PUBLIC REDACTED VERSION

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVANOS MEDICAL, INC.,

Petitioner,

v.

STRATUS MEDICAL, LLC,

Patent Owner.

Case IPR2024-01212
Patent 10,925,664

PETITIONER'S REPLY TO THE PATENT OWNER RESPONSE

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PETITIONER'S UPDATED EXHIBIT LIST

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

Exhibit No.	Description
1017	U.S. Patent No. 6,652,516 to Gough (filed November 19, 1999 and issued on November 25, 2003) ("Gough '516").
1018	U.S. Patent No. 5,728,143 to Gough (filed February 14, 1996 and issued on March 17, 1998) ("Gough '143")
1019	Cohen et al., Randomized Placebo-controlled Study Evaluating Lateral Branch Radiofrequency Denervation for Sacroiliac Joint Pain, Anesthesiology, Vol. 109, Issue 2, 279-288 (2008) ("Cohen")
1020	U.S. Patent No. 6,551,302 to Rosinko (filed on October 26, 2000 and issued on April 22, 2003) ("Rosinko")
1021	U.S. Patent No. 5,855,576 to LeVeen et al. (filed on December 12, 1996 and issued on January 5, 1999) ("LeVeen")
1022	U.S. Patent No. 7,918,852 to Tullis et al. (filed May 1, 2006 and published January 18, 2007) ("Tullis")
1023	U.S. Patent No. 4,411,266 to Cosman (issued October 25, 1983) ("Cosman '266")
1024	U.S. Patent No. 7,195,629 to Behl et al. (filed August 18, 2003 and issued March 27, 2007) ("Behl")
1025	U.S. Patent No. 5,782,827 to Gough et al. (filed December 19, 1995 and issued July 21, 1998) ("Gough '827")
1026	U.S. Patent No. 5,928,229 to Gough et al. (filed October 30, 1997 and issued July 27, 1999) ("Gough '229")
1027	U.S. Patent No. 9,078,678 to Zerfas et al. (filed March 21, 2013 and issued July 14, 2015) ("Zerfas")
1028	U.S. Patent App. Pub. No. 2007/0203486 to Young (published August 30, 2007) ("Young '486")
1029	U.S. Patent App. Pub. No. 2005/0159797 to Chandran et al. (published July 21, 2005) ("Chandran")
1030	U.S. Patent App. Pub. No. 2008/0269774 to Garcia et al. (published October 30, 2008) ("Garcia")
1031-1033	Reserved
1034	Declaration of Dr. Robert D. Tucker (July 26, 2024)

Exhibit No.	Description
1035	CV of Robert D. Tucker, Ph.D., M.D.
1036	Petitioner's Requests for Production
1037	Highlighted version of Stratus Exhibit 2015 (confidential designated version of Jorgensen Declaration) **PROTECTIVE ORDER MATERIAL—OUTSIDE COUNSEL ONLY** (based on Stratus's designation)
1038	Stratus Press Release dated Aug. 8, 2019, *available at* https://stratusmedical.com/2019/08/09/med-venture-holdings-announces-new-ceo-appointment-for-nimbus/
1039	Stratus Press Release dated Jan. 15, 2020, *available at* https://stratusmedical.com/2020/01/15/stratus-medical-completes-private-placement-financing-and-acquisition-of-the-nimbusrf-business-for-expansion-in-the-interventional-pain-medicine-space/
1040	Stratus "Clinical References," *available at* https://stratusmedical.com/clinical-compendium/
1041	Stratus "2023 Product Catalog," *available at* https://stratusmedical.com/product-catalog/
	New Exhibits Submitted with Reply
1042	Reply Declaration of Dr. Robert D. Tucker (Sept. 5, 2025)
1043	Declaration of Mark Konno (Aug. 29, 2025) **Protective Order Material—Outside Counsel Only**
1044	Declaration of Dennis Johnson (Sept. 4, 2025) **Protective Order Material—Outside Counsel Only**
1045	Transcript of the Cross-Examination of Peter Crosby (Aug. 5, 2025)
1046	Transcript of the Cross-Examination of Prof. Marc Russo (Aug. 22, 2025)
1047	Transcript of the Cross-Examination of Cody Jorgensen (Aug. 26, 2025) **Protective Order Material—Outside Counsel Only**
1048	Public Redacted Version of Ex-1047 Jorgensen transcript

Exhibit No.	Description
1049	FDA 510(K) Approval No. K121773, *Nimbus Electrosurgical Radiofrequency Multitined Expandable Electrode* (Sept. 21, 2012), *available at* https://www.accessdata.fda.gov/cdrh_docs/pdf12/K121773.pdf
1050	U.S. Patent No. 10,661,078 to Crosby et al. (filed Dec. 22, 2017 and issued May 26, 2020) ("Crosby Patent")
1051	Robert E. Wright, *Radiofrequency Ablation in Interventional Pain Management Using RF Multitined Expandable Electrode*, 1st Ed, Full Book (n.d.)
1052	Public Redacted Version of Ex-1043 Konno Declaration
1053	Public Redacted Version of Ex-1044 Johnson Declaration
1054	File History for U.S. Provisional Application No. 61/280,557 to Wright et al., filed Nov. 5, 2009.
1055	Baylis Medical SInergy™ System, User Guide (PM1013 Rev 09/08) (Sept. 2008).
1056	Shealy, C. Norman. "Facet denervation in the management of back and sciatic pain." Clinical Orthopaedics and Related Research® 115 (1976): 157-164.
1057	Reserved
1058	Cosman Brochure: TEW Trigeminal Neuralgia Kit (2005), available at: https://www.argigrup.com/Files/urunlerpdf/cosman/BrochureTEW.pdf
1059	Reserved
1060	Stratus's Revenue and Marketing Expenditures for 2020-2024 [Served on Avanos as Stratus Exhibit 2040 on July 25, 2025] **Protective Order Material—Outside Counsel Only**
1061	Public Redacted Version of Ex-1060 [Served on Avanos as Stratus Exhibit 2041 on July 25, 2025]
1062	James M. Gere, Mechanics of Materials (5th ed. 2001) (excerpts)
1063	Serope Kalpakjian, et al., Manufacturing Processes for Engineering Materials (4th ed. 2003) (excerpts)

Exhibit No.	Description
1064	FDA 510(k) Approval No. K190259, *Vesta RF Cannula* (Feb. 7, 2020), *available at* https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190259.pdf

GLOSSARY

Term	Meaning
"'664 Patent" or "patent"	U.S. Patent No. 10,925,664 to Wright et al. (issued Feb. 23, 2021)
"Challenged Claims"	Claims 1-29 of the '664 Patent
"Board"	USPTO Patent Trial and Appeal Board
"POSA"	Person of ordinary skill in the art at the time of the '664 Patent's alleged invention
"RF"	Radiofrequency
"Stratus"	Patent Owner Stratus Medical, LLC
"Crosby"	Peter Crosby
"Russo"	Prof. Marc Russo
"Jorgensen"	Cody Jorgensen
"Dr. Tucker"	Dr. Robert D. Tucker
"Pet."	The Petition for IPR
"POR"	Patent Owner's Response
"ID"	Institution Decision

I. INTRODUCTION

Stratus's Patent Owner Response takes a kitchen sink approach, shoehorning the facts into every theory of nonobviousness it can conjure. But this case is much clearer than Stratus's disjointed arguments. The claimed invention is old elements—an RF needle, a removable probe, and deployable filaments—arranged together with each performing its already well-known, expected function. The combination was obvious, and Stratus fails to offer any compelling evidence otherwise.

II. THE PATENT'S FIELD

Stratus argues that the '664 patent's field definition ("thermal ablation systems and methods") is too broad and should be limited to "RF neurotomy ablation systems and methods." POR, 26-28; Ex-1003, 1:24-27. According to Stratus, RF neurotomy involves ablating nerve tissue, so RF ablation of *other* tissues—"like tumor ablation and cardiac ablation"—should be ignored. POR, 2-5, 26-28, 34-36, 59-60. The evidence overwhelmingly contradicts Stratus's narrow view of the field.

1. The specification is not limited to RF neurotomy.

The field is determined "by reference to explanations of the invention's subject matter in the patent application, including the embodiments, function, and structure of the claimed invention." *Netflix, Inc. v. DivX, LLC*, 80 F.4th 1352, 1359

(Fed. Cir. 2023). The '664 patent plainly and "generally" defines its field: "thermal ablation systems and methods." Pet., 11; Ex-1003, 1:24-27. Although the field includes, "more particularly," RF neurotomy, the inventors defined the more "general[]" scope for a simple reason: their invention was never *limited* to RF neurotomy. *See* Ex-1003, 1:24-27.

As Crosby confirmed, the patent claims are not limited to neurotomy. Ex-1045, 257:1-257:22; Ex-1003, 31:32-34:23. Moreover, the intrinsic evidence is unequivocal: "the delivery of RF energy to tissue in the anatomy is practiced for a multitude of reasons and *embodiments of needles described herein may be adapted (modified or scaled)* for use in other medical procedures." Ex-1003, 31:6-10;[1] Ex-1054, 30 (provisional disclosing "*this invention* can be tailored" for "*any* procedure requiring tissue ablation"). The specification describes using RF needles for "cauterize[ing] 'feeder vessels'" in ulcers and for "cardiac ablation" generally—*not RF neurotomy*. Ex-1003, 31:10-22; Ex-1046, 34:7-10, 142:9-145:8 (discussing cardiac ablation).

Although Stratus casts RF neurotomy and tumor ablation as *unrelated* (POR, 26-27, 34-36, 59-60), the patent does the opposite—expressly stating the target volume can be a "nerve or a tumor," Ex-1003, 1:34-35. Likewise, the "Summary"

[1] All emphasis is added unless otherwise indicated.

characterizes the invention as "methods, systems, and related apparatuses for performing *thermal ablation in general*." Ex-1003, 1:66-2:1.

Stratus nevertheless argues the patent's "central focus" is RF neurotomy within the "broad[er]" ablation field. POR, 26. That approach invites error: "The field of endeavor is 'not limited to the specific point of novelty … or the *particular focus within* a given field.'" *Netflix*, 80 F.4th at 1359 (citing cases). The evidence here leaves no doubt that the field is not limited to RF neurotomy.

2. RF neurotomy is not an isolated field.

Stratus tries to justify its narrow view of the field by arguing RF neurotomy is a "highly specialized subfield that has *never* had any meaningful overlap with other types of RF ablation," exclusively citing its experts. POR, 27 (*see also* 2-5, 26-28, 34-36, 59-60). But upon cross-examination, Russo and Crosby confirmed that the opposite is true—RF neurotomy *has* very meaningfully overlapped with other types of RF ablation.

Russo agreed that cooled-tip technology (providing "enlarged lesions") was originally developed for cardiac and tumor RF ablation needles and then *adapted* for RF neurotomy. Ex-2001, ¶107; Ex-1046, 69:24-70:23, 125:10-25; Ex-2004, 3902-3903, 3906; *see also* Ex-1055 and Ex-1015 (describing cooled-tip neurotomy needles). Russo also confirmed that this cooled-tip technology transfer reflects "cross-pollination" between tumor ablation and RF neurotomy—precisely what

Stratus argues "never" occurs. Ex-1046, 126:1-8; *cf.* POR, 5, 27. Moreover, this cross-pollination has been very meaningful: Avanos sells [redacted] of cooled-tip RF neurotomy devices annually. Ex-1044, ¶5-8.

Indeed, Stratus's lead inventor (Wright) was working with cooled-tip neurotomy needles (the Baylis SInergy™) *immediately before* the alleged invention. Ex-1046, 72:12-73:19, 58:4-60:11, 90:3-93:10; Ex-2004, 3902; Ex-1055 (SInergy user guide). Wright then began "trying to conceive of an alternative device that could *match the lesion created by the internally cooled electrode*." Ex-2004, 3903. So the claimed invention was developed by benchmarking a needle with cooled-tip technology adopted from cardiac/tumor ablation. Ex-1046, 75:1-24; Ex-1051, 5, 8 (benchmarking cooled-RF).

Implausibly, Stratus attempts to rewrite this history to suggest that cardiac/tumor ablation technology has no relevance to neurotomy. Even Crosby admitted that his own RF neurotomy patent was, in fact, an RF ablation device for *both neurotomy and tumor ablation*. Ex-1050, 16:3-42, 17:9-12 (Crosby's patent); Ex-1045, 44:12-45:20, 194:5-197:8, 201:12-202:15; Ex-2006, ¶13. The evidence contradicts Stratus's argument that RF neurotomy never overlaps with other RF ablation technology, the Board should reject Stratus's narrow field definition.

III. LEVEL OF ORDINARY SKILL

A. Stratus's POSA definition is untethered to the specification and rebutted by its experts.

Stratus's improperly narrow field also infects its view of the level of skill. Stratus's proposed POSA requires experience as a neurotomy physician *and* engineer. POR, 30. With one person unlikely to have this experience, Stratus concedes the POSA may "be a team of two or more people working together" and offers testimony from Crosby, an engineer, and Russo, a physician.

First, Stratus errs by requiring "significant experience performing RF neurotomy procedures" when the patent's field is not limited to neurotomy. Indeed, the claims are not limited to neurotomy at all. Ex-1045, 211:7-213:18; Ex-1003, 31:32-34:23.

This flaw is highlighted by Crosby and Russo's cross-examination testimony: *they never relied on one another for their testimony*. Ex-1045, 21:7-23:20; Ex-1046, 26:2-27:11. Each agreed his expertise is limited to his half of the POSA's skillset, but neither sought the expertise of the other. Ex-1045, 105:10-107:2; Ex-1046, 39:6-10. Crosby is not a physician but didn't need Russo to form his opinions. Ex-2006 (generally); Ex-1045, 105:10-107:2. Yet Crosby believed himself competent to offer testimony on *all aspects* of the Stratus patents and the prior art, including operating the devices. Ex-1045, 98:5-101:10; Ex-2006, ¶21,

275; *see generally* Ex-2008. If Crosby didn't need a physician's skills to opine on the claims and art for Stratus, the Board shouldn't require that for a POSA, either.

Furthermore, Stratus requires "experience in the design and development of devices and methods for applying electromagnetic energy to nerves." POR, 30. But under this definition, the POSA could have experience only with stimulating nerves—*but no experience in RF ablation*. Ex-1045, 30:1-5. This further distances Stratus's POSA definition from the patent's field ("thermal *ablation* systems and methods").

B. Petitioner's POSA definition is correct.

Factors for determining the level of ordinary skill include the type of problems encountered in the art; solutions to those problems; how rapidly innovation happens; the sophistication of the technology; and the education of active workers in the field. *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Here, the patent addresses an *engineering problem*—how to expand the RF needle's ablation volume. POR, 5; Pet., 2-3, 7; Ex-1003, 5:42-45, 6:11-22; Ex-2006, ¶91; Ex-2001, ¶121-122; Ex-2004, 3903. And the patent discloses an *engineering solution*—albeit an obvious one—using well-known deployable filaments to increase ablation volume. Pet., 7, 15-27, 35-47; Ex-1034, ¶63-77, 91, 118-131. The inventors may be physicians (POR, 29), but this is not the skill set they used to arrive at the invention (*see* Ex-2004, 3903 (describing Wright's

"'garage' experiments")), and their background is outweighed by the other factors. *In re GPAC*, 57 F.3d at 1579.

The art reflects the same engineering-based approach. Racz, Fitz, and Lee all describe and claim *RF ablation devices* with features engineered to provide controllable ablation volumes. Ex-1009, Abstract, 3:38-4:23, 9:24-10:50; Ex-1010, Abstract, ¶0084, Claims 1-33; Ex-1011, Abstract, ¶0001, 0017-0021, Claims 1-10. And even without adopting a specific POSA definition, the Board may rely on the level of skill reflected in the substantial prior art in the record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC*, 57 F.3d at 1579.

Petitioner's POSA definition is consistent with the patent's field, the problems/solutions in the art, and the sophistication of the technology. Pet., 11. Dr. Tucker confirmed that when he referred to a POSA having "at least" 3 years of relevant experience (or 1 year depending on education), he offered his testimony based on the minimum amounts. Ex-1042, ¶6-7. Thus, the Board may remove "at least" from Dr. Tucker's POSA definition and rely on his testimony. *See* ID, Paper 9 at 13.

IV. DR. TUCKER'S TESTIMONY SHOULD RECEIVE FULL WEIGHT.

Regardless of the POSA/field definition, Dr. Tucker's testimony is entitled to full weight. Stratus does not dispute that Dr. Tucker is an "expert in the field of thermal ablation systems and methods." POR, 30-32 (criticizing his clinical

experience and analysis only). Nor should they. Dr. Tucker has designed over 50 devices for RF neurotomy—all of which were FDA approved and commercialized. Ex-2020, 195:13-198:5. He is immensely qualified. Ex-1034, ¶2-14; Ex-2020, 20:7-21:14).

Dr. Tucker reaffirmed his testimony even under Stratus's restrictive POSA definition. Ex-1042, ¶8-11. And because the issues presented fall within the province of an engineer (without needing clinical experience to understand), Dr. Tucker's testimony deserves full weight. *See Abiomed, Inc. v. White Swell Med. Ltd.*, IPR2021-01478, Paper 37, 29-35 (Apr. 4, 2023) (according weight to opinions falling within the province of the expert's skill).

V. THE PETITION'S ART IS ANALOGOUS.

1. Lee is analogous art.

Resolving the field correctly also compels dismissing Stratus's non-analogous art arguments with respect to Lee. POR, 34-36. The parties agree that Lee discloses an RF ablation needle. POR, 22; Ex-2006, ¶34. And Lee's needle shares a similar structure and function to the patent's needle: a cannula (16/1615), pointed tip (14/1614), deployable filaments (22/1622) emitting RF energy, and an actuator. *See* Pet., 17-21, 36-41; *cf.*, Ex-1003, 1:32-62, 5:33-6:22, 24:35-38; *In Re Deminski*, 796 F.2d 436, 422 (Fed. Cir. 1986) (affirming that references were within the field of endeavor of the invention where they "have essentially the same

function and structure"). Thus, Lee is within the patent's field of "thermal ablation systems and methods." Pet., 17.

Even if outside the field, Lee remains "reasonably pertinent" to the inventors' problem: expanding the needle's ablation volume. POR, 5; Pet., 2, 7; Ex-1003, 5:42-45, 6:11-22; Ex-2006, ¶91; Ex-2001, ¶121-122; *Netflix*, 80 F.4th at 1361-62. Crosby agreed that Lee's "purpose" was "to increase the volume of ablated tissue." Ex-2006, ¶117; Pet., 22-25, 40, 48; Ex-1010, ¶0012, 0084, 0123-0131 (controlling size, shape, and location of ablation volume); Ex-1034, ¶129, 138-139. Lee is unquestionably pertinent.

Stratus's argument that Lee lacks pertinence because it describes tumor ablation instead of neurotomy (POR, 35) conflates the field of endeavor and reasonable pertinence inquiries, "effectively exclud[ing] consideration of any references outside [the patent's] field."[2] *Donner Technology, LLC v. Pro Stage Gear, LLC*, 979 F.3d 1353, 1360 (Fed. Cir. 2020). Stratus ignores the POSA's ability to adapt technology from one RF ablation discipline to another—the wrong approach. *Id.*; *cf.* Ex-1054, 39 (incorporating technology from other fields). Lee is

[2] This is *precisely* what Crosby suggests. Ex-2006, ¶127 ("a POSITA would not have found Lee in a search for prior art on RF neurotomy"); Ex-1045, 204:1-8, 205:18-206:10.

both within the patent's field and directly pertinent to the inventors' problem. There is no basis for excluding it.

2. Young '965 and Scheibe are analogous art.

Stratus vaguely suggests that Young '965 "lacks relevance" but does not assert that it is non-analogous art. POR, 59-60. This argument is therefore waived. Scheduling Order, Paper 10, 10. Nevertheless, Young '965 is directed to an RF ablation needle with deployable filaments (Pet., 62-65) and is analogous for the same reasons discussed above for Lee.

With respect to Scheibe, Stratus again conflates the patent's field with the reasonable-pertinence inquiry, improperly excluding all non-neurotomy art. POR, 60-61; *Donner Tech.,* 979 F.3d at 1360. But Schiebe is pertinent. The patent discloses an actuator to deploy/retract filaments. Ex-1003, 5:53-55, 17:34-35. The actuator provides a fluid connection (e.g., "a Luer fitting") and allows a dominant hand to actuate the filaments (e.g., "rotational motion" of the actuator results in "linear motion" of an advancing hub). Ex-1003, 17:45-55.

Schiebe's actuator addresses these problems—including a "luer fitting" that "allows various fluids to be injected through the sheath" and a rotatable actuator causing linear movement of a hub to allow single-handed actuation. Ex-1013, ¶0024-0025, 0029-0036; *see also id.*, ¶0037 ("cardiac stimulation"); *cf.*, Ex-1003,

31:13-22 ("cardiac ablation"). Scheibe is thus reasonably pertinent and analogous art.

VI. THE PRIOR ART DISCLOSES ALL CLAIMED FEATURES.

There is no dispute that the combination of prior art outlined in the Petition discloses every feature recited in the challenged claims. Stratus argues that some references should be ignored (POR, 34-36), attacks the references individually (POR, 36-37), and suggests a POSA would not have successfully combined them (POR, 43-59). But Stratus cannot dispute that the prior art—as combined—discloses the claimed invention.

VII. MOTIVATION TO COMBINE

A. The Petition identifies an explicit motivation to combine.

It is undisputed that Racz's standard, single-tip RF neurotomy needle would have generated a limited ablation volume—a ***known problem*** identified by Fitz. Pet., 22-25; Ex-2006, ¶160 (Crosby agreeing standard, single-tip RF neurotomy needles lack adequate coverage); Ex-2001, 112, 121, 148-150; POR, 62-63. There is also no dispute that using deployable filaments was a ***known technique*** for increasing ablation volume, as disclosed in Fitz/Lee. Ex-2006, ¶158 (conceding Fitz teaches "general idea [of] deployable electrodes to increase ablation volume"), 117 ("The purpose of [Lee's] invention … is to increase the volume of ablated

tissue …."), 34 (conceding Fitz and Lee represent "a class of RF ablation needles having deployable/retractable filaments").

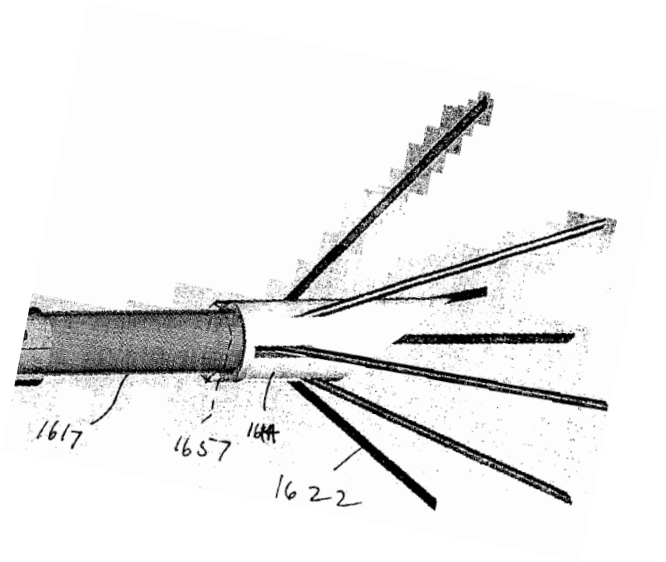
"[I]f there's a known technique to address a known problem using 'prior art elements according to the established functions,' then there is a motivation to combine." *Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1380 (Fed. Cir. 2023). This is precisely the case here; there should be little question regarding the Petition's combination. Pet., 5-6, 21-27; Ex-2020, 115:3-7.

Stratus argues that the Petition is "too vague" and demands a comprehensive accounting of Racz and Lee's merger (including multiple views, unclaimed dimensions, and manufacturing details). POR, 37-42. But obviousness does not require the art be "physically combinable," much less in the exacting detail Stratus suggests. *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (noting "[t]he test for obviousness" does not require "bodily incorporation" motivation to combine "to achieve the claimed invention"). Here, there is evidence of a known problem, known solution, and that combining the prior art was within the skill of a POSA—"nothing more is required to show a motivation to combine." *Intel*, 61 F.4th at 1381. 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. Pet., 23-27, 35-45; Ex-1034, ¶143-148, 157-179.

B. Neither Racz nor Lee teach away.

Stratus argues that Racz "teaches away from deploying a flexible electrode from a cannula in the context of neurotomy." POR, 52. This argument is baseless.

Racz indicated that 90's-era electrodes having flexible, curved tips (like the Radionics TEW kit) were effective "in certain neural regions such as the trigeminal ganglion or the pituitary gland." Ex-1009, 2:26-35. This is still RF neurotomy. Ex-1046, 62:2-63. Moreover, the curved-tip electrodes Racz mentions bear no resemblance to the deployable filaments in Fitz/Lee. *Cf.*, Ex-1010, Fig. 48; Ex-1058 (Radionics TEW). Neither Crosby nor Russo were familiar with these electrodes, removing any credibility from their teaching away testimony. Ex-1045, 138:21-140:8; Ex-1046, 128:15-129:9.



Lee's RF Needle

Radionics TEW Kit

Moreover, while Racz cautions that "*flexible curved* tips … cannot penetrate tough tissue," Ex-1009, 2:35-38, Lee teaches "*straight* electrodes … have superior

mechanical advantage over curved," allowing them to "push[] into and through … "touch fibroid tumor[s]." Ex-1010, ¶0087. So a POSA would not be dissuaded from using Lee's filaments to expand Racz's ablation volume.

Stratus also argues that Racz requires a curved/bent tip (POR, 53-56) and that Lee requires anchors (POR, 56-57), framing both as teaching away. This is again the wrong approach. "The inquiry is not whether a [POSA] would combine [Racz's] feature with a [Lee's] feature to meet requirements of [Racz] that are not requirements of the claims at issue," but whether a POSA would have combined them *in the way the claims do*. *Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957 (Fed. Cir. 2023). The claims do not require a straight (or bent) tip or anchors. Ex-1003, 31:32-34:23. Petitioner's arguments do not turn on them either. Ex-2020, 46:16-48:3, 68:17-69:13.

Regardless, Racz's bent tip is useful in "difficult-to-reach" areas of the spine—not in all neurotomy applications. Ex-1009, 2:3-25, 2:39-41. Straight-tip neurotomy needles were well-known and effective. Ex-1046, 44:16-45:13; Ex-1009, 1:43-2:2. At most, Racz suggests a preference for a bent tip in limited scenarios but never requires it. Ex-1045, 129:15-131:2, 133:17-134:10. Likewise, Lee is unequivocal that its anchors are optional. Ex-1010, ¶0090; 0104. This is not teaching away. *See Meiresonne v. Google, Inc.*, 849 F.3d 1379, 1382 (Fed. Cir.

2017) (expressing a "preference" without criticizing, discrediting, or discouraging investigation "into the claimed invention" is not teaching away).

C. A POSA would have preserved Racz's removable RF probe, including transmitting RF energy by physical contact.

Stratus argues that none of the references disclose "deployable filaments that are energized at the distal end by an insertable RF probe." POR, 36-37, 57-58. But Petitioner does not allege anticipation. Instead, the Petition explained how a POSA would use Racz's probe to energize the filaments when combining the references. Pet., 35-38. As Crosby agreed, Racz's removable RF probe (and central lumen receiving the probe/fluid)—is a "central feature." Ex-2006, ¶162. And Dr. Tucker explained why a POSA would have preserved that *central feature* and maintained Racz's method of transmitting RF energy—"physical contact" between the probe, tip, and filaments. Ex-1034, ¶161-164; Ex-2020, 101:9-19, 116:12-21, 154:18-155:8, 184:16-185:6. Stratus argues there is a "simpler way" to combine the references (POR, 58-59). But this path eliminates Racz's probe (the opposite of what a POSA would do) and, regardless, leads to "legal error." *Honeywell Int'l Inc. v. 3G Licensing, S.A.*, 124 F.4th 1345, 1355 (Fed. Cir. 2025) (explaining that requiring "best" or "preferred" approach to combine is erroneous).

VIII. REASONABLE EXPECTATION OF SUCCESS

A. Combining the art was within the level of skill.

Stratus argues that the proposed combination would be too challenging to manufacture, leaving a POSA with no expectation of success. POR, 43-51. The specification belies Stratus's position—nowhere does it teach how to manufacture the disclosed system or devices.

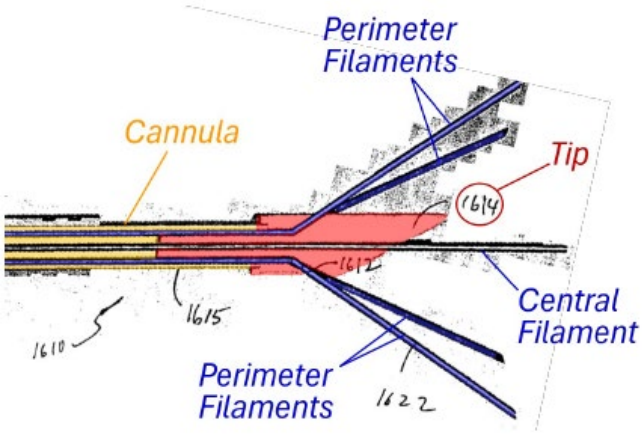
The patent describes an elongate cannula, RF probe, deployable filaments, actuator, and a filament-guiding tip (separately attached or formed as a "single unitary structure" with the cannula). Ex-1003, 5:33-6:22, 8:46-53. The patent is *silent* on how to make these components (and mostly silent regarding their assembly). This silence demonstrates that the "purported novelty" was not in *manufacturing* the claimed invention—that was within the level of ordinary skill. *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994); *Uber Techs., Inc. v. X One, Inc.*, 957 F.3d 1334, 1339 (Fed. Cir. 2020). Otherwise, the patent would be invalid for lack of enablement.

Crosby testified that a POSA would have been able to make the disclosed RF needles in the '688 patent (which shares the '664 patent's specification). Ex-1045, 272:9-279:15. Likewise, the prior art is silent on manufacturing techniques, further reflecting that making RF needles is within the level of ordinary skill. *See* Ex-1045, 280:6-12, 284:8-285:17, 295:7-22 (Crosby testimony regarding Racz/Lee).

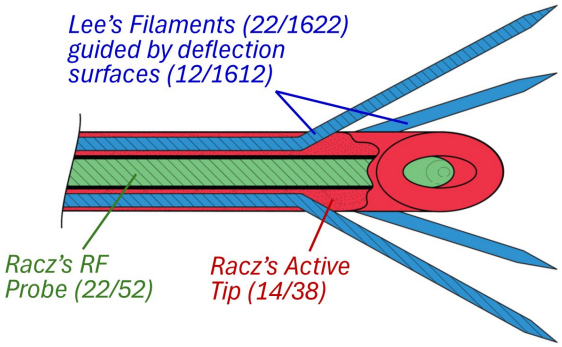
Ultimately, "absolute predictability" is not required. *In re O'Farrell*, 853 F. 2d 894, 903-904 (Fed. Cir. 1988). The mechanical nature of this technology is highly predictable, and nothing about the combination would have been unexpected, further reinforcing the POSA's reasonable expectation of success. *See Tokai Corp. v. Easton Enters. Inc.*, 632 F.3d 1358, 1371 (Fed. Cir. 2011).

B. Lee provides precise guidance.

Moreover, Lee provides a blueprint for how to implement deployable filaments. Pet., 31-38. As Dr. Tucker explained, Lee illustrates how the filaments can be arranged around the cannula's inner perimeter and deployed around the tip. Ex-1034, ¶125-131, 140-148. This is an ideal configuration to preserve the functionality of Racz's probe. Ex-1034, ¶140-143, 145-146, 161.



Ex-1034, ¶131 (Lee)

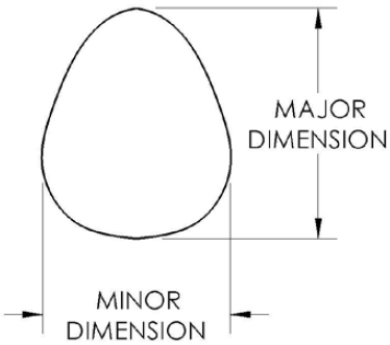


Ex-1034, ¶143 (Racz-Fitz-Lee combined)

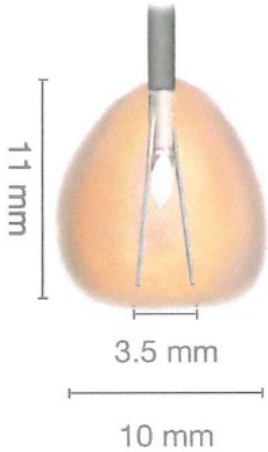
The effectiveness of Lee's deployable filaments was also predictable. Crosby argues that Lee's commercial embodiment (Ex-2010) reflects the ablation shape/size that a POSA would understand Lee's device would create. Ex-2006,

¶56, 230-232; Ex-1045, 161:15-162:19. A POSA would have known that Lee's device would produce an ablation volume having a nearly identical shape to the claimed invention, as illustrated below.

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



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



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

See Ex-1045, 161:15-162:19, 175:19-176:5; Ex-2006, ¶230-232; Ex-2010, 21-22; Ex-1051, 1.

Crosby also walked back his original testimony, admitting that Lee's ablation volume is not "orders of magnitude" too large for RF neurotomy. Ex-1045, 168:3-170:10, 177:16-20, 189:12-190:4; Ex-2006, ¶230-232 (relying on Ex-2010 for size of Lee's ablation volume); POR, 22. A POSA would know that Lee's ablation size (e.g., 19x17mm) would be close to Stratus's advertised ablation size (11x10mm) and *smaller* than ablation volumes that Stratus claims are effective for neurotomy. *See* Ex-1001, 25:27-30 (2,000mm^3 ablation volume); Ex-1046, 148:17-

25; Ex-1051, 1, 8 (28x10x13mm volume effective for neurotomy); Ex-2010, 21-22. Lee's precise guidance strongly supports the POSA's reasonable expectation of success.

C. Stratus's arguments depend on false assumptions.

Notably, ***all*** of Stratus's reasonable expectation of success arguments depend on its experts' unsupported—and false—testimony that neurotomy needles cannot be larger than 16-gauge. POR, 4, 43-44, 48, 50; Ex-2006, ¶158, 228-253, 267; Ex-2001, ¶47, 155-169, 210-215. The only reliable evidence shows the opposite.

The parties agree that Racz discloses an RF neurotomy needle. POR, 19. Racz expressly teaches that its needle comes in "many variations," including from *10- to 30-gauge*. Ex-1009, 8:10-15. There are other examples of RF neurotomy needles larger than 16-gauge too. *See* Ex-1015, ¶0040 (12-gauge); Ex-1056, 160 (12-gauge). By contrast, Stratus's only "evidence" of its assertion are its expert declarations, POR, 4, 43-44, 48, 50, and neither Crosby nor Russo point to *any evidence* that neurotomy needles must be 16-gauge or smaller. Ex-2006, ¶158, 228-253, 267; Ex-2001, ¶47, 155-169, 210-215. Even the challenged patent is not size-limited. Ex-1003, 8:10-15 (needle is "any appropriate size" and 16-gauge or smaller in one embodiment).

Stratus's remaining hodgepodge of arguments are equally flawed. Crosby offers *unsupported* assertions about the ineffectiveness of nitinol filaments (Ex-

2006, ¶276-282) and the inability to manufacture the Petition's combination (Ex-2006, ¶221-260). This testimony is entitled to no weight. 37 C.F.R. § 42.65(a). Moreover, Mr. Crosby's calculations on filament strength are completely wrong. Ex-2006, ¶276-279 (using bending moment formula); Ex-1045, 258:1-263:12 (Crosby thought he was calculating Euler moment); Ex-1062, 342-343 (bending moment formula Crosby used), 748 (different Euler formula). And an engineering textbook refutes Crosby's testimony that the proposed combination would be "impossible" to manufacture. Ex-2006, ¶234-253; Ex-1063, 541, 546 (EDM and LBM allow for 0.1mm and 0.005mm precision, respectively).

Moreover, Stratus's arguments are at odds with the Stratus patents. Crosby says 0.2mm nitinol filaments don't work, Ex-2006, ¶276-282, but the patents say they do. Ex-1003, 9:62-64; Ex-1001, 21:49-52, 22:37-49. Crosby says Dr. Tucker's proposed tip/channels could not be manufactured, but the patents suggest they can be (separately or as a "unitary structure" with the cannula). Ex-2006, ¶224-260; Ex-1003, 8:51-53; Ex-1001, 20:26-36.

For these reasons, the evidence shows that a POSA would have had a reasonable expectation of success in combining the prior art.

IX. STRATUS'S SECONDARY CONSIDERATIONS EVDIENCE IS UNCOMPELLING

Stratus's purported "evidence" of secondary considerations deserves no weight. Stratus relies on a made-up "need," half-baked "copying" evidence,

"praise" untethered to the product or patent, and specious evidence of "commercial success."

A. Stratus's long-felt need is fiction.

Stratus argues that the Nimbus was a "game changer" because it produced a "unique shape" that "enables perpendicular placement" of the needle. POR, 63. This is wrong.

Stratus's long-felt need arguments rest entirely on Russo's testimony (POR, 61-65), which collapsed during his cross-examination. Russo admitted that at the time of the alleged invention, Wright was trying to "match the lesion created by [an] internally cooled electrode"—a Baylis device that already existed *and enabled perpendicular placement*. Ex-2004, 3903; Ex-1046, 71:21-73:19, 75:1-24; Ex-1055, 2, 5-7, 24-25; Ex-1015, ¶0005-0006, 0045, 0071, 0094, 0103-0104, 0117-0123, 0133-0135. Russo admitted that cooled-tip RF neurotomy needles were known (Ex-1046, 88:20-89:5), produced a distally extending lesion like the Nimbus (Ex-1046, 77:23-78:21, 84:7-87:1), and enabled perpendicular placement (Ex-1046, 90:3-91:12, 92:25-95:10). Russo didn't read the prior art disclosing these facts (Godara) despite the Petition relying on it (Ex-1046, 95:17-96:1, 104:19-105:7; Pet., 72-75), and confirmed that the perpendicular approach was used even *before* cooled-tip technology (Ex-1046, 146:4-16). The Nimbus is not a "game changer," it was just another option to perform known techniques.

Moreover, Russo confirmed that obtaining the Nimbus lesion shape requires the filaments to be deployed within certain direction/length parameters. Ex-1046, 115:6-118:10, 123:12-124:7, 150:25-151:4. But the patent claims are not limited to any of these parameters and cover devices that wouldn't meet even the *alleged* long-felt need.

B. Copying

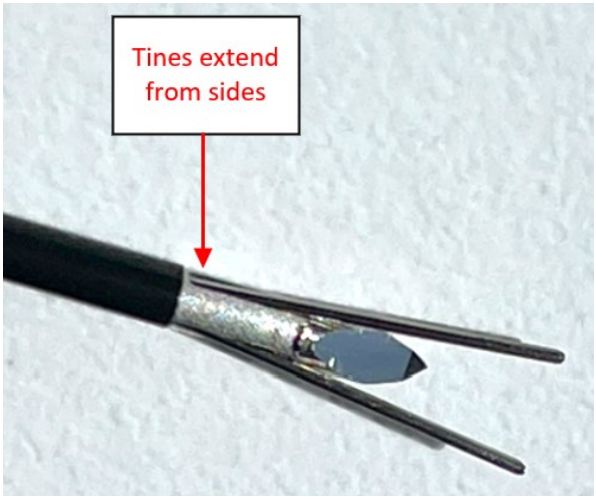
Copying requires "duplication" or "replication of a *specific product*" based on "access to that work." *Liqwd, Inc. v. L'Oreal USA, Inc.*, 941 F.3d 1133, 1137 (Fed. Cir. 2019) (quoting cases). But Stratus stated it "is not aware *of any instance* in which one of its devices has fallen *into a competitor's* hands." Paper 23, 9. If there is no access, there is no copying. Stratus nevertheless relies on Jorgensen's testimony comparing the Nimbus and Trident devices. POR, 66-67. But Jorgensen's testimony fell apart on cross-examination.

Stratus first argues that statements to the FDA about "equivalence" of the Trident to its predicate device (Nimbus) "prove copying." POR, 66. Jorgensen testified the opposite: asserting 510(k) equivalence to a predicate device "does *not mean* it's a copy." Ex-1047, 66:22-67:6; Ex-1047, 65:5-66:15.

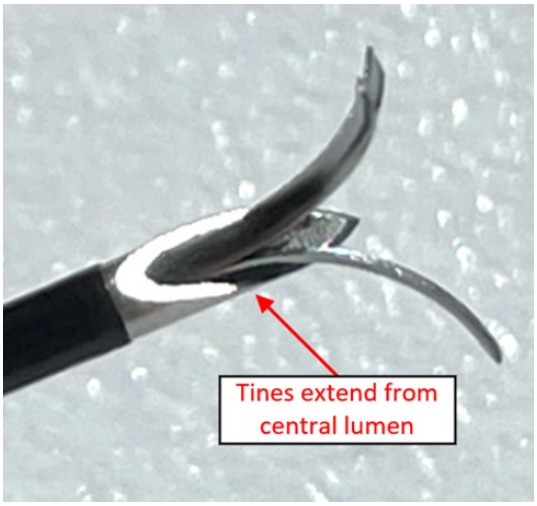
Jorgensen also admitted that he "only identif[ed] the similarities and not any differences" between the products and agreed there were *several* differences. Ex-1047, 67:7-68:2; *see generally* Ex-1047, 57:18-62:7. Jorgensen's declaration says

the "similarities are clear" (Ex-2015, ¶33-37), but on cross-examination Jorgensen admitted these similarities are conventional device features. Ex-1047, 46:16–49:16, 51:15-55:5.

Moreover, Jorgensen lacked an understanding of the devices in his deposition. He alleged that the tines in both devices "aren't coming out of the actual tip," Ex-1047, 59:11-61:6, which is false: The Trident's tines *are* deployed out of the tip's central lumen, while the Nimbus's tines deploy from channels behind the tip. Ex-1042, ¶22.



Nimbus



Trident

The differences between Nimbus and Trident are numerous. Dr. Tucker compared the devices and opines, as an engineer,[3] that the Trident's tines are a

[3] *Compare* Ex-1047, 14:12-16:7 (Jorgensen has "no engineering training or experience"), *with* Ex-1034, ¶2-14 (Tucker's experience).

different shape, different material, different arrangement, more numerous, and deploy differently than Nimbus. Ex-1042, ¶12-22. Moreover, the Trident's probe, surrounded by the tines, never contacts the needle's tip. Ex-1042, ¶23. This is not "copying."

Furthermore, Stratus's reference to its "complaint showing infringement" and similar product appearances are facially insufficient. *Liqwd*, 941 F.3d at 1137. Stratus's copying arguments and evidence deserve no weight.

C. Praise

At most, Stratus presents evidence that its *company* received praise, as a whole, but no evidence that "the industry praised *a claimed invention* or *a product* that embodies the patent." *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1053 (Fed. Cir. 2016); *Ancora Techs., Inc. v. Roku, Inc.*, 140 F.4th 1351, 1361 (Fed. Cir. 2025) (press release not directed to "the challenged claims" was insufficient). Stratus proffers (1) a "ranking" where three-year revenue growth was "the *only* basis," Ex-2025; Ex-1047, 41:13-42:7; and (2) Pepperdine identifying Stratus among a list of "most fundable companies," Ex-2026; Ex-2015, ¶55. There is no link between the Deloitte ranking and the Nimbus product, and Jorgensen concedes "several company variables" influenced the Pepperdine selection—only one of which is "intellectual property." Ex-2015, ¶54-55. This evidence is not probative of nonobviousness.

D. Commercial Success

Stratus's proffered "market data" and supposed success within that market (POR, 68-73) cannot be considered because it is inadmissible hearsay, as Avanos will later show in its motion to exclude. At minimum, it deserves no weight.[4] Even if considered, Stratus's commercial success evidence and argument fail for several reasons.

1. No Nexus

Stratus's only attempt to show nexus is that its "product embodies the invention and is *coextensive* with it.'" POR, 73 (citing case). Even *assuming* the Nimbus "embodies" the claims, Stratus presents *no evidence* of any sales of the complete, "claimed invention."

It is undisputed that all claims require an RF probe. *E.g.*, Ex-1003 (claim 1); Ex-1045, 95:22-96:9 (Crosby testifying claims satisfied only when needle and probe of same length are combined). But Jorgensen testified that the proffered revenue data includes sales of just probes, just Nimbus electrodes, and *another* Stratus product—*none of which embody the claims*. Ex-1047, 35:21-37:12, 38:22-39:14 (admitting Stratus sells 4 different electrodes and 6 probes of different

[4] Stratus's witness admitted that all his testimony about other participants in the market came from *unidentified third parties*. Ex-1047, 86:22-89:4, 75:21-77:5.

lengths), 82:6-17, 83:16-84:17. One cannot determine how many Nimbus "cannulas [Stratus] sold versus how many probes it sold," and before October 2021 Stratus did not sell any probes (a claimed feature). Ex-1047, 35:21-36:20, 82:6-17, 83:16-84:17. *Id.*

Stratus argues "[redacted] of its revenue is "from sales of its Nimbus devices and the RF probes" so "[redacted]." POR, 69 (citing Ex-2015, ¶14). But Jorgensen's cross-examination confirms it is *impossible* to tell which, if any, of those sales were of the electrode and probe *together*—the complete invention. Regardless, Stratus's electrode sales [redacted] probe sales (Ex-1060; Ex-1047, 95:10-96:5), further confirming that its sales data is not "coextensive" with the invention, and nexus cannot be presumed.

Stratus presented no other evidence or argument as to nexus; these are now waived. Scheduling Order, Paper 10, 10.

2. Artificial and incorrect market share

Next, the "market data" is artificially circumscribed and incorrect. Relying exclusively on Jorgensen, Stratus argues it has [redacted] and "[redacted]" other competitors. POR, 71; Ex-2015, ¶17-26. Stratus and Jorgensen crow about "successfully competing" with Avanos's Trident and COOLIEF* products, suggesting "Avanos's downward trajectory" in the market is due to "Stratus

converting COOLIEF[*] customers to Nimbus customers." Ex-1047, 70:12-72:15; Ex-2015, ¶49.

But cross-examination revealed a sleight-of-hand in Jorgensen's charts and market-share calculations: they limit the "market" to *just* "RFA cannula" sales themselves, *excluding* sales of Avanos's dominant COOLIEF* product. Ex-1047, 72:12-15, 90:15-93:2. That choice is striking: Stratus admits that Nimbus competes with COOLIEF*, both companies market to the same customers for neurotomy procedures, and Stratus even *advertises* Nimbus can create lesions "comparable to" cooled-RF. Ex-1047, 92:2-95:9; Ex-2015, ¶49. COOLIEF* may be a "premium" product, but Joregensen's exclusion of COOLIEF* from the market data—which reflects Nimbus sales to the *same customers*—is plainly disingenuous. Ex-1047, 91:18-95:9.

Stratus distorts the market to suggest it had "a [redacted] share of the US RFA cannula market than Avanos in 2024 and it is "[redacted] other market participants" in "growth rate." Ex-1047, 90:15-91:17, Ex-2015, ¶22-24. But hard data shows Avanos's COOLIEF* alone earned [redacted] the Nimbus in 2023 and 2024—almost half Jorgensen's overall "market." *Compare* Ex-1044, ¶5-8 (Avanos employee testifying to sales of [redacted]), *with* Ex-2015, ¶15 *and* Ex-1047, 82:2-5 [redacted]). This is not merely due to

pricing[5]—COOLIEF* outsold Nimbus [redacted], too (based on the Stratus's estimated revenue, average sale price, and simple math). *Id.* (same data in both documents); *see also* Ex-1047, 95:10-96:5 (Nimbus prices).

Stratus spins a tale of a "[redacted]" who has "[redacted]" the "[redacted], including Avanos. POR, 71. But that whale of a tale turns on an improper market definition that ignores Avanos's massive sales while touting Stratus's meager sales to the same customers. The market data, even if admissible, is not a success story.

3. Alleged "success" is not significant

Even *if* the facts in Jorgensen's declaration are true (including nexus), the Nimbus has not achieved significant commercial success.

Petitioner has provided an analysis of Stratus's commercial success information by Mark Konno, an expert in evaluating medical device companies, who *assumed* Jorgensen's facts were accurate. Ex-1043, ¶1-12. As Konno observes, Stratus's growth to [redacted] in revenue over five years (2020-2024) is "almost categorically insignificant." Ex-1043, ¶13-15. While Stratus's supposed

[5] Jorgensen analogized COOLIEF* to a "Ferrari" and Nimbus to a "Corvette." Ex-1047, 94:18-95:9.

growth is painted as hefty, that's because they started at nothing; Stratus's growth rate has [redacted] for three years. Ex-1043, ¶16-19; Ex-2015, ¶15-16.

Konno explains that Jorgensen's testimony portrays the alleged market leaders [redacted]. Ex-1043, ¶20-24. Rather than "remarkable" success (Ex-2015, ¶13), Stratus is [redacted] among the other "[redacted]." Ex-1043, ¶25; *cf.,* POR, 71; Ex-1047, 97:3-13. Konno also highlights the unreliability of Jorgensen's "CAGR" data (Ex-1043, ¶26-27) and the absence of evidence that Stratus sells its device at a price premium (Ex-1043, ¶29). There is also no evidence of customer substitution—curiously, the Jorgensen data shows neither Avanos nor Diros achieving significant success despite allegations of "copying." Ex-1043, ¶30-35.

Finally, it's undisputed that the Nimbus was FDA-cleared in 2012, but there were basically no sales for *eight years* until Stratus started marketing/selling the unchanged device. Ex-1047, 29:9-32:22. Whatever success the Jorgensen data might show, it is attributable to marketing—not product superiority. *See* Ex-1047, 77:6-80:13.

In sum, Stratus has no real evidence of commercial success, or any other secondary considerations.

X. CONCLUSION

For these reasons, Petitioner reaffirms its request for cancellation of Claims 1-29.

Respectfully submitted,

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

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

Pursuant to 37 C.F.R. § 42.24(d), Petitioner certifies that the foregoing Petitioner's Reply contains 5,586 words, excluding the portions as permitted by § 42.24(a).

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

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and agreement of the parties, I certify that:

- On August 5, 2025, copies of the documents now marked as Exhibits 1050 and 1051 were served on counsel for the Patent Owner via hand delivery during the cross-examination of Mr. Croby;
- On August 22, 2025, a copy of the document now marked as Exhibit 1055 was served on counsel for the Patent Owner via hand delivery during the cross-examination of Prof. Russo;
- On August 26, 2025, the document now marked as Exhibit 1049 was served on counsel for Patent Owner via electronic delivery during the cross-examination of Mr. Jorgensen; and
- On September 5, 2025, copies of this Petitioner's Reply and Exhibits 1042-1048, 1052-1054, 1056, 1058, and 1060-1064 were served on counsel for the Patent Owner by email to:

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