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On behalf of **Imperative Care, Inc.**

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL INC.,
Patent Owner.

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

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

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LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,697,011 (“the ’011 patent”)
1002	’011 Patent Prosecution History Excerpt
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
1006	U.S. Patent Publication US 2003/0116731 A1 to Hartley (“Hartley”)
1007	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
1008	Drawings Submitted During Prosecution of U.S. Patent Application No. 10/371,190 dated June 18, 2003
1009	U.S. Patent No. 5,429,616 to Schaffer (“Schaffer ’616”)
1010	U.S. Patent Publication US 2011/0144592 A1 to Wong et al. (“Wong”)
1011	U.S. Patent Publication US 2015/0173782 A1 to Garrison et al. (“Garrison”)
1012	Declaration of Joshua J. Stowell in Response to Patent Owner’s Objections to Imperative Care’s Evidence
1013	Certified File History of U.S. Patent Application 10/371,190
1014	Supplemental Expert Declaration of Troy Thornton
1015	Deposition Transcript of PO’s Expert Paul Zalesky, Ph.D. dated June 23, 2025
1016	Decision Granting Institution of IPR, IPR2025-00156, U.S. Patent No. 11,697,012 B2

IPR Petition – Patent 11,697,011
Imperative Care, Inc. v. Inari Medical Inc.

Exhibit No.	Description
1017	Decision Granting Institution of IPR, IPR2025-00289, U.S. Patent No. 11,554,005 B2
1018	U.S. Patent No. 12,109,384 B2 to Merritt et al.
1019	New Oxford American Dictionary, 3rd ed. (2010) – definitions of “diameter,” “filament,” and “loop”
1020	Order Denying Motion for Preliminary Injunction (Dkt. #136) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued September 29, 2025)
1021	Decision Granting Institution of IPR, IPR2025-00728, U.S. Patent No. 11,844,921 B2
1022	Patent Owner’s Preliminary Response submitted in IPR2025-00728 relating to U.S. Patent No. 11,844,921 B2

Pursuant to 37 C.F.R. § 42.64 and the Scheduling Order (Paper 8), Petitioner Imperative Care, Inc. opposes Patent Owner’s (“PO’s”) Motion to Exclude (Paper 28) for the reasons presented herein.

I. SUMMARY OF ARGUMENT

PO argues the Board should exclude the declarations of Petitioner’s expert, Troy Thornton (Exhibits 1003 and 1014), under F.R.E. 702 and 703 because Mr. Thornton allegedly applied an underexperienced definition of a person of ordinary skill in the art (“POSITA”). The Board should deny PO’s motion because Mr. Thornton applied the correct definition of a POSITA that is supported by the evidence. Further, even if Mr. Thornton’s definition were deficient, his application of the definition goes to the weight of his opinions, not their admissibility. Also, PO fails to identify any evidence that adopting PO’s definition over Mr. Thornton’s definition would materially impact the invalidity analysis.

PO also argues the Board should exclude Exhibit 1008, and the portions of Mr. Thornton’s declarations relating Schaffer (Ex. 1005) because Mr. Thornton relies on Exhibit 1008 to interpret Schaffer. Exhibit 1008 is replacement drawings submitted to the Patent Office during prosecution of Schaffer. PO argues that the drawings are “extrinsic evidence” and, therefore, lack relevance to the invalidity grounds under F.R.E. 401-403. The Board should deny PO’s motion because the drawings are not “extrinsic evidence,” but intrinsic evidence and highly relevant to

interpreting Schaffer. Moreover, even if the drawings were “extrinsic evidence,” the Board can weigh the relevance of the drawings without risk of prejudice or confusion, making exclusion inappropriate.

For these reasons, and those discussed below, Petitioner requests that the Board deny PO’s motion to exclude.

II. THE BOARD SHOULD NOT EXCLUDE MR. THORNTON’S EXPERT TESTIMONY BASED ON HIS DEFINITION OF A POSITA

The wholesale exclusion of an expert’s declaration is “rarely justified.” *Foursquare Labs, Inc. v. Boardactive Corp.*, IPR2023-00919, 2024 WL 4906282, at *37 (P.T.A.B. Nov. 27, 2024). Here, the exclusion of Mr. Thornton’s expert declarations would be particularly inappropriate.

PO does not dispute that Mr. Thornton qualifies as a POSITA under either party’s definition. (*See e.g.*, Ex. 1015, 12:3-5 (PO’s expert agreeing Mr. Thornton is an expert in hemostasis valves).) Mr. Thornton has “more than 35 years of experience in the cardiovascular medical device field, including significant experience designing, developing, testing, and manufacturing catheters and catheter systems for minimally invasive cardiovascular procedures.” (Ex. 1003, ¶14; *see also id.* ¶¶6-13.) He also has experience selecting and designing hemostasis valves for intravascular medical devices, as well as experience hiring and supervising other engineers who helped design hemostasis valves. (Ex. 2007, 18:19-20:15.) Mr. Thornton is therefore qualified to “offer expert testimony from the perspective of a

skilled artisan” in this case. *Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369, 1376–77 (Fed. Cir. 2022); (Ex. 1021, 12 (concluding that “Mr. Thornton ... appear[s] to have at least the qualifications of the POSA and [is] capable of testifying about the POSA’s perspective”).)

PO’s ancillary attacks on Mr. Thornton’s opinions based on his definition of a POSITA fail for several reasons. **First**, Mr. Thornton’s definition of a POSITA is correct and supported by the evidence. **Second**, the definition of a POSITA applied by Mr. Thornton goes to the weight of his opinions, not their admissibility. **Third**, PO fails to cite any evidence supporting its argument that the differences in the POSITA definitions are meaningful, much less that they warrant the extraordinary relief of exclusion.

A. The Evidence Supports Mr. Thornton’s Definition Of A POSITA

Mr. Thornton has consistently applied the correct definition of a POSITA that is supported by the evidence, specifically a person with “an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of product design or engineering experience.” (Ex. 1003, ¶35.) Mr. Thornton based his definition on his “experience assigning engineers to work on mechanical design projects, including projects to design hemostasis valves or incorporate them into catheter-based projects.” (*Id.*, ¶36.) Mr. Thornton explained that for such projects, he “would assign an engineer with the experience” identified in his POSITA

definition. (*Id.*; *see also* Ex. 2007, 180:1-25 (Mr. Thornton confirming, “I’ve certainly hired engineers that came from other fields besides medical devices.”).) Such an engineer could have gained relevant experience working with valves outside of the medical device field, such as valves used in fluid operations, which would assist in their understanding and ability to design a hemostasis valve. In the Institution Decision, the Board correctly concluded (based on the preliminary record) that Mr. Thornton’s definition “appears to be reasonable and not inconsistent with the cited prior art.” (Paper 7, 11.)

In a related IPR involving U.S. Patent No. 11,844,921, which shares a specification with the ’011 patent, the Board preliminarily determined that in addition to their degree in mechanical engineering or a related engineering discipline, a POSITA “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.” (Ex. 1021, 11-12.) However, the Board clarified that a POSITA “need not have had first-hand experience *designing* hemostasis valves” and that the POSITA’s “experience related to developing such devices “could be as simple as bench testing and looking at clinical data.” (*Id.*, 12.) Thus, while the Board concluded that Petitioner’s proposed definition was “too broad,” the Board also rejected PO’s arguments that a POSITA

would have needed specific experience designing a hemostasis valve or other medical devices. (*Id.*, 11-12.)

While Petitioner maintains that a POSITA could have gained the requisite experience from product design work outside the field of endovascular devices and the surgical procedures that use such devices, the '921 Institution Decision confirms that PO's motion should be denied because a POSITA would not need first-hand experience designing a hemostasis valve or other medical device. (*Id.*) Those supposed requirements are the sole basis for PO's attempt to exclude Mr. Thornton's testimony. (*See* Paper 28, 2-5.) Moreover, as explained below, the Board credited Mr. Thornton's testimony in the '921 Institution Decision despite its preliminary findings regarding the qualifications of a POSITA, further demonstrating that PO's motion should be denied. (*Infra* §II.B.)

In contrast to Mr. Thornton's consistent and supported testimony, PO and its expert have applied shifting and inconsistent positions regarding a POSITA. In the POPR, PO "applied Petitioner's definition of a POSITA" (POPR, 21-22), while PO's expert Dr. Zalesky did not identify a definition (Ex. 2001). Later, in the POR, PO and Dr. Zalesky largely adopted Mr. Thornton's definition but added the additional requirement that the person's 2-4 years of product design or engineering experience involve "designing medical devices in the field of the '011 Patent." (Ex. 2008, ¶68.) PO defined the "field of the '011 Patent" as "hemostasis valves for use during

intravascular procedures.” (POR, 22.) However, Dr. Zalesky then contradicted PO’s argument that a POSITA must have experience designing hemostasis valves (i.e., “medical devices in the field of the ’011 Patent”) during his deposition:

Q. So a person of ordinary skill in the art does not need to have prior experience designing a hemostasis valve. Is that right?

A. *I think that’s fair. Yes.*

(Ex. 1015, 72:21-73:2 (emphasis added)).

In the current Motion, PO again changes the definition of a POSITA by suggesting that a POSITA needs experience designing only medical devices generally, not experience designing hemostasis valves. (Paper 28, 4-5.) Yet again, however, Dr. Zalesky contradicts this argument by testifying that a POSITA would *not* need to have experience designing any medical devices, including hemostasis valves, catheters, or stents. (See e.g., Ex. 1015, 74:18-75:1 (“Q. But they wouldn’t specifically need experience in designing the devices. Is that correct? A. Yeah. I think that’s correct.”); see also *id.*, 72:21-73:2, 73:18-74:2.) PO’s muddled and inconsistent definition of a POSITA confirms that the Board should not adopt PO’s proposed requirement for specific experience designing a hemostasis valve or other medical device here.

Because Mr. Thornton’s definition is supported by the evidence, the Board should deny PO’s motion. See, e.g., *Microchip Tech. Inc. v. Aptiv Techs. Ag*,

IPR2024-00230, 2025 WL 2166118, at *23 (P.T.A.B. July 14, 2025) (denying petitioner’s motion to exclude expert testimony allegedly “based on an incorrect [POSITA] standard/definition” because the Board “d[id] not adopt Petitioner’s definition of a [POSITA]”). Moreover, even if the Board concludes that Mr. Thornton’s definition is “too broad” as it did in the ’921 Institution Decision, that would not justify excluding his testimony.

B. Mr. Thornton’s Definition Goes To The Weight Of His Testimony

Even if PO proved that Mr. Thornton applied a deficient definition of a POSITA, his definition would go to the weight of his testimony, not its admissibility. Notably, despite its finding that Mr. Thornton’s POSITA definition was “too broad” “if interpreted generically” in the ’921 Institution Decision, the Board nonetheless credited Mr. Thornton’s testimony and found that “Mr. Thornton ... appear[s] to have at least the qualifications of the POSA and [is] capable of testifying about the POSA’s perspective.” (Ex. 1021, 12; *see also id.*, 28-35 (crediting Mr. Thornton’s testimony).) The Board credited Mr. Thornton’s testimony despite PO’s arguments in the POPR that it should be given “little or no weight” due to his proposed POSITA definition. (Ex. 1022, 11-12.)

The Board’s assessment of Mr. Thornton’s testimony in the ’921 Institution Decision is consistent with other Board decisions. PO does not cite a single case where the Board or a court has excluded an expert declaration for applying the wrong

definition of a POSITA. To the contrary, the Board has ***declined*** to exclude expert testimony on such grounds because “it is within [the Board’s] discretion to assign the appropriate weight to be accorded evidence.” *Sk Hynix Inc. v. Netlist, Inc.*, IPR2017-00667, 2018 WL 3490806, at *16-17 (P.T.A.B. July 18, 2018); *see also Westinghouse Air Brake Techs. Corp. v. Siemens Mobility, Inc.*, IPR2017-00580, 2019 WL 164710, at *28 (P.T.A.B. Jan. 10, 2019) (denying motion to exclude expert declaration where expert “admitted during his deposition that he is proposing a definition of a [POSITA] that does not conform with either party’s proposals”).

“A motion to exclude is not the proper vehicle to challenge the sufficiency of Mr. [Thornton’s] testimony.” *Westinghouse*, 2019 WL 164710 at *28. The Board can evaluate the impact, if any, of the different definitions of a POSITA offered by the parties and accord the appropriate weight to the experts’ opinions, just as it did in the ’921 Institution Decision. *Id.* For this additional reason, PO’s motion should be denied.

C. PO Provides No Evidence That The Definition Of POSITA Is Material

PO argues that Mr. Thornton’s definition of a POSITA is deficient because “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 described in the prior art. (Paper 28, 4.) Yet, PO cites ***no*** evidence to support this attorney argument. (*See id.* at 4 (citing no support).) Further, PO’s argument that

an engineer with 2-4 years of experience would “lack any understanding” of hemostasis valves and “would have no understanding” of Schaffer’s design is not credible or consistent with the education and level of experience. (*Id.*)

Moreover, PO’s attorney argument is contradicted by both experts. As explained above, Mr. Thornton testified that he hired engineers to work on catheters and hemostasis valves that had no prior medical device experience and confirmed they possessed the necessary skills. (*Supra* §I.B.) Likewise, Dr. Zalesky confirmed that a POSITA would not need experience designing medical devices. (Ex. 1015, 74:5-75:1.)

PO also fails to explain how applying a definition of a POSITA that is allegedly too *low* renders “the underlying principles of the opinions unreliable.” (Paper 28, 4); *see, e.g., TRW Auto. US LLC v. Magna Elecs. Inc.*, IPR2014-00266, 2014 WL 2965901, at *7 (P.T.A.B. June 26, 2014) (rejecting argument that petitioner’s POSITA definition “infect[ed] [the] entire obviousness analysis” because patent owner “d[id] not explain sufficiently ... *why* [petitioner’s] definition renders [it’s] obviousness analyses incorrect”).

Mr. Thornton opines that a POSITA would have found the challenged claims obvious in view of the prior art because *inter alia*, combining the prior art would have merely entailed the simple substitution of known elements in a predictable manner. (Ex. 1003, ¶¶76-100.) If 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. *See, e.g., Innovention Toys, LLC v. MGA Entmt't, Inc.*, 637 F.3d 1314, 1323 (recognizing that “what is obvious to a layperson is necessarily obvious to one with a higher level of skill in the field of the invention”). Thus, even if PO justified a higher level of experience for the POSITA, PO has failed to show that a heightened level materially impacts Mr. Thornton’s opinions.

III. THE BOARD SHOULD NOT EXCLUDE EXHIBIT 1008 OR ANY OF MR. THORNTON’S TESTIMONY RELATING TO SCHAFFER

Petitioner and Mr. Thornton rely on Schaffer, a patent application published in 2003, for the unpatentability Grounds asserted in the Petition. (Petition, 15.) Petitioner focused its arguments on the valve embodiment illustrated in Schaffer’s Figures 30-34. Figures 30-34 in the Schaffer’s patent publication are darkly tinted and hard to read. (Ex. 1005, Figs. 30-34.) However, the applicant submitted replacements for Figures 30-34 during Schaffer’s prosecution. (Petition, 17 n. 2; Ex. 1005; Ex. 1008; Ex. 1013, 66-84.) The replacement drawings do not include the dark tint and are generally easier to read.

Petitioner and Mr. Thornton consulted the replacement drawings when assessing Schaffer and used those drawings in the Petition because they are clearer and easier to read. (Petition, 17 n. 2; Ex. 1003, ¶54 n.1.) PO does not dispute that the replacement drawings reproduced in the Petition were publicly available when

the Schaffer application published pursuant to 37 C.F.R. § 1.11. PO also does not dispute the authenticity or accuracy of those figures, which are present in the certified file history of the Schaffer application.¹ (Ex. 1013, 66-84; Ex. 1012.)

PO argues the Board should exclude Exhibit 1008 and Mr. Thornton’s related testimony because Exhibit 1008 is “extrinsic evidence” with respect to Schaffer. (Paper 28, 5-6.) PO is wrong. The replacement drawings reflected in Exhibit 1008 are part of Schaffer’s prosecution history (Ex. 1013), and thus are *intrinsic* evidence, not extrinsic evidence. (Ex. 1013, 66-84); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005); *see also Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378-1380 (Fed. Cir. 2006) (holding that two figures submitted in Canadian patent application but omitted from the issued patent were prior art under § 102(b)); *see also* MPEP 901.02 (all material submitted during the prosecution of a published patent application “may be used as prior art”).).

Because the replacement drawings are part of Schaffer’s intrinsic record, Mr. Thornton properly considered them in assessing Schaffer, and it was likewise proper for Petitioner to use those drawings in the Petition. *See, e.g., Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1363 (Fed. Cir. 2007) (holding that

¹ Because PO alleges that Exhibit 1008 is “extrinsic evidence,” Petitioner files herewith Exhibit 1013, which is a certified file history of the Schaffer application. The drawings that comprise Exhibit 1008 are found at pages 66-84 of Ex. 1013. Petitioner timely identified Ex. 1013 as supplemental evidence pursuant to 37 CFR §§ 42.64(a) and 42.64(b)(2).

district court properly considered prosecution history of prior art patent in obviousness analysis). As was the case in *Bruckelmyer*, the Schaffer publication would have provided a POSITA “a roadmap to the application file,” including the versions of the figures in Exhibit 1008, all of which were part of the publicly accessible file history. *Bruckelmyer*, 445 F.3d at 1379. Thus, neither Petitioner nor Mr. Thornton is relying on any extrinsic evidence to “fill in gaps” in Schaffer’s disclosure. PO therefore fails to show that Exhibit 1008 and any of Mr. Thornton’s testimony regarding Schaffer is unreliable, irrelevant, or unfairly prejudicial. PO’s request to exclude Mr. Thornton’s testimony and Exhibit 1008 should therefore be denied.

Further, even if the replacement drawings were extrinsic evidence to Schaffer (they are not), “[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].” *Monsanto Tech. LLC v. E.I. Dupont de Nemours & Co.*, 878 F.3d 1336, 1345 (Fed. Cir. 2018) (internal quotation omitted); *see also In re Baxter Travenol Labs.*, 952 F. 2d 388, 390 (Fed. Cir. 1991) (holding that “extrinsic evidence may be considered when it is used to explain, but not expand, the meaning of a reference”). That is exactly how Petitioner and Mr. Thornton use Schaffer’s replacement drawings in Exhibit 1008. The replacement drawings merely confirm how a POSITA would have understood Schaffer’s written disclosure and the darkly tinted

versions of Figures 30-34 in the published application. (Petition, 17 n. 2; Ex. 1003, ¶54 n. 1.) The replacement drawings show the same components and features as the darkly tinted versions in the publication; they are simply easier to see.² Thus, neither Petitioner nor Mr. Thornton are relying on the replacement drawings to “fill in gaps” or supply any limitations that are absent from the published application.

Further, none of PO’s cited caselaw supports its argument that Schaffer’s figures are improper “extrinsic evidence.” For example, in *Wilson v. Martin*, the patent owner argued that the Board erred in relying on expert testimony, which the patent owner characterized as “extrinsic evidence improperly used ‘to fill the gaps’ in” the prior art. *Wilson v. Martin*, 789 F. App’x 861, 870 (Fed. Cir. 2019). The Federal Circuit disagreed with the patent owner’s characterization of the expert’s testimony and held that the Board did *not* err by relying on the testimony. *Id.* Notably, *Wilson* did not involve patent figures, nor did it hold that patent figures within the prosecution history of a prior art patent publication are extrinsic evidence that cannot be considered when evaluating the disclosure of the patent publication.

² PO argues that the darkly tinted versions of Figures 30-34 in the published application “omit various features necessary for the arguments made in the Petition.” (Paper 28, 6.) PO’s statement is unsupported attorney argument and fails to identify any such feature. (*Id.*) PO likewise fails to identify, or even allege, that there are any differences between Figures 30-34 in Schaffer’s publication and the replacement drawings other than the image clarity. Nor can it because no material differences exist.

Similarly, in *Scripps Clinic & Research Foundation v. Genentech, Inc.*, the Federal Circuit noted that “[t]he role of extrinsic evidence [in anticipation] 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.” 927 F. 2d 1565, 1577 (Fed. Cir. 1991). In *Scripps*, the defendant filed multiple declarations from the author of a Ph.D. dissertation attempting to explain his dissertation. *Id.* at 1576-78. The court did not assess, let alone hold, that replacement drawings in the file history of a prior art patent publication are “extrinsic evidence” that cannot be considered by a POSITA to understand the reference. *See id.*

PO’s other cited case, *R.J. Reynolds Vapor Co. v. Altria Client Services*, also did not involve patent figures that were part of the intrinsic record of a prior art patent publication. Rather, in *R.J. Reynolds* the petitioner relied upon three prior art articles describing a prior art device for its invalidity grounds. *R.J. Reynolds Vapor Co. v. Altria Client Servs. LLC*, IPR2021-00746, 2021 WL 4860883, at *5-6 (P.T.A.B. Oct. 8, 2021). The Board denied institution of the IPR because the articles failed to disclose that the prior art device disclosed specific claim limitations. *Id.* Again, nothing in the Board’s decision suggests that figures that are part of the intrinsic record of a prior art patent publication cannot be considered to understand the reference.

IV. CONCLUSION

For the foregoing reasons, PO has failed to meet its burden to show that any portion of Mr. Thornton’s expert declarations (Exhibits 1003 and 1014) or Exhibit 1008 should be excluded. Petitioner therefore respectfully requests that the Board deny PO’s Motion to Exclude.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, pursuant to 37 C.F.R. § 42.6(e), a true and correct copy of **PETITIONER’S OPPOSITION TO PATENT OWNER’S MOTION TO EXCLUDE, EXHIBITS 1012, 1013, 1021, 1022** are being served electronically on October 10, 2025, to the e-mail addresses shown below:

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