

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 REPLY TO PETITIONER'S OPPOSITION TO
MOTION TO EXCLUDE**

Table of Contents

I. Exhibits 1003 and 1014..... 1

II. Exhibit 1008 3

Patent Owner (“PO”) submits this Reply in support of its Motion to Exclude Exhibits 1003, 1008, and 1014. The challenged exhibits are inadmissible under the Federal Rules of Evidence (“F.R.E.”) 401, 402, 403, 702, and 703 and should be excluded.

I. Exhibits 1003 and 1014

In the institution decision in the related IPR of U.S. Patent No. 11,844,921, (“the ’921 IPR”), in which Petitioner proposed the same definition of a POSA as here, the Board stated that “Petitioner’s proposed POSA definition lacks specificity” and explained that “a POSA would also have had 2-4 years of design or engineering experience related to products in the field of the invention, which involves endovascular devices and the surgical procedures that use such devices.” EX1021, pp. 11-12. That is consistent with the definition of a POSA set forth by PO here requiring “2 to 4 years of product design or engineering experience designing medical devices in the field of the ’011 Patent.” EX2008, ¶68. As such, Petitioner’s expert testimony here from the wrong perspective is unreliable and not relevant to the understanding of a POSA.

Petitioner’s assertion that “[i]f a POSITA with a lower level of experience would have found the combinations obvious, certainly a POSITA with a higher level of experience would have found them obvious,” (Paper 29 at 9-10), is incorrect. As

explained in the motion to exclude, a POSA with a lower level of 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.

Indeed, as Petitioner's own expert explained at deposition, the starting point to design or select a hemostasis valve is an understanding of the requirements of the particular medical procedure for which the valve will be used, as follows:

Q. So then is it fair to say, in selecting a hemostasis valve for use with a procedure, to determine the design requirements for the hemostasis valve, you would need to understand the needs of the procedure?

[Objections]

THE WITNESS: I think, as engineers, we always design to the needs of the physician, the procedure, the environment, the sterilization plan, which was another design requirement I just thought of.

BY MR. HAMILTON: Q. And all those requirements relate to the needs from the procedure; is that right?

[Objections]

THE WITNESS: Needs from the physician, the needs of the procedure, the needs of the patient.

EX2007, 24:5-21.

Yet, Petitioner's expert's testimony is from the perspective of an individual having no experience or understanding of the "[n]eeds from the physician, the needs of the procedure, the needs of the patient." *See* EX2007, 33:11-20 ("[Q.] Does paragraph 35 set forth the definition of a person of ordinary skill in the art as you've applied it in your declaration? A. Yes."); EX2011, 8:11-25 ("[Q.] Is there anything you want to change in your first declaration, Exhibit 1003? A No."). Thus, that testimony set forth in Exhibits 1003 and 1014 should not only be accorded no weight, it is both unreliable and irrelevant to the issues here and should be excluded.

II. Exhibit 1008

Petitioner does not dispute that the grounds in this IPR rely on the Shaffer publication (EX1005) and do not include EX1008. As such EX1008 cannot be used to fill in gaps in the Schaffer publication. *See Wilson v. Martin*, 789 F.Appx. 861, 869 (Fed. Cir. 2019) (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” (citations omitted)).

Petitioner’s cases and MPEP citation are either not relevant or support Patent Owner’s position. First, Petitioner’s assertion that Exhibit 1008 is “intrinsic evidence, not extrinsic evidence” (Paper 29 at 11) confuses what Schaffer, a prior art publication, discloses with what qualifies as intrinsic and extrinsic evidence when construing issued patent claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (file history is intrinsic evidence in claim construction).

Next, Petitioner cites cases or the MPEP regarding whether a file history is a printed publication for prior art purposes, not whether a file history can fill in gaps in another prior art publication. *See Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378-1380 (Fed. Cir. 2006) (“The single legal issue in this appeal is whether figures 3 and 4 of the ’119 application were ‘printed publications’ under 35 U.S.C. § 102(b).”); MPEP §901.02 (“The information that is available to the public under 37 CFR 1.11(a) may be used as prior art under pre-AIA 35 U.S.C. 102(a) or 102(b) or 35 U.S.C. 102(a)(1) as of the date the information became publicly available.”).

Next, Petitioner cites a case where a file history itself was a printed publication and supported nonobviousness. *See Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1363 (Fed. Cir. 2007) (finding the file history consistent with

nonobviousness because “viewing the prior art as a whole, the prior art showed ‘that Takeda was actively conducting research in many directions, and had not narrowed its focus to compound b.’”).

And finally, Petitioner’s other cited cases support that the file history cannot be used to fill in gaps in a prior art publication. *See In re Baxter Travenol Labs.*, 952 F. 2d 388, 390 (Fed. Cir. 1991) (“extrinsic evidence may be considered when it is used to explain, but not expand, the meaning of a reference”); *Monsanto Tech. LLC v. E.I. Dupont de Nemours & Co.*, 878 F.3d 1336, 1345 (Fed. Cir. 2018) (“[e]xtrinsic evidence may be used to interpret the allegedly anticipating reference and [to] shed light on what it would have meant to [a POSITA]” (citation omitted)).

Petitioner’s assertion that EX1008 simply “show[s] the same components and features as the darkly tinted versions in the publication” is contradicted by its own expert’s testimony. *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*”) (emphasis added). Accordingly, Exhibit 1008 should be excluded from this proceeding because Petitioner’s and Mr. Thornton’s reliance on Exhibit 1008 to fill in gaps in the Schaffer publication confuses the issues and renders the testimony unreliable, irrelevant, and unfairly prejudicial.

Respectfully submitted,

Date: October 17, 2025 By: / Joseph P. Hamilton /
Joseph P. Hamilton, Reg. No. 51,440
Perkins Coie LLP
1888 Century Park East, Suite 1700
Los Angeles, CA 90067
Phone: 310-788-3271

Counsel for Patent Owner

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 17, 2025

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

Document(s) served: **PATENT OWNER'S REPLY TO PETITIONER'S
OPPOSITION TO PATENT OWNER'S MOTION
TO EXCLUDE**

Persons served: Joshua J. Stowell
Joshua.Stowell@knobbe.com

Joseph R. Re
Joe.Re@knobbe.com

Brian C. Barnes
Brian.Barnes@knobbe.com

BoxImperative011@knobbe.com

/ Kate Rose /

Senior Paralegal
Perkins Coie LLP