

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVANOS MEDICAL, INC.,
Petitioner,

v.
STRATUS MEDICAL, LLC,
Patent Owner.

Case IPR2024-01210
Patent 10,736,688

DECLARATION OF DR. ROBERT TUCKER
(Claims 1-17 and 48-52)

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I. INTRODUCTION

A. Experience

1. My name is Robert D. Tucker. I have been retained by Counsel for Avanos Medical, Inc. (“Avanos”) as an expert in this matter. A detailed description of my professional qualifications, including a listing of my specialties, expertise and professional activities, and a list of cases in which I have testified in the last ten years, is contained in my curriculum vitae, a copy of which is attached as Appendix A. Below is a short summary of my professional qualifications.

2. In 1969, I earned my Bachelor of Science with a double major in Mathematics and Physics from the University of Nebraska. I then earned my Ph.D. in Biophysics from the University of Minnesota in 1975 where I studied the tissue effects of electric, magnetic, and electromagnetic fields. I also earned my M.D. degree from the University of Nebraska College of Medicine in 1978. I specialized in pathology and completed my pathology residency at the University of Minnesota in 1983.

3. Since 1983, I have been a Professor at the University of Iowa where I direct an active research program in radiofrequency electrosurgical procedures and instrumentation. I am currently an Associate Professor in the Department of Pathology at the University of Iowa College of Medicine. I am also an Adjunct

Associate Professor in the Department of Biomedical Engineering at the University of Iowa.

4. I have extensive clinical experience, both in a leadership capacity and in carrying out clinical activities.

5. I have also been continuously involved in research and teaching in the fields of pathology, biomedical studies, biomedical engineering, and electrosurgical instrumentation and procedures since 1978. I first started my research into radiofrequency electrosurgery and its effects on tissue in 1978, working with a group of gastroenterologists to develop bipolar electrodes. I have continued working over the years to develop and test new electrosurgical products and procedures. From 1992 through 2016, I worked as a consultant for several electrosurgical companies evaluating their electrosurgical instruments. The studies involved comparing the damage caused by different surgical modalities (e.g., standard electrosurgery, argon coagulators and ultrasound). Comparisons were done by quantifying the amount of tissue necrosis and thermal damage for the surgical modalities using histology of samples from multiple organ tissues in both in vitro and in vivo, acutely, and over time.

6. I have authored over 70 peer reviewed scientific publications and 14 book chapters on assorted topics including biologic responses to magnetic fields, electrosurgery circuitry and associated ramifications, physics and pitfalls of

electrosurgery, low frequency currents for electrosurgery, bipolar electrosurgical devices, tissue effects of electrosurgery, ablation of cancer with implantable rods, monopolar electrosurgery, and many more. These works have been published in well-respected publications. A sample of these publications includes the American Journal of Surgery, IEEE Biomedical Engineering, Journal of Applied Biomaterials, Journal of Endourology, Biomedical Instrumentation and Technology, Journal of Urology, The American Journal of Gastroenterology, and others.

7. I have served as a trusted peer reviewer of many manuscripts for multiple well- respected publications. A sample of these publications includes Biophysical Journal, Journal of Investigative Surgery, Journal of Gynecologic Surgery, IEEE, International Journal of Hyperthermia, and others.

8. I have given presentations and speeches on numerous topics for audiences of my colleagues and many others. A sample of the related topics includes human perception of magnetic fields, electrosurgery physics, case studies on electrosurgery, electrosurgical active electrodes with ultrasound, radiofrequency electrosurgery, advanced principles of electrosurgery, new radiofrequency bipolar artery fusing systems, and many more. I have given over 80 presentations at national meetings and international meetings on the topic of radiofrequency electrosurgical procedures and instrumentation.

9. I am a named inventor on multiple patents. A sample of the related topics includes local application tumor treatment, device and method for sealing tissues, radiation and thermal energy sources, and others.

10. I have received multiple awards for excellence in my profession. I received the 1993 Biomedical Instrumentation and Technology Research Award for the most outstanding research manuscript of 1992, “Capacitive Coupled Stray Currents During Laparoscopic and Endoscopic Electrosurgical Procedures”; 2010 Honorary Professor, Universidad de San Martin Porres, Lima, Peru; and 2010 Honorary Doctorate, Universidad de San Martin Porres, Lima, Peru.

11. I have extensive teaching experience at the university level, in a clinical setting, and at various seminars. I have been the course director for a national continuing medical education course and have taught close to 100 university courses on such diverse topics as biomedical engineering, physics, biophysics, pathology, clinical laboratory science, biomedical measurements, instrumentation in clinical laboratory science, human pathology, pharmacy, and many others. I have given numerous seminars on various topics such as radiofrequency electrosurgery, laparoscopic electrosurgery, thermal ablation, lab computing, the physics behind radiofrequency electrosurgery, and many others. In addition, I have served as an advisor or overseer of many residents, master's thesis candidates, Ph.D. candidates, and post-doctoral fellows.

12. I have served in various leadership capacities at multiple universities including the University of Iowa, University of Nebraska, and University of Minnesota.

13. I am being compensated at the rate of \$700/hour for my work in this proceeding. My compensation does not depend on the outcome of this proceeding.

14. In view of this experience, I regard myself as an expert in the field of thermal ablation systems and methods.

B. Materials considered

15. In forming my opinions expressed in this declaration, I have reviewed and considered the documents identified in the list of exhibits below, each of which were provided to me by counsel at Meunier Carlin & Curfman LLC. To the extent I am provided with additional documents and information in this proceeding, including any expert declarations, I may offer further opinions. In forming my opinions, I have also relied on my education and experience.

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)

Exhibit No.	Description
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")
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")

Exhibit No.	Description
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”)

C. GLOSSARY

Term	Meaning
“’688 Patent” or “Challenged Patent”	U.S. Patent No. 10,736,688 to Wright et al. (issued August 11, 2020)
“Challenged Claims”	Claims 1-17 and 48-52 of the ’688 Patent
“Board”	USPTO Patent Trial and Appeal Board
“POSA”	Person of ordinary skill in the art at the time of the ’688 Patent’s alleged invention
“RF”	Radiofrequency

Term	Meaning
“Racz’s modified device”	Racz’s cannula (10/33) modified by a POSA to include deployable filaments as disclosed in Fitz and Lee.

D. Legal Principles

16. I have been informed by counsel for Avanos that the following legal principles apply to an assessment of patentability. I have applied these legal principles throughout my analysis in this declaration.

1. Priority date

17. I have been instructed to assume that claims of the ’688 Patent are entitled to claim priority to the earliest filed provisional application noted on the ’688 Patent, which was filed on November 5, 2009 (the “Priority Date”). I understand that the language of a patent and the content of the prior art are analyzed from the perspective of a person of ordinary skill in the art (“POSA”) at the time of the patent’s priority date. Accordingly, I have been asked to opine on issues related to the patentability of the patent’s claims in view of the prior art (including patents and printed publications) publicly available as of May 2009 and in view of the knowledge possessed by POSA around May 2009 (i.e., one year before the priority date).

2. Claim construction

18. I have been instructed that, to assess the patentability or unpatentability of a claim, one must first ascertain the scope of the claimed

invention, which requires understanding the terms in the claim. In particular, I have been informed that the claims of the patent should generally be given their ordinary and customary meaning as they would be understood by one of ordinary skill in the art in view of the '688 Patent's specification and prosecution history.

3. Anticipation

19. I have been told that for a claim to be anticipated, and therefore unpatentable, every limitation of the claimed invention must be found in a single prior art reference, either expressly or required through inherency, as arranged in the claim. The understanding that a POSA would have after reviewing the prior art reference is the standard for determining what the reference discloses.

4. Obviousness

20. I have been informed that a claim may be rendered obvious, and therefore unpatentable, even though the claimed invention is not identically disclosed in a single prior art reference, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.

21. When considering obviousness, I was asked to (i) determine the scope and content of the prior art; (ii) ascertain the differences between the prior art and the claims at issue; (iii) resolve the level of ordinary skill in the pertinent art; and

(iv) consider evidence of objective indicia (or “secondary considerations”) of nonobviousness (if available). I note that I am not presently aware of any evidence of secondary considerations for the ’688 Patent that affects my opinions presented in this declaration.

22. I have been instructed that a reference may be modified or combined with other references or with the person of ordinary skill’s own knowledge if the person would have found the modification or combination obvious. I have also been instructed that the obviousness analysis may take into account the inferences and creative steps that a person of ordinary skill in the art would employ.

23. In determining whether a prior art reference could have been combined with another prior-art reference or other information known to a POSA, I have been instructed that the following principles may be considered: (i) a combination of familiar elements according to known methods is likely to be obvious if it yields predictable results; (ii) the substitution of one known element for another is likely to be obvious if it yields predictable results; (iii) the use of a known technique to improve similar items or methods in the same way is likely to be obvious if it yields predictable results; (iv) the application of a known technique to a prior art reference that is ready for improvement is likely obvious if it yields predictable results; (v) any need or problem known in the field and addressed by the reference can provide a reason for combining the elements in the manner

claimed; (vi) a person of ordinary skill may be able to fit the teachings of multiple references together like a puzzle.

24. I have also been instructed that, while there is no requirement that the prior art contain an express suggestion to combine known elements to achieve the claimed invention, a suggestion to combine known elements to achieve the claimed invention may come from the prior art as a whole or individually, as understood with the knowledge of one skilled in the art. In addition, I have been instructed that the inferences and creative steps a person of ordinary skill in the art would employ are also relevant to the determination of obviousness.

25. I have been instructed that, when a work is available in one field, design alternatives and other market forces can prompt variations of it, either in the same field or in another. I have also been instructed that if a POSA can implement a predictable variation and would see the benefit of doing so, that variation is likely to be obvious. I have been instructed that in many fields, there may be little discussion of obvious combinations, and in these fields market demand may drive design trends. I have been instructed that, when there is a design need or market pressure and there are a finite number of identified, predictable solutions, a POSA has good reason to pursue those known options.

26. I have been instructed that there is no rigid rule that a reference or combination of references must contain a “teaching, suggestion, or motivation” to

combine references. But I also have been instructed that a “teaching, suggestion, or motivation” found in the prior art can be a useful guide in establishing a rationale for combining elements of the prior art.

27. I have been instructed that it is impermissible to rely on the ’688 Patent’s teachings to combine prior art references, as such analysis would involve impermissible hindsight.

28. Furthermore, I have been informed that where there is a reason to modify or combine the prior art to achieve the claimed invention, the claims may be obvious provided there is also a reasonable expectation of success—though not an “absolute predictability” of success. The teachings of the prior art can provide a sufficient basis for a reasonable expectation of success.

II. BACKGROUND

29. To assist the Board in understanding the technology described in the Challenged Patent, I have been asked to provide background information relating to thermal ablation systems and methods and specifically radiofrequency ablation. In my opinion, all the information included in this “Background” section would have been understood and well-known by a POSA in the field of thermal ablation system and methods in the late 2000’s time frame (e.g., on or before May 2009).

A. Radiofrequency Ablation

30. Radiofrequency ablation (“RF ablation”) is a well-known electrosurgical procedure in which an RF needle having one or more electrodes is inserted into targeted patient tissue and activated with RF energy. Ex-1009, 3:60-4:23, 5:41-51. The RF energy transmitted from the needle’s electrode (or multiple electrodes) heats the patient tissue surrounding the needle and generates a lesion on this tissue. Ex-1009, 7:44-50. When heated sufficiently, the tissue is “ablated” or “destroyed.” Ex-1012, ¶0002-0003. As I will explain further herein, RF ablation is a technique useful for a variety of applications, including pain management and cancer treatment. Ex-1009, 1:4-9; Ex-1012, ¶0002.

B. Applications of RF Ablation

31. Surgeons in different fields have long used RF ablation to overcome the limitations of more invasive surgical procedures. For example, RF ablation electrodes were known as a “common instrument for use in neurosurgery” by the 1980’s. Ex-1023, 1:6-7. In RF neurotomy procedures, RF energy is used to interrupt nerves that transmit pain signals to the brain. Ex-1009, 1:4-10, 2:46-48; Ex-1011, ¶0001-0005; Ex-1014, 3:43-44. This is accomplished by placing RF ablation electrode(s) near a nerve, heating the tissue by transmitting RF energy, and thereby ablating the nerve. Ex-1011, ¶0002; Ex-1009, 4:18-23, 44-58. It was well known to a POSA that such procedures could be performed on a patient’s spine,

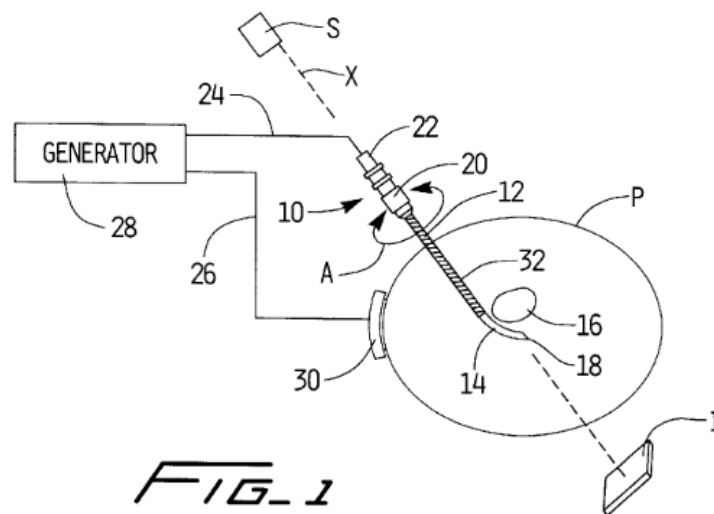
and that “heat ablation of a portion of the patient’s tissue near the tip of a needle is *routinely performed*” in such procedures. Ex-1009, 1:55-63 (emphasis added).

32. RF ablation electrodes were also used “to treat patients with tissue anomalies, such as liver anomalies and many primary cancers,” including “cancers of the stomach, bowel, pancreas, kidney and lung.” Ex-1012, ¶0002; *see also* Ex-1021, 5:1-6 (discussing RF ablation devices that have long been used to destroy targeted tumor tissue, such as cancerous tumors); *see also* Ex-1010, ¶0084 (discussing RF ablation devices targeting uterine fibroids). In fact, RF ablation devices were “proposed for treatment of liver and other solid tumors” in the 1990s. Ex-1021, 1:62-65. By placing an RF ablation electrode in (or in proximity to) targeted tumor tissue, the targeted tumor tissue can be heated using RF energy and destroyed. Ex-1012, ¶0002-0003; Ex-1010, ¶0087, 0092. Surgeons understood that RF ablation of this type can produce larger and more effective lesions than competing procedures like cryosurgery and laser ablation. Ex-1021, 1:24-37, 1:50-60.

33. In sum, well before the alleged invention of the Challenged Patent, RF ablation was a well-understood procedure for destroying targeted tissue (including nerve tissue, tumorous tissue, liver anomalies, and the like) and was applied across a wide range of surgical specialties.

C. Radiofrequency Ablation Systems

34. Radiofrequency ablation systems generally include an RF needle for insertion into a patient and an RF generator for supplying RF energy to the RF needle during an RF ablation procedure. Ex-1010, ¶0024-0025, 0083; Ex-1009, 1:13-54, 3:60-4:23; Ex-1012, ¶0022, 0034-0036, 0041, Fig. 1. For context, Racz provides an example overview of an RF ablation system. As shown below in Figure 1, Racz's system includes an RF needle (10) that is "inserted directly through the skin of [a] body portion P to locate the [needle's] tip 14 in a target position within the body." Ex-1009, 3:42-45. The system also includes an RF generator (28), which outputs RF energy that is transmitted to the RF needle (10). When RF energy is supplied from the generator (28) to the RF needle (10), the needle (10) transmits the RF energy from its exposed tip (14) (an electrode) into the targeted tissue.



35. The radiofrequency generator is often referred to in the art as a “power supply,” “RF generator,” “signal generator,” or simply “generator.” See Ex-1021, 6:30-35 (“RF power supply”); Ex-1009, 4:2 (“signal generator”); Ex-1010, ¶0025 (“RF generator”); Ex-1027, 4-16-22 (“generator”). Generators known in the art can be configured to output various frequencies, voltages, and currents that are suitable for RF ablation procedures. Ex-1010, ¶0025-0026; Ex-1024, 6:17-27; Racz, 1:17-24; Ex-1012, ¶0036.

36. When the surgeon energizes the RF needle’s electrode to deliver energy to the tissue, the RF current heats the tissue surrounding the electrode and causes the tissue cells to die. Ex-1010, ¶0025. In this way, the RF needle is used to achieve destruction (“ablation”) of the tissue near the electrode. Although Racz’s example system in Figure 1 is described in relation to an RF neurotomy procedure, as demonstrated by the evidence I cite in this section, RF ablation systems of this type were widely used for RF neurotomy, RF tumor ablation, and other RF ablation procedures at the time of the Challenged Patent’s alleged invention.

D. RF Needles

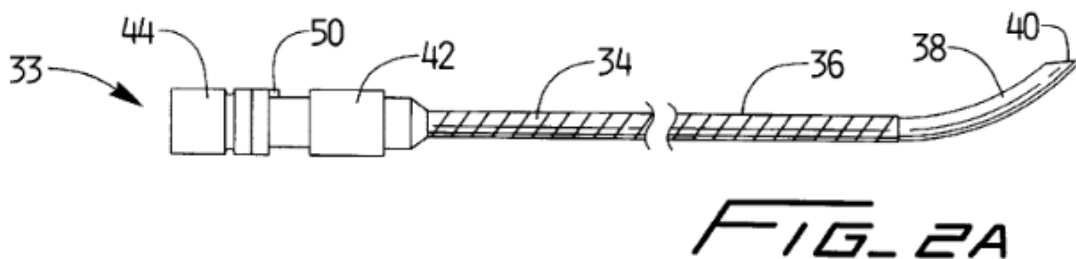
37. As I noted above, RF needles are generally configured to be inserted within a patient such that the needle’s one or more electrodes can be placed at a desired location (e.g., proximate to targeted tissue). In the thermal system and ablation arts, RF needles are referred to by various names, including “cannula” or

“RF cannula” (Ex-1009, 3:39-45), “electrode” (Ex-1009, 3:39-45; Ex-1014, 5:28-6:44), “probe” or “probe assembly” (Ex-1012, ¶0022-0023, 0032), and “trocar” (Ex-1010, ¶0091-0093). As described in this section, many different configurations of RF needles were known in the art.

1. The Needle Shaft and Tip

38. RF needles generally include an elongate shaft and distal tip.

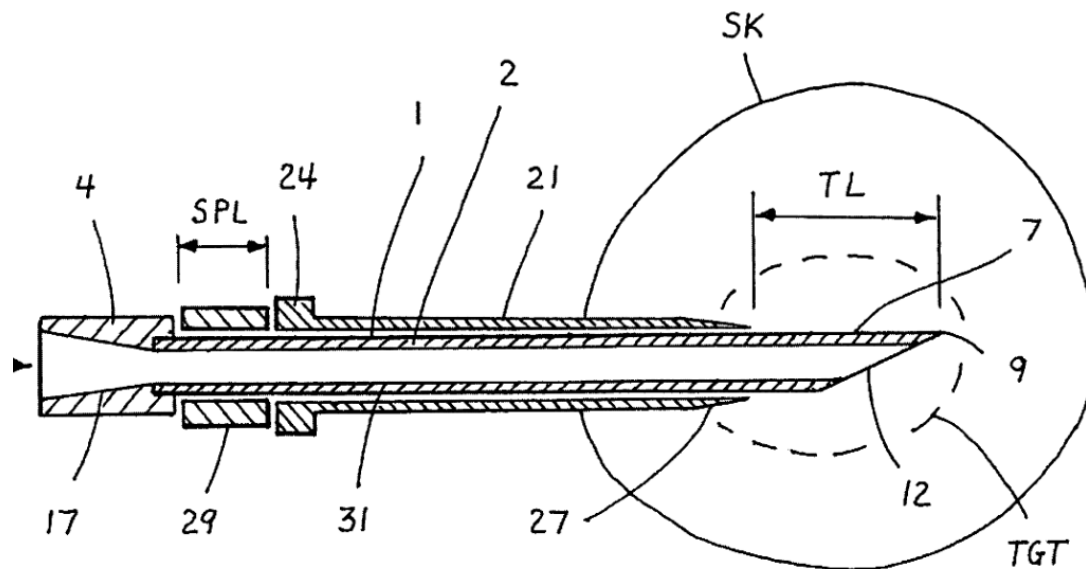
Referring again to Racz as an example, Figure 2A shows that an RF needle (33) having an elongate shaft (34) defining a distal tip (38). Ex-1009, 4:59-5:5.



Racz – Fig. 2A

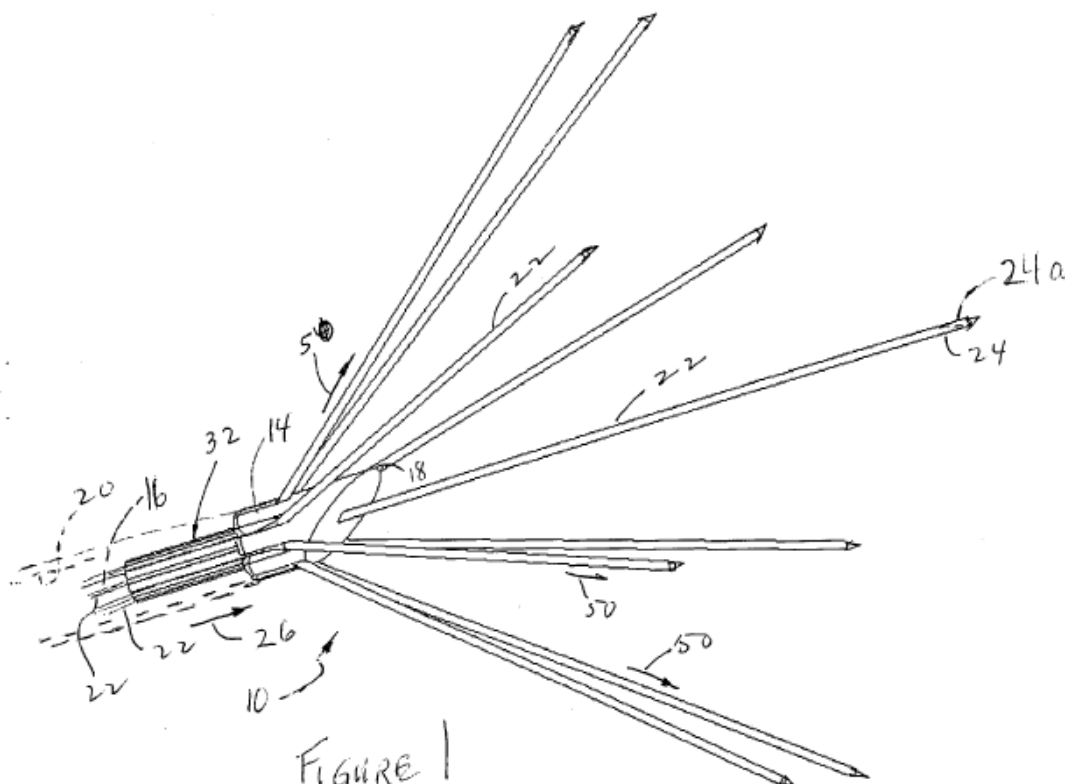
39. The configurations of the shaft and tip can be varied in many respects to provide desirable ablation characteristics. For example, in some RF needles the shaft and the tip and made of a single unitary structure. Ex-1009, 2:48-53, 1:33-36 and 46-49; Ex-1016, ¶0028. In Racz’s Fig. 2A, for example, the shaft (34) “comprises a hollow metal tube” that also defines the tip (38). Ex-1009, 4:59-5:5. In other words, the “tip portion 38 is an extension of the metal tube.” *Id.* Cosman

'542 shows another example of an RF needles having a shaft and tip formed as a single unitary structure. Ex-1014, 3:28-42, 5:28-6:7.



Cosman '542 – Fig. 1

40. In other RF needles, the tip can be a separate member attached to the end of the shaft (e.g., a tip mandrel secured to the end of an elongate shaft). Ex-1012, ¶32; Ex-1010, ¶91. For example, Lee's Fig. 1 shows a "trocar point 14 ... mounted on a cannula 16." Ex-1010, ¶91. I note that Lee's RF needle is also shown with deployable filaments (22), which I will discuss in greater detail below.



Lee – Fig. 1

41. The shape of the RF needle's shaft and tip can also be varied. In many RF needles, the shaft and tip are comprised of a substantially straight elongate member (i.e., a shaft of substantially free of curves or a bent shape). Ex-1010, ¶ 12; Ex-1022, 6:23-25; Ex-1024, Fig. 2. However, other RF needles may be provided with bent or curved shapes. For example, as disclosed in Racz, it was known that a “curved tip needle electrode” can be “steered around” anatomical structures and deliver RF energy to nerves “running near the surface” of such “bony structures” of a patient. Ex-1009, 4:49-55, Fig. 2A. Thus, to treat different anatomies within

the patient, it was known to impart various shapes to the overall profile of the shaft and/or tip of the RF needle.

42. The RF needle's shaft and tip can also be made of various materials. In many RF needles, both the shaft and tip are constructed from electrically conductive materials. For example, the shaft and tip can both be formed from metal (e.g., where both the shaft and tip are a single unitary structure formed from a metal tube or where a metal tip is attached to the distal end of a metal shaft). Ex-1009, 2:47-51; Ex-1014, 2:47-54; Ex-1010, ¶118; Ex-1012, ¶0031-0032. When the RF needle's shaft and/or tip are made of an electrically conductive material, the shaft and/or tip can be used to conduct RF energy (e.g., received from the RF generator). Ex-1009, 5:41-51.

43. To ensure the entire length of the RF needle is not conductive, a substantial portion of the RF needle's shaft is often insulated. For example, a substantial length of the shaft can be "insulated over its outer surface except for the surface of the electrode's distal tip." Ex-1023, 1:12-13. In RF needles where the shaft and tip are both defined by a metal tube, the uninsulated portion of the metal tube defines an "exposed electrical tip" (i.e., an electrode for transmitting RF energy to tissue). Ex-1009, 4:21-22. For example, Racz shows that its shaft (34) includes an insulated portion (36) and exposed tip (34). Ex-1009, Fig. 1.

44. Different ways of insulating the RF needle's shaft were well known in the art. In some RF needles, insulation is coated directly onto a portion of the needle's shaft. Ex-1016, ¶0028; Ex-1014, 1:56-58; Ex-1023, 1:6-11; Ex-1015, ¶42. For example, a "thin coating or microscopic layer" of insulation can coat the RF needle's shaft, leaving an "exposed surface at the tip." Ex-1023, 7:29-33. In other RF needles, a separate insulating member can be provided around the shaft. Ex-1014, 2:52-54; Ex-1024, 12:67-13:2 ("The proximal conductor 62 extends distally through an insulated outer sheath 80"). For example, some RF needles include a separate "insulating sleeve" that is placed around the shaft (e.g., a separate sleeve or tube constructed from plastic, Teflon, or another insulating material). Ex-1014, 2:52-54, 5:44-50, 7:45-56, 8:30-50, 8:65-9:14, 9:43-65. In other instances, the RF needle's shaft itself can be constructed from an insulating material (e.g., plastic) with a tip secured to a distal end of the plastic shaft. Ex-1010, ¶91 ("Cannula 16 may be made of ... plastic"); Ex-1012, ¶0032 ("cannula 12 is made from a non-conductive material"), ¶23 ("cannula 12 is composed of a suitable material, such as plastic, metal, or the like).

45. A POSA also would have known that the "extent of insulation vs. exposed electrode" can be variable to control the size or exposed area of the RF needle's electrode (e.g., the tip). Ex-1009, 8:16-20. Various RF needles have been configured such that an insulating member fixed to the needle's shaft and tip can

be selected, replaced, and/or positionally adjusted. Ex-1014, 2:52-54, 5:44-50, 7:45-56, 8:30-50, 8:65-9:14, 9:43-65. In other words, “[t]he position of the insulating sleeve can determine the degree of unexposed electrode tip, or the size or length of the uninsulated electrode tip.” Ex-1014, 2:65-67.

46. It was also well known that various size shafts (or cannulas) could be used in the RF needle. For example, Racz notes that its needle’s shaft and exposed electrode tip “can be made from extremely small gauges (e.g., 30 gauge) to much larger sizes (e.g., 10 gauge).” Ex-1009, 8:13-15. This wide range of RF needle sizes was well-known in the art. Ex-1014, 7:23-26 (“in one example, for spinal high frequency treatment of pain, the tubing can range in gauge size from 23 gauge for the smaller range to 22, 20, 19, 18, 17, or 16 gauge for larger target sites”); Ex-1022, 7:32 (cannulas used can range “from 12 G[auges] to a smaller 26 G[auges]”).

47. The RF needle’s tip can also be provided in a variety of configurations. In some RF needles, the tip includes a pointed end so that the needle is “self-penetrating” and capable of piercing a patient’s skin. Ex-1009, 1:20-30, 8:45-57; Ex-1014, 5:31-33 (“Pointed distal tip can include a bevel 12 which has a pointed tip 9 for piercing and penetrating skin and tissue of a patient’s body”); Ex-1010, ¶92 (“Improved piercing may be obtained by sharpening the tip 24 to form a point 24a”); Ex-1012 ¶31 (“The operative electrode 92 also has a sharp distal tip 94 for piercing tissue.”). In other configurations, “rounded” or

“blunt” tips can be used (e.g., in soft tissue or where the surgeon desires the tip to be deflected away from certain structures rather than pierce them). Ex-1009, 1:28-30, 8:23-44; Ex-1015, ¶0040 (“The shape of distal end 106 may vary depending on the application. Possible shapes include, but are not limited to, blunt, rounded, sharp, and beveled.”); Ex-1023, 7:13-15 (“FIG. 3D illustrates a design similar to FIG. 3A ...but in this case the electrode tip has a blunt, rounded end.”).

48. In many RF needles, the tip also includes an opening that allows the tip to inject or otherwise deliver fluid inside the patient. Ex-1016, 9:6-9, Fig. 2. For example, radiofrequency ablation procedures can include injecting “anesthetic, contrast fluids, or other diagnostic or therapeutic agents” into the patient during a procedure. Ex-1009, 6:2-11. To enable delivery of these liquids, the RF needle’s shaft is typically hollow and in fluid communication with a connector for a fluid source. Ex-1009, 5:66-6:2; Ex-1014, 6:31-43. In addition, the tip may include an opening in fluid communication with the shaft (e.g., a lumen that extends through the shaft and the tip). Ex-1009, 8:54-57 (“In the pointed-tipped needle shown in FIG. 2, the aperture or opening 46 for injecting fluids lies at the very distal end of the tip 38”).

49. The RF needle’s connector—commonly referred to as “fitting” or “hub”—allows a fluid source to be connected to the RF needle for delivery of fluid through the tip. Ex-1009, 3:60-65, 5:66-6:4. The hub/fitting is typically located at a

proximal end of the RF needle (e.g., the end opposite the needle's tip). Ex-1009, 5:9-10. The hub/fitting can be "capable of connection to stylets, electrical probes, syringes, or injection tools" used in the RF ablation procedure. In the medical field, a common example of a "hub" or "fitting" for fluid delivery is a luer fitting. Ex-1009, 5:66-6:2; Ex-1014, 5:31. Luer fittings are very common in the medical field and allow a fluid source with a mating luer fitting to be fluidically connected (e.g., to a central lumen). *See* Ex-1013, ¶0031. Another example of a hub is the "standard hypodermic needle" type hub as described by Racz. Ex-1009, 5:67.

50. Additionally, because the RF ablation is often intended to occur at or near the RF needle's tip, the tip often includes one or more temperature sensors configured to monitor the temperature of tissue being heated by RF energy. Indeed, "temperature control or monitoring of the electrode's tip" has been used as a method for "grading the degree of [tissue] destruction and quantifying the lesion size." Ex-1023, 1:35-42; *see also* Ex-1022, 2:14-17 (temperature sensors allow for an "indication of the temperature of the tissue being subjected to ablation" and can be used to "regulate the application of power to the electrode assembly").

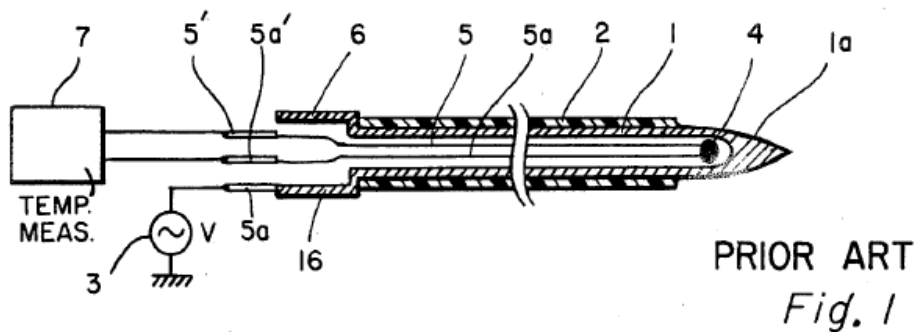
Temperature sensors were known to be positioned internally within the RF needle's tip (Ex-1023, 1:35-66, Fig. 1) and externally at the RF needle's tip (Ex-1023, 5:26-61). It was also known that a temperature sensor could be incorporated into the tip

of a removable RF probe (e.g., where the “probe tip” is positioned proximate to the RF needle’s tip when the RF probe is inserted). Ex-1009, 5:28-30.

2. RF Energy Transmission and Removable RF Probes

51. As I noted above, RF ablation systems include an RF generator to supply RF energy to the RF needle. It was well known to a POSA that RF energy could be conducted from the RF generator to the RF needle’s electrode(s) in a variety of ways.

52. As one example, RF needles have often used a direct electrical connection between the generator and the shaft/tip to transmit RF energy. An example of this is shown in Cosman ’266, which illustrates an RF needle having an RF generator (3) that is electrically connected to the RF needle’s conductive shaft (1) (and thereby its tip 1a) via a contact pin (5a) on the shaft’s hub (6/16) (e.g., with lead wires between the generator (3) and the contact pin (5a)). Ex-1023, 1:6-57, Fig. 1. Wire-based methods of this type for electrically connecting the RF generator to the RF needle’s electrode(s) are well-known. Ex-1026, 6:32-35 (“An energy source 20 is connected with [a] multiple antenna device 12 with one or more cables 22.”); Ex-1021, 7:26-28 (“electrically conductive wires ... are bundled at a proximal end and connected to terminal 16 to conduct RF current therefrom”); Ex-1025, 3:24 (“A cable connects the primary antenna to the energy source.”).

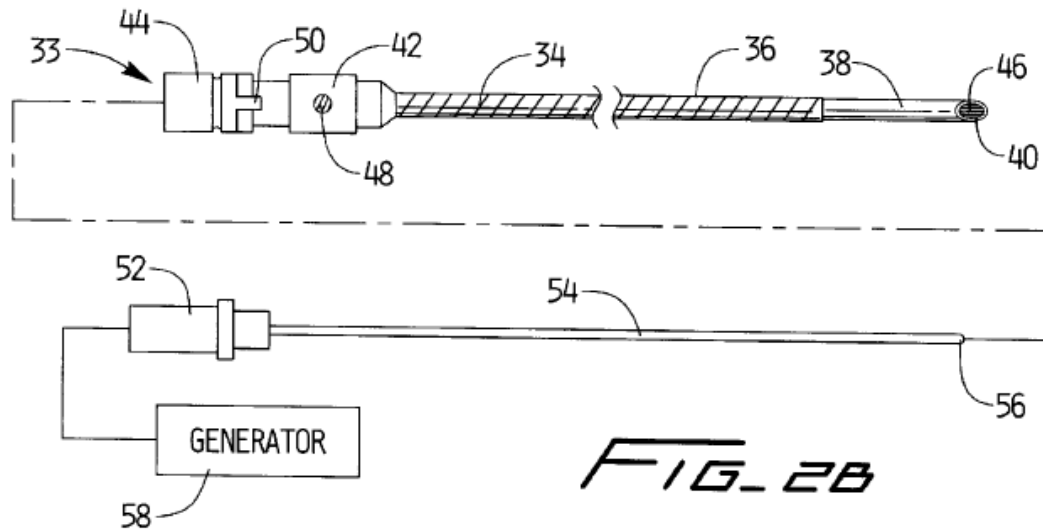


Cosman '266 – Fig. 1

53. In other configurations, intermediate elements are used to conduct RF energy through the RF needle. For example, Young '965 discloses an RF needle in which an internal, movable, and conductive shaft (disposed within the RF needle's cannula) provides an electrical connection between an RF generator and the RF needle's electrodes (deployable filaments and an active tip). Ex-1012, ¶0022-0023, 0033-0034, 0036, Figs. 1-3, 5-6. Likewise, in Young '201, the RF needle includes a slidable electrode member (a tube) having deployable tines at its distal end. Ex-1016, ¶0026-0027, 0030, 0033-0035, Fig. 2. The RF generator is connected to the RF needle's hub, which is in turn electrically connected to the slidable electrode member and its distal tines. Ex-1016, ¶0026-0027, 0030, 0033-0035, Fig. 2.

54. Removable RF probes were also commonly used to transmit RF energy from the RF generator to the RF needles. For example, Racz discloses that RF energy is conveyed to its cannula's exposed tip (38) via a removable RF probe (52), which is connected to a signal generator (58). Ex-1009, 5:26-30, 5:41-45, Fig. 2B. When the removable RF probe (52) is fully inserted into the cannula (33),

“physical contact” between the probe (52) and the cannula’s tip (38) conducts the RF energy to the tip (38). Ex-1009, 3:60-65, 4:18-23, 5:41-48, Fig. 2B. In this way, the removable probe (52) can be reused (e.g., with other RF needles similarly configured).



Racz – Fig. 2B

55. As another example of a removable RF probe, Cosman ’542 discloses a removable RF probe (38) (referred to as a “conductive shaft”) that is configured to be inserted into the RF needle’s shaft (2) to conduct RF signals to the exposed tip (7). Ex-1014, 6:14-17, 6:27-31, 4:11-22, Fig. 1. Cosman ’542’s probe is shown in the figure below.

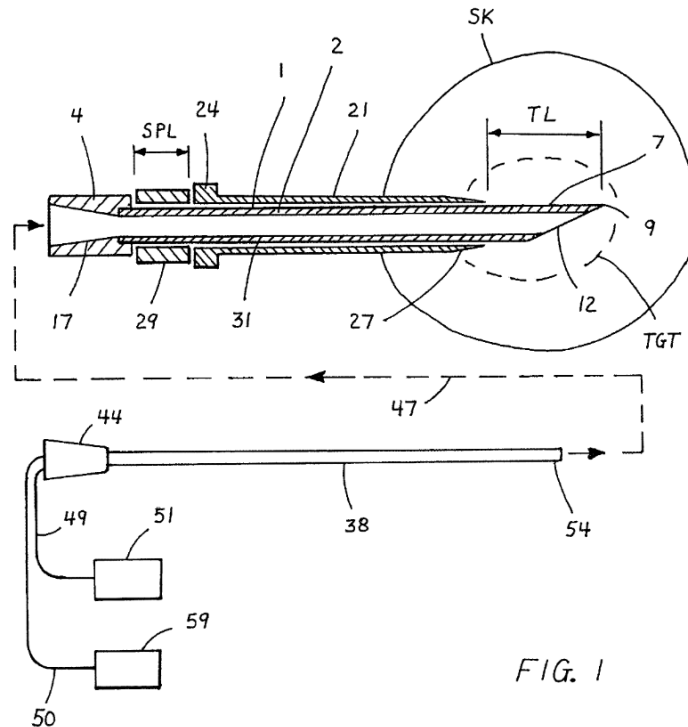


FIG. 1

Cosman '542 – Fig. 1

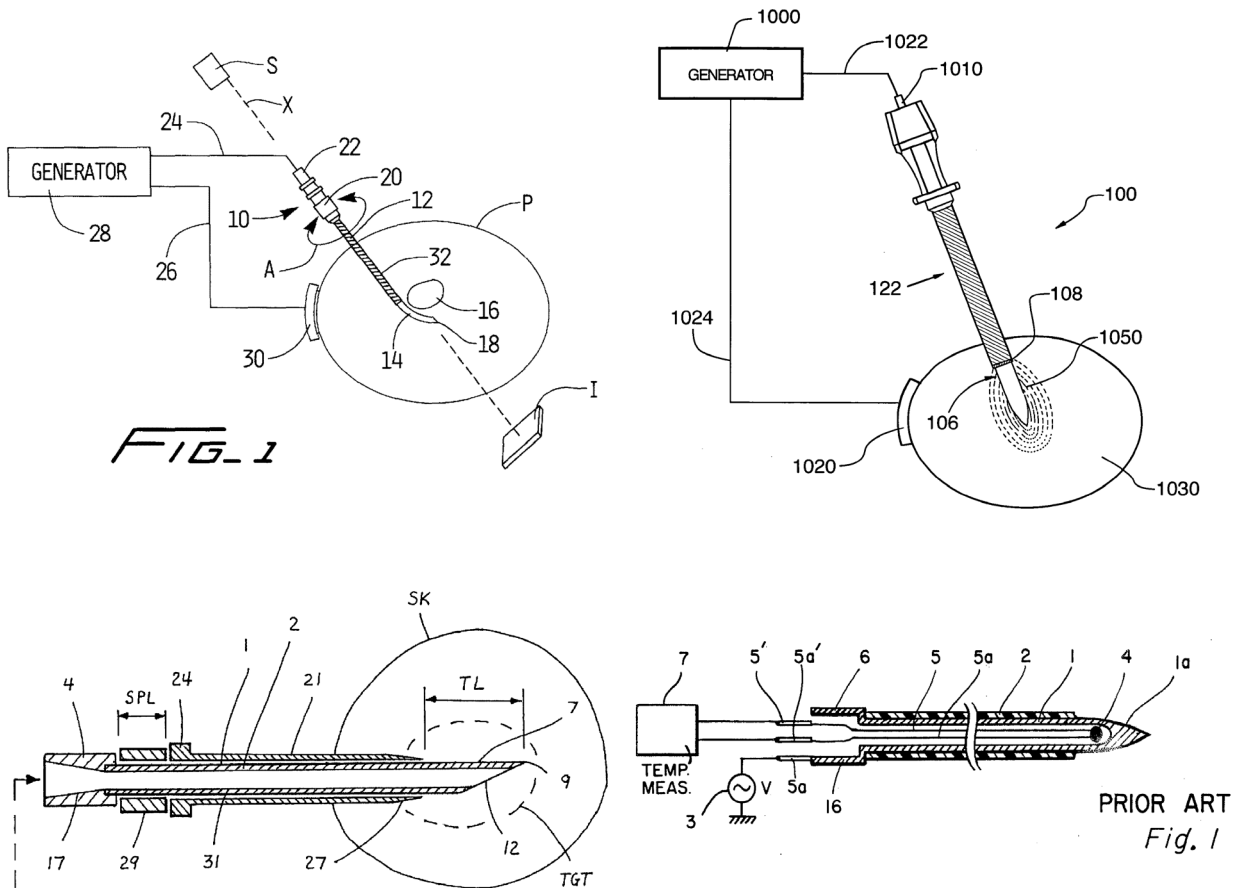
56. In sum, the removable RF probe technique was widely adopted and would have been well-known by a POSA. *See also* Ex-1029, ¶0050-0054, Fig. 10 (discussing “physical contact” between the removable probe and RF needle’s cannula). Moreover, it was known that removable RF probes were adaptable for both monopolar and bipolar configurations. Ex-1022, 5:20-25 (discussing a removable RF probe (referred to as a “supply electrode” and noting that the probe can be configured for use with both bipolar and monopolar cannulas).

3. Single-Tip Electrodes

57. As I noted above, RF needles include one or more electrodes for transmitting RF energy from the RF needle to targeted patient tissue. Many RF needles are configured as “single-tip” RF needles, which include a single electrode

tip at their distal end. Often, the single electrode tip is a distal “uninsulated” or “exposed” portion of the needle’s conductive shaft. Ex-1009, 4:21-22; 7:44-46.

Single-tip RF needles of this type have been used for decades and I have included just some examples below for reference. Ex-1009, Fig. 1, 4:18-23; Ex-1029, ¶51, Fig. 10, Ex-1014, Fig. 1, 6:8-27; Ex-1023, Fig. 1, 1:7-24.



***Clockwise (from top left): Racz (Fig. 1); Chandran (Fig. 10);
Cosman '266 (Fig. 1); Cosman '542 (Fig. 1)***

58. Using single-tip RF needles, surgeons control the location of lesions generated on targeted tissue based by positioning the exposed needle tip. Ex-1009, 7:46-50. Positioning and maneuverability of the electrode tip can be aided by the

shape of the exposed tip. For example, in RF neurotomy procedures, bent electrode tips can allow for “a curved approach to the spinal structures and the intravertebral disc” and facilitate placement “in such a way as to hug or conform the outer aspect of the superior articular facet.” Ex-1009, 7:3-6. Generally, “[a] wide variety of electrode geometries” can be used for the shape of the tip itself. Ex-1009, 1:25-42.

59. Other modifications to single-tip RF needles have also been investigated. In some single-tip RF needles, the electrode tip may be cooled to control the temperature of the tip (and the targeted tissue being heated). Ex-1015, ¶0045-0054. For example, cooled single-tip RF needles “may be cooled by the internal circulation of a cooling fluid.” Ex-1015, ¶0045, Fig. 3A.

4. Limitations of Single-Tip Electrodes

60. Although single-tip RF needles remain suitable for various applications, a well-known limitation of single-tip RF needles is that they produce ablation volumes of limited size in targeted tissue. Ex-1025, 1:65-2:10. Fundamentally, this limitation is due to the fact that—when RF energy is transmitted from the needle’s electrode tip—“current spreads out radially from the electrode tip, so that current density is greatest next to the tip, and decreases progressively at distances from it.” Ex-1025, 1:55-2:24. As a result, heating of the targeted tissue is “greatest next to the electrode and decreases with distance from it.” Ex-1025, 2:11-24. As the lesion is produced by the heating of the tissue, the

lesion's size is limited by the decrease in tissue temperature away from the electrode tip. Ex-1025, 1:65-2:10.

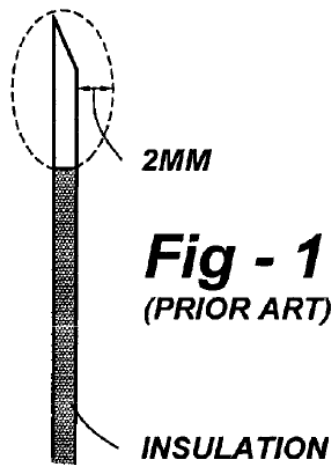
61. Although a POSA would have known and understood the physics of lesioning targeted tissue, I note that the limitations of single-tip RF needles were well documented. In the mid-1990's, Gough '827 discussed the limitations of single-tip RF needles extensively in the context of RF ablation for tissue masses generally, "including but not limited to tumors." Ex-1025, 7:17-23; 1:55-2:24. LeVeen, filed in 1996, also described the limitations of a "single needle" for tumor ablation. LeVeen explained that that "high currents and temperatures have been employed" using single needles, "but produce charred and carbonized tissue, without enlarging the tissue volume being treated." Ex-1021, 1:67-2:3. In the context of RF neurotomy procedures, Fitz also highlighted the limitations of single-tip needles:

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 differs from patient to patient, and the target medial branch may not be in the same place

with respect to different individuals. In the cervical and thoracic spine in particular, the ideal target is known to lie in variable locations.

Although multiple lesions may be created in order to enhance coverage, this is more time-consuming and usually more painful to the patient. The creation of multiple lesions also exposes the patient to more radiation, as fluoroscopy is used to place and replace the needles. In the cervical spine, six separate needle locations are at times used to obtain adequate coverage of one medial branch nerve. Since at least two medial branches are treated, this can extend the length of the procedure to three or four hours.

Ex-1011, ¶0004-0005 (emphasis added). Fitz's Figure 1 illustrates this limitation graphically.



Fitz – Fig. 1

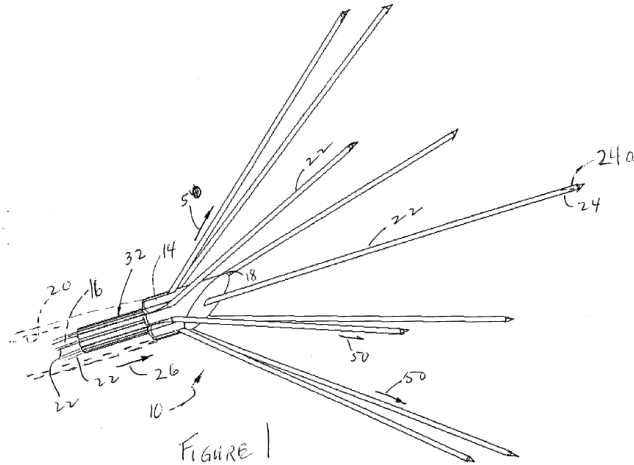
62. For the reasons I have noted above, a POSA also would have understood that the size of lesions produced by single-tip RF needles would be limited by the physics of RF ablation. However, a POSA also would have been

well aware that deployable electrodes are often used in RF needles to provide an expanded and controllable ablation volume.

5. Deployable Electrodes

63. A well-known method for overcoming the limitations of a single-tip RF needles was the use of RF needles having deployable electrodes. Often referred to as “electrodes,” “wires,” “tines,” “arrays,” “antennas,” and/or “stylets,” deployable electrodes are generally configured to be adjusted between a retracted configuration (in which the electrodes are positioned within the RF needle’s shaft of cannula) and a deployed configuration (in which the electrodes extend outwardly from the RF needle). Ex-1012, ¶24; Ex-1016, ¶0003, 0030; Ex-1027, 8:35-36; Ex-1024, 2:61-64; Ex-1025, 7:49; Ex-1010, ¶24; Ex-1021, 5:22-6:14, 6:36-53. When deployed, the electrodes expand the tissue volume the RF needle can ablate compared to non-expandable, single-tip electrodes (e.g., expanding the total ablation volume or expanding the area the electrodes are able to reach when the RF needle is in a given position).

64. As one example, Lee’s Figure 1 shows the tip of an RF needle with deployable electrodes (22) in a deployed position extending outwardly from the needle’s tip (14). Ex-1010, ¶0091-0093, Fig. 1.



Lee – Fig. 1

65. The use of deployable electrodes was well-known and well-documented. In the interest of providing a helpful overview for the Board, I have summarized certain deployable electrode configurations and design considerations below. As I explain below, a POSA would have been well versed in using deployable electrodes to both expand and control the size, shape, and location of lesions generated by an RF needle on targeted tissue.

a. Deployable Electrode Materials

66. Deployable electrodes are formed from a conductive material to transmit RF energy to targeted tissue. Typically, the deployable electrodes are “springy wire-like member[s]” formed from an elastic material. Ex-1010, ¶0092; Ex-1012, ¶0029-0030; Ex-1021, 5:22-6:14, 6:36-53, 7:26-51. The thin, wire-like configuration of the deployable electrodes allows them to be housed within an RF

needle's shaft or cannula when in the retracted position. Ex-1010, ¶0092; Ex-1012, ¶0023, 0029-0030; Ex-1021, 5:22-6:14, 6:36-53, 7:26-51.

67. Commonly, the materials used for deployable electrodes are selected to achieve a desired electrode shape or other characteristic (e.g., strength, resiliency, etc.). Ex-1012, ¶0029 (“The electrodes 26 can be made from a variety of electrically conductive elastic materials. Very desirable materials of construction, from a mechanical point of view, are materials which maintain their shape despite being subjected to high stress.”); Ex-1010, ¶0087, 0139. For example, shape memory materials, “such as stainless steel, nickel-titanium alloys, spring steel alloys, and the like” were commonly used to allow the electrodes to assume a predefined shape when exiting the needle. Ex-1021, 5:58-59, 7:26-51; Ex-1012, ¶0029; Ex-1011, ¶0010, 0018, 0019. In particular, nickel-titanium (NiTi) alloys (also known as Nitinol¹) have been widely adopted for use in forming deployable electrodes in RF needles. Ex-1010, ¶0087 (“The electrodes can be made of a shape

¹ I note that Nitinol is a well-known shape memory alloy (also referred to as a “superelastic shape set material”) commonly used in medical devices. Ex-1030, ¶0048. “NITINOL” is the brand name for “Nickel Titanium Naval Ordinance Laboratory, a commercially available family of nickel titanium alloys.” Ex-1030, ¶0048.

memory material such as NiTi.”); Ex-1025, 5:28-32 (“In some applications, all or a portion of secondary electrode 16 can be made of a shaped memory metal, such as NiTi); Ex-1012, ¶0029; Ex-1016, ¶0032; Ex-1027, 5:30-35.

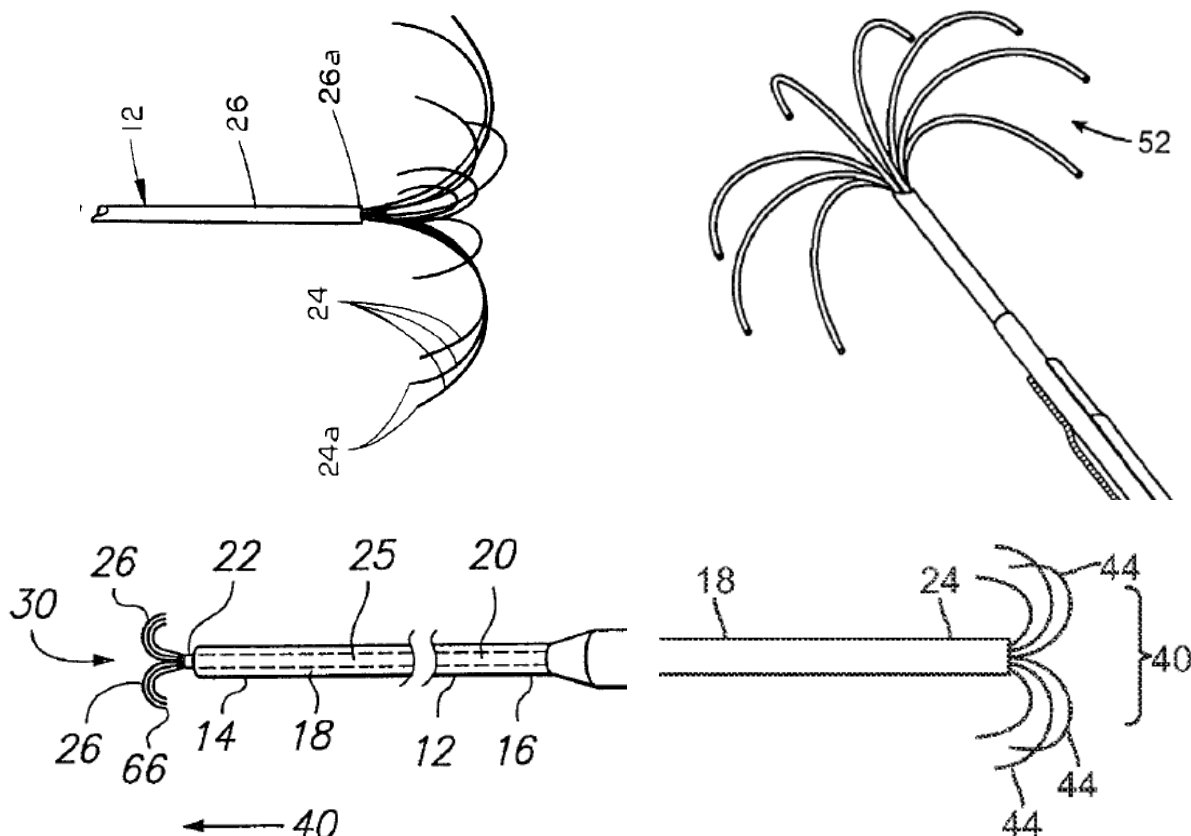
68. By using shape memory alloys, it was well-known that deployable electrodes could be configured to emerge from the RF needle in “generally straight lines” or “shaped to curve radially outwardly.” Ex-1024, 9:42-44; Ex-1021, 5:45-52. Indeed, straight or curved deployable electrodes can be selected depending on the application or surgical requirements. Ex-1012, ¶0027 (“each electrode 26 has a flared curvilinear profile that resembles a portion of a parabola”); Ex-1010, ¶0017 (“Each of the stylets may be configured to assume a substantially straight configuration”), ¶0087 (“straight electrodes have greater column strength and will have superior mechanical advantage over curved electrodes”). It was also known that the electrodes could “evert proximally so that they face partially or fully in the proximal direction when fully deployed.” Ex-1024, 9:44-46. Thus, it was known that using “conductive metals having a suitable shape memory,” the electrodes could be configured to “diverge in a desired pattern” when deployed into tissue. Ex-1021, 5:55-59; Ex-1010, 0103-0106.

b. Deployable Electrode Configurations

69. The use of shape memory materials to construct deployable electrodes—in combination with a variety of deployment configurations—has

enabled deployable electrodes to be provided in nearly any desired configuration. Indeed, the number, shape, pattern, arrangement, position, angle, length, and actuation of deployable electrodes can all be varied. Ex-1010, ¶¶0012, 0084, 0103-0106, 0123-0131, 0084; Ex-1012, ¶¶0026-0028; Ex-1018, 6:52-59, 7:12-17; Ex-1021, 5:22-6:14, 6:36-53. By varying these known parameters using routine engineering principles, a POSA can configure an RF needle with nearly any desired configuration of deployable electrodes.

70. RF needles have been configured to deploy electrodes from a variety of positions, including from the needle's tip, shaft, or both. For example, many RF needles are configured with electrodes configured to be deployed from a lumen defined in the RF needle's tip. Often, the electrodes are deployed in an "array" and configured to assume a "fountain" shape when deployed. Ex-1024, 9:15-22; 10:10-44; 12:31-48; 13:3-5, Fig. 3; Ex-1021 1:8-11; 7:26-37, 8:28-33, 9:4-5; Fig. 1; Ex-1016, ¶¶0030-0032, ¶¶0033, Fig. 1; Ex-1027, 1:18-22; 3:48-53; 5:3-7; Fig. 3. I have provided some examples of these deployable electrodes below.



***Clockwise (from top left): LeVeen (Fig. 1); Behl (Fig. 3);
Zerfas (Fig. 3); Young '201 (Fig. 1)***

71. In other instances, RF needles have been configured such that the deployable electrodes extend outwardly around the needle's tip. In other words, rather than extending outwardly from a central lumen in the needle's tip, the deployable electrodes extend from ports, openings, or surfaces in the needle's tip (or shaft) such that they surround or otherwise extend outwardly from the distal-most portion of the needle's tip. Ex-1010, ¶0092-0093, 0102-0103, 0142-0146, Figs. 1 and 48; Ex-1012, ¶0025-0028, 0037, Fig. 6; Ex-1011, ¶0021, Fig. 5; Ex-1025, 8:40-50, Fig. 7. Indeed, in some instances the deployable electrodes are

deflected outwardly by elements of the RF needle's tip (Ex-1010, ¶0016-0018, 0096, 0099, 0145, Claims 1, 8-10) while in others the deployable electrodes are directed through side openings in the shaft or cannula (Ex-1012, claims 2/14 (“plurality of openings on the [cannula] body ... sized for allowing the respective electrodes”); ¶ 0032 (“openings 80”); Fig. 2 (illustrating “openings 80”); Ex-1025, 5:46-54 (“apertures”); 6:54-57; 7:28-30; Ex-1011, ¶0020-0021, Fig. 4, 5). I have provided just some examples of these configurations below.

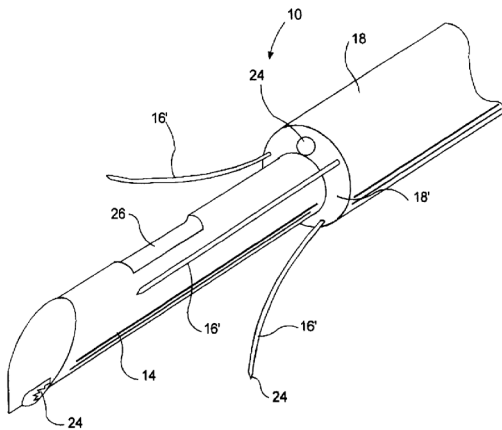
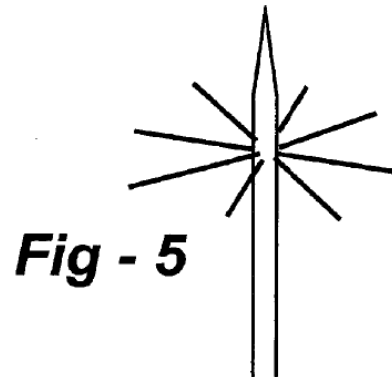
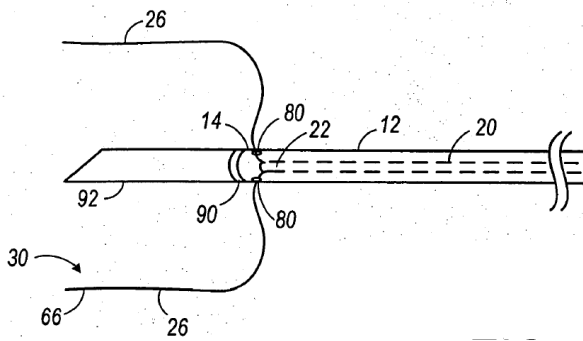
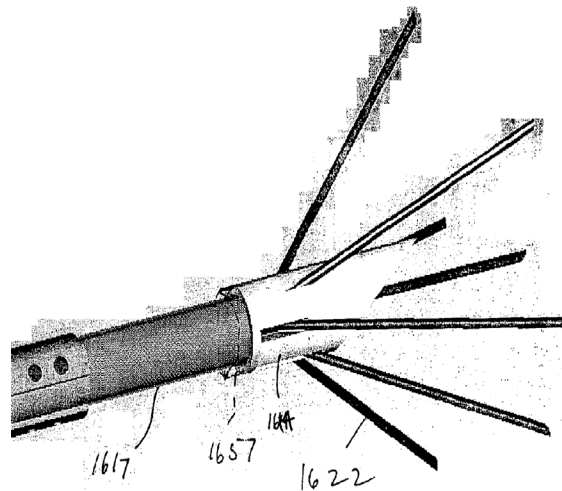
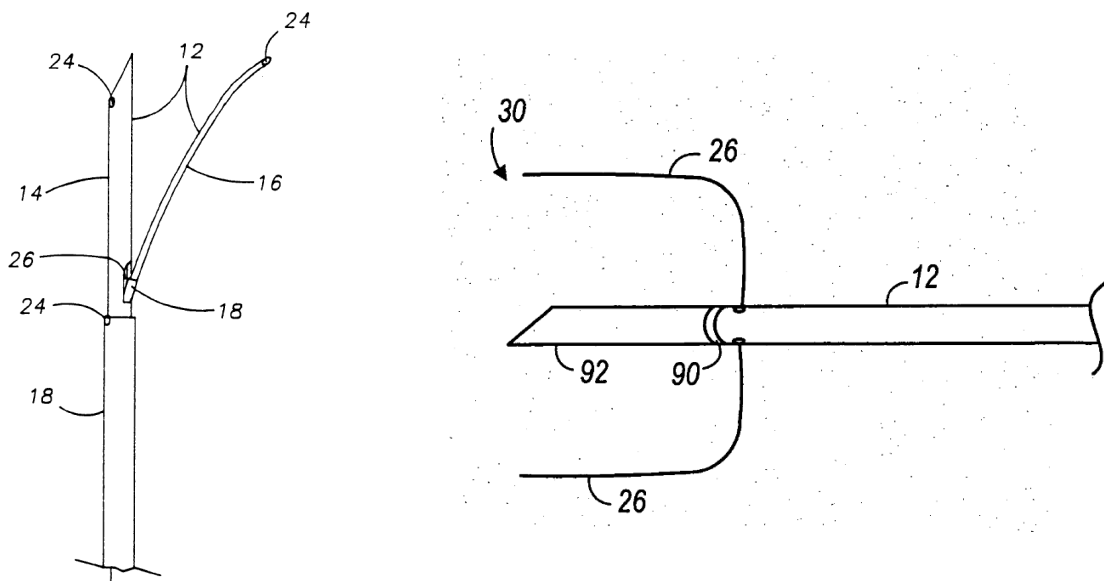


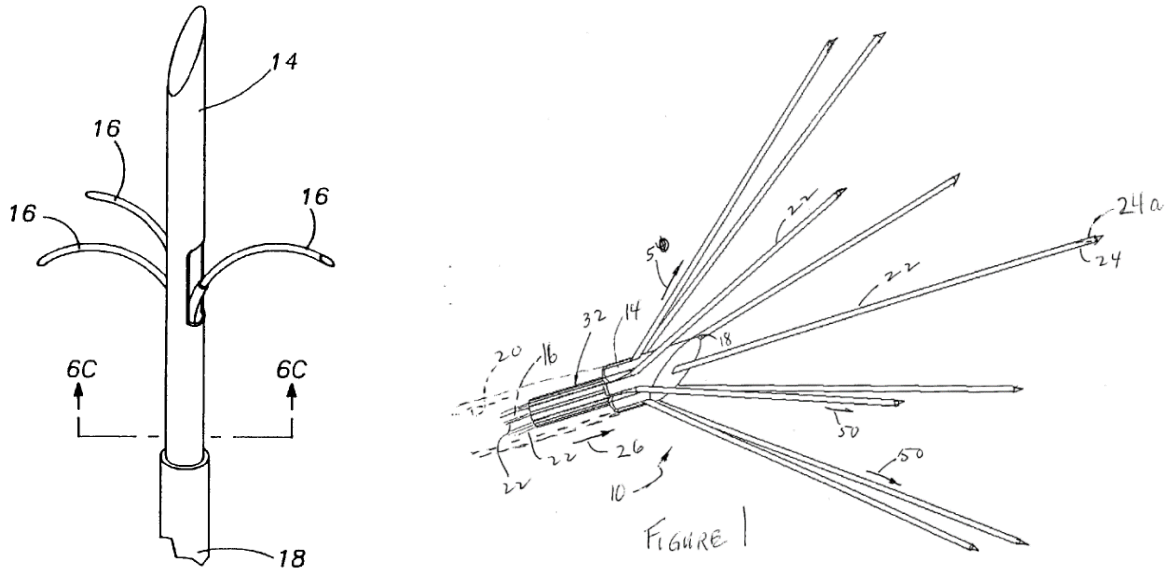
FIG. 7



***Clockwise (from top left): Young '965 (Fig. 6); Fitz (Fig. 5);
Gough '827 (Fig. 7); Lee (Fig. 48)***

72. In sum, it was well known in the art that deployable electrodes could be deployed from various locations at the RF needle's tip, shaft, or combinations of both. Additionally, the number of deployable electrodes was commonly varied. For example, in very simple configurations, a single deployable electrode may be used. *See e.g.*, Ex-1026, 4:55-57. However, to provide different ablation areas, it was also routine for RF needles to include multiple deployable electrodes. Ex-1018 3:20-21; Young965, ¶0028 (“in other embodiments, the probe can have more or fewer than two electrodes 26”). Ultimately, it was known that configuring an RF needle to have any number of deployable electrodes was within the skill of a POSA. Ex-1016, ¶31; Ex-1010, ¶0103-0106; Ex-1021, 3:38-54. As just some examples, I have shown below RF needles having one, two, three, and nine deployable electrode configurations. Ex-1026, 4:55-57; Ex-1012, ¶0028; Ex-1026, 5:4-6; Ex-1010, ¶0092.





***Clockwise (from top left): Gough '229 (Fig. 1), Young '965 (Fig. 4);
Gough '229 (Fig. 6B); Lee (Fig. 1)***

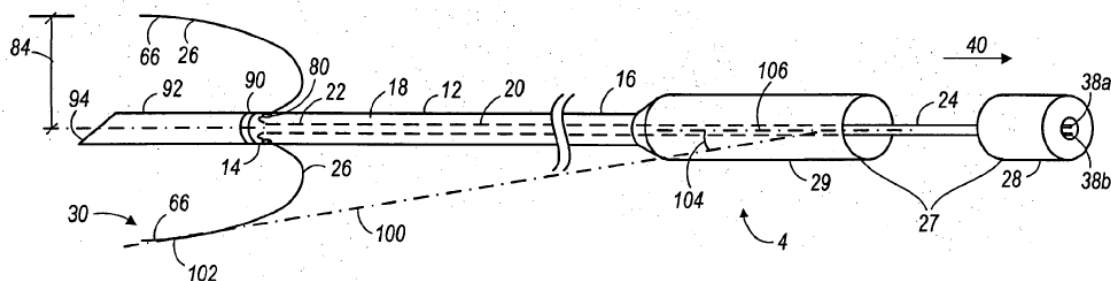
73. It was also well-known that deployable electrodes could be configured in a symmetrical or asymmetrical arrangement (e.g., relative to one or more axes of the RF needle). For example, Young '201 explains that deployable electrodes can be arranged in “a substantially uniform and/or symmetric pattern” and that, alternatively, “the deployed array 40 may even have a non-symmetrical orientation.” Ex-1016, ¶0031; *see also* Ex-1012, ¶0028. In Gough '229, an RF needle having a “single laterally deployed” electrode is shown and described (i.e., a single asymmetrical electrode arrangement). Ex-1026, 4:54-57. Gough '516 likewise illustrates two “laterally deployed” electrodes extending outwardly from the same side of RF needle’s shaft/cannula (i.e., asymmetric). Ex-1017, 7:56-65, Fig. 5.

74. The length of the deployable electrodes was yet another design parameter routinely varied amongst RF needles. Ex-1025, 4:56-57 (“Lengths of primary and secondary antennas 14 and 16 can be adjustable”); Ex-1018, 6:52-59. For instance, Lee explains that it was known to “vary[] the extent to which [electrodes] are extended from the distal end” of the needle. Ex-1010, ¶129. A POSA would understand that varying the length of the electrodes could be performed both by making the electrodes themselves longer (e.g., as explained by Gough ’143) and/or by operating an actuator to partially extend an electrode so that the length that is deployed is shorter than the length of the entire electrode (as explained by Lee). Ex-1018, 6:52-59; Ex-1010, ¶129.

75. The angle that the deployable electrodes make relative to each other and/or the needle shaft was also routinely varied. Ex-1018, 7:12-17 (“wide variation in the amount of deflection... any number of geometric configurations”). Indeed, Lee explains that “a variety of angles may be desired” for the deployable electrodes and that one way to achieve this was to adjust the “curvature of the ‘paths’” taken by each deployed electrode. Ex-1010, ¶0012. Likewise, Young ’486 explains that the angle of deployed electrodes relative to the RF needle’s shaft/cannula can be varied. Ex-1028, ¶0027, Fig. 3 (“angle 104 [] is less than 90° with an axis 106 of the cannula” but that “in alternative embodiments, the electrodes 26 can have different deployed profiles”). I also note that it is

immediately apparent from the example illustrations of deployable electrode configurations that I have provided herein that virtually any angle of electrode deployment can be achieved using a combination of shape memory alloys and deflection surfaces. *See e.g.*, Ex-1018, Fig. 6B (curved electrode tips pointing towards a proximal end of the RF needle's shaft); Ex-1012, Fig. 6 (curved electrode tips pointing towards distal end of RF needle); Ex-1010, 0017-0018, Figs. 1 and 48 (substantially straight electrode tips pointing outwardly from distal end of RF needle); Ex-1021, 5:57-59, 6:50-54.

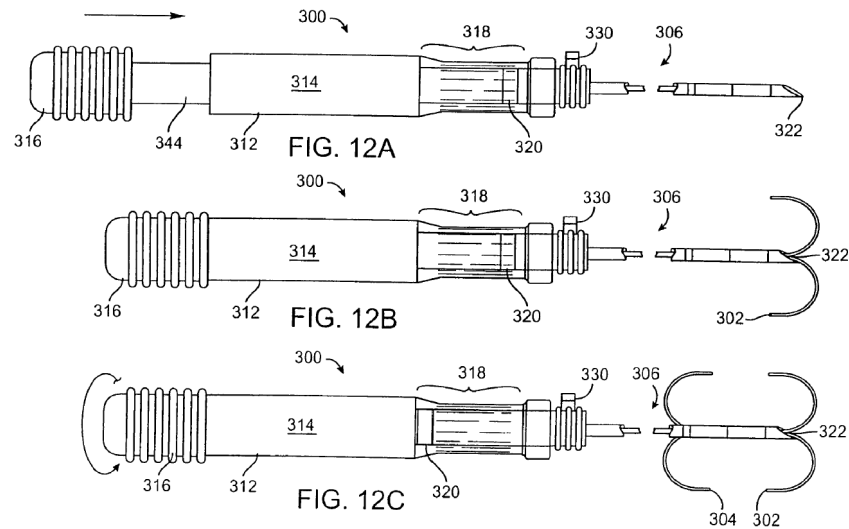
76. In many RF needles, the deployable electrodes are also configured to be energized in combination with the RF needle's tip. Ex-1024, 13:10-23 (electrode array 54 energized as an "integrated electrode" with the tip 86). For example, Young '965 discloses an RF needle in which an "array 30 of electrodes 26 and [an] 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." Ex-1012, ¶0033. As shown below, Young '965's electrode (92) "is secured to the distal end 14 of the cannula 12" and "has a sharp distal tip 94 for piercing tissue." Ex-1012, ¶0031.



Young '965 – Fig. 3

77. Deployable electrodes were also known to be actuated between their retracted and deployed positions using a variety of actuation devices. Ex-1010, ¶0106 (deployable electrodes can be deployed by “suitable advancement and retraction mechanisms” including those of “conventional design”); Ex-1016, ¶0034 (both “axial” and “rotational” movements were conventional techniques for deploying electrodes); Ex-1011, ¶0009 (“each electrode slides within its respective cannula”); Ex-1010, ¶0106; Ex-1012, ¶0038; Ex-1025, 7:48-49 (“secondary antenna distal end 16' being introduced and retracted in and out of primary antenna”); Ex-1026, 8:20-21 (“secondary antennas 16 are deployed and retracted”). A variety of well-known actuators were known in the art, including linear actuators (e.g., sliding handles) and rotational actuators (e.g., rotatable handles and knobs). For example, as shown above in Fig. 3, Young '965 discloses an RF needle having a “handle portion” coupled to the shaft can be “push[ed] or pull[ed] linearly “to advance the electrodes.” Ex-1012, ¶0038, Fig. 3, 5, 6. Young '965 also notes that the “handle assembly 27 can be configured such that the electrodes 26 can be deployed by rotating the handle portion 28 relative to the handle body 27” (e.g.,

using a “screw-like configuration”). Ex-1012, ¶¶0038. Similarly, as shown below, Behl discloses an actuator using a combination of linear and rotational movement to deploy electrodes from its distal tip. Ex-1024, 4:21-25, 15:21-60, Figs. 12A-12C.



Behl – Figs. 12A-12C

78. I also note that the use of actuators for analogous medical devices was well known and that a POSA in the field thermal ablation systems and methods would have been aware of such actuators. For example, 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. As shown below, Scheibe’s actuator (142) is positioned in a deflectable catheter (or sheath) and is configured to actuate a pullwire (130) through a lumen to steer the distal end of the catheter (much in the same way an RF needle’s actuator moves deployable electrodes through a shaft or cannula). Ex-1013, ¶¶0016-0019, 0021-0029, 0035,

Figs. 1-2. A POSA would have immediately recognized that rotational actuators like those disclosed in Scheibe could be used for actuating deployable filaments in RF needles.

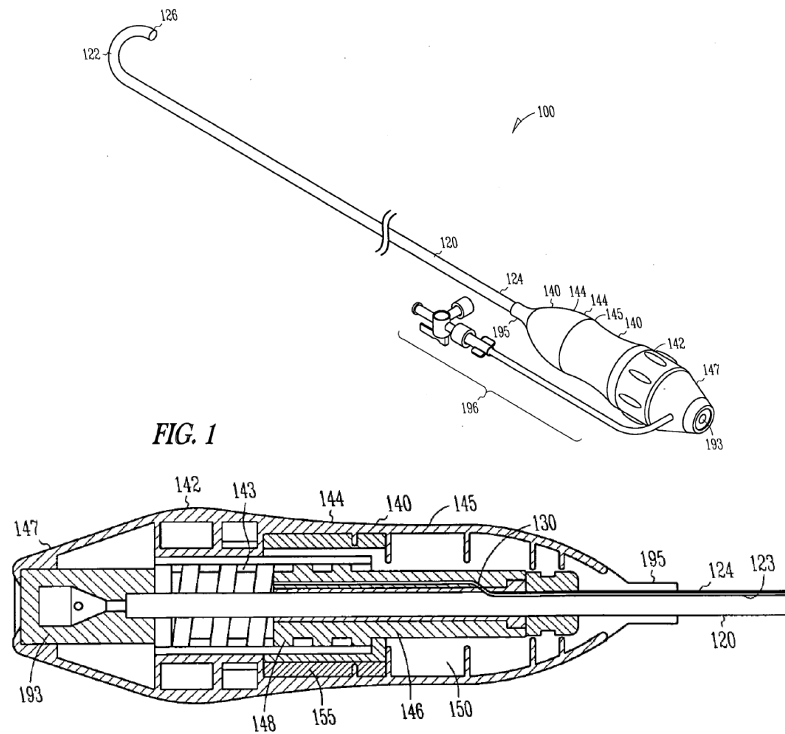


FIG. 1

FIG. 2

Scheibe – Figs. 1 and 2

c. Use of Deployable Electrodes to Define and Control the Ablation Volume

79. As RF needles can be provided with deployable filaments having “any number of geometric configurations,” a given RF needle can be configured to generate lesions in targeted tissue such that “the geometry of the ablated mass is selectable and controllable.” Ex-1017, 6:19-28 and 53-63. As a general matter, “the destruction of target tissue [occurs] at the site where the electrodes are located.”

Ex-1010, ¶0084; Ex-1011, ¶0008 (electrodes are deployed “to the area to be treated”). Thus, a POSA would understand that the ablation volume generated by an RF needle may be varied by adjusting any characteristic of the deployable electrodes—including length, direction, angle, size, number, pattern, position, and/or arrangement. *See e.g.*, Ex-1010, ¶0012, 0084, 0103-0106, 0123-0131.

80. As one example, Lee notes that “variations in ablation volume may be achieved by varying the extent to which [deployable electrodes] are extended from the distal end of the trocar and the direction in which [deployable electrodes] extend.” Ex-1010, ¶0129. Lee emphasizes repeatedly that deployable electrodes can be arranged and used singly or in combination to form “any desired pattern.” Ex-1010, ¶0103, 0105. Indeed, “the patterns of ... electrode deployment may be varied to achieve *any desired effect*.” Ex-1010, ¶0106 (emphasis added).

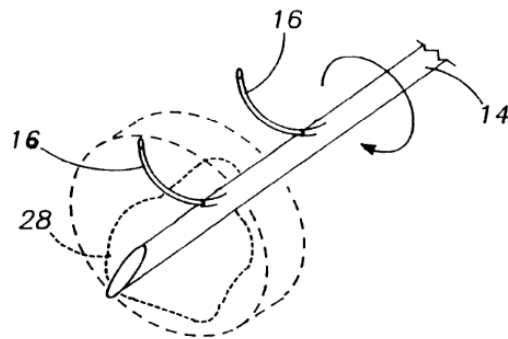
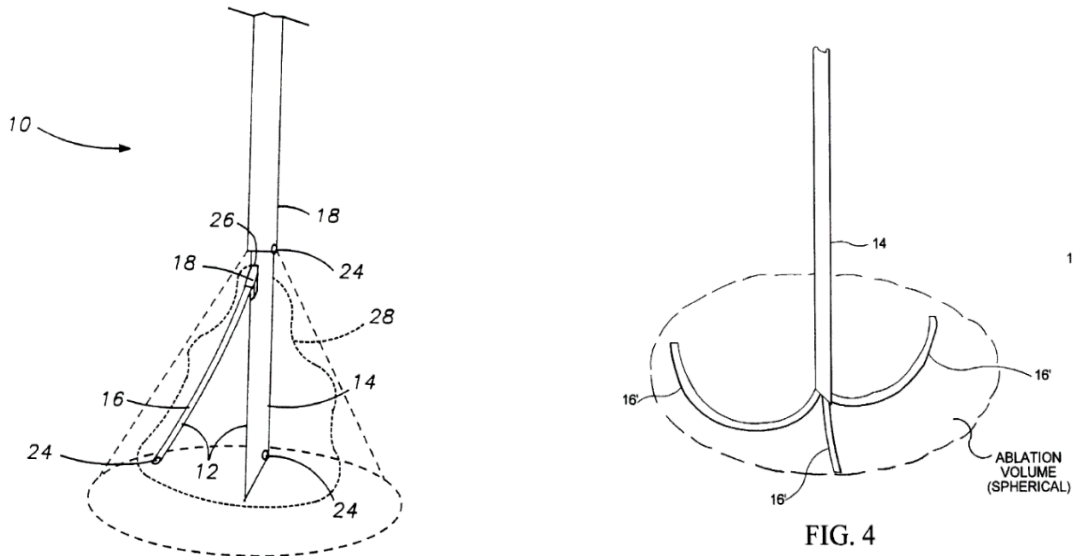
81. Gough ’229 also explained that the adjustability of its deployable electrodes allows “[a]ny number of different ablation geometries [to] be achieved” and that “the geometry of the ablated mass is selectable and controllable.” Ex-1026, 7:7-11. Referencing the variable configurations of its deployable electrodes (“antennas”), Gough ’229 explains the adjustability of the ablation volume:

Each secondary antenna 16 also has an adjustable energy transfer surface or length. *The adjustability of the lengths permits ablation of a wide variety of geometric configurations of a targeted mass.* Lengths of primary and secondary antennas 14 and 16 are adjusted, and

primary antenna 14 is moved up and down, rotationally about its longitudinal axis, and back and forth, in order *to define, along with sensors, the periphery or boundary of the ablated mass and ablate a variety of different geometries* that are not always symmetrical.

Ex-1026 at 5:36-45 (emphasis added).

82. Applying these principles, Gough '229 provides an example of a “conic” ablation volume in Figure 2. Ex-1026, 4:58-59. Gough '229 also explains how a “cylindrical” ablation volume can be generated using multiple deployed electrodes (Fig. 5), while Gough '827 explains how a “spherical” ablation volume may also be achieved using multiple deployed electrodes (Fig. 4). Ex-1026, 8:19-23; Ex-1025, 8:7-10, Fig. 4.



***Clockwise (from top left): Gough '229 (Fig. 2);
Gough '827 (Fig. 4); Gough '229 (Fig. 5)***

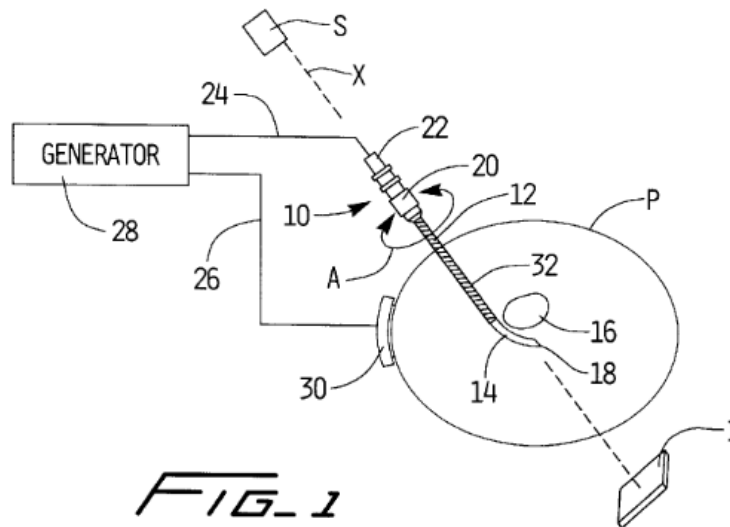
83. As evidenced by these disclosures, it was well-known in the art (and would have been well known to a POSA) that deployable electrodes could be configured to produce any desired ablation volume in the targeted tissue.

6. Monopolar and Bipolar Configurations

84. RF needles—including both single-tip RF needles and needles having deployable electrodes—were known to be provided in both monopolar and bipolar configurations. For example, in a monopolar configuration, the RF needle is

“coupled to one pole of the power supply and a second, dispersive electrode (typically placed on an exterior body surface) [is] coupled to the other pole of the power supply.” Ex-1024, 4:13-18. The “passive or dispersive” electrode is used to “complete the return path for the circuit being created.” Ex-1021, 6:16-25; Ex-1014, 6:30; Ex-1009, 4:11-12; Ex-1021, 3:11-15. The dispersive electrode is also referred to as a “grounding pad,” “ground plate,” “reference electrode” “passive electrode,” and “neutral, or common electrode.” Ex-1024, 4:15-18; Ex-1015, ¶0088; Ex-1009, 4:1-5; Ex-1014, 6:26-31; Ex-1021, 6:17-20.

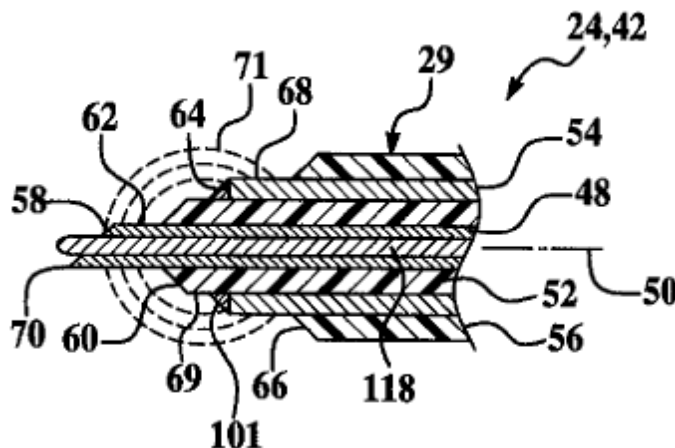
85. Racz provides an example of a single-tip RF needle (having a removable RF probe) that is provided with a monopolar configuration. As shown below, Racz’s dispersive electrode (30) (referred to as a “reference electrode”) is placed on the patient’s body (P). A pair of “electrical connections 24 and 26” are used to connect the dispersive electrode (30) and RF probe (22) to the RF generator (28), thereby “forming a complete electrical circuit permitting current flow.” Ex-1009, 4:9-12. During the ablation process, it is only the “pole” of the RF needle’s tip (14) that generates the lesion (not the dispersive electrode (30)). Ex-1009, 4:21-22. Thus, the RF needle is in a “monopolar” configuration.



Racz – Fig. 1

86. Single-tip RF needles were also known to be configured in a bipolar configuration. In a needle configured for bipolar operation, “the need to use the ground pad of a monopolar assembly is eliminated.” Ex-1022, 16:65-17:3. For example, Tullis describes a single-tip bipolar RF needle in which “a potential is applied across contacts ... thereby sending a current through the tissue and completing the circuit.” Ex-1022, 6:13, 48-51. As shown in Tullis’ Figure 15 below, “because [the] first active contact 62 and the second active contact 68 are separated axially by an insulating ring 69 of the insulating inner sleeve 52, a current path or 65 energy field 71 is generated between the contacts 62, 68 by the control console 22 when the tool 24 is in the operating state 42 thus creating a lesion in the target tissue.” Ex-1022, 6:62-67. In other words, the contacts 62, 68 at

the RF needle's tip are “bipolar” contacts generating a lesion in the tissue. Ex-1022, 7:6-14.



Tullis – Fig. 15

87. It was also well-known that RF needles with deployable electrodes could be provided in both monopolar and bipolar configurations. For example, Young '965 notes that its RF needle may be configured “for delivering ablation energy in a monopolar configuration,” where a dispersive electrode is attached to the patient. Ex-1012, ¶0033. In particular, Young '965’s “array 30 of electrodes 26 and the operative electrode 92 are monopolar electrodes, and current will pass from the electrodes 26 and the electrode 92 to the dispersive electrode to thereby deliver ablation energy in a monopolar configuration.” Ex-1012, ¶0033. However, in a bipolar configuration, electrodes are “attached to opposite poles of the power supply.” Ex-1024, 6:23-27. For example, Young '965 also discloses a bipolar configuration in which “the array 30 of electrodes 26 and the operative electrode

92 are used to deliver RF current in a bipolar fashion, which means that current will pass between the array 30 of electrodes 26 and the operative electrode 92.”

Ex-1012, ¶032.

88. Indeed, it was well established that configuring RF needles (having a single-tip and/or deployable electrodes) for either monopolar or bipolar operation was nothing more than a routine engineering exercise. Ex-1021, 4:8-11 (“RF current flow is then established between the at least two electrodes (i.e., bipolar) or among at least the two electrodes and a separate return electrode (i.e. monopolar)”); Ex-1022, 16:65-17:3, 22:6-23 (bipolar and monopolar versions); Ex-1024, 4:13-18, 5:6-8, 6:23-27, 7:37-39; Ex-1012, ¶0003 (“The tines may be energized in a bipolar mode (i.e., current flows between closely spaced electrode tines) or a monopolar mode (i.e., current flows between one or more electrode tines and a larger, remotely located common electrode) to heat and necrose tissue within a precisely defined volumetric region of target tissue.”).

III. THE ’688 PATENT

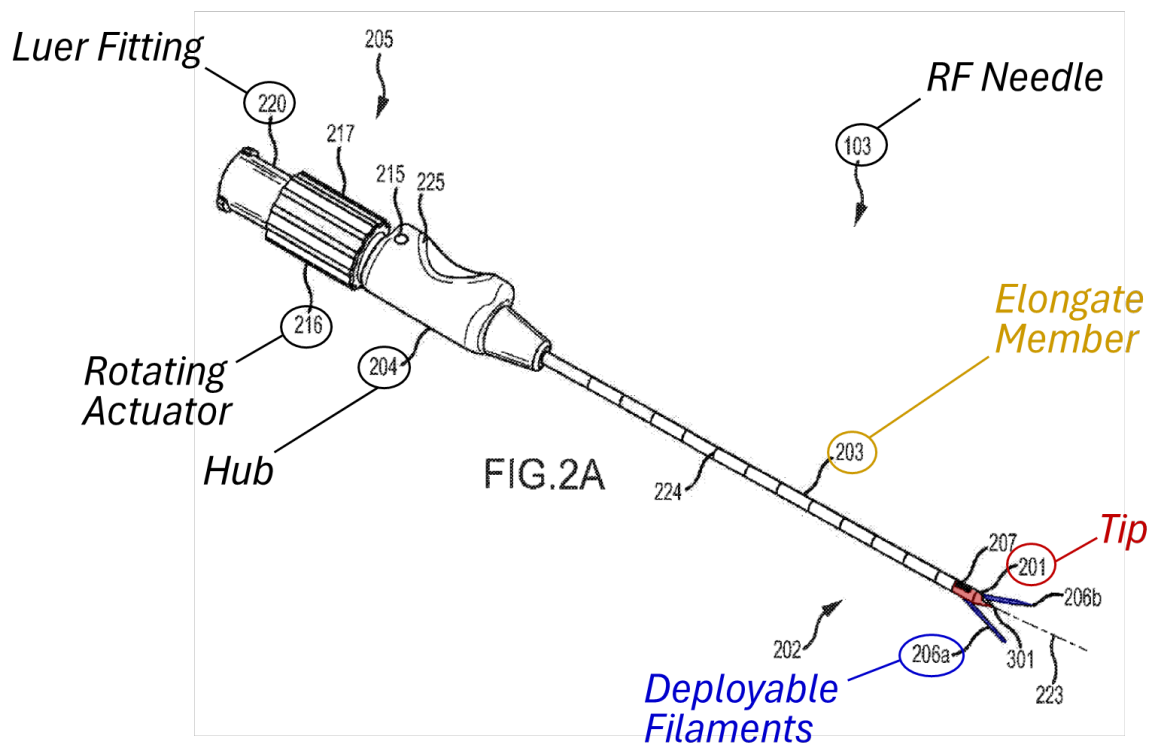
A. Overview

89. To assist the Board in evaluating the Challenged Claims, I have summarized the ’688 Patent’s disclosure below. I have included annotations to several figures and illustrations of the Challenged Patent and various prior art references discussed herein. Wherever these figures are annotated or otherwise

modified from their original form, such modifications have been made at my instruction to assist the Board in understanding how a POSA would have understood the teachings of the prior art.

90. Based on my review, the '688 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-1002, 4:34-56, 30:63-31:14.² 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-1002, 5:25-47, 6:37-43. 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-1002, 5:25-47, 8:15-25. A Luer fitting (220) at the proximal end of the needle (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-1002, 4:66-5:7, 5:48-59, 17:47-54. The illustration below shows the relationships between these elements.

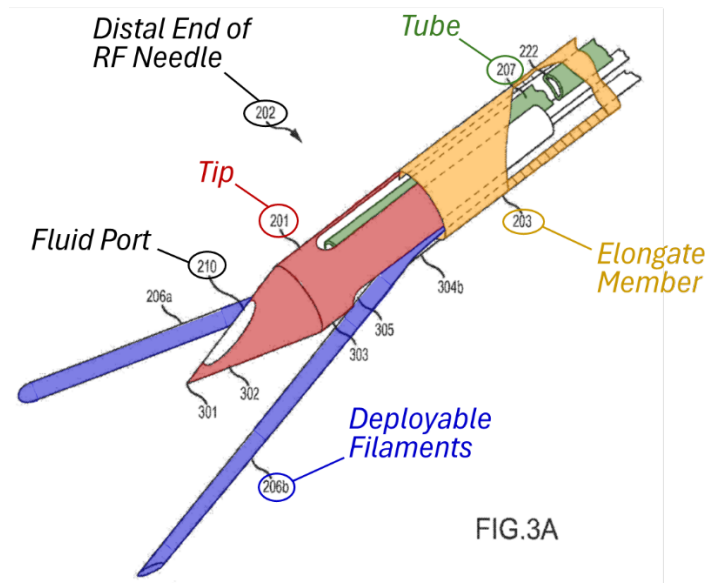
² The '688 Patent includes 21 figures (labeled 1-15) showing various needle configurations. One example is described herein for context and brevity.



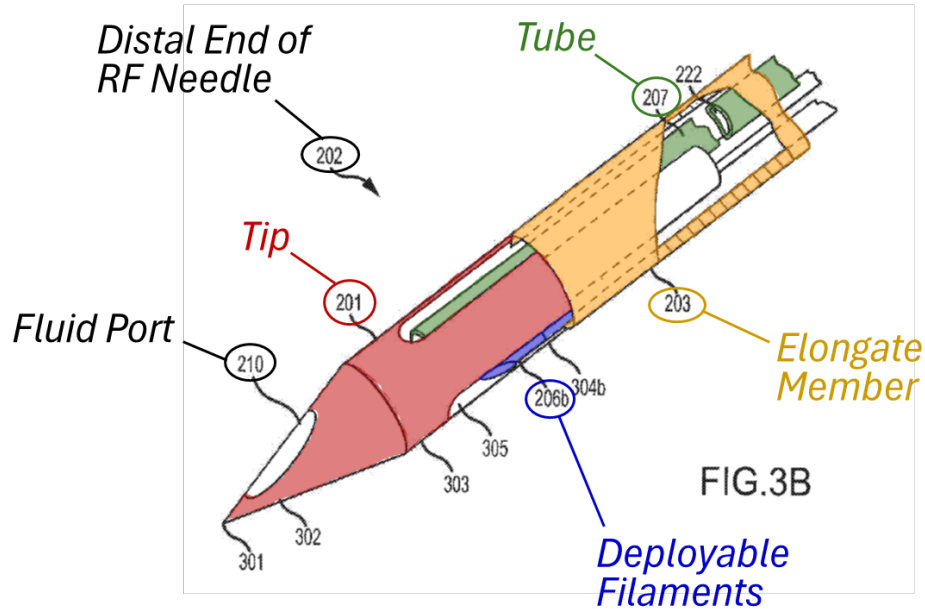
'688 Patent – Fig. 2A

91. As shown above, the filaments (206a-b) are deployed/retracted by a rotating actuator (216). Ex-1002, 5:45-47, 17:9-18:32. When deployed, the filaments (206a-b) “expand the volume of effective RF energy delivery as compared to known single-electrode RF probes.” Ex-1002, 5:34-41. 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-1002, 11:11-23, 11:57-12:35, 13:37-14:5.

92. As shown in Figs. 3A-3B (annotated below), the needle's tip (201) is positioned at the elongate member's distal end. Ex-1002, 5:25-31; 6:25-36. 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-1002, 5:25-28, 7:34-50, 17:47-53.



'688 Patent – Fig. 3A



'688 Patent – Fig. 3B

93. Although the tip (201) and elongate member (203) may be a “unitary structure,” annotated Figs. 3A and 3B show a configuration where the tip (201) is a separate member “fixedly interconnected” to the elongate member (203). Ex-1002, 8:40-50. 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-1002, 6:44-7:33.

94. To transmit RF energy to the tip (201) and filaments (206a-b), “the RF probe 401 is inserted within the tube 207, [and] 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-1002, 8:52-57, 5:48-58. 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-1002, 9:43-47. In this way, the tip (201) and filaments (206a-b) operate together as an electrode. Ex-1002, 9:47-53.

B. Prosecution History

95. The '688 Patent issued from U.S. Patent Application No. 15/098,673 (the '673 Application”) filed on April 14, 2016. The '673 Application was a continuation of US 12/940,974 (filed November 5, 2010) and claims priority to two US provisional applications (61/347,351 filed on May 21, 2010 and 61/280,557 filed on November 5, 2009). The '673 Application’s prosecution history is summarized below for brevity, but, as noted in § I.B (Materials considered), I reviewed the prosecution history of each of these applications.

96. The '673 Application was filed on April 14, 2016 with a single claim, reproduced below.

1. A needle for insertion into a patient during an RF ablation procedure, the needle comprising:

a hub;

an elongate member fixed to the hub;

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

a plurality of filaments disposed within at least a portion of the elongate member;

an actuator interconnected to the plurality of filaments, wherein movement of the actuator relative to the hub moves the plurality relative to the tip; and

a lumen within the elongate member, wherein the lumen and the tip are configured to accept an RF probe such that an electrode of an inserted RF probe, the tip, and the first and second filaments are operable to form a single monopolar RF electrode.

On September 11, 2018, the single claim was rejected in a first Non-Final Office Action. Ex-1007, 124. The Non-Final Office Action rejected claim 1 as anticipated by U.S. Patent Publication No. US20060084965A1 to Young (“Young ’965”)³ under 35 U.S.C. 102(b). Ex-1007, 125-26.

97. The same Non-Final Office Action also objected to claim 1 as omitting the word “filament” from the phrase “the plurality relative to the tip.” Ex-1007, 125.

98. On March 11, 2019, Stratus filed an Office Action Response. Ex-1007, 142. The response amended claim 1 to recite a fitting for “injection of fluid through the fitting” and “to allow insertion of an RF probe into the lumen.” Ex-1007, 153. Stratus further amended claim 1 to recite a “filament” in the phrase “the plurality of **filaments** relative to the tip.” *Id.*

³ The examiner referred to Young ’965 as simply “Young.” I refer to it as “Young ’965” throughout my review of the prosecution history to be clear which Young is referred to.

99. Stratus further amended the claims to add new claims 2-20, where claim 17 recited “a system comprising the needle of claim 1; and the RF probe” and claim 19 recited a method of using the needle of claim 1 by “rotation the actuator ... and operating the RF probe” Ex-1007, 153-56.

100. On June 18, 2019, the USPTO issued a Final Office Action. Ex-1007, 157. The Final Office Action rejected claims 1-18 and withdrew claims 19 and 20 from consideration as being directed to a non-elected invention. Ex-1007, 158-159.

I summarize the specific grounds of rejection below:

- Claims 1-3, 7, 8, 12, 13, and 15-18 under pre-AIA 35 U.S.C. 103(a) as unpatentable over Young '965 in view of U.S. Patent Publication No. 2006/0206111 to Young (“Young '111”), in further view of U.S. Patent Publication No. 2002/0143302 to Hinchliffe (“Hinchliffe”).
- Claims 4 and 5 under pre-AIA 35 U.S.C. 103(a) as unpatentable over Young '965, Young '111, and Hinchliffe.
- Claim 6 under pre-AIA 35 U.S.C. 103(a) as unpatentable over Young '965, Young '111, and Hinchliffe, in further view of U.S. Patent No. 7,108,696 to Daniel et al.
- Claim 14 under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Young '965, Young '111, and Hinchliffe in further view of U.S. Patent Publication No. 2009/0292259 to Delano et al. (“Delano”).

Ex-1007, 158-168.

101. During an interview on July 12, 2019, Stratus and the examiner discussed “physical contact between the probe and the lumen” and that “while not clear in the drawing, the probe can extends [sic] through the tube to make contact with the distal tip.” Ex-1007, 203. “Applicant expressed the intent to incorporate claim language regarding separately accepting RF probe and fluid at different time periods.” *Id.* The interview summary notes that “there was an agreement that the following subject matter overcomes the rejection of record- the plurality of filaments are within the elongate member when the RF probe is fully withdrawn from the elongate member.” *Id.*

102. On August 19, 2019, Stratus filed an Office Action Response. The response amended claim 1 to recite that “the plurality of filaments are disposed within at least a portion of the elongate member,” that the RF probe “is separate from the needle.” Stratus further added the following limitation:

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

Ex-1007, 209-10.

103. The August 19, 2019 response further amended the claims to include:

- Claims 21-50, variously dependent on claim 1;
- Independent claim 51 and dependent claims 52-53, reciting a system including an RF ablation needle and probe; and
- Independent claim 54 and dependent claims 55-72, reciting a needle for RF ablation including a including a luer fitting.

Ex-1007, 212-22.

104. Applicant's Summary of the Interview, included in the August 19, 2019 response, asserted that the interview included agreement that two limitations would "separately and independently overcome[] the rejection of record." The applicant characterized these limitations as:

(1) The plurality of filaments are within the elongate member when the RF probe, in its entirety, is absent from the elongate member; and separately and independently,

(2) The fitting is structurally limited to being a luer fitting.

Ex-1007, 225.

105. The Examiner's summary of the same interview stated that "such claim amendment *appears* to overcome the rejection of record, however **further search and/or consideration is required.**" Ex-1007, 203 (emphasis added). Stratus filed this response with a request for continued examination (RCE) to restart prosecution after the final rejection. Ex-1007, 205.

106. On September 3, 2019, the USPTO issued a second Non-Final Office Action. Ex-1007, 237. The Non-Final Office Action rejected claims 1-18, and 21-72. Ex-1007, 238. Claims 19 and 20 remained withdrawn from consideration as being directed to a non-elected invention. Ex-1007, 239. The Office Action rejected:

- Claims 1-3, 6-8, 12, 13, 15, 16, 18, and 21-72 under pre-AIA 35 U.S.C. 103(a) over U.S. Patent 5,599,346 to Edwards et al. (“Edwards”) in view of U.S. Patent publication 2006/0095029 to Young (“Young ’029”) in further view of Hinchliffe;
- Claims 4 and 5 under pre-AIA 35 U.S.C. 103(a) over Edwards, Young ’029, and Hinchliffe in further view of U.S. Patent Publication 2010/0049192 to Holtz (“Holtz”); and
- Claims 9-11 under pre-AIA 35 U.S.C. 103(a) over Edwards, Young, Hinchliffe, and U.S. Patent Publication 2004/0260282 to Gough (“Gough ’282”).

Ex-1007, 239-49.

107. The Office Action further issued a nonstatutory double patenting rejection in view of Young ’029 and co-pending Stratus application 15/092,945 (which I note issued as the Stratus ’618 Patent). Ex-1007, 250.

108. A second interview was held on September 13, 2019. Ex-1007, 272. Stratus argued that various combinations were improper, either due to a lack of

motivation to combine teaching away. Ex-1007, 274. The examiner did not find these arguments persuasive, noting for example that “modifying the position of the filaments is known in the art and would involve routine skill in the art.” *Id.*

109. Stratus also suggested limiting the operation of the device to “a single monopolar electrode” based on “electrical connection[s]” in the device. *Id.* In response “Examiner suggested further limiting the claim to include mechanically connected to clarify that all the elements are physically and electrically connected to form the single monopolar electrode.” *Id.*

110. A third examiner interview was conducted February 11, 2020. Ex-1007, 340. In that interview, stratus “proposed amending the claim to recite that the RF probe, the needle and the filament are in physical contact so as to be electrically connected to operate or form a single monopolar electrode” and “Examiner agreed that such amendment appears to overcome the rejection of record.” *Id.*

111. In an Office Action Response dated February 24, 2020, Stratus amended each of the claims to variously recite that the probe “physically contact(s)” the needle to operate with the needle as a single monopolar electrode. Ex-1007, 367-81. Claim 17 was canceled and withdrawn claims 19 and 20 were also amended. Ex-1007, 370.

112. By the same February 24, 2020, amendment, Stratus added new claims 73-76 dependent on claim 1. Claim 73 recited that “the conductive portion of the needle is at a distal end of the needle.” Ex-1007, 381.

113. A second Final Office Action issued on March 19, 2020. Ex-1007, 424. The second final office action allowed claims 51-53, but rejected claims 1-16, 18-50, 54-72, and 74-76. Again, I summarize the grounds of rejection:

- Claims 1-3, 6-8, 12, 13, 15, 16, 18, and 21-50, 54-72, 74, and 75 under pre-AIA 35 U.S.C. 103(a) over U.S. Patent 7,918,852 to Tullis et al. (“Tullis”) in view of Young ’029 and Hinchliffe;
- Claims 4 and 5 under pre-AIA 35 U.S.C. 103(a) over Tullis, Young ’029, Hinchliffe and Holtz;
- Claims 9-11 under pre-AIA 35 U.S.C. 103(a) over Tullis, Young ’029, Hinchliffe, and Gough;
- Claim under pre-AIA 35 U.S.C. 103(a) over Tullis, Young, Hinchliffe in further view of Delano; and
- Claim 73 (dependent on claim 1) was indicated as allowable if rewritten in independent form.

Ex-1007, 425-38.

114. On March 28, 2020, Stratus filed an After-Final response with the USPTO, amending rejected independent claims 1 and 54 to include the limitation of claim 73 (“the conductive portion of the needle is at a distal end of the needle”).

Ex-1007, 468, 478. Stratus also amended withdrawn dependent claims 19 and 20, and requested that they be rejoined. Ex-1007, 471-72, 484.

115. A fourth examiner interview was held on April 6, 2020. Ex-1007, 499. The examiner “stated that the claims are in condition for allowance and that the withdrawn claims 19-20 will be rejoined.” *Id.*

116. On April 9, 2020, a notice of allowance was mailed. Ex-1007, 493. When the claims were re-numbered for issuance, pending claim 54 issued as claim 56, and pending claim 51 issued as claim 53. The notice of allowance also rejoined claims 19-20 by an examiner’s amendment. Ex-1007, 495. The notice of allowance provided the following reasons for allowance of the claims:

- **Independent Claim 1 (issued claim 1):** “Tullis fails to disclose that the conductive portion is at a distal end of the needle...”
- **Independent Claim 51 (issued claim 53):** ... Tullis fails to disclose an RF probe ... comprising an electrode.”

Ex-1007, 495-96.

117. As noted above, the examiner had previously indicated that Independent Claim 54 (issued claim 56) was allowable because “Tullis fails to disclose a RF probe (Fig. 17) comprising an electrode.”

118. I note that among the prior art references I rely on for invalidity grounds, only Young ’965 was discussed during prosecution. I also note that prior

to allowance of the '688 Patent, the pending rejection was over Tullis, Young '029 and Hinchliffe, and that Stratus distinguished the claims from this art by pointing to the “probe” and “conductive portion is at the distal end of the needle,” which were allegedly not disclosed by Tullis (as discussed above, *see* ¶114). I discussed Tullis above as part of the background knowledge possessed by a POSA. But I do not directly rely on Tullis for any of Invalidity Grounds. None of the remaining references in the Invalidity Grounds were discussed during prosecution.

IV. LEVEL OF ORDINARY SKILL IN THE ART

119. The '688 Patent identifies its technical field as relating to “thermal ablation systems and methods,” which includes RF neurotomy systems. Ex-1002, 1:16-20. Based on that identification, my review of the cited prior art documents, and my own experience, in my opinion 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.

V. CLAIM CONSTRUCTION

120. I have been instructed that, to assess the patentability or unpatentability of a claim, one must first ascertain the scope of the claimed

invention, which requires understanding the terms in the claim. In particular, I have been informed that the claims of the patent should generally be given their ordinary and customary meaning as they would be understood by a POSA in view of the patent's specification and prosecution history. In my opinion, the terms in the Challenged Claims would be understood by a POSA to have their plain and ordinary meaning and do not require a special construction or definition.

VI. SUMMARY OF INVALIDITY GROUNDS

121. It is my opinion that the Challenged Claims 1-17 and 48-52 of the '688 Patent would have been obvious in view of the prior art noted in the table below. I explain below in detail my conclusion as to why a POSA would find the claims invalid.

	Claims	Statute	Prior Art
A	1, 6-9, 12-14, 17, 48-52	§ 103(a)	Racz, Fitz, and Lee
B	1, 6-9, 12-14, 17, 48-52	§ 103(a)	Racz, Fitz, Lee, and Young '965
C	1-9, 12-14, 17, 48-52	§ 103(a)	Racz, Fitz, Lee, and Scheibe
D	1-9, 12-14, 17, 48-52	§ 103(a)	Racz, Fitz, Lee, Young '965, and Scheibe
E	9	§ 103(a)	Racz, Fitz, Lee, and Young '201
F	9	§ 103(a)	Racz, Fitz, Lee, Young '201, and Young '965
G	9	§ 103(a)	Racz, Fitz, Lee, Young '201, and Scheibe
H	9	§ 103(a)	Racz, Fitz, Lee, Young '201, Young '965, and Scheibe
I	10, 11, 15	§ 103(a)	Racz, Fitz, Lee, and Gough '516
J	10, 11, 15	§ 103(a)	Racz, Fitz, Lee, Gough '516, and Young '965

	Claims	Statute	Prior Art
K	10, 11, 15	§ 103(a)	Racz, Fitz, Lee, Gough '516, and Scheibe
L	10, 11, 15	§ 103(a)	Racz, Fitz, Lee, Gough '516, Young '965, and Scheibe
M	16	§ 103(a)	Racz, Fitz, Lee, and Rosinko
N	16	§ 103(a)	Racz, Fitz, Lee, Rosinko, and Young '965
O	16	§ 103(a)	Racz, Fitz, Lee, Rosinko, and Scheibe
P	16	§ 103(a)	Racz, Fitz, Lee, Rosinko, Young '965, and Scheibe

122. I have been instructed by counsel that the following references were issued/published more than one year before the '688 Patent's earliest claimed priority date (November 5, 2009) and are therefore prior art under pre-AIA 35 U.S.C. § 102(b):

- U.S. Patent 6,146,380 to Racz et al. (granted November 14, 2000);
- U.S. Patent Publication 2005/0059,964 to Fitz (published March 17, 2005);
- U.S. Patent Publication 2007/0016,183 to Lee et al. (published January 18, 2007);
- U.S. Patent Publication 2006/0084965 to Young ("Young '965") (published April 20, 2006);
- U.S. Publication No. 2007/0260223 to Scheibe et al. (published November 8, 2007);
- U.S. Patent No. 6,652,516 to Gough (issued November 25, 2003); and
- U.S. Patent No. 6,551,302 to Rosinko et al. (issued April 22, 2003).

123. I have also been instructed by counsel that U.S. Publication No. 2009/0112201 to Young (“Young ’201”) was filed on October 28, 2008, and published April 30, 2009, and is therefore prior art under at least pre-AIA 35 U.S.C. § 102(e).

VII. GROUND A: CLAIMS 1, 6-9, 12-14, 17, 48-52 ARE OBVIOUS IN VIEW OF RACZ, FITZ, AND LEE.

A. Prior Art Overview

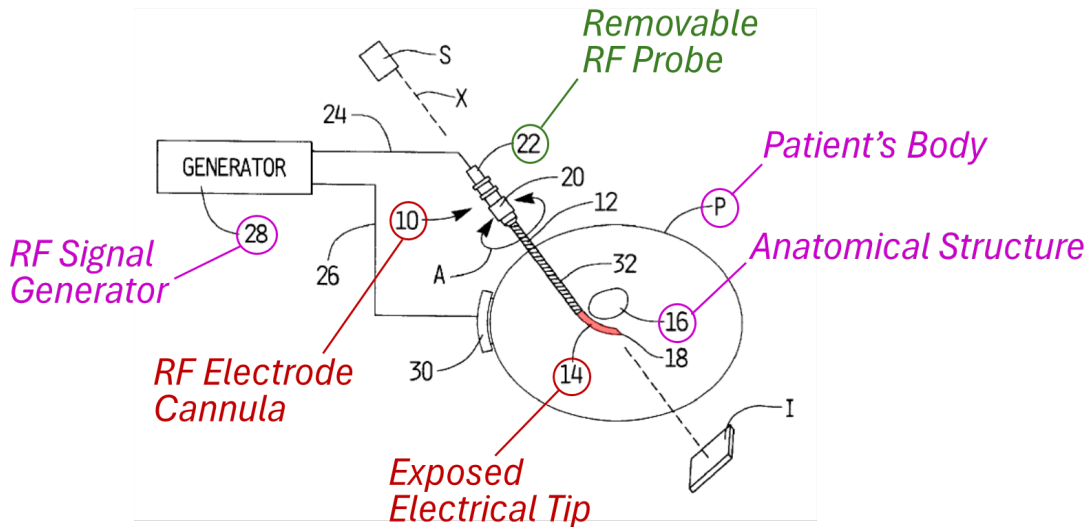
1. Overview of Racz

124. 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. It is therefore my opinion that Racz is directed to the same field as the ’688 Patent (“thermal ablation systems and methods”). *See* Ex-1002, 1:16-20.

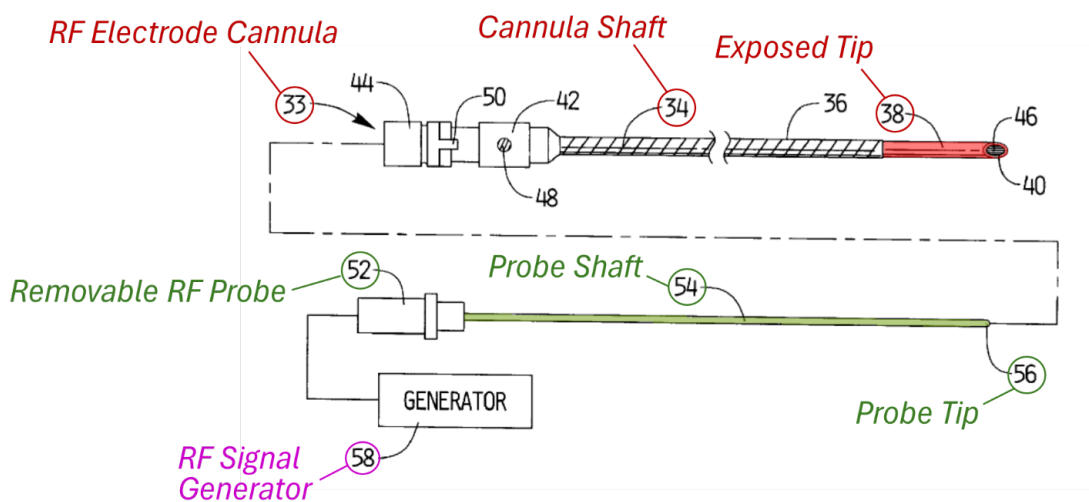
125. I have provided below an annotated version of Racz’s Figure 1. As shown in Figure 1, Racz’s system includes a “radio-frequency electrode cannula 10” (aka “electrical needle”) that is “inserted directly through the skin of [a] body portion P to locate the [cannula’s] tip 14 in a target position within the body.” Ex-1009, 3:42-45. RF energy is conveyed to the electrode cannula’s exposed distal tip (14) via a removable electrical probe (22), which can be inserted into a lumen of the electrode cannula (10). Ex-1009, 3:60-63, 4:18-23. I note that Racz’s distal tip is shaded red in the annotated figure below.

126. A signal generator (28) outputs RF energy that is transmitted to the electrical probe (22). Ex-1009, 4:18-20. When the probe (22) is inserted into the cannula (10), physical contact between the probe (22) and the cannula's exposed tip (14) transmits the RF energy to the tip (14). Ex-1009, 3:60-65, 5:41-45. In this way, the cannula's tip (14) can provide "electrical stimulation or high-frequency heating of tissue near the exposed electrical tip 14" (e.g., tissue at the internal anatomical structure (16) in Fig. 1). Ex-1009, 3:60 to 4:23. Additionally, a reference electrode (30) may be placed on the patient's body (P), allowing the cannula's exposed tip (14) to function as a monopolar electrode. Ex-1009, 4:3-23. In the late 1990's (when Racz was filed), "this practice [was] well known in the arts of stimulation and ablation." Ex-1009, 4:21-23.

127. I note that 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. For example, the cannula (33) corresponds to the cannula (10). Thus, for clarity, I refer herein to common features in Figures 1 and 2A/2B using the convention "cannula (10/33)." Ex-1009, 4:59 to 5:6.



Racz – Fig. 1 (annotated)



Racz – Fig. 2B (annotated)

128. Figure 2A/2B's cannula (10/33) includes a shaft (34) defining an internal lumen. Ex-1009, 5:41-45. The shaft's proximal portion is covered with insulation (36), while the shaft's distal portion is exposed and defines a distal tip but includes an uncovered, exposed distal tip (14/38) (tip 14 corresponds to "tip portion 38") (again, I have **shaded red** the distal tip (14/38)). 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.

129. RF energy is conveyed to the cannula’s exposed tip (14/38) via a removable electrical probe (22/52) (“probe 22” corresponds to “probe 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.

130. 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. A POSA would have understood that the configuration of Racz, which uses a single active electrode and a reference electrode placed on the patient would be a *monopolar* electrode. As I explained earlier in §II.D.6, the reference electrode is used to ground the circuit and provide a return path for the current—not as an active electrode for ablating tissue. Therefore, a POSA would have

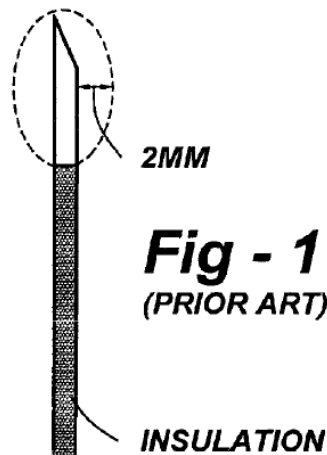
understood that the single active electrode of Racz provides a single “mono” electrical pole for RF ablation.

131. As noted above, I will refer throughout the rest of this report to the common elements of Racz Fig. 1 and Figs. 2A/2B as the “cannula (10/33),” the “probe (22/52),” the “tip (14/38),” the “signal generator (28/58),” and so on. Where I use this convention, it is my opinion that a POSA would understand that the “specific embodiment” of Fig. 2 refers to these same components as Fig. 1 of Racz.

2. Overview of Fitz

132. Fitz is directed to an “improved-coverage” RF neurotomy device. Ex-1011, ¶0001-0002, 0009, Abstract, Claim 1. It is therefore my opinion that Fitz is also directed to the ’688 Patent’s field (“thermal ablation systems and methods”). *See* Ex-1002, 1:16-20.

133. 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.



Fitz – Fig. 1

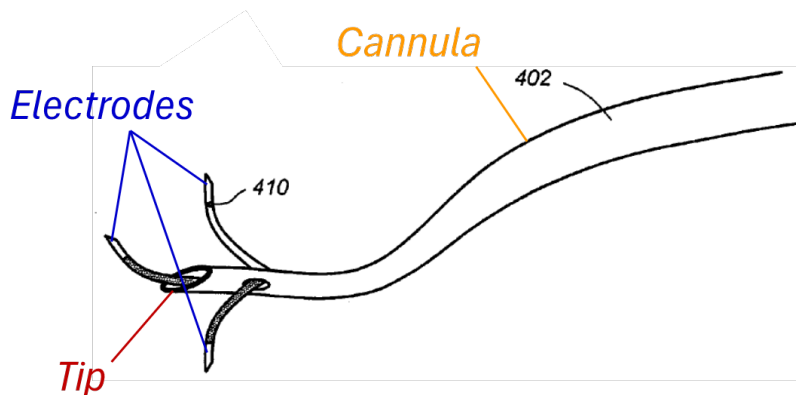
134. To solve the problem of inadequate coverage in single-tip neurotomy devices, Fitz suggests providing a deployable “set of electrodes” that extend outwardly from the “exposed distal tip” of an RF neurotomy cannula. Ex-1011, ¶0009, Abstract, Claim 1. The deployable electrodes may be made from a “shape-memory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

135. 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-

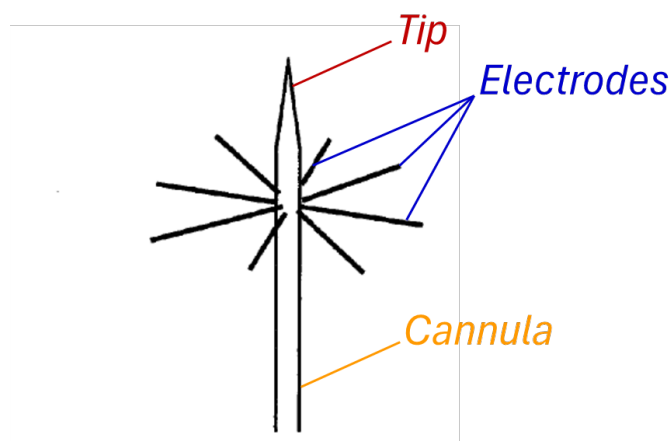
1011, ¶0020, Fig. 4. The “sideport(s) 410 may be provided for an aesthetic administration, with or without electrical insulation.” *Id.*

136. 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. Fitz refers to Fig. 5 as a “radial array, which may introduce from the tip, or some distance from the tip. Ex-1011, ¶0016. Fitz also explains that different shapes of arrays are possible: “Although the side electrodes are shown as emanating from more or less the same distance from the tip, this is not necessary, in that a helix or spiral of apertures may alternative be used.” Ex-1011, ¶0021.

137. In each example of Fitz, the electrodes are deployed outwardly from the cannula’s distal tip to enhance the device’s energy coverage area. In describing the embodiment of Fig. 2, Fitz explains that the electrodes “enhance the energy coverage area,” and a POSA would understand that the electrodes in other embodiments (e.g., Figs. 4 and 5 below) would likewise enhance the energy coverage area for the same reason. Indeed, because each of the electrodes heats tissue and thereby creates a lesion proximate to its location, adding spaced electrodes expands the resulting ablation area. Ex-1011, ¶0004, 0009.



Fitz – Fig. 4 (annotated)



Fitz – Fig. 5 (annotated)

3. Overview of Lee

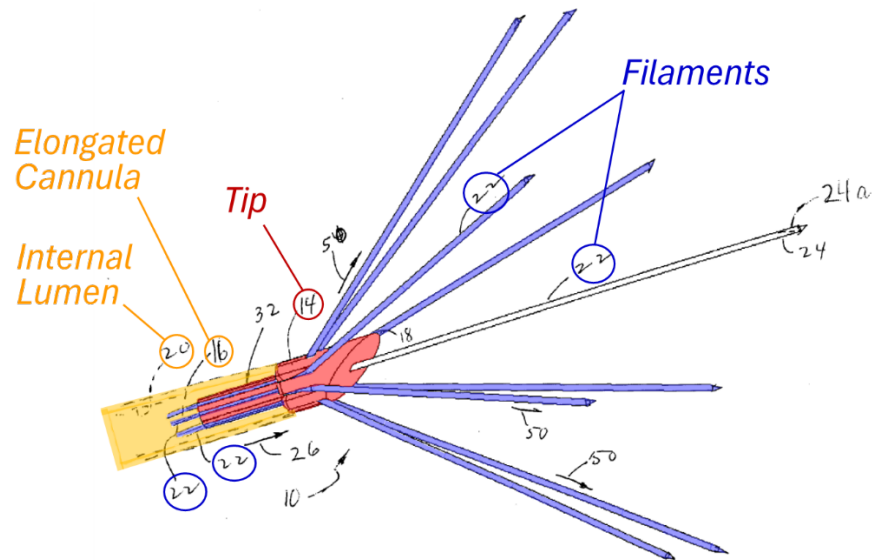
138. Lee discloses various techniques for deploying electrodes from the tip of an RF ablation device. *See e.g.*, Ex-1010, ¶¶0012, 0107. Thus, Lee is also directed to the '688 Patent's field. *See* Ex-1002, 1:16-20.

139. 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 annotated Figure 1 below identifies several elements of Lee’s device. In particular, 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.

140. I note that a POSA would understand what Lee describes as “stylets” are equivalent to the “filaments” described (and claimed) in the Challenged Patent. Lee’s 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 member[s]” constructed from a nickel titanium alloy, which a POSA would understand to be “filaments.” Ex-1010, ¶0092, 0087. Likewise, the filaments of the ’688 Patent are shown as thin wires extending outward from the tip of the needle (see filaments 206a 206b in provided annotation of Fig. 2A of the ’688 Patent, *supra* § III.A), and they “may be constructed from ... a metal such as stainless steel, Nitinol or shape memory alloy.” Ex-1002, 10:54-56. So, in my opinion, a POSA would understand that the stylets (22) disclosed by Lee are structurally and functionally the same as the filaments as described by the Challenged Patent. For clarity, I refer to Lee having

“filaments” instead of “stylets” (including as illustrated in the annotated figures below).

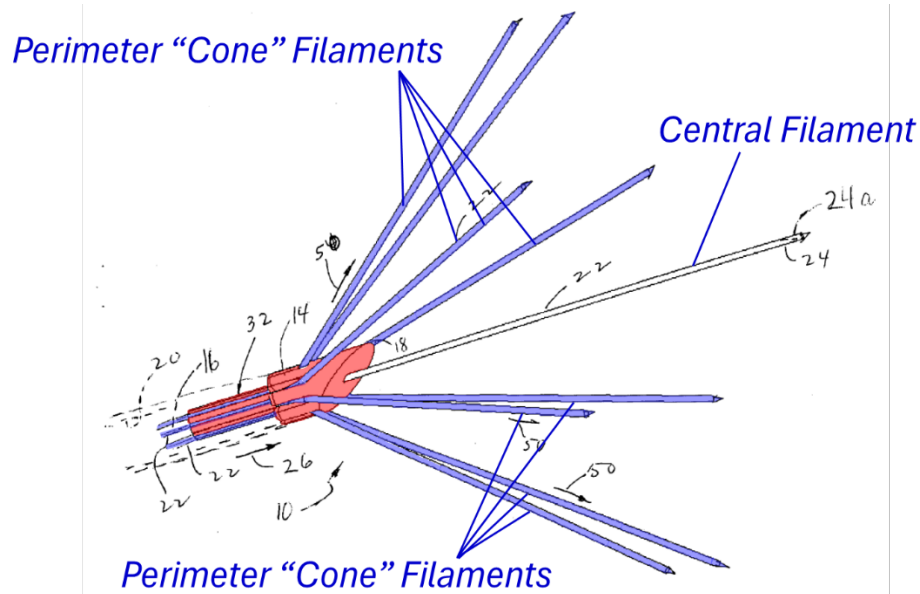


Lee – Fig. 1 (annotated)

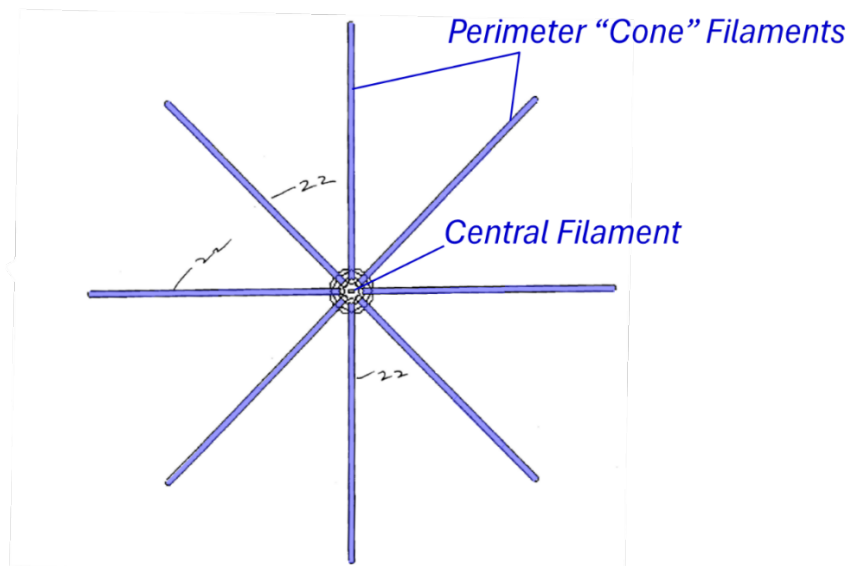
141. Figure 1 shows Lee’s filaments (22) in a deployed position. Ex-1010, ¶¶0092, 0093, 0099, 0102. The tip (14) includes delivery mandrel surfaces (12) (or “deflection surfaces”) comprising channels and ramps positioned in the cannula (16). Ex-1010, ¶¶0016, 0018, Claims 8, 10. The filaments (22) are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

142. As shown in the annotated version of Fig. 1, 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.



Lee – Fig. 1 (annotated)

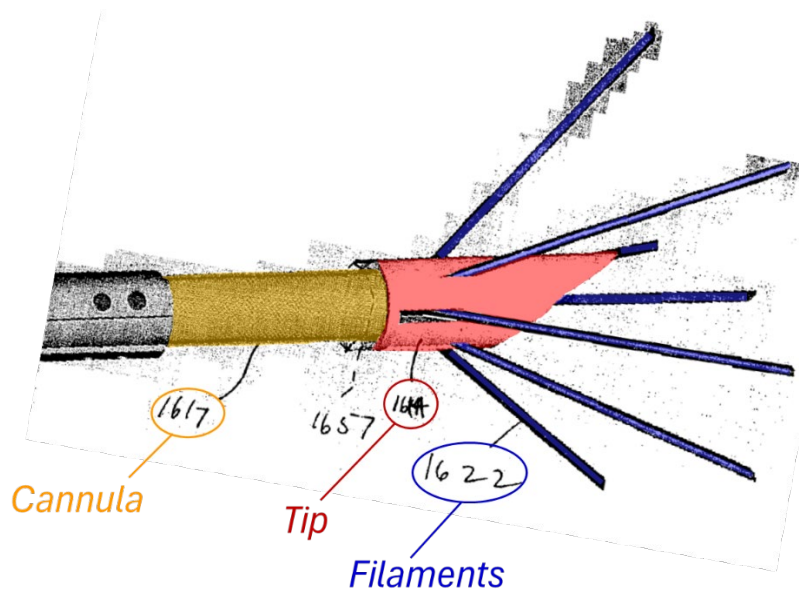


Lee – Fig. 5 (annotated)

143. Lee discloses that when the filaments (22) “exit the mandrel into the tissue they define an ablation volume in the target tissue.” Ex-1010, ¶0012. Lee

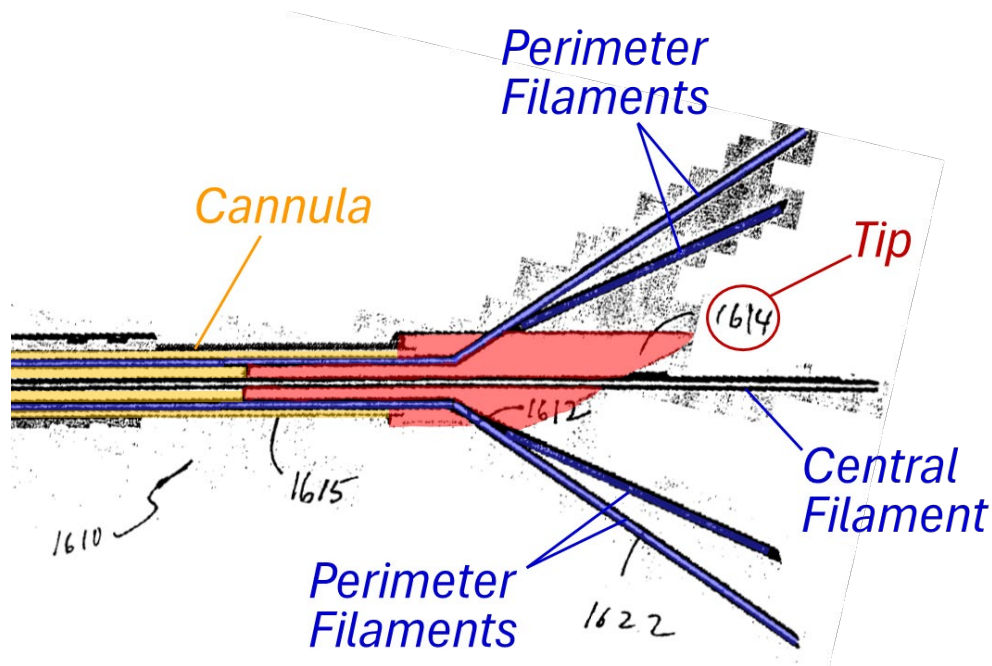
also notes that the ablation volume may be varied by adjusting the extent to which the stylets (22) are extended, the direction in which the stylets extend, and the stylets' arrangement or pattern. *See* Ex-1010, ¶¶0123-0131, 0084. Thus, “the destruction of target tissue [occurs] at the site where the 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.

144. Lee provides additional detail regarding filament deployment with reference to a trocar (1610) (Figs. 48-49). Annotated Fig. 48 below (color-coded for clarity) shows the relationship between the hypotube, stylets, and tip. 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. 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)

145. 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 shown in the annotated figure below, the deployed filaments (1622) extend outwardly around the tip (1614). Ex-1010, ¶0142, 0146. 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.

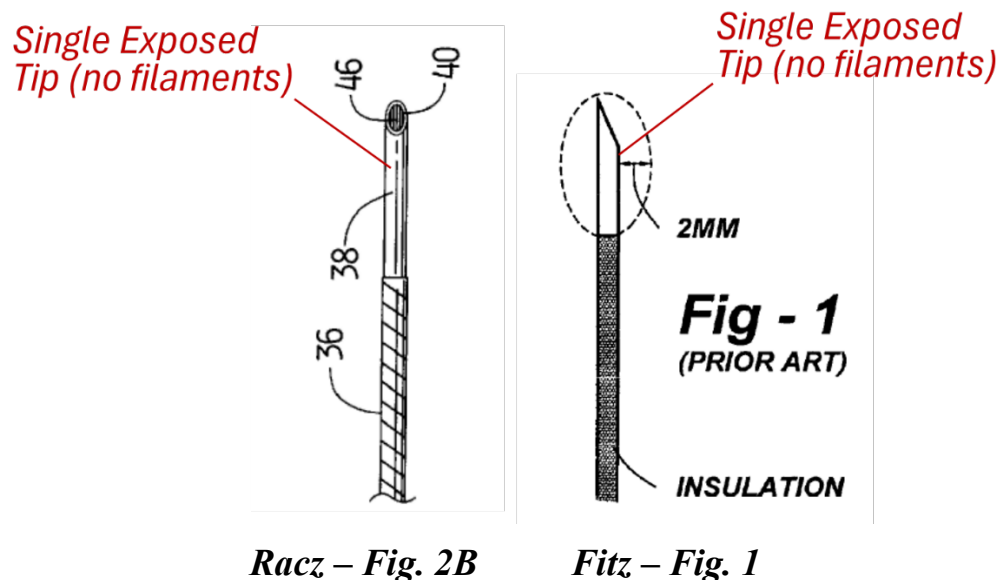
146. Considering Racz, Fitz, and Lee together, it is my opinion that a POSA would have been motivated to implement deployable filaments on the distal tip (14/38) of Racz's electrode cannula (10/33). As I explained above, Fitz and Lee disclose a technique for solving the problem of inadequate coverage in single-tip RF ablation devices: providing deployable filaments at a distal tip to expand and control the ablation volume compared to single-tip devices with inadequate energy coverage. Ex-1011, ¶0009-0010, Abstract; Ex-1010, ¶0012, 0084, 0123-0131. Thus, a POSA would have recognized that the Fitz/Lee technique would improve the energy coverage area of Racz's single-tip device.

147. In my opinion, several factors would have motivated a POSA to combine the references. Racz discloses a conventional RF neurotomy needle with a removable electrical probe. Ex-1009, 1:43-54, 5:37-51. The Racz RF neurotomy needle is characterized by an elongated cannula (10/33) having a single exposed tip (14/38) for generating radiofrequency lesions. Ex-1009, 2:46-56, 3:60 to 4:23, 5:41-51, 8:10-22. Indeed, single-tip RF neurotomy needles with removable electrical probes were generally well-known at the time of Racz's filing in 1998, including the single-tip needle in the Cosman '542 reference that I discuss in the background §II.D.1 herein. Ex-1009, 1:43-54.⁴

148. 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. According to Fitz, single-tip RF neurotomy needles produce lesions that "extend[] only a few millimeters" from the exposed needle tip, which often requires creating multiple lesions to achieve adequate coverage. Ex-1011, ¶0004-0005. Fitz therefore teaches a POSA that this limited coverage problem would be present in Racz's device due to its

⁴ At the time of its filing, Racz characterized the advancement of its disclosed needle as the bent shape of its distal tip (38). Ex-1009, 2:46-56, 9:1-6.

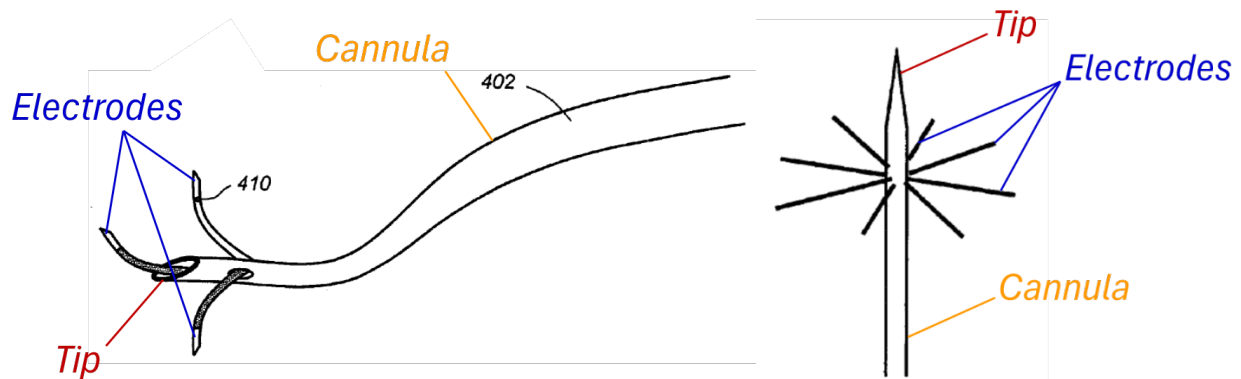
single-tip configuration (see comparison below). Ex-1011, ¶0004, 0012, 0017. Fitz attributed the inadequate coverage problem specifically to single-tip RF neurotomy needles like those disclosed in Racz.



149. Fitz also teaches a solution to this problem: providing a deployable set of electrodes on the exposed distal tip. Ex-1011, ¶0009, Abstract. The deployable electrodes may be made from a “shape-memory alloy” and can be configured to be deployed outwardly from the distal tip of a cannula “to an area to be treated.” Ex-1011, ¶0009-0010, 0018-0021, Abstract. For example, the electrodes may be “deployed through the tip and/or multiple side ports” (as shown in Fig. 4) or exclusively through “side ports to form an array of electrodes once deployed” (as shown in Fig. 5). Ex-1011, ¶0020-0021, Figs. 4-5.

150. Fitz would have accordingly motivated a POSA to solve the limited energy coverage problem in Racz’s device by providing deployable electrodes on

Racz's exposed tip (14/38). Ex-1011, ¶0009, Abstract. 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)

151. 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). 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). Thus, it is my opinion that Fitz would have motivated a POSA to add deployable electrodes to the distal tip (14/38) of Racz's cannula (10/33).

152. 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 to combine the references. For example, Lee discloses that its filaments (22/1622) "define an ablation volume in the target tissue" as "the destruction of target tissue [occurs] at the site where the electrodes are located." Ex-1010, ¶0012, 0084. As a result, "variations in ablation volume" may be achieved by controlling the number of filaments (22/1622) used as well as their length, direction, and arrangement. Ex-1010, ¶0123-0131, 0084. Indeed, the "arrangement of [filaments] may ... form any desired pattern" (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). Thus, a POSA would understand from Lee the relationship between the configuration of the filaments and the shape/size lesion created. From this relationship a POSA would be motivated to use filaments in

radiofrequency ablation devices to control the shape and/or size of the lesions created by the device.

153. In sum, Lee would have confirmed to a POSA that providing deployable filaments (e.g., stylets (22/1622)) at the distal tip of an ablation device can be used to not only to expand the ablation volume but to precisely control the size and shape of the ablation volume. For at least these reasons, a POSA would have been further motivated by Lee to add deployable filaments to the distal tip (14/38) of Racz's cannula (10/33) to not just expand—*but also control*—the ablation volume generated by Racz's device.

154. Lee also would have taught a POSA that deployable filaments (22/1622) could be easily implemented on the distal tip (14/38) of Racz's cannula (10/33). As explained above (*supra* §VII.A.3), Lee discloses that 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. So a POSA would have understood that Lee's deployable filaments (22/1622) could be arranged to accommodate Racz's centrally located removable probe (22/52) (e.g., in the same way they are arranged to accommodate Lee's central filament).

155. 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. It is also my opinion that this would have confirmed to a POSA that Lee's perimeter filaments could be configured to both physically contact Racz's active tip (14/38) and be deployed outwardly around Racz's active tip (14/38). A POSA would therefore understand that this physical contact would electrically connect the filaments and tip and thereby cause Lee's perimeter filaments (22/1622) to join Racz's existing monopolar tip (14/38) in functioning together as a single monopolar electrode.

156. I also note that Lee discloses “anchors” in addition to stylets. The “disclosed anchor systems allow the operator to stabilize the delivery device prior to deployment or withdrawal of the electrodes.” Ex-1010, ¶¶0089. In some embodiments disclosed by Lee, the anchors are configured so that they can be used for ablation. Ex-1010, ¶¶0023. But Lee explains that that “there are circumstances where the anchors might not be applied at all,” and “anchoring functions may also be performed by ablation stylets.” Ex-1010, ¶¶0090. So, a POSA would understand from Lee that Lee's anchors are merely optional features. A POSA looking at the combined teachings of Lee (and Fitz) and Racz would understand that the stylets (i.e., filaments, as explained above) disclosed by Lee are the *primary feature* for controlling the volume of ablation.

157. 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.

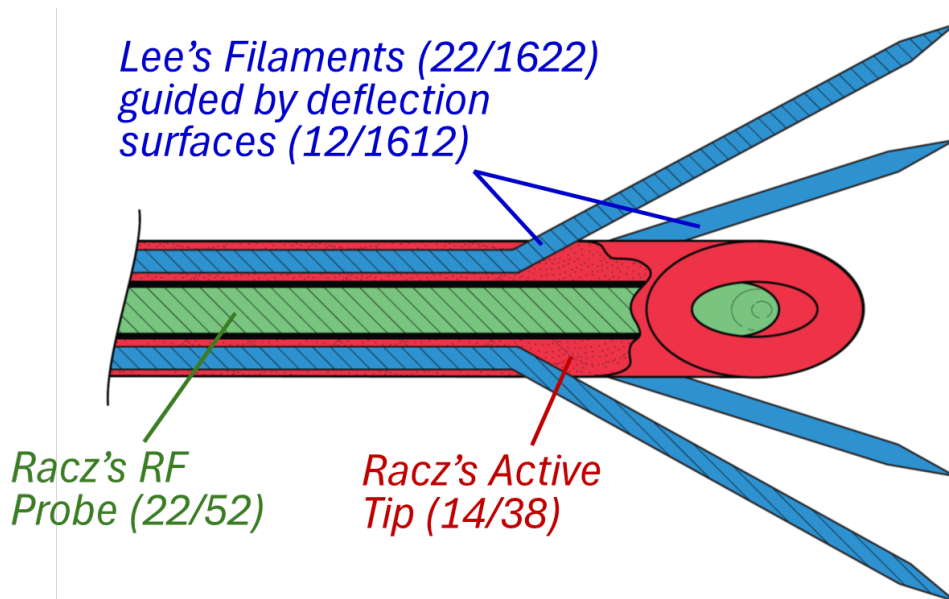


Illustration of an example modification of Racz (showing one example of how a POSA would modify Racz to include Lee's filaments)

158. In the modified version of Racz's device, a POSA would have implemented 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). 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). Below, I provide two examples of how incorporating Lee's deployable filaments (22/1622) as monopolar electrodes at Racz's distal tip (14/38) would have been a matter of routine engineering within the skill of a POSA.

159. As a first example, it is my opinion that a POSA would be able to define channels (as disclosed in Lee) as an integral part of Racz's cannula and dimension the channels to accommodate Lee's filaments. A POSA would understand from Lee's disclosure of channels and ramps within a tip (14), that such channels could be formed within the tip of Racz's cannula. Doing so would merely require recognizing that the channels and ramps defined on Lee's tip could be formed as an integral part of Racz's tip, and therefore that the channels would be part of Racz's cannula. Forming channels in Racz's cannula with an integral tip would only be an application of the ordinary skill of a POSA. Moreover, I note that Lee shows how its perimeter filaments can be arranged around a central element

(Lee's central filament). *Supra* § VII.A.3. A POSA would have been motivated to preserve the functionality of Racz's probe (22/52) would therefore have provided the channels for guiding the deployable filaments (22/1622) around the lumen that receives the RF probe (22/52) (e.g., a similar way to how the perimeter channels and filaments are arranged to accommodate Lee's central filament).

160. I also note that a 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. While the Challenged Claims do not recite a specific size for the claimed needle, adjusting the sizes of the cannula, tip, filaments, and channels to operate together would have been a matter of routine engineering for a POSA. For example, I note that Racz teaches that a POSA would "recognize that many variations" of "geometries" and sizes could be used and were within the level of skill in the art. Ex-1009 8:10-22 (teaching a range of sizes of cannulas used in neurotomy procedures from "small gauges (e.g., 30 gauge) to much larger sizes (e.g., 10 gauge)" as well as that the "shape of the tip and the extent of insulation vs. exposed electrode can be variable, depending on the application).⁵

⁵ I note that, according to the standard ISO 6009, 10-gauge needles have an outer diameter of approximately 3.4mm and 30-gauge needles have an outer diameter of approximately 0.31mm.

And a POSA would have known that filament electrodes used in the art were of sizes that could be easily accommodated by Racz's cannula (including preserving space for the removable RF probe (22/52)). *See e.g.*, Ex-1012, ¶0030 (discussing filament electrodes Young '965's as small as 0.2mm (wide) and 0.05mm (thick). Based on this teaching, a POSA would understand the size of the cannula could be varied across a wide range of gauges to accommodate different sizes of filaments in channels formed integrally with the cannula, and to preserve the functionality of Racz's probe.

161. As a second example, it is also my opinion that a POSA would also have been able to implement the combination of Racz and Lee using a separate tip defining channels (as disclosed in Lee). Ex-1010, ¶0012, 0016, 0018, 0022, 0087, 0092, 0142. The decision to form the channels for filaments in a separate tip attached to the cannula would also have been a matter of routine engineering in the same way that making the tip integrated to the cannula would be. For example, Lee discloses that its tip mandrel can be made from metal, define channels and deflection surfaces, and be attached to a cannula. Ex-1010, ¶0025, 0051, 0118, 0119. Because Racz discloses that its tip (14/38) is active, a POSA would have secured Lee's tip to the end of the cannula in a way that would electrically connect the tip to the cannula's shaft (and the removable probe and the deployable filaments). *See* Ex-1010, ¶0119 (a POSA would simply not include the insulating

plastic annular member 813). Forming an electrical connection between conductive materials by touching them together is a matter of routine engineering that would be within the skill of a POSA. In view of Lee's teachings, a POSA would have had a reasonable expectation of success in defining channels to guide deployable filaments on a separate tip secured to the cannula (as disclosed in Lee) and configuring the tip to be conductive and engage the removable RF probe (as disclosed in Racz).

162. As I explained below with respect to Claim 1's limitations, in my opinion, 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. The resulting device (Racz's cannula modified to include Lee's filaments) would include every limitation of Claims 1-27.

C. Ground A: Independent Claim 1

1. Racz discloses the preamble [1pre] and limitations [1a]-[1e], [1h], [1i], and [1k]

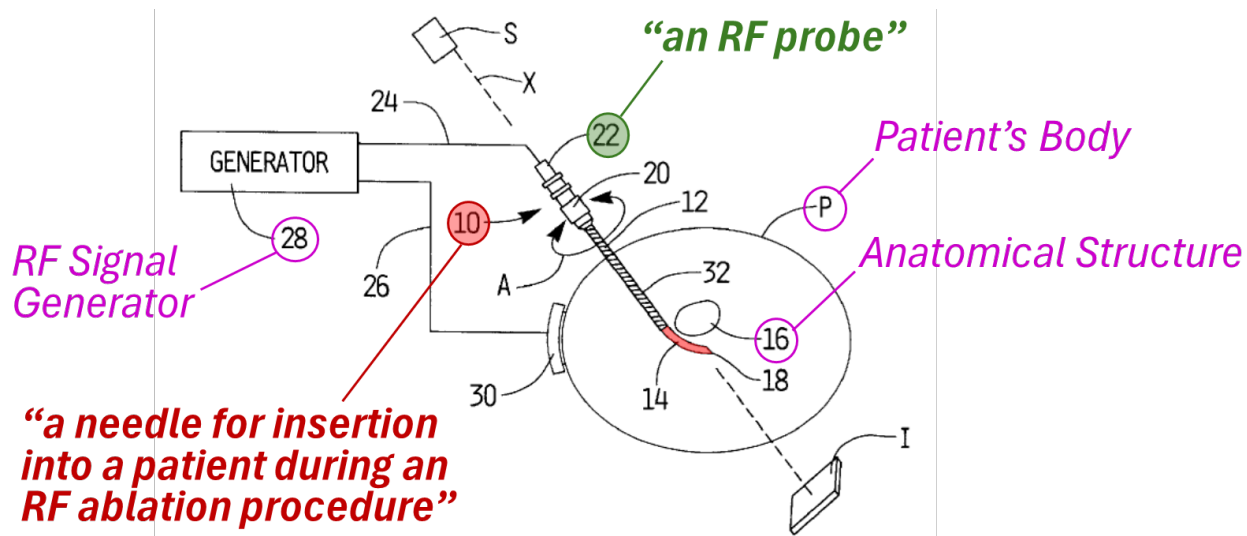
a. [1pre]

163. Claim 1's preamble recites "a system" ([1pre]). Although the preamble is not limiting, Racz is directed to a "a system for pain relief." Ex-1009, 1:4-9, 2:46-65. Thus, Racz discloses [1pre].

b. [1a] and [1b]

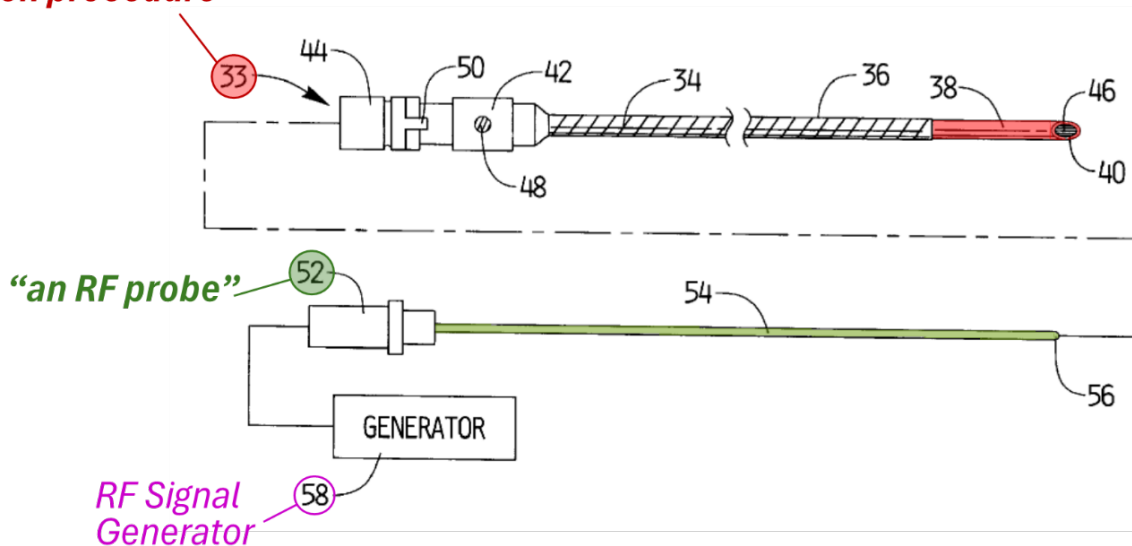
164. Claim 1 recites that its system includes “an RF Probe” ([1a]) and “a needle for insertion into a patient during an RF ablation procedure” ([1b]). As shown in Figure 1, Racz discloses that its system includes an RF electrode cannula (10/33) configured to receive a removable electrical probe (22/52) (**shaded green**). Ex-1009, 3:38-45, 3:60-65, 4:59-62, 5:7-51, Figs. 1, 2A/B. The probe (22/52) is connected to a signal generator (28), which provides “pulsed radio-frequency output ... or other electrical waveforms” (i.e., RF energy). Ex-1009, 2:53-56, 3:66 to 4:20, 5:38-45, 6:4-7, 7:43-50. The probe (22/52) conveys this RF energy to the cannula’s tip (14/38). Ex-1009, 4:18-23, 4:1-3. Thus, Racz’s probe (22/52) is “an RF Probe” ([1a]).

165. As shown in annotated Racz Figs. 1 and 2A below, Racz’s cannula (10/33) is an “electrical needle” (or “spinal needle”) configured to deliver “electrical stimulation pulses or high-frequency signals to the vicinity of a neural structure.” Ex-1009, 1:4-10, 2:46-65, 3:24-26, 4:59-62, 5:35-45, 6:38-45, 6:59 to 7:10. With the probe (22/52) inserted, the cannula (10/33) can be used to generate “radio-frequency heat lesions” via the exposed tip (14/38) (**shaded red**) and thereby “modify or coagulate” nerves along a patient’s spine. Ex-1009, 4:49-58, 7:43-50. Thus, Racz’s electrode cannula (10/33) is a “a needle for insertion into a patient during an RF ablation procedure” ([1b]).



Racz – Fig. 1 (annotated to show [1a] and [1b])

“a needle for insertion into a patient during an RF ablation procedure”



Racz – Fig. 2B (annotated to show [1a] and [1b])

c. [1c] and [1d]

166. Claim 1 recites that its radiofrequency neurotomy needle comprises “a hub” ([1c]) and “an elongate member fixed to the hub, the elongate member comprising a lumen at an interior thereof” ([1d]). The proximal end of Racz’s

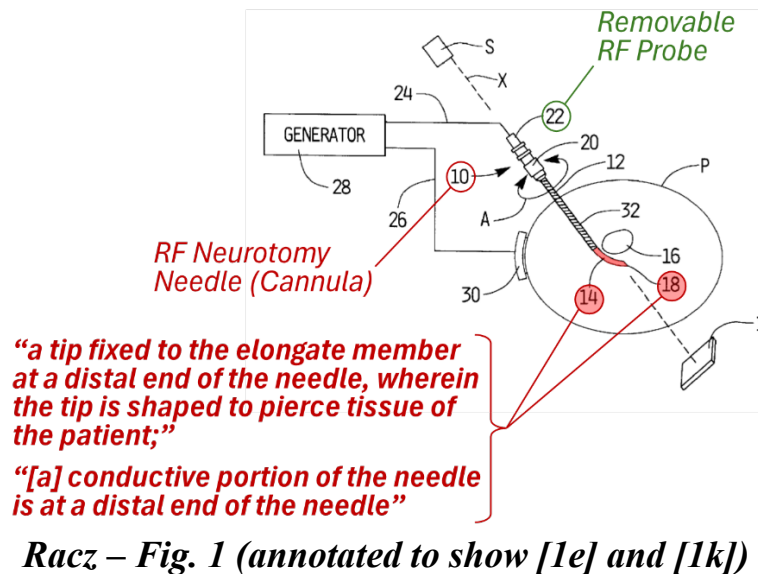
cannula (10/33) includes a “hub” (20/42/70) that is fixed to cannula’s shaft (12/34). Ex-1009, 3:59-4:3, 5:5-20, 5:66-6:17, 9:44-48. In particular, the hub (20/42/70) is “capable of accommodating an electrical probe 22, which includes a segment that is inserted into and received by the shaft 12 of the cannula 10.” Ex-1009, 3:59-65. Thus, in my opinion, Racz’s cannula (10/33) includes “a hub” [1c].

167. I note that Racz’s cannula (10/33) is also “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) 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, a POSA would understand that Racz’s shaft (12/34) is “an elongate member fixed to the hub, the elongate member comprising a lumen at an interior thereof” as recited in [1e]. Annotated versions of Racz Figs. 1 and 2B, below, highlight this configuration disclosed by Racz.

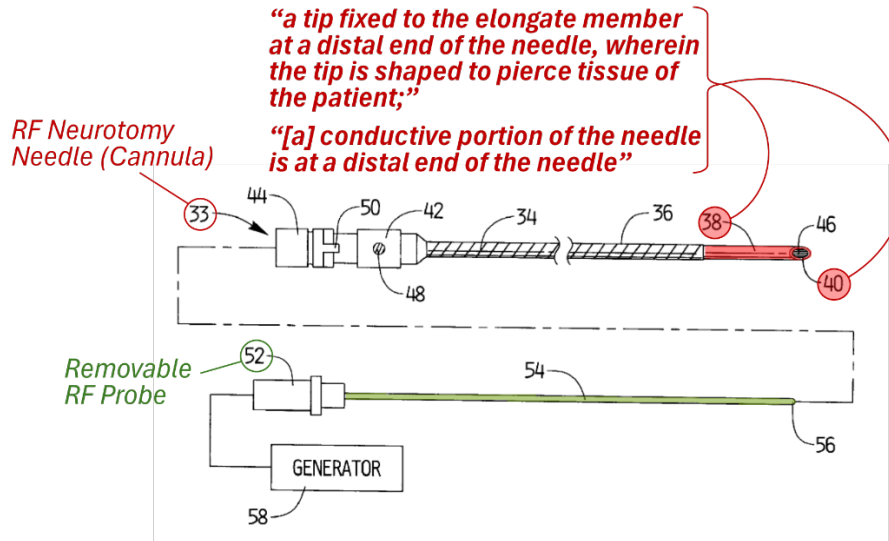
the patient” ([1e]) and “wherein the conductive portion of the needle is at a distal end of the needle” ([1f]). Racz also teaches that the exposed tip (14/38) can define a “self-penetrating point” (18/40). Ex-1009, 3:47-51, 1:28-30, 3:4-7, 5:3-5, 5:31-34. This allows the cannula (10/33) to be “inserted directly through the skin of the body portion P” and to penetrate “tough tissue near hard, bony structures.” Ex-1009, 3:42-45, 3:4-18, 5:3-5, 6:54-58, 5:31-34, Fig. 1 and 2A/2B. Thus, Racz’s tip (14/38) is “fixed to the elongate member at a distal end of the needle” and “shaped to pierce tissue of the patient” [1e].

169. Racz also discloses that the 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, 5:41-48, Fig. 2B. Thus, a POSA would understand that Racz's tip (14/38) is “[a] conductive portion of the needle [that] is at a distal end of the needle” [1k].⁶



⁶ Claim 12 of the '688 Patent confirms that the elongate member and the tip may “comprise a single unitary structure.” Claims 48-49 confirm that the needle’s “conductive portion” may comprise “the conductive material of the tip.”



Racz – Fig. 2B (annotated to show [1e] and [1k])

e. [1h]

170. The proximal hub (20/42/70) of Racz’s cannula is a fitting, such as “a standard hypodermic needle or luer type hub, capable of connection to stylets, electrical probes, syringes, or injection tubes.” Ex-1009, 5:66 to 6:7. The hub/fitting (20/42/70) 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. Thus, it is my opinion that Racz’s device includes “a fitting in fluid communication with the lumen, the fitting being configured to provide a connection for injection of fluid through the fitting and through the lumen” [1h].

171. In addition to receiving fluid from a fluid source, Racz’s hub/fitting (20/42/70) is also configured for receiving the probe (22/52) (for transmitting RF energy). Ex-1009, 3:59-65, 5:14-18, 6:9-12, 1:29-33, 5:66 to 6:7, 9:30-39, 10:8-10.

Thus, it is my opinion that Racz's fitting is further "configured to allow for insertion of the RF probe into the lumen through the fitting" [1h].

f. [1i]

172. When Racz's probe (22/52) is "inserted into and received by the shaft 12 of the cannula 10," the "physical relationship between the probe 22 and the shaft 12 facilitates electrical contact between the two elements." 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 (emphasis added).

173. 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. 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, 8:58-62.⁷ A POSA would recognize that the probe's temperature sensor could not accurately measure the tissue temperature if the probe's tip (56) were not positioned at the cannula's tip (14/38) when the probe (22/52) is inserted.

174. Because 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. As the electrical probe's shaft (54) has a uniform profile and extends the full length of the cannula shaft (12/34), a POSA would understand that the probe (22/52) would necessarily contact the shaft (12/34) along its full length (including the tip (14/38)). Thus, it is my opinion that when Racz's RF probe (22/52) is inserted into the shaft (12/34) ("the lumen at the interior of the elongate member"), the RF probe will "physically contact a conductive portion of the needle" [1i].

⁷ See also Ex-1011, ¶0003 (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").

2. Racz as modified in view of Fitz and Lee discloses limitations [1f], [1g], [1j], and [1l]

175. For the reasons explained above, it is my opinion that 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* § VII.B("Motivation to Combine"). Furthermore, it is also my opinion that 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* § VII.C.2.a. 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 [1f], [1g], [1j], and [1l] as I describe below (and, as I described above, the features of [1a]-[1e], [1h], [1i], and [1k]).

a. [1f] and [1j]

176. Claim 1 recites that its radiofrequency neurotomy needle comprises "a plurality of filaments;" ([1f]) and that physical contact between the probe and lumen "thereby electrically connect the RF probe to the tip and the plurality of filaments, such that energy emitted by the RF probe passes through the tip and the plurality of filaments, and such that the RF probe, the tip, and the plurality of filaments operate together as a single monopolar RF electrode," ([1j]).

177. 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 [1f], [1j] and are therefore referred to herein as “filaments (22/1622).” In §VII.A.3 (Overview of Lee) above, I further explain why a POSA would understand that the stylets/electrodes of Lee are “filaments.”

178. 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:

(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* § VII.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* § VII.A.3);

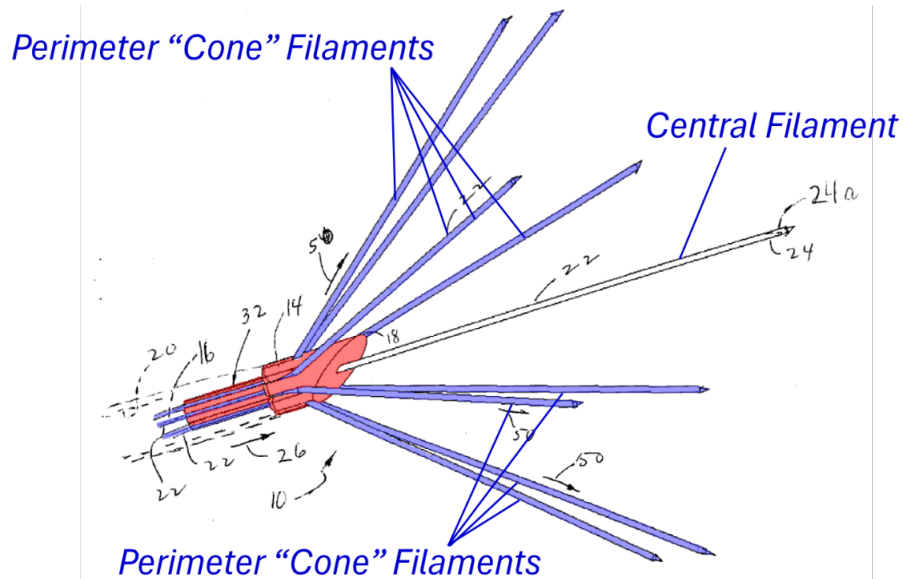
(vii) when deployed, Lee's perimeter filaments (22/1622) extend outwardly and around the cannula's tip in a "cone" shape (Ex-1010, ¶0103, Figs. 1, 5, 48-49);

(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

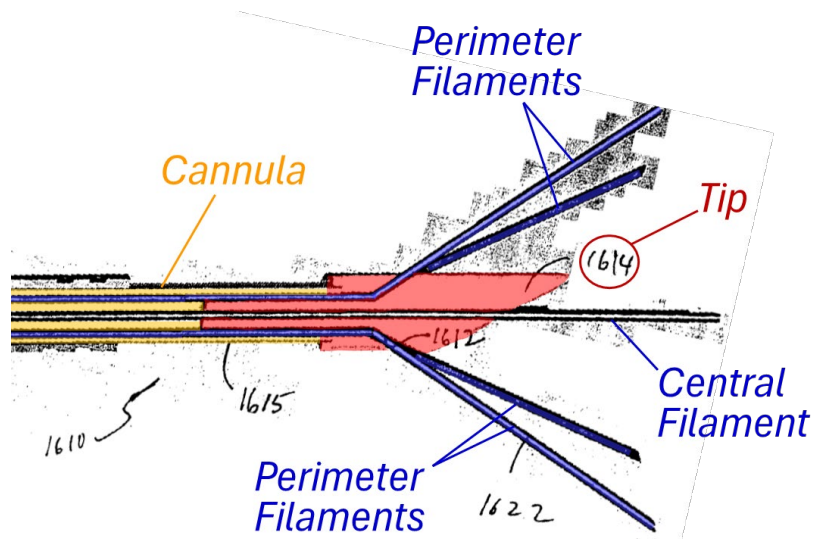
(ix) "variations in ablation volume may be achieved by varying the extent to which [filaments] are extended from the distal end of the trocar and the direction in which [filaments] extend" and that "the arrangement of [filaments] may ... form any desired pattern" (Ex-1010, ¶0123-0131, 0084, 0103).

179. In view of these teachings in Racz and Lee, as well as the teachings of the other prior art cited in the Background section above (specifically §II.D.5, discussing known “deployable electrodes”), it is my opinion that 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. 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 supra* § VII.B (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 as the unshaded central filament in annotated Figs. 1 and 49 of Lee). Ex-1009, 3:60-63, 4:18-23 (describing the tip (14/38) as an active electrode). Thus, a POSA would have been motivated to implement a plurality of 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. As Lee (and Fitz)

confirm, this would improve Racz's device by providing an expanded and controlled energy coverage area. The annotated versions of Lee Figs. 1 and 49 below show arrangements of perimeter filaments with the unshaded central filament.



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



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

180. 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. It also would have been obvious to provide openings in Racz's distal tip (14/38) (e.g., in communication with the internal deflection surfaces as disclosed in Lee) such that Lee's perimeter filaments (22/1622) can—when deployed—exit Racz's distal tip (14/38). Ex-1010, ¶¶0092, 0102.

181. 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) according to ordinary engineering principles. Ex-1010, ¶¶0091, 0092, 0098, 0102; *see supra* § VII.B. 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* § VII.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). In

short, a POSA would have recognized that by implementing Lee's perimeter filaments around the internal perimeter of Racz's cannula, the "internal lumen" of Racz's cannula would be preserved. Thus, a POSA would therefore understand that the functionality of Racz's electrical probe (22/52) (which is needed to transmit RF energy) would be preserved in the modification of Racz.

182. Thus, in Racz's device modified to include Lee's perimeter filaments (22/1622), Racz's probe (22/52) would "electrically connect the RF probe to the tip and the plurality of filaments, such that energy emitted by the RF probe passes through the tip and the plurality of filaments" as recited in [1j]. This would be true both when the perimeter filaments (22/1622) are in a "deployed position" and a "retracted position."

183. Although the filaments (22/1622) could be implemented in a variety of ways, I have described two examples of how the filaments could be implemented in § VII.B, above. The figure showing the 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) is reproduced below. As I also explained above, it is my opinion that Lee's deflection surfaces (channels and ramps) could have been easily formed as an integral portion of Racz's distal tip (14/38) (e.g., by defining internal channels and

Channels and ramps defined as deflection surfaces (12/1612) within Racz's tip (14/38) to guide the filaments (22/1622) in/out of the cannula

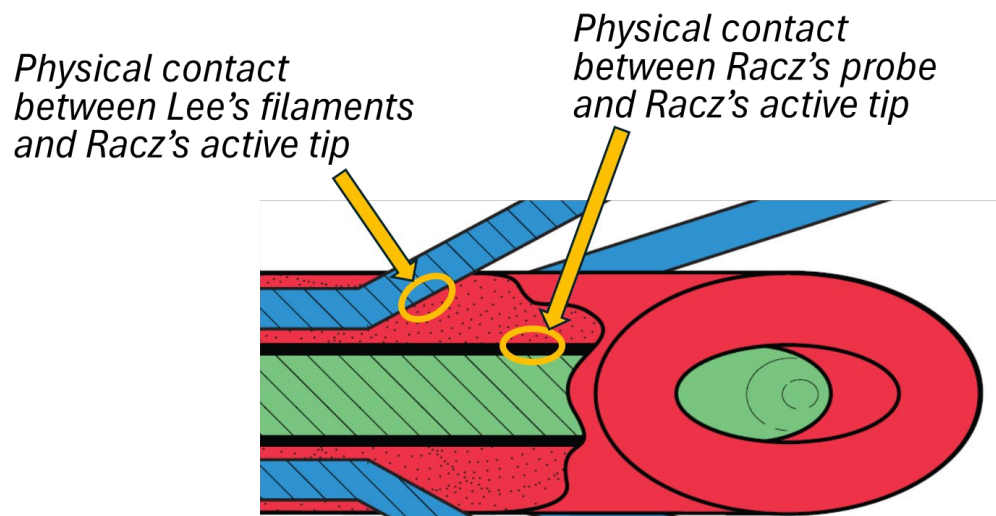
Lee's Filaments (22/1622)

Racz's RF Probe (22/52)

Racz's Tip (14/38)

184. 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. When Racz's exposed distal tip (14/38) is modified to include deflection surfaces (channels and ramps), the tip's deflection surfaces would physically contact the filaments (22/1622) to guide them as they are deployed and retracted from Racz's cannula. The below figure shows a magnified section of that example modified version of Racz, with annotations provided showing where a POSA would understand physical contact would occur in the combination.



Magnified and annotated view of the example modification of Racz

185. 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. Racz explains that the "physical relationship between the probe 22 and the shaft 12 facilitates electrical contact

between the two elements.” Racz, 3:63-65. A POSA would recognize from Racz (as well as common engineering and physics principles) that RF energy inherently flows between physically contacting conductive materials. In other words, a POSA would understand that physical contact between conductive materials creates an electrical connection between those materials. So a POSA would understand that physical contact could be used to create an electrical connection between elements of the device. Specifically, in the modified Racz, a POSA would understand that 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).

186. For at least these reasons, it is my opinion that Racz’s cannula (10/33)—as modified by a POSA to include Lee’s perimeter filaments (22/1622)—would include “a plurality of filaments” [1f] and be configured such that the RF probe (22/52) physically contacts a conductive portion of the needle to “thereby electrically connect the RF probe to the tip and the plurality of filaments, such that energy emitted by the RF probe passes through the tip and the plurality of filaments” [1j].

187. The additional limitations in [1j] relating to the tip (14/38) and filaments (22/1622) operating together as a single monopolar electrode also would

have been obvious. In Racz's modified device, it is my opinion that 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. 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, the POSA would understand that Racz's distal tip (14/38) would already have been configured as a monopolar electrode. 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.

188. Additionally, it is my opinion that 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. 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.

189. In my opinion, a POSA also would have had a reasonable expectation of success in implementing this configuration. To start, 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. And both monopolar and bipolar configurations of electrodes and radiofrequency generators were well-known in the art, as described in §II.D.6. In particular, Lee explains that “electrodes may be used in a monopolar fashion with the ablation stylets excited with RF energy and a return electrode being applied usually in the form of a conductive pad in contact with a remote surface on the patient.” Ex-1010, ¶0024. Likewise, Racz’s configuration includes “a first electrical connection 24 couples the cannula 10 to an external signal generator 28” and “a second electrical connection 26 connects the external signal generator 28 to a reference electrode 30 in contact with the patient’s body.” Ex-1009, 4:1-5. A POSA would understand Racz’s “reference electrode” and Lee’s “conductive pad” to both by types of grounding pads used in monopolar systems (as opposed to a bipolar system where both poles are coupled to ablation electrodes, as described in § II.D.6). Thus, a POSA would understand Racz’s configuration with one pole coupled to the cannula and the other pole coupled to a “reference electrode” to be a monopolar configuration like Lee’s configuration where the stylets are energized with RF energy and a “conductive pad” attached to the patient. In implementing Lee’s filaments (22/1622) to expand and control the

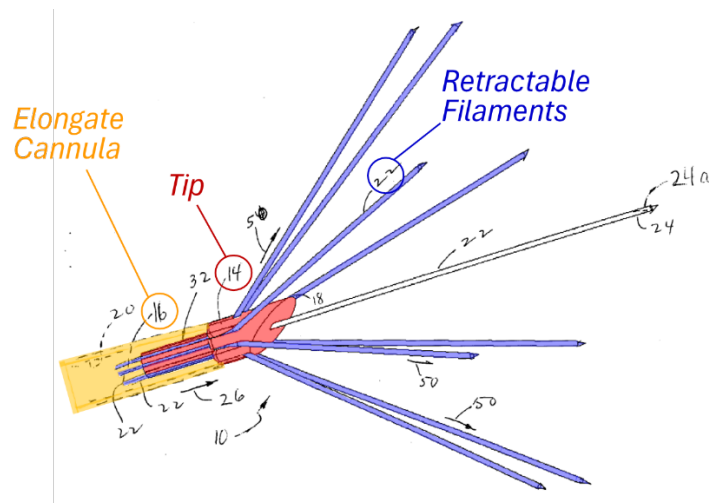
ablation volume of Racz's device, a POSA would have had no reason to deviate from Racz's monopolar configuration and would have been motivated to electrically connect Lee's filaments (22/1622) to function as a single monopolar electrode with Racz's tip (14/38). Moreover, coupling an electrode in a monopolar mode would be a matter of routine engineering for a POSA, in light of the teachings of Racz and Lee explaining how signal generators known in the art can be coupled in monopolar modes. *See also* § II.D.6 (reviewing other art in the field teaching RF needles with monopolar configurations). For the reasons explained above, Racz's device—as modified by a POSA in view of Fitz and Lee—would be configured “such that the RF probe, the tip, and the plurality of filaments operate together as a single monopolar RF electrode” as further recited in [1j].

b. [1g] and [1l]

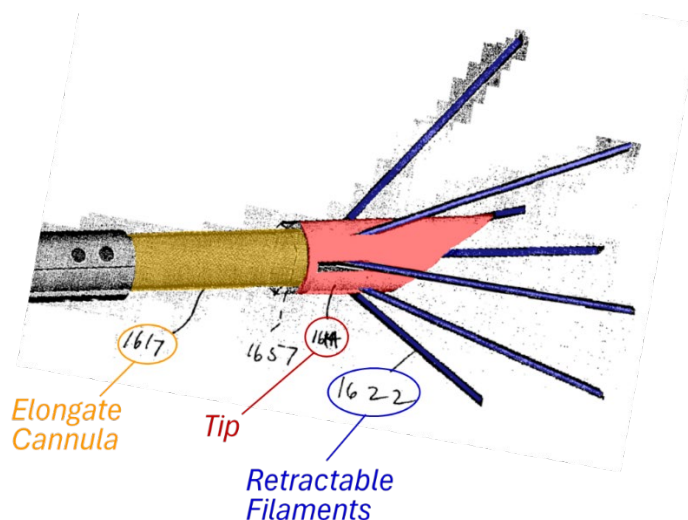
190. Claim 1 recites further that “wherein, when the RF probe is fully separated from the needle in a non-inserted state, such that none of the RF probe is within the needle, the plurality of filaments are movable via the actuator from the retracted position, in which the plurality of filaments are disposed within said at least a portion of the elongate member, to the deployed position.” ([1l]) and that the radiofrequency neurotomy needle comprises “an actuator interconnected to the plurality of filaments, wherein movement of the actuator in a first direction relative to the hub moves the plurality of filaments relative to the tip to a deployed position”

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

191. Lee discloses that its perimeter filaments (22/1622) are configured to be adjusted between a deployed position (where the filaments extend outwardly from the cannula to define the ablation volume) and a withdrawn position (where 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. Thus, it would have been obvious to a POSA modifying Racz’s electrode cannula (10/33) to include Lee’s perimeter filaments (22/1622) would have configured the filaments to be “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” ([1g]). As shown in the annotated illustration of Lee Fig. 1 and Fig. 48, Lee illustrates how its filaments (22/1622) extend beyond the tip of its device.



Lee – Fig. 1 (annotated)



Lee – Figure 48 (annotated)

192. Thus, it is my opinion that 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 distally beyond the tip (14/38) in a deployed configuration (e.g., to expand the ablation volume of Racz’s device) and to be positioned within the shaft (12/34) in a withdrawn configuration (e.g., to enable effective withdrawal and insertion of Racz’s modified device).

193. To adjust the filaments (22/1622) between the deployed and withdrawn positions, Lee discloses that its perimeter filaments (22/1622) “may be connected to suitable advancement and retraction mechanisms” (i.e., an actuator). Ex-1010, ¶0106. Lee also notes that “[s]uch mechanisms may be of a conventional design.” Ex-1010, ¶0106. In selecting an actuator to use for deployment and retraction of Lee’s filaments (22/1622) from Racz’s tip (14/38), a POSA would have identified an actuator that would not obstruct Racz’s central lumen. In particular, a POSA would have selected an actuator that would preserve the functionality of Racz’s removable RF probe (22/52) and allow space for the probe to be inserted and removed from Racz’s cannula (10/33). A POSA would have been aware of a variety of conventional actuators that would provide this functionality, such as rotational actuators (e.g., actuators configured to advance and retract the filaments linearly through the cannula (10/33) in response to rotational motion of the actuator around the longitudinal axis of the cannula (10/33). *See supra* ¶¶77-78. In my opinion, 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). Moreover, as Racz’s hub (20/42/70) is fixed to the cannula’s shaft (12/34) and the filaments (22/1622) must move relative to the shaft (12/34) to be

withdrawn/retracted, movement of the actuator to adjust the filaments (22/1622) would necessarily be in first/second direction relative to the hub (20/42/70).

194. Accordingly, in view of Lee's teachings, it is my opinion that a POSA modifying Racz's cannula (10/33) to include Lee's perimeter filaments (22/1622) would have been motivated (and would have found it obvious) to implement "an actuator" (i.e., a suitable advancement and retraction mechanism) that is "interconnected to the plurality of filaments, wherein movement of the actuator in a first direction relative to the hub moves the plurality of filaments relative to the tip to a deployed position distally beyond the tip, and wherein movement of the actuator in a second direction relative to the hub retracts the plurality of filaments to a retracted position in which the plurality of filaments are disposed within at least a portion of the elongate member" [1g].

195. As explained with respect to [1f] and [1j], it is also my opinion that a POSA would have implemented Lee's filaments (22/1622) in Racz's device by arranging the perimeter filaments, channels, and ramps around the inner perimeter of Racz's cannula (10/33) for the purpose of not obstructing the interior lumen of Racz's shaft (12/34). *Supra* § VII.C.2.a. This would preserve the functionality of Racz's electrical probe (22/52), which is needed to transmit RF energy to Racz's tip (14/38). *Supra* § VII.A.1. In this configuration, Racz's probe (22/52) would be insertable (and withdrawable) from the cannula (10/33) without interfering with

filaments (22/1622) or their associated actuator. Thus, regardless of whether the probe (22/52) is in an inserted or non-inserted state, a POSA would understand that in Racz's modified device, the filaments (22/1622) would be adjustable between their deployed position and retracted position.

196. Accordingly, in my opinion, a POSA modifying Racz's cannula (10/33) to include Lee's perimeter filaments (22/1622) would have configured the filaments (22/1622) and probe (22/52) such that "when the RF probe is fully separated from the needle in a non-inserted state, such that none of the RF probe is within the needle, the plurality of filaments are movable via the actuator from the retracted position, in which the plurality of filaments are disposed within said at least a portion of the elongate member, to the deployed position" [11].

197. For at least these reasons, in my opinion Claim 1 is obvious in view of Racz, Fitz, and Lee.

D. Ground A: Claims 6-8

198. **Claim 6.** 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. Therefore it is my opinion that a POSA would understand that Racz's "tip comprises a fluid port in fluid communication with the lumen such that an anesthetic and/or an image enhancing dye may be introduced

into a region around the tip through the fluid port” [6]. Claim 6 is therefore obvious in view of Racz, Fitz, and Lee.

199. **Claim 7.** Lee discloses that deployable filaments were known to be “preformed with a curved configuration which they assume after exiting a sharp trocar-tipped catheter.” Ex-1010, ¶0007.⁸ Lee also claims an ablation device in which some filaments (aka “stylets”) are “deformed into a curved configuration.” Ex-1010, Claim 33. According to Lee, “[v]arious shape ablation may be defined by varying the configuration of the curves which are preformed into the various springy antennae” (i.e., filaments). Ex-1010, ¶0007. Thus, in my opinion, a POSA would have appreciated that configuring Lee’s filaments (22/1622) to have a preformed curved shape would allow the filaments (22/1622) to extend to desired ablation areas relative to the position of Racz’s tip (14/38) (e.g., ablation areas that would not be reached by a straight filament).

⁸ I note that Lee suggests using “straight electrodes” due to their “greater column strength” in some instances, but that this is limited to uses for penetrating “tough fibroid tumor tissue” and a POSA would understand that the higher column strength of straight electrodes would be unnecessary for other applications including RF neurotomy. Ex-1010, ¶0008, 0087.

200. Additionally, I note that Fitz confirms that deployable filaments used for RF neurotomy may be “constructed of a shape-memory material to control deployment” and enhance directionally and navigation. Ex-1011, ¶0010, 0018-0019; *see also* Ex-1010, ¶0087, 0092. I also note that Fitz illustrates deployable filaments having a curved shape in Figs. 3, 2, and 4. Thus, Fitz would have also confirmed to a POSA that the filaments with a curved profile (preformed using a shape-memory alloy) would be effective for RF neurotomy.

201. Accordingly, in my opinion, a POSA would have found it obvious to configure each of Lee’s filaments (22/1622) deployed from Racz’s tip (14/38) to have “a pre-set bias such that the filament is curved when in the deployed state” [7]. Claim 7 is therefore obvious in view of Racz, Fitz, and Lee.

202. **Claim 8.** As I explained for Claim 1, a POSA would have found it obvious to implement Lee’s filaments (22/1622) at Racz’s tip (14/38) such that—when deployed—the filaments extend outwardly from and beyond the tip (14/38). *Supra* § VII.C.2.b; Ex-1010, ¶0129, Figs. 1, 48, 49. A POSA would understand that extending the filaments outwardly from any beyond the tip would expand Racz’s ablation volume, which I note is the problem Fitz identifies as being present in Racz’s unmodified device. *Supra* § VII.A.2. For these reasons and those I explained above for Claim 1, a POSA would have found it obvious to configure Racz’s modified device such that “when each filament of the plurality of filaments

[22/1622] is in the deployed position, the filaments extend outwardly from the tip [14/38]” [8]. Claim 8 is therefore obvious in view of Racz, Fitz, and Lee

E. Ground A: Claims 9-11

203. **Claim 9.** The location of Lee’s deployed filaments (22/1622) “define[s] an ablation volume in the target tissue.” Ex-1010, ¶0012, 0084, 0123-0131; *see also supra* §II.D.5.c. Moreover, a POSA understood that “variations in ablation volume may be achieved by varying the extent to which [filaments] are extended from the distal end of the trocar and the direction in which stylets extend.” Ex-1010, ¶0129. In my opinion, adjusting the geometry of Lee’s filaments would be a matter of routine engineering for a POSA, who would understand both the physics of RF ablation and the relationship between the filament geometry and the geometry of the lesions caused by the filaments. *Supra* § II.D.5.c. Thus, in my opinion, a POSA would understand that Lee’s filaments (22/1622) can be adjusted (e.g., in length/direction) to define an ablation volume in any desired area relative to the device’s tip.

204. As also explained above, a POSA understood that it was advantageous to use different geometries of needle to treat different anatomical structures (e.g., Racz’s curved needle for contouring the surface of a “bony structure” with nerves at the surface). *Supra* § II.D.3. In many scenarios, a POSA would be motivated to define an ablation volume in an area asymmetrical and offset relative to the central

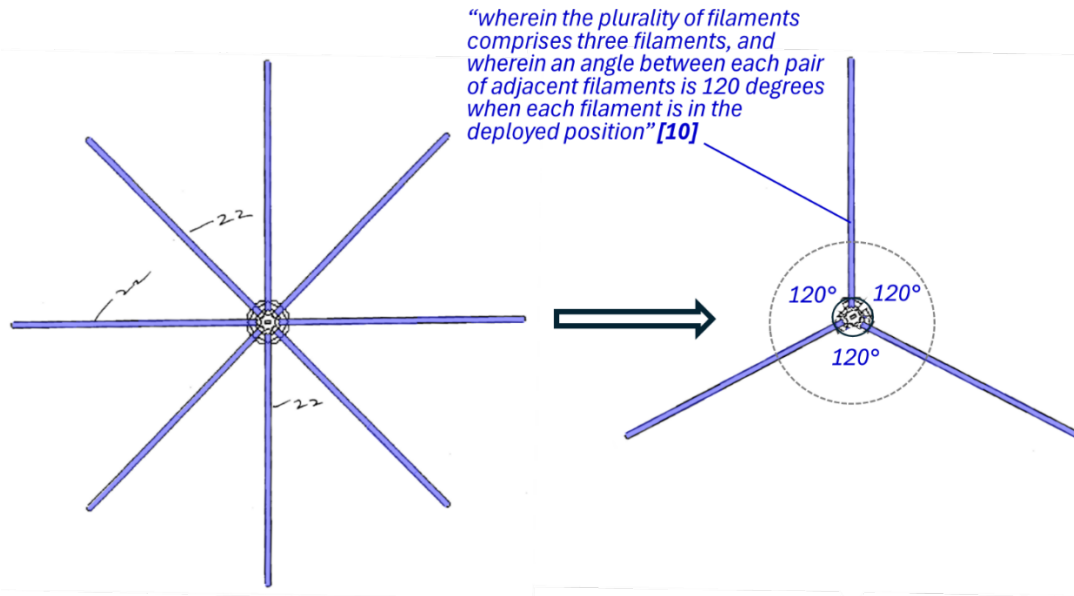
longitudinal axis of Racz's device. This allows the needle to be positioned adjacent/parallel to a nerve and ablate the nerve without damaging the rest of the tissue around the needle. Limiting/focusing the RF ablation is particularly important in the neurotomy context, which can require forming lesions adjacent to a patient's spine. As Racz explains "the uninsulated portion of the tip ... can be made to lie parallel to neural structures.... [t]his configuration is advantageous in those clinical situations in which a radiofrequency heat lesion is to be made on the neural structures, as the uninsulated tip used to generate the lesions conforms better to the target neural structures." Ex-1009, 7:44-50. For example, Racz notes that its tip (14/38) may be configured to apply RF energy "only on one side of the cannula to facilitate directional stimulation or ablation" (e.g., asymmetric relative to the cannula's longitudinal axis). Ex-1009, 8:16-22. Finally, I again note that configuring the shapes of filaments was a matter of routine engineering to a POSA, who understood both that filaments could be directed using features like a "deflection surface" and/or that "[v]arious shape ablation volumes" could be configured by "varying the configuration of the curves" of springy filaments. Ex-1010, ¶7, 87. Thus, in my opinion a POSA would be motivated to configure Racz's device modified with Lee's filaments (22/1622) such that "each filament comprises a distal end, wherein the distal end of each filament defines a point when each filament is in the deployed position, and wherein an average of all the points is

offset from a central longitudinal axis of the elongate member” [9]. Claim 9 is therefore obvious in view of Racz, Fitz, and Lee.

205. **Claims 10 and 11.** In Lee’s Figs. 1 and 5, the filaments (22/1622) are arranged to form a cone-shaped pattern. Ex-1010, ¶0103, Figs. 1 and 5. As I described with reference to claim 9 and § II.D.5.c above, the relationship between electrode geometry and lesion geometry was well understood by a POSA, and the lesion geometry could be adjusted using routing engineering principles to adjust the electrodes to achieve desired lesion geometries. Thus, as the location of the deployed filaments (22/1622) “define[s] an ablation volume in the target tissue,” a POSA would understand that the configuration of filaments (22/1622) in Figs. 1 and 5 would result in a generally conical ablation volume. Ex-1010, ¶0012, 0084, 0123-0131. Moreover, Lee expressly contemplates that “variations in ablation volume” may be achieved by controlling the number of filaments (22/1622) as well as their length, direction, angle, and arrangement. Ex-1010, ¶0012, 0123-0131, 0084. Indeed, the “arrangement of [filaments] may ... form any desired pattern.” Ex-1010, ¶0103; *see also* ¶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”).

206. In view of Lee’s teachings, it is my opinion that a POSA would have found it obvious to provide “three filaments ... [where] an angle between each pair

of adjacent filaments is 120 degrees when each filament is in the deployed position” [10]. A POSA would have adopted this configuration in any scenario where the targeted ablation volume corresponds to this filament configuration. The annotated illustration from Lee helps show how three filaments offset by 120 degrees is simply a matter of routine engineering. The filament arrangement of Lee FIG. 5, on the left, includes eight filaments evenly spaced around the needle tip. As shown on the right, removing 5 of Lee’s filaments, and slightly adjusting the angle of the remaining three to one another, results in the remaining three filaments being separated by 120 degrees. Based on Lee’s teaching that “any number of filaments” can be used in “any desired pattern,” determining to use three filaments in an evenly spaced pattern is simply a matter of routine engineering and well within the skill of a POSA. In sum, this would be a simple design choice to a POSA, involving evenly spacing the three perimeter filaments 120 degrees apart from one another around Racz’s tip (14/38) (e.g., as opposed to the eight evenly spaced filaments (22) shown in Lee’s Figs. 1 and 5). The result would have been entirely predictable—the formation of a lesion defined by the location of the filaments (22/1622). *Supra* § II.D.5.c.



Annotated/modified Lee FIG. 5

207. A POSA also would have appreciated that arranging three evenly spaced filaments (22/1622) at Racz’s tip (14/38) would result in the filaments being “configured to form a lesion having a pyramidal shape” [11]. A POSA would know that arranging the filaments (22/1622) in this triangular pattern would change the base of the lesion from being a substantially circular shape in Lee’s Figs. 1 and 5 (resulting in a conical lesion) to being a substantially triangular shape (resulting in a pyramidal lesion with a triangular shape defined by the three filaments). Ex-1010, 0103, Fig. 5. Again, as I explain above § II.D.5.c, this is simply the result of the lesion being defined by the location of the filaments, so that three filaments extending from the point of a needle define a pyramid with a three-sided base tapering to a point at the end of the needle. Ex-1010, ¶¶0012, 0084, 0123-0131.

208. For at least these reasons, it is my opinion that Claims 10 and 11 are each obvious in view of Racz, Fitz, and Lee.

F. Ground A: Claims 12-14 and 17

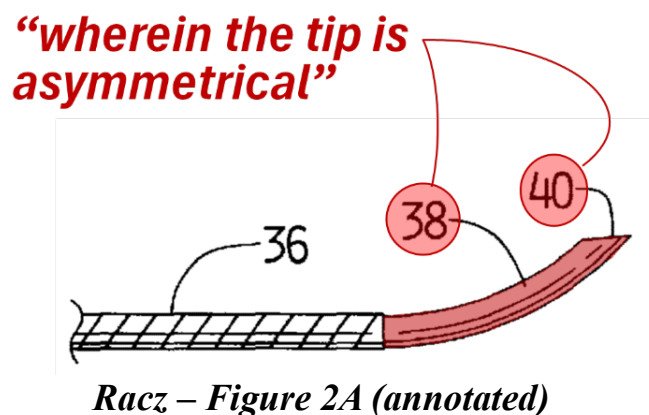
209. **Claim 12.** Racz's tip (14/38) includes a pointed end (40), which allows the cannula (33) to "penetrat[e] tough tissue." Ex-1009, 5:3-5. As shown in Racz's Fig. 2A, the distal portion of the tip (14/38) tapers to define the pointed end (40). Thus, it is my opinion that Racz's "tip tapers to a point" [12a].

210. As I explained above, Racz's cannula (10/33) can be a metal tube defining both the metal shaft (12/34) and the exposed tip (14/38). Ex-1009, 4:60 to 5:1, 5:45-48. Thus, in Racz's device modified to include Lee's filaments, it is my opinion that the POSA would understand "the elongate member and the tip comprise a single unitary structure" [12b]. Claim 12 is therefore obvious in view of Racz, Fitz, and Lee.

211. **Claim 13.** As I explained for [1c] and [1d], the proximal end of Racz's shaft (12/34) is fixed to the hub (20/42/70). *Supra* § VII.C.1.c. Thus, it is also my opinion that, in Racz's modified device, "a proximal end of the elongate member is fixed to the hub" [13]. Claim 13 is therefore obvious in view of Racz, Fitz, and Lee.

212. **Claim 14.** Racz's tip (14/38) is asymmetrical both with respect to its pointed end (40) and its bent configuration. As shown in annotated Figure 2A

below, Racz's tip (14/38) tapers to a point (40) that is positioned towards one side of the tip (14/38) and offset from the shaft's central longitudinal axis. Ex-1009, Fig. 2A, 5:3-5. Additionally, I also note that in the embodiment of Figure 2A, the tip (14/38) is bent to help physicians "follow neural structures, hug bony structures, and avoid certain organs." Ex-1009, 2:57-65, 4:24-28, 4:59-5:4. Because the curved needle of Figure 2A curves in one direction (e.g., toward or around the bony structures), it is asymmetric in that direction (e.g., the direction offset from the shaft's "central longitudinal axis"). In other words, the needle has a single tip that is offset from the axis, and therefore the tip is asymmetrical with respect to that axis in at least one direction. In both respects, Racz's "tip is asymmetrical" [14a].



213. I further note that Racz's hub (20/42/70) also includes a marker (48/74) to "indicate the orientation of the curved tip [14/38] for convenient steering or navigating of the cannula 33." Ex-1009, 5:18-22, 6:13-20, 7:66-8:9, 9:44-48. Thus, in my opinion, Racz's "hub comprises an indicator that is oriented to

communicate an orientation of the asymmetrical tip” [14b]. Claim 14 is therefore obvious in view of Racz, Fitz, and Lee.

214. **Claim 17.** As I described in § VII.A.1, Racz’s system includes a “signal generator 28” for providing “radio-frequency output.” Ex-1009, 4:1-9. The “output of the signal generator 28 is conveyed via [a] first electrical connection 24 to the probe 22.” Ex-1009, 4:18-23. As I also described in § II.D.2, using electrical conductors, including electrical cables, to connect a signal generator to different parts of the needle was a matter of routine engineering in the art of RF ablation. A POSA would therefore know that a cable is a common electrical connector between RF signal generators and RF probes. Thus, in my opinion, Racz’s “RF probe comprises a cable for use in connecting the RF probe to a radiofrequency generator” [17]. Claim 17 is therefore obvious in view of Racz, Fitz, and Lee.

G. Ground A: Claims 48-50

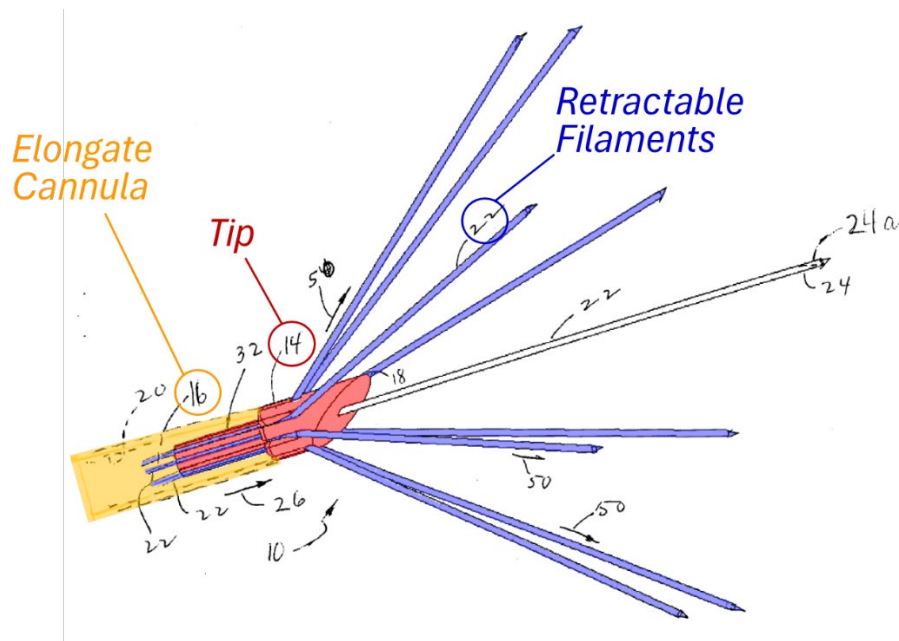
215. **Claim 48.** Racz’s tip (14/38) is made of a conductive material (e.g., where the cannula’s “shaft (34) comprises a hollow metal tube,” the tip (14/38) may be “an extension of the metal tube”). Ex-1009, 4:60 to 5:1, 5:45-48. As I explained for [1i-k], the shaft (54) of Racz’s probe (22/52) fully extends through Racz’s cannula (10/33) so that the temperature sensor at its tip (56) is positioned at the pointed end (18/40) of the tip (14/38) (if the tip could not reach the distal end of Racz’s needle, then the temperature sensor could not measure the temperature of

ablation at the tip). *Supra* § VII.A.1. Thus, the cannula’s “internal lumen” necessarily extends through the cannula’s tip (14/38), thereby defining a tip channel for receiving the distal end of probe (22/52). Ex-1009, 4:65 to 5:1, 5:41-48. Therefore, it is my opinion that Racz’s “tip comprises a conductive material and defines a channel, and wherein a distal end of the RF probe is received within the channel of the tip of the needle when the RF probe is fully inserted into the needle” [48]. Claim 48 is therefore obvious in view of Racz, Fitz, and Lee.

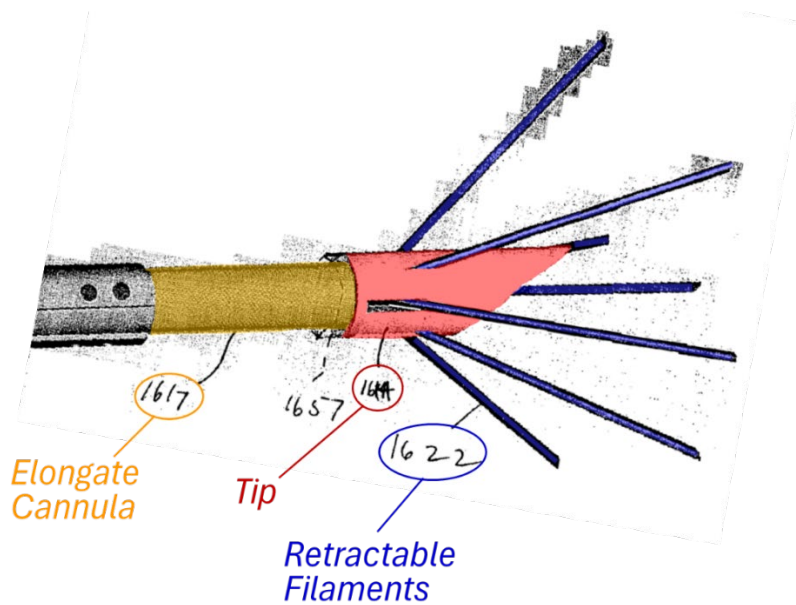
216. **Claim 49.** As I explained for [1e] and [1k], Racz’s tip (14/38) is both a conductive portion of the cannula (10/33) and a tip configured to pierce tissue. *Supra* § VII.C.1.d. Thus, it is my opinion that in Racz’s device, “the conductive portion of the needle comprises the conductive material of the tip” [49]. Claim 49 is therefore obvious in view of Racz, Fitz, and Lee.

217. **Claim 50.** As I explained for [1g] and [8], a POSA would have found it obvious to implement Lee’s filaments (22/1622) at Racz’s tip (14/38) such that the filament tips are positioned outwardly from and beyond the tip (14/38). *Supra* §§ VII.D, VII.C.2.b. And, as I also discussed above, 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). The annotated figures below illustrate

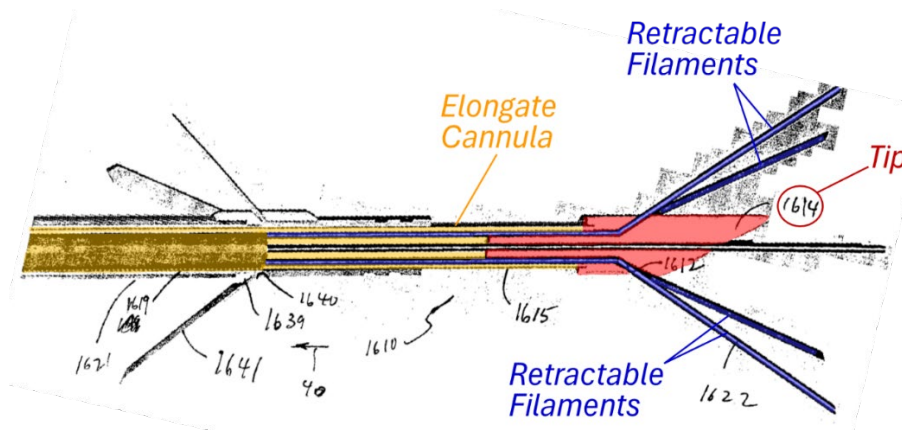
that Lee's filaments (22/1622) extend beyond the tip of its device. *See e.g.*, Ex-1010, Figs. 1, 48, 49.



Lee – Fig. 1 (annotated)



Lee – Figure 48 (annotated)



Lee – Figure 49 (annotated)

218. A POSA would recognize that configuring the filaments (22/1622) to extend beyond Racz's tip (14/38) would expand the ablation volume, a problem Fitz identifies as being present in Racz's unmodified device. *Supra* § VII.A.2. Moreover, in my example combination of Racz/Fitz/Lee, the filaments (22/1622) extend beyond Racz's tip (14/38) to expand the ablation volume. *Supra* § VII.B. And as explained in §VII.B, it is my opinion that a POSA would have found such configurations of Lee's filaments (22/1622) on Racz's tip (14/38) to be a matter of routine engineering well within the skill of a POSA.

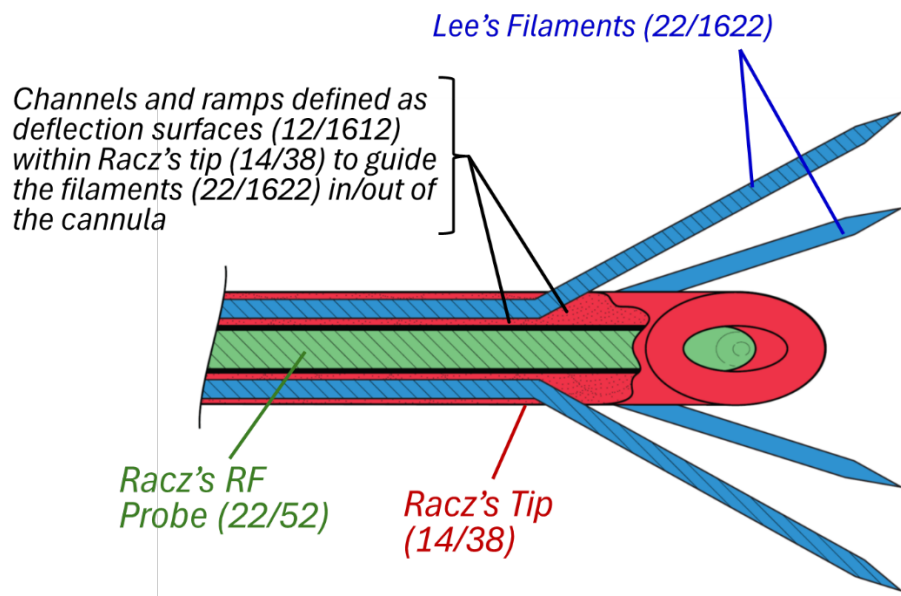


Illustration of an example modification of Racz

219. As “the destruction of target tissue [occurs] at the site where the electrodes are located,” the position of Lee’s filaments (22/1622) would “define [the] ablation volume in the target tissue.” Ex-1010, ¶¶0012, 0084, 0124, 0129. I describe how a POSA was familiar with this known relationship between electrode position and lesion formation in detail above. *See Supra* § II.D.5.c. In short, electrical current dissipates as it radiates outwardly from the electrodes into the tissue. Thus, the highest current density (and therefore heating) is closest to the electrodes, with the heating effect diminishing at greater distances from the electrodes. This relationship between electrode geometry and lesion geometry is one of the motivations for using expandable electrodes, so that the shapes of those electrodes can be used to define shapes of the lesions (e.g., electrodes beyond the tip define lesions beyond the tip). *See id.* Therefore Accordingly, with Lee’s

filaments (22/1622) implemented such that their tips extend beyond Racz's tip (14/38), the lesion produced will be distally offset from Racz's tip (14/38) (and the probe (22/52)). Thus, in my opinion, a POSA would have found it obvious to configure Lee's filaments (22/1622) such that "the plurality of filaments extend distally beyond a distal end of the RF probe when the RF probe is fully inserted into needle and when the plurality of filaments are in the deployed position, such that when RF energy is delivered to the RF probe, the plurality of filaments conduct RF energy that emanates from the RF probe beyond the distal end of the RF probe to produce within the patient, during the RF ablation procedure, a lesion that is distally offset from the distal end of the RF probe" [50]. Claim 50 is therefore obvious in view of Racz, Fitz, and Lee.

H. Ground A: Claims 51-52

220. Claim 51 recites "a method comprising: using the system of claim 1, wherein said using comprises: inserting the needle into a patient; rotating the actuator to transition the plurality of filaments from the retracted position to the deployed position; and operating the RF probe, the tip, and the plurality of filaments as a monopolar electrode." Racz (in combination with Fitz and Lee) discloses each of these steps. For example, Racz discloses a "method for delivering anesthesia, pain relief, or other treatment involving a firmly curved tip needle electrode." Ex-1009, 2:46–48. Racz's 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.

Likewise, Lee’s device is first positioned in a target area within a patient prior to its filaments (22/1622) being deployed. Ex-1010, ¶0098, 0091. Thus, in my opinion, Racz and Lee plainly disclose “a method comprising” [51pre] “using the system of claim 1, wherein said using comprises” [51a] “inserting the needle into a patient” [51b].

221. Lee discloses that after the filaments (22/1622) have been deployed, RF energy is applied to the filaments to heat the tissue. Ex-1010, ¶0107, 0099, 0087. Additionally, Racz discloses that—once 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. In view of these teachings, a POSA would have inserted Racz’s modified device to a target location in a patient and, after inserting Racz’s modified device, the POSA then would have deployed Lee’s filaments (22/1622) and activated the filaments (22/1622) and tip (14/38) with RF energy to ablate a targeted volume of tissue. And, as I explained in relation to limitation [1j], the tip (14/38) and filaments (22/1622) would have been activated together as a single monopolar electrode. *Supra* §VII.C.2.a (and specifically ¶187-189).

222. Thus, after Racz’s modified device has been inserted into a target position, a POSA would have found it obvious to “transition the plurality of filaments from the retracted position to the deployed position” [51c] and “operate

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

[51d].

223. A POSA also would have been motivated to deploy the filaments (22/1622) by “rotating the actuator” [51c]. As I discussed above, Lee’s filaments (22/1622) may be deployed and retracted by actuators “of a conventional design.” *Supra* §VII.C.2.b (and specifically ¶193-194); Ex-1010, ¶0106. And, I explained earlier, rotational actuators were commonly used in medical devices at the time of the invention. In my opinion, POSA would have found it plainly obvious in view of Lee to configure the actuator to rotate to deploy/retract the filaments (22/1622). This would have been particularly obvious for the purpose of preserving the functionality of Racz’s cannula (10/33) (e.g., such that it could receive the probe (22/52)).

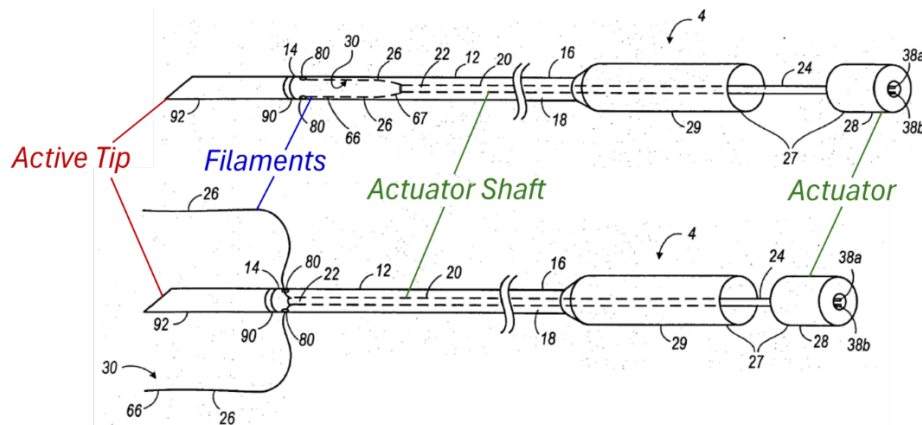
224. Lastly, to activate the tip (14/38) and filaments (22/1622) and conduct RF energy, as I have discussed at length herein, a POSA would have “insert[ed] the RF probe into the lumen of the needle” [52]. Ex-1009, 5:37-51; *see also, e.g., supra* §VII.C.1.e ([1h]), VII.C.2.a ([1f]). Thus, Claims 51 and 52 are obvious in view of Racz, Fitz, and Lee.

VIII. GROUND B: 1, 6-9, 12-14, 17, 48-52 AND ARE OBVIOUS IN VIEW OF RACZ, FITZ, LEE, AND YOUNG '965

A. Overview of Young '965

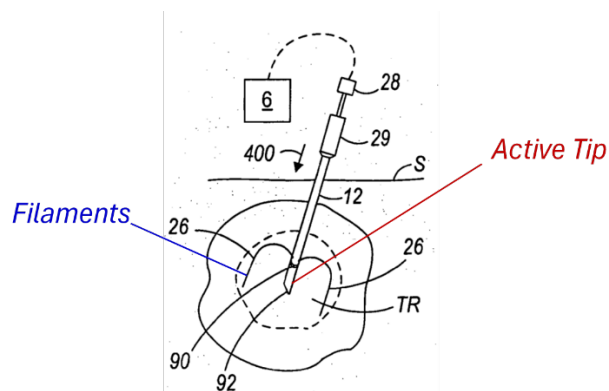
225. Young '965 discloses a “tissue ablation system” having “a probe assembly 4 configured for introduction into the body of a patient for ablative treatment of target tissue, and a radio frequency (RF) generator 6 configured for supplying RF energy to the probe assembly 4.” Ex-1012, ¶0022. Thus, Young '965 is in the same field as the '688 Patent. *See* Ex-1002, 1:16-20.

226. 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. The annotated figures from Young '965, below, show these elements.



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

227. 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.



Young '965 – Fig. 7C (annotated)

228. As I further explain below, 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, 7, 10, and 51.

B. Ground B: Claim 1

229. 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.*

230. Thus, in my opinion, 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 would have been effective for tissue ablation. Considered in combination with Racz, Fitz, and Lee, it is my opinion that a POSA would have been further motivated by Young '965 to modify Racz's device "such that the RF probe, the tip, and the plurality of filaments operate together as a single monopolar RF electrode" [1j].

231. I also note that 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. In my opinion, a POSA would have recognized that Young '965's shaft (20) could also 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)). Thus, in my

opinion, a POSA would have been further motivated by Young '965 to modify Racz's device to include “an actuator interconnected to the plurality of filaments, wherein movement of the actuator in a first direction relative to the hub moves the plurality of filaments relative to the tip to a deployed position distally beyond the tip, and wherein movement of the actuator in a second direction relative to the hub retracts the plurality of filaments to a retracted position in which the plurality of filaments are disposed within at least a portion of the elongate member” [1g] and “wherein, when the RF probe is fully separated from the needle in a non-inserted state, such that none of the RF probe is within the needle, the plurality of filaments are movable via the actuator from the retracted position, in which the plurality of filaments are disposed within said at least a portion of the elongate member, to the deployed position” [1i].

232. 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. Ex-1009, 8;9-15. I note that under the standard system of cannula gauges, 10-gauge cannulas are up to a 3.404mm outer diameter and a 2.692 mm inner diameter. Thus, in my opinion, Young '965 would have confirmed to a POSA that Lee's filaments (22/1622) could be provided in sizes as small as 0.2mm wide and easily implemented into Racz's neurotomy cannula that is as large as 10 gauge.

233. Accordingly, in my opinion, Claim 1 (and dependent Claims 6-9, 12-14, 17, 48-52) are further obvious in view of Racz, Fitz, Lee, and Young '965.

C. Ground B: Claim 7

234. Young '965 discloses that its filaments (26) can be formed from shape-memory alloys to have “a flared curvilinear profile that resembles a portion of a parabola and has a distal end that points at least partially towards a distal direction when deployed.” Ex-1012, ¶¶0037, 0029, 0026-0027. As I explained in § VII.D, configuring filaments to have a pre-set bias was a matter of routine engineering skill in the art. I also note that Lee explicitly contemplates the use of “shape memory material such as NiTi [Nitinol]” and Young '965 also discloses “nickel/titanium alloys” for the electrodes. Ex-1010, ¶0087; Ex-1012, ¶0029. So configuring Lee’s NiTi electrodes to have the curved shape disclosed by Young '965’s NiTi electrodes would be a matter of routine engineering (applying Young’s curved shape-memory electrode configuration to Lee’s straight shape-memory electrodes). As Young '965 discloses that that these curved filaments are effective for tissue ablation, in my opinion, a POSA would have found it further obvious to configure each of Lee’s filaments (22/1622) deployed from Racz’s tip (14/38) to have “a pre-set bias such that the filament is curved when in the deployed state” [7]. Ex-1012, ¶¶0011-0012, 0033, 0039-0042; Claim 7 is therefore further obvious in view of Racz, Fitz, Lee, and Young '965.

D. Ground B: Claim 10

235. Young '965 discloses that its filaments (26) have “a deployed configuration that defines a volume” and “assume a desired configuration when advanced into tissue.” Ex-1012, ¶0026. Young '965's device “can have more ... than two electrodes 26” and “pairs of adjacent electrodes 26 can be spaced from each other in similar or identical, repeated patterns and can be symmetrically positioned about an axis of the shaft 20.” Ex-1012, ¶0028, 0026, 0003. A POSA would understand that the variations in numbers of electrodes in Young '965 and Lee were merely routine engineering decisions made by Young '965 and Lee, and that three electrodes was within the known range of possible electrodes (e.g., at least between the two of Young and eight of Lee). So, deciding to use three evenly spaced electrodes instead of the *two* evenly spaced electrodes of Young '965 (or *eight* of Lee) would be a matter of simply picking another number of electrodes within a known range of working possibilities (e.g., between two and eight) and spacing them evenly, based on the explicit teaching of both Young and Lee to use symmetric/repeating patterns for the electrodes. Since a complete circle is a 360-degree arc, even spacing of filaments in a 360-degree circle results in a 120 degree separation between each filament (360 degrees/3 filaments = 120 degrees/filament).

236. Thus, in combination with Lee's teachings regarding the arrangement of its filaments (22/1622), Young '965 would have further confirmed to a POSA that Racz's modified device would be effectively configured for tissue ablation with "three filaments ... [where] an angle between each pair of adjacent filaments is 120 degrees when each filament is in the deployed position" [10]. Claim 10 is therefore further obvious in view of Racz, Fitz, Lee, and Young '965.

E. Ground B: Claim 51

237. Young '965's "handle assembly 27 can be configured such that the electrodes 26 can be deployed by rotating the handle portion 28 relative to the handle body 27." Ex-1012, ¶0038. "[T]he shaft 20 can have a screw-like configuration, which allows the shaft 20 to be distally advanced or proximally retracted by rotation of the shaft 20" and "the array 30 of electrodes 26 is rotatably coupled to the distal end 22 of the shaft 20 such that rotation of the shaft 20 does not rotate the electrodes 26, but move them in an approximate longitudinal direction." *Id.*

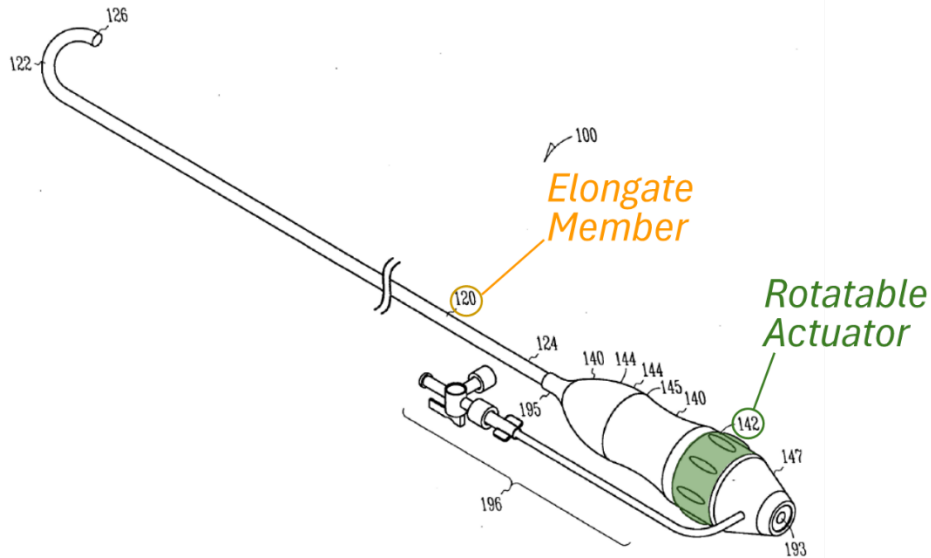
238. Thus, in my opinion, Young '965 would have further motivated a POSA to configure Racz's modified device to include a rotatable actuator to enable "rotating the actuator to transition the plurality of filaments from the retracted position to the deployed position" [51c]. Claim 51 is further obvious in view of Racz, Fitz, Lee, and Young '965.

IX. GROUND C AND D: CLAIMS 1-9, 12-14, 17, 48-52 ARE OBVIOUS IN VIEW OF RACZ, FITZ, LEE, AND SCHEIBE (AND, OPTIONALLY, YOUNG '965)

A. Overview of Scheibe

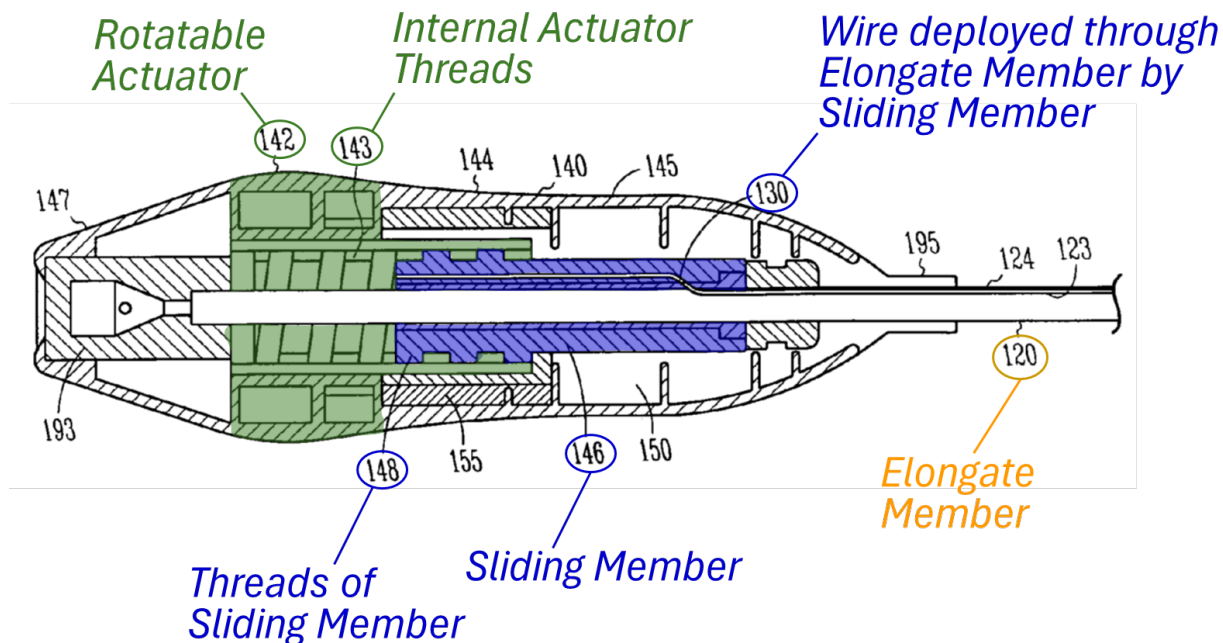
239. Scheibe discloses a rotational actuator (142) for linearly translating a sliding member (146) within a medical device. Ex-1013, ¶¶0019, 0021, 0024-0029, 0032-0035. Scheibe also notes that its teachings are not limited to catheters and are relevant to “other types of body stimulating systems.” Ex-1013, ¶0037. As Scheibe’s actuator (142) is adapted for linear translation of a pullwire (130) through the lumen of an elongate body (120), in my opinion, it is at least reasonably pertinent to the ’688 patent. *Id.*

240. Scheibe’s actuator (142) is shown in a deflectable catheter (or sheath), which includes an elongate, deflectable body (120), a housing assembly (140), and a pullwire (130). Ex-1013, ¶0016, Fig. 1. The device’s pullwire (130) is secured to a distal end of the deflectable body (120), 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. The annotated versions of Scheibe Figs. 1 and 2 show an actuation mechanism disclosed by Scheibe.



Schiebe – Fig. 1 (annotated)

241. The rotatable actuator (142) (**shaded green**) rotates about the longitudinal axis of Schiebe's device but is otherwise fixed in place. Ex-1013, ¶0025. 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 (140) 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: Claim 1

242. In my opinion, in view of Scheibe's teachings, 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 actuating Lee's filaments (22/1622) without compromising the functionality of Racz's probe (22/52). As Scheibe's pullwire (130) is secured to its sliding member (146), a POSA would have appreciated 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. And because Scheibe's pullwire (130) is moved through its elongate body (120), it is also my opinion that a POSA would have appreciated that the rotatable actuator (142) would retract and deploy Lee's filaments (22/1622) through Racz's shaft

(12/34). Moreover, Scheibe's actuator (142)—by rotating—would move in first/second directions relative to Racz's hub (20/42/70) to deploy and withdraw the filaments (22/1622). A POSA would understand that, because the sliding member (146) does not rotate, the filaments (22/1622) would not be twisted when the rotatable actuator (142) is used to deploy the filaments.

243. It is also my opinion that a POSA would have appreciated that Scheibe's rotatable actuator (142) would be well suited for Racz's device as the rotatable actuator (142) and sliding member (146) are adapted to avoid interference with the lumen of the elongate body (120). A POSA would understand that this allows the actuator (142/146) 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. Indeed, Scheibe notes that a Luer fitting may be provided at a distal end of its device, which would confirm to the POSA that its actuator (142/146) would not obstruct the elongate body (120). Ex-1013, ¶0031. Finally, Scheibe notes that its teachings are not limited to catheters and are relevant to "other types of body stimulating systems." Ex-1013, ¶0037.

244. 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.

245. A POSA would have easily implemented Scheibe's actuator (142) and sliding member (146) into Racz's modified device. As one example, I note that 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. 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. Thus, Scheibe's handle assembly (140) could be implemented into Racz's device without impacting the functionality of Racz's probe (22/52) or fluid delivery.

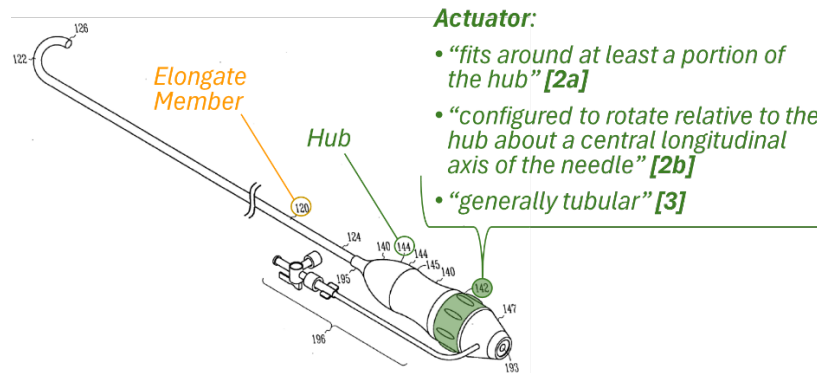
246. Accordingly, in my opinion, a POSA would have recognized that Scheibe's rotating actuator (142) and sliding member (146) would be a suitable filament actuator to implement into Racz's modified device for deployment and retraction of Lee's filaments (22/1622). *See* Ex-1010, ¶0106 (filaments "may be connected to suitable advancement and retraction mechanisms"). Thus, it is my opinion that, in combination with Racz, Fitz, and Lee, Scheibe would have further motivated a POSA to implement "an actuator interconnected to the plurality of filaments, wherein movement of the actuator in a first direction relative to the hub moves the plurality of filaments relative to the tip to a deployed position distally

beyond the tip, and wherein movement of the actuator in a second direction relative to the hub retracts the plurality of filaments to a retracted position in which the plurality of filaments are disposed within at least a portion of the elongate member” [1g] and “wherein, when the RF probe is fully separated from the needle in a non-inserted state, such that none of the RF probe is within the needle, the plurality of filaments are movable via the actuator from the retracted position, in which the plurality of filaments are disposed within said at least a portion of the elongate member, to the deployed position” [1i].

247. Accordingly, Claim 1 (and dependent Claims 6-9, 12-14, 17, 48-52) are further obvious in view of Racz, Fitz, Lee, and Scheibe (Ground C).

C. Ground C: Claims 2-5

248. **Claim 2.** As shown in the annotated figures below, Scheibe’s handle assembly (140) includes a main hub in the form of a housing (144), which is secured to the elongate member (120). Ex-1013, 0019-0021, Figs. 1-2. As also shown in Fig. 1, Scheibe’s actuator (142) “fits around at least a portion of the hub” [2a] (the “hub” being the housing (144)).



Scheibe – Fig. 1 (annotated)

249. Furthermore, the actuator (142) is configured to rotate about the central longitudinal axis of Scheibe’s elongate member (120). Ex-1013, 0019, 0021, 0024-0025, Figs. 1-2. That “central longitudinal axis” is defined a line drawn down the center of Schiebe’s elongate member (120), and extending out both ends of the elongate member (120). So the actuator (142) surrounds this “central longitudinal axis” of the elongate member (120). Thus, when implemented into Racz’s modified device, the actuator (142) would rotate about the central longitudinal axis of Racz’s shaft (12/34). Accordingly, in my opinion, it would have been obvious to include the actuator (142) in Racz’s modified device such that it is “configured to rotate relative to the hub about a central longitudinal axis of the needle” [2b]. The hub/housing (144) also includes a central support (170)

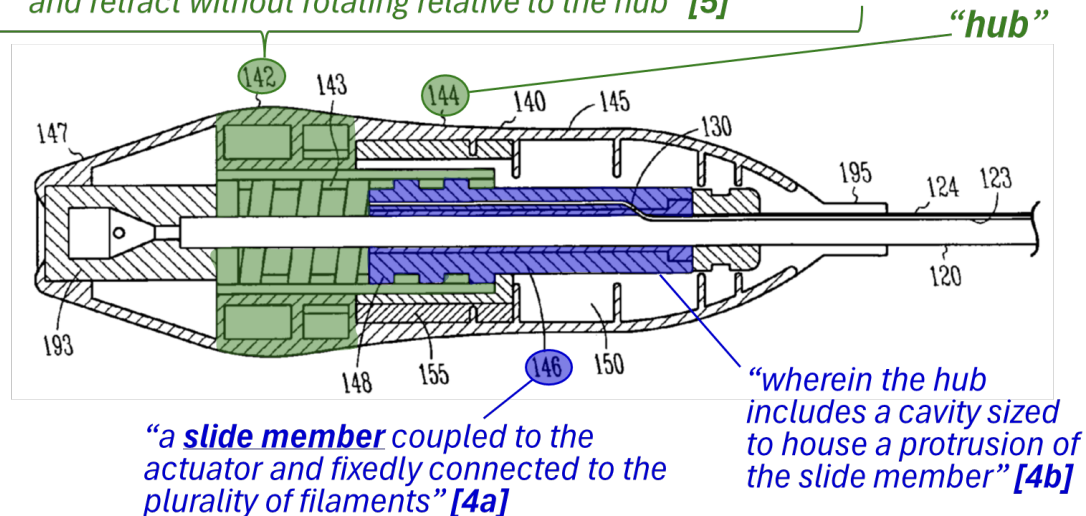
which the actuator (142) fits around. Ex-1013, ¶0028-0030, Fig. 4A. Thus, a POSA would understand that the actuator (142) is “generally tubular” [3].⁹

250. As discussed above, a POSA would have found it obvious to implement Scheibe’s actuator (142) such that Lee’s filaments (22/1622) are secured to the sliding member (146). *Supra* § IX.B. As the actuator (142) rotates, the slide member (146) is limited to linear motion and axially advances/retracts without rotating. Ex-1013, ¶0018-0019, 0024-0025, 0029, 0035. For example, Scheibe explains that the “sliding member translates longitudinally” and “fixed longitudinally, causing the sliding member 146 to translate longitudinally.” Ex-1013, ¶0032. A POSA would understand Scheibe’s discussion of “longitudinal” motion to refer to linear back-and-forth motion, and therefore that actuators disclosed by Scheibe can move (“translate”) the slide member that is “fixed” to not rotate relative to the hub.

⁹ The ’688 Patent indicates its actuator is “generally tubular” because it “fits around a longitudinal hub projection.” Ex-688Patent, 19:12-14. However, to the extent Scheibe’s actuator is not regarded as tubular, reshaping the actuator (142) to be generally tubular would have been an obvious design choice. It is my opinion that a POSA would have found adjusting the proportions and sizes of the actuator to make it “generally tubular” would have been a matter of routine engineering.

- “wherein the slide member is limited to a linear motion relative to the hub as the actuator is rotated” [4c]

- “wherein the slide member is configured to axially advance and retract without rotating relative to the hub” [5]



Scheibe – Fig. 2 (annotated)

251. Thus, it is my opinion that Racz’s device modified to include Scheibe’s actuator (142) and sliding member (146) would result in the “the needle further compris[ing] a slide member coupled to the actuator and fixedly connected to the plurality of filaments” [4a]. As shown above in the annotations of Figure 2, provided above, “the hub includes a cavity sized to house a protrusion of the slide member” [4b]. Additionally, as discussed above, “the slide member is limited to a linear motion relative to the hub as the actuator is rotated” [4c]. Ex-1013, ¶0024-0025, 0029. Finally, the “slide member [146] is configured to axially advance and retract without rotating relative to the hub” [5]. *Id.*

252. Accordingly, for these reasons and those discussed above in relation to Claim 1, Claims 2, 4, and 5 are each obvious in view of Racz, Fitz, Lee, and Scheibe (Ground C).

D. Ground C: Claims 51 and 52

253. For the reasons I explained above with respect to Claims 1-5, it is also my opinion that Scheibe would have further motivated a POSA to configure Racz's modified device to include a rotatable actuator (142) configured such that "rotating the actuator to transition the plurality of filaments from the retracted position to the deployed position" [51c]. *Supra* §§ IX.B, IX.C. Claim 51 (and dependent Claim 52) are therefore further obvious in view of Racz, Fitz, Lee, and Scheibe.

E. Ground D

254. It is also my opinion that 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. Given this teaching, in my opinion, a POSA would be further motivated to select a suitable rotational actuator (such as Scheibe's) for use in deploying Lee's filaments (22/1622) from Racz's device. Both Scheibe and Young '965 disclose actuators that can be used to extend/retract wires (e.g., Scheibe's "pull wire" and Young '965's "electrode tine which resembles the shape of a needle or wire"), so a POSA would understand that Scheibe's actuator performs the function of actuators disclosed in Young '965. For

example, a POSA would recognize that Scheibe actuator could be “configured such that the electrodes 26 can be deployed by rotating the handle portion 28 relative to the handle body 27” as described by Young ’965. Furthermore, as discussed above in Ground B, Young ’965 provides supporting disclosure for additional features in Claims 1, 7, 10, and 51. *Supra* § VIII. Thus, Claims 1-9, 12-14, 17, 48-52 are further obvious in view of Racz, Fitz, Lee, Young ’965, and Scheibe (Ground D).

X. GROUNDS E-H: CLAIM 9 IS OBVIOUS IN VIEW OF RACZ, FITZ, LEE, AND YOUNG ’201 (AND YOUNG ’965 OR YOUNG ’965 AND SCHEIBE)

255. I note that Young ’201 is directed to “radio frequency (RF) electrosurgical probes or ablation devices for the treatment of tissue.” Ex-1016, ¶0002. Thus, Young ’201 is in the same field as the ’688 Patent. *See* Ex-1002, 1:16-20.

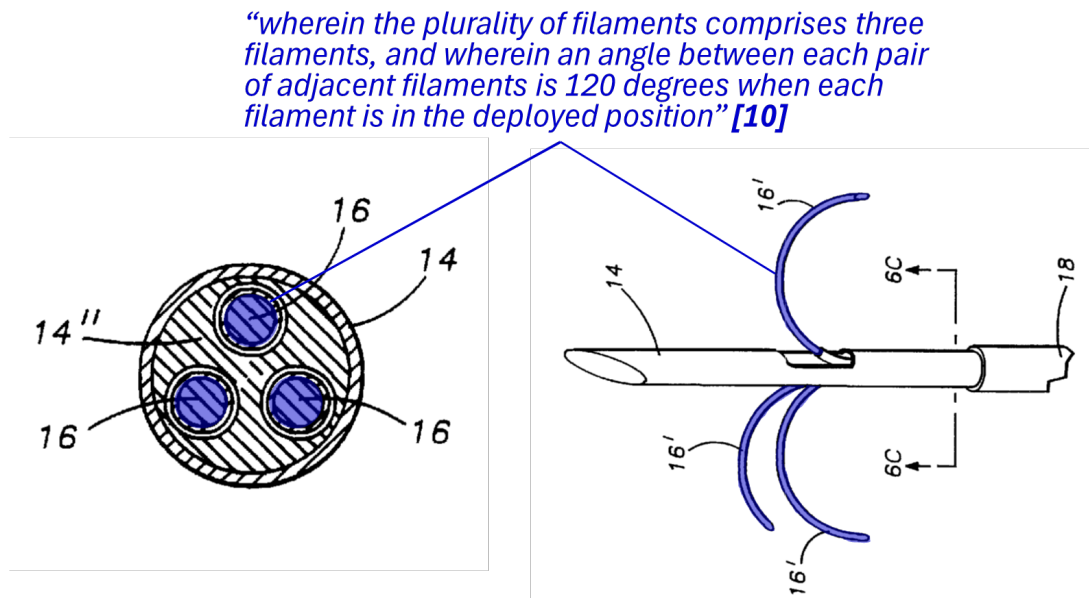
256. Young ’201 discloses that its deployable array (40) of electrode tines may have “a non-symmetrical orientation” (i.e., asymmetric). Ex-1016, ¶0031. In my opinion, Young ’201’s teaching that asymmetric electrode tines are effective for ablation would have further motivated a POSA to configure Racz’s device modified to include Lee’s filaments (22/1622) such that “the distal end of each filament defines a point when each filament is in the deployed position, and wherein an average of all the points is offset from a central longitudinal axis of the elongate member.” Thus, it is my opinion that Claim 9 is obvious in view of Racz,

Fitz, Lee, and Young '201 (Ground E). For the same reasons, it is also my opinion that Claim 9 is obvious in view of Racz, Fitz, Lee, Young '201, and: Young '965 (Ground F; *supra* § VIII) or Scheibe (Ground G; *supra* § IX) or Young '965 and Scheibe (Ground H; *supra* § IX).

XI. GROUNDS I-L: CLAIMS 10, 11, AND 15 ARE OBVIOUS IN VIEW OF RACZ, FITZ, LEE, AND GOUGH '516 (AND YOUNG '965 OR YOUNG '965 AND SCHEIBE)

257. Gough '516 is directed to an apparatus having deployable “energy delivery devices 16” configured for ablation of targeted tissue. Gough516, 3:54-4:22. Thus, Gough '516 is in the same field as the '688 Patent. *See* Ex-1002, 1:16-20.

258. **Claims 10 and 11.** Gough '516's apparatus (12) includes an introducer tip (14) and deployable “energy delivery devices 16” (i.e., filaments) made from shape memory alloy. Ex-1017, 4:13-67. The deployable filaments (16) deliver RF energy to targeted tissue and may be provided in “any number of geometric configurations,” which allows the apparatus (12) to generate lesions in which the “the geometry of the ablated mass is selectable and controllable.” Gough516, 6:19-28 and 53-63. In one example, “three energy delivery devices are deployed” from Gough '516's apparatus (12) are shown symmetrically spaced (i.e., 120 degrees apart). Gough516, 7:66-8:11, Figs. 6B-6C.



Gough '516 – Figs. 6B and 6C (annotated)

259. Thus, it is my opinion that, in combination with Lee’s teachings regarding the arrangement of its filaments (22/1622) (which would extend beyond Racz’s tip (14/38)), Gough ’516’s teaching that a symmetrical three-filament configuration is effective for tissue ablation would have further confirmed to a POSA that Racz’s modified device would be configured with “three filaments ... [where] an angle between each pair of adjacent filaments is 120 degrees when each filament is in the deployed position” [10]. As explained above, it is also my opinion that a POSA would have appreciated that this evenly spaced three-filament configuration would result in the filaments being “configured to form a lesion having a pyramidal shape” [11]. See § II.D.5.c.

260. **Claims 15.** Gough ’516 also discloses that the handle of its apparatus includes “markings to show the length of lateral deployment of energy delivery

devices 16 from introducer 14.” Gough’516, Thus, for the purpose of providing a visual indication of the length (i.e., depth) of filament deployment, a POSA would have found it obvious in view of Gough ’516 to provide “markings to indicate a depth of deployment of the plurality of filaments” [15] on the modified Racz devices’ hub or actuator. Adding such markings would be a matter of routine engineering, who would be motivated to incorporate such markings by the clear benefit of indicating the location of the filaments, and therefore also indicating the location of the corresponding RF lesion(s) formed by the filaments.

261. Thus, it is my opinion that Claims 10, 11, and 15 are therefore obvious in view of Racz, Fitz, Lee, and Gough ’516 (Ground I). For the same reasons, Claims 10, 11, and 15 are obvious in view of Racz, Fitz, Lee, Gough ’516, and: Young ’965 (Ground J; *supra* § VIII) or Scheibe (Ground K; *supra* § IX) or Young ’965 and Scheibe (Ground L; *supra* § IX).

XII. GROUNDS M-P: CLAIM 16 IS OBVIOUS IN VIEW OF RACZ, FITZ, LEE, AND ROSINKO (AND YOUNG ’965 OR YOUNG ’965 AND SCHEIBE)

262. Rosinko discloses a steerable catheter having a rotational actuator (156) for linearly translating an inner deflection knob (154) secured to a pull cable. Ex-1020, 11:1-5, 11:62-12:15, 19:26-46. As Rosinko’s rotating actuator (156) imparts linear translation of the pull cable through a catheter used with RF energy, it is analogous to the ’688 Patent. *Id.*

263. Rosinko discloses that its actuator (156) engages “detents” (185) as the actuator is rotated. Ex-1020, 11:62-12:15, Fig. 4. This “provides an indexed mechanism, which allows a tactile response by the physician so as to control or at least be aware of the degree of deflection caused by said rotation of the actuator 156.” *Id.* Thus, in view of Rosinko, a POSA would have found it obvious to position detents for engagement with Scheibe’s rotating actuator (142) in order to “to provide a tactile feedback of a position of the plurality of filaments” [16] in Racz’s modified device.

264. Claim 16 is therefore obvious in view of Racz, Fitz, Lee, and Rosinko (Ground M). For the same reasons, it is also my opinion that Claim 16 is obvious in view of Racz, Fitz, Lee, Rosinko, and: Young ’965 (Ground N; *supra* § VIII) or Scheibe (Ground O; *supra* § IX) or Young ’965 and Scheibe (Ground P; *supra* § IX).

XIII. CONCLUSION

265. For the reasons described above, it is my opinion that the Challenged Claims are unpatentable.

I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code

Executed on: July 26, 2024

Signature:

A handwritten signature in blue ink, appearing to read "RAT Tucker". The signature is fluid and cursive, with the first part "RAT" being more distinct and the last part "Tucker" being more stylized and connected.

By: Dr. Robert Tucker

XIV. CLAIMS LISTING

Claim Element	Challenged Claims
[1pre]	A system comprising:
[1a]	an RF probe; and
[1b]	a needle for insertion into a patient during an RF ablation procedure, the needle comprising:
[1c]	a hub;
[1d]	an elongate member fixed to the hub, the elongate member comprising a lumen at an interior thereof;
[1e]	a tip fixed to the elongate member at a distal end of the needle, wherein the tip is shaped to pierce tissue of the patient;
[1f]	a plurality of filaments;
[1g]	an actuator interconnected to the plurality of filaments, wherein movement of the actuator in a first direction relative to the hub moves the plurality of filaments relative to the tip to a deployed position distally beyond the tip, and wherein movement of the actuator in a second direction relative to the hub retracts the plurality of filaments to a retracted position in which the plurality of filaments are disposed within at least a portion of the elongate member; and
[1h]	a fitting in fluid communication with the lumen, the fitting being configured to provide a connection for injection of fluid through the fitting and through the lumen, the fitting further being configured to allow for insertion of the RF probe into the lumen through the fitting,
[1i]	wherein the lumen at the interior of the elongate member is configured to accept the RF probe therein to physically contact a conductive portion of the needle and
[1j]	thereby electrically connect the RF probe to the tip and the plurality of filaments, such that energy emitted by the RF probe passes through the tip and the plurality of filaments, and such that the RF probe, the tip, and the plurality of filaments operate together as a single monopolar RF electrode,
[1k]	wherein the conductive portion of the needle is at a distal end of the needle, and
[1l]	wherein, when the RF probe is fully separated from the needle in a non-inserted state, such that none of the RF probe is within the

Claim Element	Challenged Claims
	needle, the plurality of filaments are movable via the actuator from the retracted position, in which the plurality of filaments are disposed within said at least a portion of the elongate member, to the deployed position.
[2a]	2. The system of claim 1, wherein the actuator fits around at least a portion of the hub, and
[2b]	wherein the actuator is configured to rotate relative to the hub about a central longitudinal axis of the needle.
[3]	3. The system of claim 2, wherein the actuator is generally tubular.
[4a]	4. The system of claim 1, wherein the needle further comprises a slide member coupled to the actuator and fixedly connected to the plurality of filaments,
[4b]	wherein the hub includes a cavity sized to house a protrusion of the slide member, and wherein the slide member is limited to a linear motion relative to the hub as the actuator is rotated.
[5]	5. The system of claim 4, wherein the slide member is configured to axially advance and retract without rotating relative to the hub.
[6]	6. The system of claim 1, wherein the tip comprises a fluid port in fluid communication with the lumen such that an anesthetic and/or an image enhancing dye may be introduced into a region around the tip through the fluid port.
[7]	7. The system of claim 1, wherein each filament of the plurality of filaments has a pre-set bias such that the filament is curved when in the deployed state.
[8]	8. The system of claim 1, wherein when each filament of the plurality of filaments is in the deployed position, the filaments extend outwardly from the tip.

Claim Element	Challenged Claims
[9]	9. The system of claim 8, wherein each filament comprises a distal end, wherein the distal end of each filament defines a point when each filament is in the deployed position, and wherein an average of all the points is offset from a central longitudinal axis of the elongate member.
[10]	10. The system of claim 1, wherein the plurality of filaments comprises three filaments, and wherein an angle between each pair of adjacent filaments is 120 degrees when each filament is in the deployed position.
[11]	11. The system of claim 1, wherein the plurality of filaments are configured to form a lesion having a pyramidal shape.
[12a]	12. The system of claim 1, wherein the tip tapers to a point, and
[12b]	wherein the elongate member and the tip comprise a single unitary structure.
[13]	13. The system of claim 1, wherein a proximal end of the elongate member is fixed to the hub.
[14]	14. The system of claim 1, wherein the tip is asymmetrical, and wherein the hub comprises an indicator that is oriented to communicate an orientation of the asymmetrical tip.
[15]	15. The system of claim 1, wherein the hub and/or the actuator includes markings to indicate a depth of deployment of the plurality of filaments.
[16]	16. The system of claim 1, wherein the hub and/or the actuator includes detents to provide a tactile feedback of a position of the plurality of filaments.
[17]	17. The system of claim 1, wherein the RF probe comprises a cable for use in connecting the RF probe to a radiofrequency generator.

Claim Element	Challenged Claims
[48]	48. The system of claim 1, wherein the tip comprises a conductive material and defines a channel, and wherein a distal end of the RF probe is received within the channel of the tip of the needle when the RF probe is fully inserted into the needle.
[49]	49. The system of claim 48, wherein the conductive portion of the needle comprises the conductive material of the tip.
[50]	50. The system of claim 1, wherein the plurality of filaments extend distally beyond a distal end of the RF probe when the RF probe is fully inserted into needle and when the plurality of filaments are in the deployed position, such that when RF energy is delivered to the RF probe, the plurality of filaments conduct RF energy that emanates from the RF probe beyond the distal end of the RF probe to produce within the patient, during the RF ablation procedure, a lesion that is distally offset from the distal end of the RF probe.
[51pre]	51. A method comprising:
[51a]	using the system of claim 1, wherein said using comprises:
[51b]	inserting the needle into a patient;
[51c]	rotating the actuator to transition the plurality of filaments from the retracted position to the deployed position; and
[51d]	operating the RF probe, the tip, and the plurality of filaments as a monopolar electrode.
[52]	52. The method of claim 51, wherein said using further comprises inserting the RF probe into the lumen of the needle.