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

_____

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

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PATENT OWNER'S REPLY TO PETITIONER'S OPPOSITION TO PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE

TABLE OF CONTENTS

I. RACZ'S MODIFIED DEVICE, AS PRESENTED IN THE PETITION WITH FILAMENT CHANNELS IN THE NEEDLE SIDEWALL ***IS*** THE PETITION'S INVALIDITY POSITION. 1

II. EXHIBIT 1063 CAN BE EXCLUDED UNDER FRE 106 IN THESE CIRCUMSTANCES. 3

III. EXHIBIT 1063 IS MISLEADINGLY INCOMPLETE AND SHOULD BE EXCLUDED. 4

TABLE OF AUTHORITIES

Cases

Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd., 821 F.3d 1359 (Fed. Cir. 2016) 3

SAS Inst. Inc. v. Iancu, 138 S. Ct. 1348 (2018) 3

Statutes

35 U.S.C. § 312 3

Regulations

37 C.F.R. § 42.1(b) 3

37 C.F.R. § 42.104 3

37 C.F.R. § 42.23(b) 3, 4

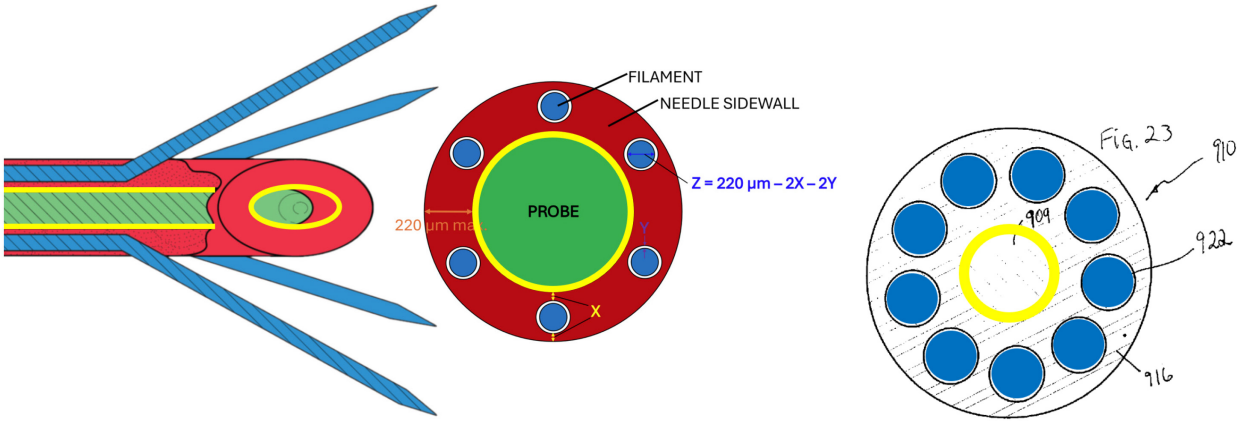
Other Authorities

Fed. R. Evid. 106 ..... 1, 3, 4, 5

Stratus hereby responds to the petitioner's opposition (Paper 53, herein "opposition" or "Opp'n") to Stratus' motion (Paper 49, herein "motion" or "Mot.") to exclude Exhibit 1063 under FRE 106.

I. Racz's Modified Device, as Presented in the Petition With Filament Channels in the Needle Sidewall *Is* the Petition's Invalidity Position.

The opposition tries to distance itself from Racz's modified device (RMD), *see* Opp'n at 2-5, but RMD ***is*** the petition's proposed combination of the prior art alleged to render the claims obvious. Read pages 24-27 of the petition. There and elsewhere, the petition explains its proposed combination of Racz and Lee, clearly saying that the filaments in RMD are "arranged ***around the inner perimeter of a cannula***" – that is, Racz's cannula. *See* Pet. at 38; *see also id.* at 41 ("[A] POSA would have arranged the perimeter filaments, channels, and ramps ***around the internal perimeter of Racz's cannula***."). This "inner perimeter" or "internal perimeter of Racz's cannula" is shown in yellow below on the left and in the middle:

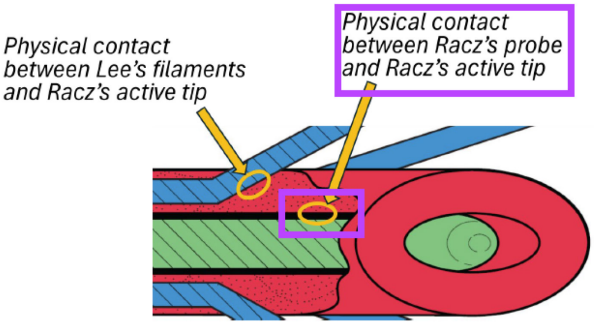


See Pet. at 27, 43 (cleaned-up; yellow added); Surreply at 16 (yellow added). Also shown above on the right is Lee's Figure 23 (color added), which the petition cites

as supporting the arrangement of Lee's filaments around the "inner perimeter" of Racz's cannula. *See* Pet. at 25.

This is necessary in the petition's proposed combination of Racz and Lee because the combination must retain Racz's removable probe, a feature required in Stratus's claims but absent from Lee. *See* Pet. at 25 ("Lee's ... filaments ... would be easily arranged to accommodate Racz's centrally located removable probe"), 42 ("To preserve the functionality of Racz's removable electrical probe ...").

The challenged claims also require physical and electrical contact between the removable probe and the needle, as the petition emphasizes, as shown to the right. *See* Pet. at 44 (purple added).



Dr. Tucker Declaration at ¶170

The filaments in RMD not only must be outside the inner perimeter of Racz's cannula but must also engage with deflection surfaces to force the filaments outward as they move distally. The only way the petitioner and Dr. Tucker could imagine to do this was to use part of the needle sidewall itself as the deflection surfaces as illustrated above. Ergo, the filaments must be in channels fully enclosed within the sidewall of Racz's needle. That is an essential feature of the proposed combination, which the petition and Dr. Tucker call RMD as a shorthand. *See* Pet. at vi.

Dr. Tucker's vague references to other ways to construct RMD during his

deposition, *see* Opp'n at 4-5, are not part of the petition. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) (quoted in Response at 36-37); *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018) (petition "defines the contours of the proceeding"). Nor were they even argued in the reply; thus they are waived. Nor have they been presented with the required "particularity," "precis[ion]," or "specific[ity]." 35 U.S.C. § 312; 37 C.F.R. § 42.104.

II. Exhibit 1063 Can be Excluded Under FRE 106 in These Circumstances.

Stratus agrees with the petitioner that FRE 106 is primarily a rule of inclusion. Stratus has therefore requested that Exs. 2024-25 be included, notwithstanding Rule 42.23(b). *See* Paper 50. Including Exs. 2024-25 in the record and considering them rather than the incomplete version of Kalpakjian that is Ex. 1063 would moot Stratus's motion to exclude Ex. 1063.

However, if the Board does not consider Exs. 2024-25 for any reason, then the Board should grant Stratus's motion and exclude Ex. 1063. FRE 106 is not purely a rule of inclusion. Inherent in FRE 106 is a power to exclude incomplete evidence when warranted, as courts have sometimes done. Inherent in the Federal Rules of Evidence, of which FRE is a part, is a power to exclude evidence. Inherent in the Board's powers to administer its own rules, which incorporate the Federal Rules of Evidence, is the power to conduct this proceeding "to secure [a] just, speedy, and inexpensive resolution." 37 C.F.R. § 42.1(b).

The opposition distinguishes this case from other cases in which courts have excluded evidence under FRE 106. *See* Opp'n at 10-12. However, FRE 106's power to exclude is not strictly limited to the facts of those two cases. Exclusion is equally justified here, as Ex. 1063 by itself leaves an incomplete evidentiary record on an important issue, and it appears that the petitioner submitted Ex. 1063 sans expert interpretation so that it could insulate its expert from having to answer questions about Kalpakjian and so that the petitioner could use Rule 42.23(b) as a shield to prevent consideration of contradictory content in Kalpakjian just a few pages after the petitioner's cited pages. These circumstances warrant exclusion of Ex. 1063.

The Board cases cited in the opposition cannot be read as prohibiting exclusion of evidence under FRE 106 in all circumstances. *See* Opp'n at 9. In no other case has the Board been confronted with a situation such as the one here. Considering Ex. 1063 while not considering Exs. 2044-45 would be a manifest injustice and a bad precedent, encouraging every petitioner in subsequent cases to follow the same playbook: Submit incomplete reply evidence without expert testimony and then use Rule 42.23(b) as a shield to block more complete evidence.

III. Exhibit 1063 is Misleadingly Incomplete and Should be Excluded.

The opposition portrays Ex. 1063 as "admissible documentary evidence of the level of skill in the art that further demonstrates the unreliability of Mr. Crosby's testimony." Opp'n at 8. The issue is whether it is complete, not whether it informs

the level of skill in the art. Ex. 1063 is an ***incomplete*** picture of the understanding of the level of skill in the art, and the omitted portions of Ex. 1063 corroborate Mr. Crosby's testimony. *Compare* Ex. 2044 at 549 *with* Crosby Decl. ¶¶ 225, 238, 241.

The opposition defends its incomplete portions of Kalpakjian by relying on Kalpakjian's statement that "hole depth-to-diameter ratios of 50 to 1" are possible with LBM. Opp'n at 14 (citing Ex. 1063 at 456). Generously assuming the holes are 0.2 mm in diameter, that equates to a depth of less than 0.4 inches (0.2 mm x 50 = 10 mm = 1.0 cm = 0.39 inches) – far too short for any ablation needle.

Finally, the opposition suggests that Stratus should have submitted Exs. 2044-45 sooner or by another means. *See* Opp'n at 2, 10 n. 5. But, Stratus timely objected to Ex. 1063 as incomplete under FRE 106, *see* Paper 34 at 5, and the petitioner did not supplement by its September 26 deadline, the same deadline for Stratus's surreply. Stratus therefore provided Exs. 2024-25 as more complete versions of Ex. 1063 on September 26, acting in the role the petitioner chose not to fill. Moreover, Stratus filed those exhibits at its earliest possible opportunity; the Kalpakjian textbooks were not immediately available to Stratus, as the petitioner presumes. *See* Opp'n at 2. Accordingly, Stratus respectfully requests that the Board exclude Ex. 1063, unless the Board keeps in the record and considers Exhibits 2044 and 2045.

Date: 2025 Oct. 31

/ M.C. Phillips /
Matthew C. Phillips, Reg. No. 43,403

CERTIFICATE OF SERVICE

I hereby certify that on **October 31, 2025**, copies of the foregoing PATENT OWNER'S REPLY TO PETITIONER'S OPPOSITION TO PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE 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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