

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Case No. IPR2024-01157
U.S. Patent No. 11,697,011

**PATENT OWNER'S MOTION TO EXCLUDE
PURSUANT TO 37 C.F.R. §§ 42.62 AND 42.64**

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OTHER AUTHORITIES

37 C.F.R. §§ 42.62, 42.64(b)(1), 42.64(c)	1
Fed. R. Evid. 401, 402, 403, 702, 702(c), 703	1, 2, 5, 8, 9

Under 37 C.F.R. §§ 42.62 and 42.64(c), Patent Owner moves to exclude Exhibits 1003, 1008, and 1014, which were filed by Petitioner with its Petition for *inter partes* review (“IPR”) on July 8, 2024 (Paper 1) and Petitioner’s Reply on July 11, 2025 (Paper 18), under Federal Rules of Evidence (“F.R.E.”) 401, 402, 403, 702, and 703.

I. Introduction

The F.R.E. govern the admissibility of evidence in IPR proceedings pursuant to 37 C.F.R. § 42.62. In accordance with 37 C.F.R. § 42.64(b)(1), Patent Owner timely filed objections to Exhibits 1003 and 1008 within 10 business days of the institution decision, and to Exhibit 1014 within five business days of service. *See* Papers 9 and 19.

Exhibits 1003 and 1014, the expert declarations of Troy Thornton, should be excluded in their entirety under F.R.E. 702 and 703 because they are based on an incorrect definition of a person of ordinary skill in the art (“POSA”), rendering the underlying principles of the opinions unreliable. Furthermore, the statements set forth in Exhibits 1003 and 1014 concerning U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer Publication”) should be excluded for improperly relying on Exhibit 1008—drawings submitted during the prosecution of U.S. Patent Application No. 10/371,190—to fill in gaps in the Schaffer Publication.

Finally, Exhibit 1008 should be excluded under F.R.E. 401, 402, and 403 because it is not part of grounds, making it irrelevant, likely to confuse the issues, and unduly prejudicial.

II. Exhibits 1003 and 1014

For the reasons set forth below, Patent Owner respectfully requests that the Board exclude Exhibits 1003 and 1014 in their entirety, or in the alternative, paragraphs related to the Schaffer Publication, namely, 54-56, 59, 63-75, 80-88, 93-100, 102-108, 110-111, 113-114, 116, 118-130, 132-136, 138, 140, and 142 in Petitioner's Exhibit 1003 and paragraphs 9, 13, 14, 15, 18, 19, 21, 26, 27, 31-35, 38, 39, 41, 43-45, 48, and 49 in Petitioner's Exhibit 1014.

A. Incorrect Definition of Person of Ordinary Skill in the Art (POSA)

Expert declarations are admissible only if they are “the product of reliable principles and methods,” and if the facts or data underlying an expert's opinion are “of a type reasonably relied upon by experts in the particular field.” *See* Fed. R. Evid. 702(c); Fed. R. Evid. 703 advisory committee's note to 1972. A POSA is a hypothetical person who is assumed to possess knowledge of the pertinent field at the relevant point in time. *In re GPAC*, 57 F.3d 1573, 1579, 35 USPQ2d 1116, 1121 (Fed. Cir. 1995); *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962, 1 USPQ2d 1196, 1201 (Fed. Cir. 1986). “To offer expert testimony from

the perspective of a skilled artisan in a patent case ... a witness must at least have ordinary skill in the art. Without that skill, the witness' opinions are neither relevant nor reliable.” *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1376-77 (Fed. Cir. 2022). Like the testimony of an expert lacking the experience of a POSA, testimony from the perspective of an individual lacking the experience of a POSA should also be excluded.

Patent Owner's expert, Dr. Zalesky, opined that a POSA in September 2017 would have had “an undergraduate degree in mechanical engineering or a related engineering discipline and 2 to 4 years of product design or engineering experience designing medical devices in the field of the '011 Patent.” EX2008, ¶68. In contrast, the definition of a POSA set forth by Petitioner and its expert is incorrect because it does not require any specific medical device experience, let alone in the field of the invention. *See* Petition at p. 13 (“A POSA in September 2017 would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of product design or engineering experience (Ex. 1003, ¶35.).” Even though Petitioner's expert testified that the field of invention of the '011 Patent is “hemostasis valves for use during intravascular procedures,” (EX2007, 16:13-20), Petitioner and its expert's definition omits any requirement of experience in designing medical devices generally, let alone in the field of the '011 Patent. In fact,

Petitioner's expert testified that a POSA has no experience designing medical devices at all. *Id.* at 180:5-25.

As such, a POSA having no medical experience would lack any understanding of the design considerations and requirements for the various features of a hemostasis valve as disclosed in the references cited in all grounds here, including Schaffer (EX1005), Hartley (EX1006), and Eller (Exhibit 1007), each of which pertains to hemostasis valves intended for use in medical procedures. For example, a POSA having no medical experience at all would have no understanding why Schaffer is designed to seal via nonconforming actuating members that apply compression to an internal conforming seal member and would have given no weight to the advantages of such a configuration or why a POSA would not have modified Schaffer to arrive at the claimed invention.

Petitioner may argue that Patent owner's expert, Dr. Zalesky testified that no medical device experience is necessary. He did not. Dr. Zalesky expressly testified that a POSA would have had "experience designing medical devices in the field of the '011 Patent." EX2008, ¶68. And when deposed, Dr. Zalesky stated that he does not believe "the POSITA would necessarily have direct experience with [designing] hemostasis valves," but would be generally familiar with them and further confirmed that the POSITA "would have experience with catheters and devices involved in the

bloodstream” that are used with hemostasis valves. EX1015, 72:11–20. Therefore, a lack of specific experience designing hemostasis valves does not negate the requirement that a POSITA possess experience in designing medical devices, including experience with catheters and devices involved in the bloodstream. Accordingly, Petitioner’s expert’s opinions from the perspective of an individual having no medical device experience are not “the product of reliable principles and methods” and should be excluded.

B. Reliance on Exhibit 1008

The portions of Mr. Thornton’s declarations and testimony related to the Schaffer Publication (EX1005), the primary reference for grounds 1-4, should be excluded under F.R.E. 702 and 703 because it is not “the product of reliable principles and methods,” and not “of a type reasonably relied upon by experts in the particular field.” The Federal Circuit has held that the “purpose of extrinsic evidence in an anticipation analysis ‘is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill gaps in the reference.’” *Wilson v. Martin*, 789 F.Appx. 861, 869 (Fed. Cir. 2019) (citing *Scripps Clinic & Rsch. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991), overruled on other grounds by *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009)). See also *R.J. Reynolds Vapor Co. v. Altria Client Servs. LLC*, IPR2021-00746, Paper

8, at 12-15 (P.T.A.B. Oct. 8, 2021) (Denying institution of an *inter partes* review and rejecting Petitioner’s suggestion that the Juulpod device discloses a “device compartment” as claimed in the subject patents because “Petitioner’s obviousness challenge is based on the Juul Articles, not the subsequently launched Juulpod device.”).

Here, grounds 1-4 rely on the Schaffer Publication (Petition at 15), and do not include Exhibit 1008. Exhibit 1008 consists of replacement drawings submitted to the USPTO during prosecution of Schaffer and include features not visible in the Schaffer Publication’s figures. *See* Petition at p. 17, n. 2. But, because the Schaffer Publication includes Figures 30-34 that are of poor quality and thus omit various features necessary for the arguments made in the Petition, Petitioner’s expert Mr. Thornton improperly relies on Exhibit 1008 to fill in the gaps in the Schaffer Publication. As such, Mr. Thornton’s testimony regarding the purported disclosure of the Schaffer Publication is both incorrect and tainted by his improper reliance on Exhibit 1008 as if it is part of the Schaffer Publication, casting doubt upon the entirety of his statements concerning what the Schaffer Publication purportedly discloses.

Specifically, Mr. Thornton treated the drawings in Exhibit 1008 as though they were part of the Schaffer Publication’s disclosure in order to establish what the

Schaffer Publication purportedly discloses. EX2007 at 42:6-9 (“Q. So when you refer to Shaffer in your declaration, you’re referring to both Exhibit 1005 and Exhibit 1008; is that right? A. Yes.”). Mr. Thornton justified his approach by stating that the drawings in Exhibit 1008 are “clearer than the copies of the drawings in Schaffer’s published application.” EX1003, n.1. But, Mr. Thornton admitted that the Schaffer Publication’s own Figures 30-34 omitted certain features necessary to his opinions regarding the Schaffer Publication’s disclosure thus requiring his reliance on EX1008. *See* EX2010, 56:13-17 (“Q. And why did you review 1008 when interpreting the Schaffer reference? A. Because the images in the 1005 images for Figures 30 through 34 are dark, and it’s unclear what they’re showing”); EX2007, 41:15-19 (“Q. And you used Exhibit 1008 to understand the disclosure of Exhibit 1005, is that right? A. Yes. They were better images of [] certain figures, specifically Figures 30 through 34 that had used from 1008.”); 41:20-42:1 (“Q. When you say ‘better images,’ you can see features in the images in 1008 that you can't see in 1005; is that right? [Objections.] The Witness: The images seem to be almost photographs and were unclear for certain features in 1005.”). Notably, Figures 30-34 from Exhibit 1008 represent the primary embodiment of the Schaffer publication relied upon in the Petition. Petition at 21-32. In fact, Figures from Exhibit 1008, not the Schaffer publication, are reproduced throughout the Petition and accompanying expert

reports. Thus, to determine what is disclosed in the most critical embodiment of the primary reference, the Schaffer publication, Petitioner's expert did not rely on the Schaffer publication itself, but treated figures shown in EX1008 that are not found in the Schaffer Publication as the Schaffer publication's figures.

But, Petitioner's patentability challenges in grounds 1-4 are based on the Schaffer Publication, not Exhibit 1008. *See* Petition at 15. Because Petitioner's expert improperly relied upon Exhibit 1008 to fill in the gaps of the Schaffer publication, his testimony regarding the Schaffer publication's actual disclosure is both incorrect and tainted. Accordingly, that testimony should be excluded as unreliable, irrelevant, and unfairly prejudicial under F.R.E. 401, 402, 403, 702, and 703. Specifically, Exhibit 1003, ¶¶54-56, 59, 63-75, 80-88, 93-100, 102-108, 110-111, 113-114, 116, 118-130, 132-136, 138, 140, and 142, and Exhibit 1014, ¶¶9, 13, 14, 15, 18, 19, 21, 26, 27, 31-35, 38, 39, 41, 43-45, 48, and 49 relate to Petitioner's expert's understanding of the disclosure of Schaffer that is incorrect and improper due to consideration of Exhibit 1008, and therefore should be excluded.

III. Exhibit 1008

Exhibit 1008 should be excluded in its entirety because it is not part of the Schaffer Publication, and as explained above, Petitioner and its expert cannot rely

on Exhibit 1008 to fill in gaps in the disclosure of the Schaffer Publication. *See Scripps Clinic & Rsch. Found. v. Genentech, Inc.*, 927 F.2d at 1576.

Accordingly Exhibit 1008 is not relevant under F.R.E. 401, as it does not tend to prove or disprove any fact of consequence regarding what the Schaffer Publication discloses. Moreover, its introduction serves only to confuse the issues, in violation of F.R.E. 403, by presenting information that was not part of the Schaffer Publication. The use of Exhibit 1008 risks conflating the actual content of the Schaffer Publication with figures that are not found in that publication. As explained above, any consideration of those figures taints any understanding of what the Schaffer Publication actually discloses.

For these reasons, Exhibit 1008 should be excluded from the record and given no weight in this proceeding.

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IV. Conclusion

For the foregoing reasons, Patent Owner respectfully requests that the Board exclude Exhibits 1003, 1008, and 1014, from the record in this IPR proceeding.

Respectfully submitted,

Date: October 3, 2025

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that service on Petitioner was made as follows, in accordance with 37 CFR 42.6(e):

Date of service: October 3, 2025
Manner of service: 1. Electronic submission through the USPTO Patent Trial and Appeal Board P-TACTS System
2. Electronic mail
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