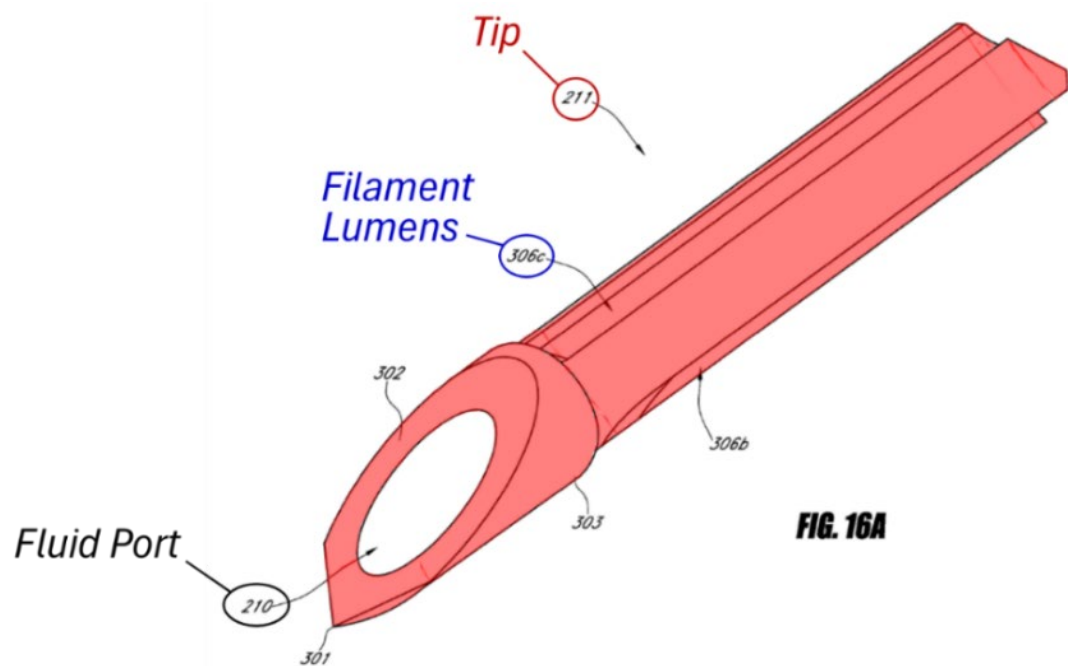
'782 Patent:



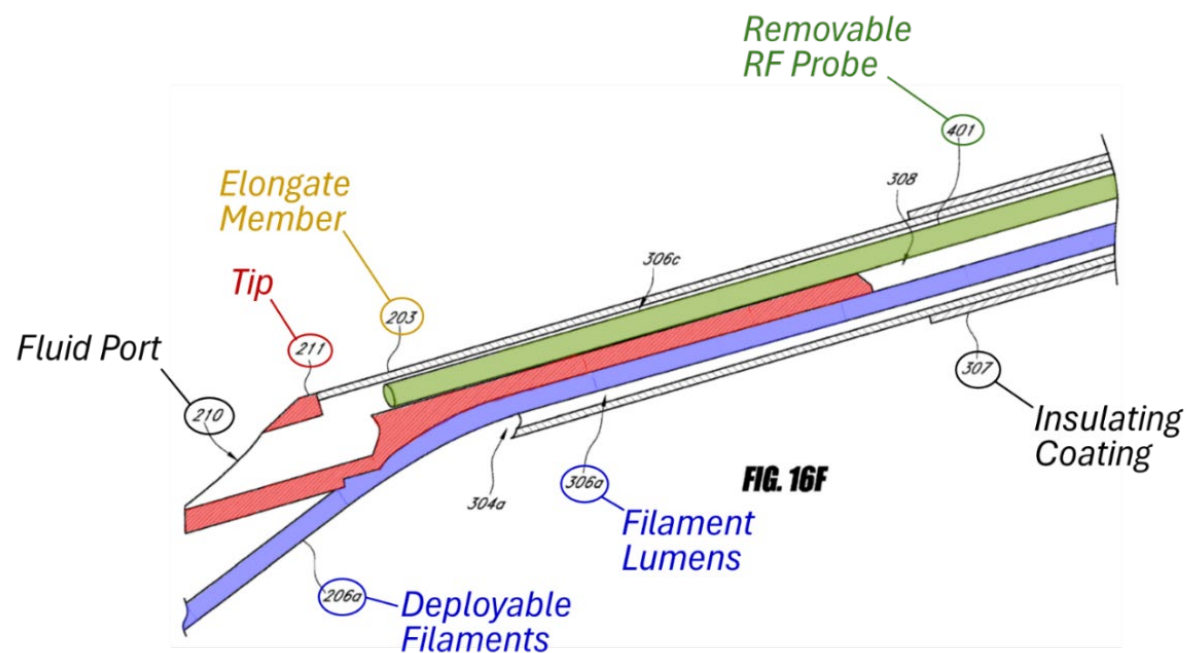
Pet., 7, 8; Ex-1001, Figs. 2D, 3D

Stratus Patents: Figures

'782 Patent:



'782 Patent:



Pet., 9; Ex-1001, Figs. 16A, 16F

Ground A: Racz + Fitz + Lee

Ground A: Racz + Fitz + Lee

No dispute:

- If the prior art is combined as proposed in the Petition, the combination discloses every limitation of the challenged claims

Stratus argues:

- Different field and level of ordinary skill
- Lee is non-analogous art
- Insufficient motivation to combine
- Insufficient expectation of success
- Secondary considerations

Reply, 11; POR, 26-74

Prior Art: All limitations disclosed

	782 Patent (Claim 1)
1pre	A system comprising:
1a	a radiofrequency probe; and
1b	a radiofrequency neurotomy needle operable with the radiofrequency probe, the radiofrequency neurotomy needle comprising:
1c	a conductive portion at a distal end of the radiofrequency neurotomy needle;
1d	a tip configured to pierce tissue of a patient;
1e	an elongate member comprising a lumen configured to accept the radiofrequency probe therein such that the radiofrequency probe physically contacts and is electrically connected to the conductive portion, the tip being at a distal end of the elongate member;

Disclosed in Racz

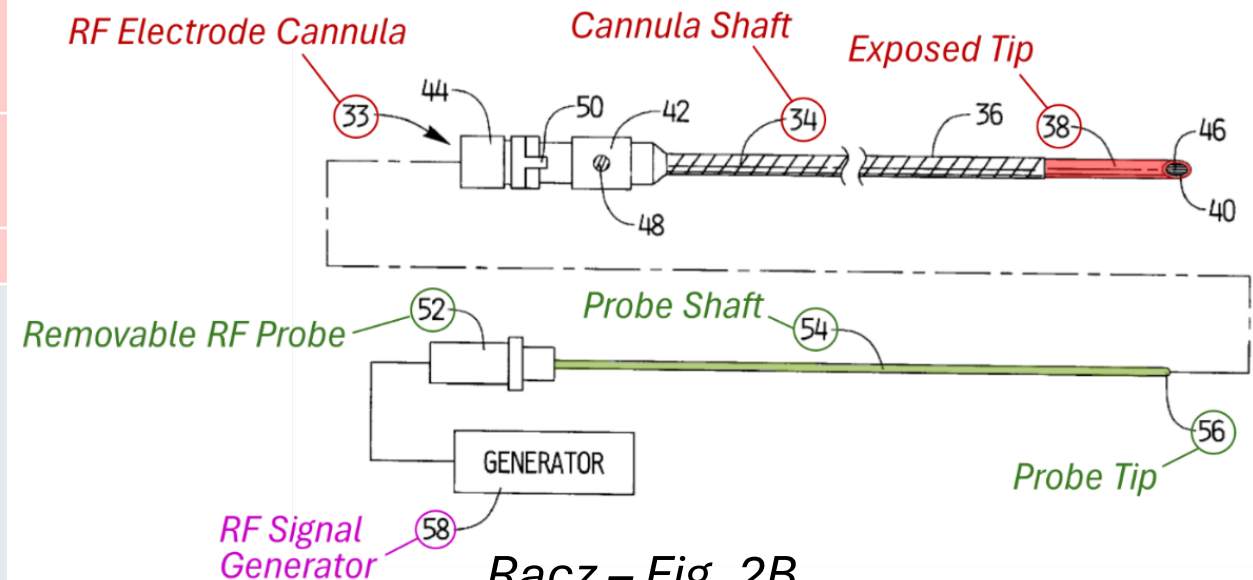
Pet. 29-36

Prior Art: All limitations disclosed

	782 Patent (Claim 1)
1pre	A system comprising:
1a	a radiofrequency probe ; and
1b	a radiofrequency neurotomy needle operable with the radiofrequency probe, the radiofrequency neurotomy needle comprising:
1c	a conductive portion at a distal end of the radiofrequency neurotomy needle;
1d	a tip configured to pierce tissue of a patient;
1e	an elongate member comprising a lumen configured to accept the radiofrequency probe therein such that the radiofrequency probe physically contacts and is electrically connected to the conductive portion, the tip being at a distal end of the elongate member;

Racz:

Conventional, single-tip RF neurotomy needle with a removable RF probe



Racz – Fig. 2B

Pet. 13-16, 29-32; Ex-1031, ¶113-114

Prior Art: All limitations disclosed

	782 Patent (Claim 1)
1pre	A system comprising:
1a	a radiofrequency probe; and
1b	a radiofrequency neurotomy needle operable with the radiofrequency probe, the radiofrequency neurotomy needle comprising:
1c	a conductive portion at a distal end of the radiofrequency neurotomy needle;
1d	a tip configured to pierce tissue of a patient;
1e	an elongate member comprising a lumen configured to accept the radiofrequency probe therein such that the radiofrequency probe physically contacts and is electrically connected to the conductive portion , the tip being at a distal end of the elongate member;

***Racz:** “physical contact” transmits RF energy*

The electrode cannula **10** further comprises a hub **20**. The hub **20** is capable of accommodating an electrical probe **22**, which includes a segment that is inserted into and received by the shaft **12** of the cannula **10**. This physical relationship between the probe **22** and the shaft **12** facilitates electrical contact between the two elements.

other electrical application can be made. 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 an internal lumen defined by the electrode shaft **34**. If the electrode shaft **34** or cannula is a metal tube and the probe shaft **54** has a metal outer surface, then this can be accomplished simply through physical contact between the probe shaft **54** and the electrode shaft **34**. When the application of therapeutic electrical signals is complete, the probe **52** is withdrawn from the cannula **33**, and the electrode can then be withdrawn from the patient.

Pet. 34-36; Ex-1009, 3:60-65, 5:41-51

Prior Art: All limitations disclosed

782 Patent (Claim 1)	
1f	a filament electrically connected to the conductive portion and the tip due to physical contact of conductive materials at the distal end of the radiofrequency neurotomy needle such that the filament and the tip operate together as a single electrode,
1g	the filament being movable between a retracted position , in which the filament is at least partially in the elongate member, and a deployed position , in which at least a portion of the filament is out of the elongate member; and
1h	an actuator interconnected to the filament to move the filament between the retracted position and the deployed position,
1i	wherein the filament and the tip are configured to transmit radiofrequency energy from the radiofrequency probe and operate together as the single electrode in a monopolar mode when the filament is in the deployed position and the radiofrequency probe is accepted in the lumen and is in physical contact with the conductive portion at the distal end of the radiofrequency neurotomy needle.

***Disclosed in the
combination of
Racz, Fitz, and Lee***

Pet. 36-47

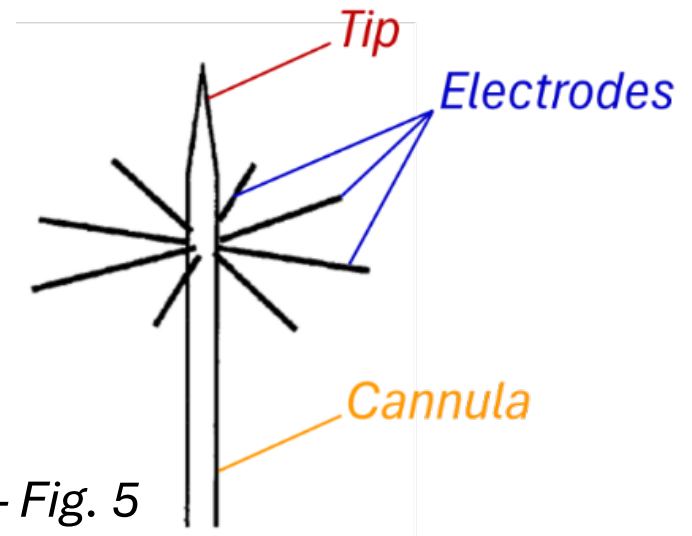
Prior Art: All limitations disclosed

782 Patent (Claim 1)

- 1f** a **filament** electrically connected to the conductive portion and the tip due to physical contact of conductive materials at the distal end of the radiofrequency neurotomy needle such that the filament and the tip operate together as a single electrode,
- 1g** the filament being **movable** between a **retracted position**, in which the filament is at least partially in the elongate member, and a **deployed position**, in which at least a portion of the filament is out of the elongate member; and
- 1h** an **actuator** interconnected to the filament to move the filament between the retracted position and the deployed position,
- 1i** wherein the **filament and the tip are configured to transmit radiofrequency energy from the radiofrequency probe and operate together** as the single electrode in a monopolar mode when the filament is in the deployed position and the radiofrequency probe is accepted in the lumen and is in physical contact with the conductive portion at the distal end of the radiofrequency neurotomy needle.

Fitz:

Adding deployable electrodes to an RF neurotomy needle expands the ablation volume compared to single-tip needles



Fitz – Fig. 5

Pet. 16-18, 23-25; Ex-1011, ¶4-5, 9-10, 21, Fig. 5

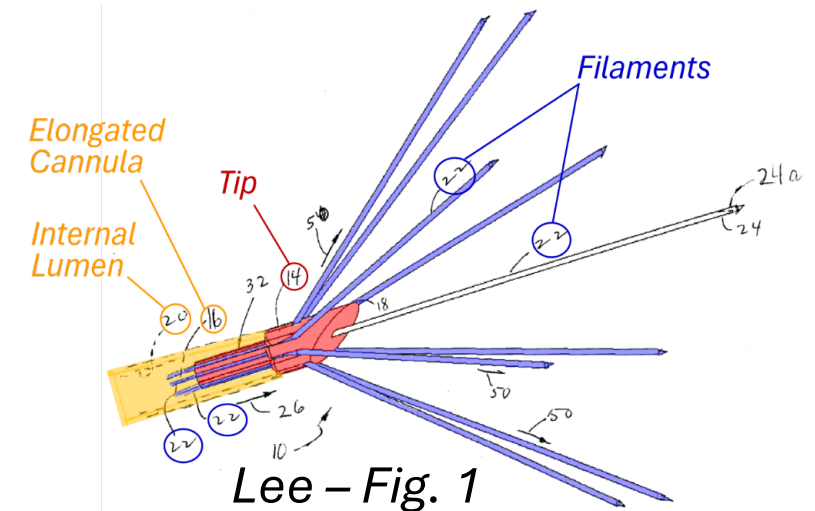
Prior Art: All limitations disclosed

782 Patent (Claim 1)

- 1f a **filament** electrically connected to the conductive portion and the tip due to physical contact of conductive materials at the distal end of the radiofrequency neurotomy needle such that the filament and the tip operate together as a single electrode,
- 1g the filament being **movable** between a **retracted position**, in which the filament is at least partially in the elongate member, and a **deployed position**, in which at least a portion of the filament is out of the elongate member; and
- 1h an **actuator** interconnected to the filament to move the filament between the retracted position and the deployed position,
- 1i wherein the **filament and the tip are configured to transmit radiofrequency energy from the radiofrequency probe and operate together** as the single electrode in a monopolar mode when the filament is in the deployed position and the radiofrequency probe is accepted in the lumen and is in physical contact with the conductive portion at the distal end of the radiofrequency neurotomy needle.

Lee:

Deployable filaments can be guided around the tip of an RF needle using channels, and the filaments act as electrodes to define the ablation volume



Pet. 18-20; Ex-1010, ¶12, 16-18, 32, 84, 123-131, Fig. 1

Field of the Invention

Patent Field:

Field

The present application generally relates to thermal ablation systems and methods, and more particularly to systems and methods for radio frequency (RF) neurotomy, such as spinal RF neurotomy.

Specification:

Not limited to RF neurotomy

It will be appreciated that the delivery of RF energy to tissue in the anatomy can be practiced for a multitude of reasons, and embodiments of the needles described herein may be adapted (e.g., modified or scaled) for use in other medical procedures. For example, embodiments of needles

Reply, 1-2; Pet., 11; Ex-1001, 1:28-31, 48:28-32

RF Neurotomy: *Not an isolated field*

PO Expert (Russo) Direct Testimony:

performed by cardiologists. As a result, there has historically been little to no cross-talk between or cross-pollination of the various fields in which RF ablations are performed.

Russo Article (Ex-2004):

Cooled Radiofrequency Neurotomy

Cooled radiofrequency ablation was first developed in the late 1990s for use in the cardiac field for arrhythmia management,^{48,49} and then found application in tumour ablation as a method to enlarge the tumour destruction volume.⁵⁰⁻⁵² The technology was first introduced into the pain management field via custom designed equipment for treatment of sacroiliac joint pain.⁵³⁻⁵⁸ It has since been

Reply, 3-4; POR, 27; Ex-2001, ¶76; Ex-2004, 3902

Field of the Invention

Patent Field:

Field

The present application generally relates to thermal ablation systems and methods, and more particularly to systems and methods for radio frequency (RF) neurotomy, such as spinal RF neurotomy.

Specification:

Not limited to RF neurotomy

It will be appreciated that the delivery of RF energy to tissue in the anatomy can be practiced for a multitude of reasons, and embodiments of the needles described herein may be adapted (e.g., modified or scaled) for use in other medical procedures. For example, embodiments of needles

Reply, 1-2; Pet., 11; Ex-1001, 1:28-31, 48:28-32

RF Neurotomy: *Not an isolated field*

PO Expert (Russo) Direct Testimony:

performed by cardiologists. As a result, there has historically been little to no cross-talk between or cross-pollination of the various fields in which RF ablations are performed.

Russo Article (Ex-2004):

Meeting.⁶¹ By early 2009, Wright was trying to conceive of an alternative device that could match the lesion created by the internally cooled electrode and be compatible with all RF generators at price that would allow for widespread adoption. In this mindset, he describes nervously fidgeting

Reply, 3-4; POR, 27; Ex-2001, ¶76; Ex-2004, 3903

Field of the Invention

Patent Field:

Field

The present application generally relates to thermal ablation systems and methods, and more particularly to systems and methods for radio frequency (RF) neurotomy, such as spinal RF neurotomy.

Specification:

Not limited to RF neurotomy

It will be appreciated that the delivery of RF energy to tissue in the anatomy can be practiced for a multitude of reasons, and embodiments of the needles described herein may be adapted (e.g., modified or scaled) for use in other medical procedures. For example, embodiments of needles

Reply, 1-2; Pet., 11; Ex-1001, 1:28-31, 48:28-32

RF Neurotomy: *Not an isolated field*

PO Expert (Russo) Direct Testimony:

performed by cardiologists. As a result, there has historically been little to no cross-talk between or cross-pollination of the various fields in which RF ablations are performed.

Russo Cross-Examination:

1	Q	So the application of cooled RF technology
2		from tumors to neurotomy is cross-pollination, is it
3		not?
4	A	Correct.
5	Q	So it's not true that technology used in
6		cardiac or tumor RF ablation is necessarily irrelevant
7		to RF neurotomy; right?
8	A	Not necessarily irrelevant? Correct.

Reply, 3-4; POR, 27; Ex-2001, ¶176; Ex-1046, 126:1-8

Level of Ordinary Skill

Dr. Tucker's definition is correct

- Bachelor's degree in biomedical engineering or a related field;
- 3 years of experience with **thermal ablation systems and methods** (or 1 year with an advanced degree)

Pet. Expert (Dr. Tucker)

- Dr. Tucker **reaffirmed** his testimony even under Stratus's more restrictive definition.
- Dr. Tucker's testimony is entitled to **full weight** under either definition.

Pet., 11; Ex-1031, ¶105; Reply, 6-8; Ex-1042, ¶8-11

Stratus's Definition:

- Unnecessarily requires additional experience as "**interventional pain-specialist physician**"

PO Experts (Crosby & Russo):

- Russo (doctor) and Crosby (engineer) testified without seeking the expertise of one another

PO Sur-Reply:

- Zero pages addressing level of skill

Reply, 5-6; POR, 30; Ex-1045, 21:7-23:20, 105:10-107:2; Ex-1046, 26:2-27:11, 39:6-10

Lee is Analogous Art

Lee is in the same field

- Under the correct definition, Lee is in the field of thermal ablation systems and methods

Lee is reasonably pertinent

- Lee addresses the same problem faced by the inventors: **expanding** and **controlling** the ablation volume
- **PO's Expert (Crosby):**
Lee's purpose is to "increase the volume of ablated tissue"

Reply, 8-10; Pet. 25-26; Ex-1010, ¶12, 84, 103, 123-131; Ex-2006, ¶117

Problem addressed in the Stratus patents:

change. These tissue changes limit penetration of the RF energy beyond a leading edge defined by the shape and size of an active needle tip. Accordingly, the size of a radiofrequency lesion using conventional single needle technology is thus practically limited after achievement of a certain temperature delivered for a certain time.

The needle 103 with deployable filaments 206a, 206b 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. The use of multiple filaments 206a, 206b provides additional conduits for RF energy creating a multiple electrode RF field effect. The size, shape and location of a lesion created with the needle 103 may be established by the quantity, location and orientation of the filaments, and may be beneficially modified to suit a specific anatomical application by changing various aspects of the filaments as discussed below.

Ex-1001, 10:53-11:10

Motivation to Combine

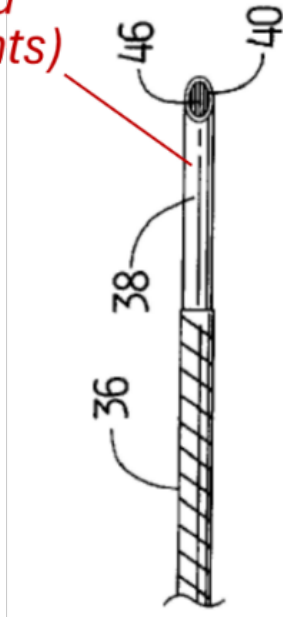
“[I]f there’s a **known technique** to address a **known problem** using ‘prior art elements according to their **established functions**,’ then there is a motivation to combine.”

Intel Corp. v. PACT XPP Schweiz AG, 61 F.4th 1373, 1380 (Fed. Cir. 2023).

Motivation to Combine

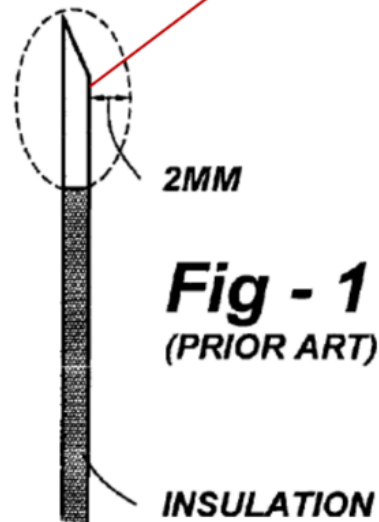
Racz

Single Exposed
Tip (no filaments)



Fitz

Single Exposed
Tip (no filaments)



Pet., 22-25; Ex-1011, ¶1, 4, 12, Fig. 1;
Ex-1031, ¶134-137

Fitz identifies a known problem

[0001] This invention relates generally to RF neurotomy and, in particular, to improving the coverage of the procedure.

[0004] A problem with current designs is that they do not allow for adequate coverage of the target area. In terms of anatomy, a straight needle is generally used to cover a small nerve on a rounded bony surface. As shown in FIG. 1, a spherical lesion is produced through the heat generated at the tip of the needle, but this extends only a few millimeters at the diameter of the midportion of the lesion. Worst, if the tip is over 2 mm away from the nerve (which cannot be directly visualized), then it is not lesioned at all. Anatomy

[0012] FIG. 1 is a drawing of a prior art needle tip, showing the limited area of coverage;

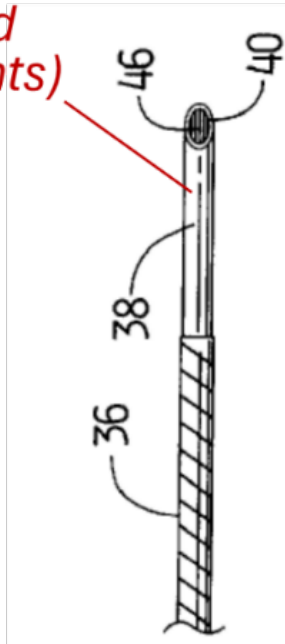
Pet. Expert (Tucker):

- Fitz “teaches a POSA that this limited coverage problem would be present in Racz’s device due to its single-tip configuration”

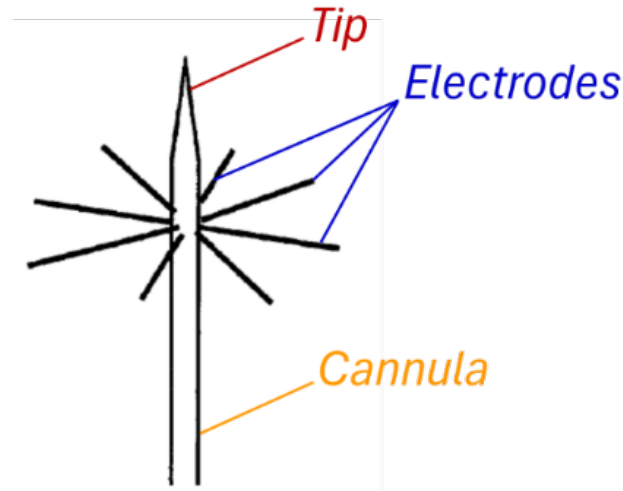
Motivation to Combine

Racz

Single Exposed
Tip (no filaments)



Fitz



Fitz – Fig. 5

Pet., 22-25; Ex-1011, ¶9, 21, Fig. 5; Ex-1031, ¶134-137; Reply, 11; Ex-2006, ¶158

Fitz identifies a known solution

SUMMARY OF THE INVENTION

[0009] This invention resides in improved-coverage RF neurotomy instrumentation, including an introducer used to deploy a set of electrodes to an area to be treated. The

[0021] Turning now to FIG. 5, yet a further alternative embodiment of the invention is depicted, in this case utilizing an introducer having a tip and sufficient side ports to form an array of electrodes once deployed. Although the side

Pet. Expert (Tucker):

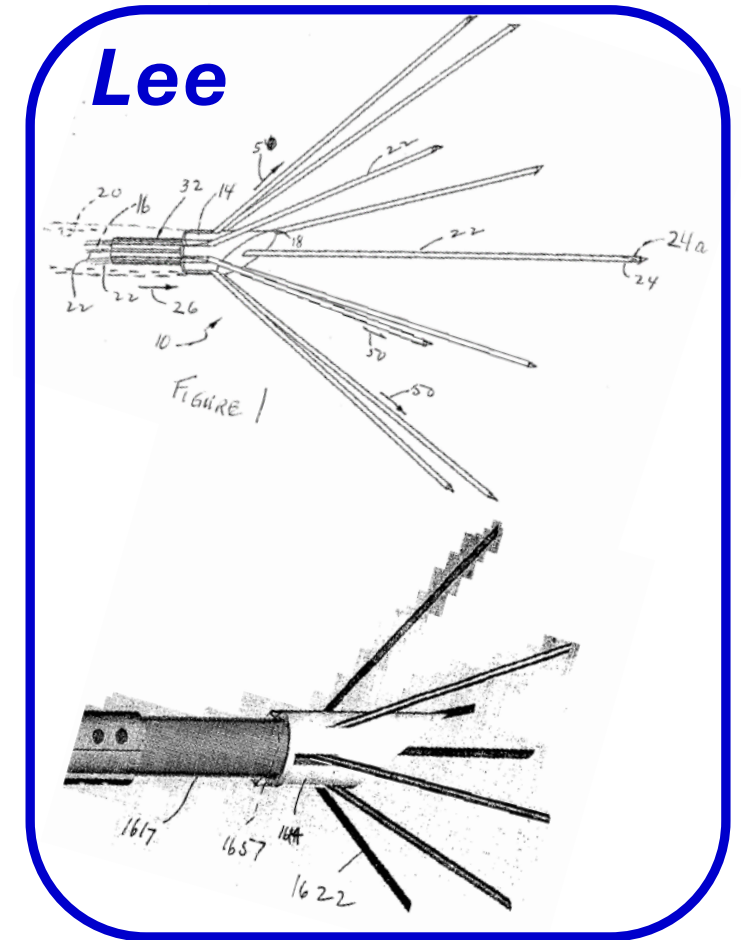
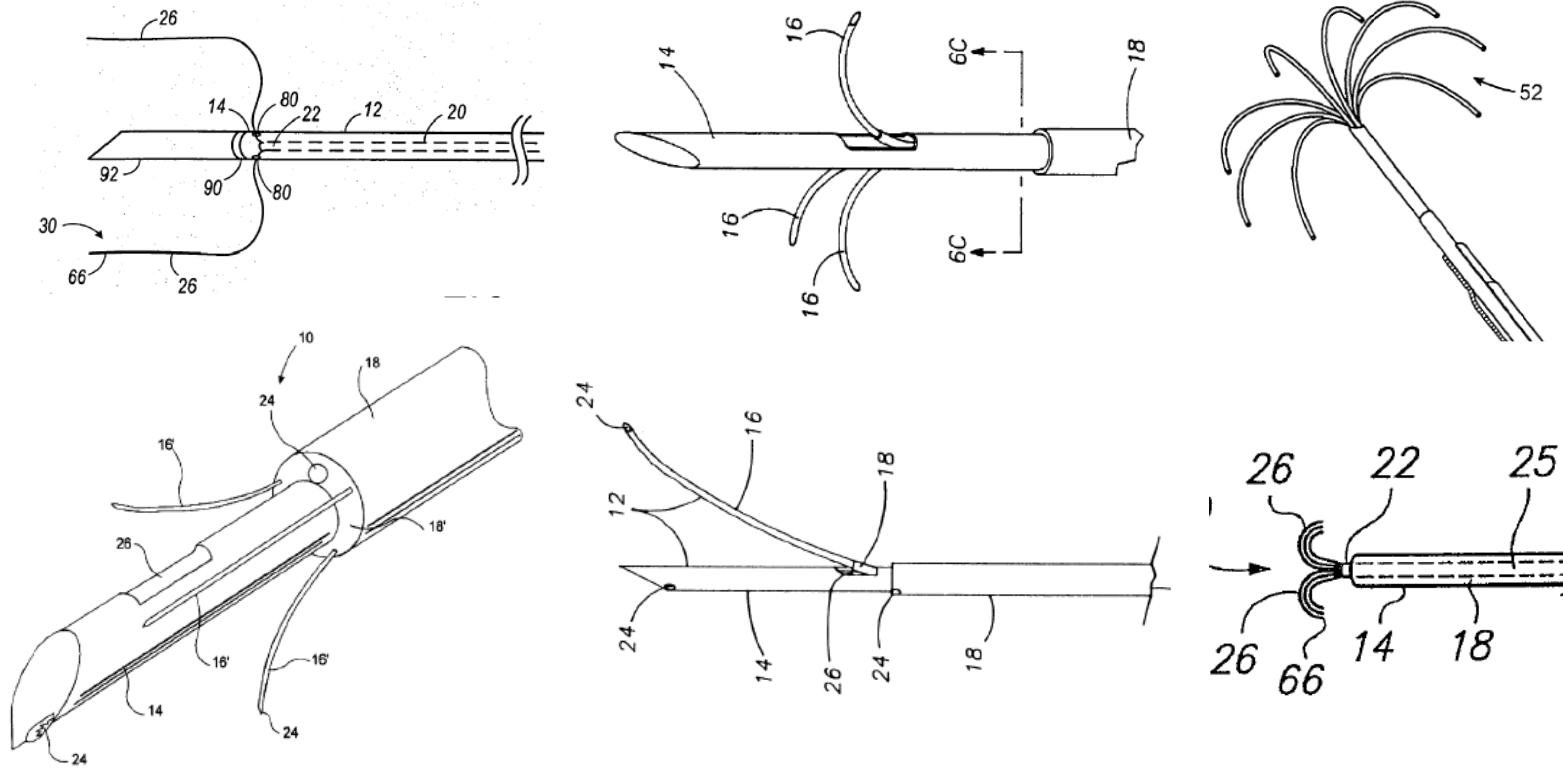
- “Fitz explains that the deployable electrodes can be used to solve the problem of inadequate coverage for single-tip neurotomy devices”

PO's Expert (Crosby):

- Fitz teaches “general idea [of] deployable electrodes to increase ablation volume”

Motivation to Combine

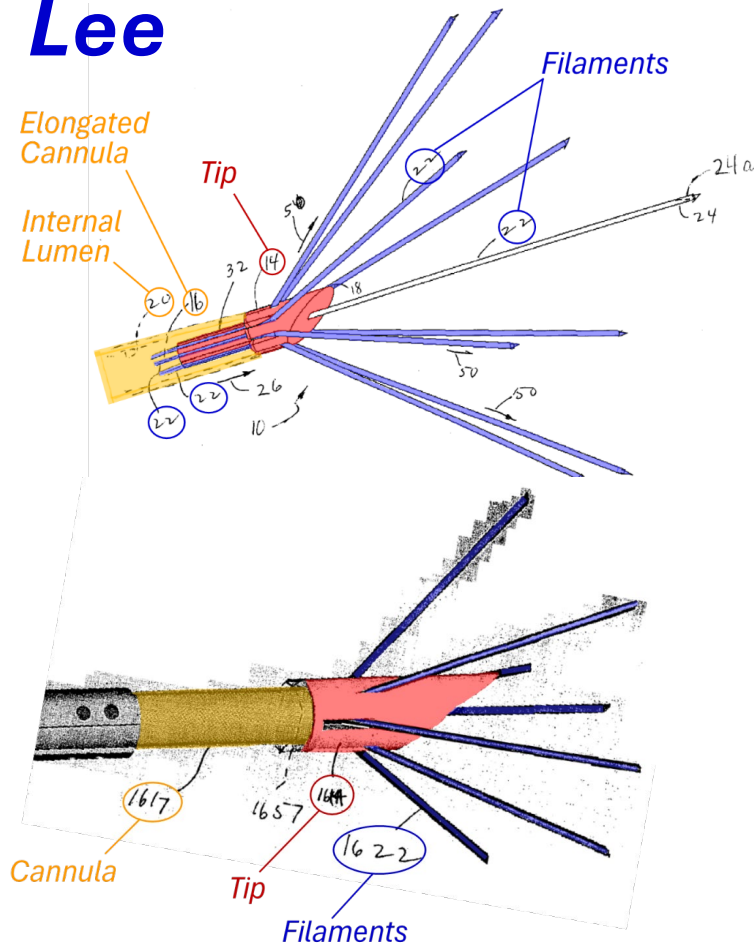
At the time of the alleged invention, deployable filaments were already **well-known**:



Pet., 23; Ex-1031, ¶¶69-72

Motivation to Combine

Lee



Lee provides more motivation, detailed solution, and established functions

- Deployable filaments **expand** and **control** the ablation volume
- Filaments “define an ablation volume” in the target tissue
- “variations in ablation volume” by controlling number of filaments, length, direction, and arrangement
- “arrangement of [filaments] may ... form any desired pattern”

Pet. Expert (Tucker):

- Configuring Lee’s filaments “to extend beyond Racz’s tip (14/38) would expand the ablation volume”

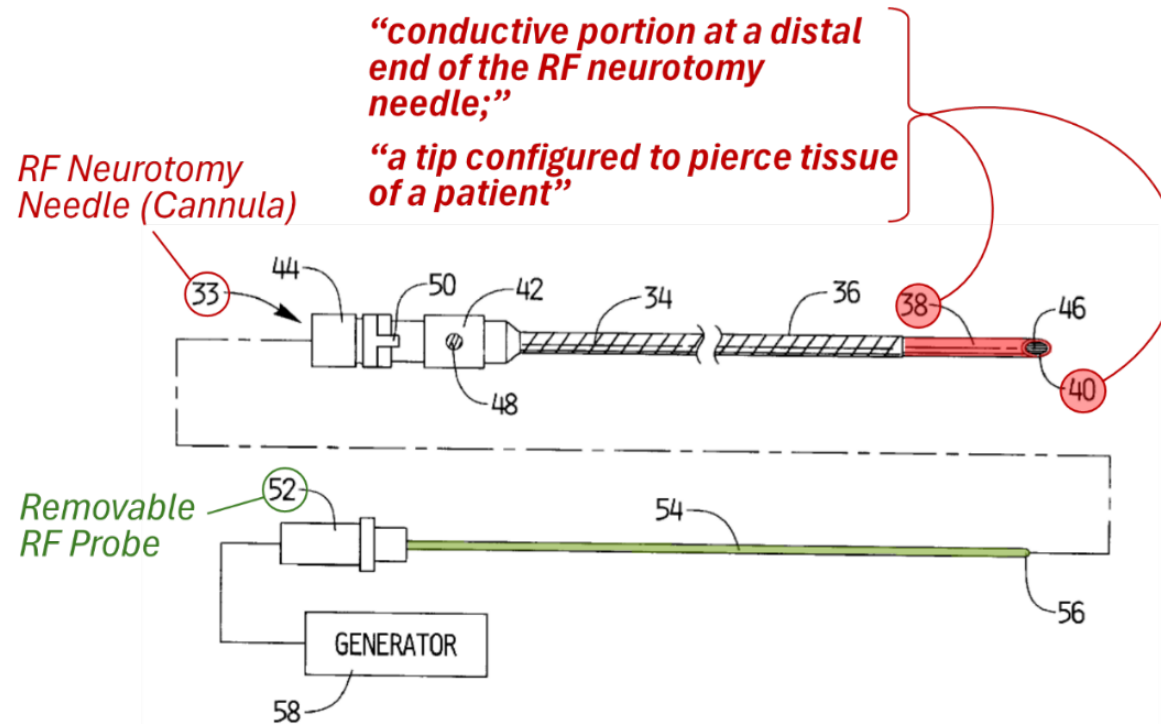
PO’s Expert (Crosby):

- Lee’s purpose is to “increase the volume of ablated tissue”

Pet., 25-26, 38-39; Ex-1010, ¶84, 103, 123-131; Ex-1031, ¶138-139, 164-165, 201; Reply, 11; Ex-2006, ¶117

Motivation to Combine

A POSA would **preserve** the functionality of **Racz's removable probe**



Pet. 31-36, 40-41; Reply, 15; Ex-1031, ¶167-168, 191; Ex-2006, ¶162; Ex-1009, 8:54-57, 1:46-54, 3:60-65, 5:25-27, 5:66 to 6:2

Pet. Expert (Dr. Tucker):

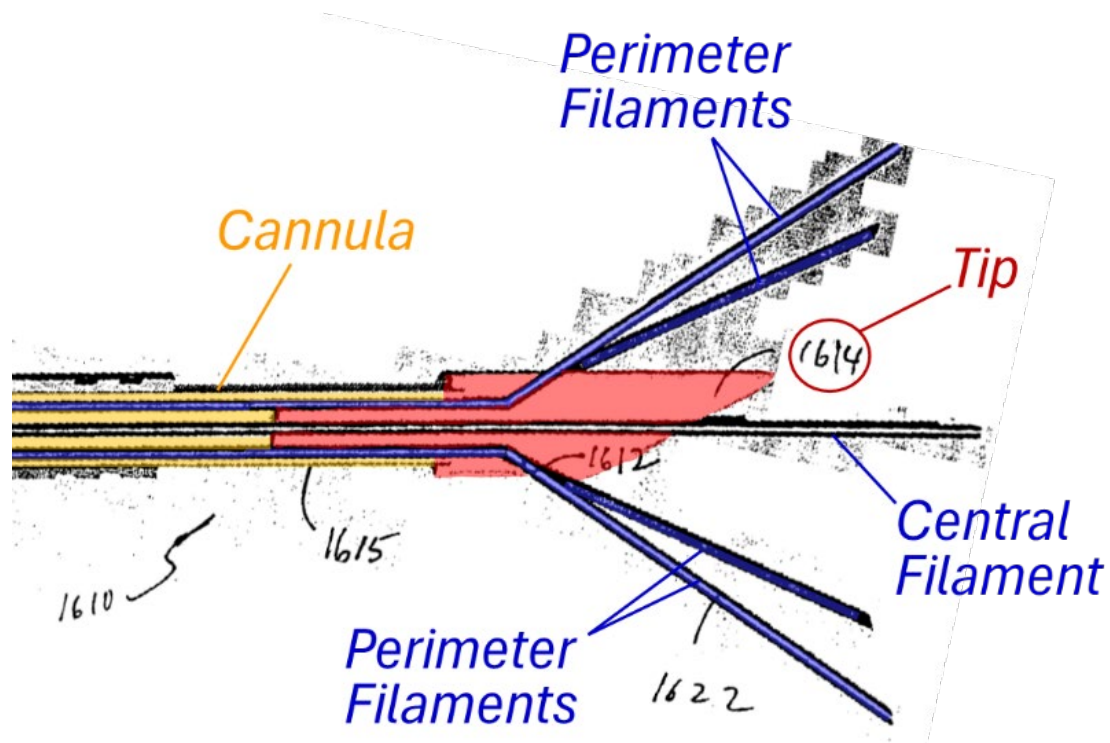
- “Racz’s distal tip (14/38) is electrically active via ‘physical contact’ between the **removable probe** (22/52) and **tip portion** (14/38) of the cannula (10/33)”
- POSA “would **preserve** the functionality of Racz’s electrical probe (22/52), which is needed to transmit RF energy”
- Racz’s cannula is configured for receiving the probe **and** fluid

PO’s Expert (Crosby):

- Racz’s removable probe is a “**central feature**”

Motivation to Combine

Lee: adding filaments around the perimeter



Pet. Expert (Dr. Tucker):

POSA would consider:

- “Lee’s filaments (22/1622) physically contact and are guided by ‘deflection surfaces’ (channels and ramps) at the tip of Lee’s RF cannula”
- “Lee’s perimeter filaments (22/1622) extend outwardly and around the cannula’s tip in a ‘cone’ shape”
- Lee’s perimeter filaments “provide space for a central element”

Pet. 26-27, 37-40; Ex-1031, ¶140-141, 164-165; Ex-1010, ¶92-94, 99, 102, 125, 146, Fig. 49, Fig. 1

Combination Was Obvious

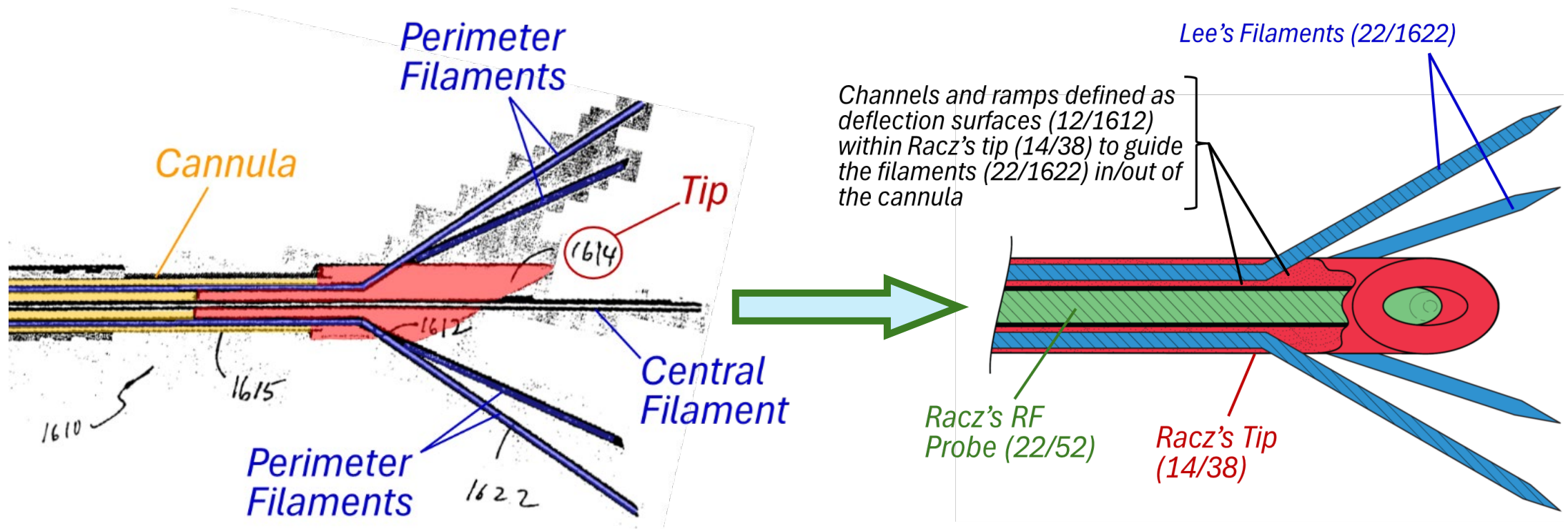
“If a **technique has been used to improve one device**, and a [POSA] would recognize that **it would improve similar devices in the same way**, using the technique is obvious unless its actual application is beyond his or her skill.”

Intel Corp. v. PACT XPP Schweiz AG, 61 F.4th 1373, 1380 (Fed. Cir. 2023)

Reply, 12

Combination Was Obvious

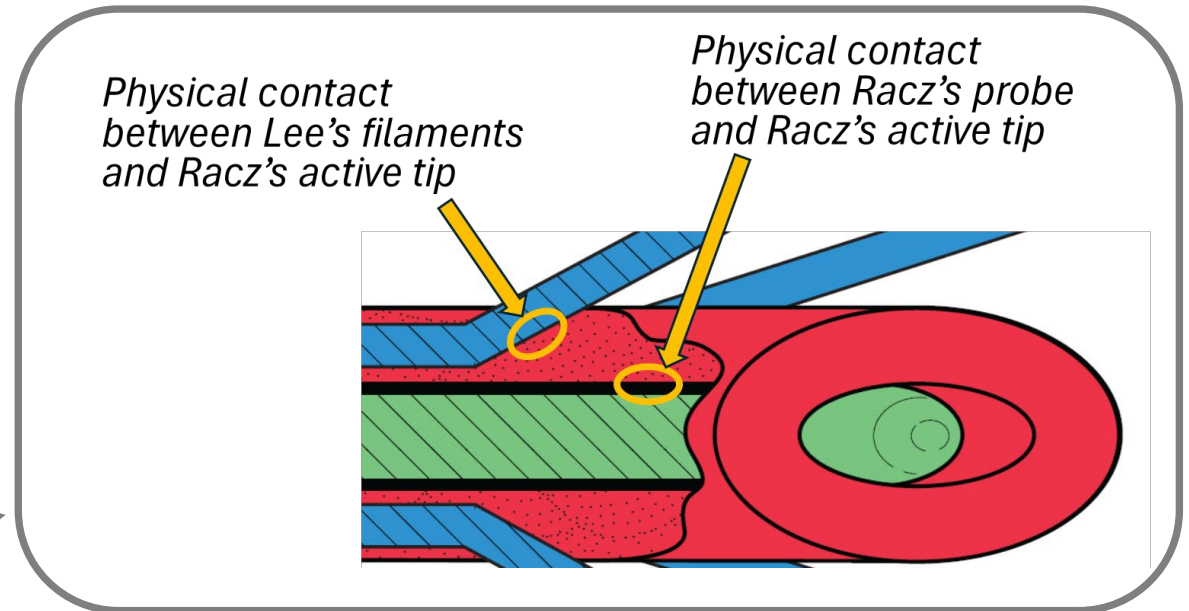
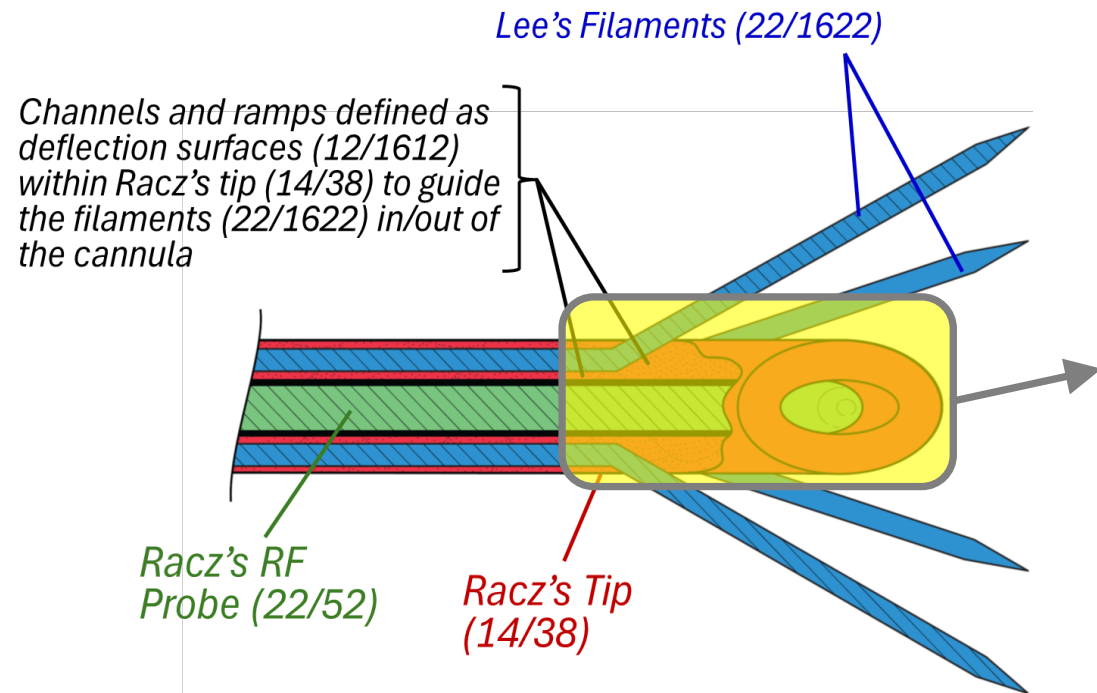
Obvious: Lee's perimeter **filaments** around Racz's central **probe**.



Pet. 40-44; Ex-1031, ¶169-171

Combination Was Obvious

*Physical contact energizes Lee's perimeter **filaments**.*



Pet. 40-44; Ex-1031, ¶169-171

Combination Was Obvious

Stratus Arguments:

- Combination is a “**paper design**”
- Combination based on “**hindsight**”

result in the feature missing from each reference. *See* Crosby Decl. ¶ 37. Because obviousness must be based on the actual teachings of the prior art, not a challenger’s reconstruction using bits and pieces of the prior art, all challenges fail. *See KSR*, 550 U.S. at 421; *compare Cheese Sys. v. Tetra Pak Cheese & Powder Sys.*, 725 F.3d 1341, 1352 (Fed. Cir. 2013) (obviousness “cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.”), *with* Tucker Dep. Tr. 90:17-92:9 (Tucker “read all of the Stratus patents prior to looking at the prior art” then combined “components” from that prior art into Racz’s modified design.).

Dr. Tucker Cross-Examination

14 Q Is it fair to say, Dr. Tucker, that this
15 is a paper design?

16 MR. KELLY: Objection. Form.

17 A Well, I think the important thing is as
18 you call it paper design, you're taking components
19 that have been in the literature and you're using
20 them for the same purpose and in the same fashion
21 as they were used in the patents. Everything in
22 here.

1 So with that said, because it is a
2 design that has the components that have shown
3 that they work, the chance for success of making
4 it is very high. And anyone of ordinary skill in
5 the art can make this.

POR, 36-37; Ex-2020, 90:17-92:9

Combination Was Obvious

Stratus Arguments:

- Obviousness based on a “**particular modification**”
- Combination is too “**vague**”

All challenges in the petition are premised on “Racz’s modified device,” a particular modification of Racz’s device to add deployable filaments (Lee’s stylet’s).

Every challenge ground of every IPR is based on the same proposed combination of Racz, Fitz, and Lee (*i.e.*, Racz’s modified device). Additionally,

But the requisite clarity, specificity, and particularity are lacking from the petition’s description of Racz’s modified device, the centerpiece of all challenges.

POR, 19, 34, 38

Petition was clear:

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 (12/1622) both physically contacting Racz’s active tip (14/38) and being deployed outwardly around Racz’s active tip (14/38). Ex-1031, ¶141-142. 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.*

Pet., 26-27

Combination Was Obvious

Stratus Arguments:

- Obviousness based on a “**particular modification**”
- Combination is too “**vague**”

All challenges in the petition are premised on “Racz’s modified device,” a particular modification of Racz’s device to add deployable filaments (Lee’s stylet’s).

Every challenge ground of every IPR is based on the same proposed combination of Racz, Fitz, and Lee (*i.e.*, Racz’s modified device). Additionally,

But the requisite clarity, specificity, and particularity are lacking from the petition’s description of Racz’s modified device, the centerpiece of all challenges.

POR, 19, 34, 38

Petition was clear:

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) could still be received into the cannula’s central lumen). Ex-1031, ¶¶168-169. According to Dr. Tucker, Lee’s deflection

Pet., 41-40

Combination Was Obvious

Stratus Arguments:

- Obviousness based on a “**particular modification**”
- Combination is too “**vague**”

All challenges in the petition are premised on “Racz’s modified device,” a particular modification of Racz’s device to add deployable filaments (Lee’s stylet’s).

Every challenge ground of every IPR is based on the same proposed combination of Racz, Fitz, and Lee (*i.e.*, Racz’s modified device). Additionally,

But the requisite clarity, specificity, and particularity are lacking from the petition’s description of Racz’s modified device, the centerpiece of all challenges.

POR, 19, 34, 38

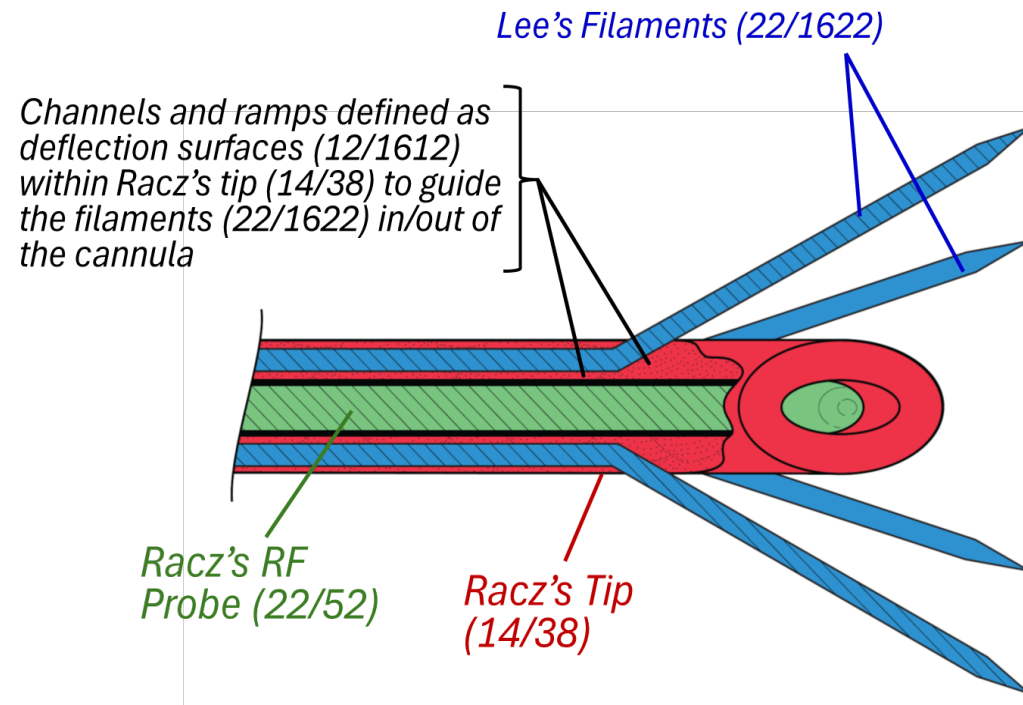
Dr. Tucker (Ex-1031):

143. In my opinion, using ordinary skill and routine engineering, a POSA would have combined the teachings of these references to modify Racz with a reasonable expectation of success. To illustrate how Racz and Lee could be combined as a matter of routine engineering, I instructed a draftsman to prepare the figure shown below. The figure shows *one example* of how a POSA (motivated by both Fitz and Lee) would have incorporated Lee’s deployable filaments (22/1622) as monopolar electrodes at Racz’s distal tip (14/38). This figure is not intended to be limiting or represent the only way Racz’s device would have been modified, but I am providing it as a helpful illustration of how the references would be combined in one example.

Pet., 27; Ex-1031, ¶143

Combination Was Obvious

The combination could be achieved in different ways.



Pet. Expert (Dr. Tucker):

POSA:

- “would understand how to size the relative components of the cannula, tip, filaments, and channels to make the combination of Racz and Lee operable”

Unitary Tip:

- “define channels (as disclosed in Lee) as an integral part of Racz's cannula . . . such channels could be formed within the tip of Racz's cannula”

Separate Tip:

- “implement the combination of Racz and Lee using a separate tip defining channels (as disclosed in Lee)”

Pet., 40-42; Ex-1031, ¶145-147, 169-171

Racz Does Not Teach Away

Stratus Arguments:

- Racz *teaches away* from “from deploying a flexible electrode from a cannula in the context of neurotomy”
- Filaments added to Racz’s device would be “*damaged or diverted*”

POR, 51-53

Racz:

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



Radionics TEW Kit (Ex-1058)

Reply, 13-14; Ex-1009, 2:26-35; Ex-1058

Racz Does Not Teach Away

Stratus Arguments:

- Racz **teaches away** from “from deploying a flexible electrode from a cannula in the context of neurotomy”
- Filaments added to Racz’s device would be “**damaged or diverted**”

POR, 51-53

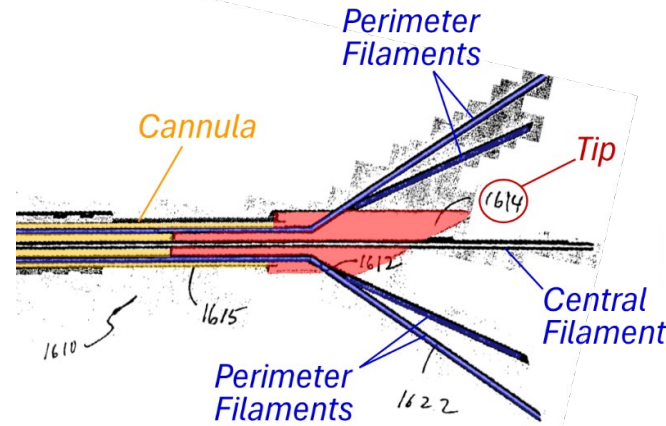
Lee

Tough Filaments:

- Lee’s filaments can be “pushed into and through ... tough fibroid tumor tissue”

Nitinol Filaments:

- Lee’s filaments can be made from “nickel titanium alloy” (i.e., Nitinol)



Lee – Fig. 48



Radionics TEW Kit

Reply, 13-14; Pet. 37-38;
Ex-1010, ¶87, 17, 92

Racz Does Not Teach Away

Stratus Arguments:

- Racz *teaches away* from “from deploying a flexible electrode from a cannula in the context of neurotomy”
- Filaments added to Racz’s device would be “*damaged or diverted*”
- Racz’s ***curved tip is a necessity***

POR, 53-56

Stratus takes the wrong approach:

- “The inquiry is **not** whether a relevant artisan would combine a first reference's feature with a second reference's feature to meet requirements of the first reference that are not requirements of the claims at issue.”
Axonics, Inc. v. Medtronic, Inc., 73 F.4th 950, 957 (Fed. Cir. 2023)

Racz:

- Bent tip is preference in limited circumstances, not a requirement

Dr. Tucker Cross-Examination:

- “I think that one skilled in the art would see that the degree of curvature can be varied ... so yes, it could include zero.”
Reply, 14-15; Ex-1009, 2:3-25, 2:39-41; Ex-2020, 46:16-48:3, 68:17-69:13; Ex-1045, 129:15-131:2, 133:17-134:10

Reasonable Expectation of Success

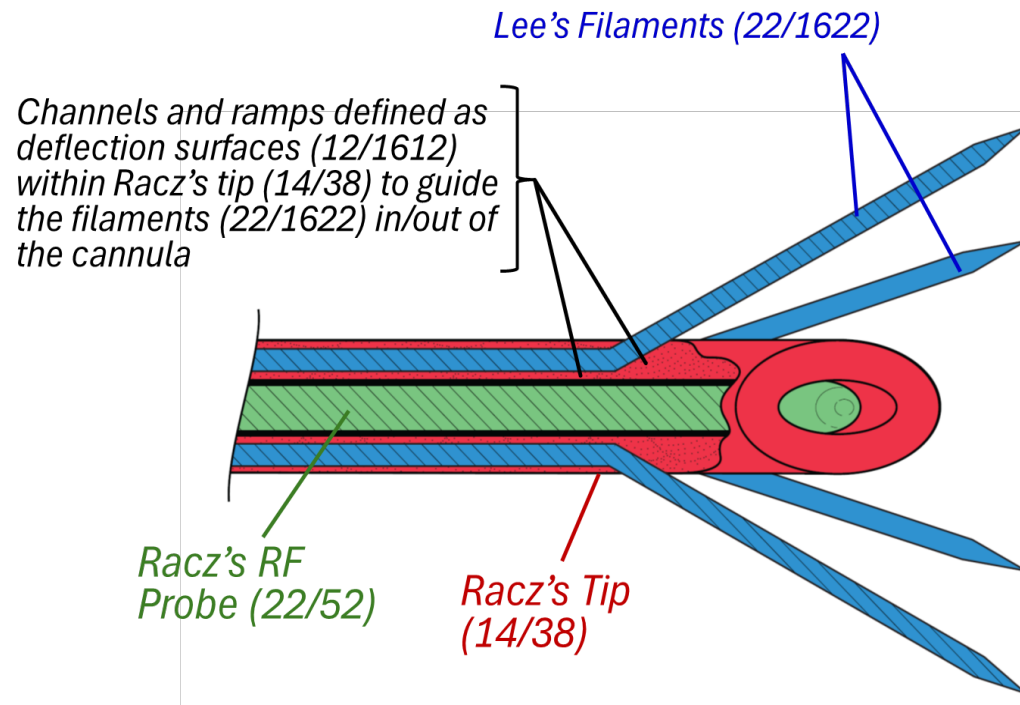
“Obviousness **does not require absolute predictability** of success[,]
... all that is required is a **reasonable expectation of success.**”

In re O'Farrell, 853 F.2d 894, 903-904 (Fed. Cir. 1988).

Reply, 17

Reasonable Expectation of Success

The combination was **predictable** and **routine**.



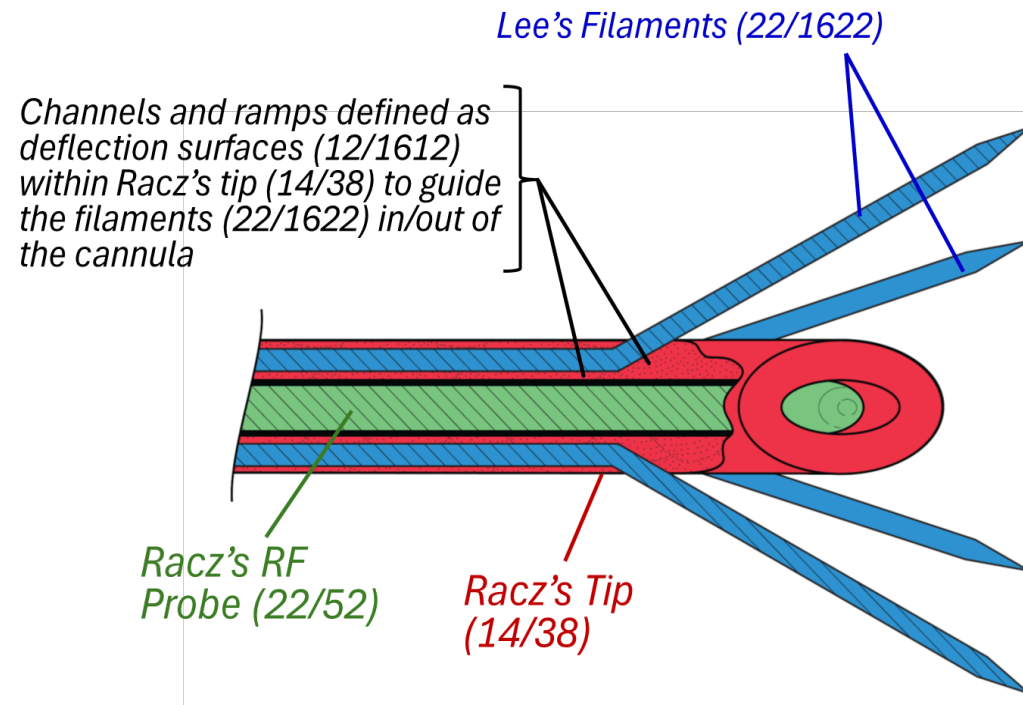
Pet. Expert (Dr. Tucker):

- POSA “would have found implementing Lee’s perimeter filaments (22/1622) on Racz’s distal tip (14/38) to be a **routine engineering task**”
- “This implementation would involve nothing more than using **prior art elements** like the filaments (22/1622), cannula (10/33), active tip (14/38), and removable probe (22/52) according to their **established functions**, which would have been known to a POSA”
- “Combining these elements would achieve an entirely **expected improvement** (the ability to expand and control the ablation volume generated by Racz’s device).”

Pet., 28, 39-43; Ex-1031, ¶144, 165, 166-170

Reasonable Expectation of Success

The combination was *predictable* and *routine*.



Pet. Expert (Dr. Tucker):

22	Lee's central filament. Take Lee's filament out
1	of that central channel, all the filaments are
2	along the outside of that channel, and put Racz's
3	probe down that channel.
4	Q And you believe that would be routine
5	engineering?
6	A Amen.

Reply, 15; Ex-2020, 184:16-185:6

Reasonable Expectation of Success

Crosby Direct Testimony:

- “Acessa” is the commercial embodiment of Lee

231. Fig 12.1 from the Acessa User's Guide is shown below. Recall that Acessa is the commercial embodiment of Lee:

Ablation Zone							
Deployment	0 cm	0.5 cm	1.5 cm	2.5 cm	3.5 cm	4.5 cm	5.0 cm

Ex-2006, ¶231-232; Ex-2010, 21

Reasonable Expectation of Success

Crosby Direct Testimony:

- “Acessa” is the commercial embodiment of Lee
- POSA would have believed Lee’s ablation volume was “*orders of magnitude*” too large (evidenced by Acessa User Guide)

232. This shows that in the physical embodiment of Lee, the tines can be deployed up to 5 cm. A deployment of the tines at the minimum of 0.5 cm and energy time of 1 minute yields an ablation size of 1.9 cm x 1.7 cm, and a deployment of 5 cm yields an ablation size of 6.0 cm x 5.0 cm. These are *orders of magnitude* larger than would be appropriate for RF neurotomy.

Ex-2006, ¶231-232; Ex-2010, 21

Reasonable Expectation of Success

Crosby Direct Testimony:

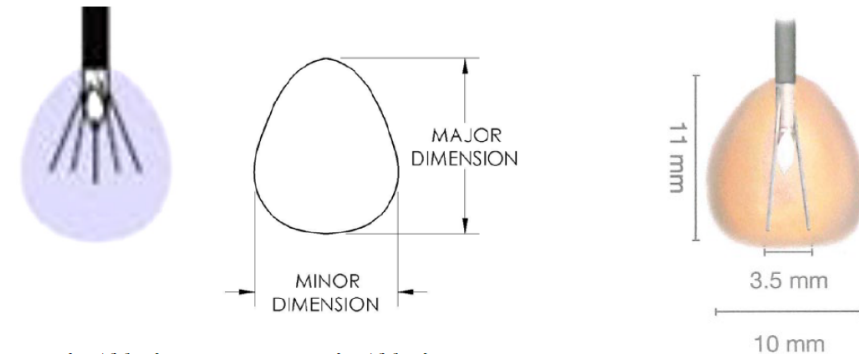
- “Acessa” is the commercial embodiment of Lee
- POSA would have believed Lee’s ablation volume was “*orders of magnitude*” too large (evidenced by Acessa User Guide)

232. This shows that in the physical embodiment of Lee, the tines can be deployed up to 5 cm. A deployment of the tines at the minimum of 0.5 cm and energy time of 1 minute yields an ablation size of 1.9 cm x 1.7 cm, and a deployment of 5 cm yields an ablation size of 6.0 cm x 5.0 cm. These are *orders of magnitude* larger than would be appropriate for RF neurotomy.

Ex-2006, ¶231-232; Ex-2010, 21

Crosby Cross-Examination:

- Admitted that **Lee** produces ablation volumes of 19mm x 17mm
- **NOT** “orders of magnitude” too large
- POSA would have known that Lee’s filaments would produce the lesion shape shown in the **Acessa User Guide**



Lee's Ablation Shape
(Ex-2010, 21)

Lee's Ablation Dimensions:
19mm x 17mm
(Ex-2010, 21-22)

Stratus Ablation Shape/Dimensions:
11mm x 10mm
(Ex-1051, 1)

Reply, 18-19; Ex-1045, 168:3-170:10, 177:16-20, 189:12-190:4

Combination Was Not “Impossible” to Make

Stratus’s “impossible” to make arguments fail:

- All of Stratus’s arguments are incorrectly premised on neurotomy needles being **16-gauge or smaller**

Racz:

- No dispute that Racz’s needle is for neurotomy
- RF Neurotomy needles can be **10-30 gauge**

Those individuals skilled in the art will recognize that many variations of the electrode geometries depicted in FIGS. 1–3 are possible without departing from the invention. Various sized electrodes can be made, from extremely small gauges (e.g., 30 gauge) to much larger sizes (e.g., 10 gauge). Also, the shape and degree of tip curvature may vary

Stratus’s only evidence that neurotomy needles must be 16-gauge or smaller:

- **Unsupported** testimony from Russo and Crosby (entitled to **no weight**)

Reply, 19-20; Ex-1009, 8:10-15; c.f. POR, 4, 44, 48, 51

Combination Was Not “Impossible” to Make

Stratus’s “impossible” to make arguments fail:

- *All of Stratus’s arguments are incorrectly premised on neurotomy needles being **16-guage or smaller***
- *Stratus’s alleged novelty does not relate to **manufacturing***

Stratus demands more than it discloses:

- Specification is silent regarding how to manufacture the claimed invention

“[T]he Board's observation that appellant **did not provide the type of detail in his specification that he now argues is necessary in prior art references** supports the Board's finding that one skilled in the art **would have known how to implement the features of the references** and would have concluded that the reference disclosures would have been enabling.”

In re Epstein, 32 F.3d 1559, 1568 (Fed. Cir. 1994)

Reply, 16-17; POR, 43-51

Combination Was Not “Impossible” to Make

Stratus’s “impossible” to make arguments fail:

- *All of Stratus’s arguments are incorrectly premised on neurotomy needles being **16-guage or smaller***
- *Stratus’s alleged novelty does not relate to **manufacturing***

PO Expert (Crosby):

4 Q. Would you agree that the 688
5 patent is silent on how to manufacture the
6 needle shown in figure --

7 A. Oh, is silent. I didn't hear
8 the word "silent".

9 MR. PHILLIPS: Same objection.

10 A. The 688 patent does not give
11 details of manufacturing techniques, no.

Reply, 16; Ex-1045, 275:4-11; POR, 43-51

Combination Was Not “Impossible” to Make

Stratus’s “impossible” to make arguments fail:

- *All of Stratus’s arguments are incorrectly premised on neurotomy needles being 16-guage or smaller*
- *Stratus’s alleged novelty does not relate to **manufacturing***

PO Expert (Crosby):

13 Q. Okay. And despite that, a
14 POSITA would have been able to make the
15 needle that cease shown in the patent?
16 MR. PHILLIPS: Objection. Scope.
17 A. I believe so because the
18 description is fairly detailed. A POSITA
19 reading this in a large patent application
20 and looking at all illustrations I think
21 would have been able to make this.

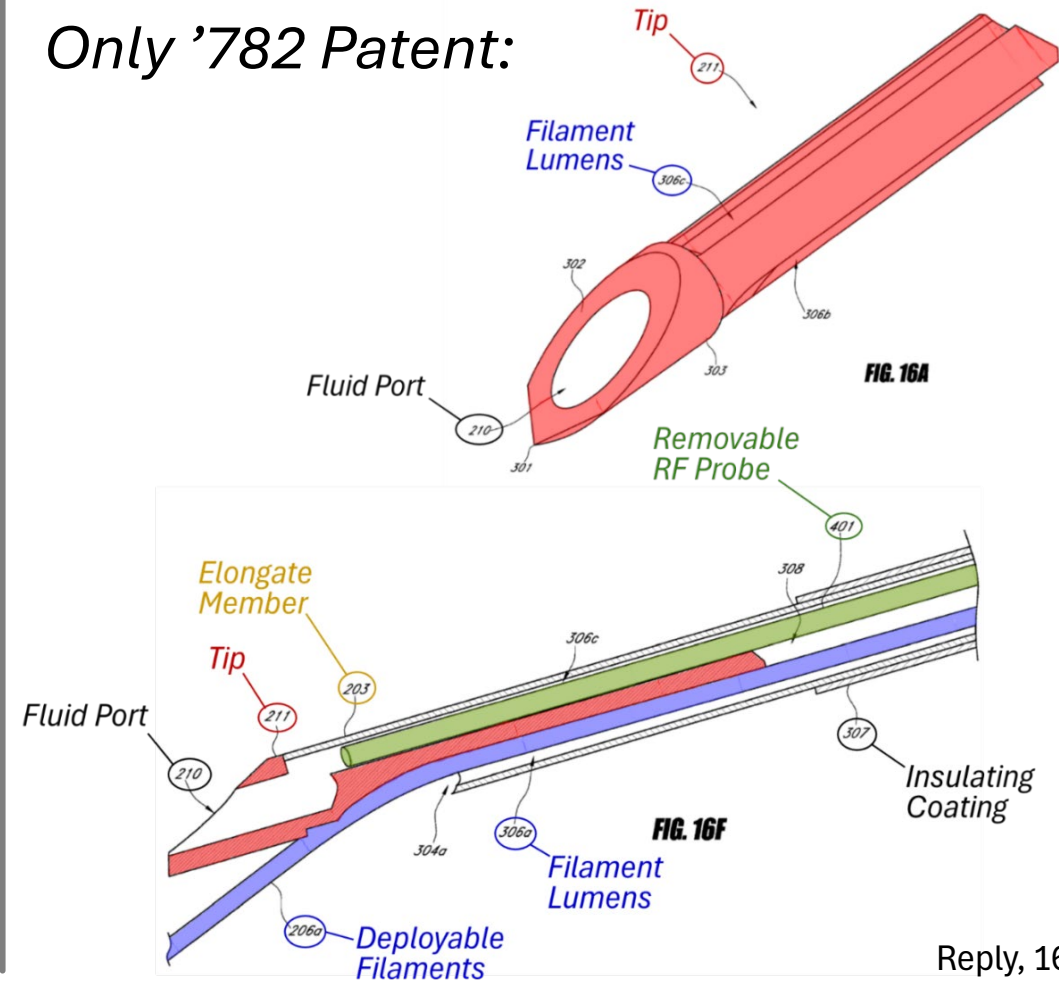
Reply, 16; Ex-1045, 275:13-21; POR, 43-51

Combination Was Not “Impossible” to Make

'688 and '664 Patent:

No cut-away views

Only '782 Patent:



Reply, 16-17

Combination Was Not “Impossible” to Make

Stratus’s “impossible” to make arguments fail:

- *All of Stratus’s arguments are incorrectly premised on neurotomy needles being 16-guage or smaller*
- *Stratus’s alleged novelty does not relate to **manufacturing***

PO Expert (Crosby):

7 Q. No. I'm asking, does the 688
8 patent illustrate the position of the probe
9 relative to the filaments?
10 A. I don't believe so, no.
11 Q. Okay. And despite that, a
12 person of ordinary skill in the art at the
13 time of the invention would have been able to
14 make this needle?
15 A. I believe so.
16 MR. PHILLIPS: Objection. Form.

Reply, 16; Ex-1045, 279:7-15; POR, 43-51

Secondary Considerations

Stratus Argues:

Evidence Shows:

1. *Long-felt need* —————→ ***Alleged need already met***
2. *Copying* —————→ ***No copying by Avanos***
3. *Industry Praise* —————→ ***No praise of product / features***
4. *Commercial Success* —————→ ***No significant success***

POR, 61-74; Reply, 21-30

No Long-Felt Need

POR relies on Russo:

The improved size and shape of the ablation volume with the invention enable the physician to approach the target nerve from a perpendicular direction, rather than a parallel approach as with prior-art devices. *Compare* Russo Decl. ¶¶ 108-118 (describing prior-art parallel approach) *with id.* ¶¶ 119-127 (describing perpendicular approach possible with invention). The prior-art parallel approach

But the perpendicular approach (illustrated below) made possible by the invention is “safer, faster, and easier to learn.” *Id.* ¶ 123; *see also id.* ¶ 124

The Nimbus’s lesion shape enables perpendicular placement with its attendant advantages. *See id.* ¶ 122. Traditional neurotomy needles require parallel placement to effectively or reliably ablate nerves because perpendicular placement would require pinpoint accuracy that is not possible with the small ablation region at the distal tip of a traditional neurotomy needle. *See id.* ¶¶ 108-118.



Nimbus Device

POR, 8-9, 63-64

No Long-Felt Need

POR relies on Russo:

The improved size and shape of the ablation volume with the invention enable the physician to approach the target nerve from a perpendicular direction, rather than a parallel approach as with prior-art devices. *Compare* Russo Decl. ¶¶ 108-118 (describing prior-art parallel approach) *with id.* ¶¶ 119-127 (describing perpendicular approach possible with invention). The prior-art parallel approach

But the perpendicular approach (illustrated below) made possible by the invention is “safer, faster, and easier to learn.” *Id.* ¶ 123; *see also id.* ¶ 124

The Nimbus’s lesion shape enables perpendicular placement with its attendant advantages. *See id.* ¶ 122. Traditional neurotomy needles require parallel placement to effectively or reliably ablate nerves because perpendicular placement would require pinpoint accuracy that is not possible with the small ablation region at the distal tip of a traditional neurotomy needle. *See id.* ¶¶ 108-118.

Russo says the opposite:

23 Q So the device described in the Stratus patents
24 was not the first device to enable the perpendicular
25 approach to be used for the sacroiliac joint; is that
1 correct?

2 MR. PHILLIPS: Objection, scope.

3 THE WITNESS: Correct.

4 BY MR. KELLY:

5 Q And the perpendicular approach was already
6 made possible using cooled RF at the time of the
7 invention; right?

8 MR. PHILLIPS: Objection, form.

9 Objection, scope.

10 THE WITNESS: Yes.

Reply, 21-22; Ex-1046, 94:23-95:10; c.f. POR, 8-9, 63-64

No Long-Felt Need

POR relies on Russo:

The improved size and shape of the ablation volume with the invention enable the physician to approach the target nerve from a perpendicular direction, rather than a parallel approach as with prior-art devices. *Compare* Russo Decl. ¶¶ 108-118 (describing prior-art parallel approach) *with id.* ¶¶ 119-127 (describing perpendicular approach possible with invention). The prior-art parallel approach

But the perpendicular approach (illustrated below) made possible by the invention is “safer, faster, and easier to learn.” *Id.* ¶ 123; *see also id.* ¶ 124

The Nimbus’s lesion shape enables perpendicular placement with its attendant advantages. *See id.* ¶ 122. Traditional neurotomy needles require parallel placement to effectively or reliably ablate nerves because perpendicular placement would require pinpoint accuracy that is not possible with the small ablation region at the distal tip of a traditional neurotomy needle. *See id.* ¶¶ 108-118.

Russo says the opposite:

4 Q Okay. And my recollection is that you
5 described in the palisade approach that these standard
6 RF needles are inserted perpendicularly into the patient
7 about 10 millimeters apart from one another; is that
8 right?

9 A Correct.

10 Q Okay. So even before cooled RF technology, a
11 perpendicular approach was being used in neurotomy; is
12 that right?

13 MR. PHILLIPS: Objection, form and
14 foundation.

15 THE WITNESS: For sacroiliac joint
16 denervation, yes.

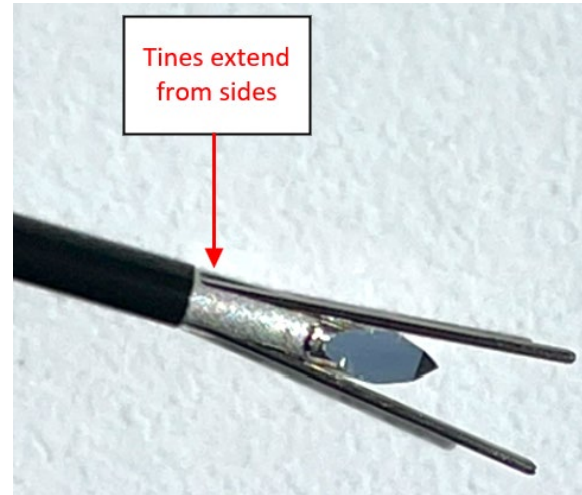
Reply, 21-22; Ex-1046, 146:4-16; c.f. POR, 8-9, 63-64

No Copying

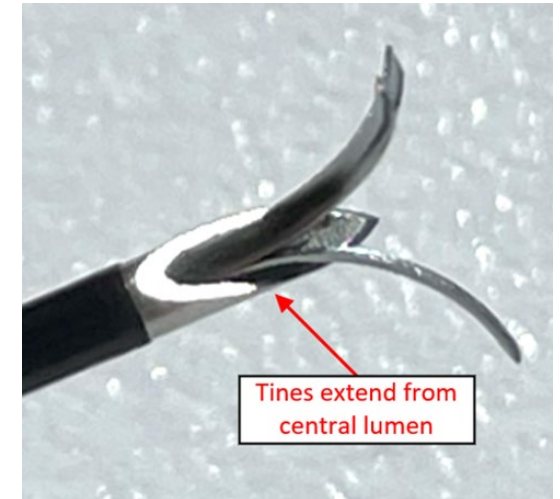
Pet. Expert (Dr Tucker):

Avanos's Device:

- Different **shaped** tines
- Different **material** tines
- Different **arrangement** of tines
- Greater **number** of tines
- Different tine **deployment**
- Probe does **not contact tip**



Stratus's Nimbus Device



Avanos's Trident Device

Jorgensen Cross-Examination:

21 Q. So you were only identifying the
22 similarities and not any differences?
1 MR. LAURENCE: Objection, form.
2 A. That is correct.

Reply, 23-24; Ex-1042, ¶12-22; c.f. POR, 66-67; Ex-1047, 67:21-68:2

No Industry Praise

Stratus Evidence:

- *Pepperdine Graziadio Most Fundable Companies*
- *Deloitte Technology Fast 500*

Reply, 24-25; POR, 67-68; Ex-1047, 41:13-21

Patent Owner Response:

“Evidence that the industry praised a claimed invention or a product that embodies the patent claims weighs against an assertion that the same claimed invention would have been obvious.” *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1053 (Fed. Cir. 2016).

Jorgensen Cross-Examination:

13 Q. And selection for this program is based
14 on an applicant's fiscal year revenue growth
15 percentage over a three-year period, correct?

16 A. I believe -- I believe document --
17 Exhibit 2042 has some of the information on the
18 submission. But, yes, that is -- that is part of
19 the basis.

20 Q. It's the only basis, isn't it?

21 A. Yes.

No Commercial Success

No evidence of commercial success:

1. *Stratus shows no nexus*

No basis for finding a nexus:

- All claims require an **RF probe**
- Only nexus argument is **coextensive** sales
- **Impossible** to tell which sales (if any) are coextensive
- **Imbalance** of electrode vs. probe sales

Jorgensen Cross-Examination:

8 Q. And other than 2020 when Stratus didn't
9 sell any probes, for the other years this chart does
10 not indicate how many cannulas it sold versus how
11 many probes it sold, correct?
12 A. Correct.

Reply, 25-26; POR, 69; Ex-1047, 84:8-12

No Commercial Success

No evidence of commercial success:

1. *Stratus shows no nexus*

No basis for finding a nexus:

- All claims require an **RF probe**
- Only nexus argument is **coextensive** sales
- **Impossible** to tell which sales (if any) are coextensive
- **Imbalance** of electrode vs. probe sales

Stratus Electrode Sales

2020	2021	2022	2023	2024

Stratus Probe Sales

2020	2021	2022	2023	2024

Reply, 25-26; POR, 69; Ex-1060; Ex-1047, 95:10-96:5

No Commercial Success

No evidence of commercial success:

1. *Stratus shows no nexus*
2. *Stratus's market data is incorrect and inadmissible*

Stratus **competes** with Avanos's COOLIEF*

- POR: [REDACTED]

- POR: [REDACTED]

But **excluded** COOLIEF* from market data:



2024 Stratus Nimbus Sales



2024 Avanos COOLIEF* Sales
(excluded from Stratus data)

Regardless, Stratus's market data is inadmissible

- Jorgensen testimony is hearsay

Reply, 27-28; POR, 18, 71; Ex-1044, ¶5-8; Ex-2015, ¶15, Pet. Mot. to Excl., 2-10

No Commercial Success

No evidence of commercial success:

1. *Stratus shows no nexus*
2. *Stratus's market data is incorrect and inadmissible*
3. *Stratus's market data shows no meaningful success*

Even if correct, Stratus's data does not show meaningful commercial success.

Pet. Commercial Expert (Konno)

- Stratus's growth is insignificant
- Stratus's growth rate is [REDACTED]
- Same dominant market leaders
- No evidence of price premium

Reply, 28-30; Ex-1043, ¶13-25, 29