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

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

MEDTRONIC, INC., MEDTRONIC VASCULAR, INC.,

Appellants,

v.

TELEFLEX INNOVATIONS S.A.R.L.,

Appellee.

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

APPELLANTS MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC.'S COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC

BRITTANY BLUEITT AMADI
JENNIFER L. GRABER
WILMER CUTLER PICKERING
HALE AND DORR LLP
2100 Pennsylvania Avenue, N.W.,
Washington, DC 20037
(202) 663-6000

MARK C. FLEMING
TASHA J. BAHAL
MADELEINE C. LAUPHEIMER
HANNAH E. GELBORT
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Attorneys for Appellants Medtronic, Inc. and Medtronic Vascular, Inc.

July 7, 2023

CERTIFICATE OF INTEREST

Counsel for Appellants Medtronic, Inc. and Medtronic Vascular, Inc. certifies the following:

1. Represented Entities. Fed. Cir. R. 47.4(a)(1). Provide the full names of all entities represented by undersigned counsel in this case.

Medtronic, Inc. and Medtronic Vascular, Inc.

2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2). Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.

None.

3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3). Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.

Medtronic plc

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

ROBINS KAPLAN LLP: Cyrus A. Morton, Sharon Roberg-Perez, Christopher A. Pinahs, William E. Manske, Emily J. Tremblay

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

Medtronic, Inc. v. Teleflex Innovations S.A.R.L., Nos. 2021-2357, -2360, -2364 (Fed. Cir.)

Medtronic, Inc. v. Teleflex Innovations S.A.R.L., Nos. 2021-2359, -2362, -2366 (Fed. Cir.)

Medtronic, Inc. v. Teleflex Life Sciences Limited, Nos. 2022-1605, -1606, -1721, -1722 (Fed. Cir.)

Medtronic, Inc. v. Teleflex Life Sciences Limited, Nos. 2022-1721, -1722 (Fed. Cir.)

Vascular Solutions LLC, et al. v. Medtronic, Inc., et al., No. 0:19-cv-01760 (D. Minn.)

QXMedical, LLC v. Vascular Solutions, LLC, No. 0:17-cv-01969 (D. Minn.)

Medtronic, Inc. v. Teleflex Innovations S.A.R.L., IPR2020-01341 (P.T.A.B.)

Medtronic, Inc. v. Teleflex Innovations S.A.R.L., IPR2020-01342 (P.T.A.B.)

Medtronic, Inc. v. Teleflex Innovations S.A.R.L., IPR2020-01343 (P.T.A.B.)

Medtronic, Inc. v. Teleflex Innovations S.A.R.L., IPR2020-01344 (P.T.A.B.)

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

None.

Dated: July 7, 2023

/s/ Mark C. Fleming
MARK C. FLEMING
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

Page(s)

STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel decision is contrary to the following precedents of this Court: *Scott v. Finney*, 34 F.3d 1058 (Fed. Cir. 1994); *Cooper v. Goldfarb*, 154 F.3d 1321 (Fed. Cir. 1998); *Brown v. Barbacid*, 276 F.3d 1327 (Fed. Cir. 2002).

Based on my professional judgment, I believe that this appeal requires answers to the following precedent-setting questions of exceptional importance:

1. Where an invention's intended purpose is to provide an "improvement" or "increase" in benefits over prior designs, whether the patentee can demonstrate the invention works for that purpose without conducting any comparative testing.
2. Whether a patentee can satisfy the requirement to show independent corroboration of reducing an invention to practice through only (i) vague declarations from persons with no independent or personal knowledge of testing of the relevant prototypes and who cannot place testing of relevant prototypes within a timeframe before the critical date, and (ii) documentary evidence that says nothing about testing.

/s/ Mark C. Fleming
MARK C. FLEMING

INTRODUCTION

The majority and dissenting opinions offer irreconcilable answers to two important questions regarding reduction to practice, each of which warrants rehearing.

First, the majority found a reduction to practice of Teleflex's "GuideLiner" product before the critical date, even though Teleflex admittedly conducted no comparative testing of its GuideLiner device to determine whether it satisfied its intended purpose of increasing backup support as compared to a standard guide catheter.

Second, the majority concluded that Teleflex corroborated reduction to practice even though it proffered no independent corroboration of testing relevant prototypes before the critical date. At most, the documentary evidence cited by the majority instead related to conception or assembly of the device, not testing.

Judge Dyk's common-sense dissent is faithful to this Court's precedents. The only tests the inventors claimed they conducted "[did] not relate to whether the prototypes provided increased backup support." Diss.3-4, n.5. Judge Dyk also properly concluded that even the tests the inventors claim to have performed lack any corroboration from non-inventors, which should have compelled a finding of no reduction to practice. No non-inventor declarant or document indicated what tests were done, when, by whom, or with what result.

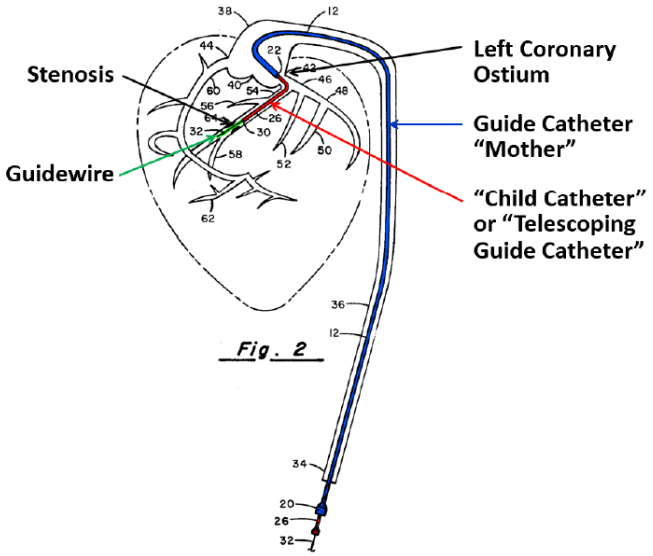
Under the majority's new reduction-to-practice standard, a patentee may rely exclusively on self-serving inventor testimony and possession of a prototype's parts, without any evidence that those parts were tested to show that the invention worked for its intended purpose before the critical date. The consequence of this published opinion will be significant: inventors will have no incentive to retain documents that track the timing, development, and testing of their inventions. Rather, a party in Teleflex's shoes can now take for itself what a third party has put in the public domain simply through self-serving inventor testimony, without any independent corroboration of successful testing before the critical date.

BACKGROUND

A. Prior Art

Over 40 years ago, physicians developed a non-invasive procedure to alleviate blockages ("occlusions") in the coronary artery. Appx1650-1655(¶¶33, 38-44). A surgeon inserted a guidewire, followed by a tube called a "guide catheter," through an artery in the wrist or thigh that leads to the aorta, continuing until the end of the guide catheter furthest from the physician was a few millimeters into the coronary artery's opening ("ostium") and the guidewire extended to the occlusion site. At that point, a cardiology device for treating the occlusion, such as a balloon or stent, could be inserted through the guide catheter, along the guidewire. Appx1662-1664(¶¶63-69).

A problem occasionally arose, however, as the device passed through the occlusion: it could produce backward force strong enough to dislodge the guide catheter from the ostium due to a lack of backup support. Appx1664-1665(¶¶70-71). The prior art accordingly developed "guide ***extension*** catheters," which were designed to lessen the likelihood of dislodgement. Such systems used a "mother-and-child" catheter assembly wherein a smaller, longer catheter (the "child") was inserted into the guide catheter (the "mother") and extended beyond the guide catheter's distal tip to the occlusion. Prior-art guide extension catheters thus held in position when the interventional cardiology device was advanced to the occlusion. Appx1665-1671(¶¶72-85); Appx1845; Appx1856-1861; Appx1920-1923(6:18-24, 6:29-34, 12:9-14:39, Fig.1A,6A-F).

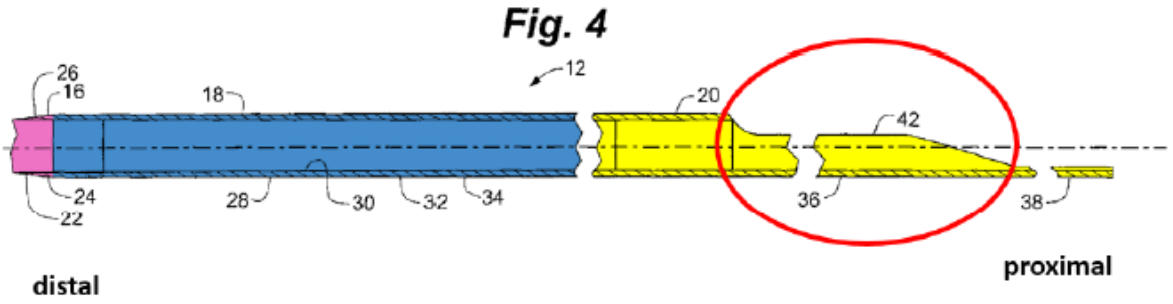


Appx1667(¶74) (U.S. Patent No. 5,120,323 to Shockey, issued June 9, 1992, Fig.2).

U.S. Patent No. 7,736,355 ("Itou") was filed on September 23, 2005, over seven months before the earliest effective filing date of the Teleflex patents involved in this appeal. Itou disclosed a catheter assembly for alleviating obstruction of blood flow. Appx1837(1:13-16). Itou's assembly included an outer guide catheter that was inserted into a coronary artery ostium, Appx1826(Abstract); Appx1839-1840(5:32-34, 7:7-11), and a longer inner catheter insertable through the guide catheter that extended beyond the guide catheter's distal end to the matter causing the obstruction. Appx1826(Abstract); Appx1838(3:59-61); Appx1827(Figs.1A-B); Appx1831-1832(Figs.5-6).

B. Teleflex's Patents And Reduction-To-Practice Arguments

Teleflex's patents, each entitled "*Coaxial Guide Catheter for Interventional Cardiology Procedures*," descend from a common application and share a common specification. The patents-in-suit describe using a guide extension catheter to reduce the likelihood that a guide catheter will dislodge from the ostium. Appx380-400. The specification explains that the device includes a rigid proximal (nearest the physician) portion that transitions to a tube and contains a transitional side opening (red circle) for inserting interventional cardiology devices into the guide extension catheter between the tube and a pushrod. Appx381(Fig.1); Appx384(Fig.4); Appx390(Figs.13-16); Appx396-399(6:38-54, 8:34-40, 10:63-11:3).



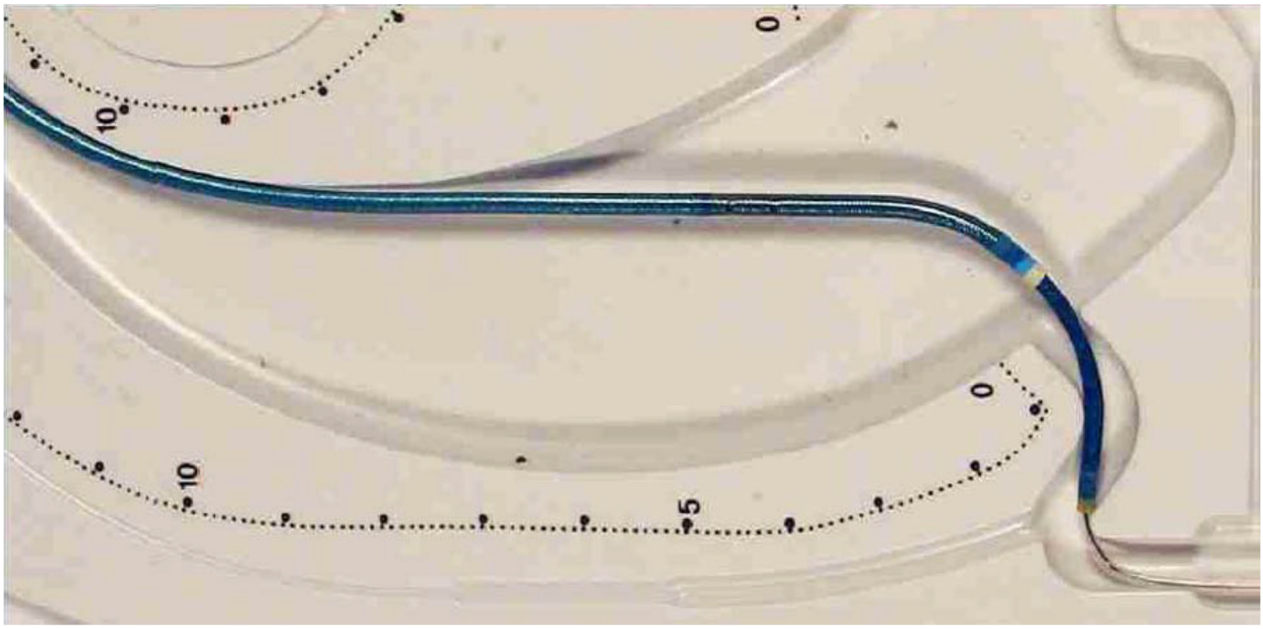
Appx1693-1695(¶¶133-134).

By summer 2005, Teleflex's predecessor-in-interest (Vascular Solutions, Inc.) conceived of two distinct devices, both of which it named "GuideLiner." One was an "over-the-wire" device composed of a smaller guide extension catheter with a full-length tube—*i.e.*, with no angled opening or pushrod. Appx394(2:40-56). This over-the-wire GuideLiner is undisputedly "not part of the inventions of the [challenged] patents" and resembles the prior art mother-and-child design. Appx19 (citing Ex. 1001 [Appx394(2:17-44)]).

The other "GuideLiner" was a "rapid-exchange" ("RX") design. Its guide extension catheter was only full-circumference at its distal end, which transitioned at its proximal end through an angled opening to a substantially rigid portion including an angled opening. *See supra* (Fig. 4). Teleflex asserted that this rapid-exchange device practiced the patents-in-suit. Appx19 n.10; Appx24077 n.3.

Inventors Howard Root and Gregg Sutton claim that they first reduced the claimed invention to practice by assembling components sourced from third parties

and then testing the resulting prototypes in April and July 2005. But Teleflex offered no corroboration of Root's and Sutton's purported testing of the prototypes, which they asserted was done by delivering interventional cardiology devices through prototypes within a "benchtop model," a two-dimensional dry model representing vasculature. Appx11982-11983(¶41); Appx11999, Appx12001-12002(¶¶6, 11-12). The record contains only one photo of a benchtop model, and it undisputedly depicts the unclaimed ***over-the-wire*** GuideLiner—not the claimed rapid-exchange GuideLiner:



Appx9723-9725 (cropped); Appx43 (Board acknowledging the photograph depicts the over-the-wire device).

No document mentions testing of the claimed ***rapid-exchange*** device. Two declarants used the word "testing," but neither had personal knowledge of any

specific tests of the relevant prototypes, and neither offered testimony that testing occurred before the critical date. Machinist Steve Erb referred to testing of "early prototypes" that are not claimed to have reduced the invention to practice, and beyond that, simply stated that "subsequent prototypes" were tested but did not say when. Appx12002(¶12). Indeed, the only timeframe he provided was vague and largely fell outside of the critical pre-September-2005 period. *See* Appx11999(¶6) (noting that work on the GuideLiner occurred "in the 2005-06 timeframe"). Deborah Schmalz, Teleflex's former Vice President of Regulatory and Clinical Affairs—who was not involved in any alleged testing—testified that she recalled that a working prototype of the rapid-exchange GuideLiner was created, Appx9878-9879, but did not provide details regarding whether that prototype embodied the claims, whether testing of that prototype was performed and, if so, what it entailed. Appx9876-9881.

C. Board Proceedings

After Teleflex sued Medtronic for infringement, Medtronic petitioned for *inter partes* review. Medtronic relied on Itou as an anticipation and obviousness reference. As relevant here, the parties' primary dispute was whether Teleflex proved reduction to practice before Itou's September 23, 2005 critical date.

Even though Teleflex presented no laboratory notebook entries, no testing protocols, no testing results, and no photographic evidence documenting any rapid-

exchange testing, the Board found that Teleflex tested rapid-exchange prototypes in April and July 2005 and determined that they worked for the claims' intended purpose of increasing backup support compared to using a guide catheter alone. Appx61. While the Board cited declarations of non-inventors Erb and Schmalz in support, it could not and did not cite them for any detail regarding testing of the relevant prototypes (because those declarations provide no such detail). Appx48-49.

D. Panel Decision

On appeal, Medtronic argued *inter alia* that (1) the Board erred in not requiring comparative testing to demonstrate the invention worked for its intended purpose—providing ***increased*** backup support compared to a guide catheter alone; and (2) the Board erred in finding corroboration of rapid-exchange testing despite legally insufficient evidence.

The panel majority acknowledged that the tests Teleflex's inventors claimed to have performed "did not specifically compare the invention prototype with a guide catheter alone," but nonetheless found their claimed testing sufficient to demonstrate that "the prototype would work for its intended purpose—providing increased backup support as compared with a guide catheter alone." Op.10. The majority further concluded that the inventors' accounts of reduction to practice—including testing—were sufficiently corroborated by (1) the testimony of non-

inventors Erb and Schmalz, (2) evidence that Teleflex had materials that it ***could have used*** to build a prototype and a benchtop model that it ***could have used*** to test any such prototype, and (3) documents "linked" to the alleged invention that made no mention of testing. Op.12-13.

Judge Dyk dissented, concluding that "Itou has been shown to be prior art" because "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." Diss.1-2. ***First***, he explained that "[t]he 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***."[1] Diss.3 (quoting *Elmore v. Schmitt*, 278 F.2d 510, 513 (C.C.P.A. 1960)). Here, Judge Dyk concluded, "[t]he testimony of the inventors … never describes (1) any specific tests showing the RX GuideLiner prototypes would work for their intended purpose of providing increased backup support or (2) the results of the tests they did conduct." Diss.3-4.

Second, Judge Dyk concluded that the evidence the Board relied on as corroboration of testing does not suffice because it either pertains to the wrong prototypes or does not actually discuss testing. Diss.4-5. The additional evidence

[1] All emphases added unless otherwise noted.

the majority, but not the Board, relied on—documentation of Teleflex's purchasing component parts from third parties and a Computer Aided Design ("CAD") drawing of the device—"may corroborate assembly of prototypes" or conception of the alleged invention, "but hardly corroborates testing, let alone successful testing by the critical date." Diss.6-7.

Finally, Judge Dyk rejected the majority's "suggest[ion] that finding the evidence insufficient here would impose an 'impossible standard of "independence" on corroborative evidence.'" Diss.7. He noted that "Teleflex produced essentially no internal documents corroborating any testing" of the relevant prototype, and "[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." Diss.7-8.

REASONS FOR GRANTING THE PETITION

I. REHEARING IS WARRANTED TO RESTORE THE CORRECT REDUCTION-TO-PRACTICE ANALYSIS

To establish actual reduction to practice before Itou's September 23, 2005 critical date, Teleflex had to prove the inventors "(1) constructed an embodiment or performed a process that met all the limitations of the [claimed invention]"; and (2) "determined that the invention would work for its intended purpose." *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). Inventor testimony alone cannot carry that burden; Teleflex must produce "sufficient evidence to

corroborate inventor testimony regarding these events." *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1169 (Fed. Cir. 2006).

Here, Teleflex and the Board agreed that the invention's intended purpose is to "provid[e] ***improved*** backup support for a guide catheter," Appx53; *see* Op.10, which requires an improvement ***compared to*** what existed before, Appx44; Appx52. The majority erred by disregarding the longstanding requirement that the invention be shown to work for its intended purpose, and instead finding reduction to practice where (1) no ***comparative*** testing was ever done, and (2) there was no corroboration of ***any*** testing of the relevant rapid-exchange prototype before the critical date.

A. The Majority Erred By Not Requiring Comparative Testing Where The Invention's Intended Purpose Specifically Required An "Increase" Or "Improvement" Over A Standard Guide Catheter

The majority accepted the Board's finding that the invention's intended purpose was "providing increased backup support ***as compared with*** a guide catheter alone." Op.10. Yet it erred in finding that the testing the inventors claim was done—which did not assess the claimed device's "improvement" or "increase" in backup support "as compared with" a standard guide catheter—was legally sufficient to show the device worked for its intended purpose.

The inventors generally described the simple delivery of interventional cardiology devices in benchtop cardiac models and "pull tests to assess the

durability of the prototype[s]." Diss.3 n.5 (citing Appx11816(¶18); *see also* Appx11982(¶41)). They conceded, however, that this testing was not done to ensure the device would increase backup support compared to a guide catheter alone, but merely to ensure a rapid exchange device "could deliver interventional cardiology devices." Appx11816.

Medtronic challenged the inventors' asserted testing as legally insufficient to show an improvement or increase in backup support. Opening Br. 41-43. The majority misconstrued Medtronic's legal challenge as one about the sufficiency of the evidence. Op.10. The question was not evidentiary, but whether Teleflex "demonstrated a solution to the problem intended to be solved by the invention." *Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994). As the dissent recognized, "[o]n their face, these tests do not relate to whether the prototypes provided increased backup support." Diss.3-4 n.5.

Where, as here, the invention's intended purpose requires an improvement over prior art solutions—as the Board found (and the majority accepted) it does[2]—

[2] *E.g.*, Appx44 (describing the intended purpose of "***providing increased backup support*** as compared to a guide catheter alone"); Appx53 (noting that the "inventors were concerned with a broader primary purpose, namely generally providing ***improved backup support*** for a guide catheter"); Appx55 ("[T]he 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.").

reduction to practice requires showing a delta or demonstrated change in how the device works compared to prior designs. *See*, *e.g.*, *z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1352-1353 (Fed. Cir. 2007) (where the invention's purpose was the "*reduction*, rather than the elimination, of [software] piracy," a reasonable jury could have found no reduction to practice because "the anti-piracy feature of [the invention] did not work even to *reduce* piracy"). The majority legally erred by finding comparative testing was not required despite the comparative nature of the intended purpose.

Teleflex does not dispute no testing was done to compare the rapid-exchange device's backup support against that of a standard guide catheter. *See*, *e.g.*, Diss.3-4 n.5 (inventors testified they "observed the forces involved in navigating the GuideLiner prototype through such a [benchtop coronary] model, but they did not provide any explanation of what the testing found and how any results indicated that the devices provided increased backup support" (citations omitted)). Yet the majority erroneously concluded that tests that "did not specifically compare the invention prototype with a guide catheter alone," and which were more "qualitative than quantitative," were somehow legally sufficient to show the prototype provided increased backup support. Op.10.

In short, there is a complete disconnect between the testing the inventors claim occurred, *see* Appx11816, and the testing needed to show the device would

work for the claims' intended purpose of ***improving*** backup support compared to a guide catheter alone. The majority legally erred by finding the rapid-exchange device worked for that intended purpose without any comparative testing.

If left in place, this legal error will seriously undermine the longstanding reduction-to-practice requirement that an invention be shown to work for its intended purpose. When parties like Teleflex seek to predate a published reference, they must be held to their burden of proving their inventions actually worked for their specific intended purposes before the critical date. Performing ***any testing*** is insufficient where the inventors themselves admit that testing was for an entirely different purpose. *See Scott*, 34 F.3d at 1063.

B. The Majority Erred By Failing To Require Corroboration Of Testing Of The Relevant Prototype Before The Critical Date

The majority also legally erred in finding that rapid-exchange GuideLiner testing before September 23, 2005 was independently corroborated. The majority permitted corroboration of ***assembly*** to stand in as corroboration for ***testing***—even though assembly and testing are two separate and distinct requirements. *See In re Garner*, 508 F.3d 1376, 1380-1381 (Fed. Cir. 2007) (corroboration of prototype's existence was insufficient "to establish corroboration of reduction to practice" because "it is also necessary to corroborate that the device worked for its intended purpose").

The majority highlighted three pieces of evidence as purported corroboration, but none independently corroborates pre-critical date ***testing*** of the relevant rapid-exchange device—as the dissent recognized. *See* Diss.4-7.

First, the majority cites the testimony of machinist Erb. But Erb's only reference to dates is to a general "2005-2006 timeframe," which he says is when "we were first working on the GuideLiner." Appx11999(¶6). Because the critical date is September 2005, much of the "timeframe" Erb identifies is too late.

The only testing Erb discusses either (1) involves prototypes Teleflex does not claim reduced the invention to practice, or (2) does not specify the timing of the testing. Erb claims he worked on the "early protoypes," which Teleflex does not claim to have reduced to practice, *compare* Appx12001(¶10) (discussing the process of machining down hypotubes for the "earliest prototypes") *with* ¶11 (continuing discussion of "these prototypes"); *see* Diss.5 ("The early 2005 prototypes Erb worked on are not claimed to have reduced the invention to practice," and thus have "no corroborative value for the question of whether the April and July prototypes were ever tested and shown to work for their intended purpose"). In any event, Erb acknowledges he "was not personally involved in, tests of the GuideLiner prototypes involving the delivery of stents and balloons in a benchtop heart model," Appx12001(¶11), which is the only test the majority found

showed the device worked for its intended purpose and which requires independent corroboration.

Regarding the relevant April and July 2005 prototypes, Erb's declaration recited only that "additional testing, including testing of the kind mentioned above, ***was performed*** on these subsequent prototypes." Appx12002(¶12). He provided no detail about ***when*** any such testing occurred, let alone whether it was before Itou's critical date. *See* Diss.6 (noting Erb provided "no specific description of what tests were performed or the results of the tests" for the relevant prototypes, or "when the tests were performed and whether they were performed before the critical date"). If Erb truly had independent knowledge that a rapid-exchange prototype was tested before the critical date, he could easily have so specified. But his vague declaration failed, as a matter of law, to corroborate the performance or timing of the testing, and the majority erred by relying on it as legally sufficient corroboration.

Second, the majority relied on the declaration of Deborah Schmalz, who testified that she "specifically recall[ed] that a working prototype of the rapid exchange version of GuideLiner was created" by August 2005. Op.12 (citing Appx9878-9879). But Ms. Schmalz claimed no first-hand knowledge of any ***testing*** and did not describe any testing purportedly performed. Op.12. In any

event, as the dissent recognized, that "a working prototype was created does not corroborate the inventors' testimony of testing." Diss.6.

Third, the majority cites "documentary evidence," but none of this evidence—even by the majority's analysis—corroborates testing. For example, the majority references "reports and invoices show[ing] that [Teleflex] ordered specialized hypotubes for prototypes" "in the first half of 2005." Op. 12. While the purchase of such parts may corroborate ***assembly*** of a prototype, it says nothing of testing. Diss.6.

Similarly, the majority cites "a July 2005 sales presentation" that depicts a photograph of the unclaimed over-the-wire device in a benchtop model. Op.12. Based on this photograph—which undisputedly shows the separate, unpatented over-the-wire device—the majority concludes that "a benchtop model" "***could have been used*** to test a device like the rapid-exchange GuideLiner." *Id*. That a benchtop model "***could have been used***" to test a rapid-exchange prototype in no way corroborates that the inventors ***actually*** tested one before the critical date. *See* Diss.5 ("Evidence that does not even correspond to an embodiment of the patented invention cannot corroborate that invention's reduction to practice."). By requiring no corroboration of testing or results, the majority's rule allows would-be inventors to claim reduction to practice based solely on a ***capability*** to test the invention—

even if no disinterested witness testifies that any testing actually happened before the critical date.

Finally, the majority relies on the "corroborative value" of a Computer Aided Design ("CAD") from August 2005. Op.13. As the dissent recognized, the CAD drawing may corroborate conception—which was not in dispute on appeal—but it says nothing about whether a prototype was ***tested*** before the critical date. Indeed, inventor Sutton provided the only testimony attempting to tie the CAD drawing to testing. Appx11981(¶39). But nothing in the drawing itself evidences testing, and because he is an inventor, Sutton's testimony needs corroboration; he cannot corroborate himself.

In short, the majority's corroboration analysis deviates from this Court's precedents. It excuses the requirement that inventors' assertions of reduction to practice—including testing—before the critical date be independently corroborated. *Garner*, 508 F.3d at 1380-1381; *Brown v. Barbacid*, 276 F.3d 1327, 1335 (Fed. Cir. 2002). Instead, the majority permitted Teleflex to substitute corroboration of assembly of the relevant prototype for corroboration that the relevant prototype was tested and shown to work for its intended purpose before the critical date.

The requirement to provide independent corroboration of inventors' reduction to practice claims is the main guardrail that ensures the rule of reason

achieves its purpose: to police against awards of priority based on self-interested inventor narratives regarding events that occurred long ago. *See*, *e.g.*, *Medichem*, 437 F.3d at 1171-1172; *Reese v. Hurst*, 661 F.2d 1222 (C.C.P.A. 1981). That is, independent corroboration ensures that the inventor testimony is legally sufficient.

Here, the majority removed that guardrail by replacing independent corroboration with reliance on documents that say nothing about testing and vague testimony unanchored to the critical date. Not one piece of evidence cited by the majority corroborates the inventors' assertion that the rapid-exchange GuideLiner was tested and shown to work for its intended purpose before the critical date. As Judge Dyk recognized (Diss.7-8), the majority's disregard of the narrow requirements giving teeth to the rule of reason will excuse the destruction of invention records, rather than encouraging their retention. Moreover, contrary to clear guidance from this Court that "[e]ven the most credible inventor testimony is *a fortiori* required to be corroborated by independent evidence," *Medichem*, 437 F.3d at 1171-1172, the majority's opinion here will enable parties to establish reduction to practice based solely on an inventor's *post hoc* assertion that "of course testing happened then." Rehearing is warranted to restore the critical requirement of independent corroboration for testing of a claimed device to show it worked for its intended purpose.

If rehearing is granted, the Court should also review the Board's finding that Teleflex showed diligence between September 2005 (Itou's filing date) and the filing of Teleflex's priority patent application in May 2006. Medtronic challenged the Board's finding of diligence, and the issue was fully briefed before this Court, but the panel majority did not address it. Op.14 (noting there was "no need to reach the issue of whether or not reasonable diligence was exercised"). As Judge Dyk recognized, "the corroborating evidence for reasonable diligence is equally lacking during the vast majority of the relevant period." Diss.8, n.7.

CONCLUSION

The petition should be granted.

Respectfully submitted,

/s/ Mark C. Fleming

MARK C. FLEMING
TASHA J. BAHAL
MADELEINE C. LAUPHEIMER
HANNAH E. GELBORT
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Attorneys for Appellants Medtronic, Inc. and Medtronic Vascular, Inc.

BRITTANY BLUEITT AMADI
JENNIFER L. GRABER
WILMER CUTLER PICKERING
HALE AND DORR LLP
2100 Pennsylvania Avenue, N.W.,
Washington, DC 20037
(202) 663-6000

July 7, 2023