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.

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

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PATENT OWNER'S BRIEF IN SUPPORT OF ITS FILING OF EXHIBITS 2044 AND 2045

TABLE OF AUTHORITIES

Cases

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All challenges are based on "Racz's modified device" (RMD), a modification of Racz's neurotomy needle to add Lee's filaments in multiple channels fully enclosed within the sidewall of Racz's needle. Those tiny filaments must smoothly glide within their long, extremely narrow channels to deploy and retract from the needle tip into human tissue. Stratus argued that RMD would have been impossible to build. *See* Response (Papers 13-14) at 43-51. All challenges therefore lack a reasonable expectation of success, and the references are not enabling. *See id*. (citing Crosby Decl. ¶¶ 221-271 (considering all reasonable ways in which a POSITA would have tried to make the filament channels in RMD)).

In response, the petitioner asserted via attorney argument, sans expert support, that electrical-discharge machining (EDM) and laser-beam machining (LBM) could have been employed to make RMD's sidewall channels. The petitioner's sole support for that is Ex. 1063, which is eight substantive pages of a 900-plus-page book (Kalpakjian). *See* Reply (Papers 30-31) at 20 (citing Ex. 1063).

But the petitioner did not include in Ex. 1063 other parts of Kalpakjian that contradict the petitioner's positions regarding EDM and LBM. In the same section, just a few pages later (but not cited in the Reply or provided in Ex. 1063), Kalpakjian explains that (1) "deep slots and narrow openings should be avoided" and "the surface finish specified should not be too fine" with EDM and (2) LBM "designs should avoid deep cuts" and cautions about "adverse effects ... on surface finish and

integrity." Ex. 2044 at 549. A subsequent, 2009 edition of Kalpakjian warns that "deep cuts will produce tapered walls" with LBM, rather than the uniform channels in RMD, and notes adverse effects due to "the high local temperatures and heat-affected zone." Ex. 2045 at 572. Kalpakjian echoes Mr. Crosby's concerns. *See* Crosby Decl. (Ex. 2007) ¶¶ 225, 238, 241.

Because the petitioner did not submit expert testimony regarding Ex. 1063, Stratus had no opportunity, under the rules, to bring these inconsistencies to the Board's attention via cross-examination of a reply declarant. So, Stratus provided with its surreply (Papers 40-41) Ex. 2044, a more complete copy of Kalpakjian (adding just seven more pages to complete the section partially included in Ex. 1063), as well as Ex. 2045, a subsequent edition of Kalpakjian with similar content.

Exs. 2044 and 2045 should remain in the record for many reasons. First, Ex. 2044 is just a more complete version of Ex. 1063 and thus not "new evidence" subject to 37 C.F.R. § 42.23(b). Ex. 2045 is analogous to Ex. 2044 in this respect. Second, Federal Rule of Evidence (FRE) 106 expressly authorizes a party to introduce "any other part" or "any other statement" that "in fairness ought to be considered" to complete partial, incomplete evidence. FRE 106 applies to this case via 37 C.F.R. § 42.62 and does not restrict the time for introducing the evidence. Third, due process requires that Stratus be afforded a fair opportunity to present rebuttal evidence. *See* 5 U.S.C. § 556(d) ("A party is entitled ... to submit rebuttal

evidence ... as may be required for a full and true disclosure of the facts"); *see also Dell Inc. v. Acceleron, LLC*, 818 F.3d 1293, 1301 (Fed. Cir. 2016) (applying 5 U.S.C. § 556(d) in IPR). Stratus did so at the first available opportunity and to the minimum extent necessary. Rule 42.23(b) cannot be applied in violation of FRE 106, 5 U.S.C. § 556(d), or constitutional due process. Indeed, the Board has broad discretion to apply its rules (or not) "to secure the ***just*** ... resolution of every proceeding" because no set of inflexible rules could possibly cover every situation. 37 C.F.R. § 42.1(b). Fourth, the Board should consider everything Kalpakjian has to say about EDM and LBM relevant to the sidewall channels in RMD. The truth and completeness trump Rule 42.23(b). Fifth, striking Exs. 2044-45 may reward gamesmanship, a possible scheme by the petitioner to hide the omitted, inconsistent portions of Kalpakjian behind Rule 42.23(b). The petitioner's failure to provide inconsistent portions of Kalpakjian may have violated 37 C.F.R. § 42.51(b)(1)(iii). The petitioner's choice not to submit expert testimony regarding Ex. 1063 may have been a strategic choice to deny Stratus an opportunity to cross-examine a witness about the omitted, inconsistent portions of Kalpakjian. And the petitioner did not supplement Ex. 1063 in response to Stratus's objection under FRE 106.

Stratus therefore requests that the Board keep Exs. 2044-45 in the record. If Exs. 2044-45 are struck, the Board should grant Stratus's concurrently filed motion to exclude Ex. 1063. Under no circumstances should the Board rely on Ex. 1063.

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CERTIFICATE OF SERVICE

I hereby certify that on **October 17, 2025**, copies of the foregoing PATENT OWNER'S BRIEF IN SUPPORT OF ITS FILING OF EXHIBITS 2044 AND 2045 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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