United States Court of Appeals for the Federal Circuit

MEDTRONIC, INC., MEDTRONIC VASCULAR, INC.,
Appellants

v.

TELEFLEX INNOVATIONS S.À.R.L.,
Appellee

2021-2356, 2021-2358, 2021-2361, 2021-2363, 21-2365

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2020-00126, IPR2020-00128, IPR2020-00132, IPR2020-00135, IPR2020-00137.

Decided: May 24, 2023

TASHA JOY BAHAL, Wilmer Cutler Pickering Hale and Dorr LLP, Boston, MA, argued for appellants. Also represented by MARK CHRISTOPHER FLEMING, HANNAH ELISE GELBORT, MADELEINE C. LAUPHEIMER; BRITTANY BLUEITT AMADI, JENNIFER L. GRABER, Washington, DC.

J. DEREK VANDENBURGH, Carlson, Caspers, Vandenburgh & Lindquist PA, Minneapolis, MN, argued for appellee. Also represented by PETER M. KOHLHEPP, TARA CATHERINE NORGARD, JOSEPH W. WINKELS.

Before MOORE, *Chief Judge*, LOURIE and DYK, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* LOURIE.

Dissenting opinion filed by *Circuit Judge* DYK.

LOURIE, *Circuit Judge*.

Medtronic, Inc. and Medtronic Vascular, Inc. (collectively, "Medtronic") appeal from five final written decisions of the United States Patent and Trademark Office Patent Trial and Appeal Board ("the Board") finding that Itou[1] does not qualify as prior art to related U.S. Patents 8,048,032, RE45,380, RE45,776, RE45,760, and RE47,379 (collectively, "the challenged patents") under pre-AIA first-to-invent provisions, and Medtronic had therefore not shown the challenged claims to be unpatentable. *Medtronic, Inc. v. Teleflex Innovations S.À.R.L.*, IPR2020-00126 (P.T.A.B. Jun. 7, 2021) ("*Decision*"), J.A. 1–75; *Medtronic, Inc. v. Teleflex Innovations S.À.R.L.*, IPR2020-00128 (P.T.A.B. Jun. 7, 2021), J.A. 76–150; *Medtronic, Inc. v. Teleflex Innovations S.ÀR.L.*, IPR2020-00132 (P.T.A.B. Jun. 7, 2021), J.A. 151–222; *Medtronic, Inc. v. Teleflex Innovations S.À.R.L.*, IPR2020-00135 (P.T.A.B. Jun. 7, 2021), J.A. 223–98; *Medtronic, Inc. v. Teleflex Innovations S.À.R.L.*, IPR2020-00137 (P.T.A.B. Jun. 7, 2021), J.A. 299–373.[2] For the reasons provided below, we affirm.

---

[1] U.S. Patent 7,736,355 to Itou et al. ("Itou").

[2] The five final written decisions in the IPRs consolidated on appeal share similar sections on conception and reduction to practice. The decision in *Medtronic, Inc. v. Teleflex Innovations S.À.R.L.*, IPR2020-00126 (P.T.A.B. Jun. 7, 2021), J.A. 1–75, is representative and cited throughout as such.

BACKGROUND

The challenged patents, developed by Vascular Solutions Inc. ("VSI") but now owned by appellee Teleflex Innovations S.À.R.L. ("Teleflex"), all descend from a common application filed on May 3, 2006 and share a common specification. The challenged patents are directed to guide extension catheters that use a tapered inner catheter that runs over a standard coronary guidewire to reduce the likelihood that a guide catheter will dislodge from the coronary artery's opening (*i.e.*, ostium). *See, e.g.*, '032 patent, col. 1 ll. 32–36, col. 2 ll. 53–59.

According to Teleflex, VSI conceived the claimed invention in early 2005 and then worked to develop it under the "GuideLiner" name. Teleflex asserts that what was known as the "rapid exchange" or "RX" version of the GuideLiner practices the challenged patents. *Decision*, J.A. 17. However, in the same time period, VSI also worked on developing an "over-the-wire" or "OTW" version of the GuideLiner, which was more akin to the prior art guide extension catheters and does not practice the challenged patents. *Id.* at J.A. 19. Because the over-the-wire GuideLiner was more similar to devices already in existence, it had fewer challenges to overcome and work on it progressed more rapidly than for the rapid exchange device. *Id.* at J.A. 36. The rapid exchange GuideLiner eventually entered the market in 2009. *Id.* at J.A. 61.

Medtronic filed thirteen petitions for *inter partes* review ("IPR") of the challenged patents, eleven of which were instituted and five of which are consolidated in this appeal. These five IPR petitions asserted Itou as the primary prior art reference under pre-AIA 35 U.S.C. § 102(e) (2012). Following institution, Teleflex filed a consolidated response addressing conception and reduction to practice, asserting that Itou did not qualify as prior art because the claimed inventions were (1) conceived prior to Itou's filing date of September 23, 2005 (*i.e.*, the critical date), and (2)

were (a) actually reduced to practice before the critical date or (b) diligently pursued until their constructive reduction to practice through their effective filing in May 2006. In support of its contentions, Teleflex submitted numerous declarations, including from inventors and noninventors, as well as nearly 75 documentary exhibits including inventor lab notebooks, internal company memoranda and presentations, invoices and sales orders, photographs, engineering drawings, and documents from outside patent counsel. *Decision*, J.A. 13.

The Board found that the evidence demonstrated that the claimed inventions were (1) conceived no later than August 2005, *i.e.*, before the critical date, and (2) either (a) actually reduced to practice for their intended purpose in April and July 2005, prior to the critical date, or (b) diligently worked on toward constructive reduction to practice on May 3, 2006, the challenged patents' effective filing date. *Id*. at J.A. 34, 61–62, 71. In so doing, the Board found that the intended purpose of the claimed inventions was providing improved backup support for the guide catheter, rejecting Medtronic's suggestion that the intended purpose, or additional intended purpose, was providing backup support necessary for accessing and crossing tough or chronic occlusions. *Id*. at J.A. 53. The Board therefore determined that Itou did not qualify as prior art to the challenged patents under pre-AIA 35 U.S.C. § 102(e), thereby eliminating the challenges presented in the five IPRs relevant to this appeal. The Board thus concluded that Medtronic had failed to demonstrate that the challenged claims were unpatentable.

Medtronic appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

In considering whether or not a reference qualifies as prior art under pre-AIA 35 U.S.C. § 102(e), we must consider whether or not "the invention was described in . . . a

patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent." A patent owner may antedate an asserted prior art patent by showing conception of the claimed invention prior to the critical date and either actual reduction to practice prior to the critical date or "reasonably continuous diligence" in reducing the invention to practice until its effective filing date. *See ATI Techs. v. Iancu*, 920 F.3d 1362, 1369 (Fed. Cir. 2019); *Tyco Healthcare Grp. v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968, 975 (Fed. Cir. 2014). Inventor declarations submitted to antedate a reference must be corroborated, and corroboration is governed by a "rule of reason" standard. *Perfect Surgical Techs., Inc. v. Olympus Am., Inc.*, 841 F.3d 1004, 1007–09 (Fed. Cir. 2016).

In an IPR, the petitioner bears the ultimate burden of persuasion on invalidity, which never shifts to the patent owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). However, when a patent owner attempts to antedate an asserted prior art reference, the patent owner takes on a temporary burden of production. *Id*. at 1378–79. Once that burden is met, the burden shifts back to the petitioner. *Id*. at 1379.

We review the Board's factual findings on reduction to practice and diligence for substantial evidence, and its legal conclusion of priority *de novo*. *E.I. du Pont de Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1075 (Fed. Cir. 2019). Medtronic does not challenge the Board's findings of conception prior to the critical date on appeal, but challenges both the Board's findings on actual reduction to practice and reasonable diligence toward constructive reduction to practice. We address each argument in turn.

I

To establish actual reduction to practice before the critical date, it must have been shown that "(1) [the inventors] constructed an embodiment or performed a process that

met all the limitations of the [claimed invention]; and (2) [the inventors] determined that the invention would work for its intended purpose." *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). Medtronic challenges the Board's determinations regarding both of these elements on three grounds. First, Medtronic argues that the Board erred in identifying the intended purpose of the claimed inventions. Second, Medtronic argues that, even if the Board's finding of the intended purpose was correct, the Board erred in not requiring comparative testing to demonstrate that the invention worked for that purpose. Third, Medtronic argues that the Board erred in relying solely on uncorroborated inventor testimony as evidence of actual reduction to practice. We disagree for the reasons provided below.

A

Medtronic argues that the intended purpose should be both, as the Board found, providing increased backup support as compared with a guide catheter alone *and* facilitating the delivery of interventional devices through tough or chronic occlusions. Medtronic faults the Board for relying on extrinsic evidence to determine the intended purpose when the patents' specifications and claims are the proper source of information. Medtronic further argues that had the Board correctly determined the intended purpose, it could not have found that Teleflex proved that the prototypes functioned for that purpose. Teleflex argues that Medtronic waived the argument that the Board erred by considering extrinsic evidence in determining the intended purpose when it repeatedly urged the Board to consider extrinsic evidence and failed to point the Board to any intrinsic evidence, and the Board's determination of the intended purpose is correct.

Similar to claim construction, a determination of an invention's intended purposes is a legal issue, reviewed *de novo*. *See z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340,

1352 (Fed. Cir. 2007) (affording no deference to district court's reading of patents' language to "define[] the 'intended purpose' of the invention"). Because we evaluate the intended purpose without deference to the Board's determination, it is of no consequence whether the Board relied on extrinsic evidence or whether Medtronic waived the argument that doing so would have been in error. Regardless, although the patents themselves are the most important and, indeed, most persuasive evidence of the patents' intended purpose, we find it is appropriate to consider extrinsic evidence, particularly when it does not contradict the patents themselves. Medtronic cites no case showing otherwise.

We, like the Board, find Medtronic's proposed intended purpose to be overly narrow. *See Decision*, J.A. 52–53. Although the challenged patents do mention crossing "tough" or "chronic" occlusions, we find that to be a specific example within a broader general purpose. Indeed, as the Board found, the challenged patent specification itself recognizes a broader purpose when discussing the field and background of the invention. *See, e.g.*, '032 patent at col. 1 ll. 8–11 ("More particularly the present invention relates to methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta."), col. 2 ll. 45–49 ("Thus, 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 in the ostium of the coronary artery."). Although that intrinsic evidence is sufficient, a broader purpose than that urged by Medtronic is further supported by both expert and inventor testimony. *See Decision*, J.A. 54–55 (citing J.A. 12012; J.A. 11815–16; J.A. 11834).

Moreover, the evidence suggests a broader intended purpose than the Board found may even be appropriate. The challenged patents are titled "Coaxial Guide Catheter

for Interventional Cardiology Procedures," and the claims are generally directed to a "device for use with a standard guide catheter." *See, e.g.*, '032 patent at Title, col. 10 ll. 21; *see also* J.A. 11816 (inventor describing the intended purpose). The claims do not mandate a purpose beyond performing the functions of a guide extension catheter. This is not an obviousness inquiry. The very title of the patents themselves, "Coaxial Guide Catheter for Interventional Cardiology Procedures," describes the purpose of the claimed inventions, and it is undisputed that the claim language does not impose a further purpose than this. We therefore reject Medtronic's argument that the intended purpose of the claimed invention should be narrower than that determined by the Board.

B

Medtronic further argues that, even assuming the Board's determined intended purpose is correct, there is no evidence that Teleflex's claimed device compared favorably with a guide catheter alone (*i.e.*, worked for the Board's determined intended purpose of "providing *improved* backup support for a guide catheter"). *Decision*, J.A. 53 (emphasis added). Teleflex argues that Medtronic forfeited the argument that comparative testing was required by not raising it before the Board, and, regardless, testing is not required to confirm aspects of the invention that would have already been known to a person of ordinary skill in the art.

As an initial matter, we do not find Medtronic's argument on this point to be forfeited. Generally, a federal appellate court does not consider issues not raised before the lower tribunal. *Singleton v. Wulff*, 428 U.S. 106, 120 (1976). The exact phrasing of the argument need not have been used below "so long as it can be said that the tribunal was 'fairly put on notice as to the substance of the issue.'" *Nike Inc. v. Adidas AG,* 812 F.3d 1326, 1342 (Fed. Cir. 2016) (citing *Consolidation Coal Co. v. United States,* 351 F.3d 1374, 1378 (Fed. Cir. 2003) (quoting *Nelson v. Adams,*

529 U.S. 460, 469 (2000) ("But [issue preservation] does not demand the incantation of particular words; rather, it requires that the lower court be fairly put on notice as to the substance of the issue."))). But even if an issue was not presented below, there is no absolute bar to considering and deciding the issue on appeal, as forfeiture is a matter of discretion. *Harris Corp. v. Ericsson Inc.*, 417 F.3d 1241, 1251 (Fed. Cir. 2005) ("An appellate court retains case-by-case discretion over whether to apply waiver.").

Here, Medtronic argued in their Reply that "Teleflex cannot prove VSI performed *any* testing, much less testing to confirm intended purpose." J.A. 24495; *see also* J.A. 25042 ("The Board cannot evaluate whether Teleflex's testing 'evidence' proves that VSI demonstrated that [the invention] would work for its intended purpose."). We consider these assertions sufficient to preserve Medtronic's argument that comparative testing was required given the intended purpose determined by the Board. Although Medtronic's statements before the Board more generally addressed the insufficiency of the evidence and corroboration of testing, without a specific mention to "comparative" testing, they still address the same, general issue: whether or not the testing showed the invention worked for its intended purpose.

Regardless, we find the testing performed to be sufficient to show that the claimed invention worked for its intended purpose as determined by the Board. Sufficiency of the testing required to show an invention worked for its intended purpose is a question of fact reviewed for substantial evidence. *See z4 Techs.*, 507 F.3d at 1352 ("[T]he necessity and sufficiency of such testing are factual issues."); *Scott v. Finney*, 34 F.3d 1058, 1061–62 (Fed. Cir. 1994) ("[T]he testing requirement depends on the particular facts of each case."). Here, the Board thoroughly reviewed and analyzed the evidence of testing in the record, and we decline to remake or reweigh its factual findings.

Namely, we find the Board's conclusion that the claimed invention was determined to work for its intended purpose was supported by substantial evidence. As the Board noted, both inventors Howard Root and Gregg Sutton testified regarding testing performed on a prototype of the claimed invention. *Decision*, J.A. 44 (citing J.A. 11815, 11834, 11971, 11982–83). Although these tests did not specifically compare the invention prototype with a guide catheter alone, they enabled the inventors to observe the forces exerted on the prototype and the durability of the prototype. *Id*. The Board determined that these tests, although "more qualitative than quantitative," were sufficient to enable the inventors to confirm that the prototype would work for its intended purpose—providing increased backup support as compared with a guide catheter alone. *Id*. We agree. The Board's determined intended purpose did not mandate a 1:1 comparison or quantitative assessment to show an "increase" or "improvement" in function. Rather, it simply requires that an inventor, a skilled artisan, would observe the tests and understand that they indicate the prototype is more effective than a guide catheter alone. And that is the case here. *See, e.g.*, J.A. 12010–12 (expert testimony that "actual reduction to practice of the GuideLiner invention would have required little if any testing," and that, to the extent it did, "qualitative testing would have been sufficient").

Because we find the Board's finding of actual reduction to practice under its determined intended purpose supported by substantial evidence, we find the same would be true for our suggested, broader, intended purpose of simply functioning as a guide extension catheter. Indeed, as counsel for Appellant conceded at oral argument, "[w]e may not need comparative testing if the Board had found a different intended purpose." Oral Arg. at 3:18–22.

C

Finally, Medtronic argues that Teleflex's evidence of actual reduction to practice is insufficiently corroborated. Inventor testimony may serve as evidence of reduction to practice, but it must be corroborated by independent evidence. *Cooper*, 154 F.3d at 1330. The sufficiency of such corroborating evidence is evaluated under a "rule of reason," considering all pertinent evidence. *Id.* Corroboration can come from documentary evidence, noninventor testimony, or a combination of both. *Loral Fairchild Corp. v. Matsushita Elec. Indus. Co.*, 266 F.3d 1358, 1364 (Fed. Cir. 2001) ("Under the 'rule of reason,' the inventor's testimony must be sufficiently corroborated by independent evidence, but not necessarily documentary evidence."). Corroborating evidence may also be circumstantial. *Cooper*, 154 F.3d at 1330 ("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."). Nor must every individual aspect of reduction to practice be corroborated. *E.I. du Pont*, 921 F.3d at 1077. Rather, the corroborative evidence simply needs to be sufficient to support the credibility of the inventors' story. *Id.*

Here, we find the inventors' testimony of actual reduction to practice, including that the invention worked for its intended purpose, sufficiently corroborated. Inventors Root and Sutton testified regarding the building and testing of a prototype of the claimed invention. J.A. 11815, 11834, 11971, 11982–83. As the Board found, that testimony was supported by both documentary evidence and noninventor testimony. *Decision*, J.A. 36–51. For example, Steven Erb, a former Research & Development Technician at VSI, testified that he "worked on the early GuideLiner prototypes," including the "first rapid exchange GuideLiner prototypes in early 2005." J.A. 12000. He confirmed that "[t]hese prototypes were then tested, including for

durability . . . and for functionality," which informed them that "it would work." J.A. 12001–02. Erb testified that he was both personally involved in some of the testing, and recalls watching the inventors perform testing on the prototypes on multiple occasions. *Id*. Deborah Schmalz, the former Vice President of Regulatory and Clinical Affairs at VSI, testified that she "specifically recall[ed] that a working prototype of the rapid exchange version of GuideLiner was created" prior to August 24, 2005. J.A. 9878–79.

Those findings are further supported by documentary evidence. For example, reports and invoices show that VSI ordered specialized "hypotubes" for prototypes of the rapid exchange GuideLiner in the first half of 2005. *See, e.g.*, *Decision*, J.A. 37–51; J.A. 9592–97 (project spend report); J.A. 11468 (invoice and purchase orders); J.A. 11471 (invoice and purchase orders). As the Board found, the dimensions of that hypotubing are consistent with the dimensions provided in the patents themselves and engineering drawings specific to the rapid exchange GuideLiner. *See, e.g.*, *Decision*, 38–51; '032 patent at col. 3 ll. 30–32, 43–46, 55–59, col. 7 ll. 19–25; J.A. 11592–93, 11595 (engineering drawings). Even Medtronic's expert witness acknowledged that it "doesn't make a lot of sense" for VSI not to have assembled the purchased parts together once they were ordered and received. J.A. 13920 at 208:10–25. And Medtronic concedes that a benchtop model depicted in a July 2005 sales presentation could have been used to test a device like the rapid exchange GuideLiner. *See* J.A. 9725 (photograph); *Decision*, J.A. 58 (citing *Medtronic, Inc. v. Teleflex Innovations S.À.R.L.*, IPR2020-00126, Conception and Reduction to Practice Reply at 17–18); *see also* J.A. 12011–12 (expert testimony regarding bench model testing). That evidence, taken together, is, at minimum, circumstantial evidence of corroboration.

Medtronic's main complaint is that some of the evidence in the record of corroboration is unclear as to whether or not it relates to the over-the-wire GuideLiner

or the rapid exchange GuideLiner. That is true, and certain documents could only be connected to the rapid exchange prototype through inventor testimony, which carries little to no weight in the context of corroboration; one cannot corroborate oneself, after all. However, when viewing the pertinent evidence in its entirety, we still find the inventors' story corroborated. Erb's and Schmalz' testimony, along with that of others and numerous documents, specifically mention the rapid exchange GuideLiner or can be connected to that version of the device in ways independent of the inventors' testimony.

For example, Teleflex asserts that a Computer Aided Design schematic from August 2005, J.A. 9751–52, corroborates the inventors' testimony that they had moved beyond prototyping and testing at that point in time. Medtronic challenges the Board's reliance on inventor Root's testimony to connect that document to the reduction to practice of the rapid exchange prototype. Although Root's testimony certainly enunciates that connection, his testimony is not required to establish the document's corroborative value. The document is labeled "GuideLiner Rapid Exchange/Preliminary Design Assumptions/Rev X03," indicating that the drawing is indisputably linked to the rapid exchange prototype, not the over-the-wire prototype, and that it is not the first, or even second, version of that drawing. *See Decision*, J.A. 42–43. The part number (20-0658) on the drawing is also consistent with those identified in certain purchase documents for tubing. *Compare* J.A. 9751–52 *with* J.A. 9749–50, J.A. 11480–84, *and* J.A. 11466–71. Moreover, the "law does not impose an impossible standard of 'independence' on corroborative evidence by requiring that every point of a reduction to practice be corroborated by evidence having a source totally independent of the inventor; indeed, such a standard is the antithesis of the rule of reason." *Knorr v. Pearson*, 671 F.2d 1368, 1374 (CCPA 1982). We find the inventors' testimony regarding

reduction to practice sufficiently corroborated under the rule of reason standard.

Because we find the Board's determination of actual reduction prior to the critical date supported by substantial evidence, we affirm the Board's finding that Itou does not qualify as prior art to the challenged patents under 35 U.S.C. § 102(e). Because Itou does not qualify as prior art, we likewise affirm the Board's holding that Medtronic did not demonstrate by a preponderance of the evidence that the challenged claims of the challenged patents are unpatentable.

II

Medtronic additionally argues that the Board erred in finding that there was reasonably continuous diligence in reducing the invention to practice during the critical period. Because we agree with the Board that the claimed invention was actually reduced to practice prior to the critical date and affirm the Board's finding that Itou did not qualify as prior art on that basis, there is no need to reach the issue of whether or not reasonable diligence was exercised.

CONCLUSION

We have considered Medtronic's remaining arguments but find them unpersuasive. For the foregoing reasons, the decision of the Board is affirmed.

AFFIRMED

United States Court of Appeals for the Federal Circuit

MEDTRONIC, INC., MEDTRONIC VASCULAR, INC.,
Appellants

v.

TELEFLEX INNOVATIONS S.À.R.L.,
Appellee

2021-2356, 2021-2358, 2021-2361, 2021-2363, 2021-2365

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2020-00126, IPR2020-00128, IPR2020-00132, IPR2020-00135, IPR2020-00137.

DYK, *Circuit Judge*, dissenting.

Contrary to the majority, I think that Itou[1] has been shown to be prior art to the patents at issue[2] and therefore could support a determination of anticipation or obviousness. This is so because, under the pre-America Invents

---

[1] U.S. Patent No. 7,736,355 to Itou et al. ("Itou").

[2] The challenged patents claim priority to the application that led to U.S. Patent No. 8,048,032 ("'032 patent"), filed on May 3, 2006.

Act ("AIA") 35 U.S.C. § 102(e), applicable to this case,[3] Itou has an earlier filing date than that of the '032 patent, and the evidence in this case fails to adequately corroborate inventor testimony that the rapid exchange ("RX") GuideLiner invention had been reduced to practice before Itou's filing date of September 23, 2005. I agree with the majority that the Board correctly identified the object of the invention as "providing increased backup support,"[4] Panel Op. 6, and that the testimony and corroborating evidence support the Board's finding that prototypes reflecting the invention were assembled before the priority date. Panel Op. 12. My disagreement lies with respect to the issue of testing. Specifically, the evidence does not corroborate that testing of the RX GuideLiner prototypes before the critical date had shown them to work for their intended purpose.

I

"To show reduction to practice, [a patent owner] must demonstrate that the invention is 'suitable for its intended

---

[3] The AIA's first-to-file provisions do not apply to the challenged patents, because they apply to patents with an effective filing date on or after March 16, 2013. *See* AIA, Pub. L. No. 112-29, § 3(n)(1), 125 Stat. 284, 293 (2011).

[4] The majority confusingly suggests the intended purpose of the invention may be even broader than the purpose identified by the Board and urged by Teleflex. Panel Op. 7–8; *see also* J.A. 52 (noting that Teleflex's position was that the intended purpose of the invention was "to increase backup support" (citation omitted)). I do not understand the majority to rest its disposition on a purpose broader than that found by the Board. And reviewing the Board's decision using a different standard than the Board's own standard would present a problem under *Securities & Exchange Commission v. Chenery Corp.*, 332 U.S. 194, 196 (1947).

purpose.'" *Scott v. Finney*, 34 F.3d 1058, 1061 (Fed. Cir. 1994) (quoting *Steinberg v. Seitz*, 517 F.2d 1359, 1363 (C.C.P.A. 1975)). This case does not involve a situation where the invention is "so simple and [its] purpose and efficacy so obvious that [its] complete construction is sufficient to demonstrate workability." *Id.* (citation omitted). Under such circumstances, testing is required to establish a reduction to practice. *Id.* at 1063 (citation omitted). As both the majority and the Board assumed, testing was required to establish a reduction to practice here. *See* Panel Op. 9–10; J.A. 57 n.22. "The issue . . . is not whether it might be possible to reduce the invention to practice by laboratory testing, but whether the particular tests made by [the inventor] were sufficient for that purpose." *Elmore v. Schmitt*, 278 F.2d 510, 513 (C.C.P.A. 1960). The evidence must show that the "tests accurately reproduced the operating conditions which would be encountered in *any practical use* of the invention." *Id.*

II

The testimony of the inventors here never describes (1) any specific tests showing the RX GuideLiner prototypes would work for their intended purpose of providing increased backup support[5] or (2) the results of the tests

---

[5] The inventors do describe in general terms tests regarding the simple delivery of cardiology devices in bench-top cardiac models, and they mention "pull tests to assess the durability of the prototype[s]." J.A. 11816 (Root Decl. ¶ 18); *see also* J.A. 11982 (Sutton Decl. ¶ 41). The Board also described the "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," in which these tests were performed. J.A. 43. On their face, these tests do not relate to

they did conduct. One inventor characterized the tests as "more qualitative than quantitative," J.A. 11983 (Sutton Decl. ¶ 41), and both declarant inventors relied in large part on their own assessment that they knew that the prototypes would work. *See, e.g.*, J.A. 11834 (Root Decl. ¶ 47) (testifying that, before performing any tests, the inventor "already had confidence that the rapid exchange GuideLiner would work for its intended purpose").

III

Even if the inventors' testimonies were sufficient to show relevant testing, "[i]n order to establish an actual reduction to practice, an inventor's testimony must be corroborated by independent evidence." *Cooper v. Goldfarb*, 154 F.3d 1321, 1330 (Fed. Cir. 1998). As with all "inventive facts," an "inventor's testimonial assertions" regarding testing "require corroboration by independent evidence." *Brown v. Barbacid*, 276 F.3d 1327, 1335 (Fed. Cir. 2002).

With respect to testing, the Board barely addressed the issue of corroboration. At best, it relied on two items. First, the Board referenced a July 2005 sales presentation that includes a picture of an over-the-wire ("OTW") GuideLiner device inserted into a benchtop cardiac model. *See* J.A. 43; J.A. 58. Second, the Board may have relied on the testimony of two non-inventor witnesses, Steven Erb (a technician and machinist at Vascular Solutions), *see* J.A. 58, and Deborah Schmalz (former Vice President of Regulatory and

---

whether the prototypes provided increased backup support. On that question, the inventors testified that they "observed the forces involved in navigating the GuideLiner prototype through such a [benchtop coronary] model," J.A. 11816 (Root Decl. ¶ 18); *see also* J.A. 11983 (Sutton Decl. ¶ 41), but they did not provide any explanation of what the testing found and how any results indicated that the devices provided increased backup support.

Clinical Affairs at Vascular Solutions). *See* J.A. 45. Neither the 2005 sales presentation nor the non-inventor testimony is adequate corroboration.

As to the first—the 2005 sales presentation—even if the single picture of an OTW GuideLiner device could lend some support for testing of that OTW GuideLiner device, it shows nothing about testing the RX GuideLiner prototypes, the devices at issue here. The OTW device is quite different: As the majority agrees, the OTW GuideLiner "was more akin to the prior art guide extension catheters and does not practice the challenged patents," and, as a result, "it had fewer challenges to overcome and work on it progressed more rapidly than for the rapid exchange device." Panel Op. 3. Evidence that does not even correspond to an embodiment of the patented invention cannot corroborate that invention's reduction to practice. *See In re NPT, Inc.*, 654 F.3d 1279, 1292 (Fed. Cir. 2011).

As to the second, the non-inventor testimony also does not offer adequate corroboration. The Board relied on Erb's testimony that he "worked on the early GuideLiner prototypes," including the "first rapid exchange GuideLiner prototypes in early 2005," related to prototypes allegedly made in January or February 2005. J.A. 12000 (Erb Decl. ¶ 8); J.A. 37. But the inventor testimony of reduction to practice is based on later prototypes, the so-called April and July prototypes. *See* J.A. 11834 (Root Decl. ¶ 48). The early 2005 prototypes Erb worked on are not claimed to have reduced the invention to practice. *See* J.A. 36 n.17. Accordingly, Erb's testimony about his work on these early prototypes has no corroborative value for the question of whether the April and July prototypes were ever tested and shown to work for their intended purpose, let alone that these later prototypes were tested and shown to work by the critical date.

As for the April and July prototypes, all Erb testified is that "[a]dditional testing . . . was performed on these subsequent prototypes" and that "[he] recall[ed] watching [inventor] Howard Root and others working in R&D test these subsequent prototypes, as well." J.A. 12002 (Erb Decl. ¶ 12). There is no specific description of what tests were performed or the results of the tests. Most significantly, there is no specific testimony of when the tests were performed and whether they were performed before the critical date.

The Board also mentioned Schmalz's testimony that she "specifically recall[ed] that a working prototype of the rapid exchange version of GuideLiner was created" before August 24, 2005." *See* J.A. 45 (quoting J.A. 9879 (Schmalz Decl. ¶ 7)). The fact a working prototype was created does not corroborate the inventors' testimony of testing. Schmalz did not testify to witnessing any tests, much less testify regarding what tests were performed, when they were performed, or the results of the tests. We have held that, absent other corroborating evidence, "vague testimony" like this by non-inventors is insufficient to corroborate inventor's testimony that an experiment demonstrated an invention had been reduced to practice. *Brown*, 276 F.3d at 1337.

The majority relies on additional items for corroboration not relied on by the Board to corroborate testing. The majority relies on documents related to the purchasing of parts. *See* Panel Op. 12 (citing J.A. 9592–97; J.A. 11468; J.A. 11471). This may corroborate assembly of prototypes but hardly corroborates testing, let alone successful testing by the critical date.

The majority also relies on an August 2005 Computer Aided Design ("CAD") schematic of an RX GuideLiner device. *See* Panel Op. 13 (citing J.A. 9751–52). While this CAD schematic may corroborate the inventors' testimony

that they had conceived of the RX GuideLiner invention before the critical date—which is not in dispute—it says nothing about testing of an RX GuideLiner device. The only testimony connecting the CAD schematic to the question of testing of the RX GuideLiner is the conclusory testimony of the inventors. *See* J.A. 11835 (Root Decl. ¶ 49) (the schematic "reflects the fact that we had moved past the prototyping phase and were getting ready to begin the formal quality process for bringing a completed medical device to market"); J.A. 11981 (Sutton Decl. ¶ 39). The majority agrees that the testimony of the inventors "carries little to no weight in the context of corroboration." Panel Op. 12–13; *see also Apator Miitors ApS v. Kamstrup A/S*, 887 F.3d 1293, 1296 (Fed. Cir. 2018).

IV

The majority suggests that finding the evidence insufficient here would impose an "impossible standard of 'independence' on corroborative evidence by requiring that every point of reduction to practice be corroborated by evidence having a source totally independent of the inventor." Panel Op. 13 (quoting *Knorr v. Pearson*, 671 F.2d 1368, 1374 (C.C.P.A. 1982)). That is hardly the case. Teleflex produced essentially no internal documents corroborating any testing that Vascular Solutions was doing with the RX GuideLiner prototypes in the critical period in 2005. *See* J.A. 11817–18 (Root Decl. ¶ 20). Common sense, and Teleflex's own testimony,[6] suggest that these documents would exist if testing had occurred. Teleflex's theory is that the relevant documents did exist at one time but have since

[6] "In [Jim Kauphusman's] role [as the primary engineer working on RX GuideLiner], he's creating some level of work product every day, and, you know, it comes in the form of drawings, prototypes, test results, you know, and written reports." J.A. 5244 (Sutton Dep. 36:23–37:2).

been destroyed. *See* J.A. 11817 (Root Decl. ¶ 20); J.A. 5197 (Erb Dep. 29:13–19). A rule that favors the retention of relevant documents does not create an "impossible standard" for inventors seeking to enforce a patent for a claimed invention.

V

Because the corroborating evidence that the RX GuideLiner prototypes had been tested and shown to work for their intended purpose was insufficient, I would reverse the Board's holding that the invention had actually been reduced to practice before Itou's priority date.[7] I respectfully dissent.

---

[7] The Board also found that Teleflex had demonstrated reasonable diligence between Itou's September 23, 2005, filing date and the filing date of the RX GuideLiner patent application on May 3, 2006. The majority does not reach the question of reasonable diligence. I note only that, with the exception of two law firm invoices covering work for a small portion of the diligence period, the corroborating evidence for reasonable diligence is equally lacking during the vast majority of the relevant period.