UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVANOS MEDICAL, INC.,
Petitioner,

v.

STRATUS MEDICAL, LLC,
Patent Owner

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

PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE

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I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(c), Stratus conditionally requests that, if its Exhibits 2044 and 2045 are struck from the record or otherwise not considered by the Board, then Exhibit 1063 must be excluded under Federal Rule of Evidence ("FRE") 106 for violating the doctrine of completeness.

Exhibit 1063 is a few cherry-picked pages of the "Kalpakjian" textbook filed as Exhibit 1063 for the first time with the petitioner's Reply (Papers 32-33) as evidence of a reasonable expectation of success for making Racz's modified device (RMD). *See* Reply at 20. Missing from Exhibit 1063 were portions that directly contradict the cherry-picked portions included in Exhibit 1063, as Stratus pointed out in its Surreply (Papers 42-43). Specifically, Stratus cited to a more complete copy of Kalpakjian (Ex. 2044) and an updated version of Kalpakjian (Ex. 2045). *See* Surreply at 14. The petitioner is attempting to strike Exhibits 2044 and 2045 as new surreply evidence in violation of 37 C.F.R. § 42.23(b). *See* Ex. 3003.

Meanwhile, Stratus objected to Exhibit 1063 under FRE 106 as incomplete, *see* Paper 36 at 5, and the petitioner did not serve supplemental evidence to augment Exhibit 1063. As a result, the Board is now faced with a choice of three options:

(1) Keep only a misleadingly incomplete version of Kalpakjian (*i.e.*, Ex. 1063) in the record while striking the more complete and updated versions (*i.e.*, Exs. 2044 and 2045);

(2) Allow the more complete and updated versions of Kalpakjian (*i.e.*, Exs. 2044 and 2045) to remain in the record along with Exhibit 1063; or

(3) Grant this motion to exclude Exhibit 1063, in which case consideration of the more complete and updated versions (*i.e.*, Exs. 2044 and 2045) becomes unnecessary.

Option (1) is the petitioner's preference. Either option (2) or (3) would be acceptable to Stratus, as both options would be fair and would result in the Board having an undistorted evidentiary record on the issue of reasonable expectation of success (and the related enablement issue). This motion justifies option (3).

II. BACKGROUND

RMD is the centerpiece of all challenges in this case. All challenges are based on RMD. RMD is 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, particularly its long narrow channels in the sidewall of needle. *See* Response (Papers 15-16) at 43-51. All challenges therefore lack a reasonable expectation of success, and the references would not have enabled a person of ordinary skill in the art (POSITA) to have made RMD without undue experimentation (or at all). *See id*. Stratus's

position is supported by detailed testimony from Peter Crosby, an expert medical-device engineer, who considered all reasonable ways in which a POSITA would have tried to make the filament channels in RMD. *See* Crosby Decl. ¶¶ 221-271. In short, Mr. Crosby established that it would have been impossible to build RMD. That fatal flaw in the petition's case is dispositive of all challenges.

The petitioner did not directly dispute what Mr. Crosby said about the impossibility of making RMD. Instead, the Reply attempted to salvage RMD and to demonstrate that a POSITA would have had a reasonable expectation of success to build RMD, by citing to Exhibit 1063. *See* Reply at 20 (citing Ex. 1063 at 541, 546). Exhibit 1063 is an excerpt from a 900-plus-page textbook entitled "Manufacturing Process for Engineering Materials" by Serope Kalpakjian and Steve R. Schmid, 4th edition, published in 2003 ("Kalpakjian"). Exhibit 1063 consists of pages 540-547 as well as the cover pages, copyright page, and table of contents of Kalpakjian. Pages 540-544 include section 9.13 directed at "Electrical-Discharge Machining," and pages 544-547 include section 9.14 directed at "High-Energy-Beam Machining."

Specifically, the Reply's entire response on this point is the following single sentence of attorney argument, devoid of any expert support: "[A]n engineering textbook refutes Crosby's testimony that the proposed combination would be 'impossible' to manufacture. Ex-2006 [Crosby Decl.] ¶234-253; Ex-1063, 541, 546

(EDM and LBM allow for 0.1mm and 0.005mm precision, respectively)." Reply (Papers 32-33) at 20. This sentence suggests that the filament's channels in the sidewall of Racz's needle in RMD would be within the dimensions possible with EDM and LBM.

EDM is electrical-discharge machining. Despite the petitioner's apparent assertion that it would have been possible to make the filament channels in RMD via EDM because EDM allows for 0.1 mm precision, *see id.*, Kalpakjian does not support that assertion. On page 549 in section 9.16 entitled "Design Considerations" (not cited in the Reply or provided in Ex. 1063), Kalpakjian explains that "[d]eep slots and narrow openings should be avoided" and "the surface finish specified should not be too fine" with EDM:

9.16 | Design Considerations

The important design considerations for the processes and operations described in this chapter are outlined as follows:

. . .

In electrical-discharge machining, the bulk of the workpiece should preferably be preshaped by other processes to reduce machining time; deep slots and narrow openings should be avoided; and, for economic production, the surface finish specified should not be too fine.

3. **High-energy-beam processes.** Any adverse effects of the processes on surface finish and integrity should be considered. In laser-beam machining, dull and unpolished workpiece surfaces are preferable, and designs should avoid deep cuts or very sharp profiles. In electron-beam machining, part size and shape are limited by the size of the vacuum chamber, and if a part requires machining on only a small portion, consideration should be given to making the part in a number of small components.

Ex. 2044 at 549. 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:Mr. Crosby noted the same concerns (although he did not specifically address EDM). *See* Crosby Decl. ¶¶ 225, 241.

LBM is laser-beam machining, which is synonymous with high-energy beam machining and laser drilling. According to the petitioner, it would have been possible to make the filament channels in RMD via LBM because LMM allows for 0.005 mm precision. *See* Reply at 20. But Kalpakjian does not support that assertion. On the same not-cited, not-provided page 549 in "Design Considerations" section 9.16, Kalpakjian says that LBM "designs should avoid deep cuts" and cautions that "[a]ny adverse effects . . . on surface finish and integrity should be considered." Ex. 2044 at 549 (block quoted above). Mr. Crosby expressed the same concerns about laser drilling. *See* Crosby Decl. ¶¶ 238, 241.

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":

9.16.6 Laser- and electron-beam machining

1. Designs with sharp corners should be avoided since they can be difficult to produce.
2. Deep cuts will produce tapered walls.
3. The reflectivity of the workpiece surface is an important consideration in laser-beam machining; dull and unpolished surfaces are preferable.
4. Any adverse effects on the properties of the machined parts caused by high local temperatures and heat-affected zone should be investigated.

Ex. 2045 at 572.

Significantly, despite the highly technical nature of these issues, no expert testified for the petitioner regarding EDM or LBM or Exhibit 1063. Had the petitioner proffered such expert testimony, Stratus would have been entitled to cross-examine that witness about Exhibit 1063 and Kalpakjian's other teachings regarding EDM and LBM. Stratus could have, for example, questioned the reply witness about section 9.16 of Kalpakjian and the teachings therein against EDM and LBM to form the filament channels in the sidewall of the needle of RMD. Because the petitioner did not offer that expert testimony, Stratus was not afforded that opportunity.

Stratus filed Exhibits 2044 and 2045 with its Surreply and included in its Surreply arguments pointing out the portions of Exhibits 2044 and 2045 contrary to the passages in Exhibit 1063 cited by the petitioner. Exhibit 2044 is a more complete version of Kalpakjian. To be clear, Exhibit 2044 is based on the exact same document as Exhibit 1063 (the 4th edition of Kalpakjian published in 2003). Specifically, Exhibit 2044 includes everything in Exhibit 1063 plus pages 548-554,

which includes the rest of chapter 9, including section 9.16 entitled "Design Considerations." Exhibit 2045 is the next (5th) edition of Kalpakjian, published in 2009. *See* Ex. 2045 at copyright page. Specifically, Exhibit 2045 includes the cover pages, copyright page, table of contents, and pages 561-577, which includes, *inter alia*, section 9.13 entitled "Electrical-Discharge Machining," section 9.14 entitled "High-Energy-Beam Machining," and section 9.16 entitled "Design Considerations."

The petitioner complained about Stratus's filing of Exhibits 2044 and 2045 and Stratus's Surreply arguments citing to those exhibits. *See* Ex. 3003 at 2-3. In response, the Board invited Stratus to file a brief, not exceeding three pages, to justify its filing of those exhibits. Stratus is filing that brief contemporaneously with this motion.

III. IDENTIFICATION OF OBJECTION

On September 12, 2025, pursuant to 37 C.F.R. § 42.64(b)(1), Stratus timely filed and served objections to the petitioner's reply evidence, including the following objection to Exhibit 1063:

> **12**. Stratus objects to Exhibit 1063 under Rule 106 of the Federal Rules of Evidence because it appears to be an incomplete excerpt of a longer document.

Paper 36 at 5. The petitioner did not provide any supplemental evidence in response.

IV. EXHIBIT 1063 SHOULD BE EXCLUDED UNDER FRE 106.

A. Federal Rule of Evidence 106

FRE 106 is entitled "Remainder of or Related Writings or Recorded Statements" and reads as follows: "If a party introduces all or part of a statement, an adverse party may require the introduction, at that time, of any other part — or any other statement — that in fairness ought to be considered at the same time. The adverse party may do so over a hearsay objection." FRE 106.

"The rule is an expression of the rule of completeness" and is "grounded in fairness." *Id.* at Adv. Committee Notes. That is, the rule recognizes that an incomplete document or statement may be unfair to an adverse party.

The rule contemplates completion via either (1) "any other part" of the same statement or (2) "any other statement." FRE 106. That is, the completion may come from other parts of the same document or another related document "that in fairness ought to be considered." *Id.* That is also reflected in the rule's title, which refers to a "[r]emainder of" the statement or a "related" statement. *Id.* Title. The "statement" in the rule may be in "[w]riting" or "[r]ecorded," that is, written or oral. *Id.*

The rule does not restrict who may submit the other part of the same statement or the other statement. Either the proponent of the incomplete evidence or the adverse party may submit the other part of the statement or the other statement.

Although the rule does not explicitly mention exclusion of incomplete statements, courts have interpreted the rule as having that power when warranted. *See United States v. Woods*, No. CR422-016-1, 2023 WL 3098834, slip op. at 2 (S.D. Ga. Apr. 26, 2023) ("[T]he incomplete version of [the evidence] is EXCLUDED, pursuant to Federal Rule of Evidence 106, but Woods remains free to offer a complete version of that document"). Indeed, without the power of exclusion, the rule may be ineffectual in circumstances in which access to the evidence is not balanced. *See United States v. Sherman*, 293 Fed. App'x 158, 159 (3d Cir. 2008). *But see Argentum Pharms. LLC v. Research Corp. Techs., Inc.*, IPR2016-00204, Paper 85 at 48-49 (Mar. 22, 2017) (nonprecedential) ("[R]ather than providing a basis for excluding evidence, FRE 106 is a vehicle for entry of additional evidence, allowing an adverse party to a proffered writing or statement (in this case Petitioner) the opportunity to require entry of any other part of the proffered writing/statement, or any other writing or recorded statement, which should be considered contemporaneously with the proffered writing/statement, based on fairness").

B. Exclusion of Exhibit 1063 is Warranted in This Case if Exhibits 2044 and 2045 are Struck.

The omitted and related parts of Kalpakjian are necessary to provide context and to prevent misleading impressions to ensure that a full, fair picture is presented of what a POSITA would have concluded regarding the teachings of Kalpakjian

regarding the feasibility of making RMD via EDM and LBM. The omitted teachings include, for example, that "deep slots and narrow openings should be avoided" and the "designs should avoid deep cuts" – the very features needed in RMD.

It would thus be unfair to consider just the petitioner's cherry-picked portions of Kalpakjian that omit content conflicting with the petitioner's selections. The petitioner should not be permitted to rely on incomplete perspectives concerning an issue critical to the patentability of the claims at issue. On this basis, the Board should, pursuant to FRE 106, either exclude Exhibit 1063 or consider Exhibits 2044 and 2045 as more complete evidence.

Stratus's objection to Kalpakjian provided the petitioner with notice that Kalpakjian is incomplete under FRE 106. The petitioner had a window under 37 C.F.R. § 42.64(b)(2) to serve supplemental evidence. The opportunity to serve supplemental evidence dovetails with the opportunity afforded under FRE 106 for a proponent of the evidence to place the remainder in evidence that in fairness should be considered at the same time. The petitioner opted not to use that opportunity so that all relevant portions of Kalpakjian could be considered.

Because Ex. 1063 is incomplete and the petitioner did not provide supplemental evidence, Stratus filed Exhibits 2044 and 2045 at the first available opportunity to do so, on September 26, 2025 with its Surreply.

Exhibit 2044 is a more complete version of Kalpakjian. The additional portions of Exhibit 2044, relative to Exhibit 1063, are pages 548-554, which teach "Design Considerations," which teach against the use of EDM and LBM to make long thin channels like those required by RMD. In the parlance of the rule, those additional pages (*i.e.*, pages 548-554) in Exhibit 2044 are a relevant "[r]emainder of" or "other part" of Exhibit 1063. FRE 106. Those additional pages "in fairness ought to be considered at the same time" as the portions of Kalpakjian submitted by the petitioner in Exhibit 1063 because those teachings relate directly to whether a POSITA would have had a reasonable expectation of success to make RMD using either EDM or LBM. *Id.*

Exhibit 2045 is a subsequent, 2009 edition of Kalpakjian. In the parlance of the rule, Exhibit 2045 is a relevant "[r]elated [w]riting" or "any other statement." *Id.* Exhibit 2045 largely echoes the design considerations in prior the edition of Kalpakjian and adds other design considerations against using LBM to make long thin channels like those required by RMD. *See* Ex. 2045 at 572. Exhibit 2045 "in fairness ought to be considered at the same time" as the Exhibit 1063 because Exhibit 2045, as a subsequent writing by the same authors on the same topics, relates directly to whether a POSITA would have had a reasonable expectation of success to make RMD using either EDM or LBM. *Id.*

Stratus appreciates the opportunity to file a brief in support of keeping Exhibits 2044 and 2045 in the record. *See* Ex. 3003. But, if Exhibits 2044 and 2045 are struck from the record, the Board should exclude Exhibit 1063. Unless the Board excludes Exhibit 1063 or permits Exhibits 2044 and 2045 to remain in the record, the record will be incomplete and misleading on an important point, and Stratus will be unable to rectify the misleading record.

In a non-precedential decision involving FRE 106, the Board denied a petitioner's motion to exclude incomplete exhibits submitted with the patent owner's response. *Mylan Pharm. Inc. v. Yeda Research & Dev. Co.*, IPR2015-00644, Paper 91 (Dec. 2, 2016). In that case, the petitioner asserted that reliance on the incomplete excerpts was unfair and prejudicial. *Id.* at 39-40. Critically, the patent owner made the complete document available to the petitioner, who could have included the complete version with its reply but did not do so. *Id.* The situation is quite different in the present case, as (1) the petitioner here did not provide a complete copy of Kalpakjian to Stratus and (2) the petitioner here is actively trying to prevent Stratus from submitting completing evidence. *See* Ex. 3003 at 2-3.

Rule 106 "allows the party against whom the document is introduced to place the remainder in evidence[.]" 1 Weinstein on Evidence 106.02[1]. However, 37 C.F.R. § 42.23(b) proscribes a surreply from being accompanied by new evidence. In essence, FRE 106 expressly permits what Rule 42.23(b) seems to prohibit at the

stage in this case when this issue arose (after the petitioner's Reply). If the Board concludes that Exhibit 1063 cannot be excluded under FRE 106, then the Board's rules will conflict in this case. On one hand, Rule 42.23(b) may seem not to permit Exhibits 2044 and 2045, but, on the other hand, 37 C.F.R. § 42.62 makes the Federal Rules of Evidence, including FRE 106, applicable to *inter partes* reviews, and FRE 106 gives Stratus the right to submit evidence to complete incomplete documents, as explained above. In these circumstances, the conflicting rules should not be applied so as to result in a distorted incomplete evidentiary record. *See* 37 C.F.R. § 42.1(b) (requiring that the Board's rules be applied "to secure the just, speedy, and inexpensive resolution of every proceeding"). At bottom, the petitioner should not be permitted to benefit from a procedural loophole that prevents Stratus from countering misleadingly incomplete evidence.

C. Other Considerations

The petitioner ***may*** have been required under 37 C.F.R. § 42.51(b)(1)(iii) to provide a more complete version of Kalpakjian as "relevant information that is inconsistent with a position advanced by the party" when the petitioner filed Exhibit 1063 with its Reply. *See also* 37 C.F.R. § 42.11(a) (referring to "a duty of candor and good faith"). To be sure, the petitioner was required to provide a more complete version of Kalpakjian "concurrent with the filing of the document or things that contains the inconsistency" ***if*** it was aware of any other content in Kalpakjian

inconsistent with its positions. 37 C.F.R. § 42.51(b)(1)(iii). In this case, the inconsistent portions of Kalpakjian are in the same chapter, just a few pages beyond the pages cited and provided by the petitioner. The petitioner's failure to provide a more complete copy of Kalpakjian forced Stratus to expend time and money to find, obtain, and thoroughly check Exhibits 2044-45.

It is also ***possible*** that the petitioner strategically chose not to submit expert testimony regarding Exhibit 1063 so that Stratus would not have an opportunity to cross-examine such an expert about Kalpakjian, including the omitted, inconsistent portions.[*] That is, it is ***possible*** that the petitioner opted not to support its assertions with an expert analysis to avoid a scenario in which the petitioner's expert would be confronted with a complete copy of Kalpakjian or an updated edition of Kalpakjian and questioned about omitted sections that contradict those cited by the petitioner. The petitioner should not be permitted to submit an incomplete document to present a one-sided perspective that acts as a substitute for a declaration of an expert to sidestep any potential for exposing a more complete version of Kalpakjian in a

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[*] It is also possible that the petitioner could not find an expert witness willing to provide testimony in support of the petitioner's interpretation of Kalpakjian because Kalpakjian, in its totality, does not support the petitioner's position.

deposition. The mere possibility of such gamesmanship is another reason to rule in Stratus's favor regarding Exhibits 1063, 2044, and 2045.

Finally, Stratus reminds the Board that Exhibit 1063 should be struck or at least disregarded as improper new evidence that could and should have been presented in the petition. *See* Surreply at 14. 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). If Exhibit 1063 is struck or disregarded as improperly belated reply evidence, then this motion and the related issues regarding Exhibits 2044 and 2045 are moot.

V. CONCLUSION

Accordingly, Stratus respectfully requests that the Board exclude Ex. 1063, unless the Board keeps in the record and considers Exhibits 2044 and 2045.

Respectfully submitted,

Date: 2025 Oct. 17

By: /M.C. Phillips/
Matthew C. Phillips
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CERTIFICATE OF SERVICE

I hereby certify that on **October 17, 2025**, copies of the foregoing STRATUS'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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