

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVANOS MEDICAL, INC.,
Petitioner,

v.

STRATUS MEDICAL, LLC,
Patent Owner.

IPR2024-01209
U.S. Patent No. 10,966,782

IPR2024-01210
U.S. Patent No. 10,736,688

IPR2024-01211
U.S. Patent No. 10,736,688

IPR2024-01212
U.S. Patent No. 10,925,664

DECLARATION OF PETER CROSBY

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I, Peter Crosby, declare as follows:

I. INTRODUCTION

1. I have been retained by Laurence & Phillips IP Law, which represents Stratus Medical, LLC, to provide my independent expert analysis and opinions in connection with the following *inter partes* reviews (IPRs) at the United States Patent Trial and Appeal Board of the United States Patent and Trademark Office (USPTO):

IPR No.	U.S. Pat. No.
IPR2024-01209	10,966,782
IPR2024-01210	10,736,688
IPR2024-01211	10,736,688
IPR2024-01212	10,925,664

2. I will refer to the three patents listed above collectively as the “Stratus Patents.”

3. I am being compensated at a rate of \$775 per hour for my work on these cases, including providing this declaration. I have no financial interest in Stratus or the Stratus patents, and my compensation is not dependent on the outcome of these cases or any related proceeding. My compensation does not in any way affect the substance of my testimony in this declaration.

II. QUALIFICATIONS AND EXPERTISE

4. I have over 45 years of experience in the medical device industry. Exhibit 2007 is my current resume, including a list of all the cases in which I have testified in the last five years.

5. I earned my bachelor's degree in electrical engineering in 1974 and my master's degree in engineering science in 1976, both from the University of Melbourne, Australia. My M. Eng. Sci. degree was in Biomedical Engineering, and I took courses and received training in advanced engineering, anatomy, and physiology as part of my M. Eng. Sci. work.

6. I am a named inventor of over 50 issued U.S. patents and public applications (and foreign equivalents). Most of my patents are in the general field of medical devices. Some of my patents focus on the application of electromagnetic energy to nerves, and some focus on radiofrequency ablation. I have performed many prior art searches in my development of patent applications, and I have developed many Information Disclosure Statements as required when submitting a U.S. patent application. My most recent patent application was in February 2025.

7. I have been responsible for the development and maintenance of the patent portfolios of several companies. I have presented to USPTO patent examiners during examiner interviews and to the Appeals Board of the European Patent Office.

8. During my career I have worked as an engineer in Research and Development responsible for developing medical devices and have run the Research and Development function for several medical device companies. I spent approximately 15 years in product research and development, including participation in design, engineering, manufacturing ramp-up, clinical trial design and execution,

and regulatory submissions. Since then, I have spent most of my career in general management.

9. I have served as the Chief Executive Officer of six medical device companies in four countries. I have served as a member of the board of directors (including Chairman of the Board) of thirteen companies. In my career, I have brought over a dozen products from concept to market release, through Research and Development, manufacturing introduction, and clinical trials and regulatory approval in the United States as well as other markets worldwide, followed by development of a sales force and sales growth. I am keenly aware of the work and investment required to create a successful company in the medical device industry, and how the success of a new product often depends on its novelty, and how breakthrough innovations can enjoy broad commercial success.

10. I have several years' experience in the engineering of devices to deliver electromagnetic energy to the body, including nerves. My experience includes for the companies Cochlear (electrical stimulation of the auditory nerve to treat profound deafness), Teletronics (cardiac pacemakers, implantable defibrillators, and implantable nerve stimulators for myoplasty), and Mainstay Medical (electrical stimulation of the medial branch of the dorsal ramus nerve in the lumbar spine to treat chronic low back pain).

11. I have direct experience in radio frequency (RF) ablation and coagulation of tissue. As part of my work as Director of the Northern Region Biomedical Engineering Service, I was responsible for selection, purchasing, maintenance, and training on several types of RF electrosurgery equipment.

12. As part of my work at NeoVision, I co-developed prototypes of equipment for RF ablation and cauterization of breast cancer tissue. I am an inventor

on a patent in this area – U.S. Patent No. 6,106,524, entitled “Methods and Apparatus for Therapeutic Cauterization of Predetermined Volumes of Biological Tissue.”

13. From July 2009 through October 2017, I was the CEO of Mainstay Medical International PLC, a medical device company in the field of therapy for chronic lower back pain. I founded Mainstay in conjunction with the physician who invented the original idea, and I recruited key team members, consulted with pain physicians, contributed to the product design, designed the feasibility Clinical Study and the clinical trial needed for marketing approval, and started the commercialization of a product in 2017. One option for therapy for treatment of chronic lower back pain is RF ablation of nerve tissue (“neurotomy”), and I am an inventor on a patent in this field – U.S. Patent No. 10,661,078 “Modular Stimulator for Treatment of Back Pain, Implantable RF Ablation System and Methods of Use.”

14. I have significant experience with the design of electrodes for access to neural tissue, in particular nerves associated with the spine, such as the medial branch of the dorsal ramus (one of the subjects of the Stratus Patents). I am an inventor on some patents in this area. For example, US 9,079,019, entitled “Apparatus and Methods for Anchoring Electrode Leads for Use With Implantable Neuromuscular Electrical Stimulator” and US 9,999,763, entitled “Apparatus and Methods for Anchoring Electrode Leads Adjacent to Nervous Tissue.”

15. In 2023 I served as an expert for Patent Owner in the International Trade Commission in Certain Dermatological Treatment Devices and Components Thereof, Inv. No. 337-TA-1356 (the “1356 Investigation”) on a number of topics, including the validity and practice of several of the patents at issue in that case. The case was about RF microneedling devices in which RF electromagnetic energy is

delivered through one or more needles to ablate dermatological tissue to tighten the skin.

16. I currently work as a consultant, board member, and expert witness through my consulting business, Biomedical Business Resources, LLC. I serve as Chairman of the Board of two companies and a member of the Board of Directors of one other company.

III. BACKGROUND OF THESE CASES

A. Stratus Patents

17. I understand that the patent application that led to the '782 Patent was filed at the USPTO on July 20, 2020, and claims benefit or priority to several earlier-filed patent applications. The first provisional application to which priority is claimed was filed on May 21, 2010, and the first utility patent application to which priority is claimed, by way of a series of continuations, was filed on May 4, 2011.

18. I understand that the patent application that led to the '688 Patent was filed at the USPTO on April 14, 2016, and claims benefit or priority to several earlier-filed patent applications. The first provisional application to which priority is claimed was filed on November 5, 2009, and the first utility patent to which priority is claimed, by way of continuation, was filed on November 5, 2010.

19. I understand that the patent application that led to the '664 Patent was filed at the USPTO on July 20, 2020, and claims benefit or priority to several earlier-filed patent applications. The first provisional application to which priority is claimed was filed on November 5, 2009, and the first utility patent to which priority is claimed, by way of a series of continuations, was filed on November 5, 2010.

20. I understand that the '688 and '664 Patents have essentially the same disclosure, including drawings and text, except for the claims. I understand that the '782 Patent includes much of the same text and many of the same drawings as the '688 and '664 Patent and further includes additional text and drawings.

21. I understand that Stratus makes and sells an RF neurotomy device called the “Nimbus® Multi-tined Expandable Electrode” (Nimbus Device). I have personally inspected the Nimbus Device and compared it to the claims of the Stratus Patents. Details of that comparison are included in Exhibit 2008, which I incorporate into this declaration as part of my testimony. It is my opinion that the Nimbus Device is covered by at least some claims of each of the Stratus Patents.

B. IPR Petitions

22. I understand that Avanos filed the four IPR petitions on July 26, 2024. I will refer to the four IPR petitions as the “1209 Petition,” “1210 Petition,” “1211 Petition,” and “1212 Petition.” I will refer to these IPR petitions collectively as the “IPR Petitions.”

23. I understand that the IPR Petitions rely on the following references, which the IPR Petitions allege to be prior art to the Stratus Patents:

- Racz: US 6,146,380
- Fitz: US 2005/0059964A1
- Lee: US 2007/0016183 A1
- Young '965: US 2006/0084965 A1
- Scheibe: US 2007/0260223 A1
- Cosman: US 7,976,542 B1
- Young '201: US 2009/0112201 A1
- Godara US 2007/0027449 A1

24. I understand that each IPR petition was filed with a declaration from Dr. Robert Tucker. Those declarations are exhibit nos. 1031, 1032, 1033, and 1034 in IPR2024-01209, IPR2024-01210, IPR2024-01211, and IPR2024-01212, respectively. I will refer to those declarations collectively as the “Tucker Declarations.” When referencing the Tucker Declarations, I may cite specifically to just one particular declaration that is representative of the others. The substantive content of the four Tucker Declarations is largely overlapping.

C. Related Cases

25. I understand that Stratus has a related patent in Australia for the same or similar inventions claimed in the Stratus Patents in the United States. I understand that a company called “Diros” attempted to invalidate the related Stratus Australian patent as part of an effort to enter the Australian market with an RF neurotomy device similar to the Stratus Nimbus. I understand that case settled under confidential terms, which I do not know.

26. I understand that Avanos, the petitioner, has since acquired Diros. I further understand that Avanos now makes and sells an RF neurotomy device which is the same as or substantially similar to the Diros device.

27. I understand that on or about May 2, 2025, Stratus sued Avanos and Diros for infringement of the Stratus Patents. I understand that the lawsuit was filed in the U.S. District of Delaware as Case No. 1:25-cv-00546. I have had no involvement in that case.

IV. SUMMARY OF OPINIONS

28. As explained in more detail in section V-A below, it is my opinion that the pertinent field for the Stratus patents must include RF neurotomy specifically and cannot be RF ablation in general.

29. It is also my opinion, as explained in more detail in section V-B below, that a person of ordinary skill in the art (POSITA) would have the combined skills of an interventional pain-specialist doctor (the type of doctor who performs RF neurotomy procedures) and an engineer with experience designing and developing devices for applying electromagnetic energy to nerves.

30. It is also my opinion, as explained in more detail in section XI-B below, that a POSITA would consider Lee to have little to no relevance to RF neurotomy, and hence to Racz, Fitz, and the Stratus patents, because Lee concerns a device for a completely different type of RF ablation.

31. It is also my opinion, as explained in more detail in sections VII-A and XI-B below, that a POSITA would not interpret Racz as teaching a straight tip in any circumstances and that a POSITA would understand Racz as teaching against having a straight tip.

32. It is also my opinion, as explained in more detail in section VII-B below, that Fitz does not provide an enabling disclosure of his embodiment illustrated in Fig. 5.

33. It is also my opinion, as explained in more detail in sections VII-C and XI-F below, that a POSITA would understand Lee to require anchors except perhaps when Lee's stylets are deployed one at a time.

34. It is also my opinion, as explained in more detail in section XI-C below, that a POSITA would consider Fitz and Lee, on one hand, and Racz, on the other hand, to be examples of alternative, not complementary, designs for RF ablation devices. A POSITA would view Fitz and Lee as representative of a class of RF ablation needles having deployable/retractable filaments but not a removable RF probe, whereas a POSITA would consider Racz to be representative of a filament-less device employing a removable RF probe. A POSITA would not, in my opinion, attempt to combine those two different alternative approaches.

35. It is also my opinion, as explained in more detail in section VII-A below, that none of Racz, Fitz, or Lee teaches energizing deployable/retractable filaments at the distal end with a removable RF probe, and that such a teaching would not have been suggested to a POSITA from the teachings of Racz, Fitz, and Lee.

36. It is also my opinion, as explained in more detail in section XII-A below, that a POSITA would find the description of Racz's modified device, as set forth in the petition, Dr. Tucker's declaration, and in light of Dr. Tucker's deposition testimony, to be vague, ambiguous, and incomplete.

37. It is also my opinion, as explained in more detail in section XII-D below, that Racz's modified device, as best understood, is not the most straightforward way for a POSITA to increase ablation volume (the asserted motivation to make Racz's modified design) based on the teachings of Racz, Fitz, and Lee. In my opinion, this indicates that Racz's modified device has been concocted based on impermissible hindsight to match the claims of the Stratus Patents, not what a POSITA would naturally do based on the teachings of the references.

38. Perhaps most significantly, it is also my opinion, as explained in more detail in sections XII-C and XII-D below, that Racz's modified device, as best understood, would be impossible to build by a POSITA without undue experimentation. That is, it is my opinion that Racz, Fitz, and Lee collectively do not enable how to make Racz's modified device.

39. Just as significantly, it is also my opinion, as explained in more detail in section XII-E below, that a POSITA would not have had a reasonable expectation of success to make Racz's modified device, as best understood.

40. It is also my opinion, as explained in more detail in section XII-E below, that a POSITA would not have had a reasonable expectation of success to use Racz's modified device, as best understood, to perform an RF neurotomy procedure.

41. It is also my opinion, as explained in more detail in section XIII below, that the proposed combination of Young '965 with Racz, Fitz, and Lee suffers from similar limitations to those of Lee with Racz and Fitz and introduces further complications that would dissuade a POSITA from that combination.

42. It is also my opinion, as explained in more detail in section XIII below, that Scheibe's teachings are not reasonably pertinent to the purpose of deploying Lee's filaments from Racz's modified device.

V. ORDINARY SKILL IN THE ART

A. Pertinent Field of Art

43. Dr. Tucker asserts that “the ’782 Patent identifies its technical field as relating to ‘thermal ablation systems and methods,’ which includes RF neurotomy systems. Ex-1001, 1:28-31.” (Ex. 1031 ¶ 105) I disagree.

44. First, Dr. Tucker does not explain his rationale for this assertion. As a result, I am unable to assess his reasoning.

45. Second, Dr. Tucker only partially quotes the Stratus Patents. The ’782 Patent, for example, says in full at the indicated passage: “The present application *generally* relates to thermal ablation systems and methods, and *more particularly to systems and methods for radio frequency (RF) neurotomy*, such as spinal RF neurotomy.” (’728 Patent at 1:28-31 (emphases added)) As can be seen, the Stratus Patents only relate “generally” to thermal ablation. It relates “more particularly to RF neurotomy.” In fact, the main thrust of the patent is RF neurotomy. All the embodiments described in the Stratus Patents relate exclusively to RF neurotomy. All the independent claims of the ’728 Patent, for example, specifically recite “RF neurotomy.” RF neurotomy is an indispensable part of the patent. However, as I explain below, Dr. Tucker incorrectly focuses on the general at the expense of the more particular field of the Stratus Patents.

46. The Stratus Patents briefly mention RF ablation outside of the neurotomy context, but those passing mentions are limited to the background section where related (but different) technology is briefly noted. The Stratus Patents also hint at non-neurotomy applications for the inventions described in the patent, but those hints are very brief with no details. I understand that sort of thing is common

in patents, and it is clear that the nearly exclusive thrust of the patent is RF neurotomy.

47. Third, the field of RF ablation is extremely broad and encompasses many different devices and methods used to treat a broad variety of different types of tissue in patients having diverse medical conditions treated by doctors with different, non-overlapping specialties. Other prominent examples of bodily tissue (other than nerves) treated with RF ablation include cancerous tumors, uterine fibroids, and liver cancer. The clinicians (physicians treating patients) who perform those RF ablation treatments are specialists such as oncologists, gynecologists, hepatologists and general surgeons.

48. In my experience as a medical device engineer and medical device company executive, I have observed that different specialist doctors, such as the ones noted above, have practically no overlap with each other and have no overlap with pain-medicine specialists, the type of clinicians that perform RF neurotomy exclusively or nearly exclusively.

49. It is therefore my opinion that Dr. Tucker's assertion that the technical field is RF ablation in general is overbroad. That field includes many subfields wholly unrelated to RF neurotomy. By defining the field in this way, Dr. Tucker includes subfields that are irrelevant to RF neurotomy and sweeps in persons and technology involved in non-neurotomy RF ablation but with no relation whatsoever to RF neurotomy, which is the actual focus of the Stratus Patents.

B. Person of Ordinary Skill in the Art

50. Dr. Tucker defines a person of ordinary skill in the art (POSITA, or what he calls a "POSA") as follows:

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 [sic] and methods; or (ii) an advanced degree in the same areas of academic study with at least 1 years of experience with thermal ablation systems and methods.

(Ex. 1031 ¶ 105) I disagree with this definition.

51. First, I find it unclear what he means by “experience with thermal ablation system[s] and methods.” Does he mean studying such systems and methods, designing such systems and methods, developing such systems and methods as commercial products, using such systems and methods as a clinician to treat patients, testing such systems and methods, and/or something else?

52. Second, Dr. Tucker perpetuates the mistake he makes defining the field of the art as RF ablation. Dr. Tucker's definition of a POSITA/POSA encompasses persons with no knowledge of or experience with RF neurotomy at all because RF ablation is such a broad diverse field, as I explain above. A person who has an entire career designing RF ablation devices for treating uterine fibroids would not have the required knowledge and experience to design a device for RF neurotomy. The correct definition of a POSITA in this case must include knowledge of and experience with RF neurotomy.

53. Third, Dr. Tucker's definition of a POSITA/POSA fails to capture the perspective of the clinicians who perform RF neurotomy procedures. Those are interventional pain-specialist physicians. That perspective is critical because they are the people who use the devices and methods on actual patients, know the relevant target tissue (nerves) and surrounding anatomy, understand how to use an RF

neurotomy tool to approach the target tissue, understand what clinical endpoints should be achieved, and know the risks and complications of the devices and methods. In fact, much of the description in the Stratus Patents is directed towards access to the target tissue (nerves), and deployment of the electrodes for neurotomy.

54. Biomedical engineering is the intersection of engineering, biology and medicine. In my experience as a medical device engineer and medical device company executive, medical devices are always developed at least in consultation with the type of physician who would use the device. Very often, it is such a physician who envisions the device that he/she needs and guides the development. Such a physician is an indispensable part of the development team and must be included in the definition of a POSITA.

55. I also note that the inventors of the Stratus Patents are both medical doctors with a specialty in pain treatment. I note as well that the inventors listed on the references cited in the IPR Petitions are mostly, if not exclusively, medical doctors. These facts are consistent with my experience and opinions stated above.

56. For example, one of the asserted prior art patents is US 2007/0016183 with the first named inventor Dr. Bruce Lee. The Acesa System based on the Lee patent application was developed and commercialized by Halt Medical and received a 510(k) K094009 in June 2010 with the Intended Use as follows: “The Halt 2000G1™ Electrosurgical Radiofrequency Ablation System is indicated for use in percutaneous, laparoscopic, and intraoperative coagulation and ablation of soft tissue.” The Acesa System is used by Dr. Bruce Lee for treating uterine fibroids and advertised on his web site <https://bruceleemd.com/meet-acessa-inventor/>. The Acesa System is currently sold by Hologic Inc.

57. Dr. Tucker’s definition of a POSITA requires a “degree in biomedical engineering, or a related field, such as mechanical engineering, biomechanical engineering, or bioengineering”—that is, all examples require some form of an engineering degree. I agree.

58. In my opinion, the key attributes of a POSITA in this case would be a combination of (1) an interventional pain-specialist physician with significant experience performing RF neurotomy procedures and (2) an engineer with a degree in biomedical engineering or a related field and experience in the design and development of devices and methods for applying electromagnetic energy to nerves. The POSITA should have either a bachelor-level degree with three years of the design/development experience noted above or an advanced degree with one year of the design/development experience noted above. Such a POSITA could be a team of two or more people working together.

59. I understand that the POSITA’s perspective is at the time of the invention, which is the effective filing date of the patent application. In this case, I have assumed that is November 2009 through May 2011. My opinions and statements in this declaration about what a POSITA would know, understand, etc. are intended to be as of that time frame, even if I use the present tense. My opinions in this declaration would be the same, however, if the relevant time frame were slightly later or earlier.

60. By May 2010, I had engineering skills and knowledge exceeding those needed by a POSITA. I worked regularly with people having the engineering skills and knowledge of a POSITA, typically as engineers that I supervised and pain-specialist physicians that I worked with, so I am familiar with the engineering skills and knowledge of a POSITA at the relevant time.

VI. APPLICABLE LEGAL PRINCIPLES

61. I am not a patent attorney, but I understand aspects of patent law that are relevant to my analysis and opinions. I summarize my understanding of some relevant patent law principles below.

62. I understand that in an IPR, the burden of proof is on the petitioner to show that each challenged claim is unpatentable and that the petitioner must do so by the preponderance of the evidence.

63. Even though none of the challenges in these IPRs are anticipation challenges, I recount my understanding of key aspects of anticipation for completeness.

64. I understand that, for a patented invention to be anticipated, a single prior-art reference alone must disclose every limitation in a claim, thus “anticipating” the claim.

65. I understand that, for anticipation to exist, there must be no difference between the claimed invention and the reference disclosure, as viewed by a POSITA.

66. I understand that anticipation requires that each element of the claim at issue be found, either expressly or under principles of inherency, in the reference.

67. I understand that inherent disclosure requires that the feature necessarily be present in the reference. The mere possibility that the feature is present is not enough to support inherent disclosure.

68. I understand that anticipation requires more than simply locating each element entirely within a single document, but that document must also disclose those elements arranged together as in the claim.

69. I also understand that invalidity by anticipation requires that the prior-art reference's teaching of the claimed invention must teach a POSITA how to make and use the invention without undue experimentation.

70. I understand that, for a patented invention to be obvious, there must be prior-art references that alone or in combination would have rendered the claimed invention obvious to a POSITA at the time of the invention.

71. I understand that for a claim to be found obvious, every limitation of the claim must result from either a combination of the teachings of multiple prior-art references or a modification of a single prior-art reference.

72. I understand that the factors that should be assessed in the obviousness analysis include at least: (1) the scope and content of the prior art; (2) the differences between the prior art and the claim at issue; (3) the level of ordinary skill in the art; and (4) objective evidence as indicia of non-obviousness.

73. I understand that obviousness must take into account the ordinary knowledge, skills, and creativity of a POSITA.

74. I understand that a reason must be shown that would have prompted a POSITA to have combined or modified known elements in the fashion claimed by the patent at issue. Assertions that a combination or modification would have been obvious cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

75. I understand that there must be a reasonable expectation of success in making or practicing the claimed invention based on the combination or modification of the prior-art reference(s) used to render a claimed invention obvious.

76. I understand that the combination cannot modify a prior-art reference such that it would render the reference unsatisfactory for its intended purpose, change the principle of operation of a reference, or require a substantial redesign or reconstruction of the reference.

77. I understand that obviousness does not require that the teachings of the references be bodily incorporated together; rather, the focus is on the concepts taught by the references.

78. I understand that prior-art references must be considered as a whole, including aspects that teach away from a claimed invention or that may rebut a showing of obviousness.

79. I understand that the obviousness inquiry must guard against slipping into use of hindsight and resist the temptation to read into the prior art the teachings of the invention in the patent at issue. Isolated elements from the prior art should not be picked and chosen and then combined using the invention as a blueprint if such a combination would not have been obvious at the time of the invention. In other words, it is impermissible to use the patent as a template (or reason) for combining prior-art references because that would be applying hindsight. A POSITA would have needed a reason to combine the references to create the claimed invention independent of the patent.

80. I understand that obviousness requires that the prior-art references collectively must teach a POSITA how to practice the invention without undue experimentation. I understand that this is a form of the enablement requirement, which considers the following so-called *Wands* factors: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the

state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

81. I have not considered objective evidence of non-obviousness in this case, but I know that there is such evidence which further supports my opinion that the claims of the Stratus Patent are not obvious.

VII. TECHNICAL BACKGROUND

82. I explain here some technical background regarding RF neurotomy and devices used in RF neurotomy procedures.

83. In RF ablation, an electrode (e.g., the tip of an insulated needle) is placed in or near the target tissue, and RF electromagnetic energy is delivered. The volume of tissue ablated depends on many variables including the shape of the electrodes and the amount of energy delivered.

84. RF ablation is sometimes used to destroy cancerous tissue (tumor), in organs like the liver and uterus. RF ablation is sometimes used to treat skin. The goal of RF ablation for cancer treatment is destruction of a large amount of tissue.

85. Neurotomy is a specialized form of RF ablation. It is a minimally invasive procedure that sends an RF signal through nerve tissue to heat and thereby ablate that nerve tissue to disrupt pain signals from being transmitted via that nerve tissue. RF neurotomy is often used to treat chronic pain in the spine (neck and back) that hasn't responded to other more conservative treatments. The goal of RF neurotomy is to destroy a small amount of tissue in a small anatomical structure – a nerve. The nerves that are the target of RF ablation in RF neurotomy are significantly smaller than the tumors and other structures targeted in other fields of RF ablation.

As a result, RF neurotomy is a much more precise procedure than other uses of RF ablation.

86. Many nerves contain both small diameter afferent (meaning towards the brain) pain conducting nerve fibers and large diameter efferent (meaning from the brain) fibers responsible for initiating muscle contraction. In many cases, the physician performing RF neurotomy seeks to destroy only afferent nerve fibers conducting pain signals while preserving efferent motor fibers responsible for body movement. Because of this, the delivery of RF electromagnetic energy in RF neurotomy must be precisely controlled, which is fundamentally different from RF ablation to destroy tumors.

87. In an RF neurotomy procedure, the clinician advances a small needle, usually under fluoroscopic (X-Ray) guidance to the location of the target nerve. Nerves cannot be seen on X-Ray, so the clinician uses anatomical landmarks seen on fluoroscopy to help navigate the needle to the appropriate place. The needle is insulated over most of its length and has an exposed tip. Once the physician is satisfied that the needle is in the appropriate place, RF electromagnetic energy is applied to the tip of the needle. The current flows between the needle and a return electrode – usually a conductive pad placed for example on the buttocks or thigh.

88. An illustration of a typical RF neurotomy configuration from the Stratus Patents ('782 Patent Fig. 1) is reproduced below.

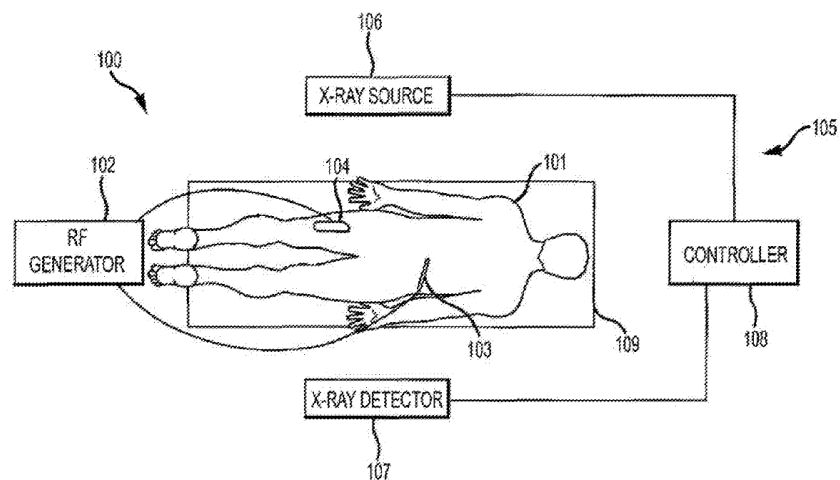


FIG. 1

89. To help understand the clinical procedure, Fig. 14 from the '782 Patent is reproduced below. Fig. 14 illustrates RF neurotomy of a medial branch nerve to the lumbar spine to treat facet joint pain (also known as the zygapophyseal joint or Z-joint). The facet joint is between adjacent vertebrae (1301 and 1302) and helps support the spine while allowing a wide range of motion, and can become worn and painful over time. The medial branch nerve (1303) emerges from the spinal cord and passes adjacent to the spinous process. An ablation needle (103) is placed near the nerve and RF energy is applied.

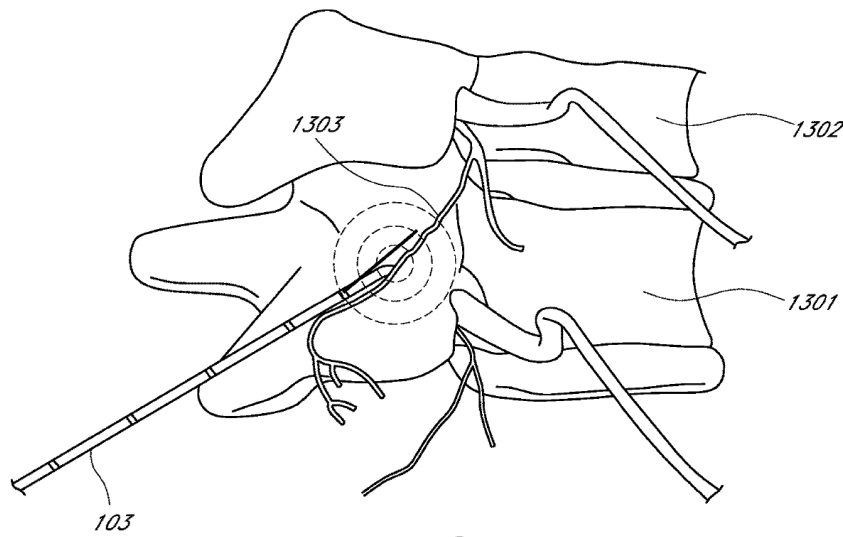


FIG. 14

90. The variable anatomy of the medial branch between people and between spine segments in the same person makes this procedure challenging. The task for the clinician performing the RF neurotomy procedure is to find the nerve and deliver the right amount of energy to destroy the afferent nerve fibers. In many cases, the needle must be advanced and retracted multiple times.

91. As taught by the Stratus Patents, one way of improving the RF neurotomy procedure is to increase the volume of tissue ablated with each delivery of RF energy. That is an objective of the Stratus Patents.

92. The Stratus Patents teach a removable RF probe which includes a temperature sensor, such as a thermocouple, for temperature monitoring. This is an advantage for RF neurotomy because the risks of applying too much energy include destroying efferent motor fibers in the nerve and/or damage to adjacent structures to the target nerve, particularly the nerve roots of the spinal cord. Temperature monitoring is less of an issue for RF ablation of tumors.

93. A removable RF probe, such as taught by the Stratus Patents, is highly advantageous for neurotomy procedures. That is for at least two reasons.

94. First, a removable RF probe may be reusable (as opposed to single use disposable). An RF probe can be expensive to manufacture. That is especially true of a thermocouple probe, which requires calibration. A reusable RF probe thus reduces the overall cost of the neurotomy procedure.

95. Second, a removable RF probe allows the lumen to be used (without the probe) to infuse fluids such as anesthetic using the full cross section of the lumen. This is typically desirable during an RF neurotomy procedure to infuse local anesthetic prior to application of RF energy. As a result, the lumen should be sufficiently large to be able to effectively deliver fluid through its length and out its open distal tip. If the diameter of the lumen is too small, fluid mechanics would hinder such a use. Think of a drinking straw – one can drink from a straw with an internal diameter of several mm, but not from a straw with an internal diameter of <1 mm – it takes too much force.

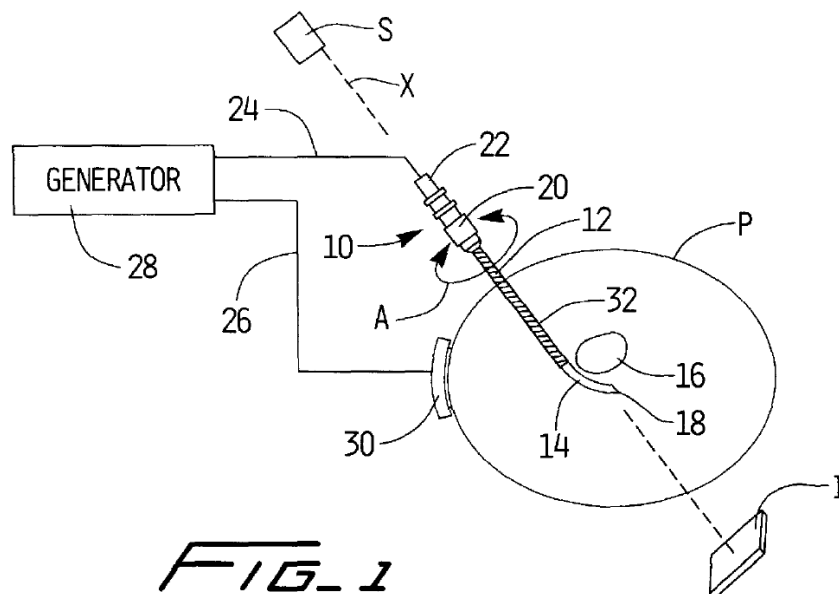
VIII. SUMMARY OF MAIN REFERENCES

96. Dr. Tucker references eight patent documents in his declarations, three of which are the most central to his analysis:

- Racz: US 6,146,380
- Fitz: US 2005/0059964 A1
- Lee: US 2007/0016183 A1

A. Racz

97. The title of Racz is “Bent Tip Electrical Surgical Probe.” Racz explains that the purpose of the invention is to deliver “anesthesia, pain relief, or other treatment involving a firmly curved tip needle electrode” (Racz 2:45-47). The basic invention is a single metal tube with a bent tip, and a single lumen through which fluids or a probe may be introduced. This is illustrated in Racz Fig. 1, reproduced below:



98. The tip is non-insulated, and the remainder of the needle is insulated. The bend at the tip is the *raison d'être* of the invention. As Racz explains, “A further advantage of using a small-gauge spinal needle with a curved or bent distal end is that it can be accurately steered into narrow and relatively difficult-to-access portions of a patient's spine” (Racz 6:59-63). The invention involves “a firmly curved tip needle electrode.” (Racz 2:46-48) Each of the three independent claims recite “wherein the distal tip portion includes an uninsulated, rigidly bent portion to facilitate placement of the distal tip portion at the target region.”

99. Racz describes two major embodiments: One in which the aperture of the lumen is at the distal end of the needle, and one in which the aperture of the lumen is on the concave side of the curve at the tip. Racz teaches that the needle can be manipulated (e.g., under fluoroscopic imaging) by rotation of the hub, which thereby reorients the tip. Racz 2:66-3:2) This rotation requires torsional rigidity of the needle.

100. The version with the aperture of the cannula at the end of the needle is used for a variety of purposes, whereas the version with the aperture on the concave side of the tip is not used for application of electrical energy (Racz 6:8-20).

101. Racz is made from a shaft 34, which is a “hollow metal tube” and has a single lumen for accepting the electrical probe 22. (Racz 4:62-65) Racz explains, “The electrode cannula 10 further comprises a hub 20. The hub 20 is capable of accommodating an electrical probe 22, which includes a segment that is inserted into and received by the shaft 12 of the cannula 10. This physical relationship between the probe 22 and the shaft 12 facilitates electrical contact between the two elements” (Racz 3:59-65). In other words, RF electromagnetic energy is delivered by probe 22 and insulated tip 14.

102. Racz’s shaft 34 (a hollow metal tube) is partially covered with an insulating coating, forming a more proximate insulated portion 36 and a distal tip portion 38, which is “at least partially uninsulated.” (Racz 4:62-5:1)

103. Racz is directed towards access to a difficult-to-reach anatomical location and requires a firmly curved tip (description and all independent claims) which inhibits any complex mechanism at the distal end.

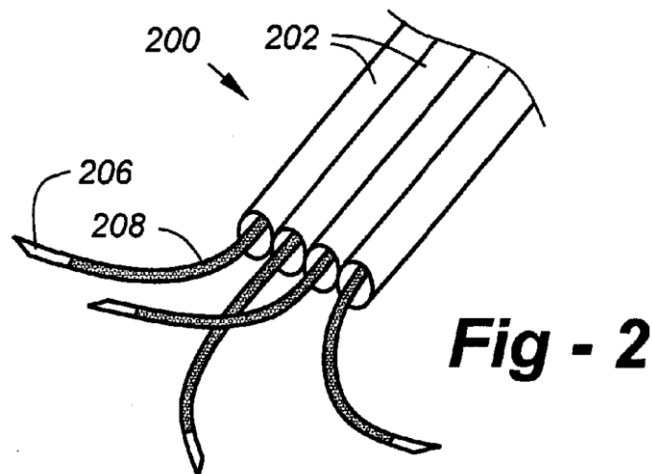
104. There is nothing in Racz to teach how to expand the ablated volume.

105. Indeed, Racz indicates that electrode probes where expansion at the distal tip by a flexible member is undesirable in the neurotomy space . . . that's certainly my takeaway and a POSITA's takeaway. (Racz 2:26-38)

B. Fitz

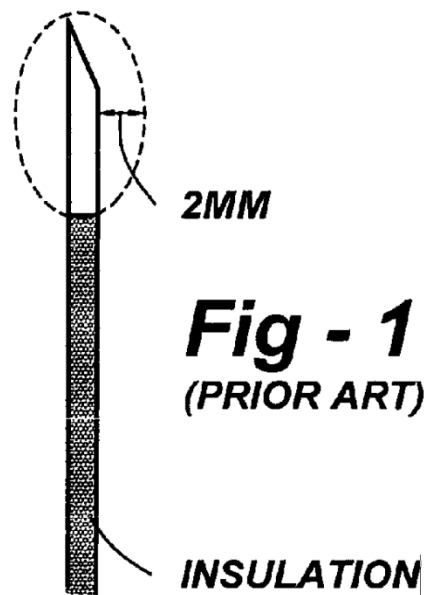
106. The title of Fitz is “Enhancing the Effectiveness of Medial Branch Nerve Root RF Neurotomy.”

107. Fitz does not describe a neurotomy needle but instead describes an introducer with one or more elongated co-extensive cannula for introducing multiple, independently insulated, RF ablation electrodes (see Fitz Figs. 2, 3, and 4). Fitz's Fig. 2 is reproduced below.

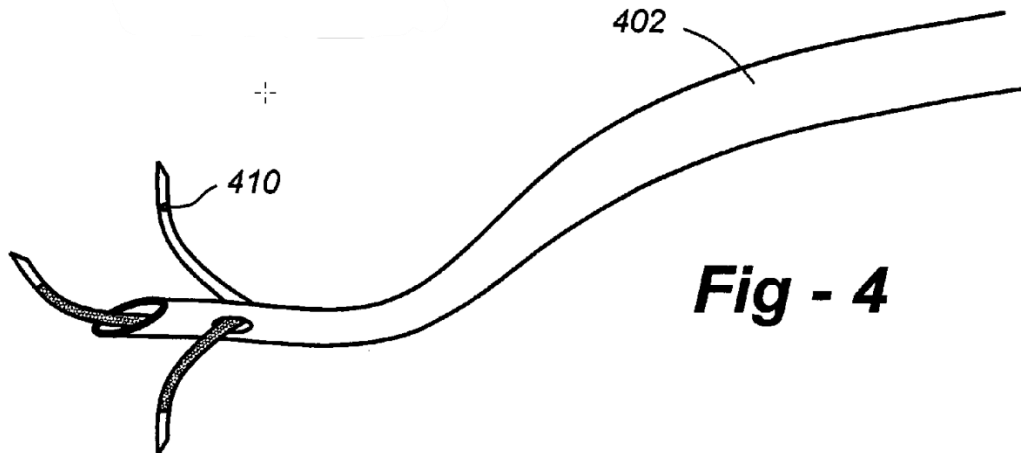


108. Fitz describes that “*each* electrode has a proximal end configured for attachment to a source of energy, and an exposed distal tip to deliver the energy to a localized region, and *each* electrode slides within its respective cannula so to enhance the energy coverage area” (emphases added). Fitz addresses the problem of increasing the volume of RF neurotomy by having multiple independent electrodes.

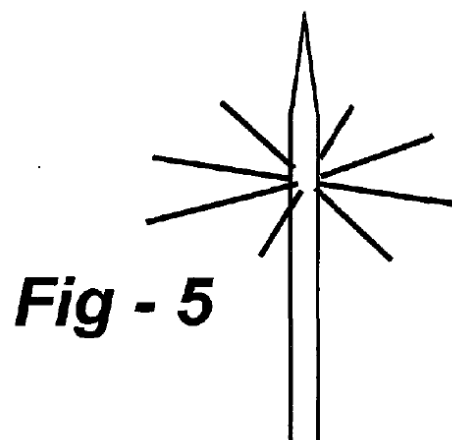
109. Because each of the Fitz electrodes 206 are insulated by lengthwise insulation 208, the ablation volume around each electrode 206 is potentially the same as the ablation volume depicted around the prior art electrode in Fig 1, which is reproduced here:



110. Fitz Fig. 4 (reproduced below) also shows insulated electrodes, and each of the electrodes is the same as the electrodes in Figs. 2, 3 and 5. In Fig. 4, the introducer 402 has side ports, and two of the electrodes 410 as shown in Fig. 4 extend from side ports. Fitz Fig. 4 and its description are too vague and lacking in detail to present a meaningful teaching of how to achieve that embodiment. In particular it is not clear to me (and would not have been clear to a POSITA) from Fitz Fig. 4 and its one-paragraph ([0020]) description in the text how this embodiment is constructed to achieve the deployed configuration shown. For example, it is not clear in what manner the electrodes 410 are to be moved from a position within the introducer 402 and then directed through the side ports. Fitz does not teach how to make a functional device having the deployed electrodes as shown in Fig. 4.



111. Fitz Fig. 5 (reproduced below) does not show insulated electrodes, but the context makes it clear to a POSITA that each of the electrodes in the radial array is the same as the electrodes in Figs. 2, 3 and 4. Furthermore, Fitz Fig. 5 does not show an aperture at the end of the catheter and it is described as “an introducer having a tip and sufficient side ports to form an electrode array once deployed.” (Fitz [0021]).



112. As with Fitz Fig. 4, Fitz Fig. 5 and its description are too vague and lacking in detail to present a meaningful teaching of how to achieve that embodiment. In particular it is not clear to me (and would not have been clear to a POSITA) from Fitz Fig. 5 and its one-paragraph ([0021]) description in the text how this embodiment is constructed to achieve the deployed configuration shown. Fitz

does not disclose sufficient details to understand how the electrodes in Fig. 5 are deployed and does not teach how to make a functional device having the deployed electrodes as shown in Fig. 5.

C. Lee

113. Lee (US 2007/0016183) was subsequently issued as US Patent No. 8,080,009 on December 20th, 2011. The discussion herein refers to the published application as referred to in the IPR Petitions.

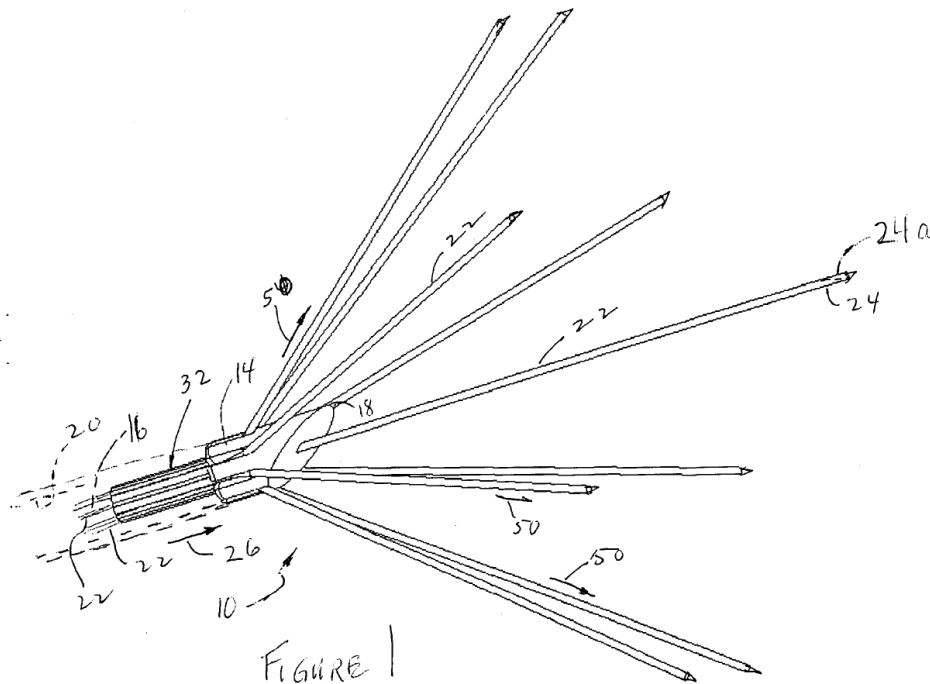
114. Neither of the words “nerve” nor “neurotomy” appear anywhere in Lee. There is nothing in Lee to indicate that Lee considered RF ablation of a nerve, or neurotomy. Lee teaches that “the present invention is thus directed to a device for the treatment of uterine fibroids and other tissue masses that meets the needs of women by conserving the uterus and reducing recovery time from 6 to 8 weeks to 3 to 10 days.” (Lee [0031])

115. The Lee invention is a trocar – a surgical instrument used to create an incision. A POSITA would have understood that the term “trocar” is sometimes used interchangeably with “cannula,” but technically, the trocar refers to the entire instrument including the pointed tip that makes the incision, while the cannula is just the hollow tube allowing passage of things into or out of the body – fluids, instruments, wires and the like.

116. Lee does not disclose any variation of his device which has a curved tip – in fact, all examples have a straight tip because the tip must pierce the tough tissue of a uterine fibroid, and a curved tip simply would not work.

117. The purpose of the invention in Lee is to increase the volume of ablated tissue, particularly in treatment of uterine tumors/fibroids. As shown in Fig. 1 of Lee reproduced below, Lee achieves this with a plurality of metal “stylets” (22) that exit

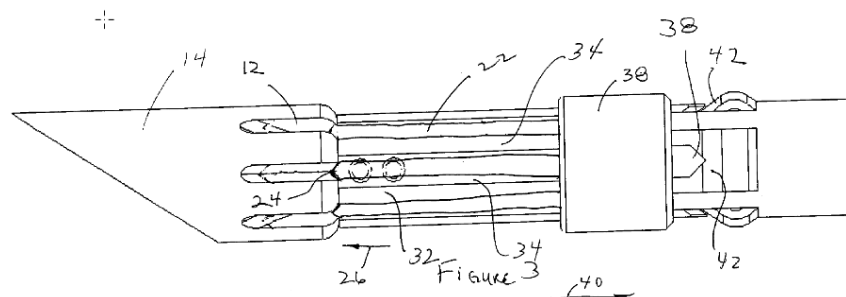
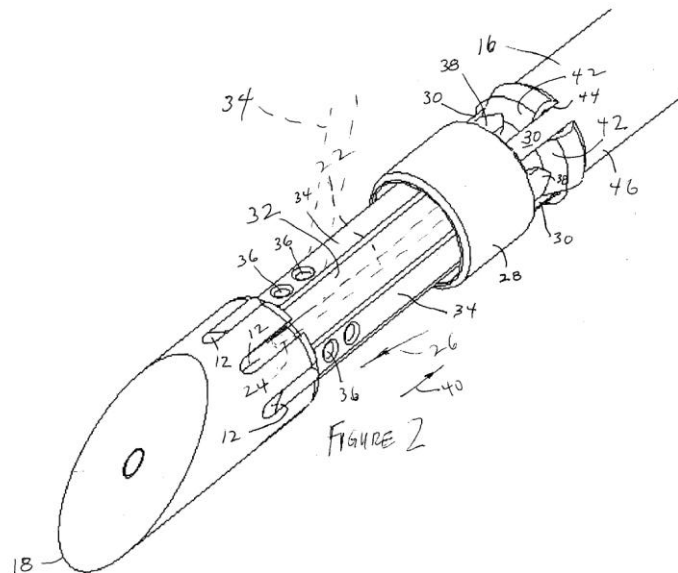
the trocar tip (14) at acute angles relative to the longitudinal axis of the trocar (i.e., a radial direction) and in the general direction of the direction of insertion of the trocar.

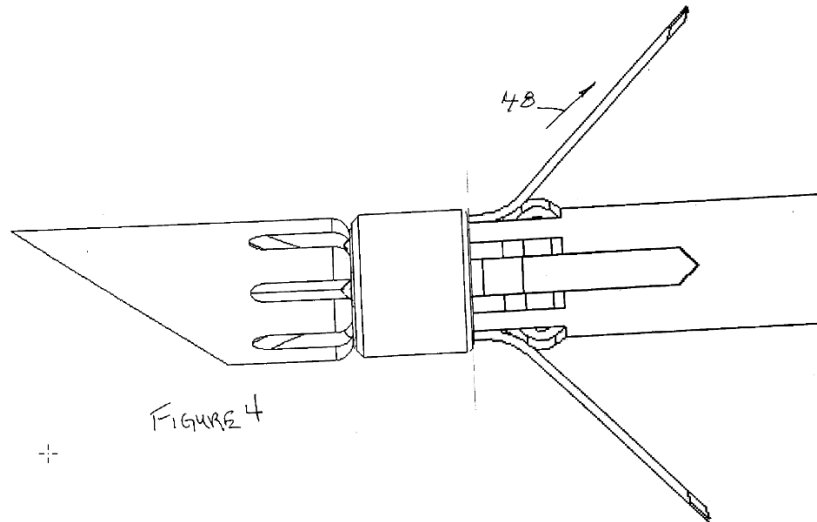


118. Lee does not include a lumen through which an RF probe is advanced. Lee teaches that the advancement of the stylets may meet mechanical resistance which could tend to move the cannula from the desired position. “Furthermore, in accordance with the invention, it is recognized that it is useful if the electrodes or their delivery device experience minimal migration in the forward and backward directions during and after the electrode placement process.” (Lee [0086])

119. To prevent this, Lee teaches anchors. “The anchors prevent the device from migrating backward when pushing the electrodes into the firm tissue or forward when pulling the electrodes out.” (Lee [0089]) Lee’s anchors are “mounted for movement between an internal position and an anchoring position extending laterally from the trocar surface through points external to the lumen” (Lee [0019])

Lee explains, “The anchor comprises at least two pointed members mounted for movement in directions which have vector components which extend away from the axis of the cannula and away from each other.” (Lee [0020]) “The anchors may be deployed in response to rotary motion. The anchors are deployed by bearing against a deflection surface. The anchors are made of a springy material which may assume a curved configuration when not subjected to external forces.” (Lee [0030]) Lee Fig. 2 is reproduced below, in which anchors 34 are in a non-deployed position, held by a collar 28, parallel to the longitudinal axis of the cannula. Lee Fig. 3, reproduced below, is a side view of the same, and Fig. 4, reproduced below, is a side view with the anchors deployed and the collar moved distally forward:





120. According to Lee, “A plurality of anchors 34 are secured by numerous means such as fasteners 36 or laser welding to inner sleeve 32. Anchors 34 terminate at points 38 which are sharpened to easily pierce the tissue and thus anchor the trocar.” (Lee [0095]) A POSA would understand that the anchors are permanently attached and are an important component of Lee, at least when all the stylets are deployed simultaneously. Lee mentions a possible scenario in which anchors may not be deployed “by advancing the ends of stylets 22 one at a time, thus minimizing their tendency to displace the trocar,” but Lee does not describe or enable a mechanism for deploying the stylets individually. (Lee [0104])

121. The “anchoring may be implemented by withdrawal of inner sleeve 32 into cannula 16. As sleeve 32 is withdrawn into cannula 16, it pulls anchors 34 in the direction indicated by arrow 40, pushing anchor points 38 against deflection surfaces 42, causing the flexible resilient anchors 34 to be deflected laterally in the directions illustrated in FIG. 4, under the combined influence of the inner surface of collar 28 and deflection surfaces 42 which induce an outward lateral bend.” (Lee [0099]) If it is necessary to withdraw and advance the trocar to a different position, the anchors must first be withdrawn (Lee [0110]).

122. A POSITA would have understood that Lee generally discloses a trocar point and the cannula as separate components. “A deflection surface is positioned between the trocar point and the proximal end of the cannula” (Lee [0012]). “The trocar member has a proximal end secured proximate to the distal end of the elongated cannula. The outside surface of the cannula and the outside surface of the trocar point define a trocar surface” (Lee [0015]). “The cannula may be secured to the trocar member with the outside surface of the cannula proximate to the outside surface of the trocar member” (Lee [0018]). Specifically, “trocar point 14 is mounted on a cannula 16.” (Lee [0091])

123. Not only are the trocar and cannula separate components, but there is another component – “cannula 16 includes a collar 28 secured to a plurality of axially oriented ridges 30 disposed around the circumference adjacent cannula 16. Collar 28 is rigidly secured to ridges 30 and is in spaced relationship to substantially concentric inner sleeve 32. (Lee [0094])

124. A close look at Lee Fig 1. (reproduced in part below) shows the trocar point 14 mounted on the cannula 16 which defines a lumen 20. A POSITA would have understood that this configuration is necessary because the trocar point 14 is a very small but complicated mechanical part and manufacturing it (especially in volume) presents multiple engineering challenges which would take a lot of effort to address. Lee states “a wide variety of materials may be used to manufacture the inventive trocar 10. For example, all members may be made of plastic except for the very tip of forward piercing edge surface 18 and stylets 22. (Lee [0097]) Lee provides no guidance on which “plastic” would be suitable, and the mechanical requirements (including the stylet deflecting surfaces) are very challenging.

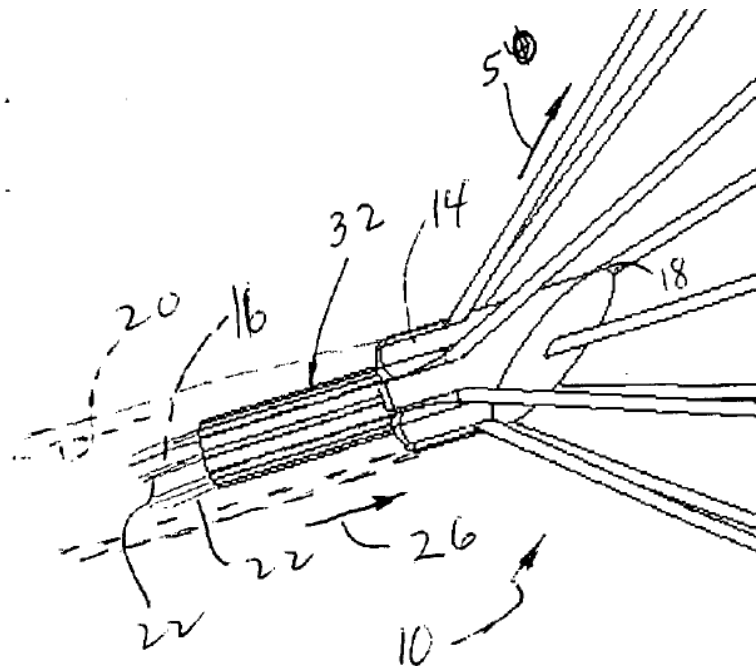


FIGURE 1

125. Lee teaches that the electrodes can be used in either monopolar fashion or “bipolar fashion where one set of electrodes, such as the tip electrodes could serve as negative electrodes and the anchor electrodes may serve as the positive electrodes and create an ablation volume between the two sets of electrodes.” (Lee [0024]) A POSITA would have understood that the proposed bipolar configuration requires insulation between the “positive” electrodes and the “negative” electrodes. Although Lee does not teach how and where that insulation is located, it must be there.

126. Several embodiments in Lee do not include a central cannula through which something could be inserted and are not considered further herein (e.g., Lee Figs. 41-44 and Lee [0137]).

127. Lee is confined to a device for RF ablation of tumors, specifically uterine fibroids. Lee does not mention neurotomy or nerves, and the background states “an RF ablation probe of the type used to treat tumors in the human liver by hyperthermia has been successfully demonstrated to substantially shrink or eliminate

uterine fibroids.” (Lee [0005]) In my opinion, a POSITA would not have found Lee in a search for prior art on RF neurotomy and would not have looked to the field of Lee. Therefore, in my opinion, Lee has little to no relevance to the Stratus Patents.

IX. DR. TUCKER’S PROPOSED INVALIDITY GROUNDS

128. Dr. Tucker opines that all claims of the Stratus Patents would have been obvious over at least Racz, Fitz, and Lee.

129. Dr. Tucker opines (Ex. 1031, pages 63-64) that all claims of the ’782 Patent would have been obvious over those three references and others and provides a table reproduced below:

	Claims	Statute	Prior Art
A	1-27	§ 103(a)	Racz, Fitz, and Lee
B	1-27	§ 103(a)	Racz, Fitz, Lee, and Young ’965
C	1-27	§ 103(a)	Racz, Fitz, Lee, and Scheibe
D	1-27	§ 103(a)	Racz, Fitz, Lee, Young ’965, and Scheibe
E	7-9	§ 103(a)	Racz, Fitz, Lee, and Cosman ’542
F	7-9	§ 103(a)	Racz, Fitz, Lee, Cosman ’542, and Young ’965
G	7-9	§ 103(a)	Racz, Fitz, Lee, Cosman ’542, and Scheibe
H	7-9	§ 103(a)	Racz, Fitz, Lee, Cosman ’542, Young ’965, and Scheibe
I	13	§ 103(a)	Racz, Fitz, Lee, and Young ’201
J	13	§ 103(a)	Racz, Fitz, Lee, Young ’201, and Young ’965
K	13	§ 103(a)	Racz, Fitz, Lee, Young ’201, and Scheibe
L	13	§ 103(a)	Racz, Fitz, Lee, Young ’201, Young ’965, and Scheibe
M	15	§ 103(a)	Racz, Fitz, Lee, and Godara
N	15	§ 103(a)	Racz, Fitz, Lee, Godara, and Young ’965
O	15	§ 103(a)	Racz, Fitz, Lee, Godara, and Scheibe
P	15	§ 103(a)	Racz, Fitz, Lee, Godara, Young ’965, and Scheibe

130. Dr. Tucker opines (Ex. 1032, pages 68-69) that claims 1-17 48-52 of the ’688 Patent would have been obvious over the same three references and others and provides a table reproduced below:

	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

131. Dr. Tucker opines (Ex. 1033, page 68) that claims 18-47 and 53-74 of the '688 Patent would have been obvious over the same references and provides a table reproduced below:

	Claims	Statute	Prior Art
A	18-47, 53-74	§ 103(a)	Racz, Fitz, and Lee
B	18-47, 53-74	§ 103(a)	Racz, Fitz, Lee, and Young '965
C	18-47, 53-74	§ 103(a)	Racz, Fitz, Lee, and Scheibe
D	18-47, 53-74	§ 103(a)	Racz, Fitz, Lee, Young '965, and Scheibe
E	35-46, 54-55, 66-73	§ 103(a)	Racz, Fitz, Lee, and Cosman '542
F	35-46, 54-55, 66-73	§ 103(a)	Racz, Fitz, Lee, Cosman '542, and Young '965
G	35-46, 54-55, 66-73	§ 103(a)	Racz, Fitz, Lee, Cosman '542, and Scheibe
H	35-46, 54-55, 66-73	§ 103(a)	Racz, Fitz, Lee, Cosman '542, Young '965, and Scheibe

132. Dr. Tucker opines (Ex. 1034, pages 61-62) that all claims of the '664 Patent would have been obvious over the same references and provides a table reproduced below:

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

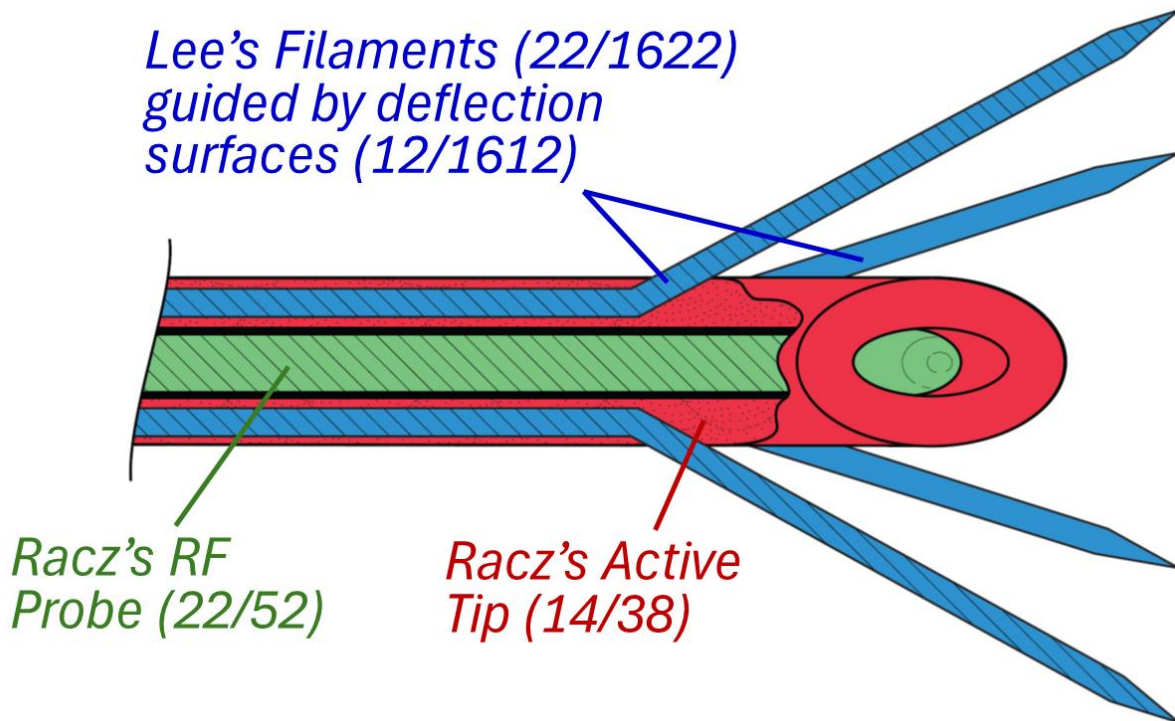
	Claims	Statute	Prior Art
G	11-17, 19, 27, and 29	§ 103(a)	Racz, Fitz, Lee, Godara, and Scheibe
H	11-17, 19, 27, and 29	§ 103(a)	Racz, Fitz, Lee, Godara, Young '965, and Scheibe
I	18 and 28	§ 103(a)	Racz, Fitz, Lee and Cohen
J	18 and 28	§ 103(a)	Racz, Fitz, Lee, Cohen, and Young '965
K	18 and 28	§ 103(a)	Racz, Fitz, Lee, Cohen, and Scheibe
L	18 and 28	§ 103(a)	Racz, Fitz, Lee, Cohen, Young '965, and Scheibe

133. All these grounds are based on a combination of Racz, Fitz, and Lee. Therefore, I will address initially that proposed combination.

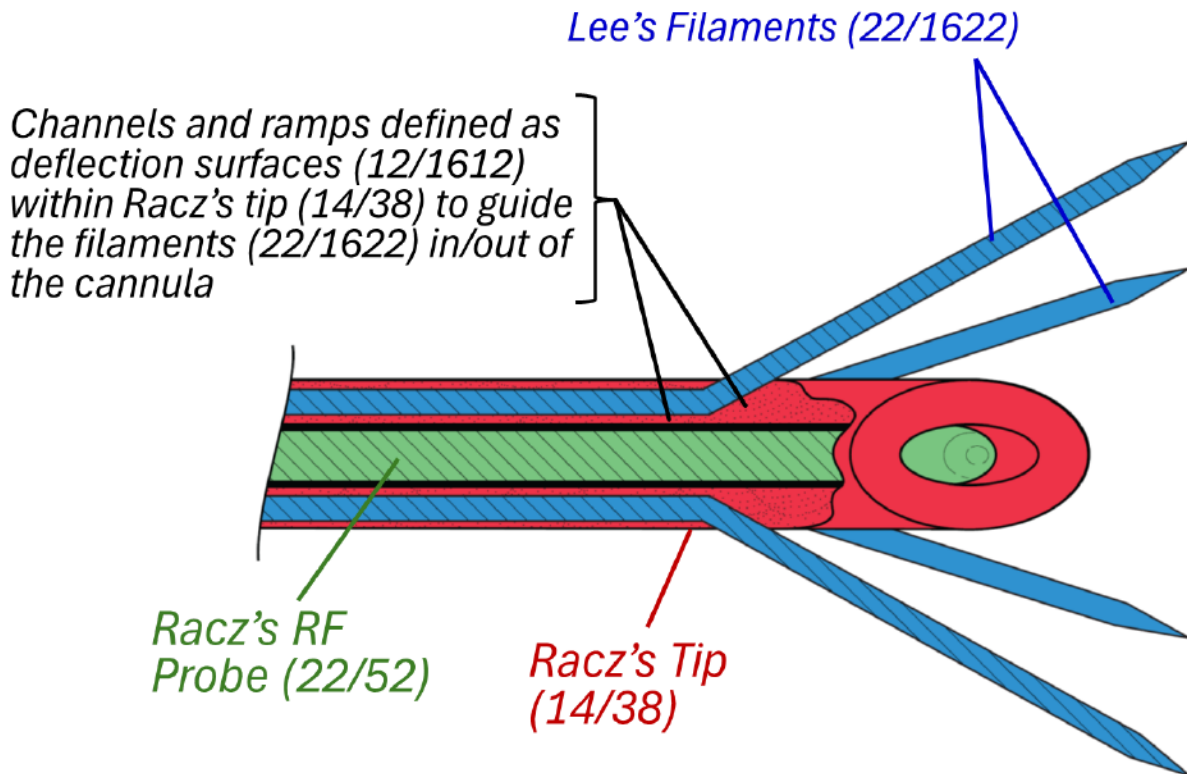
X. RACZ'S MODIFIED DEVICE, AS PROPOSED BY DR. TUCKER

134. Dr. Tucker proposes to combine Racz, Fitz and Lee (Ground A in all cases) into what he calls “**Racz’s modified device.**” (Ex. 1031 at 8, Ex. 1032 at 8, Ex. 1033 at 8, Ex. 1034 at 8). I will therefore also refer to this proposed combination as “Racz’s modified device.”

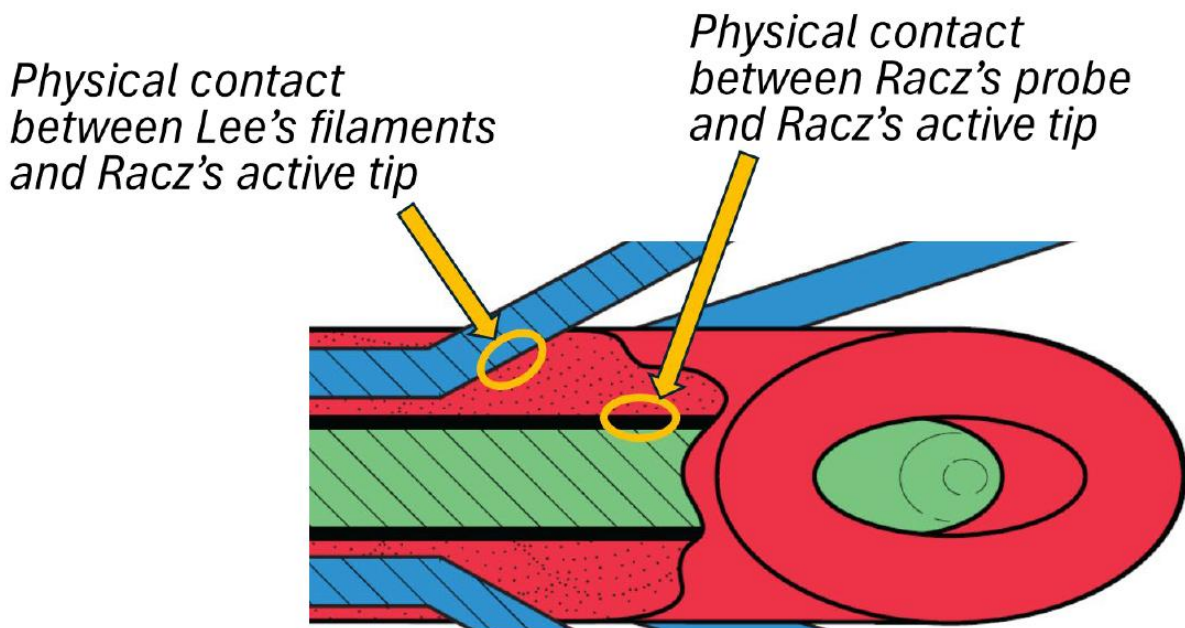
135. In his declarations, Dr. Tucker provides two examples of “how a POSA (motivated by both Fitz and Lee) would have incorporated Lee’s deployable filaments (22/1622) as monopolar electrodes at Racz’s distal tip (14/38)” (Ex. 1031 Tucker Decl. ¶143). He provides the visual rendition reproduced below (Ex. 1031 ¶ 85), which I understand to illustrate both examples:



136. He provides the same visual rendition of Racz’s modified device with different annotations as follows (Ex. 1031 ¶ 108):



137. Dr. Tucker provides another visual rendition of Racz's modified device, as reproduced below, enlarging a portion of the prior renditions to show some additional features, as labeled below (Ex. 1031 ¶ 109):



138. Dr. Tucker explains “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.” (Id. ¶ 144)

139. As I understand Racz’s modified device, as proposed by Dr. Tucker, he proposes modifying Racz’s neurotomy needle in various ways to result in a different device that falls within the scope of the Stratus patent claims. To do so, Dr. Tucker appears to propose that the sidewalls of at least Racz’s tip (and possibly the sidewalls of Racz’s needle along the entire length of the needle) (shown in red) would be modified to have channels sized and shaped such that filaments (shown in blue) can move longitudinally through the channels. As shown in Dr. Tucker’s sole drawing of this proposed modification, those channels appear to be cylindrical channels fully within the (red) body of the sidewall of the tip/needle.

140. The channels added within the sidewalls of Racz’s tip/needle terminate at the distal end where there are openings on the exterior sidewalls. At those points, the filaments are deployed out of the sidewall both radially outwardly and longitudinally forward (in the distal direction) into surrounding tissue of the patient’s body. Dr. Tucker shows that the channels are ramped radially outwardly near those

exit points, rather than ending abruptly at a right angle, to urge the filaments outward as they travel distally past the exit points.

141. Dr. Tucker also makes clear that the tip (shown in red in his drawings) in Racz's modified device is metal.

142. Racz's modified device, as proposed by Dr. Tucker, retains Racz's removable RF probe (shown in green in his drawings). According to Dr. Tucker, electrical energization of the (green) RF probe would energize the (blue) filaments via electrical conduction through the (red) metal tip/needle.

XI. PRELIMINARY OBSERVATIONS ABOUT RACZ'S MODIFIED DEVICE

143. I have several specific criticisms of Racz's modified device, principally that a POSITA would have understood that Racz's modified device would be impractical, if not impossible, to make, and I detail those criticisms in a later section. But, first, I make the following preliminary observations.

A. None of Racz, Fitz, or Lee Teaches or Suggests Energizing Deployable/Retractable Filaments at the Distal End With a Removeable RF Probe.

144. One of the primary innovations made by Stratus, as reflected in the Stratus Patents, is an RF neurotomy device that energizes deployable/retractable filaments at the distal end with an insertable RF probe. Neither Racz, Fitz, nor Lee teaches or suggests that feature.

145. Racz does not teach deployable/retractable filaments at all.

146. Lee teaches deployable/retractable filaments, but those filaments are energized by their connection to an RF signal source at the proximal end. There is, therefore, no need for an RF probe in Lee.

147. Fitz teaches multiple deployable insulated RF electrodes, each of which is connected to an RF signal source at the proximal end. At a stretch, a POSITA might consider the multiple electrodes as similar to the filaments in Lee.

148. While Racz has a removeable RF probe, that probe energizes just the tip, not deployable/retractable filaments. It would be clear to a POSITA reading Racz that Racz did not consider the substantial challenges of energizing deployable/retractable filaments at the distal end with a removeable RF probe.

149. Racz, on one hand, and Fitz and Lee, on the other hand, teach two mutually exclusive approaches to energizing the distal end of an RF ablation device:

- (1) using a removeable RF probe to energize the tip only at the distal end; or
- (2) energizing deployable/retractable filaments at the proximal end.

150. The second approach is straightforward because the proximal ends of the filaments must in any case extend to the proximal end of the device where the deployment/retraction mechanism is located. No one before Stratus bridged the gap between those two fundamentally different approaches. In particular, Racz, Fitz, and Lee do not teach bridging that gap but instead are each exemplary of one approach or the other.

B. Lee Has Limited Relevance to Fitz and Racz.

151. As I explain above, Lee is not concerned with RF neurotomy, whereas Fitz and Lee are. This is a significant difference. RF neurotomy is a unique type of RF ablation with several notable differences compared to other types of RF ablation.

152. First, RF neurotomy devices and the nerves they target are considerably smaller than most other RF ablation devices and target tissues. This has significant ramifications on the design of RF neurotomy devices as compared to other RF ablation devices. The space constraints of RF neurotomy devices may preclude designs that may be possible only in larger devices.

153. While it can be desirable to increase the ablation volume for both RF neurotomy and non-neurotomy applications, that desire is animated by different considerations. In tumor ablation, for example, a larger ablation volume is desirable because complete ablation of the entire tumor is the clinical objective, even if that means some collateral damage to nearby tissue. Indeed, in tumor removal or treatment, including RF ablation, the clinicians and surgeons often refer to “margins” to excise or treat a tumor. That refers to extra tissue surrounding the tumor. In RF neurotomy, on the other hand, the reason for desired increased ablation volume is to increase the likelihood that the relatively tiny nerve tissue targets are not missed during the ablation process.

154. Another significant difference is that the physicians who perform RF neurotomy procedures (pain-treatment specialists) are different specialists from the physicians who perform other RF ablation procedures, as I note above. The physicians in these different specialties live in different professional worlds, read different professional literature, attend different conferences, etc. They do not overlap professionally to any appreciable degree.

155. Additionally, RF neurotomy procedures are performed many times more often than all other RF ablation procedures. A pain-treatment specialist may perform numerous RF neurotomy procedures each day, whereas RF ablation of tumors, for example, is a relatively rare event. Moreover, most RF neurotomy patients must repeat the procedure periodically as nerve tissue regenerates.

156. This difference in how often and how many procedures are done in a facility significantly impacts the design and construction of the RF ablation devices used for neurotomy as compared to other applications. For example, it can be quite valuable to have removable, reusable parts – like an RF probe – in an RF neurotomy device, whereas reusability is simply not a factor in the other RF ablation treatments because of their relative rarity. This is especially true considering the expense of an RF probe, which may incorporate a thermocouple, electrical connector, and other electronic components.

157. Given the differences between RF neurotomy and other fields of RF ablation, a POSITA would not have been reasonably likely to find Lee at all in a literature search. If a POSITA did become aware of Lee, the POSITA would likely dismiss Lee as irrelevant to the field of RF neurotomy. If a POSITA were to consider Lee at all, the POSITA would give little weight to Lee’s teachings because of the limited relevance of other types of RF ablation to RF neurotomy

158. It is also my opinion that a POSITA would not consider Lee reasonably pertinent to the specific problem of increasing ablation volume for RF neurotomy. Lee’s solution to a similar problem for RF ablation of uterine fibroids is not readily applicable to RF neurotomy because of the differences in, for example, needle size, target tissue size, surrounding tissue type. For example, I understand that the needles used for RF neurotomy are 16 gauge maximum and often smaller. Also, a POSITA

would consider Lee's stylets inappropriate for use in RF neurotomy because, for example, they would be too fragile and/or deformable if they contact bone, such as spinal bones near the most common (by far) neurotomy sites. If a POSITA in search of a way to increase ablation volume for RF neurotomy were to come across Lee (which is unlikely for reason I explain above), the POSITA would, at most, take from Lee the general idea of deployable stylets but not Lee's implementation of deployable stylets. In that sense, Lee is cumulative to Fitz, which also discloses the general idea deployable electrodes to increase ablation volume. But a POSITA would still be left wondering how to incorporate that general idea into an RF neurotomy needle in a workable way. Neither Fitz nor Lee teaches that.

C. Inadequate Motivation to Combine Racz, Fitz and Lee in the Form of Racz's Modified Device.

159. Dr. Tucker opines "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 explain 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 POSITA would have recognized that the Fitz/Lee technique would improve the energy coverage area of Racz's single-tip device." (Ex. 1031 Tucker Decl. ¶132) I disagree.

160. However, I do agree with Dr. Tucker 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. 1031 Tucker Decl. ¶ 134, quoting Fitz ¶ 0004-0005)

161. Dr. Tucker obscures the fact that the Racz device, on one hand, and the Fitz and Lee devices, on the other hand, represent alternative approaches, not complementary approaches.

162. A central feature of Racz's device is that the center cannula has an important dual purpose: (1) it can both deliver fluid, such as anesthesia, to the distal end of the needle, and (2) it can accept a removable RF probe.

163. The different approach epitomized by Fitz and Lee uses deployable filaments/stylets without an RF probe. In both Fitz and Lee, a POSITA would have understood that the filaments/stylets are electrically connected to the RF energy source at the proximal end and there is no RF probe.

164. Furthermore, a POSITA would have understood that limitations on available space impose limitations on dimensions. This reinforces the fact that the two approaches (removable RF probe vs. deployable filaments) are alternatives. The limited space at and near the tip of an RF ablation needle – especially in the case of RF neurotomy, where the scale is smaller – would naturally lead a POSITA away from contemplating both an RF probe and deployable filaments together. There is simply not enough room to accommodate both according to conventional thinking in the art.

165. Indeed, before the Nimbus device from Stratus, there were, to my knowledge, no RF neurotomy needles having both a removable RF probe and deployable filaments. Not in the literature. Not in commerce. In other words, that combination was not in the prior art. Dr. Tucker and the petitioner certainly have not cited any prior art disclosing that combination together.

166. I therefore do not agree that Fitz would have motivated a POSITA to provide deployable electrodes on Racz's tip, which is instead designed to accommodate a removable RF probe (and to deliver fluid when the probe is not present). Rather than motivating a hybrid of the two approaches, Fitz is simply emblematic of one approach.

167. It is therefore my opinion that Dr. Tucker has taken an unsupported leap when he asserts that a POSITA would have drawn from Racz, Fitz, and Lee any motivation to make Racz's modified device.

D. Racz's Modified Device is More Complicated Than Needed

168. I understand Dr. Tucker asserts that Racz's modified device is inspired by a desire to increase the ablation area (actually volume – it's a three-dimensional shape) created by an RF neurotomy device. In the unlikely event that a physician experienced in RF neurotomy came to me (or a POSITA) with Racz, Fitz, and Lee and asked me (or a POSITA) to use their teaching to increase the ablation volume of a RF neurotomy device, I (or a POSITA) would not have concocted the combination that Dr. Tucker proposes. There is a much easier way.

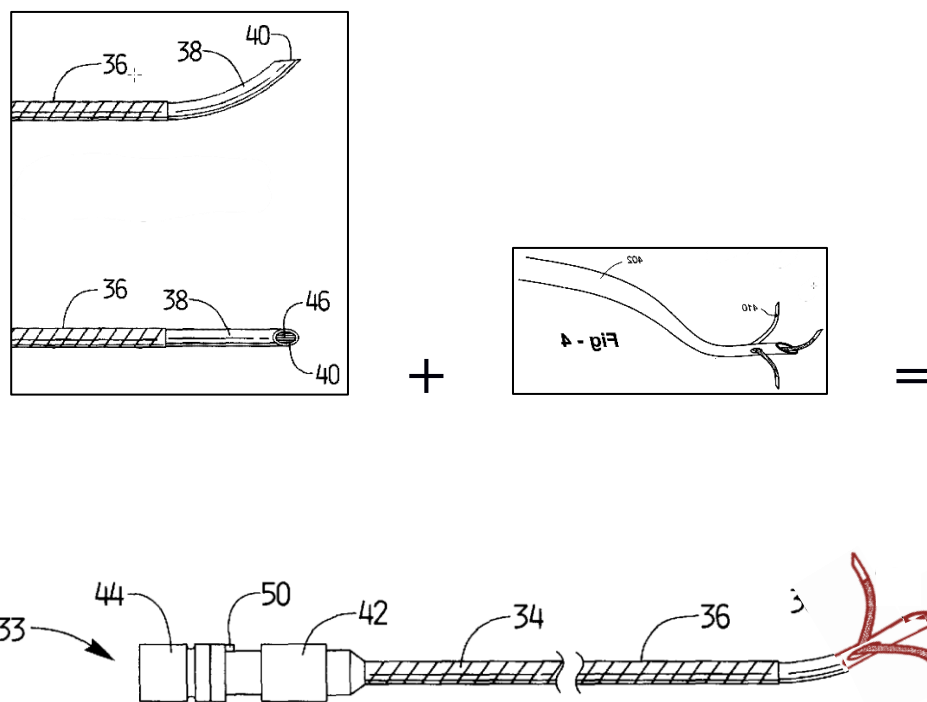
169. Racz teaches a needle for RF neurotomy but it lacks deployable/retractable filaments, so its ablation volume is limited.

170. Fitz teaches various introducers (not needles) for use in RF ablation devices for neurotomy. Fitz's introducers have multiple deployable/retractable RF electrodes.

171. Lee teaches an RF ablation device for treating uterine fibroids, so it is highly unlikely that the physician would be aware of such a reference or device and have included it in the pile of references in the first place. If Lee were included,

however, a POSITA would dismiss it as inapplicable to RF neurotomy, as I explain elsewhere in this declaration. For example, Lee's device is physically larger (and needs to be to accommodate the complicated mechanism) than would be appropriate for RF neurotomy.

172. What these three documents might have suggested to a POSITA desiring to increase the ablation volume would have been to reconfigure Racz's needle to have multiple distal apertures, as taught by Fitz, and to replace Racz's single removable RF probe with the multiple deployable RF electrodes of Fitz. The introducer shown in Fitz's Fig. 3 or 4 would be natural choices. Below is a rendition of what this might look like using Racz Figs 2A, 2B and Fitz Fig.4:



173. According to this solution, little modification would be needed to Racz's needle/cannula at the proximal end of Racz's device, and Fitz's multiple RF electrodes could connect to the RF signal source from their proximal ends, as disclosed in Fitz. As this is only a paper design, there would certainly be

complications to make such a device functional, particularly in view of Fitz's limited disclosure. For example, other modifications to Racz's needle might be necessary to enable deployment of Fitz's electrodes through the side ports, just as they would be with respect to Fitz's original device—as I noted above, Fitz is essentially devoid of enabling details on this front—but this approach is a far more straightforward combination of elements from Racz and Fitz that preserves the original design (to the extent disclosed) and operation of each element.

174. This solution would achieve the objective of increasing ablation volume while being straightforward, would not necessitate straightening Racz's bent tip, and would respect the conventional boundaries between (1) removable-RF-probe-based designs and (2) deployable-filament-based-designs. Moreover, although the details on how to make it happen are unclear from Fitz's disclosure, this solution would retain the ability to deliver fluid to the RF ablation target site. To the extent the disclosures of Fitz are taken at face value, I also note that Fitz alleges that it is able to achieve enlarged ablation volumes with its design and does not require temperature sensing with its design. Thus, replacing Racz's temperature-sensing probe with Fitz's electrodes could be seen as a reasonable functional tradeoff if the POSITA's objective were solely expansion of the ablation volume.

175. I also note that a POSITA would have arrived at this solution naturally without the benefit of having knowledge of the Stratus Patents or the Nimbus device, as all of the features of this solution come from Racz and Fitz themselves, and those features are used in this solution in the same way that Racz and Fitz intended.

176. As I note above, a POSITA would largely ignore Lee when arriving at this solution. However, to the extent that a POSITA might consider Lee relevant, the POSITA would find nothing in Lee to detract from the solution I describe above.

177. Alternatively, a POSITA might at least initially consider miniaturizing Lee to be small enough to be suitable for neurotomy. That would also accomplish the objective of increasing ablation volume. That said, miniaturization of Lee would suffer from many of the complications I discuss with respect to Racz's modified device elsewhere in this declaration. Moreover, a miniaturized version of Lee would have a number of drawbacks, including:

- (1) no ability to introduce fluid to the target ablation area;
- (2) no thermocouple and its advantages;
- (3) Lee's anchors would be undesirable for many, if not all, RF neurotomy procedures;
- (4) Lee is an overly complicated attempt to solve the problem of expanding the volume of ablated tissue in RF neurotomy; and
- (5) Lee's numerous sharp filaments extending in all directions would be dangerous to introduce anywhere near a medial branch nerve that emerges from the spine.

178. Overall, what is apparent to me, however, is that a POSITA armed with Racz, Fitz, and Lee would not, for example, attempt to alter Lee to replace its central filament with a removeable RF probe, as Dr. Tucker proposes pursuant to his "Racz's modified device." That would invite unnecessary complications if the only objective is to increase ablation volume.

179. In conclusion, Racz, Fitz, and Lee at the time of the Stratus invention would have led a POSITA one or more simple straightforward ways to achieve an RF neurotomy device with increased ablation volume, in contrast to the awkward (at

best – actually probably impossible) concoction of features envisioned by Dr. Tucker as Racz’s modified device in an effort that appears to be intended to resemble the Stratus Patent claims rather than what a POSITA would actually have done.

180. Finally, the modified device I describe above is fundamentally different from that described in the Stratus Patents.

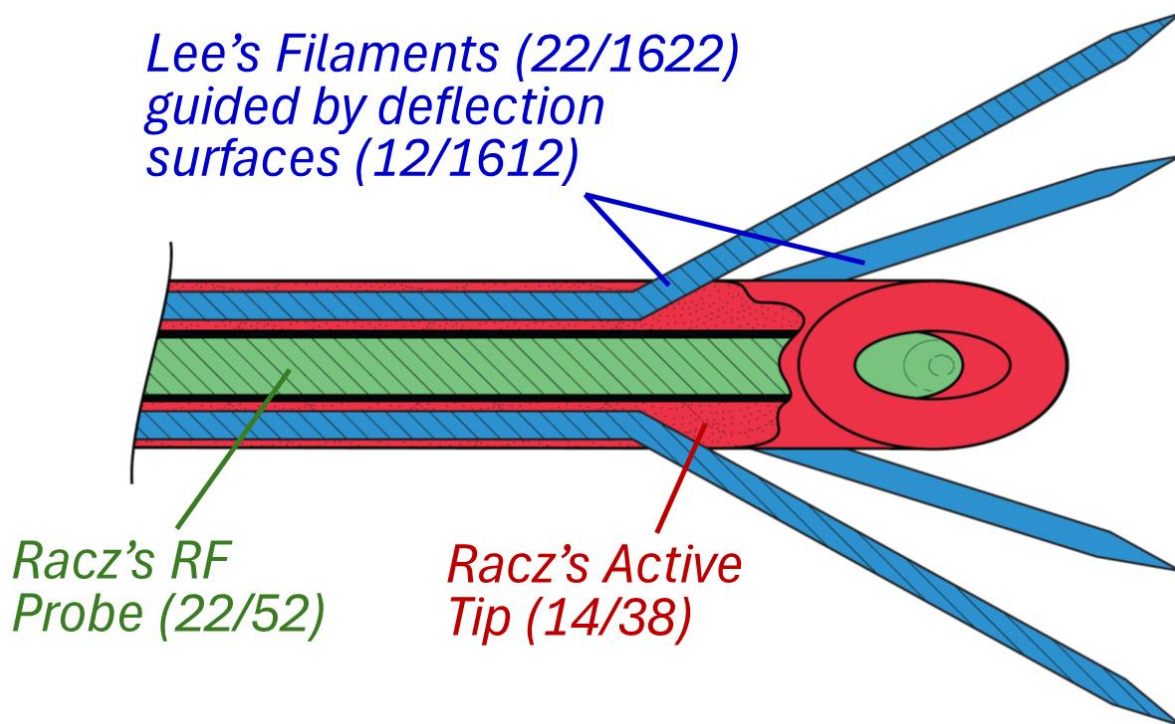
XII. SPECIFIC CRITICISMS OF RACZ’S MODIFIED DEVICE

181. In my opinion, Racz’s modified device is unacceptable for numerous reasons, some of which are the following:

- Racz’s modified device is unclear and incomplete as shown and described by Dr. Tucker.
- Racz’s modified device is unrealizable as proposed.
- Despite what Dr. Tucker asserts, implementation of Racz’s modified device is nowhere near a matter of routine engineering for a POSITA.
- A POSITA would not have had a reasonable expectation of success in arriving at Racz’s modified device or in using Racz’s modified device in practice in a patient.
- Racz, Fitz, and Lee do not provide enabling teachings of how to make Racz’s modified device.
- Racz’s modified device omits key elements of Lee.
- Racz, Fitz, and Lee would have more naturally led a POSITA to a much simpler way to increase the ablation volume of Racz’s device.

A. Lack of Clarity

182. Dr. Tucker presents just one visual rendition of Racz's modified device. The first and second renditions are the same, differing only in their annotations. The third rendition is just an enlarged portion of the first and second renditions. All three appear to be from the same perspective as a cut-away facing the side of the tip that might curve toward the viewer.



183. In Dr. Tucker's illustration of the proposed combination (see above), the cross-sectional cutaway view is either ambiguous or inaccurate. If the cutaway region were to truly show a cross section along a plane that runs through the longitudinal axis of the needle (it seems this is the intent of the illustrator, based on cross-hatching and stippling in what appears to be the cutaway region), then parts of the filaments and probe should be obscured as one moves to the right (distally) in

this image—that is, the upper and lower tines and the probe would be obscured by the needle sidewall.

184. Racz's modified device in all visual renditions in the Tucker Declarations is deficient because it fails to show sufficient length of the cannula and/or tip needed for a POSITA to understand Racz's modified device. It fails to show a sufficiently proximal portion of the device, including sufficient length of the filaments and their relation on the rest of the device, the anchors and the anchor deployment mechanism (if included), the proximal end, the electrical connection(s), and the mechanism to deploy the filaments.

185. Racz's modified device fails to show the deployment mechanism for the filaments at the proximal end. As a result, it is unclear how the filaments interact with the proximal end of the device. It is also unclear how or where the filaments are placed within the device proximal (left) of the portion shown. As a result, the overall shape and design of the device is unclear.

186. Racz's modified device fails to show where the insulation starts and stops, or even if there is any insulation as required by Racz. The location of the insulation at the distal end is quite different in Lee and Racz.

187. Racz's modified device fails to show any cross-sectional view so a POSITA could understand where the filaments and RF probe are situated inside the cannula. It appears that the filaments are situated within a lumen entirely contained within the wall of the cannula. Fig. 25 of Lee suggests a similar arrangement for a plastic component, but it is unclear how this would apply to Racz's needle. The lumens in Fig. 25 of Lee would be difficult if not impossible to make in the thin-walled metallic needle of Racz, as explained in more detail below.

188. It is also unclear regarding the filaments proximal to this illustrated distal end of the tip. For example, are the filaments electrically connected at the proximal end as taught by Fitz and Lee? That would seem unnecessary with Racz's RF probe but this ambiguity is not addressed by Dr. Tucker.

189. It is also unclear whether the RF probe is the same as taught by Racz or modified in some way. The RF probe is illustrated with a rounded tip (like Racz Fig. 2B), and there are some dashed lines which perhaps hint at a thermocouple, but that is ambiguous. If Dr. Tucker intends that Racz's modified device includes a thermocouple, then it is incumbent on Dr. Tucker to explain to a POSITA how a thermocouple is connected at the proximal end.

190. No dimensions are provided, and it is unclear what the scale of the device is and whether it is the same or different from Racz.

191. It is ambiguous whether the tip is curved, as taught by Racz, or not, because no view from a transverse angle is provided. Nor is any perspective or isometric view provided to see Racz's modified device in three dimensions.

192. Dr. Tucker provides inadequate information on materials to be used in the example.

193. It is not clear which, if any, features of Fitz are meant to be incorporated into Racz's modified device. Overall, the role of Fitz here is unclear.

194. There is no separate trocar tip and cannula as described in Lee. It is unclear if Dr. Tucker's example intends to gloss over Lee's separate trocar or expects a POSITA to assume it is no longer necessary.

195. Dr. Tucker provides two “examples” of Racz’s modified device. “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.” (IPR2024-01209 Ex. 1031 Tucker Decl. ¶ 145)

196. Dr. Tucker opines “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.” (IPR2024-01209 Ex. 1031 Tucker Decl. ¶147)

197. It is not clear to me from the Tucker Declarations what is the intended difference between Dr. Tucker’s first and second examples. He provides no drawings to illustrate the difference. I therefore am forced to assume that his visual renditions are equally applicable to both examples. The differences, then, are not illustrated. It is therefore unclear how the “separate tip” in his second example relates to the rest of the needle, where the non-tip part of the needle ends and the separate tip begins, what the interface between the non-tip part of the needle ends and the separate tip looks like, how the channels begin or match at the interface, what happens with the filaments at that interface, etc. In the absence of clarity in Dr. Tucker’s examples, it seems that a POSITA is supposed to guess Dr. Tucker’s intentions with those examples.

198. I have reviewed the transcript of Dr. Tucker’s May 7th, 2025, deposition. Although Dr. Tucker spoke at some length in his deposition elaborating on various aspects of Racz’s modified device not specifically illustrated or described

in his declarations, his discussions in the deposition are not illuminating. I am in no better position to understand Racz's modified device after his deposition than before. His explanations were not clarifying. Instead, his explanations muddled aspects the Racz's modified device that I thought I understood from his declarations and raised new questions.

199. Throughout the Tucker Declarations and his deposition, he relies heavily on "routine engineering" to fill the gaps in this description of Racz's modified device. To me and to a POSITA, routine engineering is the use of known techniques to accomplish well-defined objectives (often collected in a specification), both with a reasonable expectation of success and without requiring undue experimentation. But Dr. Tucker has not provided a well-defined objective or specification. Racz's modified device, as he and the petitioner propose, is incomplete and vague. Before a POSITA could apply proper "routine engineering" to make Racz's modified device, the POSITA must engage in creative exercises to try to figure out what Racz's modified device is. It thus appears to me that he has misused the term "routine engineering" and has wrongly injected into that term some amount of creativity to fill in important missing details.

200. While a POSITA may have an ordinary level of creativity, important, consequential aspects of the design of Racz's modified device cannot be unspecified and left to imagination. Ordinary creativity is not invention. Routine engineering (as Dr. Tucker uses the term) cannot involve invention. Yet it is clear to me that a sufficiently complete picture of Racz's modified device has not been provided, and too much subjective imagination and creativity are being asked of a POSITA just to have a sufficiently definite picture in the POSTIA's mind of what Racz's modified design is. Only with such a sufficiently definite picture in mind, can the proper question of whether the design is feasible via routine engineering be answered. I

answer that question below (that Racz's modified design cannot feasibly be made with routine engineering – it would instead require undue experimentation and there would be no reasonable expectation of success) but I want to make clear that I have to make assumptions about what Racz's modified device is just to answer that question.

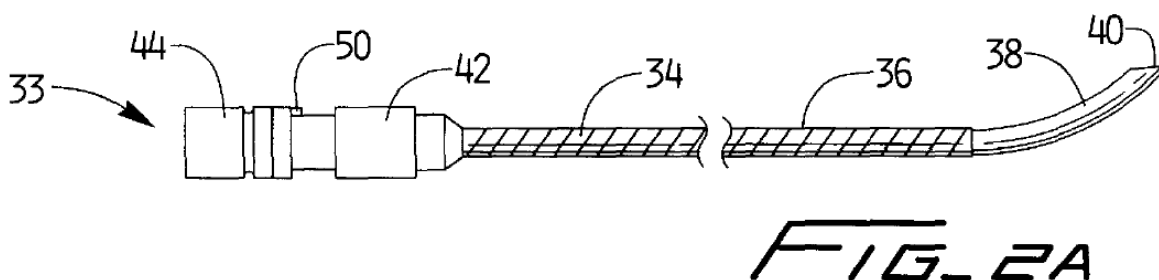
201. When I refer to Racz's modified device in this declaration, I mean as best understood by me, even if I do not explicitly say "as best understood" each time.

B. Racz Teaches Against Straightening the Tip in Racz's Modified Device.

202. As noted above, it is not clear from Dr. Tucker's declaration whether he proposes straightening the tip of Racz's device in addition to all the other modifications he proposes to the tip. As explained in subsequent sections, a curved tip significantly complicates the construction of the modified tip. But if Dr. Tucker is proposing to straighten the tip, that would be contrary to Racz's teachings.

203. A POSITA would interpret Racz as teaching that a curved or bent tip is an essential feature of Racz's probe, as I explain below.

204. Racz's tip is curved, as can be seen in Racz Fig 2A, reproduced below:



205. Racz repeatedly describes the curve at the distal tip as critical. For example, Racz's title is "**BENT** TIP ELECTRICAL SURGICAL PROBE." His abstract describes that "[t]he **curved** tip or shaft is used to steer the device with the patient's body and to avoid critical anatomical structures."

206. Racz explains the limitations of straight needles as follows at col. 1, lines 63 – col. 2, line 15:

Hence, proper placement of the needle tip in the complicated structure of a patient's spine requires great skill by the treating clinician. One limitation of the straight electrodes typically used in such procedures is that the needles may need to be withdrawn and re-inserted multiple times to achieve the proper target region for the needle tip.

The need to access other complex structures, such as lumbar-sacral discs, particularly where there is a high pelvic brim in males and in those individuals having extreme degenerative narrowing, makes needle placement even more difficult. The nerve root in the lower spine may be accidentally impaled; this presents a serious medical risk to the patient. Again, the use of straight, self-penetrating needles is limited somewhat in that the tip is collinear with the needle shaft, so navigating the tip to avoid critical structures requires redirection of the shaft and repeated manipulation. It would be desirable to facilitate such redirection in ways unachievable by a straight needle, reducing the need to withdraw and reinsert the needles.

207. Racz therefore stresses that an alternative to straight needles is needed at col. 2, lines 39-42:

It is observed that neither straight needles nor flexible electrodes have the desired characteristics for use in difficult-to-reach target regions. Accordingly, it would be desirable to have an electrode cannula for stimulation or ablation that avoids the limitations of the art.

208. Racz then explains the advantages of a bent tip as follows at col. 2, line 57 – col. 3, line 17:

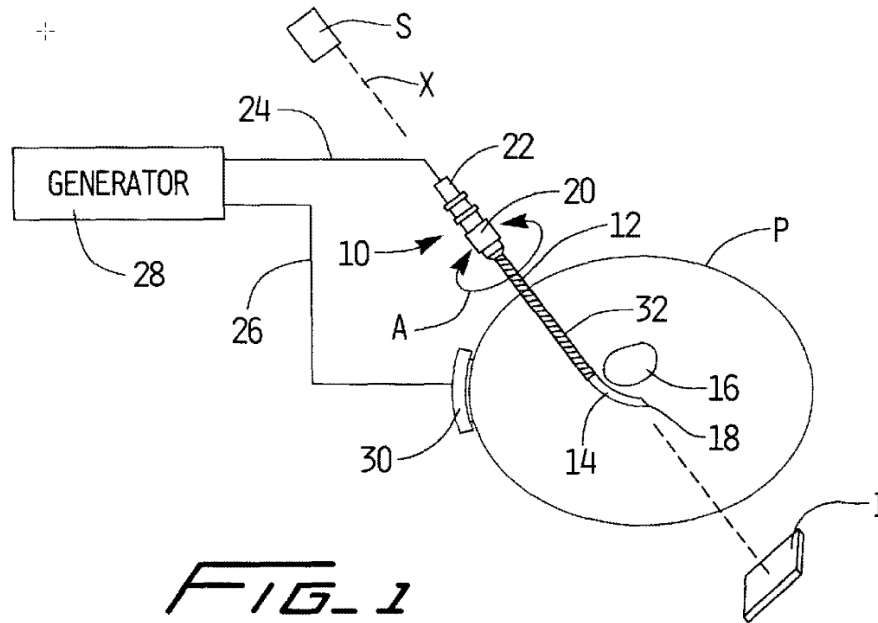
Such a robust bent tip would make possible the re-direction of the position and orientation of the tip near neural structures, bone, or critical structures, without the need to fully withdraw and re-insert the needle. Alteration of the direction of the needle hub presents another advantage. It can be advantageous with a bent tip to follow neural structures, hug bony structures, and avoid certain organs or regions at risk, which can be useful in certain clinical applications.

A further advantage of a permanently bent or curved needle is that its position can be altered to some degree by merely rotating the needle shaft; this is not the case with straight needles. Accordingly, some position adjustments can be performed with fewer manipulations than a straight needle would require. Moreover, a bent or curved needle having a pointed tip mounted at the distal end of a relatively rigid tubular or solid shaft enables self-penetration of tough tissue near hard, bony structures. This kind of manipulation is not generally possible with side outlet-bearing electrodes such as Radionics' TEW and ZHK kits because of the fragility and flexibility of their tips.

The advancement and manipulation of a bent needle or cannula can be performed under X-ray or other guidance by the clinician to place the bent tip in its target position. This provides an added advantage over a straight needle or cannula.

These features and advantages as well as others will be apparent in the detailed description that follows.

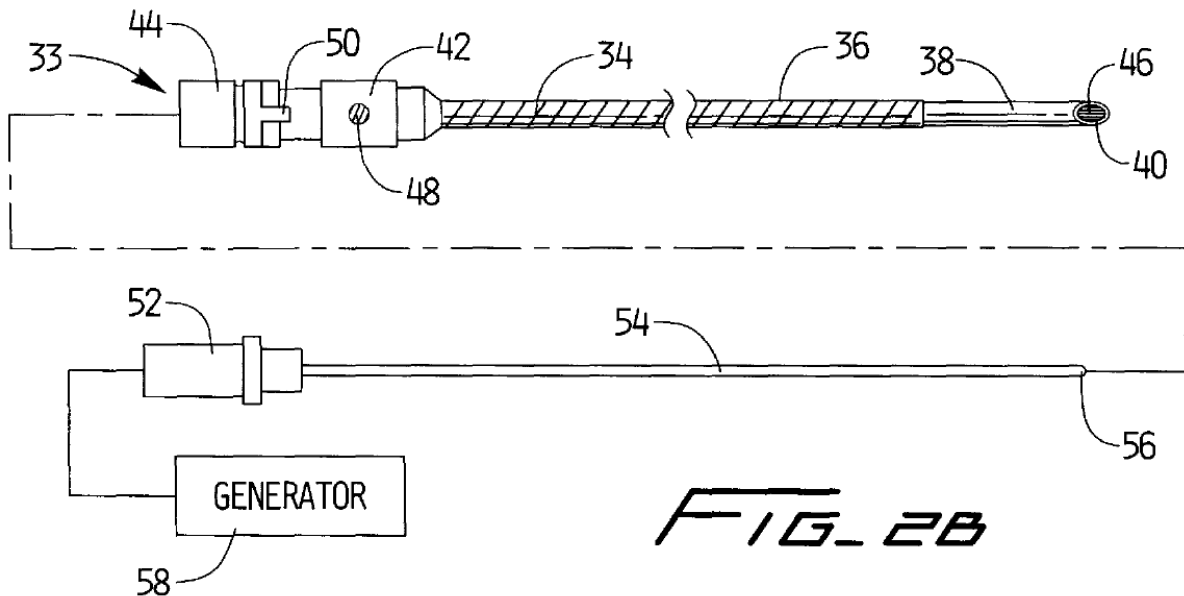
209. Racz illustrates the advantage of a bent tip with reference to Fig. 1, reproduced below, in which an “anatomical structure 16” is shown and “the curved tip 14 can be steered around the anatomical structure 16,” as described at col. 4, lines 49-58:



As an illustration, the curved tip **14** can be steered around the anatomical structure **16**. The surface of the exposed tip **14** can be positioned to “hug” or otherwise approach the contour of the anatomical structure **16**. The structure **16** may be a bony structure that has nerves running near its surface, and the clinician may desire to modify or coagulate those nerves by electrical signals sent from the tip **14** by the signal generator **28**. This procedure can be more effective when performed with the rigid bent tip **14** of the invention than with a traditional straight or flexible tip.

210. All of the claims in Racz specify that the “distal tip portion” includes “a rigidly bent portion.” See 9:39-40 (claim 1), 10:30-31 (claim 11), 10:38-43 (claim 12). Claims 1, 11 and 12 of Racz state (in part) “wherein the distal tip portion includes an uninsulated, rigidly bent portion to facilitate placement of the distal tip portion at the target region.” In other words, the curve at the distal tip is a required part of all independent claims of Racz, but Racz’s modified device, as proposed by Dr. Tucker, does not show that.

211. Racz Fig 2B is reproduced below:



212. All of Dr. Tucker's renditions of Racz's modified device are based on Racz Fig. 2B. and therefore do not depict the distal curved portion 38.

213. Because the curved tip is an important, if not indispensable, aspect of Racz's device, a POSITA would not attempt to remove that feature from Racz's device. If Racz's modified device, as proposed by Dr. Tucker, involves straightening Racz's tip, that is not something a POSITA would have done. Straightening Racz's bent tip would render Racz's device unsuitable for its intended purpose of being able to be steered around anatomical structures. In fact, a POSITA would not have straightened Racz's tip because Racz repeatedly, clearly, and unambiguously teaches against doing so. A POSITA would not have ignored those teachings in Racz. In at least this way, a POSITA would not have been motivated to make Racz's modified device.

214. I understand that Dr. Tucker testified in his deposition that that Racz can be interpreted as teaching both straight and curved tips because Racz says that

the degree of curvature can be varied. (Ex. 2020 at 44:21-48:3) I disagree. In my opinion, a POSITA would not reasonably interpret Racz in that way. The passage of Racz cited by Dr. Tucker reads as follows:

Various forms and embodiments of the bent tip needle or cannula are provided herein involving various shapes, sizes, forms, and configurations of the cannula and associated stylet, electrical connection, temperature monitoring scheme, signal generator, and other components. However, it should be recognized that other forms of the present invention may become apparent to those skilled in the art. For example, as discussed above, various configurations of tip geometry, bluntness or sharpness, degree of curvature, position of fluid injection ports, and the insulation configuration may be devised. Moreover, the curvature of the tip may be permanently established upon manufacture of the device, or in an alternative embodiment, may be modified by bending a semi-malleable structure at the time of surgery by the clinician. A family of needles or cannulae with different geometries may be created according to the invention.

215. This passage expressly refers to “forms and embodiments of the *bent* tip needle or cannula.” This passage also expressly notes that the curvature may be introduced at the time of manufacture or by the surgeon just before use. Neither scenario is consistent with a straight tip. While this passage refers to the “degree of curvature” as a design variable, neither this passage nor any other part of Racz ever says that degree of curvature could be zero.

216. Dr. Tucker’s interpretation of this passage as contemplating zero curvature (i.e., a straight tip) is contrary to the words of this passage, contrary to the many other clear statements in Racz, and would nullify the advantages that Racz emphasizes as offered by a curved tip. It is therefore my opinion that a POSITA would not reasonably interpret Racz in the way Dr. Tucker proposes.

217. Moreover, the next two paragraphs of Racz confirm that Racz intends that his device have a non-straight tip, noting that “the terms . . . used herein all denote medical and surgical tools that can accommodate the **bent** tip structure disclosed and claimed.” Racz concludes that the “scope” of the disclosed structures “is to be determined according to the claims set forth below”:

It should be noted that the terms needle, probe, cannula, etc. as used herein all denote medical and surgical tools that can accommodate the bent tip structure disclosed and claimed. There is no intention to restrict any particular embodiment of the invention to fewer than all of the foregoing implements. Furthermore, certain exemplary clinical applications have been discussed herein as those in which the invention can be successfully employed to the clinician’s advantage. However, the invention is not limited to use in such applications, and other medical and surgical procedures would be apparent to a practitioner of ordinary skill.

Thus, while certain exemplary structures and operations have been described, the invention is not so limited, and its scope is to be determined according to the claims set forth below.

218. I reiterate that all three independent claims in Racz specify “a distal tip portion” that includes “a rigidly **bent** portion to facilitate placement of the distal tip portion at the target region.”

219. In conclusion, it is my opinion that Dr. Tucker’s interpretation of Racz as encompassing a straight tip is incorrect and unreasonable. For the reasons stated above, a POSITA would interpret Racz as requiring some non-zero bend or curve in the tip.

220. I also note that in Racz’s modified device, the filaments must exit from the device at the distal end **after** the bend or curve. Only in that way can the filaments be directed at the target tissue that the bend is meant to facilitate reaching.

During his deposition, Dr. Tucker stated that the bend could be before or after the filament side ports. (Ex. 2020 129:48-14) I disagree. If the side ports are proximal to the bend, then the filaments would not deploy from those side ports toward the intended target, which is after the bend. This is, in fact, what Dr. Tucker and the petitioner illustrate in their sole illustration of Racz's modified device.

C. Racz's Modified Device Would Likely be Impossible to Build.

221. Although I do not fully (or even adequately) understand Racz's modified device, as proposed by Dr. Tucker, I understand aspects of Racz's modified device enough to realize that it would be either impossible to fabricate or doing so would require undue experimentation and have no reasonable expectation of success. It is relatively easy to create a drawing, or as Dr. Tucker calls his creation, a "cartoon," but that does not translate into ease of building what is drawn. (Ex. 2020 112:5; 123:6)

222. Dr. Tucker says many times that Racz's modified device would be "easily" done or involve merely "routine engineering," or words to that effect. For example, Dr. Tucker refers to "routine engineering" in paragraphs 143, 144, 146, 147, 148, 161, 165, 189, 191, 201 of Exhibit 1031 when describing how a POSITA would have come up with Racz's modified device. As another example, Dr. Tucker says in paragraphs 137, 140, 146, 167, 169, 228, and 237 that various aspects of Racz's modified device would have been "easily implemented," "easily formed," or "easily accommodated."

223. None of those passages cited above describe with any specificity what those allegedly "routine engineering" principles, practices, or techniques would be or how or why the described configuration would be "easily" implemented, formed, accommodated, etc. Some of those passages imply that the explanation is

provided elsewhere in the Tucker Declaration, but I cannot discern from the Tucker Declarations (any of them) what engineering principles, practices, or techniques (routine or otherwise) he has in mind. As a result of this vagueness, I am unable to assess his reasoning for why he believes only “routine engineering” or “easy” operations are required.

224. Nonetheless, I disagree with the assertion that any of this is “routine engineering.” I believe that Dr. Tucker has failed to appreciate the engineering effort that would be required to even attempt to make Racz’s modified device, which I believe is not possible to fabricate. In other words, Dr. Tucker has dreamt up a paper design that looks simple on paper but is impossible to build in practice.

225. I understand that Racz’s modified device, as proposed by Dr. Tucker, has multiple channels fully contained within the outer wall of the tip/needle, each channel accepting one filament or stylet. That would be extremely challenging, if not impossible, to fabricate. That is true even assuming that the tip in Racz’s modified device is straight; it would be even more difficult to fabricate if the tip is bent or curved, as emphatically taught by Racz.

226. Compared to Lee’s tip, in Racz’s modified device, the tip is not curved and is metal. In other words, Lee’s tip is a short straight piece which can be plastic or metal, whereas the Racz tip is long, curved, and metal.

227. All parts of Racz’s modified device at the distal end must be made of medical-grade material approved for short-term insertion in the human body. That includes at least the tip, the filaments, and the RF probe. There are limited materials that satisfy this requirement. There are limited metals that satisfy this requirement.

228. If Racz’s modified device is intended for use in neurotomy, as Dr. Tucker says, then it would have to be as a much smaller scale than Lee’s device for ablating uterine fibroids. I understand that an RF neurotomy needle must be between 16 and 22 gauge in size. The smaller the gauge number, the bigger the needle. A 16-gauge needle has an outer diameter of approximately 1.651 mm with a wall thickness of 0.229 mm. A 22-gauge needle has an outer diameter of approximately 0.718 mm with a wall thickness of 0.152 mm.

229. Racz teaches that “various sized electrodes can be made, from extremely small gauges (e.g.: 30 gauge) to much larger sizes (e.g.: 10 gauge).” Racz 8:13-15. The electrical probe 54 of Racz has to fit inside the needle lumen, which means that Racz teaches that the diameter of the probe can have a diameter between 0.159 mm and 2.693 mm. Fitz does not specify any dimensions.

230. I could not find any disclosure in Lee of the physical dimensions of his device, but a POSITA would realize that Lee’s device is significantly larger than would be desired or practical for a RF neurotomy device. The target nerves treated in RF neurotomy (medial branch of the dorsal ramus) has a diameter of 1.0 – 1.3 mm. On the other hand, uterine fibroids are much larger, typically from about 5 cm to 10 cm or more.

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



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

233. Even if I assume the large end of the range of possible sizes for a neurotomy needle (i.e., 16 gauge or 1.651 mm outer diameter), that would be significantly smaller than the scale that Lee contemplates.

234. I have considered whether a POSITA might have been able to form the channels in the sidewalls of the tip/needle in Racz's modified device, as proposed by Dr. Tucker. The technical challenges include forming the channels in a curved needle (as required by Racz), at the dimensions of a neurotomy needle. In my opinion a POSITA could not have done so, certainly not with just ordinary knowledge and creativity, and not without undue experimentation.

235. I have considered whether a POSITA might have been able to drill the channels in the sidewalls of the tip/needle in Racz's modified device, as proposed by Dr. Tucker. In my opinion that would be impossible. As an example, consider a 16 gauge needle 5 cm long. The outer diameter is approximately 1.65 mm, the inner diameter (through which the RF probe is inserted) is approximately 1.19 mm, leaving a wall thickness of approximately 0.22 mm. Assuming a stylet diameter of 0.1 mm, a POSITA would have to solve the problem of drilling a 0.1 mm diameter hole at least 5 cm long down a 0.22 mm thick sidewall while keeping the hole centered in the sidewall over the whole length.

236. First, there is no known drill bit to do so. Drilling long thin holes is challenging. A drill bit must be able to remove from the hole the material machined

out of the object. That sets a practical upper limit on the length of a drill bit as well as a practical lower limit on the diameter of the drill bit. Also, the structural strength of the drill bit limits its achievable length and feasible diameter similarly – that is why in a set of drill bits, the smaller diameter drill bits are shorter than the larger diameter drill bits. A long thin drill bit is more likely to break under the stress of a drilling operation.

237. Second, even assuming a drill bit is available for drilling such a long thin hole, the challenge of drilling the holes acceptably straight is too great. Assuming the hole is 0.1 mm diameter and 5 cm long, the thickness around the hole is about 0.06 mm $((0.22-0.1)/2)$ if the hole is perfectly straight. An engineer would want to limit the deviation to achieve a minimum thickness no worse than half that (0.03 mm), this means that the deviation over the length has to be no worse than $0.03/50 = 0.06\%$. I know of no technology that can achieve this. Nor would a POSITA.

238. I have also considered the possibility of laser drilling to make the channels. A POSITA would realize that laser drilling is not a viable option in these circumstances. Laser drilling works well for making many precise holes in a thin broad piece of material, but is not capable of drilling long thin holes, as a POSITA would know. A laser drill vaporizes the material in the hole that is formed. There must be some way for the vapor to escape the hole cavity. A POSITA would realize that the holes in the cannula/tip sidewall are too long and thin to be amenable to laser drilling.

239. Third, the structural integrity of the sidewalls would be unduly jeopardized. Heavy duty aluminum kitchen foil is approximately 0.023 mm thick, and in this example, the thickness of the sidewalls around the holes for the stylets is

about the same – which leaves a strength problem. The strength problem is exacerbated because the needle has to be able to withstand stress in three dimensions – push, pull and rotation (compression, extension and torsion). It is unlikely that a 16-gauge needle with four lumens as in Dr. Tucker’s Racz’s modified device would hold up under the forces to be expected in normal use.

240. Fourth, any lumen down which a stylet passes is required to be a close fit to the stylet – but not so close that the stylet cannot move freely. That means that tolerances on roundness of the stylet interfere with tolerances of roundness of the hole. Achieving free movement of a stylet in a hole requires the nominal diameter of the hole to be slightly bigger than the diameter of the stylet – which serves to decrease the wall thickness of the hole.

241. Fifth, the surface finish on the inside of the hole must be smooth to avoid interference of the stylet. I know of no technique to achieve excellent surface finish on the inside of such a small and long hole.

242. Finally, to achieve volume manufacturing of a quality product, there must be a method for inspection of the product. I know of no technique to allow optical inspection of such a long thin hole. Other inspection technologies such as ultrasound won’t work because the wavelength of the ultrasound is much larger than the features being inspected. X-Ray microscopy might work but it is very expensive and not practical for a disposable device.

243. Neurotomy needles typically come in 5 cm, 10 cm, and 15 cm lengths. The example above shows the challenges with a 5 cm neurotomy needle – as the length increase the challenges become overwhelming so as to make the task impossible.

244. Moreover, if the needle tip is bent, as Racz teaches, drilling the channels would be impossible. It is only possible to drill straight holes. There is no known drill or drill bit that could drill a curved hole, certainly not at the scale and precision required for Racz's modified device.

245. In summary, a POSITA would realize that there is no way in which drilling can create the channels in Racz's modified device, as proposed by Dr. Tucker. If there is a way to do so, it would take creativity well beyond what a POSITA is capable and it would take experimentation so extensive as to be undue.

246. I have further considered using a known method of making small diameter tubes called "drawing." In this method, a larger diameter tube is fabricated first, and then it is stretched (often under heat), and the diameter decreases as the length increases. This is like pulling toffee. It might be possible to make a drawn tube with multiple holes (lumens) in the sidewall, but it would take a lot of experimentation to achieve the desired result. It is easier with a polymer material but extremely difficult with a metal tube. I know of no commercially available material or process that would allow this method at the dimensions required for Racz's modified device.

247. I have considered the possibility of using any technique to make channels of Racz's modified device's tip/needle in a straight needle and then bending the needle. That would not work. The bending operation would distort the shape of the channels causing them to lose the necessary circular shape in the vicinity of the bend. If the filaments were sized to fit snugly in the channels, as Dr. Tucker's renditions appear to show (and as would be necessary for electrical contact with the needle/tip), then the bending-induced distortion of the channels would inhibit fully or partially the filaments from passing through the channels. If the channels are made

even larger initially so as to allow the filaments to pass through the channels after the bending operation, then that would exacerbate the issues already present with creating such channels in an already thin sidewall. If, alternatively, the filaments are made even thinner, to provide sufficient tolerance to pass through the channels after the bending operation, rather than the snug fit shown in Dr. Tucker's rendition of Racz's modified device, then that would be problematic. As I explain below, the thin filaments already present a serious problem and thinning them further would exacerbate that problem. Moreover, thinner filaments risk compromising the electrical contact between the filaments and the tip/needle sidewalls.

248. I have considered whether a POSITA might have been able to make the tip/needle with the channels in the sidewalls per Racz's modified device, as proposed by Dr. Tucker using casting (including lost wax casting) or sintering. It is my opinion that a POSITA could not have done so and would have dismissed that possibility, as neither technique is capable of the small dimensions and accuracy required, and certainly not for volume manufacturing with acceptable yields.

249. I have considered whether a POSITA might have been able to make the tip/needle with the channels in the sidewalls per Racz's modified device, as proposed by Dr. Tucker, by injection molding. It is my opinion that a POSITA could not have done so and would have dismissed that possibility. There are fundamental limits to the size and geometry of features that can be created with injection molding – partly determined by the fluid mechanical properties of molten plastic.

250. I have considered whether a POSITA might have been able to make the tip/needle with the channels in the sidewalls per Racz's modified device, as proposed by Dr. Tucker, by extrusion. Engineering guides to extrusion (e.g.: <https://engineeringproductdesign.com/knowledge-base/metal-extrusion/>) generally

sets a lower limit to wall thickness and the smallest wall thickness considered possible is 0.055 inches or about 1.4 mm, much bigger than the required dimensions. It is my opinion that a POSITA would have dismissed the possibility of making the modified Racz device by extrusion.

251. I have considered whether a POSITA might have been able to make the tip/needle with the channels in the sidewalls per Racz's modified device, as proposed by Dr. Tucker, by 3D printing (or even 4D or 5D printing). This is unlikely, as with even the best 3D printers available in 2025, the smallest feature size achievable is 0.1 mm (100 microns). This is insufficient. Even with 3D printing, it would be necessary to perform some sort of post processing (e.g., polishing) to achieve the desired dimensions and surface finishes. Tucker. It is my opinion that a POSITA would have dismissed the possibility of making the modified Racz device by 3D, 4D or 5D printing.

252. I understand that Dr. Tucker testified during his deposition about a separate tip piece with a "stepdown" on the proximal end of the tip for insertion into the cannula. (Ex. 2020 162:14-18, 165:8-18, 184:9-10) I understand Dr. Tucker to have testified that such a piece could be made for Racz's modified device by extrusion. (Ex. 2020 85:3-88:5) I disagree. Extrusion is a process for making pieces having a uniform cross-section. The piece Dr. Tucker describes does not have a uniform cross section along its length. A POSITA would therefore realize that this piece cannot be made by extrusion alone.

253. Moreover, extrusion of metal presents challenges, as a POSITA would know. It would not be possible to extrude a metal piece of this size with channels in the side walls. Nor would it be feasible to extrude a larger piece with channels in the side walls and then draw it lengthwise. To reduce the diameter while

maintaining the aspect ratio of all the dimensions. A piece the size of a 16 gauge needle simply cannot be extruded or extruded and drawn with such fine features.

254. Dr. Tucker's declaration clearly says this separate tip piece in Racz's modified device must be conductive, and he specifically mentions metal. (Ex. 1031 ¶147) I can find no mention in the Tucker Declarations of the separate tip piece in Racz's modified device being plastic, but I understand that he mentioned during his deposition that it could be a conductive plastic. (Ex. 2020 129:19-130:15) However, while a POSITA would have been aware of electrically conductive polymers for various niche applications, a needle (or tip portion of a needle) made from a conductive polymer is not known in the field and would not have been known to a POSITA. To make a needle (or tip portion of a needle) with multiple lumens from an electrically conductive polymer might be possible but would have required a lot of experimentation with no reasonable expectation of success, and would have been unlikely to yield a useable device that is both biocompatible and stable.

255. The construction limitations I describe above are applicable not only to Dr. Tucker's "first example" of Racz's modified device, in which the needle/cannula is one integral piece, and the filaments' channels in the cannula sidewall extend substantially the entire length of the cannula. The same limitations apply to Dr. Tucker's "second example" of Racz's modified device, in which there is a separate tip piece connected to a non-tip needle/cannula piece.

256. The most apparent form of this second example to me would have the same filament channels in the sidewall of the non-tip cannula portion, and the tip portion and the non-tip cannula portion would need to be aligned so that the channels are sufficiently aligned for each filaments to extend through a channel in the non-tip

cannula portion into a corresponding channel in the tip portion. That form would have the same problems described above.

257. If only the tip portion of the second example has channels for the filaments, then it is unclear to me where the filaments would be in the non-tip cannula portion. Nor is it clear to me how the tip portion and the non-tip portion would interface and how the filaments would function at that interface. Lee's trocar point is not suitable for use in Racz's modified device as is (no curve), and a POSITA would not immediately envision how to modify Lee's trocar point to work in Racz's modified device. Neither Dr. Tucker nor the petitioner provides any definite guidance.

258. Nor is it clear how long the tip portion would be in Dr. Tucker's second example of Racz's modified device. If the tip portion has appreciable length, then forming holes in it would face the same challenges and limitations described above. What Racz labels as the "tip portion 38" is so long as to have the same challenges and limitations.

259. What is clear to me, however, is that according to Dr. Tucker's second example of Racz's modified device, the tip portion would be curved. That is what is taught by Racz. In fact, he refers to the item 38 as "the distal curved tip portion 38." (Racz 4:65) That is also what is illustrated in Dr. Tucker's only illustration of Racz's modified device. Forming channels for the filaments in a curved tip portion would be even more difficult than forming such channels in a straight tip portion, so much so that it would be either impossible or require undue experimentation and not have a reasonable expectation of success, as I explain elsewhere.

260. In summary, I cannot conceive of any way to make the channels in Racz's modified device, as proposed by Dr. Tucker. Nor would a POSITA have been able to do so, and particularly with technology available at the priority date of the Stratus Patents.

D. Racz, Fitz, and Lee Do Not Provide an Enabling Teaching of How to Make Racz's Modified Device.

261. It is also my opinion that Racz, Fitz, and Lee individually or collectively do not provide an enabling teaching of how to make Racz's modified device, as proposed by Dr. Tucker. I understand that an enablement analysis such as this is based on the so-called *Wands* factors, which I will discuss next.

262. The first *Wands* factor is the quantity of experimentation necessary. As I explain in the previous section, it would take tremendous, if not never-ending, experimentation (and creativity) to try to make the channels in Racz's modified device, as proposed by Dr. Tucker. As I have explained above, I do not think it can be done, and a POSITA would not be aware of a way to do it. As a result, a POSITA would have to (a) conceive of a technique to possibly do it and (b) experiment with that technique to see if it can be done successfully. Part (a) is an exercise in creativity, not experimentation, but part (b) pertains to experimentation, and it would be overwhelming for a POSITA, who would likely give up in failure after a while.

263. I also note that the vagueness, ambiguities, and omissions from Dr. Tucker's renditions and descriptions of Racz's modified device introduce many other variables that would have to be resolved by experimentation just to figure out what Racz's modified device is supposed to be. That too would be undue.

264. The second *Wands* factor is the amount of direction or guidance presented. It seems to me that the direction must come from the references

themselves, not Dr. Tucker's rendition. But even with Dr. Tucker's rendition in mind, a POSITA would find in his rendition no concrete guidance as to how to make the channels shown. In fact, Dr. Tucker's declaration does not explain – at all – how the channels ought to be formed. Turning to the references, first, Racz has no such channels and perforce provides no guidance as to their formation. Next, Fitz has drawings of channels in which there are electrodes, but Fitz also provides no information regarding their creation. Besides, Fitz's sleeves are quite different from those in Racz's modified device, as proposed by Dr. Tucker. Fitz's sleeves are not channels within a thin sidewall of a metal needle or metal needle tip.

265. Turning to Lee, although Lee teaches channels for filaments, Lee's channels are fundamentally different from the channels in Racz's modified device, as proposed by Dr. Tucker, in several ways. First, Lee's filament channels are in a trocar piece, not a needle/tip sidewall. Second, Lee's trocar piece is primarily disclosed as plastic; although Lee mentions metal as a possible material of the trocar (¶ [0141]), Lee provides no enabling details for that case. Third, in all embodiments cited in the petition, Lee's trocar piece is relatively short in the longitudinal direction, not long as in Racz's modified device. Finally, the channels in Lee's trocar piece in the embodiment cited in the petitions are open three-sided grooves, whereas they are fully enclosed cylindrical channels in Racz's modified device. When Lee does disclose fully enclosed cylindrical channels (Figs. 23-26), there is no enabling disclosure of those channels in a metal trocar piece. Given these differences, a POSITA could not make tunnels in Racz's modified device using the same techniques(s) available to make Lee's trocar point. So, in conclusion, none of the three references provide meaningful direction or guidance.

266. The third *Wands* factor is the presence or absence of working examples. Here, I reiterate that Racz's modified device, as proposed by Dr. Tucker,

is *not* a *working* example. It is a paper example. A cartoon. And, as I have already explained, there is no comparable working example in any of the three references (Racz, Fitz, and Lee).

267. The fourth *Wands* factor is the nature of the invention. The nature of the invention is a needle for use in RF neurotomy. As such, it must be of an appropriate size for use as an RF neurotomy needle. That is, 16-22 gauge. That is significantly smaller than the scale of Lee's device, which is used for treating uterine fibroids, significantly bigger targets than the nerves treated in RF neurotomy. As I have explained elsewhere in this declaration, the smaller scale of RF neurotomy devices makes it even more challenging to make Racz's modified device, especially the narrow channels within the sidewall of a 16–22-gauge needle.

268. The fifth *Wands* factor is the state of the prior art. Again, I reiterate that the relevant art includes RF neurotomy devices. Lee is in a different art, albeit still involving RF ablation. I find it significant that prior to the Nimbus device from the patent owner, Stratus, there were no RF neurotomy needles with deployable filaments. The idea was known in other areas of RF ablation, but no one had figured out how to do in a RF neurotomy device, at a much smaller scale, before Stratus.

269. The sixth *Wands* factor is the relative skill of those in the art. I have explained above what I believe to be the attributes and skills of a POSITA. That skill would include a modest amount of engineering training and experience designing and developing medical devices, as detailed above. However, a POSITA with those engineering skills would definitely not be able to make Racz's modified device, as proposed by Dr. Tucker – not with any level of experimentation, and certainly not with less than undue experimentation.

270. The seventh *Wands* factor is the predictability or unpredictability of the art. The art in this case is a mixture of medicine and engineering. I address here the engineering aspect of this mixture, as that is the relevant aspect of the problem of implementing Racz's modified device, as proposed by Dr. Tucker. While engineering is typically a predictable art, there are exceptions at the limit of feasibility, which is the case here. What Dr. Tucker proposes is so novel, unusual, and extreme, there is no predictable basis for his proposal.

271. The eighth *Wands* factor is the breadth of the claims. All of the claims in the Stratus Patents at issue in these cases require a removable RF probe that is used to energize deployable filaments at the distal end. That combination of features is missing from each of Racz, Fitz, and Lee. Nothing in those three references would provide guidance to a POSITA on how to implement those features together, certainly not in the way Dr. Tucker proposes. Moreover, many of the claims of the Stratus Patents are explicitly limited to neurotomy. As I explain elsewhere in this declaration, the teachings of deployable/retractable filaments in Lee are of little to no relevance to RF neurotomy. It is therefore my opinion that the breadth of the claims does not support the enablement of Racz's modified device, as proposed by Dr. Tucker.

E. No Reasonable Expectation of Success

272. As explained above, at the scale of a neurotomy needle, with a practically workable RF probe, the needle would be rather small, and the thickness of the needle sidewall would be significantly smaller. The filaments and the channels into which they go in Racz's modified device would need to be smaller still, in fact, extremely thin and narrow.

273. For the reasons explained above, a POSITA would not have a reasonable expectation of success to make such a device.

274. Moreover, even assuming for the sake of argument, that a POSITA could make such a device, a POSITA would not have a reasonable expectation of success *using* it in a patient.

275. Using a Racz modified device for neurotomy, the physician would take the following steps:

- a) Insert the needle into the body towards the target nerve under fluoroscopic guidance.
- b) During this step, anesthetic is instilled into the tissue through the lumen in the needle.
- c) Once the target anatomical location is reached, the filaments are deployed into tissue.
- d) After the filaments are deployed, the RF probe is inserted into the lumen.
- e) RF energy is applied.
- f) If further application of RF energy is necessary as described in the Stratus Patents, the RF probe is optionally withdrawn, the filaments are retracted, the needle is repositioned, and steps (c) to (e) are repeated.
- g) When the procedure is complete, the filaments are retracted, the RF probe may be removed, and the needle is withdrawn from the body.

276. The material requirements for the filaments are daunting. The filaments have to penetrate tissue while they are being extended and must be retractable into the device for withdrawal. That means they must be rigid enough to be able to be pushed into tissue, but not so rigid that they either break or take on a permanent deformation.

277. Simple engineering calculations provide insight. To prevent a wire from bending under a pushing force, it is necessary to ensure the applied force does not exceed the material's yield stress multiplied by the wire's cross-sectional area. The required force is calculated by dividing the yield stress by the distance from the applied force to the point where bending might occur. The maximum bending moment $M_{\max} = \sigma_y \times S$ where σ_y is the yield stress and S is the wire's section modulus which, for a circular wire, is $\pi r^3/4$, and r is the radius of the wire (= half the diameter d in meters). To prevent bending, the applied force F must be less than $\sigma_y \times S/d$

278. As an example, the ultimate yield strength of Nitinol (the material suggested by Dr. Tucker) can be as high as 895 MPa. In comparison, for this exercise, I assume a yield strength of 1000 MPa to simplify the calculations. If the filaments are 0.2 mm in diameter as suggested by Dr. Tucker (Ex. 1031 Tucker Decl. ¶228), then the radius is 0.1 mm = 10^{-4} m, then the section modulus S is calculated to be $((\pi \times (1 \times 10^{-4})^3)/4) = 7.85 \times 10^{-13} \text{ m}^3$. Assuming a filament length of 10 mm and a potential bend point halfway along (5 mm), then the maximum bending force would be $10^9 \text{ Pa} \times 7.85 \times 10^{-13} / 0.005 = 0.1570 \text{ N}$. This is equivalent to 0.016 kg, or a force of 16g or about half an ounce. This simply would not work – it is not enough force to penetrate tissue, and a physician could not regulate the applied force with that accuracy.

279. Even if I consider MP35N in place of Nitinol, it would not work. MP35N is a biocompatible metal alloy with a higher yield strength. MP35N can have a yield strength as high as 1793 MPa. If I round up to 2000 MPa to simplify the calculations, the resulting maximum bending force is just one ounce. Again, this is much too weak for a physician to achieve reliable deployment of the filaments through the target tissue in a predictable manner. A POSITA with the relevant

perspective and understanding of a relevant physician (*i.e.*, an interventional pain-medicine specialist who performs RF neurotomy procedures), would likely consider this to present too great a risk of filament deformation or render it unusable.

280. If a filament is deformed during deployment or while deployed, it may not be possible to fully retract it into the needle. In that case, removal of the needle from the patient's body with a deployed filament could damage tissue in the patient's body surrounding the needle including the possibility of severing or lacerating a nerve. The consequences of that damage would depend on where the needle is in the body and the path the needle tip must traverse to exit the body. In a worst-case scenario, removal of the needle may not be possible without unacceptable tissue damage, and emergency surgery may be necessary to remove the needle. I strongly suspect that no responsible physician would take that risk if there were any appreciable chance that a deployed filament cannot be fully or nearly fully retracted.

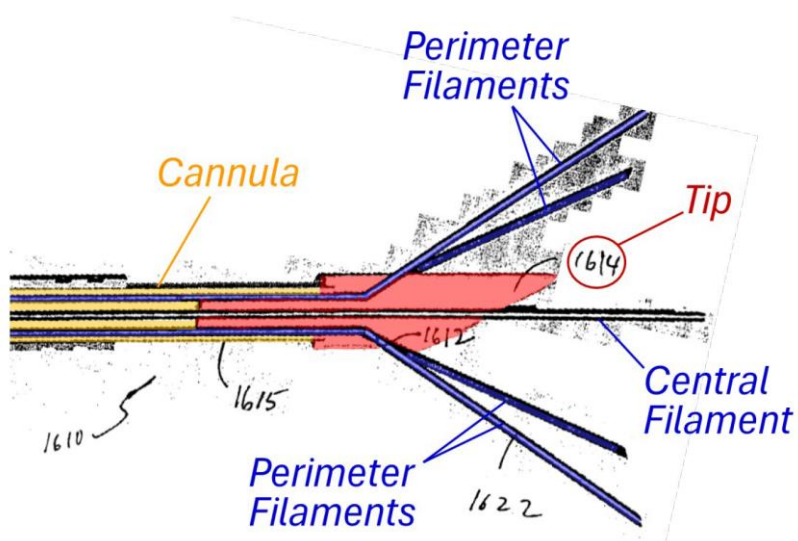
281. In any case. In the modified Racz device, Dr. Tucker proposes to use the Lee deflection surface to cause the filament to deflect when it is deployed. The calculations above show that this would be challenging, if not impossible, as the force required to extend the filaments would likely result in exceeding the yield strength of the filament.

282. I understand that Dr. Tucker testified in his deposition that he has never seen Nitinol break in use. (Ex. 2020 at 68:5-11 ("Based on my work that I've done on nitinol, they just don't break. They bend.")) However, a POSITA understands that every structure will break if subject to enough force. And a POSITA understands that extremely small filaments, as would be needed to make Racz's modified device, will break under small forces. As I explain above with calculations, which a POSITA would appreciate, Nitinol and other candidate metals for the

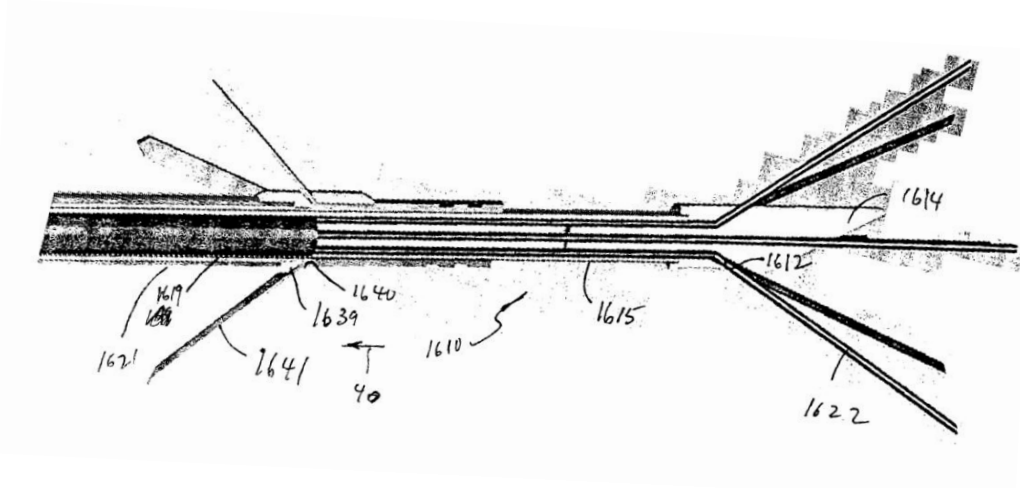
filaments at the sizes contemplated in Racz's modified device, would pose an unacceptable risk of breakage or permanent deformation in the target use case. It is therefore my opinion that a POSITA would conclude that there is not a reasonable likelihood of success in using Racz's modified device for its intended purpose (an RF neurotomy procedure).

F. Dr. Tucker Omits Key Elements of Lee From Racz's Modified Device.

283. Dr. Tucker provides an overview of Lee (Ex. 1031 ¶¶72-78). In no place does Dr. Tucker point out that Lee requires anchors. To highlight this point, Dr. Tucker provides a version of Lee Fig. 49 (cropped and annotated), reproduced below:



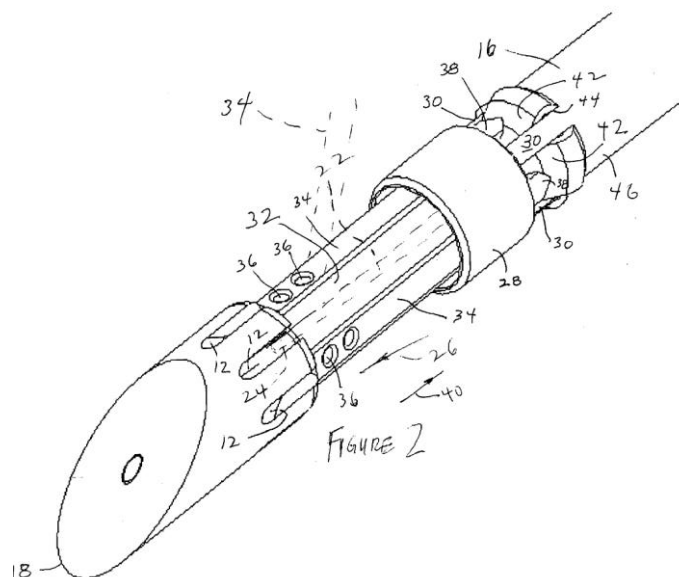
284. In my opinion, this illustration is misleading. Lee Fig. 49 is reproduced in its entirety below. It describes the “hypotube 1615 is slidably mounted within a second cannula or hypotube 1619.” (Lee [0144]) Dr. Tucker fails to describe the two tubes sliding relative to each other which is required in Lee to deploy the anchors.



285. The anchor member 1641 is attached to the deflection member 1638 (Lee [0145]). Dr. Tucker omits the crucial anchor elements.

286. Lee teaches that the hypotube 1615 and trocar point 1614 for piercing tissue are separate components, and Dr. Tucker omits that crucial aspect.

287. Lee teaches the use of a collar (element 28 in Lee Fig. 2 reproduced below) slidably mounted within cannula 16 and used to deploy the stylets. Dr. Tucker omits that crucial element.



288. A POSITA would understand that Lee's anchors necessarily accompany Lee's stylets. Thus, Racz's modified device must also have anchors, as taught by Lee, along with the stylets taught by Lee. However, Dr. Tucker and the petitioner fail to acknowledge the presence of anchors in Racz's modified device. This is another omission that would frustrate a POSITA's ability to understand Racz's modified device as proposed by Dr. Tucker and the petitioner or to make Racz's modified device.

289. Lee's anchors would be either impossible or undesirable in a neurotomy needle. Lee's anchors significantly complicate Lee's device. While that complication may be feasible at the scale of a much larger device intended to ablate uterine fibroids, there is no explanation of how the anchors could be implemented at the scale of a neurotomy needle, such as Racz's modified device. Even assuming that a POSITA could figure out a way to implement anchors in Racz's modified device, such anchors would cause unwanted tissue damage and therefore be undesirable. Because a POSITA would not incorporate Lee's stylet's into Racz's device without also incorporating Lee's anchor and because a POSITA would be unable to incorporate or be dissuaded from incorporating Lee's anchors or any similar anchoring mechanism into Racz's modified device, it is my opinion that consideration of Lee's anchors would make a POSITA not pursue Racz's modified device.

290. I understand that Dr. Tucker testified during his deposition that Lee's anchors would not be needed if a rotational actuator, rather than a longitudinally sliding actuator, is used to deploy the stylets. (Ex. 2020 at 68:17-71:4) I disagree. A POSITA would understand that the anchors resist the backward force on the device as the stylets are extended, *regardless* of the mechanism at the proximal end to extend the stylets.

291. Lee explains that the action of the stylets deploying from the tip causes a backward force that should be anchored. (Lee ¶[0104]) Lee describes only one circumstance under which the anchors are optional. That is when the stylets are deployed “one at a time” rather than all together:

[0104] If desired, anchors may first be deployed one at a time to minimize unwanted displacement of the distal end of trocar **10**. Likewise, if desired, anchors may not be deployed. An implementation of a use of the inventive trocar **10** without the anchors would be promoted by advancing the ends of stylets **22** one at a time, thus minimizing their tendency to displace the trocar.

292. This passage of Lee is inconsistent with Dr. Tucker’s understanding. If longitudinally sliding movement of an actuator created the need for anchoring, that would be true even if such movement deployed the stylets one at a time. In fact, the need for anchoring would be greater if the number of such movements were multiplied by the number of stylets. A POSITA would not share Dr. Tucker’s understanding of Lee’s anchors. Rather, a POSITA would understand that Lee’s anchors are necessary unless the stylets are deployed one at a time.

293. However, nothing in the petition or Dr. Tucker’s declaration specifies that the filaments must be deployed one at a time in Racz’s modified device. I therefore continue to believe that consideration of Lee’s anchors would make a POSITA not pursue Racz’s modified device.

XIII. THE CHALLENGES INVOLVING OTHER REFERENCES

294. Dr. Tucker invokes other references in his tables of invalidity grounds. Those other references are secondary to Racz, Fitz and Lee, and present

additional issues. I address just a few of these issues with respect to Young '965 and Scheibe, which references appear in each of the tables of invalidity grounds.

295. Young '965 is similar to Lee and thus suffers from many of the problems I have described above in combining Lee's disparate teachings with those of Racz and Fitz. Young '965 certainly does not resolve any of these problems. Like Lee, Young '965 is not directed to neurotomy (its background section focuses on cancerous tumor ablation (*see* Ex. 1012 at ¶¶ 0002, 0006)), has electrodes that are energized from a proximal end of the device (*see id.* at ¶ 0034), and does not have a mechanism for delivering anesthetic to a treatment site.

296. Moreover, the IPR Petitions and Dr. Tucker's declarations state that a "POSA would have recognized that Young '965's shaft (20) could be adapted to deploy and retract Lee's filaments (22/1622) from Racz's device." (IPR2024-01209, Paper 1 at 69; *see also* Ex. 1031 at ¶ 227) This proposal would require a substantial redesign of Racz's modified device, Young '965's shaft (20), or both, yet neither the petitions nor the declarations provide details of how such a redesign could be implemented.

297. In Young '965, the *proximal ends* of the deployable electrodes (26) are connected to the *distal end* of the shaft (20), as shown in both the retracted and deployed positions illustrated in Figures 5 and 6, respectively (reproduced below). Yet in Dr. Tucker's two examples of Racz's modified device, as I understand them, Lee's electrodes extend longitudinally through the sidewall of Racz's needle body, all the way past the proximal end of that needle body. It is not evident how these proximal ends could then be attached to the distal end of the shaft (20), for if the shaft (20) is to function in the same way that it does in Young '965, then its distal end must reside in the general vicinity of the side ports of Racz's modified device in

both the retracted and deployed positions (see Figures 5 and 6 below). It is even less evident how distal movement of the shaft (20) would then effectuate distal movement Lee's filaments in this arrangement.

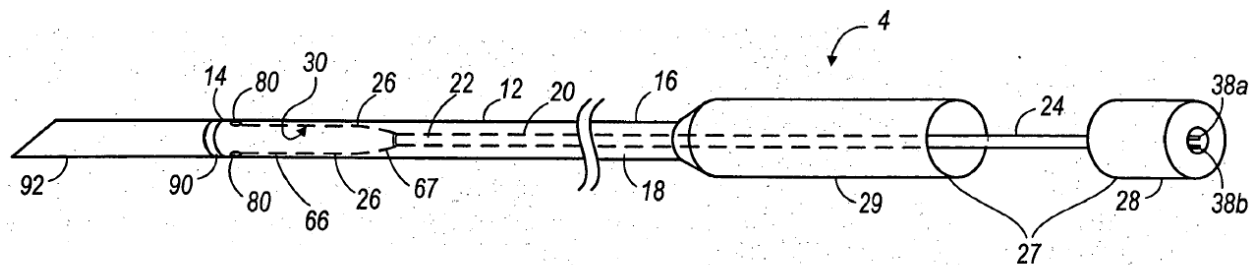


FIG. 5

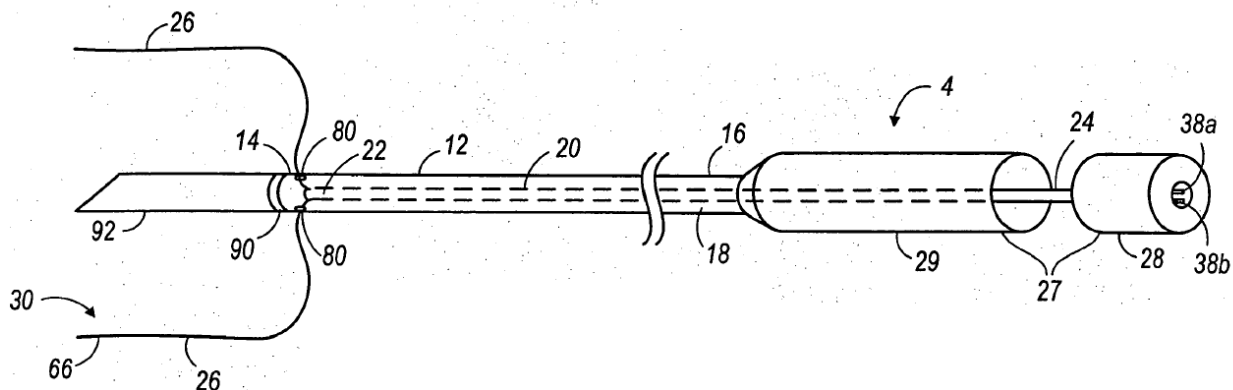


FIG. 6

298. Scheibe is far less relevant to Racz and Fitz than either Lee or Young '965, as it only discloses a deflectable catheter.

299. Further, I do not see the purpose of Scheibe's actuator as being reasonably pertinent to the purpose of advancing Lee's filaments out of Racz's modified device. The purpose of Scheibe's actuator is to place a load (tensile or compressive) on a pullwire that remains fixed within a distal end of a flexible, deflectable catheter body.

XIV. CONCLUSION

300. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful false statement and the like so made are punishable by fine or imprisonment, or both under Section 1001 of the Title 18 of the United States Code, and that such willful false statements may jeopardize the validity or enforceability of the Stratus Patent.

301. I agree to be reasonably available for cross-examination regarding the content of this declaration in the United States during the time allotted for such cross-examination in these cases.

Executed this 22nd day of May 2025 in Marthon, France.

A handwritten signature in black ink, appearing to read "P Crosby", written over a horizontal line.

Peter Crosby