UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AVANOS MEDICAL, INC.
Petitioner,

v.

STRATUS MEDICAL, LLC,
Patent Owner.

_____

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

_____

PATENT OWNER'S SURREPLY

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I. INTRODUCTION

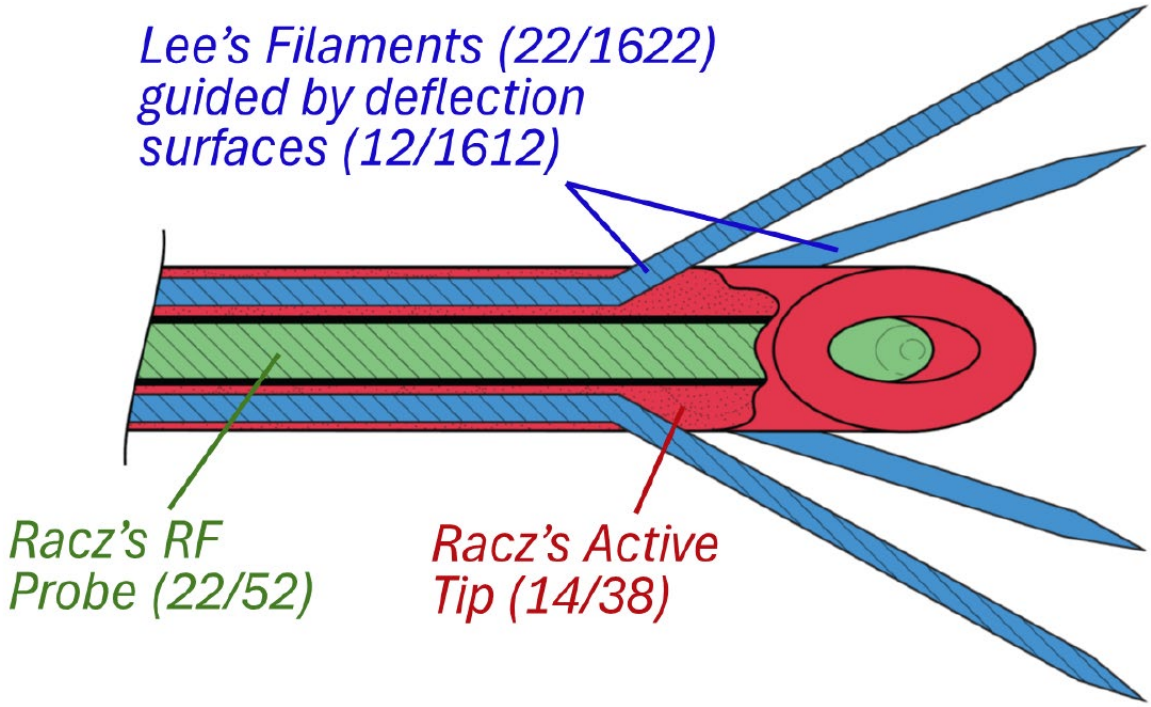
Stratus hereby responds to the petitioner's reply (Papers 32-33, herein "Reply"). The Reply's "kitchen sink" aspersions cast on Stratus's Response (Papers 15-16) simply reflect the numerosity of flaws in the petition's obviousness case. Reply, 1.

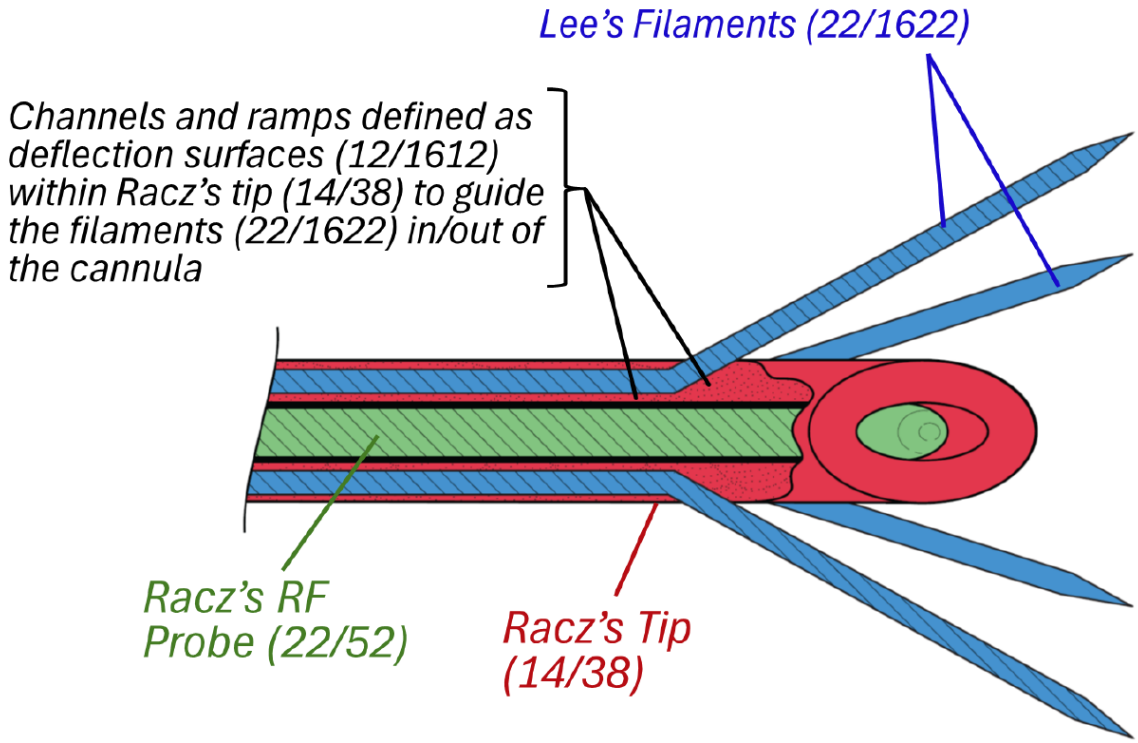
II. FATAL FLAWS IN RACZ'S MODIFIED DEVICE (RMD)

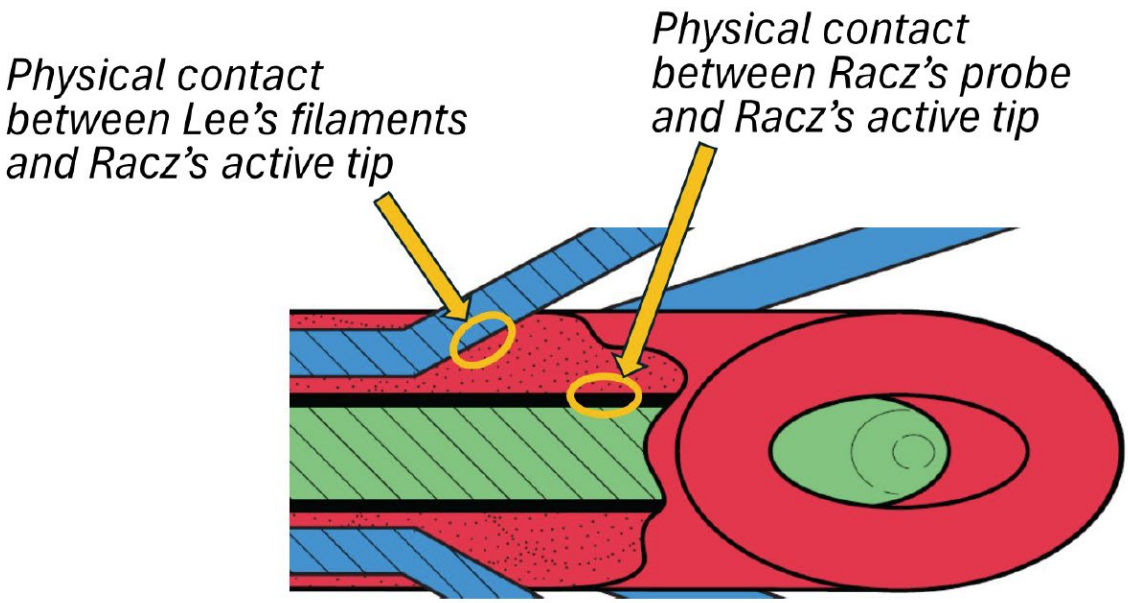
A. Vagueness

The Reply does nothing to clarify or complete Racz's modified device (RMD). Dr. Tucker says nothing in reply to clarify or complete RMD. This is a fatal flaw in the petition. Because the petition does not comply with 35 U.S.C. § 312 and 37 C.F.R. § 42.104 or provide Stratus due process, judgment must be entered in Stratus's favor.

The Reply attempts to justify RMD by arguing that bodily incorporation is not the test for obviousness. *See* Reply, 12. But the petition attempts to set forth a specific bodily incorporation of Lee's stylets into Racz's needle to achieve all features of Stratus's claims:


Lee's Filaments (22/1622) guided by deflection surfaces (12/1612)
Racz's RF Probe (22/52)
Racz's Active Tip (14/38)


Lee's Filaments (22/1622)
Channels and ramps defined as deflection surfaces (12/1612) within Racz's tip (14/38) to guide the filaments (22/1622) in/out of the cannula
Racz's RF Probe (22/52)
Racz's Tip (14/38)



Pet., 26, 41, 42.

All that can be discerned about RMD is that it incorporates Lee's deployable stylets in Racz's needle as illustrated – with those stylets in channels fully within the sidewall of Racz's needle. That is enough to conclude that RMD is not enabled, has no reasonable expectation of success, etc. But all other details of RMD necessary to have a meaningful debate about the obviousness of RMD remain mysterious. The bodily-incorporation doctrine cannot shield the petitioner from describing in sufficient detail the particular incorporation of features from Lee into Racz that form the heart of the petition's obviousness case.

The Reply argues "nothing more is required" than showing "a known problem, a known solution, and that combining the prior art was within the skill of a POS[IT]A." Reply, 12. But, RMD represents neither a known solution nor a

combination within the skill of a POSITA. First, deployable filaments were not known in an RF neurotomy needle or a needle with a removeable probe before Stratus's invention. Second, RMD was certainly not within the skill of a POSITA. RMD is an unachievable paper design, as explained in detail in the Response with supporting testimony from Peter Crosby. *See* Response, 42-48.

The Reply also argues, "The detail in the Petition and Dr. Tucker's declaration, which provided 'Racz's modified device' as a helpful example, went beyond what is required." Reply, 12. But, Dr. Tucker's RMD "example" is far from helpful; it is so vague and incomplete as to raise more questions than it answers. *See* Crosby Decl. (Ex. 2006) ¶¶ 36, 181-202. Dr. Tucker provides inadequate detail with numerous unsubstantiated assertions that "routine engineering" would fill the gaps in the petition and RMD.

The Reply attempts to downplay the central role of RMD in the petition by describing it as just a "helpful example." Reply, 12. But it is the ***only*** example of combining the teachings of Racz, Fitz, and Lee. It is the ***only*** illustration in the petition of "how a POSA (motivated by both Fitz and Lee) would have incorporated Lee's deployable filament (22/1622) as monopolar electrodes at Racz's distal tip (14/38)." Pet., 25. And it is "***this implementation***" that the petition alleges "would involve nothing more than using prior art elements according to their established

functions and combining them in a way that would achieve an expected improvement." *Id.* at 26.

B. No Enablement

Stratus's response included extensive evidence from Peter Crosby explaining how the references would not have enabled a POSITA to make RMD by any known technique. *See* Response, 48-50. Dr. Tucker says nothing to respond to that.

Nor does the Reply directly respond to the enablement issue. To the extent that the Reply's reasonable-expectation-of-success arguments could apply to enablement, Stratus addresses those arguments below.

C. No Reasonable Expectation of Success to Make RMD

Stratus's response and supporting expert testimony explained that a POSITA would not have had a reasonable expectation of success to either make or to use RMD. *See* Response, 42-48. Dr. Tucker says nothing to respond to this dispositive issue. The Reply instead responds with three attorney arguments. Each is unpersuasive, as the following subsections explain.

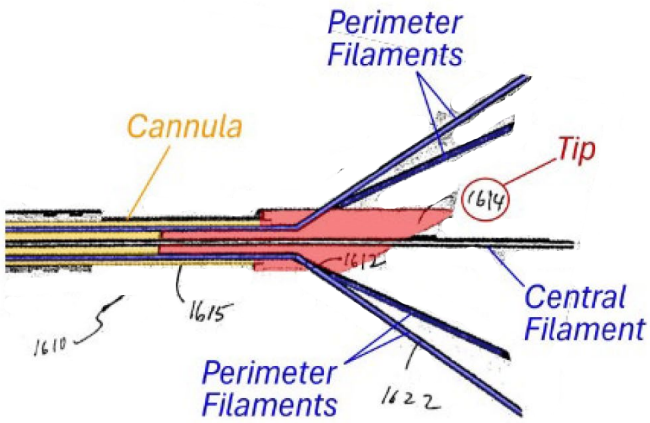
1. Comparisons to Stratus's invention are inapt.

The Reply contends that Stratus's specification does not "teach how to manufacture the disclosed system or devices," that silence "demonstrates that ... manufacturing the claimed invention ... was within the level of ordinary skill" in the

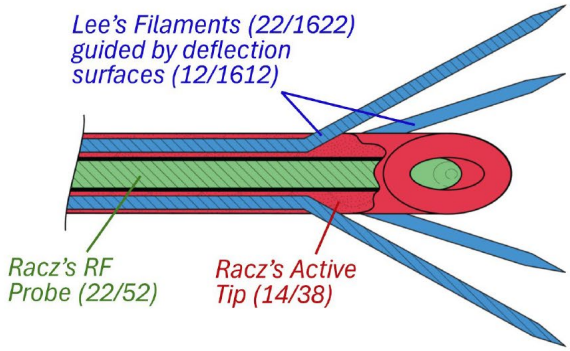
art, and that Peter Crosby's testimony that a POSITA would have been able to make the Stratus invention implies that a POSITA could have made RMD. Reply, 16-17, 20. But, Stratus's invention is ***different*** from RMD and does ***not*** have the unique enablement flaws that RMD has. Those flaws relate to having ***long narrow channels in the sidewall of a needle***. Copious evidence establishes that those long narrow channels in the sidewall of a needle cannot be made. *See* Response, 42-45. Status's invention does not have that problematic feature, and no evidence casts any doubt whatsoever on the enablement of Stratus's invention. Unsubstantiated attorney argument, such as on pages 16-17 of the Reply, are not evidence and cannot support a factual finding. *See In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997).

2. Lee's guidance is not helpful.

The Reply claims, "Lee provides precise guidance." Reply, 17. But that is guidance how to make deployable filaments in a large device for ablating uterine fibroids. Lee's filaments extend down the ***internal lumen*** of a cannula 1615 and then through short grooves in an external surface of a tip 1614. Lee does not teach how to implement his deployable filaments in impossible-to-make long narrow channels fully ***within the sidewall*** of that cannula (let alone a smaller cannula). Thus, Lee's guidance does not in any way teach how to alter Racz's needle to achieve RMD.



Ex-1031, ¶131
(Lee)



Ex-1031, ¶143
(Racz-Fitz-Lee combined)

Reply, 17 (left image cleaned up).

The Reply next argues that "the effectiveness of Lee's deployable filaments was also predictable." *Id.*, 18. That too misses the point. Whether a POSITA could have predicted that Lee's filaments would be effective has no bearing on whether the POSITA could have, based on the reference, ***made*** the long narrow channels in the sidewall of Racz's needle to accommodate those filaments.

3. Neurotomy needles were not larger than 16-gauge.

a. Racz does not support the petitioner's position.

The petitioner's sole support that an RF neurotomy needle may be larger than 16-guage is the second sentence in the following passage:

> Those individuals skilled in the art will recognize that many variations of the electrode geometries depicted in FIGS. 1-3 are possible without departing from the

> invention. Various sized electrodes can be made, from extremely small gauges (e.g., 30 gauge) to much larger sizes (e.g., 10 gauge).

Racz, 8:10-15.

That vague passage does not actually say that a ***neurotomy*** needle could be as big as 10-gauge. Rather, it suggests that a larger (or smaller) needle may be associated with one of "many variations." *Id.* Racz explains that those "many variations" include "other medical and surgical procedures" apart from neurotomy:

> 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.

Id., 9:12-18 (emphasis added).

Moreover, Racz was filed in 1998, more than a ***decade*** before Stratus's earliest priority date (2009). So, even if the state of the art in 1998 contemplated larger RF neurotomy needles, the understanding of the POSITA easily could have changed in the following eleven years. Dr. Russo was in this field this entire time, *see* Russo Dep. Tr. (Ex. 1046), 39:18-40:8; Russo Decl. (Ex. 2001) ¶ 33, and thus is the more credible source of what was known by a POSITA ***at the time of the invention.***

To the extent Racz's sentence at 8:13-15 could be interpreted as intending to apply to neurotomy, the sentence would be nothing more than a gratuitous attempt to broaden Racz's disclosure beyond reality. No matter what Racz says, no evidence in this case establishes that needles larger than 16-gauge would be safe or feasible for RF neurotomy.

b. All other evidence supports Stratus.

The petitioner offers no expert testimony to support its interpretation of Racz's sentence at 8:13-15. All evidence on this topic shows that neurotomy needles can be no larger than 16-gauge.

i. Dr. Russo's unrefuted testimony

Dr. Russo, the only neurotomy clinician to testify in this case, cogently explained why neurotomy needles are between 16- and 22-gauge. *See* Russo Decl. ¶¶ 157-169. He is a peer-recognized worldwide leader in the field of RF neurotomy and the only witness in this case to have held an RF neurotomy needle in his hands and placed it in position in a live patient to ablate a nerve – a procedure he does a dozen times per day. *Compare id.*, ¶¶ 18-23, 26, 28, 33, 129, 136 *with* Tucker Dep. Tr. (Ex. 2020), 12:16-20. The petitioner has not directly refuted the reasoning Dr. Russo provides (that needles bigger than 16-gauge are too stiff and smaller than 22-gauge are too flimsy). And, Dr. Russo ***did*** cite supporting evidence, as noted below.

ii. Dr. Tucker's testimony

Although Dr. Tucker has no personal knowledge of neurotomy needle sizes, *see* Tucker Dep. Tr., 141:18-146:16, he nevertheless cited two references (Tullis and Cosman) to support his position. Tucker Decl. (Ex. 1031) ¶ 46. But both Tullis and Cosman demonstrate that an RF neurotomy needle can be no larger than 16-gauge.

iii. Tullis

Tullis (Ex. 1022) specifies that "[f]or electrode assemblies 24 ***used for denervation procedures***, the diameter of the cannula 28 ... ***is preferably 16 G[auge] or more and more preferably 18 G[auge] or more***." Tullis, 7:32-36 (emphases added). In this context, "or more" means "or smaller" because cannula size decreases with increasing gauge.

iv. Cosman

Cosman (Ex. 1014) explains that "in one example, ***for spinal high frequency treatment of pain***, the tubing can range in gauge size ... to 22, 20, 19, 18, 17, or ***16 gauge*** for larger target sites." Cosman, 7:23-26; *see also* Tucker Decl. ¶ 46 (quoting same).

v. Godara

The Reply cites Godara (Ex. 1015) as one of two "other examples of RF neurotomy needles larger than 16-guage." Reply, 19. Specifically, the petitioner cites ¶ [0040], which states, "The size and shape of probe 100 may vary depending

on the application, and the invention is not limited in this regard." But Godara's ¶ [0138] lists a variety of applications: "[T]he present invention may be used for other applications, such as cardiac ablation, ... and ablation of malignancies or tumours, for example in the lung, liver, or bone." Thus, the gauge size disclosed in ¶ [0040] is expressly ***not*** limited solely to RF neurotomy needles.

The notion that all ranges cited in ¶ [0040] correspond with RF neurotomy needles is absurd. The range of allegedly suitable ***lengths*** provided in the same sentence is "between about 5 cm and about 40 cm." 40 cm is about 1.3 feet! The commercial embodiments of the claimed RF neurotomy needle come in three lengths: 5, 10, and 15 cm. Ex. 1041, 3. Thus, Godara's upper length limit is roughly 3x the largest commercial embodiments.

Besides, in the only "specific example" for which precise diameter measurements are provided in ¶ [0040], Godara says, "the outer diameter may be about 1.5 mm." 16-gauge is 1.65 mm; 17-gauge is 1.47 mm. So this clearly references a 17-gauge needle, which is smaller than 16-gauge.

vi. Shealy

The Reply also cites Shealy (Ex. 1056), a 1976 article, but Shealy nowhere discloses an RF neurotomy needle. Rather, Shealy discloses an ***introducer*** needle used to introduce a separate RF probe/electrode into the patient. Shealy, 160.

Once the RF probe/electrode has been inserted into the patient through the introducer, the introducer is retracted from the body and does not deliver RF energy to the patient in the subsequent RF procedure. *Id.* The RF probe/electrode (*i.e.*, the actual RF energy delivery device) must be smaller than 12-gauge in order to fit down the introducer needle.

Dr. Russo was aware of Shealy's procedure, describing this very technique. *See* Russo Decl. ¶ 98 (quoting another Shealy article, from 1974). Rather than citing the 1974 article Russo identified, the petitioner found a different article describing the same technique, but in which a larger ***introducer*** needle (12-gauge rather than 14-gauge) is used. But a larger ***introducer*** needle is irrelevant, as explained above.

Even assuming Shealy's introducer needle could be considered an "RF neurotomy needle," a POSITA's understanding of what is acceptable for RF neurotomy needles certainly could have changed in the more than three decades between Shealy's publication and Stratus's invention.

vii. Stratus's patents

As the Reply acknowledges, the Stratus patent itself teaches that a neurotomy needle is 16-gauge or smaller. *See* Reply, 19 (citing '688 Patent, 8:3-8).

***

In conclusion, the evidence establishes that an RF neurotomy needle can be no larger than 16-gauge. Besides, even if there were a 10-gauge neurotomy needle, the petitioner has not even attempted to show that the long narrow channels in the sidewall of a needle – per RMD – could be made in a needle of any size, including a 10-guage needle. That failure of proof is dispositive.

4. No reasonable expectation of success to make RMD with EDM or LBM

The Reply contends that RMD could be made by electrical discharge machining (EDM) or laser-based machining (LBM). *See* Reply, 20. No expert analysis supports those assertions. Instead, the Reply cites to cherry-picked portions of Ex. 1063 (Kalpakjian) but fails to provide a complete copy of that book, including portions inconsistent with its assertions.

Kalpakjian elsewhere (on page 549, not cited in the Reply or provided in Ex. 1063) explains, "Deep slots and narrow openings should be avoided" and "the surface finish specified should not be too fine" with EDM. Ex. 2044, 549; *see also* Crosby Decl. ¶¶ 225, 241 (same). In other words, Kalpakjian itself makes clear that EDM *is* ***not suitable*** for making multiple small diameter holes – through which filaments must smoothly slide – in the thin sidewall of a hypodermic metal tube, such as in RMD. Perhaps this is why no expert testified for the petitioner that EDM could be used to make RMD.

Regarding LBM (same as "laser drilling," which Peter Crosby's declaration addressed), Kalpakjian says on the same not-cited, not-provided page 549 that "designs should avoid deep cuts" and cautions that "[a]ny adverse effects ... on surface finish and integrity should be considered." Ex. 2044, 549; *see also* Crosby Decl. ¶¶ 238, 241 (same). Moreover, the 2009 edition of Kalpakjian warns that "deep cuts will produce tapered walls," rather than the uniform channels in RMD, and adverse effects can be "caused by the high local temperatures and heat-affected zone." Ex. 2045, 572. Again, in the face of these express teachings by Kalpakjian, it is telling that no expert testified to support the petitioner's argument that LBM could be used to make RMD.

To the extent Kalpakjian is considered to support the petitioner's position, Kalpakjian should be rejected as improper new evidence that could and should have been presented in the petition. The petitioner should have foreseen that the implausibility of RMD as a mere paper design would be an issue and should have produced its reasonable-expectation-of-success evidence in the petition. The petitioner's late attempt to fill gaps in its petition should not be permitted. *See* Consol. Trial Practice Guide at 74-75 (Nov. 2019).

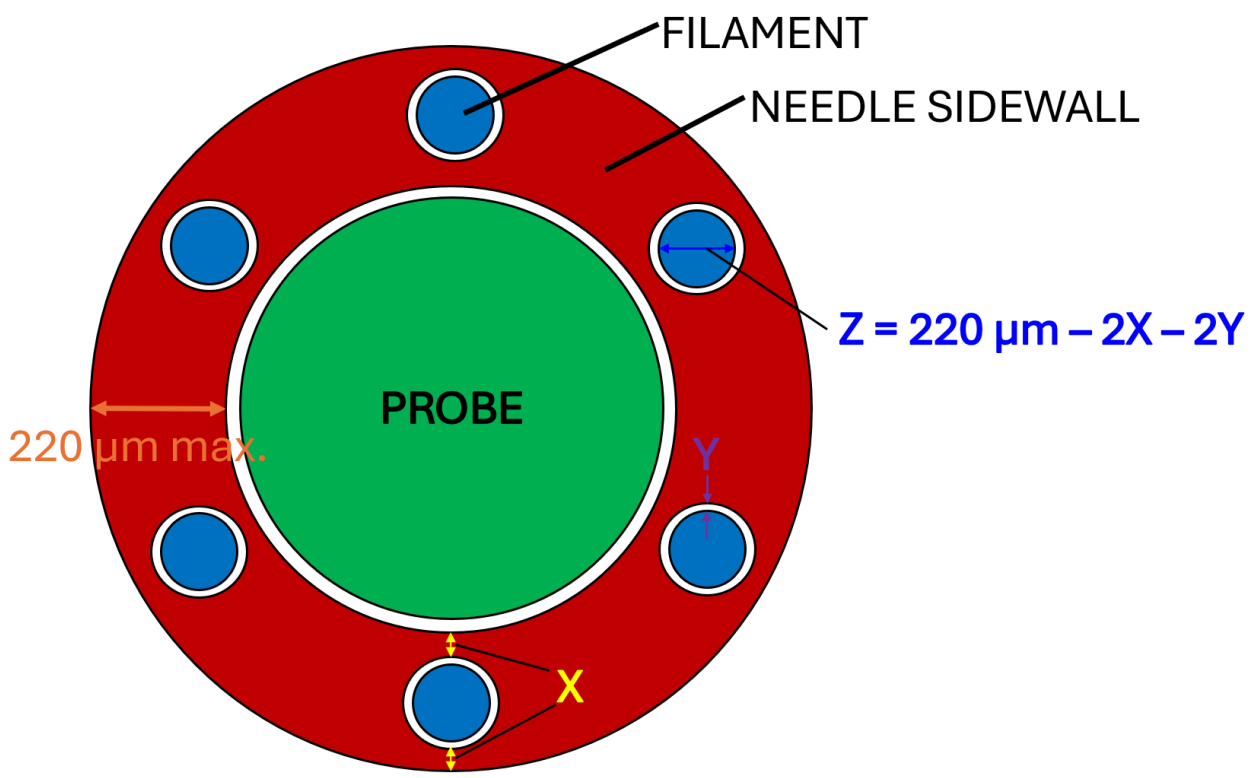
D. No Reasonable Expectation of Success to Use RMD

The Reply criticizes aspects of Peter Crosby's structural analysis that the filaments in RMD would be so thin that a neurotomy clinician would not have had

a reasonable expectation that they could be used successfully in a patient. *See* Reply, 20. However, those criticisms are just attorney argument. The petitioner has provided no expert testimony to substantiate its criticisms. *See Geisler*, 116 F.3d at 1470. The only actual evidence is Peter Crosby's unrefuted testimony.

Besides, the Reply's attorney-argument criticisms of Crosby's analysis lack merit. The Reply cites to portions of a new textbook (Ex. 1062, "Gere"), but offers no explanation of those portions, certainly no expert explanation. The Reply suggests that Crosby used the wrong formula. *See* Reply, 20. That is untrue. Crosby calculated how much axial force would cause a filament to bend permanently. *See* Crosby Decl. ¶¶ 276-281. The Reply cites to a different formula on Gere page 748 for temporary buckling (which requires even less force). The petitioner also conflates axial compression force and perpendicularly applied cantilever force. *See* Crosby Dep. Tr. (Ex. 1045), 258:10-262:17.

The Reply argues that a 0.2 mm nitinol filament must be feasible because Stratus's patent refers to a range that encompasses 0.2 mm. *See* Reply, 20 (citing '688 Patent, 9:53-56). But the commercial embodiments have considerably thicker filaments. Besides, the filaments in RMD would need to be considerably smaller than 0.2 mm, as the sidewall is at most only 0.22 mm thick, some sidewall material must remain for the needle to have structural strength, and the filaments must be smaller in cross section than the channels in which they move.



Moreover, Dr. Russo ***independently*** reached the same conclusion as Dr. Crosby. *See* Russo Decl. ¶¶ 215-226; Russo Dep. Tr., 26:20-27:11. Even if there were doubt whether a filament in RMD would permanently deform or break during an RF neurotomy procedure, Dr. Russo's concerns about unpredictable deflection for this size of filament stand unrefuted, as do his concerns that at that size, the filaments would be ineffective at expanding the ablation volume, thus fatally undercutting the only motivation for combining Lee with Racz. *See* Response, 47-48; Russo Decl. ¶¶ 219-226.

In sum, the only evidence in this case (and it is unrefuted) is that a POSITA would not have had a reasonable expectation of success to use RMD to perform a

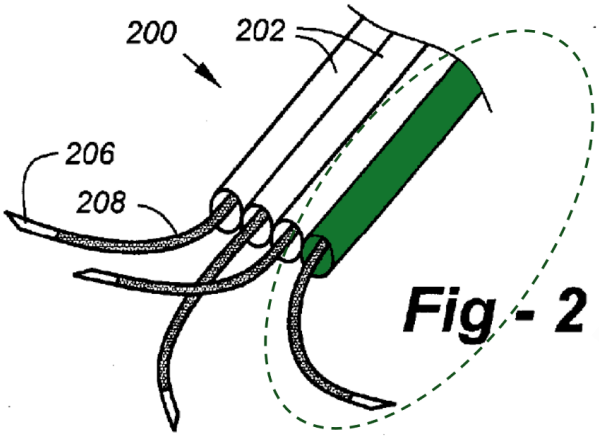
neurotomy procedure because of the risk of unpredictable filament deflection, permanent bending, and/or breakage and their attendant complications and risks. That is another fatal flaw in all challenges.

E. Teachings Away

1. Racz teaches away from RMD's flimsy filaments.

Racz expressly teaches away from deploying flexible electrodes from a cannula for RF neurotomy procedures. *See* Response, 50-52. The Reply responds that "the curved-tip electrodes Racz mentions bear no resemblance to the deployable filaments in Fitz/Lee," and emphasizes that Lee teaches "*straight* electrodes." Reply, 13. However, when Lee's filaments are modified to fit within channels in the sidewall of Racz's needle, per RMD, those filaments would be so thin they would be unable to "penetrate tough tissue or encounter hard bone without being damaged or diverted"—the very limitation Racz eschews. Racz, 2:37-38; *see also* Response, 50-52. That evidence is unrefuted. Thus, Racz teaches away from RMD.

Besides, the petitioner's assertion that "the curved-tip electrodes Racz mentions bear no resemblance to the deployable filaments in Fitz/Lee" lacks merit. Reply, 13. Even a quick glance reveals substantial resemblance:



Fitz (Annotated) ***Radionics TEW Kit***

The Reply argues, "Neither Crosby nor Russo were familiar with these electrodes, removing any credibility from their teaching[-]away testimony." *Id.* That does not matter. Racz itself views these type of deployable electrodes as undesirable for use with RF neurotomy needles and expressly says so.

2. Racz teaches away from a straight tip.

RMD, as best understood, has a straight tip. *See* Reply, 14 (doubling down on straightening Racz's tip); Tucker Dep. Tr., 108:19-112:6, 117:19-121:7; Crosby Decl. ¶¶ 182-183, 191, 202; Russo Decl. ¶¶ 151-154. That is understandable, as RMD would be even more impossible to make with a bent tip. But, straightening Racz's tip is contrary to Racz's clear teachings. *See* Response, 52-55. The Reply argues, "At most, Racz suggests a preference for a bent tip in limited scenarios but never requires it." Reply, 14. That is incorrect. The whole point of Racz is the use of a curved tip.

The Reply cites *Axonics* and *Meiresonne*, *see* Reply, 14-15, but nothing in those cases condones ignoring a clear teaching in a primary reference not to do what a proposed combination does. Also, the fact that other RF-neurotomy references may teach straight-tip needles is immaterial. The petition's obviousness case is based on Racz's cannula, which has a bent tip. The petitioner has never proposed combining a straight-tipped reference with Fitz and Lee; rather, it proposed "***Racz's*** modified device" using ***Racz's cannula*** as the starting point. *See* Pet., vi, 21-27, 35 (emphasis added).

3. Lee teaches away from an anchor-less device.

Lee requires anchors to counteract the backward force on Lee's needle caused by forward deployment of the stylets, except in the very limited circumstance in which the stylets are deployed one at a time. *See* Response, 55-56. Yet, RMD does not include anchors. The Reply's only response is that "Lee is unequivocal that its anchors are optional." Reply, 14. True, but the only condition under which Lee states the anchors may be omitted is when the filaments are deployed one at a time. *See* Lee, ¶ [0104]. The petition did not include, however, any discussion of how to implement one-at-a-time deployment of the filaments in RMD.

III. FIELD OF THE INVENTION

The petitioner thinks the '688 Patent's field is thermal ablation and need not include RF neurotomy, whereas Stratus believes the field is RF neurotomy, which is

a subfield of thermal ablation. Stratus is correct. *See* '688 Patent, 1:16-19 (full sentence "Field" statement that field is RF neurotomy after noting, for context, that RF neurotomy is one type of thermal ablation).

RF neurotomy is the almost exclusive focus of the patent, as reflected in the title, abstract, and every embodiment illustrated in the drawings or described in any detail. While the patent mentions some non-neurotomy ablation applications, it merely says that the invention can be "adapted," "modified," "scaled," or "tailored" for other RF ablation procedures. *Id.*, 30:63-31:14 ("***adapted*** (e.g., modified or scaled) for use in other medical procedures"); Ex. 1054 (provisional), 30 ("[T]his invention can be ***tailored*** to any procedure requiring tissue ablation"). If the invention can be adapted, modified, scaled, or tailored for other RF ablation procedures, then the invention itself is not directed to those procedures. For example, needles are not used for cardiac ablation. *See* Russo Dep. Tr. 36:11-37:12, 47:22-48:9, 131:2-4 (explaining that endocardial lesions are never formed using needles; instead, a catheter is run through vasculature).

Two consequences follow from this: (1) Dr. Tucker does not have the relevant expertise and (2) Lee, Schiebe, and Young '965 are not analogous art.

A. Dr. Tucker Lacks Relevant Expertise

Dr. Tucker's testimony deserves little weight because he lacks the expertise of an RF neurotomy clinician. *See Abiomed, Inc. v. White Swell Med. Ltd.*, IPR2021-01478, Paper 37 at 34-35 (Apr. 4, 2023).

The Reply therefore argues that "the patent addresses an *engineering problem*—how to expand the RF needle's ablation volume." Reply, 6. That is an oversimplification. The patent does not address a pure engineering problem, but a medical/bioengineering problem of which engineering is only a part. The problem is not simply increasing ablation volume but creating an ablation sized and shaped so as not to miss a tiny nerve during a superior RF neurotomy procedure with all the biological, anatomical, medical, and clinical constraints such a procedure entails.

The Reply mentions that Dr. Tucker has designed over 50 RF neurotomy devices. *See* Reply, 8. Dr. Tucker made that claim in his deposition only after coaching by counsel, after having originally professed ignorance of RF neurotomy. *See* Tucker Dep. Tr. 10:19-12:20, 16:8-18:22, 142:15-146:16, 195:13-196:15, 198:6-14. However, those devices were for ablating peripheral nerves, not spinal nerves, and no details of those devices, *e.g.*, whether they were ablation ***needles***, whether they were for use on humans, whether they were primarily designed to ablate nerves or just did so incidentally, his role in their design (his CV suggests just

testing/validation), etc., have been provided. It has not been established that he has ***relevant*** experience.

Dr. Tucker's lack of RF neurotomy expertise is not the only reason his testimony deserves little weight. His engineering analysis was deficient, and his testimony merely parrots the petition. *See* Response, 30-31.

Sensing the weakness in Dr. Tucker's background, the Reply complains that Dr. Russo and Peter Crosby "never relied on one another for their testimony." Reply, 5. That is incorrect. Peter Crosby had all relevant information originating from Dr. Russo. *See* Crosby Decl. ¶¶ 158, 228. Each expert gave his opinion based on his own knowledge and expertise, and each had the requisite information from the other to do so.

B. Non-Analogous Art

Lee, Schiebe, and Young '965 are in different fields and therefore are analogous art only if they are reasonably pertinent to the inventors' problem. They are not. There has been little overlap between RF neurotomy and all other forms of thermal ablation. *See* Russo Decl. ¶¶ 76, 147, 177. Indeed, the Reply identifies only one concrete real-world instance of any cross-pollination whatsoever between RF neurotomy and other forms of thermal ablation. *See* Reply, 3-4 (discussing cooled-tip ablation, which suffers from higher cost and complexity and less desirable ablation shape).

IV. OBJECTIVE INDICIA OF NONOBVIOUSNESS

A. Long-Felt-But-Unmet Need

The Reply argues that Nimbus was not a "game changer" because it theoretically was possible to conduct a perpendicular-approach procedure with a cooled RF device before Stratus's invention. *See* Reply, 21-22. But this overlooks numerous ways in which Nimbus is superior to cooled-RF devices for perpendicular-approach procedures, including its production of a preferred ablation shape. *See* Russo Dep. Tr., 131:24-135:21. More fundamentally, Nimbus enabled Dr. Russo to develop a new technique (multifidus sparing) that (1) is superior even to the perpendicular approach and (2) cannot be performed with either traditional or cooled RF neurotomy devices—facts the Reply leaves unchallenged. *See* Response, 63; Russo Decl. ¶¶ 128-136; Ex. 2005; Ex. 1051, 31, 39. Thus, even after considering the petitioner's narrowly focused cooled-RF arguments and evidence during his deposition, Dr. Russo maintained his "game changer" opinion of Nimbus. Russo Dep. Tr., 135:23-137:3. The testimony of a peer-recognized worldwide leader in the field of RF neurotomy outweighs mere attorney argument to the contrary.

The petitioner's contention that the patent claims "cover devices that wouldn't meet even the *alleged* long-felt need," even if true, is misdirected. Reply, 22. The claims are coextensive with a commercial embodiment that does meet this need.

B. Copying

The Reply, referencing a new declaration from Dr. Tucker, highlights minor differences between the Nimbus and Trident devices in an attempt to demonstrate that Diros did not copy Nimbus when developing Trident. Reply, 24. But those minor differences are irrelevant, as ***identicality*** is not the proper standard: copying is present where there is "access to, and ***substantial similarity*** to, the patented product." *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004) (emphasis added).

Further, the Reply argues that Diros could not have copied Nimbus because "Stratus ... is not aware *of any instance* in which one of its devices has fallen *into a competitor's hands*." Reply, 22. But this focus on Stratus is a ruse. Tellingly, the petitioner does ***not*** say that Diros (its wholly owned subsidiary) never possessed a Nimbus. And tellingly, the petitioner does ***not*** even allege (let alone demonstrate) that Diros independently developed Trident without intentionally copying key features of Nimbus.

Moreover, Diros affirmed to the FDA that Trident is "equivalent" (not just "substantially equivalent") to Nimbus in its key features. *See* Response, 65; Ex. 2019, 8. Diros could not have certified equivalence without having Nimbus in hand.

C. Praise

The Reply does not dispute the praise Stratus has received. Instead, the petitioner argues that company praise is not praise for the invention. *See* Reply, 24-25. But all praise for Stratus is directly attributable to Nimbus, which accounts for [redacted] of Stratus's revenue. *See* Response, 67; Jorgensen Decl. (Ex. 2015-16) ¶ 14. The Reply also argues that Stratus's intellectual property is only one of many factors that were evaluated before independent third parties gave awards to Stratus. Reply, 25. That argument is misdirected. The relevant praise is for the invention, not the patents that cover it.

D. Commercial Success

Cody Jorgensen's testimony of the commercial success of Nimbus is based on personal knowledge gained from six years in marketing roles with Stratus. *See* Jorgensen Decl. ¶¶ 2, 4. While certain of the specific figures he analyzed were obtained from third parties, he testified this data is consistent with his own knowledge of this market. *See* Jorgensen Dep. Tr. (Ex. 1047-48), 19:4-18, 74:2-13, 87:13-89:22.

1. Nexus

The Reply attempts to overcome the presumed nexus by arguing that Stratus has not presented adequate evidence of sales of the "complete, 'claimed invention.'" Reply, 25. However, there is no legal or logical requirement that all components of

the claimed invention be sold together in one transaction. Like a razor handle and a razor blade, the probe and needle (called an "electrode" by Stratus) components of the Nimbus system must be used together, even if sold separately. *See* Jorgensen Dep. Tr., 28:12-18, 36:2-20. Thus, sales of Stratus's electrodes are evidence of use of the full Nimbus system.

Accordingly, whether Stratus's needle/electrode sales "dwarf" its probe sales is irrelevant. Reply, 26. Some versions of Stratus's probe are reusable; multiple needles/electrodes can be used, in turn, with a single probe. *See* Jorgensen Dep. Tr., 36:10-16. Moreover, the Nimbus electrode is compatible with probes manufactured by other entities, including the petitioner. *See id.*, 28:9-11, 36:16-20. Thus, Nimbus's higher needle/electrode sales better indicate how many times the claimed combination is put together and used in RF neurotomy procedures.

2. Stratus's market definition is accurate.

The petitioner maligns Stratus's exclusion of the petitioner's COOLIEF* product from its comparative market data as a "sleight-of-hand," but the petitioner's focus on COOLIEF* is the true misdirection. Reply, 27. Stratus excluded COOLIEF* for the same reason Avanos acquired Diros's copycat Trident product line: COOLIEF* and Trident (and by extension, Nimbus) are in ***different*** markets. The petitioner admitted as much in its press release regarding the acquisition of Diros: "The addition of Diros' unique RF Trident™ technology is expected to ...

complement [Avanos's] premium COOLIEF* Cooled Radiofrequency product offering." Ex. 1029, 1 (emphasis added); *see also id.* (petitioner CEO stating, "With this comprehensive ***suite*** of RF offerings, we believe Avanos is poised for future growth across all major sites of patient care." (emphasis added)). Avanos presumably would not acquire and promote a product line that would cannibalize sales of its premium-priced COOLIEF* in the same market.

Paradoxically, Avanos attempts to disparage Nimbus's success in its market by providing a snapshot of the [redacted] performance of its COOLIEF* device. *See* Reply, 28. Whereas Stratus, due to Nimbus (accounting for [redacted] of revenue), experienced a compounded annual growth rate (CAGR) of [redacted] from 2020-2024, Avanos's COOLIEF* net revenue [redacted] from just 2023 to 2024. *Compare* Jorgensen Decl. ¶¶ 21-22 *with* Johnson Decl. (Exs. 1044, 1053) ¶ 5. This is [redacted] Dr. Russo's testimony that cooled RF has become disfavored by customers because of its expense and Nimbus's superior ablation shape. *See* Russo Dep. Tr., 131:24-137:3; Russo Decl. ¶ 134.

3. Stratus's success is significant.

The Reply, citing new testimony from Mark Konno, disputes whether Stratus has enjoyed commercial success. *See* Reply, 28-29. But Konno spent his career at a huge company in vastly larger markets unrelated to RF neurotomy, and he has no

experience in RF neurotomy markets. Konno Dep. Tr. (Ex. 2042-43), 7:20-8:6, 9:12-11:9, 20:8-22.

The Reply portrays Stratus's sales growth as "[redacted]" Reply, 29. That is misleading. To be clear, Stratus's sales have ***increased year-over-year every single year*** since Nimbus began selling in the United States, and Stratus's compounded annual ***growth rate*** 2020-2024 is [redacted] *See* Jorgensen Decl. ¶¶ 15, 21-22. Only year-over-year rates of growth – what Konno calls "growth trends," Konno Decl. (Ex. 1052-53) ¶ 16 – have [redacted], but that is a misleading and uninformative benchmark. Indeed, even the hypothetical scenario that Konno proposed in his deposition to illustrate his view of commercial success would have [redacted] "growth trends." *See* Konno Dep. Tr., 33:3-15, 37:8-17 (Konno's proposed ¶16-table revisions likewise yield [redacted] "growth trends" 2022-2024).

The Reply also suggests that Stratus's marketing is solely responsible for the commercial success of Nimbus due to the lack of sales in the eight-year period between FDA approval in 2012 and when Nimbus was first offered for sale in the United States in 2020. *See* Reply, 29-30. That reasoning is faulty. The petitioner provides no evidence that, once Stratus launched Nimbus in the United States in 2020, anything other than the advantages of the claimed invention have been responsible for its commercial success. Indeed, Stratus's [redacted] marketing expenditures and [redacted] sales force throughout 2020-2024 demonstrate the opposite:

The success of Nimbus is attributable to the invention it embodies, not heroic marketing of a weak product. *See* Jorgensen Decl. ¶¶ 19-20; Exs. 1060-1061.

V. CONCLUSION

Stratus respectfully requests a final written decision that the petitioner has failed to prove any claims of the ’688 Patent unpatentable.

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WORD-COUNT CERTIFICATE

I certify that the this document complies with the type-volume limitations of 37 C.F.R. § 42.24(a)-(b) and contains **5,518** words based on the word count indicated by the word-processing program used to create this document.

/ M.C. Phillips /
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CERTIFICATE OF SERVICE

I hereby certify that on **September 26, 2025**, copies of the foregoing PATENT OWNER'S SURREPLY and all documents filed with it were served via electronic mail, as agreed to by counsel, upon the following counsel for the Petitioner:

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