Filed October 24, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVANOS MEDICAL, INC.,

Petitioner,

v.

STRATUS MEDICAL, LLC,

Patent Owner.

Case IPR2024-01209
Patent 10,966,782

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

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I. INTRODUCTION

Patent Owner Stratus's Motion to Exclude Ex-1063 under FRE 106 should be denied. First, all of Stratus's arguments are premised on a mischaracterization of Avanos's obviousness grounds, which taints Stratus's arguments about the use of Ex-1063. Second, Stratus encourages a radical new use of FRE 106; as the Board and courts have concluded numerous times, FRE 106 is a rule of *inclusion*, not *exclusion*. So if there were any remedy needed under the rule, it would be to introduce additional information, not exclude Ex-1063.[1] Third, that remedy—introduction of Stratus's new Ex-2044 and Ex-2045—is not necessary here because the proposed exhibits do not relate to any misleading statement. Rather, their only potential relevance is to Stratus's distorted characterization of Petitioner's combination of the prior art (which as noted above, Stratus relies on as the basis for their motion). Therefore, Stratus's belated exhibits need not "in fairness" be introduced under FRE 106, and it would be inappropriate to exclude Ex-1063 under FRE 106. Petitioner Avanos respectfully requests that the Board deny Stratus's motion in its entirety.

[1] And as Avanos will argue in its separate brief, authorized by the Board, Stratus failed to timely seek permission to avail itself of that potential remedy.

II. ARGUMENT

A. Stratus attempts to justify its Motion by distorting the Petition's invalidity position.

Stratus's Motion purports to address the admissibility of Exhibit 1063, yet it begins with an inaccurate "Background" that bears no resemblance to the record. Petitioner is loath to recount its well-documented invalidity grounds in opposition to a motion to exclude. But Stratus's blatant distortion of Avanos's arguments *is the premise* of this Motion to Exclude and compels a response.

According to Stratus, the Petition rests on a single, specific combination of the prior art that requires Lee's filaments to be "fully enclosed within the sidewall of Racz's needle" in "long, extremely narrow channels." Paper 47 ("PO MTE"), 2. This is entirely incorrect. Neither the challenged claims nor the Petition's combination of the prior art has ever required the filaments to be "fully enclosed" in a needle's sidewall or required "long, extremely narrow channels."

The Petition repeatedly explained that it would have been obvious to provide channels[2] ***at the tip*** of Racz's needle to guide deployable filaments in and out of the cannula. *See e.g.*, Pet., 40-43 (discussing various ways to implement Lee's channels in Racz's tip). The Petition also explained that the opposite, proximal

[2] Lee also refers to its channels as "ramps" or "deflection surfaces." Pet., 19, 26 (citing Ex-1010).

ends of the filaments would be interconnected to an actuator within the cannula. *See e.g.*, Pet. 47, 54, 74. While the channels at the tip of Racz's modified needle certainly *could* extend further into the cannula's sidewall, neither Avanos nor Dr. Tucker has ever argued that this is necessary or that the filaments must be "fully enclosed" within the cannula's sidewall. Nevertheless, Stratus asserts that the Petition's example combination of the prior art somehow *requires* the entirety of the filaments to be "fully enclosed" in the needle's sidewall and that the channels guiding the filaments must be especially "long" and "extremely narrow."

Notably, this issue has already been addressed. Stratus questioned Dr. Tucker about this very point in his deposition, and Dr. Tucker confirmed that the portions of the filaments extending into the cannula (towards the actuator) did *not* have to be positioned in the cannula's sidewall. Ex-2020, 180:18-182:15 ("I told you how you don't have to put [the filaments] in the sidewall. They have to be around the perimeter of that cannula so that the active electrode, the probe, can still go down the center and energize the metallic tip and the filaments that are deployed. They have to go around the perimeter."), 182:16-185:6 (Referring to the filaments: "I said it doesn't have to be in the channels. I've explained that. Can be around the perimeter, it can go down grooves and be held in place by small pieces of plastic that holds them on the perimeter. It doesn't have to go down channels. … I'm thinking about three or four ways to make this thing."); *see also id.*, 127:20-129:3

(even if the tip's channels were extended into the cannula sidewall they need not extend the entire length of the cannula).

Dr. Tucker's cross-examination testimony was clear that the filaments simply need to be arranged around the inner perimeter of the cannula to leave a central space for Racz's removable RF probe, and that a POSA would know the filaments could be arranged in several ways. *See also* Pet., 26 ("Lee's deployable filaments (22/1622) can be arranged around the inner perimeter of a cannula such that they surround and provide space for a central element"); Pet., 41 ("the filaments (22/1622) could be implemented in a variety of ways"). Placing the entirety of the filaments in the sidewall of the cannula has never been a necessary feature of the Petition's prior art combinations.

Ignoring Dr. Tucker's testimony, Stratus's Patent Owner Response fixated on a single example illustration—"Racz's Modified Device" or "RMD" as Stratus terms it—and argued that Mr. Crosby's testimony showed that it would have been "impossible" to manufacture that single example (and therefore there is no reasonable expectation of success).[3] *See* POR, 43-44.

[3] Besides ignoring Dr. Tucker's testimony, Stratus's fixation on "RMD" is also contrary to Avanos's own representations. *Compare* Pet., 28 (noting "*one example* of how a POSA would modify Racz to include Lee's filaments" (emphasis added)),

In its Reply, Avanos explained two points that are applicable to the present motion. First, the obviousness of the claims does not depend on Stratus's narrow, distorted interpretation of "RMD," which Stratus erroneously argued must be 16-gauge or smaller in its Patent Owner Response, and now suggests also requires filaments "fully enclosed" in "long, extremely narrow channels." Reply, 19-20; POR, 43-44, 48; Sur-Reply, 3; PO MTE, 2. Second, Ex-1063—an excerpt of the 900+ page "Kalpakjian" textbook at issue—undermines Mr. Crosby's testimony because it refutes his unsupported opinion that combining the prior art was "impossible." Reply, 20.

Exhibit 1063 is documentary evidence of the level of skill in the art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).[4] And it teaches known

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and Ex-1031, ¶143 (noting "[t]he figure shows *one example* of how a POSA … would have incorporated Lee's deployable filaments"), *with* POR, 24 (removing any mention of "example").

[4] There is no dispute that Ex-1063 is prior art. See PO MTE, 3. And documentary evidence from *the relevant time* is superior to *present-day* expert testimony about what may have been possible at that time. That is particularly true here for Mr. Crosby's unsupported testimony. *See Velander v. Garner*, 348 F.3d 1359, 1371 (Fed. Cir. 2003) (citing *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776

manufacturing techniques (e.g., electrical discharge machining (EDM) and laser-based machining (LBM)) that Mr. Crosby either ignored entirely (EDM) or, without any evidence, suggested could not be used (LBM). *See generally* Ex-2006, ¶234-253.

In its Sur-Reply, Stratus characterized this second point as "attorney argument, devoid of any expert support" (Sur-Reply, 13; *see also* PO MTE, 3), continued to argue that its narrow characterization of "RMD" could not be made using EDM or LBM, and further introduced Ex-2044 and Ex-2045 as teaching various factors that "should" be considered when using both EDM and LBM. Sur-Reply, 13-14 (citing Ex-2044, Ex-2045). And now, in its Motion to Exclude, Stratus relies on its narrow characterization of "RMD" to argue that Ex-1063 should be excluded, or alternatively that Ex-2044 and Ex-2045 should be included. PO MTE, 1-7.

F.2d 281, 294 (Fed.Cir.1985) ("Lack of factual support for expert opinion going to factual determinations, however, may render the testimony of little probative value in a validity determination."); *Sandt Tech., Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1351 (Fed. Cir. 2001) (noting, in context of prior inventorship issue, that "documentary or physical evidence" from the relevant time eliminates "the risk of litigation-inspired fabrication or exaggeration").

As explained below, Ex-1063 is not "misleadingly incomplete," but instead plainly admissible documentary evidence of the level of skill in the art that further demonstrates the unreliability of Mr. Crosby's testimony.

B. Exhibit 1063 is admissible, and FRE 106 does not require introduction of Stratus's new exhibits

1. FRE 106 is a rule of inclusion, not of exclusion

Stratus's argument that Ex-1063 should be excluded under FRE 106 fundamentally misunderstands the rule's purpose. FRE 106 is a rule of inclusion designed to permit the admission of additional portions of a statement when necessary to prevent a misleading impression—not a rule of exclusion. The Ninth Circuit explained this clearly in *United States v. Ehmer*:

> [FRE 106], by its terms, does not exclude any evidence, but merely provides that, if all or part of a "recorded statement" is offered, then an opponent may require that certain additional parts or recorded statements must also be introduced contemporaneously if fairness requires … Nothing in the language of Rule 106 says that, when the remainder of the recorded statement does not exist, the portion offered into evidence must be excluded.

87 F.4th 1073, 1125 (9th Cir. 2023). The Ninth Circuit further explained that "[t]he question whether [an incomplete] statement should be admitted … raises a question of undue prejudice under Rule 403" rather than implicating FRE 106. *Id.*

(cleaned up). Thus, FRE 106 provides a mechanism for *adding* necessary context—not for *excluding* otherwise admissible evidence.

The PTAB has consistently reached the same conclusion in denying motions to exclude based on FRE 106, as Stratus appears to recognize. For example, in *Edwards Lifesciences Corp. v. Aortic Innovations, Inc.*, IPR2021-00193, Paper 49, 21 (Feb. 10, 2023) (New, APJ.), the Board concluded FRE 106 "does not provide any ground for excluding evidence as inadmissible." Stratus's Motion to Exclude cites another example, *Argentum Pharms. LLC v. Research Corp. Techs., Inc.*, where the Board concluded FRE 106 was not a "basis for excluding evidence" but a "vehicle for entry of additional evidence." IPR2016-00204, Paper 85 at 48-49 (Mar. 22, 2017), *cited in* PO MTE, 9. In *Argentum Pharms. LLC v. Novartis AG*, the Board recognized that—as is the case here—the patent owner's attempt to exclude certain evidence under FRE 106 was a "pretext to discuss various [other] portions of [the evidence] in a 'thinly veiled second sur-reply," and "in any event, [its] request would not have been proper as part of a motion to exclude." IPR2016-01479, Paper 61, 28-29 (Oct. 5, 2020). *See also Mylan Pharms. Inc. v. Yeda Research and Dev. Co.*, IPR2015-00644, Paper 91, 39-40 (Dec. 2, 2016) ("As Patent Owner correctly points out, 'Rule 106 does not prohibit admission of an incomplete document. Instead, it allows the party against whom the document is introduced to place the remainder in evidence.' … (quoting 1 Weinstein on

Evidence § 106.02[1]).”). Stratus's reliance on FRE 106 as a basis for exclusion is therefore misplaced.

None of the other authorities Stratus cites to support the proposition that courts have the “power” to exclude under FRE 106 “when warranted” are applicable here, either.[5] Stratus cites *United States v. Woods* as an example of a district court excluding an exhibit “pursuant to [FRE] 106.” PO MTE, 9. But the court excluded the exhibit because the defendant failed to respond to the government's motion, expressly noting it was “granted as unopposed.” No. 4:22-cr-00016-RSB-CLR, 2023 WL 3098834, at *2 (S.D. Ga. Apr. 26, 2023). Moreover, the government's motion in that case did not even *request* exclusion under FRE 106; rather, it argued that the exhibit at issue was incomplete because “the first page … appear[ed] to be subject to some sort of scanner or printer error,” so that it

[5] Stratus also argues that unless Ex-1063 is excluded, “the Board's rules will conflict in this case,” citing 37 C.F.R § 42.23(b). PO MTE, 11-12. Even if there was some “conflict,” a motion to exclude is not the “vehicle” to resolve it. *See Research Corp.*, IPR2016-00204, Paper 85 at 48-49. Perhaps believing, as the saying goes, that “it's better to ask for forgiveness than permission,” Stratus did not seek a resolution to this conflict or prior authorization before it elected to simply file its new evidence with the sur-reply—despite clear prohibitions on doing so.

"should be offered in full under Rule 106." United States' Motion in Limine at 8, *United States v. Woods*, No. 4:22-cr-00016-RSB-CLR (S.D. Ga. Mar. 23, 2023), ECF No. 177.[6] So the exhibit in *Woods* was subject to some "error," and the court excluded the exhibit without opposition by the offering party. Those circumstances are not present here.

Likewise, Stratus's reliance on *United States v. Sherman*, 293 Fed. App'x 158, 159 (3d Cir. 2008), is also misplaced. Stratus cites *Sherman* to argue that FRE 106 "may be ineffectual" when "access to the evidence is not balanced." PO MTE, 9. But the "access" the court was referring to in *Sherman* was when "the government improperly fails to preserve evidence" or *destroys* "potentially exculpatory portions" of the evidence. *Sherman*, 293 F. App'x at 159-60. Furthermore, when such evidence is destroyed, a party still "must prove the government acted in bad faith" for FRE 106 to "counsel exclusion." *Id.* (holding lower court did not err in admitting surveillance video evidence where an omitted portion "was destroyed as a result of the normal functioning of the recording equipment" rather than bad faith). Here, nothing was destroyed. In fact, the parties'

[6] *Available at* https://storage.courtlistener.com/recap/gov.uscourts.gasd.86281/gov.uscourts.gasd.86281.177.0.pdf.

access to the evidence was plainly "balanced" since Stratus was able to promptly locate, review, and analyze the same textbook—plus *another* edition of it.

Accordingly, there is no basis to exclude Ex-1063 under FRE 106. To the extent there is any remedy at all, at most it would be to introduce Ex-2044 and Ex-2045. As explained below, there is no reason to do that, either.

2. Ex-2044 and Ex-2045 are not required to be considered or admitted "in fairness" under FRE 106 because the only potential relevance is to Stratus's incorrect "RMD" argument

FRE 106 applies only in the "narrow circumstances" where a party "create[s] a misimpression about [a] statement, and the adverse party proffers a statement that in fact corrects the misimpression." FRE 106, Committee Notes on 2023 Amendment. The Notes also explain: "The mere fact that a statement is probative and contradicts a statement offered by the opponent is not enough to justify completion under Rule 106." *Id.* Rather, courts have interpreted FRE 106 to require admission of other statements "only when necessary to explain the admitted portion [e.g., Ex-1063], to place it into context, to ensure a fair and impartial understanding of the admitted portion, or to correct a misleading impression that might arise from excluding it." *E.g.*, *United States v. Rivera*, 61 F.3d 131, 135-36 (2d Cir. 1995).

Here, FRE 106 does not apply because Avanos's use of Ex-1063 did not create any "misimpression." Stratus claims Avanos's use of Ex-1063 distorted

"what a POSITA would have concluded regarding the teachings of Kalpakjian regarding the feasibility of making RMD via EDM and LBM." PO MTE, 9. But Avanos's statement was that Ex-1063 refutes "Crosby's testimony that *the proposed combination* would be 'impossible' to manufacture" based on its disclosure of EDM and LBM allowing for 0.1mm and 0.005 mm precision." Reply, 20 (emphasis added) (citing Ex-1063, 541, 546). Nothing in the cited portions of new Ex-2044 or Ex-2045 corrects or disputes that. Therefore, Avanos's use of Ex-1063 could not have created any misimpression regarding the fact that Ex-1063 refutes "Crosby's testimony that the proposed combination would be 'impossible' to manufacture." Reply, 20.

Rather, the only *potential* relevance of Stratus's new exhibits is to Stratus's distorted interpretation of "RMD." But as explained above and in the Reply, Stratus's arguments in connection with Ex-2044 and Ex-2045 are simply irrelevant to the issues that the Board must decide in this case. As one example, Stratus claims Ex-1063 is incomplete because the "Design Considerations" in Ex-2044 indicate that "deep slots and narrow openings should be avoided" for EDM. PO MTE, 4 (cleaned up). Likewise, Stratus argues that Ex-2045 indicates that LBM "deep cuts will produce tapered walls." PO MTE, 5-6. But Stratus's argument is that the recommendations and considerations are relevant to its distorted characterization of RMD—which erroneously requires filaments "fully enclosed"

in "long, extremely narrow channels." Thus, none of the "Design Considerations" cited in Ex-2044 or Ex-2045 have any bearing on whether a POSA would have a reasonable expectation of success in combining the Petition's prior art to arrive at the *claimed invention*.

Additionally, the portions of Ex-1063 cited in Petitioner's Reply are unequivocal that EDM (which Crosby did not even consider) uses electrodes as small as "0.1mm" and can be used to produce "small-diameter deep holes" (Ex-1063, 541), while LBM can be used to produce "[h]oles as small as 0.005mm … with hole depth-to-diameter ratios of 50 to 1" (Ex-1063, 546). *See* Reply, 20 (citing these pages of Ex-1063). Thus, whatever "deep slots," "narrow openings," or "deep cuts" Stratus's newly cited "Design Considerations" are referring to, they plainly do not restrict using EDM and LBM to produce "small-diameter deep holes" or small-diameter holes with "depth-to-diameter ratios of 50 to 1." Stratus's new evidence thus fail to cure any misimpression allegedly introduced by Ex-1063. Accordingly, aside from FRE 106 providing no basis to exclude Ex-1063, it also does not provide any basis to include Ex-2044 and Ex-2045.

III. CONCLUSION

For the foregoing reasons, Ex-1063 should not be excluded, and Stratus's Motion to Exclude should be denied.

Respectfully submitted,

/Warren Thomas/
Warren J. Thomas (Reg. No. 70,581)

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and agreement of the parties, I certify that on October 24, 2025, a copy of Petitioner's Opposition to Patent Owner's Motion to Exclude was served on counsel for the Patent Owner by email to:

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