

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC.,
Petitioner,

v.

TELEFLEX LIFE SCIENCES LIMITED,
Patent Owner.

IPR2020-01343
Patent RE46,116 E

Before SHERIDAN K. SNEDDEN, JAMES A. TARTAL, and
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

Opinion for the Board filed by *Administrative Patent Judge* TARTAL.

Opinion Concurring by *Administrative Patent Judge* PAULRAJ.

JUDGMENT
Final Written Decision
Determining Some Challenged Claims Unpatentable
35 U.S.C. § 318(a)

ORDER
Denying Petitioner's Motion to Exclude
37 C.F.R. § 42.64(c)

We have jurisdiction to conduct this *inter partes* review under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) (2018) and 37 C.F.R. § 42.73 (2019). Medtronic, Inc. and Medtronic Vascular, Inc. (“Petitioner”)¹ contends that claims 25–40, 42, 44–48, 52, and 53 (“the Challenged Claims”) of U.S. Patent No. RE46,116 E (Ex. 1001, “the ’116 patent”) are unpatentable. For the reasons discussed below, we determine that Petitioner has shown by a preponderance of the evidence that each of claims 52 and 53 of the ’116 patent is unpatentable, but has not shown by a preponderance of the evidence that any of claims 25–40, 42, and 44–48 of the ’116 patent is unpatentable.

I. INTRODUCTION

A. Summary of Procedural History

Petitioner filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of the Challenged Claims. Paper 1 (“Pet.”). We instituted an *inter partes* review of the Challenged Claims on all grounds of unpatentability asserted in the Petition. Paper 9 (“Inst. Dec.”). Teleflex Life Sciences Limited (“Patent Owner”)² filed a Patent Owner Response.³ Paper 21 (“PO Resp.”) (under seal), 22 (redacted, publicly

¹ Petitioner identifies as real parties-in-interest Medtronic, Inc. and Medtronic Vascular, Inc., and states, “Medtronic plc is the ultimate parent of Medtronic Inc.” Pet. 5.

² Patent Owner identifies as real parties-in-interest Teleflex Life Sciences Limited; Teleflex Medical Devices S.À.R.L.; Vascular Solutions LLC; Arrow International, Inc., and Teleflex LLC. Paper 4, 2. Patent Owner also states “Teleflex Incorporated is the ultimate parent of the entities listed above.” *Id.*

³ Prior to institution, Patent Owner filed a Preliminary Response directed primarily to whether discretionary denial of the Petition was warranted, not to the merits of Petitioner’s unpatentability contentions. *See* Paper 7.

accessible). Petitioner filed a Reply to the Patent Owner Response. Paper 46 (“Pet. Reply”) (under seal), 47 (redacted, publicly accessible). Patent Owner filed a Sur-reply in support of the Patent Owner Response. Paper 59 (“PO Sur-reply”).

Following oral argument, we entered a transcript of the hearing in the record. Paper 84 (“Tr.”). Petitioner bears the burden of proving unpatentability of each claim it has challenged by a preponderance of the evidence, and the burden of persuasion never shifts to Patent Owner. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d); *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

B. Related Proceedings

Petitioner challenges claims 25–55 of the ’116 patent under separate grounds in IPR2020-01344. Pet. 6; Paper 4, 3. The parties identify the ’116 patent as a subject of: (1) *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al.*, No. 19-cv-01760 (D. Minn.), and (2) *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn.). Pet. 5–6; Paper 4, 2. Patent Owner states that both of these district court proceedings are currently stayed. Paper 4, 2. The parties further state that the ’116 patent is a reissue of the ’850 patent and that the ’850 patent was a subject of: (1) *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 13-cv-01172 (D. Minn.), and (2) *Boston Scientific Corp. v. Vascular Solutions, Inc.*, IPR2014-00762, IPR2014-00763 (PTAB, terminated). Pet. 6; Paper 4, 2–3.

Additionally, Petitioner filed petitions challenging patents related to the ’116 patent in the following proceedings: IPR2020-00126 and IPR2020-00127 (Patent 8,048,032 B2); IPR2020-00128, IPR2020-00129, IPR2020-00130, and IPR2020-00131 (Patent RE45,380 E); IPR2020-00132, IPR2020-00133, and IPR2020-00134 (Patent RE45,760 E); IPR2020-00135

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and IPR2020-00136 (Patent RE45,776 E); IPR2020-00137 and IPR2020-00138 (Patent RE47,379 E); and IPR2020-01341 and IPR2020-01342 (Patent 8,142,413 B2). Institution of *inter partes* review was denied in IPR2020-00131 and IPR2020-00133.

C. The '116 Patent

The '116 patent, titled “Coaxial Guide Catheter for Interventional Cardiology Procedures,” issued August 23, 2016, from Application No. 14/195,435, filed March 3, 2014. Ex. 1001, codes (21), (22), (45), (54). The '116 patent is a reissue of U.S. Patent No. 8,292,850 (“the '850 patent”) from Application No. 13/359,059 filed on January 26, 2012, which the '116 patent states is a continuation of an application filed on November 1, 2013 (issued as U.S. Patent No. RE45,380), which is an application for the reissue of U.S. Patent No. 8,292,850, which is a division of an application filed on June 28, 2010 (issued as U.S. Patent No. 8,142,413), which is a division of an application filed on May 3, 2006 (Application No. 11/416,629 (“the '629 application”), issued as U.S. Patent No. 8,048,032). *Id.* codes (60), (64). The '116 patent is directed to “methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta.” *Id.* at 1:38–40.

The '116 patent explains, as background, that in “[i]nterventional cardiology procedures,” guidewires or other instruments, such as balloon catheters and stents, are often inserted through guide catheters into coronary arteries that branch off from the aorta. *Id.* at 1:44–50. In coronary artery disease, “the coronary arteries may be narrowed or occluded by atherosclerotic plaques or other lesions” in a phenomenon known as stenosis. *Id.* at 1:50–54. In treating the stenosis, “a guide catheter is inserted through the aorta and into the ostium of the coronary artery,”

sometimes with the aid of a guidewire, and is passed beyond the occlusion or stenosis. *Id.* at 1:59–65. However, according to the ’116 patent, “[c]rossing tough lesions can create enough backward force to dislodge the guide catheter from the ostium of the artery being treated,” which “can make it difficult or impossible for the interventional cardiologist to treat certain forms of coronary artery disease.” *Id.* at 1:66–2:3.

The ’116 patent discusses four categories of previous “attempts to provide support to the guiding catheter to prevent backward dislodgement from the coronary ostium (referred to as ‘backup support’).” *Id.* at 2:4–7. One category of guiding catheters “are configured to draw backup support from engaging the wall of the aortic arch opposing the ostium of the coronary artery that is being accessed.” *Id.* at 2:8–11. A second category are “guiding catheters that include a retractable appendage. *Id.* at 2:25–26. A third category are “guide catheters that have a portion that seeks to expand laterally to grip the interior wall of the ostium.” *Id.* at 2:36–41. A fourth category, or “technique,” of the prior attempts “includes the placement of a smaller guide catheter within a larger guide catheter in order to provide added support for the crossing of lesions or for the distal delivery of balloons and stents.” *Id.* at 2:50–53. The ’116 patent states this fourth technique was described in Takahashi,⁴ which uses a guide catheter inserted “more deeply into the ostium of the coronary artery than typically has been done before.” *Id.* at 2:53–62. The ’116 patent states that such “deep seating” by this technique “creates the risk that the relatively stiff, fixed curve, guide catheter will damage the coronary artery.” *Id.* at 2:63–65.

⁴ Saeko Takahashi, et al., *New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter*, 63 CATHETERIZATION AND CARDIOVASCULAR INTERVENTIONS 452–456 (2004) (Ex. 1010, “Takahashi”).

The '116 patent purports to resolve issues identified with the prior procedures by using “a coaxial guide catheter that is deliverable through standard guide catheters by utilizing a guidewire rail segment to permit delivery without blocking use of the guide catheter.” *Id.* at 3:20–23.

According to the '116 patent, the coaxial guide catheter “preferably includes a tapered inner catheter that runs over a standard 0.014 inch coronary guidewire to allow atraumatic placement within the coronary artery,” and this feature allows removal of the tapered inner catheter after the coaxial guide catheter is in place. *Id.* at 3:23–28.

Figures 1 and 2, reproduced below, show a coaxial guide catheter and a tapered inner catheter in accordance with the invention described in the '116 patent:

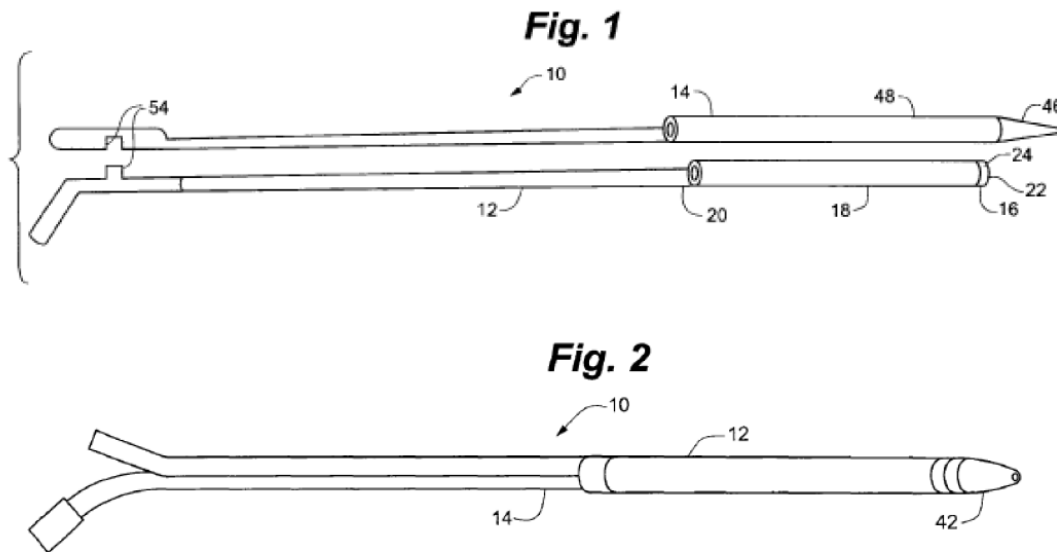


Figure 1 is a schematic depiction of the coaxial guide catheter and tapered inner catheter separately, and Figure 2 depicts those two elements assembled together. *Id.* at 5:51–56; Figs. 1 and 2. As shown above, “coaxial guide catheter assembly 10” includes coaxial guide catheter 12 and tapered inner catheter 14. *Id.* at 6:42–44. Coaxial guide catheter 12 includes tip

portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:45–46. Tapered inner catheter 14 “includes tapered inner catheter tip 42.” *Id.* at 7:26–27. Tapered inner catheter tip 42 includes tapered portion 46 at a distal end thereof, and straight portion 48. *Id.* at 7:30–31. Both tapered portion 46 and straight portion 48 are pierced by lumen 50 (not labeled in figures above). *Id.* at 7:31–32. “Tapered inner catheter 14 may also include clip 54 at a proximal end thereof to releasably join tapered inner catheter 14 to coaxial guide catheter 12.” *Id.* at 7:35–37. “The tapered inner catheter provides a gradual transition from the standard 0.014 inch diameter guidewire to the diameter of the coaxial guide catheter which is typically five to eight French.” *Id.* at 3:28–31. The coaxial guide catheter is made in at least three sizes corresponding to sizes commonly used in interventional cardiology procedures. *Id.* at 3:39–42.

Figure 4, reproduced below, shows a coaxial guide catheter in accordance with the invention described in the '116 patent:

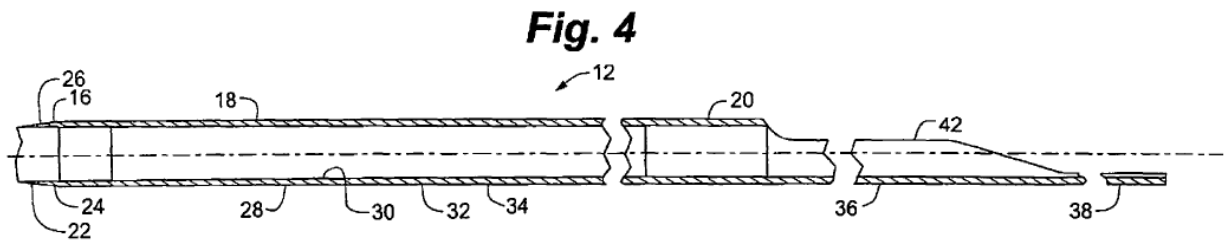


Figure 4 is a sectional view of the coaxial guide catheter with tip portion 16 depicted on the left side of the figure (rather than on the right side as shown in Figures 1 and 2). *Id.* at 5:60; Fig. 4. As shown above, coaxial guide catheter 12 has rigid portion 20 that “includes first full circumference portion 34, hemicylindrical portion 36, arcuate portion 38, and second full

circumference portion 40” (second full circumference portion 40 is shown in Figure 3). *Id.* at 7:7–10.

In operation, a guide catheter and a guidewire are used along with the coaxial guide catheter and the tapered inner catheter. Ex. 1001, 8:20–22. Figure 8, reproduced below, shows the operation of the coaxial guide catheter assembly in accordance with the invention described in the ’116 patent:

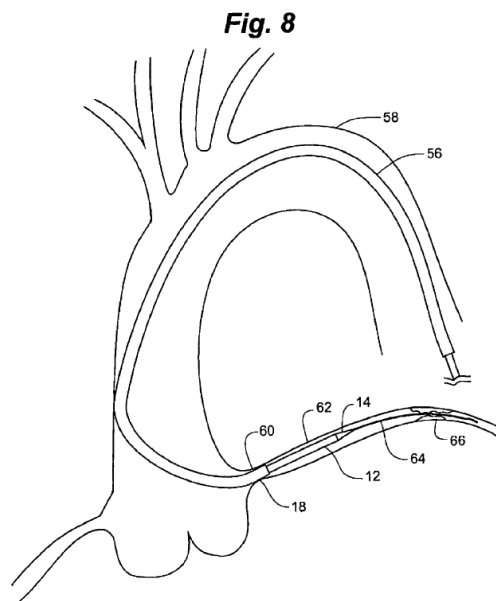


Figure 8 is a schematic view of a guide catheter and a guide wire in use with the coaxial guide catheter assembly within the aortic arch and coronary artery. *Id.* at 6:5–8; Fig. 8. First, guidewire 64 is inserted and passed through aortic arch 58 into ostium 60 of coronary artery 62. *Id.* at 7:65–66. Guide catheter 56 is then passed over guidewire 64 until the distal end of guide catheter 56 is seated in ostium 60. *Id.* at 8:4–6. Next, coaxial guide catheter 12 with tapered inner catheter 14 is passed through guide catheter 56 and over guidewire 64 into coronary artery 62. *Id.* at 8:22–24. The presence of coaxial guide catheter 12 within guide catheter 56 “provides

stiffer back up support than guide catheter 56 alone.” *Id.* at 8:38–40. “Once the coaxial guide catheter-tapered inner catheter combination has been inserted sufficiently into the ostium of the coronary artery to achieve deep seating the tapered inner catheter may be removed.” *Id.* at 4:58–62; *see also id.* at 8:30–32. Thereafter, coaxial guide catheter 12 can “accept a treatment catheter such as a stent or a balloon catheter.” *Id.* at 8:33–34. “[T]he presence of the coaxial guide catheter provides additional backup support to make it less likely that the coaxial guide catheter guide catheter combination will be dislodged from the ostium of the coronary artery while directing the coronary therapeutic device past a tough lesion.” *Id.* at 5:2–6. “[T]he invention is deliverable through an existing hemostatic valve arrangement on a guide catheter without preventing injections through existing Y adapters.” *Id.* at 5:42–44.

D. Illustrative Claim of the ’116 Patent

Petitioner challenges claims 25–40, 42, 44–48, 52, and 53 of the ’116 patent. Pet. 1. Claims 25 and 52 are independent method claims. Ex. 1001, 13:62–14:25, 17:10–18:10. Claims 26–40, 42, and 44–48 depend from claim 25 and claim 53 depends from claim 52. *Id.* at 14:26–15:41, 15:47–50, 18:11–14. Claim 25 is illustrative of the claimed subject matter and is reproduced below.

25. A method, comprising:

advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;

advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter the side

opening extending for a distance along a longitudinal axis of the guide extension catheter and accessible from a longitudinal side defined transverse to the longitudinal axis, the tubular structure having a cross-sectional inner diameter that is not more than one French size smaller than a cross-sectional inner diameter of the lumen of the guide catheter;

maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and

while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.

Id. at 13:62–14:25.

E. References and Testimony

Petitioner's contentions rely, in part, on testimony from Dr. Brecker, Dr. Hillstead, and Mr. Jones. Dr. Brecker states that he has been an interventional cardiologist for over twenty-four years, that he has been Chief of Cardiology at St. Georges University Hospitals London since 2015, and that he is a Professor of Cardiology and Chief of Cardiology Clinical Academic Group at St. George's University. Ex. 1005 ¶¶ 4, 5, 7.

Dr. Hillstead states that he is CEO of a medical device development and entrepreneurship consulting firm, the Chairman of a wound healing device company, a named inventor on numerous patents and pending applications related to catheter design, and that he has been involved in the design and development of medical devices for more than thirty years. Ex. 1042 ¶¶ 5, 10, 12. Mr. Jones states that he has worked in contract mechanical

engineering since 1997 on projects including “prototype designs for minimally invasive, surgical, and implantable devices, development and fabrication for surgical devices, test fixture design and fabrication, and process validation,” that he previously worked as an engineer on medical device design, development and manufacturing, including on catheters, and that he is a named inventor on over 100 patents. Ex. 1807 ¶¶ 8–10.

Patent Owner’s arguments rely, in part, on testimony from Mr. Keith and Dr. Graham. Mr. Keith states that his work between 1987 and 1996 as an engineer at a medical device company focused in the field of interventional cardiology and catheter design, that since 1997 he has served as an independent consultant for early stage medical device companies in product design and intellectual property development, that he co-founded a medical device company “focused on catheter-based treatments for chronic sinusitis,” and that he is a named inventor on over 140 patents. Ex. 2138 ¶¶ 3–6. Dr. Graham states that he is an interventional cardiologist at St. Michael’s Hospital, an Assistant Professor in the Division of Cardiology at the University of Toronto, and that he has over twenty years of experience in interventional cardiology. Ex. 2145 ¶ 1.

Below we provide a table identifying the references asserted.

References	Date	Ex. No.
U.S. Patent No. 7,736,355 B2 (“Itou”)	June 15, 2010	1007
U.S. Patent No. 7,604,612 B2 (“Ressemann”)	October 20, 2009	1008
US 2005/0015073 A1 (“Kataishi”)	January 20, 2005	1025

F. Asserted Grounds of Unpatentability

Petitioner alleges unpatentability of the Challenged Claims on the following grounds:

Claim(s) Challenged	35 U.S.C. §	References/Basis
52, 53	102	Ressemann
25–40, 42, 44–48, 52, 53	103	Itou, Ressemann
45	103	Itou, Ressemann, Kataishi

Pet. 8–9.

II. MOTION TO EXCLUDE

The party moving to exclude evidence bears the burden of proving that it is entitled to the relief requested—namely, that the material sought to be excluded is inadmissible under the Federal Rules of Evidence (“FRE”). *See* 37 C.F.R. §§ 42.20(c), 42.62(a) (2019). In an *inter partes* review in which we both decide admissibility and serve as the fact-finder, we are well-positioned to determine and assign appropriate weight to evidence presented, and we recognize that a complete record of the evidence is preferable to facilitate public access as well as appellate review. *See, e.g., Sony Computer Entm’t Am. LLC v. Game Controller Tech. LLC*, IPR2013-00634, Paper 32 at 31 (PTAB Apr. 14, 2015); *see also Gnosis S.p.A. v. S. Alabama Med. Sci. Found.*, IPR2013-00118, Paper 64 at 43 (PTAB June 20, 2014) (citing *Donnelly Garment Co. v. NLRB*, 123 F.2d 215, 224 (8th Cir. 1941) (“If the record on review contains not only all evidence which was clearly admissible, but also all evidence of doubtful admissibility, the court which is called upon to review the case can usually make an end of it, whereas if evidence was excluded which that court regards as having been admissible, a new trial or rehearing cannot be avoided.”))).

Petitioner moves to exclude Exhibit 2024, a document titled “Product Requirements: Guideliner Catheter System,” as well as certain portions of the deposition testimony of Steven Erb (specifically, Ex. 1799, 37:2–7, 37:20–38:6, 39:17–40:20). Paper 65 (the “Motion” or “Mot.”); *see also* Paper 74 (Petitioner’s reply in support of its motion to exclude). Patent Owner opposes the Motion. Paper 69 (“Mot. Opp.”).

Petitioner contends that Exhibit 2024 is unreliable on its face and that none of Patent Owner’s witnesses can authenticate the document. Mot. 2–9. Patent Owner responds that Exhibit 2024 is authenticated under FRE 901 based on the declaration and/or deposition testimony of Mr. Peterson (Ex. 2252 ¶ 18), Ms. Schmalz (Ex. 2039 ¶¶ 6–7), Mr. Root (Ex. 2118 ¶ 57), and Mr. Sutton (Ex. 2119 ¶ 44). Mot. Opp. 3–8.

Documents are authenticated by evidence “sufficient to support a finding that the item is what the proponent claims it is.” Fed. R. Evid. 901(a); *see Fox Factory v. SRAM, LLC*, IPR2016-01876, Paper 59 at 63 (PTAB Apr. 2, 2018) (quoting same). “Authenticity is, therefore, not an especially high hurdle for a party to overcome.” *Fox Factory*, Paper 59 at 63 (citing *United States v. Patterson*, 277 F.3d 709, 713 (4th Cir. 2002)).

We determine that Exhibit 2024 has been authenticated under the low bar required under Federal Rule of Evidence 901 based on the evidence provided by Petitioner. *See* Mot. Opp. 2–11. In addition, Petitioner’s arguments go to the weight of the evidence and not its admissibility. Accordingly, we deny Petitioner’s Motion to Exclude. We note, however, that even if we were to exclude Exhibit 2024, it would not change the outcome or our general analysis of this case.

Petitioner also argues that the portions of the testimony of Mr. Erb it seeks to exclude are prejudicial, citing FRE 403. Mot. 10–15. We find Petitioner fails to show any prejudice. As Patent Owner explains, “[t]he testimony concerned subjects in Mr. Erb’s declaration and about which Petitioner had elicited testimony, Petitioner had the opportunity to (and did) re-cross Mr. Erb, and Petitioner had the opportunity to (and did) submit a sur-reply brief.” Mot. Opp. 11–14 (citing, e.g., Ex. 1799, 10:11–12:16, 38:24–40:21; Ex. 2122 ¶¶ 17–20; IPR2020-01341, Paper 51, 14–15). Accordingly, we deny Petitioner’s motion to exclude testimony of Mr. Erb. We note, however, that even if we were to exclude the testimony at issue, it would not change the outcome or our general analysis of this case.

III. ANALYSIS OF PATENTABILITY

In our analysis of Petitioner’s unpatentability contentions with respect to the Challenged Claims, we next address the priority date of the ’116 patent; applicable principles of law; the level of ordinary skill in the art; the proposed construction of claim terms; the scope and content of the asserted prior art; and then further analyze Petitioner’s contentions with respect to each alleged ground of unpatentability for purposes of determining whether Petitioner shows by a preponderance of the evidence the unpatentability of the Challenged Claims.

A. Priority Date of the ’116 Patent

Petitioner argues that “[t]he ’116 patent is subject to the AIA⁵] first-to-file provisions because (1) it contains claims that lack written description, and therefore pre-AIA priority, and (2) it claims priority to RE 45,380

⁵ Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284 (2011).

(“the ’380 patent”), which is subject to the AIA first-to-file provisions.”

Pet. 12–13. Petitioner contends that because there is no written description support for the subject matter of at least claim 27 of the ’380 patent and claim 45 of the ’116 patent, the ’116 patent has an effective filing date after March 16, 2013. *Id.* at 12–13. Thus, according to Petitioner, the ’116 patent is subject to the AIA’s first-to-file provisions, which precludes Patent Owner from attempting to swear behind Itou’s filing date. *Id.* Patent Owner argues that the Board previously rejected Petitioner’s arguments concerning the ’380 patent, and that Petitioner’s arguments here likewise fail. PO Resp. 5–9; *see also Medtronic Inc. and Medtronic Vascular, Inc., v. Teleflex Innovations S.À.R.L.*, IPR2020-00128, Paper 127 (PTAB June 7, 2021).

The first-to-file provisions apply to patent applications “that contain[] or contained at any time a claim to a claimed invention that has an effective filing date” on or after March 16, 2013. AIA § 3(n)(1). The application for reissue for the ’116 patent was filed March 3, 2014, and sought reissue of U.S. Patent No. 8,292,850, which issued October 23, 2012, from an application filed January 26, 2012. Ex. 1001, codes (22), (64). “The effective filing date for a claimed invention in an application for reissue or reissued patent shall be determined by deeming the claim to the invention to have been contained in the patent for which reissue was sought.” 35 U.S.C. § 100(i)(2) (2018). As the “patent for which reissue was sought” in this case was issued October 23, 2012, we are not persuaded that the AIA’s first-to-file provisions apply to the ’116 patent. Indeed, Petitioner provides no legal support for the proposition that claims in a reissue patent are not entitled to a

filing date as if they appeared in the original patent for which reissue was sought.⁶

B. Principles of Law

Under one ground, Petitioner contends that claims of the '116 patent are unpatentable based on anticipation. Pet. 23–31. A claim is anticipated if a single prior art reference either expressly or inherently discloses every limitation of the claim. *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 975 (Fed. Cir. 2010). “A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference.” *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 958 (Fed. Cir. 2014) (citing *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003)).

Petitioner contends under two grounds that claims of the '116 patent are unpatentable based on obviousness. Pet. 32–80. As set forth in 35 U.S.C. § 103(a),

[a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when in evidence, objective evidence of

⁶ To the extent the original patent for which reissue was sought does not contain written description support for a reissue claim, that claim may be invalid. But this is a question we may not address in an IPR. 35 U.S.C. § 311(b).

nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). An obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007); accord *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007). However, Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). Instead, Petitioner must articulate a reason why a person of ordinary skill in the art would have combined the prior art references. *In re NuVasive*, 842 F.3d 1376, 1382 (Fed. Cir. 2016).

C. Level of Ordinary Skill in the Art

In determining whether an invention would have been obvious at the time it was made, 35 U.S.C. § 103 requires us to resolve the level of ordinary skill in the pertinent art at the time of the invention. *Graham*, 383 U.S. at 17. The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). In determining the level of ordinary skill in the art, various factors may be considered, including the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *Id.*

Petitioner contends that a person of ordinary skill in the art at the time of the invention would have been either: (1) a medical doctor who would have had “(a) a medical degree; (b) completed a coronary intervention

training program, and (c) experience working as an interventional cardiologist;” or (2) an engineer who would have had “(a) an undergraduate degree in engineering, such as mechanical or biomedical engineering; and (b) at least three years of experience designing medical devices, including catheters or catheter-deployable devices.” Pet. 13–14.

Additionally, Petitioner contends “[e]xtensive experience and technical training might substitute for education, and advanced degrees might substitute for experience.” *Id.* at 14. Further, according to Petitioner, a person of ordinary skill in the art “with a medical degree” and a person of ordinary skill in the art “with an engineering degree” may have had access to each other. *Id.* (citing Ex. 1005 ¶ 31; Ex. 1042 ¶¶ 18–19).

Patent Owner does not dispute Petitioner’s proposed level of ordinary skill. PO Resp. 5. We adopt Petitioner’s proposed level of ordinary skill in the art as it is undisputed and consistent with the level of skill reflected in the prior art and the specification of the ’116 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate level and a need for testimony is not shown”) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

As their qualifications are undisputed, we also determine that the parties’ experts are qualified to opine on the issues in this proceeding from the perspective of a person of ordinary skill in the art. Ex. 1042 ¶¶ 5, 10, 12

(Dr. Hillstead's qualifications);⁷ Ex. 1807 ¶¶ 8–10 (Mr. Jones's qualifications); Ex. 2138 ¶¶ 3–6 (Mr. Keith's qualifications); Ex. 2145 ¶ 1 (Dr. Graham's qualifications); *see Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1376–77 (Fed. Cir. 2022) (“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.”).

D. Claim Construction

“In an *inter partes* review proceeding, a claim of a patent . . . shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R. § 42.100(b). That standard “includ[es] construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.*; *see also Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

Petitioner proposes the following constructions: (1) “substantially rigid” as “rigid enough to allow the device to be advanced within the guide catheter,” (2) “side opening” needs no construction and should be given its plain and ordinary meaning, (3) “lumen” as “the cavity of a tube,” and (4) “flexural modulus” as “[a] measure of resistance . . . to bending.”

⁷ Patent Owner argues that Dr. Hillstead does not meet the definition of a person of ordinary skill in the art because he lacks a four-year undergraduate degree in engineering. PO Resp. 5 n.1 (citing, e.g., Ex. 2137, 462:8–13). As noted above, however, it is undisputed that “[e]xtensive experience and technical training might substitute for education.” Pet. 14. Patent Owner does not address Dr. Hillstead's significant professional experience, which we find sufficient to show he is qualified to opine on the issues in this proceeding from the perspective of a person of ordinary skill in the art. *See* Ex. 1043 (curriculum vitae of Dr. Hillstead).

Pet. 14–15 (quoting Ex. 1040, 772) (alterations in original). Patent Owner does not dispute at this stage of the proceeding Petitioner’s proposed construction of these terms. *See generally* PO Resp. In view of the issues we address below, we determine it is not necessary to address the express interpretation of any claim term. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017); *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy”).

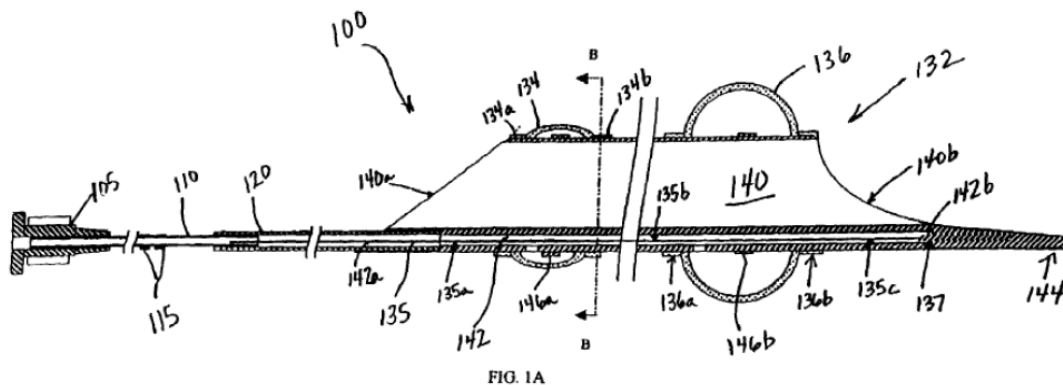
E. Scope and Content of the Prior Art

Petitioner relies on Ressemann, Itou, and Kataishi, each of which we briefly summarize in relevant part below.

1. Summary of Ressemann

Ressemann, titled “Emboli Protection Devices and Related Methods of Use,” states that it is directed to an apparatus “used to prevent the introduction of emboli into the bloodstream during and after surgery performed to reduce or remove blockage in blood vessels.” Ex. 1008, code (54), 1:13–16.

Figures 1A and 1B of Ressemann are reproduced below:



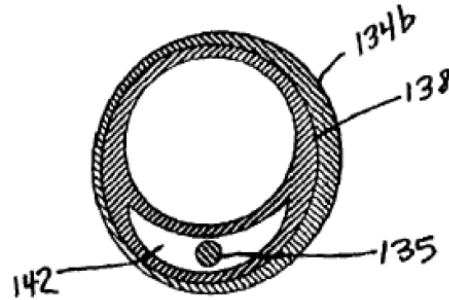


FIG. 1B

Figure 1A is a cross-sectional view of a partial length evacuation sheath. *Id.* at 3:16–18. Figure 1B is a cross-sectional view of the partial length evacuation sheath of Figure 1A, taken along line 1B–1B of Figure 1A. *Id.* at 3:19–20.

Figure 1A depicts evacuation sheath assembly 100, which “is sized to fit inside a guide catheter” and be advanced “into a blood vessel to treat a stenosis.” *Id.* at 6:18–24, Fig. 5A. Evacuation sheath assembly 100 includes a shaft having proximal shaft portion 110, intermediate shaft portion 120, and distal shaft portion 130 (not shown in Figure 1A). *Id.* at 10:30–35. Evacuation head 132 includes multi-lumen tube 138, having evacuation lumen 140 and inflation lumen 142, and is preferably made of a relatively flexible polymer. *Id.* at 6:35–64. Evacuation lumen 140 is preferably larger than inflation lumen 142 and “is designed to allow for the passage of interventional devices such as, but not limited to stent delivery systems and angioplasty catheters.” *Id.* at 6:44–47. Proximal and distal ends of evacuation lumen 140 are angled to allow for smoother passage of evacuation sheath assembly 100 through a guide catheter and to facilitate smoother passage of other therapeutic devices through evacuation lumen 140. *Id.* at 6:52–57. According to Ressemann, “[t]he larger area of

the angled open ends also allows for larger deformable particulate matter to pass through the lumen more smoothly.” *Id.* at 6:58–60.

Stiffness transition member 135 is attached to the distal end of proximal shaft portion 110, “is located co-axially in the inflation lumen 142,” and extends to soft tip 144. *Id.* at 11:30–39. Inflation lumen 142, having open proximal end 142a and closed distal end 142b, is designed to provide fluid to inflate balloons on evacuation head 132. *Id.* at 6:61–64.

In use, a guiding catheter is directed to a blood vessel, and then a coronary guide wire is advanced to a location just proximal to the distal tip of the guiding catheter. *Id.* at 12:9–14. Evacuation sheath assembly 100 is then advanced over the guide wire and positioned within the blood vessel. *Id.* at 12:19–21. In this process, evacuation head 132 is positioned with its distal end within the blood vessel while its proximal end remains in the guiding catheter. *Id.* at 12:37–39. Sealing balloons 136 and 134 are then inflated to provide a fluid seal between the sealing balloons and the blood vessel. *Id.* at 12:40–45.

Figure 6D of Ressemann is reproduced below:

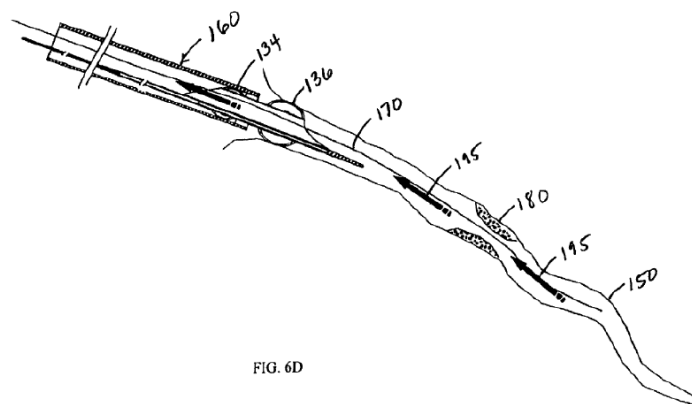


FIG. 6D

Figure 6D is a cross-sectional view of the partial length evacuation sheath of Figures 1A and 1B deployed within a blood vessel. *Id.* at 3:59–61. As shown in Figure 6D, guidewire 170 may be advanced beyond stenosis 180 in

blood vessel 150. *Id.* at 13:3–16. A therapeutic device, such as a stent, may then be advanced over guide wire 170 and across stenosis 180. *Id.* at 13:57–60. As indicated by arrows 195, blood flow within the blood vessel is directed towards evacuation sheath 100. *Id.* at 13:35–41. According to Ressemann, “[t]his retrograde flow will carry any dislodged material out of the patient and into a collection chamber.” *Id.* at 13:43–44. The assembly, which includes a guide catheter, “may be positioned within the ostium of the target vessel.” *Id.* at 12:26–27.

2. Summary of Itou

Itou, titled “Intravascular Foreign Matter Suction Assembly,” issued on June 15, 201, from a non-provisional application filed September 23, 2005. Ex. 1007, codes (22), (45), (54). Itou discloses “an intravascular foreign matter suction assembly” designed to suck, sample, and remove “foreign matter such as a thrombus or an embolus” from a blood vessel. *Id.* at 1:6–9, 1:47–49. This assembly includes a guiding catheter and a suction catheter configured to be inserted into the lumen of the guiding catheter. *Id.* at 1:49–65.

Figure 3 of Itou is reproduced below:

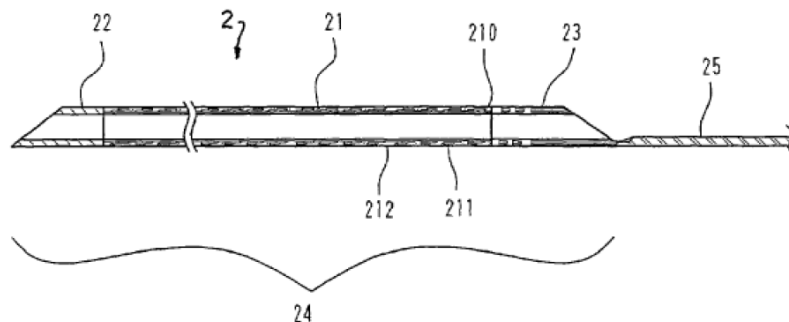


Figure 3 is a cross section of a distal end portion of suction catheter 2. *Id.* at 2:61–62. Suction catheter 2 includes distal side tubular portion 24 and proximal side wire-like portion 25, formed from a solid metal wire and an

outer layer such as a polymer coating. *Id.* at 3:46–50. Tubular portion 24 has reinforced tubular portion 21 and flexible distal tip 22. *Id.* at 2:15–51, 3:50–58. Tubular portion 24 has an outer diameter that allows it to be inserted into the lumen of a guide catheter and wire-like portion 25 has a sectional area smaller than the sectional area of the tube wall of tubular portion 24. *Id.* at 3:59–63.

Figure 5 of Itou is reproduced below:

FIG.5

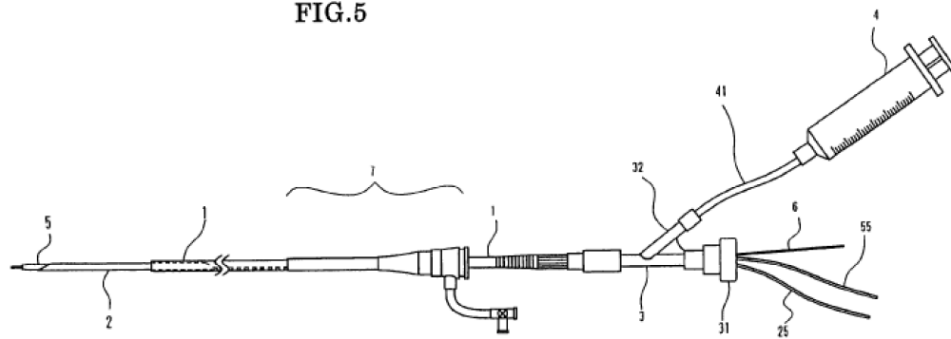


Figure 5 shows the suction assembly “in an assembled state.” *Id.* at 2:66–67. In this state, suction catheter 2 is disposed in the lumen of guiding catheter 1. *Id.* at 5:12–14. The distal end of protective catheter 5 is inserted into the lumen of suction catheter 2 and guide wire 6 is inserted into the lumen of protective catheter 5. *Id.* at 5:14–17. The proximal ends of suction catheter 2, protective catheter 5, and guide wire 6 are “introduced to the outside through main connector portion 31 of Y-shaped connector 3.” *Id.* at 5:17–20. A valve is built into main connector 31 and “can selectively clamp and fix” guide wire 6 and wire-like portions 25 or 55 “to prevent leakage of the blood.” *Id.* at 5:20–23. In one embodiment, the inner diameter of the guiding catheter is 1.8 mm and the inner diameter of the suction catheter is 1.5 mm. *Id.* at 7:55–67 (Table 1).

A portion of Figure 6 of Itou is reproduced below:

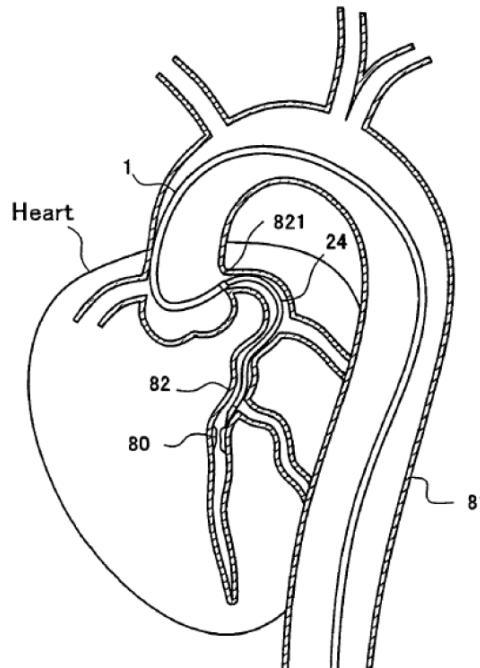


Figure 6 illustrates the disclosed apparatus disposed in a coronary artery of the heart. *Id.* at 3:1–3. In Figure 6, guiding catheter 1 is disposed in aorta 81 and its distal end “is secured in such a form that it is hooked at an ostium 821 of coronary artery 82.” *Id.* at 5:29–34. Tubular portion 24 of suction catheter 2 is inserted into coronary artery 82 and is introduced along guide wire 6 to target location 80. *Id.* at 5:35–38. According to Itou, tubular portion 24 of suction catheter 2 has a “sufficient axial length so that the proximal end of the tubular portion 24 in an open state may not leap out from the distal end of the guiding catheter 1.” *Id.* at 5:38–41.

3. *Summary of Kataishi*

Kataishi, titled “Thrombus Suction Catheter with Improved Suction and Crossing,” teaches “a thrombus suction catheter with improved suction and crossing having a small pressure loss, which is a tube having a lumen passing through from a proximal end to a distal end, a distal end opening

having an angled cut surface.” Ex. 1025, code (54), ¶ 10. Figure 1 of Kataishi, reproduced below, is a front view of a thrombus suction catheter.

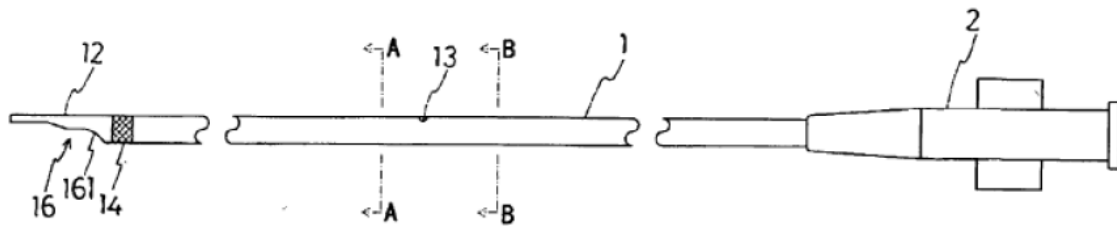


Fig. 1

As shown in Figure 1, a thrombus suction catheter includes a catheter body 1, a connector 2 provided at a proximal end of the catheter body 1, a distal end opening 12 formed by an angled cut surface, and a guide wire insertion port 13. *Id.* ¶¶ 27, 29.

F. Alleged Anticipation by Ressemann

Petitioner contends that claims 52 and 53 are anticipated by Ressemann. Pet. 23–31. Petitioner provides a detailed explanation of how it contends Ressemann discloses each of the limitations of claims 52 and 53. *Id.* In particular, Petitioner explains how Ressemann’s disclosures of the use of features including guide catheter 160, evacuation sheath assembly 100, intermediate shaft portion 120, distal shaft portion 130, lumen 140, and stent delivery system 194 correspond to the recited methods of claims 52 and 53. *Id.* Petitioner’s contentions are supported by Dr. Brecker and Dr. Hillstead. Ex. 1005 ¶¶ 164–174; Ex. 1042 ¶¶ 36–39, 58–62.

Patent Owner does not dispute that claims 52 and 53 are anticipated by Ressemann. *See generally* PO Resp; PO Sur-reply; *see also* Pet. Reply 2 (Petitioner arguing that Patent Owner did not dispute that Ressemann anticipates claims 52 and 53). After reviewing the record, we find Petitioner shows by a preponderance of the evidence that Ressemann discloses each

limitation of claims 52 and 53 and adopt Petitioner's mapping of these limitations (Pet. 23–31) as our own findings. Accordingly, Petitioner shows by a preponderance of the evidence that Ressemann anticipates claims 52 and 53 of the '116 patent.

G. Alleged Obviousness over Itou and Ressemann

Petitioner asserts that claims 25–40, 42, 44–48, 52, and 53 of the '116 patent would have been obvious over Itou in combination with Ressemann. Pet. 32–74; Pet. Reply 2–34. Patent Owner disputes Petitioner's contentions. PO Resp. 9–55; PO Sur-reply 1–28.

1. Whether Itou is Prior Art

Petitioner contends that Itou is prior art under pre-AIA § 102(e). Pet. 19. Itou was filed on September 23, 2005, published on March 30, 2006, and issued on June 15, 2010. Ex. 1007, codes (22), (45), (65). Patent Owner argues that Itou is not prior art because the “GuideLiner invention” was conceived and reduced to practice prior to the critical date of Itou's September 23, 2005, filing date. PO Resp. 2–4, 9.

a) Legal Standards

“To antedate (or establish priority) of an invention, a [patent owner] must show either an earlier reduction to practice, or an earlier conception followed by a diligent reduction to practice.” *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1365 (Fed. Cir. 2001)). “Conception is the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice.” *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998)). “A reduction to practice can be either a constructive reduction to practice, which occurs when a patent application is filed, or an actual reduction to practice.” *Id.* “In order to establish an actual reduction to

practice, the inventor must prove that: (1) he constructed an embodiment or performed a process that met all the limitations of the [claimed invention]; and (2) he determined that the invention would work for its intended purpose.” *Id.*

If a patent owner has not shown actual reduction to practice prior to the “critical date” of a reference, the patent owner may nonetheless antedate the reference by establishing prior conception and reasonable diligence towards a constructive reduction to practice. *Purdue Pharma*, 237 F.3d at 1365. “Reasonable diligence must be shown throughout the entire critical period, which begins just prior to the competing reference’s effective date and ends on the date of the invention’s reduction to practice.” *Arctic Cat Inc. v. GEP Power Prods., Inc.*, 919 F.3d 1320, 1331 (2019). However, the “diligence need not be perfectly continuous—only reasonably continuous.” *Id.*

To be persuasive, an inventor’s testimony of conception and reduction to practice must be corroborated by other independent evidence. “Conception must be proved by corroborating evidence which shows that the inventor disclosed to others his completed thought expressed in such clear terms as to enable those skilled in the art to make the invention.” *REG Synthetic Fuels, LLC v. Neste Oil Oyj*, 841 F.3d 954, 962 (Fed. Cir. 2016) (internal quotation marks omitted). “However, there is no final single formula that must be followed in proving corroboration.” *Id.* (quotation marks omitted); *see also Kolcraft Enters., Inc. v. Graco Children’s Prods., Inc.*, 927 F.3d 1320, 1324 (Fed. Cir. 2019); *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1169–70 (Fed. Cir. 2006).

“In the final analysis, each corroboration case must be decided on its own facts with a view to deciding whether the evidence as a whole is

persuasive.” *Berges v. Gottstein*, 618 F.2d 771, 776 (CCPA 1980).

Corroborating evidence may consist of “testimony of a witness, other than the inventor,” or “evidence of surrounding facts and circumstances independent of information received from the inventor.” *Medichem*, 437 F.3d at 1171. “Even the most credible inventor testimony is a fortiori required to be corroborated by independent evidence, which may consist of documentary evidence as well as the testimony of non-inventors.” *Id.* at 1171–72. We assess whether evidence corroborates conception and reduction to practice under a “rule of reason” analysis. *Cooper*, 154 F.3d at 1330.

In an *inter partes* review, 35 U.S.C. § 316(e) imposes the ultimate burden of persuasion to “prove unpatentability by a preponderance of the evidence” onto the petitioner. This burden never shifts to the patent owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). However, when the patent owner attempts to antedate the prior art, “[a] second and distinct burden, the burden of production” can shift between the petitioner and the patentee. *Id.* at 1379; *see In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1375–76 (Fed. Cir. 2016). Specifically, the patent owner “bears the burden of establishing that its claimed invention is entitled to an earlier priority date than an asserted prior art reference.” *Magnum Oil Tools*, 829 F.3d at 1375–76. Once the patent owner establishes it is entitled to an earlier priority date, the burden of production then shifts back to the petitioner “to convince the court that [the patent owner] is not entitled to the benefit” of the earlier priority date. *Dynamic Drinkware*, 800 F.3d at 1379 (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1328 (Fed. Cir. 2008)).

b) Prior Related Cases Involving Itou

Itou was asserted as prior art in several prior *inter partes* review proceedings between the parties concerning patents related to the '116 patent. IPR2020-00126 (concerning Patent 8,048,032 B2 with claims directed to a device); IPR2020-00128 and IPR2020-00129 (concerning Patent RE45,380 E with claims directed to a device); IPR2020-00132 and IPR2020-00134 (concerning Patent RE45,760 E with claims directed to a system); IPR2020-00135 (concerning Patent RE45,776 E with claims directed to a device); IPR2020-00137 (concerning Patent RE47,379 E with claims directed to methods of forming a device). In each of those cases, based on substantially the same evidence concerning the GuideLiner invention presented in this case, the Board concluded that Itou was not prior art.⁸

In this case the parties were asked to brief the issue of whether collateral estoppel or issue preclusion applied to any issue the Board previously resolved in related proceedings, including the Board's prior resolution of issues of conception and reduction to practice related to Itou as prior art. *See* Paper 75 (Order requesting additional briefing); Paper 80 (Petitioner's Opening Brief on Collateral Estoppel); Paper 81 (Patent Owner's Opening Brief on Collateral Estoppel); Paper 89 (Petitioner's Responsive Brief on Collateral Estoppel); Paper 90 (Patent Owner's Responsive Brief on Collateral Estoppel). In short, Petitioner argues, in part,

⁸ In one additional proceeding between the parties concerning a patent related to the '116 patent, Itou was asserted, however, we found Petitioner failed to show the claims challenged in that proceeding unpatentable by a preponderance of the evidence without reaching the issue of whether Itou was prior art. IPR2020-01341 (concerning Patent 8,142,413 B2 with claims directed to a method of use).

that the first set of *inter partes* review proceedings are not final because they are on appeal, and that the Board must address new reduction-to-practice issues. Paper 89, 1–3. Petitioner further argues as follows:

The Board cannot adopt its findings from the first set of IPRs, wholesale, to resolve the reduction-to-practice issues in these IPRs. PO concedes that these IPRs created new reduction-to-practice issues, specifically, whether VSI [Vascular Solutions, Inc. (“VSI”), Patent Owner’s predecessor-in-interest], performed the claimed methods, and whether those methods require using the claimed guide extension catheter *in vivo*. The intended purpose inquiry has new dimensions, too: the Board must consider whether VSI performed testing sufficient to demonstrate the methods’ intended purpose, which Petitioner contends requires (1) simulating the methods using a guide catheter and, separately, a guide catheter plus guide extension catheter, and (2) comparing the results. The Board has yet to consider whether the intended purpose—to provide increased backup support—required 4 comparative testing. Finally, though PO produced no new evidence to prove diligence, the Board must consider whether that evidence shows reasonably continuous diligence in reducing to practice the new inventions reciting more than a guide extension catheter

Id. at 4. Patent Owner argues that the prior decisions of the Board are sufficiently final, and that collateral estoppel applies, at least to certain issues related to, for example conception and reduction to practice.

Paper 90, 1–5. Patent Owner further argues that “out of an abundance of caution” we should “alternatively adopt the numerous findings that are clearly identical between the prior” proceedings and this case.” We decline to reach the issue of whether estoppel applies for purposes of this decision. Nonetheless, we find the factual determinations concerning the reduction to practice of the GuideLiner made in the prior related proceedings are highly relevant to our determination here. We find, for purposes of this proceeding, the same factual findings we previously reached upon consideration of

substantially the same evidence, as noted below. We apply those factual findings to the issue of whether Itou is prior art to the Challenged Claims in this case.

c) Conception

Patent Owner argues that Itou does not qualify as prior art based on research and development related to the GuideLiner invention that took place at VSI, Patent Owner's predecessor-in-interest, starting around early 2005. PO Resp. 9–13. In addition to declaration testimony from Mr. Root (Ex. 2118), Mr. Sutton (Ex. 2119), and Mr. Erb (Ex. 2122), Patent Owner relies on corroborating documents to show conception, including contemporaneous drawings. *Id.* (citing, e.g., Exs. 2253, 2255). The Board addressed the issue of conception of the GuideLiner invention at length in the prior *inter partes* reviews concerning related patents where Petitioner had contested conception, and concluded in those cases that conception occurred no later than August 2005. *See, e.g., Medtronic, Inc. and Medtronic Vascular, Inc., v. Teleflex Innovations S.A.R.L.*, IPR2020-00132, Paper 125, 15–31 (PTAB June 7, 2021) (the “IPR-132 Final Written Decision”).

Petitioner does not contest Patent Owner's demonstration of conception in this case. *See generally* PO Resp.; *see also* Tr. 19:11–15 (counsel for Petitioner stating “I would say that the Board can find conception in this case because we don't dispute it”). Having reviewed the undisputed argument and evidence relied upon by Patent Owner, we find that Patent Owner shows conception prior to the critical date of Itou.

d) Actual Reduction to Practice

Patent Owner argues the GuideLiner invention was reduced to practice prior to September 23, 2005, the critical date of Itou. PO Resp. 9. Patent Owner argues as follows:

Reduction to practice of method claims occurs when the inventors perform a process that meets the claimed invention and demonstrates that the invention is “suitable for its intended purpose.” *Scott v. Finney*, 34 F.3d 1058, 1061 (Fed. Cir. 1994) (citations omitted). Before the GuideLiner, standard guide catheters were limited in their ability to navigate past the ostium of a coronary artery of interest and to the point of the stenosis. Ex-1001, 1:44-3:11; *see* Ex-2151, ¶¶4-8; Ex-2215, ¶¶10-19. The intended purpose of the GuideLiner invention was to provide increased backup support with a rapid exchange configuration that would allow physicians to more effectively deliver ICDs to the treatment site. *E.g.* Ex-1001, 3:12-16; Ex-2118, ¶6, 19, 50; Ex-2123, ¶19.

Id. at 13. Patent Owner further argues that “[w]ith GuideLiner, little to no testing was required to show the invention worked for its intended purpose.”

Id. at 13–14 (further asserting that “[w]hen the principles of operation of the invention are not complex, little or no testing is required” (citing *In re Asahi/America Inc.*, 68 F.3d 442, 446–47 (Fed. Cir 1995))).

In support of actual reduction to practice, Mr. Root attests in his declaration that employees at VSI, led by co-inventors Mr. Sutton and Mr. Welch, built and tested rapid exchange (“RX”) GuideLiner prototypes between January and August 2005.⁹ Ex. 2118 ¶ 15. Mr. Sutton, as well as two non-inventors employed by VSI at the time, Steve Erb and Deborah

⁹ Mr. Root explains that Patent Owner does not have many development documents from 2005, and it obtained many of the documents relevant to actual reduction to practice from VSI’s vendors and patent prosecution firm. Ex. 2118 ¶ 23.

Schmalz, also testify about relevant details of the research and development done with regard to the GuideLiner prototypes. Ex. 2039 (Schmalz Declaration); Ex. 2119 (Sutton Declaration); Ex. 2122 (Erb Declaration). Patent Owner also presents the declarations of Mark Goemer and Amanda O’Neil, who were employed by outside vendors from whom VSI purchased components to build the prototypes. Ex. 2120 (Goemer Declaration); Ex. 2121 (O’Neil Declaration). Additionally, Patent Owner has submitted an expert declaration by Mr. Peter Keith in further support of its reduction to practice arguments. Ex. 2123. Patent Owner relies upon purchase invoices, engineering schematics, and other documentary evidence from as early as January 2005 through the September 2005 critical date of Itou in order to corroborate the fact declarants’ testimony regarding actual reduction to practice.¹⁰

We once again set forth the relevant facts based on these declarants’ testimony and corroborating evidence, and then address any disputed issues of material fact and legal issues as needed in our analysis for actual reduction to practice.

(1) Fact Findings for Actual Reduction to Practice

After the inventors came up with the initial idea for the device (*see* PO Resp. 9–13 discussing conception), VSI proceeded with the development

¹⁰ Patent Owner includes some documentary evidence created after Itou’s critical date. *See, e.g.*, Ex. 2106 (invoices dated April 2006); Exhibit 2115 (engineering drawing dated Nov. 1, 2005). We do not find this post-critical date evidence to support Patent Owner’s contentions regarding actual reduction to practice. However, we have considered some of this evidence in our analysis of whether there was diligence towards constructive reduction to practice (*see* discussion, *infra*), as well as to address Petitioner’s argument that the continuing work done at VSI with respect to the GuideLiner demonstrates a lack of actual reduction to practice before Itou.

of both an RX version and an over-the-wire (“OTW”) version of the GuideLiner concurrently. Ex. 2118 ¶ 22; Ex. 2119 ¶ 15. Although it was based on existing technology, VSI decided to pursue the OTW version based on the belief that it could be brought to market more quickly with fewer regulatory challenges than the RX version. Ex. 2118 ¶ 22; Ex. 2119 ¶ 15. Nonetheless, the RX version remained a priority for continued development at VSI. *Id.* Consistent with Mr. Root’s testimony, Mr. Sutton testifies that the RX GuideLiner was reduced to practice before September 2005, although further work towards commercialization of the product continued until he left the company. Ex. 2119 ¶ 6. According to Mr. Sutton, work for the OTW prototype “paled in comparison” to work required for the RX prototype because the OTW prototype “required very little engineering and was relatively easy to build because it was based on existing technology.” *Id.* ¶ 15. In their declarations, Mr. Root and Mr. Sutton focus on two distinct sets of prototypes of the RX version that were built and tested before Itou’s critical date: the “April 2005” prototypes and the “July 2005” prototypes. Ex. 2118 ¶ 51; Ex. 2119 ¶¶ 21–22.¹¹

Mr. Root includes claim charts identifying how the April and July 2005 prototypes satisfied the limitations of the challenged claims. Ex. 2118, App’x B; *see also* Ex. 2123 ¶ 28 (Mr. Keith opining that the April and July 2005 prototypes satisfy the claim limitations based on these claim charts). In developing these prototypes, a VSI technician and

¹¹ Although Mr. Root refers to the likelihood that other sets of prototypes were also built, the bulk of Patent Owner’s evidence and arguments relate to the April and July 2005 prototypes. Ex. 2118 ¶ 51. As such, we focus on these prototypes in determining whether there was actual reduction to practice.

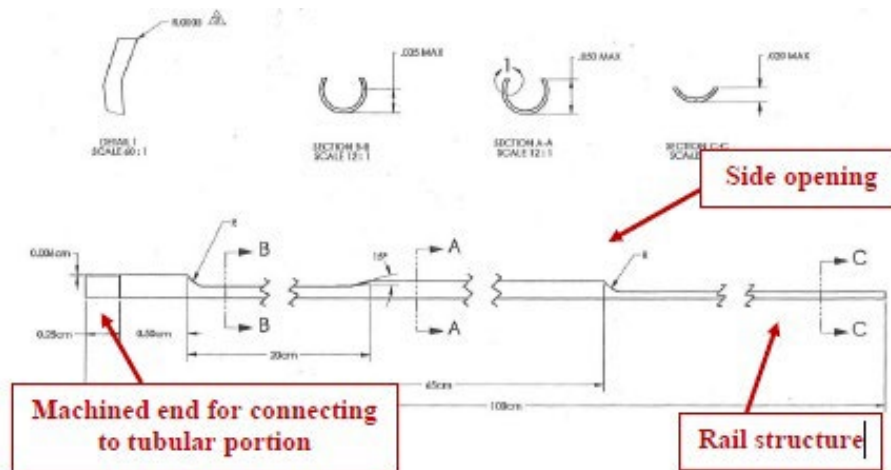
machinist, Mr. Erb, worked with the inventors to mechanically cut down stainless steel or nitinol “hypotubes” used for the proximal portion of an RX prototype. Ex. 2118 ¶ 16; Ex. 2119 ¶ 20; Ex. 2122 ¶¶ 8–10. The profile of some of these hypotubes started at full circumference at the distal end, then progressed to roughly half-round at the proximal end. Ex. 2118 ¶ 16. The hypotubes were combined with a polymer distal section to create the first RX GuideLiner prototypes. *Id.* At this time, the distal tubular portion was sometimes built by cutting a standard guide catheter to the appropriate length. *Id.* ¶ 27. The earliest prototypes, made in January or February 2005, largely comprised stock components modified through VSI’s in-house machining capabilities. *Id.* ¶¶ 18, 19, 23. However, by April 2005, the VSI engineers progressed to building more formal prototypes using custom-ordered materials from outside vendors for the proximal and distal portions of the device. Ex. 2122 ¶ 12. A spend report details at least some of the expenses that VSI incurred on purchases of the components used to build GuideLiner prototypes from February 11, 2005, to June 30, 2006. Ex. 2256; Ex. 2118 ¶¶ 24–25. According to Mr. Root, the fact that they had opened an account specific to the “Guideliner project” in May 2005, as reflected in this spend report, indicates that development had advanced to the point that they were confident with proceeding towards commercialization. Ex. 2118 ¶ 25.

With respect to the proximal portions, Patent Owner presents invoices and other documents reflecting VSI’s purchases of laser-cut hypotubes from three outside vendors: MicroGroup, Mountain Machine, Inc., and SPECTRAlytics. Ex. 2118 ¶¶ 26, 30, 32, 33, 35, 36, 43, 46 (citing Exs. 2257, 2007, 2009, 2010, 2013, 2020, 2091, 2094, 2095, 2110, 2111); Ex. 2119 ¶¶ 24–31 (discussing similar purchases); *see also* Ex. 2122 ¶ 7 (discussing purchases of stainless steel and nitinol hypotubes as reflected in

Ex. 2110).¹² Because some of these invoices show purchases of the hypotubing by the foot, Mr. Root asserts that the materials were likely used for early evaluations of the RX GuideLiner concept. Ex. 2118 ¶ 26.

Mr. Sutton similarly asserts that the hypotubing that was purchased at this time was used to make RX GuideLiner prototypes, as the OTW version never involved such hypotubing. Ex. 2119 ¶ 23. The ranges of the inner and outer diameters, wall thickness, and the overall length of the hypotubes that were ordered were consistent with what VSI would have needed at the time for prototyping the RX GuideLiner. *Id.* ¶¶ 24, 26.

Mr. Root and Mr. Sutton also reference the following annotated engineering schematics of the proximal portion of the RX GuideLiner that were drawn by a VSI engineer, Jim Kauphusman, on February 4, 2005:



Ex. 2113; Ex. 2118 ¶ 37; Ex. 2119 ¶ 30. The drawings above show a design of the proximal portion with multiple angled transition regions bookending

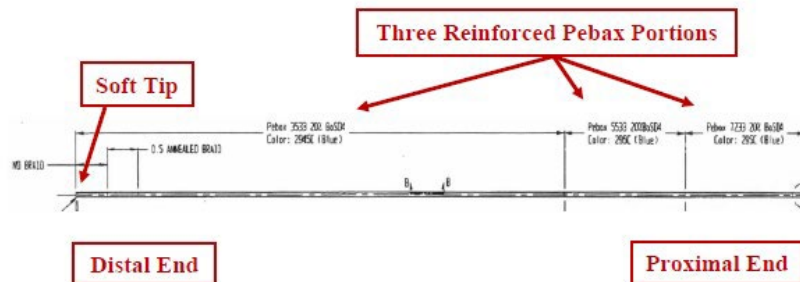
¹² Although both stainless steel and nitinol hypotubes were ordered, Mr. Sutton asserts that nitinol was significantly more expensive and required additional post-processing steps as compared to stainless steel, and these factors ultimately weighed against using nitinol for the proximal portion of the RX GuideLiner. Ex. 2119 ¶ 28.

non-inclined regions, and annotations added for this proceeding identify a “machined end for connecting to tubular portion,” a “side opening,” and a “rail structure.” Ex. 2113; Ex. 2118 ¶ 37; Ex. 2119 ¶ 30. These drawings were submitted as “prints” to SPECTRAlytics in order to specify the parameters for the hypotubes that were custom ordered, and include a drawing number “SS HYPO X04” that correlates to a purchase completed on April 4, 2005. Ex. 2118 ¶ 37; Ex. 2120 ¶ 9; Ex. 2095. Additional engineering drawings for the proximal portions were submitted to SPECTRAlytics around June 2005. Ex. 2118 ¶ 44; Ex. 2120 ¶ 11; Ex. 2114. Some of the engineering drawings are similar to figures included in the challenged patent. *Cf.* Ex. 1001, Figs. 12–16.¹³

Mr. Goemer verifies and authenticates some of the purchase documents and the engineering drawings retrieved from SPECTRAlytics’s files. Ex. 2120 ¶¶ 6–12. Additionally, Mr. Root and Mr. Sutton refer to purchases of distal tubular portions and the distal forming tips from vendors Medical Engineering & Design Inc. (“MED”) and Farlow’s Scientific Glassblowing Inc. between February and July 2005. Ex. 2118 ¶¶ 31, 34, 47, 48 (citing Exs. 2011, 2021, 2090, 2092); Ex. 2119 ¶¶ 32–34, 36 (additionally citing Exs. 2032, 2033, 2034, 2035, 2089, 2097, 2112). Ms. O’Neil, who is employed by MED’s successor TE Connectivity (“TE”), verifies and authenticates some of these purchase documents, and notes that the documents were retrieved from the files of TE, but originated with MED in 2005. Ex. 2121 ¶¶ 5–6.

¹³ Mr. Sutton faxed these drawings to VSI’s outside patent counsel on March 21, 2006. Ex. 2118 ¶ 45; Ex. 2019.

One of the documents from MED also includes engineering schematics for the distal portion that were drawn on February 10, 2005, by Mr. Kauphusman, as shown below:

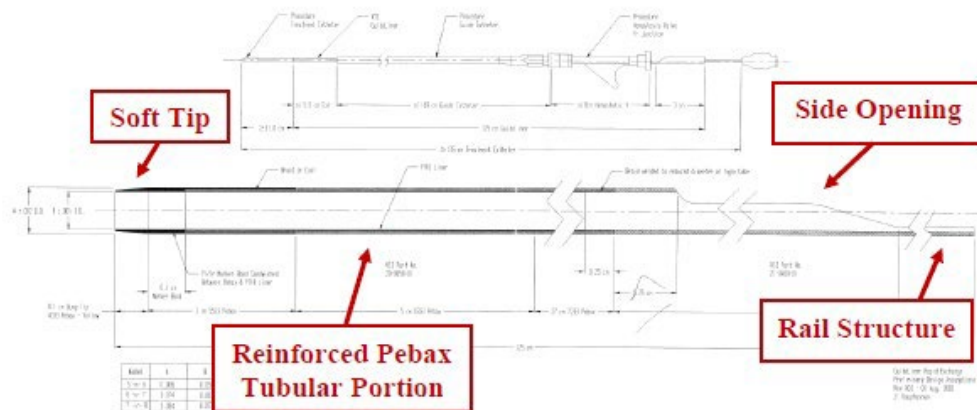


Ex. 2089, 8; Ex. 2118 ¶ 28; Ex. 2119 ¶ 32. The drawing above shows the distal portion annotated to identify a “soft tip,” “three reinforced Pebax portions,” the “distal end,” and the “proximal end.” Ex. 2089, 8. Although Exhibit 2089 does not specify that the tubing was for the RX version of the GuideLiner, Mr. Root and Mr. Sutton assert that the drawings and specifications were in fact specific to an RX device based on the notation that the proximal end should be “counter bored” (a requirement to facilitate attachment to the cut-down hypotube) as well as the overall length of 11.8 inches (because if this part were for an OTW device, it would have been significantly longer). *Id.* The order for distal portions as shown in Exhibit 2089 was placed on February 17, 2005, and the parts were shipped from MED and delivered to VSI on or about April 5, 2005. Ex. 2118 ¶ 28; Ex. 2119 ¶ 33. An update to the drawing shown in Exhibit 2089 was made on April 6, 2005, as shown in Exhibit 2092, with only minor changes, namely slightly reduced inner and outer diameters to fit a guide catheter and a slightly shortened tip. Ex. 2092, 8; Ex. 2118 ¶ 47. An order for distal

tubular portions based on the updated design was placed on April 12, 2005 and those parts were delivered to VSI on or about June 16, 2005. *Id.*

The proximal and distal portions that were custom ordered and purchased from the outside vendors were thereafter combined in-house at VSI to form the prototypes of the complete RX GuideLiner. Ex. 2118 ¶ 27 (“From the earliest stages of the project, the plan was to combine the substantially rigid proximal portion of the rapid exchange GuideLiner with a distal polymer tubular portion that would be at least partially reinforced with coil or braid”); Ex. 2119 ¶ 34 (“[W]e combined these distal sections from MED with the proximal stainless steel sections discussed above to form prototypes of the GuideLiner rapid exchange in April and July 2005”). For example, the first set of formal prototypes (the April prototypes) appear to have been made by combining the laser-cut hypotubes from SPECTRAlytics with the distal tubular sections from MED that were shipped around April 5, 2005. Ex. 2118 ¶ 38 (citing Exs. 2011, 2089). Additional prototypes (the July prototypes) appear to have been built using the hypotubes from MicroGroup shipped around April 20, 2005, and/or the hypotubes from SPECTRAlytics shipped around July 18, 2005, in combination with the updated distal portions from MED shipped around June 16, 2005. *Id.* ¶¶ 42, 43, 49 (citing Exs. 2020, 2021, 2092, 2094, 2114). In making these prototypes, VSI “used an in-house thermal process to fuse the distal tubing sections from MED to the cut-down hypotubes.” Ex. 2119 ¶ 35. VSI had the materials and equipment available to assemble the device at their facilities. *Id.*

As further evidence of an assembled device, inventors Mr. Root and Mr. Sutton reference the following engineering CAD schematics from August 1, 2005:



Ex. 2118 ¶ 52; Ex. 2119 ¶ 39; Ex. 2022. The drawings above show a version of the complete RX GuideLiner, as well as a cross-sectional view of the device with annotations to identify the “soft tip,” the “reinforced Pebax tubular portion,” the “side opening,” and the “rail structure.” Ex. 2118 ¶¶ 52, 53. The schematics are labeled “GuideLiner Rapid Exchange/Preliminary Design Assumptions/Rev X03,” which according to Mr. Root, was an indication that VSI had moved past prototyping and into commercialization. *Id.* Mr. Sutton attests that the “X03” indicates that this was the third version of the CAD drawings, and that they had built and tested prototypes of the RX GuideLiner device shown in these drawings. Ex. 2119 ¶ 39. The document also references the same part number (20-0658) as those identified in certain purchase documents for distal tubular portions from MED. Ex. 2118 ¶ 54 (citing Ex. 2021, Ex. 2089, Ex. 2092). These drawings are nearly identical to Figures 3 and 4 of the ’116 patent. *Cf.* Ex. 1001, Figs. 3–4 (depicting patent drawings that resemble the CAD drawings).

The prototypes were tested using bench-top coronary models, including two-dimensional (“2D”) acrylic heart models and three-dimensional (“3D”) glass heart models, to simulate the native anatomy and environment. Ex. 2118 ¶¶ 17, 18, 41, 50; Ex. 2119 ¶¶ 37–38, 41. These types of models were commonly used by VSI and other medical device companies to test interventional cardiology devices. Ex. 2118 ¶ 17; Ex. 2123 ¶ 21 (Mr. Keith noting that he had used similar models to test catheter designs during his time at Scimed and Boston Scientific Corporation). A sales presentation from July 2005 shows an example of a 2D coronary model. Ex. 2018, 12; Ex. 2129 (redacted version of same presentation). While this particular presentation depicts testing of the OTW version of the GuideLiner concurrently under development, Mr. Root asserts that a similar model was used to test the RX version. Ex. 2118 ¶¶ 18, 19, 41.

The testing done using this model included performing pull tests as well as simulations comprising the following steps: a) inserting a standard guide catheter into the coronary model; b) advancing the prototype into the guide catheter until the prototype’s distal end extended beyond the guide catheter’s distal end; and c) delivering a stent or balloon catheter into and through both devices. *Id.* ¶ 18, 19. Although “more qualitative than quantitative,” these tests enabled the inventors to observe the prototype’s durability and the forces exerted on the prototype. Ex. 2118 ¶¶ 18, 50; Ex. 2119 ¶¶ 23, 41. Both Mr. Root and Mr. Sutton attest that this testing was sufficient to confirm that the RX GuideLiner would work for its intended purpose, namely facilitating delivery of interventional cardiology devices into challenging coronary anatomy by providing increased backup support as compared to a guide catheter alone. Ex. 2118 ¶¶ 18, 50; Ex. 2119 ¶¶ 23, 41.

Patent Owner also presents other documentary evidence as corroboration of the testimony of inventors Mr. Root and Mr. Sutton. We have taken these documents into account, but find them somewhat less probative in showing actual reduction to practice. For instance, a June 23, 2005, market feasibility memo (Ex. 2017 (redacted at Ex. 2128)), similar to the earlier memo from February 4, 2005 (Exs. 2254, 2127), confirms that the RX GuideLiner prototype was continuing to be developed, although the OTW version had been added to the development project at that point. Ex. 2118 ¶ 40; *see also* Ex. 2017, 1 (noting that “it is possible to make the GuideLiner in an Over-the-Wire version, a Rapid Exchange version, or both”).

A “Product Requirements” document, dated August 24, 2005, sets forth the safety and performance requirements for both the OTW and RX guide catheter support systems. Ex. 2118 ¶ 57; Ex. 2119 ¶ 44; Ex. 2024.¹⁴ The document notes that “[t]hese safety and performance features are the minimal requirements for the device to be acceptable for its intended clinical use,” and that the “[a]pplicable clinical use is for increase[d] guide catheter back-up support.” Ex. 2024. Mr. Root asserts that this document marked the start of the formal quality process for the RX and OTW GuideLiner catheters. Ex. 2118 ¶ 57. Both Mr. Root and Mr. Sutton, as well as Ms. Schmalz (VSI’s Vice President of Regulatory and Clinical Affairs at the time), testify that that this document would have been created only after the product was tested, demonstrated to work, and was ready to proceed with

¹⁴ Exhibit 2024 is a subject of Petitioner’s motion to exclude. Paper 65. For the reasons we state above (*see supra* Section II) in addressing the motion to exclude, we decline to exclude Exhibit 2024 but have considered Petitioner’s arguments in determining the weight to be given to this piece of evidence.

regulatory approval and commercialization. Ex. 2118 ¶ 57; Ex. 2119 ¶ 44; Ex. 2039 ¶ 7. Ms. Schmalz specifically recalls that a working prototype of the RX version was created prior to the creation of this document. Ex. 2039 ¶ 7.

Although this document sets forth several user requirements for the device, it does not identify the product specifications and test methods correlating to those requirements. Ex. 2024, 2–4. The revision history of the document also indicates it is “pre-release,” thereby suggesting that it may not have been finalized at the time. *Id.* at 4. Mr. Root, Mr. Sutton, and Ms. Schmalz each also discuss two other documents both dated August 26, 2005—a Clinical Technical Report (Ex. 2025) and a staff meeting memo (Ex. 2040)—as further evidence that work continued on the RX GuideLiner and that VSI was ready to seek regulatory approval for the device from the Food and Drug Administration (“FDA”). Ex. 2039 ¶¶ 9–10; Ex. 2118 ¶¶ 58–60; Ex. 2119 ¶¶ 45–46. The Clinical Technical Report states that VSI “has developed, and is currently manufacturing four types of catheters . . . [including] the GuideLiner Catheter Support System used to provide physicians with additional guide catheter support allowing access to more difficult anatomy,” and goes on to describe both the RX and OTW versions of GuideLiner. Ex. 2025, 2–3, 5–6. We note, however, that the text discussing GuideLiner devices appears to be “redline” edits and does not include any signatures for “document approvals,” thus suggesting that the document submitted as Exhibit 2025 may have only been a draft. *See id.* The staff memo refers to clinical literature reviews for the GuideLiner

devices (both RX and OTW), which Mr. Root asserts was part of VSI's regulatory strategy for a "510(k)" submission to the FDA.¹⁵ Ex. 2118 ¶ 60.

(2) *Analysis for Actual Reduction to Practice*

To establish actual reduction to practice, Patent Owner must demonstrate two things: (1) that it constructed an embodiment and performed the method in a model that sufficiently met all the limitations of the invention claimed in the patent at issue; and (2) that it determined that the invention would work for its intended purpose. *Cooper*, 154 F.3d at 1327. Having considered the evidence and arguments of record, including the testimonial and documentary evidence summarized above, we find that Patent Owner has met this burden with respect to the Challenged Claims based on the prototypes of the RX GuideLiner that were built and tested at VSI prior to September 2005. We address Petitioner's arguments to the contrary.

Petitioner argues that "[t]o prove reduction to practice," Patent Owner must show "performance of a process that met all the limitations" of the claimed method, "determination that the invention would work for its intended purpose;" and "the existence of sufficient evidence to corroborate inventor testimony regarding these events." Pet. Reply 3 (citing *Medichem*, 437 F.3d at 1169). Petitioner raises three specific issues it contends show that Patent Owner failed to show it actually reduced the claimed invention to practice, each of which we find not persuasive for the reasons below.

¹⁵ A 510(k) submission is a premarket notification "to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device." See FDA, Premarket Notification 510(k), (accessed June 1, 2021), <https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k>.

First, Petitioner argues that “component parts, alone, cannot prove assembled prototypes,” and asserts that Patent Owner “failed to adduce evidence sufficient to show that VSI assembled its April and July components before Itou.” *Id.* at 4–6 (citing, e.g., *Valencell, Inc. v. Fitbit, Inc.*, 784 F. App’x 1005, 1009 (Fed. Cir. 2019)). Petitioner raised substantially the same issue previously in IPR2020-00132 and our determination here is the same. *See* IPR-132 Final Written Decision, 43–48. In this case Petitioner argues “[n]o document shows that VSI assembled its April and July components,” that assembling the prototypes “would have been difficult and required documentation,” that “[o]nly less-than-precise inventor testimony suggests that VSI assembled its April and July components before Itou,” that Mr. Erb does not corroborate the testimony of the inventors because he does not state when he assembled prototypes, and that Patent Owner “has not done enough.” Pet. Reply 4–6 (citing Ex. 1798, 47:21–48:16; Ex. 2122 ¶ 19).

We are not persuaded that the record lacks sufficient corroborating evidence of actual reduction to practice. “In order to corroborate a reduction to practice, it is not necessary to produce an actual over-the-shoulder observer. Rather, sufficient circumstantial evidence of an independent nature can satisfy the corroboration requirement.” *Cooper*, 154 F.3d at 1330 (citing *Knorr v. Pearson*, 671 F.2d 1368, 1373 (CCPA 1982)). “Furthermore, an actual reduction to practice does not require corroboration for every factual issue contested by the parties.” *Id.* (citing *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1464 (Fed. Cir. 1998); *Mann v. Werner*, 347 F.2d 636, 640 (CCPA 1965) (“This court has rejected the notion that each individual act in the reduction to practice of a count must be proved in detail by an unbroken chain of corroboration.”)). Put another way, the law

“does not require that evidence have a source independent of the inventors on every aspect of conception and reduction to practice; such a standard is the antithesis of the rule of reason.” *E.I. du Pont De Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1077 (Fed. Cir. 2019) (internal quotation omitted).

As discussed above, Mr. Root and Mr. Sutton each provide detailed and consistent testimony explaining the work done at VSI towards building and testing the April and July 2005 prototypes of the RX GuideLiner. *See*, Ex. 1798, 41:9–22 (Mr. Root testifying that assembly and testing occurred “within a matter of a week or two” of receiving parts in April and July 2005). Critical aspects of this testimony are corroborated by other (non-inventor) testimony from Ms. Schmalz (recounting the regulatory and quality process at VSI), Mr. Erb (recounting how they built early prototypes), Mr. Goemer (verifying purchases from SPECTRAlytics), and Ms. O’Neil (verifying purchases from MED). This testimony is further corroborated by a significant amount of documentary evidence, including purchase documents and engineering drawings, as set forth above.

With regard to whether the purchased components were actually assembled into an RX prototype, we find that the engineering schematic from August 2005 is strongly corroborative of an assembled device. Ex. 2022. Dr. Zalesky, one of Petitioner’s experts, acknowledges that it “doesn’t make a lot of sense” for VSI not to have assembled the purchased parts together. Ex. 2237, 208:10–25. A preponderance of the evidence supports the conclusion that the RX prototypes were assembled and the method claimed was performed to meet each of the limitations of the Challenged Claims, as set forth by Mr. Root. Ex. 2118, App’x B. As such, we find the evidence presented in this case to be more detailed than that

found insufficient in *Valencell*, cited by Petitioner. Pet. Reply 4. There, no evidence—testimonial or documentary—addressed key claims limitations, which stands in contrast to the detailed testimony and corroborating documents cited in Mr. Root’s and Mr. Sutton’s declarations.

Second, Petitioner argues that VSI did not perform the claimed method prior to the critical date of Itou, because the Challenged Claims require “advancing a guide catheter ‘through a main blood vessel to an ostium of a coronary artery’ and advancing a balloon catheter or stent ‘into the coronary artery’” and VSI “did not use prototypes *in vivo*.” Pet. Reply 7–11 (citing *TC Tech. LLC v. Sprint Corp.*, 379 F. Supp. 3d 305, 319 (D. Del. 2019)) (for the proposition that it found “computer simulations could not meet all the limitations of the asserted claims, [thus] they are insufficient to show actual reduction to practice”). In a footnote, Petitioner acknowledges that “[s]ome cases note that human testing is not necessary to determine that a medical device would work for its intended purpose,” (citing *Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994)), then proceeds to maintain that “separate from and in addition to determining that the inventions would work for their intended purpose, VSI needed to *perform the claimed methods*.” *Id.* at 8 n.5. Petitioner, however, was unable to identify any legal precedent requiring *in vivo* performance of a claimed *in vivo* method to show actual reduction to practice. Tr. 25:6–24.

Patent Owner argues that “[s]imulating a medical procedure in a model is sufficient to understand the invention works.” PO Sur-reply 11 (citing Ex. 2123 ¶¶ 20–24; Ex. 2118 ¶ 17–19). Patent Owner also explains that “the Federal Circuit noted that ‘a certain amount of common sense must be applied’ in determining testing for reduction to practice,” and explained that “[t]esting for the full safety and effectiveness of a prosthetic device is

more properly left to the Food and Drug Administration (FDA),” and that “Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office (PTO) proceedings.” *Id.* at 9 (quoting *Scott*, 34 F.3d at 1062–63). Patent Owner further reasons that “this delineation of responsibility is for good policy reasons: the FDA is the agency best positioned to oversee the safety of human testing of new medical devices and procedures, not the PTO.” *Id.* (further arguing that “[i]f reduction to practice of claimed medical procedures required *in vivo* testing, inventors might be tempted to rush to human testing before it is safe to do so, to secure their intellectual property rights”).

We agree with Patent Owner under the circumstances presented in this case. Although the Challenged Claims are directed to a method performed *in vivo*,¹⁶ the viability of the claimed method can be verified using a physical model that replicates the anatomy in which the method would likewise be performed *in vivo*. We find Patent Owner sufficiently shows actual reduction to practice of the claimed method by showing testing, as explained above, of the claimed method in a physical model replicating *in vivo* conditions. This *in vitro* testing was sufficient to show that the inventors understood the claimed method works. We agree with Patent Owner that requiring human or other *in vivo* testing to establish reduction to practice, without having obtained the necessary FDA approvals at that stage of product development, would have been premature. Moreover, as explained above, we find that Patent Owner shows that testing of the prototypes occurred prior to the critical date of Itou, and reject Petitioner’s argument

¹⁶ The claims require advancing the guide catheter “through a main blood vessel to an ostium of a coronary artery” and do not require the method to be performed in a human being. Ex. 1001, 13:62–14:25.

that Patent Owner failed to make such a showing. *See* Reply 7–11. Patent Owner argues in this regard that Mr. Root’s declaration explains how each element of the Challenged Claims was met by building and testing GuideLiner prototypes (citing Ex. 2118, App’x B) and that Dr. Zalesky “does not rebut Mr. Root’s charts addressing the ’116 patent (citing Ex. 1755, App’x A–E (providing charts only for other patents, not the ’116 patent). Sur-reply 11–12. As explained above, we find the evidence shows that testing occurred prior to the critical date of Itou. *See, e.g.*, Ex. 1798, 41:9–22; Ex. 2118 ¶¶ 15–22, 38–42, 47–51, 55; Ex. 2119 ¶¶ 16, 17, 23, 37, 38, 41; Ex. 2122 ¶¶ 5, 12, 19, 20; Ex. 1799, 10:14–11:1, 37:2–38:6; Ex. 1798, 34:18–24, 39:22–40:13, 40:24–41:8, 78:17–79:5.

Third, Petitioner argues that Patent Owner fails to show that VSI determined that “the inventions would work for their intended purpose.” Pet. Reply 11–15. According to Petitioner, demonstrating that the invention works requires testing “in all but simple cases,” and catheters “require testing.” *Id.* at 12. In particular, Petitioner argues as follows:

To determine whether the claimed methods would increase backup support, including to cross tough/total occlusions, VSI needed to set up a model simulating an occlusion, run the prototype through to test whether it could access and cross the simulated occlusion, and *compare* the prototype’s backup support to a standard GC. Ex-1764, 64:2-67:12; Ex-1797, 76:8-20, 82:11-25 (Keith confirming that simulation can test lesions and comparative testing can measure relative backup support); Ex-1755 ¶¶ 233-37, 257-58. *Increased* backup support, by definition, requires a *comparison*.

Id. at 13. Petitioner further argues that “[n]o evidence suggests that VSI compared RX prototypes to standard GC arrangements to confirm *increased* backup support.” *Id.*

Patent Owner notes that “no claimed method of the ’116 patent requires the GuideLiner to access and cross an occlusion,” and that the GuideLiner prototypes were tested “to confirm that they provided backup support.” PO Sur-reply 15–16 (citing, e.g., Ex. 1762, 193:8–194:16; Ex. 2118, App’x B. Patent Owner further argues that there is specific, non-inventor testimony that corroborates the inventors’ testing of the GuideLiner prototypes. *Id.* (citing Ex. 2122 ¶¶ 12, 19; Ex. 1799, 37:8–38:15).

When considering all of the pertinent evidence, we find that the inventors were concerned generally with providing improved backup support for a guide catheter, with crossing tough or total occlusions being one specific benefit or application of the device. We do not find that the RX GuideLiner was intended to have applicability only when there were tough or chronic occlusions in the artery that needed to be crossed. The ’116 patent recognizes this broader purpose when discussing the field and background of the invention. *See* Ex. 1001, 1:36–40 (“the present invention relates to methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta”); *id.* at 3:12–16 (“the interventional cardiology art would benefit from the availability of a system that would be deliverable through standard guide catheters for providing backup support by providing the ability to effectively create deep seating of the coronary artery”).

The documentary evidence we have considered and discussed above further supports this broader intended purpose. For example, while Mr. Sutton’s lab notebook expresses the idea for the GuideLiner device as “relat[ing] to interventional coronary procedures and specifically to accessing & crossing tough or chronic total occlusions,” it also more broadly notes that “[t]he idea is to provide a guide or support catheter more distally

into the coronary to provide more back-up support for the stent device.” Ex. 2253, 7. Mr. Sutton’s lab notebook also contains two additional notes related to the invention: “Guide-Liner is used when there is difficulty crossing lesions” and “Guide-Liner allows back-up support distally.” *Id.* at 8. Similarly, in the February 4, 2005, Market Feasibility memo, Mr. Root describes the purpose of the RX GuideLiner as “provid[ing] the ability to create a deep seating of the guide for added support in the interventional procedure.” Ex. 2254, 1. Mr. Root explains that “[b]y safely deep seating the guide catheter, the physician can then have the added support for pushing a wire through a chronic total occlusion or advancing a balloon or stent through a tight stenosis.” *Id.* The August 24, 2005, Products Requirement document indicates the “[a]pplicable clinical use” for both the RX and OTW GuideLiner to be “increas[ing] guide catheter back-up support.” Ex. 2024, 1.

Similarly, Mr. Root declares that the intended purpose of the RX GuideLiner was to “deliver interventional cardiology devices, such as a stent or balloon catheter, alongside the rail segment, into the side opening and distal tubular portion, and then out the distal end of the distal tubular portion and into challenging coronary anatomy.” Ex. 2118 ¶ 19; *see also id.* ¶ 50 (describing the intended purpose as “facilitat[ing] the delivery of balloon catheters and stents deep into coronary arteries while providing increased backup support”). During Mr. Root’s deposition, counsel for Petitioner inquired about Mr. Root’s understanding of the intended purpose. Ex. 1762, 47:11–52:17. Mr. Root repeatedly stated that accessing and crossing tough or chronic occlusions was not the sole intended purpose. *Id.* at 47:11–20 (identifying that Petitioner’s asserted intended purpose was “one of them” but “not all of them”), 50:10–12 (“The important thing is this is not just a

chronic total occlusion device. This can apply to much broader coronary interventions.”). Mr. Sutton’s declaration quotes the purpose identified in his notes in his lab notebook, discussed above. Ex. 2119 ¶ 9 (quoting Ex. 2253, 7, 8). Mr. Sutton also declares that he and his team tested the prototypes qualitatively “to determine that [they] provided backup support,” “to ensure that [stents and balloon catheters] could safely be delivered and would not snag or get caught on the device,” and “to deliver interventional cardiology devices and provide additional backup support compared to the guide catheter alone.” *Id.* ¶ 41.

In sum, the pertinent evidence demonstrates that the intended purpose of the claimed invention, as embodied in the RX GuideLiner, was to increase backup support for delivery of interventional cardiology devices. Although crossing tough or total occlusions is one noted benefit of the invention, we do not find it to be the only or primary purpose of the invention.

We next consider whether the testing conducted at VSI was sufficient to determine that the RX GuideLiner prototypes performing the claimed method would work for the intended purpose of increasing backup support for delivery of interventional cardiology devices. “Depending on the character of the invention and the problem it solves, determining that the invention will work for its intended purpose may require testing.” *Cooper*, 154 F.3d at 1327 (citing *Mahurkar v. C.R. Bard Inc.*, 79 F.3d 1572, 1578 (Fed. Cir. 1996)). “When testing is necessary, the embodiment relied upon as evidence of priority must actually work for its intended purpose.” *Id.* (citing *Scott v. Finney*, 34 F.3d 1058, 1061 (Fed. Cir. 1994)). “The testing requirement depends on the particular facts of each case, with the court guided by a common sense approach in weighing the sufficiency of the

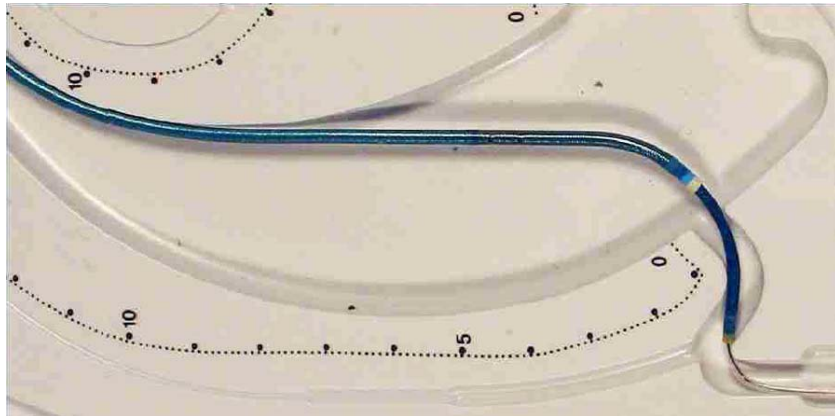
testing.” *Scott*, 34 F.3d at 1061. “This common sense approach prescribes more scrupulous testing under circumstances approaching actual use conditions when the problem includes many uncertainties,” but “permits little or no testing to show the soundness of the principles of operation of the invention” “when the problem to be solved does not present myriad variables.” *Id.* at 1063. “In tests showing the invention’s solution of a problem, the courts have not required commercial perfection nor absolute replication of the circumstances of the invention’s ultimate use.” *Id.* “[T]ests performed outside the intended environment can be sufficient to show reduction to practice if the testing conditions are sufficiently similar to those of the intended environment.” *DSL Dynamic Scis. Ltd. v. Union Switch & Signal, Inc.*, 928 F.2d 1122, 1125 (Fed. Cir. 1991) (citing *Tomecek v. Stimpson*, 513 F.2d 614, 618 (CCPA 1975)). As discussed above, for in vivo methods of use of medical device inventions, a showing of actual reduction to practice does not require human testing in actual use conditions. *Scott*, 34 F.3d at 1063.

We find that Patent Owner’s evidence of VSI’s use of benchtop models was sufficient to test that the products were suitable for the intended purpose described above.¹⁷ In this regard, we credit the testimony of Mr. Root, who states as follows:

We already knew that the GuideLiner would provide additional backup support for delivering interventional coronary devices into the distal anatomy because the over-the wire version of the concept had already been shown by others to work for that purpose. At that time, VSI was a lean company with active management focused on product development; therefore, we did

¹⁷ Because we determine that the evidence demonstrates that testing in benchtop models was sufficient, we do not address Patent Owner’s argument that no testing was necessary. *See* PO Resp. 14.

not see the need to, and we did not, create formal test protocols and reports to prove that the initial GuideLiner concept worked during its design development phase. Instead, what we did was perform confirmatory testing in a bench-top, coronary model that simulated the native anatomy and environment for the deployment of the device and the passage of interventional cardiology devices through it. Some of our testing was performed in a two-dimensional anatomical model, while other testing was performed in a three-dimensional anatomical model. Some of our testing involved submerging the anatomical model into a water bath, and sometimes our tests were performed dry. An example of such a two-dimensional coronary model is shown in the following photographs from a July 2005 PowerPoint presentation, discussed further below:



(Exhibit 2018, 2129.) Such coronary models were commonly used by VSI and other medical device companies to test interventional cardiology catheters and devices and to determine that they would serve their purpose inside a human heart. We already had such coronary models at VSI at the time we began to build and test GuideLiner prototypes.

Ex. 2118 ¶ 17. Mr. Root further explains how testing was conducted, as follows:

Testing of the GuideLiner prototypes consisted of simulating a procedure in which the GuideLiner would be used, including inserting a guidewire and a standard guide catheter over the guidewire into the coronary model and positioning the distal end of the guide catheter at the ostium of a simulated branch artery, attaching a hemostasis valve on the back (proximal

end) of the guide catheter, advancing the GuideLiner prototype through the hemostatic valve, which is sometimes referred to as a Y-adapter, when in the open/non-sealing position into the guide catheter until the distal end of the prototype extended beyond the distal end of the standard guide catheter, and then delivering a stent or balloon catheter into the guide catheter by way of the hemostatic valve, alongside the proximal rail structure of the GuideLiner prototype, into and through the tubular portion of the GuideLiner prototype and out the distal end of the GuideLiner prototype. Part of the simulation involved sealing the hemostasis valve around a portion of the proximal rail structure of the prototype GuideLiner after it had been inserted into the guide catheter. We also observed the forces involved in navigating the GuideLiner prototype through such a model, including when manipulating the proximal rail portion of each GuideLiner prototype to advance the prototype (including its side opening and tubular portion) through the lumen of the guide catheter, and we performed pull tests to assess the durability of the prototype. And, after observing how the GuideLiner prototypes operated as they were navigated through the heart models, we then withdrew the prototypes from those heart models.

Id. ¶ 18. Mr. Root further states as follows:

Such testing, including testing the rapid exchange GuideLiner prototypes in a bench-top model such as this, was sufficient to determine that the concept would work for its intended purpose – namely that a rapid exchange guide extension catheter could deliver interventional cardiology devices, such as a stent or balloon catheter, alongside the rail segment, into the side opening and distal tubular portion, and then out the distal end of the distal tubular portion and into challenging coronary anatomy. Indeed, the same types of heart models that we used to confirm the GuideLiner would work for its intended purpose in 2005 were later used to train salespeople and physicians on how to use the GuideLiner device.

Id. ¶ 19. Petitioner’s argument against Patent Owner’s testing evidence depends on its narrower intended purpose, i.e., “VSI needed to set up a model simulating an occlusion, [and] run the prototype through to test

whether it could access and cross the simulated occlusion.” Pet. Reply 13. In light of our rejection of the narrower intended purpose identified by Petitioner, we likewise reject Petitioner’s argument that the testing evidence presented by Patent Owner is insufficient. The testimony of Mr. Root, Mr. Sutton, Mr. Erb, and Mr. Keith, corroborated by the photograph of the model in the sales presentation, confirm that VSI utilized benchtop coronary models that were considered the standard for testing interventional cardiology devices such as catheters. *See* Ex. 2018; Ex. 2118 ¶¶ 17–19, 41, 50; Ex. 2119 ¶¶ 23, 37–38, 41; Ex. 2122 ¶ 11; Ex. 2123 ¶¶ 21–24. We consider this benchtop testing to be similar to the “countertop” testing that was found sufficient to show actual reduction to practice in *Mahurkar*. *See Mahurkar*, 79 F.3d at 1578 (determining for claims related to a double lumen catheter that flow and pressure drop tests conducted in the inventor’s kitchen, using glycerine to simulate blood, was sufficient for actual reduction to practice because they “showed, to the limit of their design, the utility of the claimed invention”).

Mr. Root indicated during his deposition that to reduce to practice, VSI needed to “(1) navigate RX through a guide catheter and out its distal end in a benchtop model, (2) deliver an interventional cardiology device, and (3) retrieve RX in one piece.” Ex. 1762, 100:1–102:3. We find that the “pull tests” done using the benchtop models demonstrated that the RX GuideLiner was capable of accomplishing at least this much, even if the tests were not conducted in an *in vivo* or *in vitro* environment that simulated tough lesions. Ex. 2118 ¶¶ 17–19, 41, 50. This is not a situation where there were significant variables or uncertainties that needed to be assessed in order to determine whether the RX device would work properly, and thus the “qualitative” testing done by VSI using the benchtop models was sufficient.

Ex. 2119 ¶ 41; Ex. 2123 ¶¶ 21–22. Accordingly, a preponderance of the evidence supports the conclusion that the testing done at VSI demonstrated that the RX GuideLiner would work for its intended purpose.

In addition to the three arguments addressed above concerning the sufficiency of Patent Owner’s showing of actual reduction to practice, Petitioner further argues that various documents purportedly suggest that VSI “could not have reduced to practice before Itou,” because “VSI delayed RX work . . . due to lagging engineering work.” Pet. Reply 19–21 (citing, e.g., Exs. 1755, 1762, 1766, 1767, 2024, 2025, 2128, 2130). For example, a July 2005 Research & Development (“R&D”) Update notes that “[t]he initial design is an over-the-wire configuration, with a rapid exchange version to follow.” Ex. 2130, 3.¹⁸ In contrast to the incomplete August 2005 Product Requirements document relied upon by Patent Owner (Ex. 2024), Petitioner contends that the official, completed version of the Product Requirements document for the GuideLiner project was not created until April 2009. Pet. Reply 19 (citing Ex. 1767). A “2006 Strategic Objectives” document, dated December 1, 2005, indicates that the “rapid exchange requires additional engineering and is not included in our 2006 forecasts.” Ex. 2131, 10. Likewise, Petitioner points to a GuideLiner team meeting memo from May 2, 2006, that includes as agenda items “1) Review

¹⁸ We recognize that this document appears to contradict Mr. Root’s recollection that the original idea was for the RX GuideLiner, and that the decision was later made to concurrently pursue development of the OTW version. Ex. 2118 ¶ 22. We do not find the issue of whether the initial idea was for the RX version or the OTW version to be material to our analysis on reduction to practice. Nonetheless, we note Mr. Sutton’s original notebook pages suggest that the original idea was indeed for the RX version rather than the OTW version. Ex. 2253.

Initial Design and Intended Use,” and “2) Determine what can be completed/started prior to design lock.” Pet. Reply 19; Ex. 2109.

According to another document, a “design freeze” for the GuideLiner device was expected to only take place May 30, 2007. Ex. 1769, 1. Indeed, an R&D update from July 2008 notes with respect to the GuideLiner device as follows:

Throughout this project, timelines have been pushed out due to drastic design changes and resource constraints. To date we have prototyped and tested a new design. This new design is more robust and cost effective. We are planning on an August 2008 design freeze with a 510k submission in November 2008.

Ex. 2132, 7. We have taken the foregoing evidence into account, but do not find that it detracts from Patent Owner’s evidence concerning reduction to practice based on building and testing the April and July 2005 prototypes discussed above. To be sure, the post-critical date documents highlighted by Petitioner make it clear that significant design revisions for the RX GuideLiner continued well into 2008, and these additional design changes may well have been required for FDA regulatory approval and/or commercialization of the device. Indeed, Patent Owner’s declarants attest that additional engineering work was conducted to refine the product for regulatory purposes and commercialization. *See* Ex. 2118 ¶ 62 (Mr. Root attesting that “[f]rom September of 2005 forward, I and others at VSI continued to act diligently to bring the rapid exchange GuideLiner to market.”); Ex. 2119 ¶ 44 (Mr. Sutton attesting that, after the August 24, 2005, Product Requirements document, “we continued to refine prototypes of the GuideLiner Rapid Exchange for purposes of manufacturability and commercialization”); Ex. 2122 ¶ 20 (Mr. Erb attesting that work continued on “develop[ing] manufacturing processes that were reproducible and a

refined design that was able to be commercialized”). But we see no basis to conclude that these additional engineering and design changes were an indication that the April and July 2005 prototypes failed to demonstrate that the method of use of the RX GuideLiner was capable of achieving increased backup support. Ultimately, the RX GuideLiner was not commercialized until 2009, which we recognize is far later than the initial projected timeframe of late 2005/early 2006 and the date of actual reduction to practice. Ex. 2118 ¶ 90. Mr. Root asserts that one reason for this delay was due to turnover in R&D personnel. *Id.*

Under the circumstances, we do not find that the additional engineering and design work done with respect to the RX GuideLiner to achieve regulatory approval and commercialization indicates a lack of actual reduction to practice prior to the critical date. *See Loral Fairchild Corp. v. Matsushita Elec.*, 266 F.3d 1358, 1362–63 (Fed. Cir. 2001) (“Once the invention has been shown to work for its intended purpose, reduction to practice is complete. Further efforts to commercialize the invention are simply not relevant to determining whether a reference qualifies as prior art against the patented invention.”). In sum, we find that Patent Owner has demonstrated actual reduction to practice prior to Itou’s critical date by a preponderance of the evidence based on the work done at VSI in building and testing the April and July 2005 prototypes of the RX GuideLiner.

e) Constructive Reduction to Practice

In addition to asserting actual reduction to practice, Patent Owner alternatively relies upon a theory of constructive reduction to practice. PO Resp. 28–29; PO Sur-reply 16–18. Antedating based on this theory would require Patent Owner to demonstrate diligence from just before the date Itou was filed until the date Patent Owner filed its priority application for the

'116 patent. *See Perfect Surgical Techniques, Inc. v. Olympus Am., Inc.*, 841 F.3d 1004, 1007 (Fed. Cir. 2016) (requiring diligence for the “entire critical period, which begins just prior to the competing reference’s effective date and ends on the date of the invention’s reduction to practice”).

Patent Owner argues that “VSI worked steadily on the GuideLiner invention from conception through the date the patent was filed” and “diligent work on the invention continued from before September 23, 2005 to the filing of the original priority application on May 3, 2006.”

PO Resp. 28–29 (citing various other portions of the Patent Owner Response; Ex. 2118 ¶¶ 55–80; Exs. 2023, 2041, 2096–2109, 2115, 2117, 2133). Patent Owner also discusses “The Road to Commercialization,” explaining certain activities during the relevant time frame. *Id.* at 25–28. Petitioner disregards Patent Owner’s discussion of “The Road to Commercialization,” and argues that Patent Owner’s argument “contains no facts showing diligence,” “cites exhibits without identifying the relevant facts or applying the diligence standard to those facts,” and improperly incorporates by reference arguments from one document into another. Pet. Reply 16 (citing 37 C.F.R. 42.6(a)(3)). We agree with Petitioner that Patent Owner’s argument on diligence is not extensively detailed, however, the issue of diligence concerning the GuideLiner invention was addressed by both parties at length in prior proceedings concerning related patents. *See* IPR-132 Final Written Decision, 58–67.

We discern no material difference between the arguments and evidence the parties advance concerning diligence in this case and in IPR2020-00132, particularly because the critical period is the same in both cases, from prior to September 23, 2005, the filing date of Itou, until May 3, 2006, the date of filing of the '629 application, the original priority

application in both cases. *See* Pet. Reply 16–19 (arguing that Patent Owner only shows “scattered activities, virtually none related to actual work on the RX device”). The exhibits and declaration testimony Patent Owner relies on appear to be identical in both cases, with the exception of Mr. Root’s declaration (Exhibit 2118 in both cases), which includes renumbered paragraphs and limited additional testimony not pertinent to diligence. The table below shows the paragraphs of IPR2020-00132, Exhibit 2118, cited in IPR-132 Final Written Decision, 58–67, on the left and the corresponding paragraph of Exhibit 2118 in this case.

IPR2020-00132 Exhibit 2118 (¶)	IPR2020-00132 Exhibit 2118 (¶)
42	45
49–50	52–53
52–53	55–56
59–74	62–77
75	78 and 79
76	80
89	90

We adopt the Board’s analysis in the IPR-132 Final Written Decision, 58–67, and, considering all of the pertinent evidence, we find that Patent Owner did not abandon or unreasonably delay the RX GuideLiner project during the critical period. Petitioner’s arguments implying the need for direct evidence and scouring the timeline for periods of inactivity are unpersuasive. We therefore conclude that Patent Owner demonstrates, by a preponderance of the evidence, that VSI was reasonably continuous in its diligence during the critical period. Because we have also found that Patent Owner demonstrated conception prior to Itou’s critical date, Patent Owner has met its burden to

successfully demonstrate that Itou is not prior art to the Challenged Claims of the '116 patent.

2. Conclusion on Obviousness Over Itou and Ressemann

Because Itou is not prior art to the '116 patent, Petitioner has not demonstrated that any of claims 25–40, 42, 44–48, 52, 53 would have been obvious over the combination of Itou and Ressemann.

H. Alleged Obviousness over Itou, Ressemann, and Kataishi

Petitioner contends that claim 45 would have been obvious over the combination of Itou, Ressemann, and Kataishi. Pet. 74–77. Because Itou is not prior art to the '116 patent, Petitioner has not demonstrated that claim 45 would have been obvious over the combination of Itou, Ressemann, and Kataishi.

IV. CONSTITUTIONAL CHALLENGE

Patent Owner argues that the Petition should be denied because “the manner in which administrative law judges are appointed is unconstitutional.” PO Resp. 80 (citing *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320, 1325 (Fed. Cir. 2019)). Patent Owner further argues that the remedy in *Arthrex* “severing certain removal protections, is insufficient to cure the constitutional defect, because, for example, it still does not give a properly appointed principle office the power to review administrative law judge decisions.” *Id.* at 80–81 (citing *Lucia v. SEC*, 138 S. Ct. 2044, 2055 (2018)). We decline to address Patent Owner’s constitutional challenge except to note that the constitutionality of the appointments of the Administrative Patent Judges was addressed by the United States Supreme Court in *United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021).

V. CONCLUSION¹⁹

The outcome for the Challenged Claims in this proceeding is set forth below in summary as follows:

Claim(s)	35 U.S.C. §	Reference(s)	Claim(s) Shown Unpatentable	Claims Not Shown Unpatentable
52, 53	102	Ressemann	52, 53	
25–40, 42, 44–48, 52, 53	103	Itou, Ressemann		25–40, 42, 44–48, 52, 53
45	103	Itou, Ressemann, Kataishi		45
Overall Outcome			52, 53	25–40, 42, 44–48

¹⁹ Should Patent Owner wish to pursue amendment of a Challenged Claim in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner’s attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

VI. ORDER

Upon consideration of the record before us, it is:

ORDERED that claims 52 and 53 of U.S. Patent No. RE46,116 E have been proven by a preponderance of the evidence to be unpatentable;

FURTHER ORDERED that claims 25–40, 42, and 44–48 of U.S. Patent No. RE46,116 E have not been proven by a preponderance of the evidence to be unpatentable;

FURTHER ORDERED that Petitioner’s Motion to Exclude is denied;

FURTHER ORDERED that the parties shall, no later than 14 days from the entry of this Decision, jointly file as a confidential Exhibit a proposed redacted version of this Decision, appropriate to serve as a public version of this Decision, which identifies all proposed redactions with red highlighting; and,

FURTHER ORDERED that, as this is a Final Written Decision, a party seeking judicial review of the Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC.,
Petitioner,

v.

TELEFLEX LIFE SCIENCES LIMITED,
Patent Owner.

IPR2020-01343
Patent RE46,116 E

Before SHERIDAN K. SNEDDEN, JAMES A. TARTAL, and
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

PAULRAJ, *Administrative Patent Judge*, concurring.

I fully concur with the thorough analysis set forth in the Opinion of the Board. I write separately, however, to express my view that this case could have been decided on the basis of collateral estoppel. As noted above, the Board had previously issued final written decisions for a set of *inter partes* review proceedings in which the issue of Itou's status as prior art for other related patents with the same priority date had been fully litigated by the parties in this proceeding. *See* IPR2020-00126, IPR2020-00128, IPR2020-00129, IPR2020-00132, IPR2020-00134, IPR2020-00135, and IPR2020-00137. In each of those proceedings, we considered substantially

the same evidence and arguments presented in this proceeding and determined that Patent Owner had demonstrated a) conception no later than August 2005, b) actual reduction to practice based on the work done at VSI in building and testing the April and July 2005 prototypes of the RX Guideliner, and c) constructive reduction to practice based on the diligence towards filing the earliest priority application. *See, e.g.*, IPR2020-00126, Paper 127.

It is well-established that a final written decision issued by the Board can trigger collateral estoppel in subsequent proceedings. *See, e.g., Papst Licensing GMBH & Co. v. Samsung Elecs. Am., Inc.*, 924 F.3d 1243, 1250-51 (Fed. Cir. 2019); *MaxLinear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373, 1376 (Fed. Cir. 2018). Collateral estoppel applies if: (1) a prior action presents an identical issue; (2) the prior action actually litigated and adjudged that issue; (3) the judgment in that prior action necessarily required determination of the identical issue; and (4) the prior action featured full representation of the estopped party. *VirnetX Inc. v. Apple, Inc.*, 909 F.3d 1375, 1377 (Fed. Cir. 2018).

In this case, the issue of Itou's prior art status is identical to what was previously considered by the Board. As in the prior cases, Patent Owner has sought to antedate the Itou reference by demonstrating conception and reduction to practice of the claimed invention with inventor testimony and other corroborating evidence related to VSI's development of the RX Guideliner. Indeed, Petitioner in this case does not even contest Patent Owner's evidence of conception. *See* Tr. 19:11–15 (Petitioner's counsel acknowledging "that the Board can find conception in this case because we don't dispute it"). Additionally, with regard to reduction to practice (both actual and constructive), the arguments and evidence presented in this

proceeding concerning the development and testing of RX Guideliner prototypes are nearly identical to what we had previously considered. Although the challenged claims are different in this proceeding, that does not preclude collateral estoppel so long as “the differences between the unadjudicated patent claims and adjudicated patent claims do not materially alter the question of invalidity.” *MaxLinear, Inc.*, 880 F.3d at 1377 (quoting *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013)). We had previously decided the issue of Itou’s prior art status in an identical manner in the earlier proceedings notwithstanding minor differences in the claims across the challenged patents because the parties’ contentions did not differ based on any particular claim language. Likewise, I do not consider the fact that we are dealing with method claims in this proceeding to “materially alter” the priority question that we previously decided. The method claims at issue in this proceeding require practice of the guide catheter device described in the specification (and embodied in the RX Guideliner) in accordance with its intended purpose. Indeed, the same evidence of *in vitro* testing we had previously found to support the reduction to practice of the device claims has now been relied upon to show reduction to practice of the method claims. *See* Ex. 2118 ¶¶ 17, 18, 41, 50 (Mr. Root’s testimony regarding testing); Ex. 2119 ¶¶ 37, 38, 41 (Mr. Sutton’s testimony regarding testing); Ex. 2108 (PowerPoint presentation showing testing using a benchtop model). Thus, I would find that the prior proceedings presented an identical issue regarding Itou’s prior art status.

There is also no significant dispute that the prior actions actually litigated and adjudged the issue of Itou’s prior art status, that the Board’s judgment in those prior actions necessarily required determination of the issue (indeed, it was the sole basis of the Board’s prior resolution of the Itou-

based grounds), and that the prior actions featured full representation of both Petitioner and Patent Owner. As such, the four requirements for application of collateral estoppel have been met.

I do recognize there is some ambiguity as to whether the earlier set of proceedings are considered “final” such that collateral estoppel can apply. We issued our final written decisions in those cases on June 7, 2021. The Director denied a request for review of those decisions and a request for review by the Precedential Opinion Panel (POP) was also denied. *See, e.g.*, IPR2020-00127, Papers 132 and 133. Thereafter, Petitioner filed a Notice of Appeal to the Federal Circuit Court of Appeals. *Id.*, Paper 135. In view of this pending appeal, Petitioner contends that the prior proceedings are not yet final. Paper 72, 3–4 (Petitioner’s Opening Brief on Collateral Estoppel); Paper 81, 1–3 (Petitioner’s Responsive Brief on Collateral Estoppel). Patent Owner, on the other hand, contends that our prior decisions are sufficiently final for purposes of collateral estoppel, but nonetheless acknowledges that the law is unclear on this point and urges us to either address the issues on the merits or adopt our prior findings “out of an abundance of caution.” Paper 73, 2–5 (Patent Owner’s Opening Brief on Collateral Estoppel); Paper 82, 1–3 (Patent Owner’s Responsive Brief on Collateral Estoppel).

I agree that the law is unclear on whether a prior decision that is still pending on appeal can trigger collateral estoppel. Federal Circuit decisions have gone both ways. For instance, in *Intellectual Ventures I LLC v. Capital One Financial Corporation*, the Federal Circuit applied Fourth Circuit law to hold that a district court’s partial summary judgment order “met the finality prong for the purposes of collateral estoppel” because “finality neither demands final judgment, nor requires a party’s appeal,” and there was “nothing left [for the district court] to resolve absent a reversal and

remand on appeal.” 850 F.3d 1332, 1335–38 (Fed. Cir. 2017). And in *SSIH Equipment S.A. v. U.S. International Trade Commission*, the court held that “the law is well settled that the pendency of an appeal has no affect on the finality or binding effect of a trial court’s holding.” 718 F.2d 365, 370 (Fed. Cir. 1983). By contrast, in *Vardon Golf Co. v. Karsten Manufacturing Corp.*, the court applied Seventh Circuit law, noting “[t]o be ‘final’ for purposes of collateral estoppel the decision need only be immune, as a practical matter, to reversal or amendment” and “the possibility of appeal contributes directly to this determination of finality.” 294 F.3d 1330, 1333–34 (Fed. Cir. 2002). And in *XY, LLC v. Trans Ova Genetics*, the court noted that “an affirmance of an invalidity finding, whether from a district court or the Board, has a collateral estoppel effect on all pending or co-pending actions.” 890 F.3d 1282, 1294 (Fed. Cir. 2018). That said, the Board does not apply regional circuit law for procedural issues such as collateral estoppel, and thus any differences on the issue of finality pending appeal as applied by various district courts should not govern our practice. Moreover, although the *XY* case cited by Petitioner states that an “affirmance renders final a judgement on the invalidity of a” patent, the court did not squarely hold in that case or elsewhere that *only* an affirmance or dismissal of the appeal can render final a prior Board judgement. In any event, to the extent that *XY* can be read in such a manner, such a holding would contradict the “well settled” law that “the pendency of an appeal has no affect on the finality or binding effect of a trial court’s decision.” See *SSIH*, 718 F.2d at 370.

Additionally, the Restatement (Second) of Judgments has been relied upon by the Supreme Court and the Federal Circuit when analyzing the ordinary elements of issue preclusion. *B&B Hardware, Inc. v. Hargis*

Indus., 575 U.S. 138, 148 (2015) (quoting Restatement (Second) of Judgments § 27); *Gensetix, Inc. v. Bd. of Regents of Univ. of Texas Sys.*, 966 F.3d 1316, 1333 (Fed. Cir. 2020) (same). As noted by Patent Owner, the Restatement explains: “for purposes of issue preclusion (as distinguished from merger and bar), ‘final judgment’ includes any prior adjudication of an issue in another action that is determined to be sufficiently firm to be accorded conclusive effect.” Restatement (Second) of Judgments § 13. Comment g to section 13 explains that it may be “the wisest course . . . to regard the prior final decision of the issue as final for the purpose of issue preclusion *without awaiting the end judgment.*” *Id.*, cmt. g (emphasis added). This is also consistent with the *inter partes* review statute, which provides that statutory estoppel attaches immediately following “a final written decision” and not only after the appeals have been exhausted. 35 U.S.C. § 315(e)(1).

As such, I find that the weight of authority supports the view that the prior Board decisions can be deemed final at this point, such that we can resolve the primary issue in this case on the basis of collateral estoppel.²⁰ Nonetheless, in view of the seemingly contradictory language in some of the case law, further clarification from our reviewing authorities on the issue of finality pending appeal would benefit the Board. This would not be merely an academic exercise. In this case, there was a considerable expenditure of resources by the Board and the parties to relitigate an issue that had already

²⁰ Although Patent Owner identifies other issues that are also subject to collateral estoppel, I only focus on the issue of Itou’s prior art status as that is the primary basis for our disposition in this proceeding and the prior proceedings. See Paper 73, 5–10. I do not comment on whether any of those other issues are also precluded.

been squarely decided in the prior proceedings. This is contradictory to the Board's policy of "secur[ing] the just, speedy, and inexpensive resolution of every proceeding." 37 C.F.R. § 42.1(b). Furthermore, in the absence of a proper application of the collateral estoppel doctrine, there is also a significant risk of inconsistent results stemming from new arguments and/or evidence that parties may seek to introduce in a subsequent Board proceeding, during which there would be an opportunity for gamesmanship by using the Board's prior decision as a roadmap to correct for errors or failures of proof.

For these reasons, I concur in the result.

IPR2020-01343
Patent RE46,116 E

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