No. 19-

IN THE

Supreme Court of the United States

MEDTRONIC, INC.,
Petitioner,

v.

MARK A. BARRY, M.D.,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

35 U.S.C. § 102(b) (2011) bars the patenting of an invention that was "in public use or on sale in this country, more than one year prior to the date of application for patent in the United States." The statutory bar is triggered by the sale or public use of an invention that is "ready for patenting," which can be shown by "proof of reduction to practice before the critical date." *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998). "A process is reduced to practice when it is successfully performed." *Corona Cord Tire Co.* v. *Dovan Chem. Corp.*, 276 U.S. 358, 383 (1928). In this case, however, a divided panel of the Federal Circuit ruled—as that court has in other cases—that reduction to practice required not just successful performance of the claimed process, but also the patentee's subjective determination that the process worked for a later-asserted "intended purpose" appearing nowhere in the patent.

Additionally, this Court has ruled that a patentee seeking to rely on the exception for "experimental" uses bears the burden of "full, unequivocal, and convincing" proof that the sale or public use was experimental. *Smith & Griggs Mfg. Co.* v. *Sprague*, 123 U.S. 249, 264 (1887). But the Federal Circuit has declared this Court's view not "tenable," departing from the decisions of other circuits addressing the same issue. *TP Labs., Inc.*, v. *Professional Positioners, Inc.*, 724 F.2d 965, 972 n.3 (Fed. Cir. 1984).

The questions presented are:

1. Whether a process invention is reduced to practice, and thus "ready for patenting," when all of its elements are "successfully performed," as this Court has held, or whether it must also be determined to

work for a further "intended purpose" that need not appear in the patent, as the Federal Circuit holds.

2. Whether, after proof that an invention was on sale or in public use more than one year before the patent application, the patentee bears the burden of proving experimental use by evidence that is "full, unequivocal, and convincing," as this Court and most regional circuits have held, or whether the patentee bears only a burden of production on experimental use and thus can prevail solely on the patentee's own post hoc testimony, as the Federal Circuit has held.

CORPORATE DISCLOSURE STATEMENT

Medtronic, Inc. is a wholly owned subsidiary of Medtronic plc. Medtronic plc is a publicly held corporation and no publicly held corporation owns 10 percent or more of Medtronic plc's stock.

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Medtronic, Inc. respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The Federal Circuit's opinion (App. 1a-67a) is reported at 914 F.3d 1310. The court's order denying rehearing and rehearing *en banc* is unreported. App. 93a-94a. The order of the U.S. District Court for the Eastern District of Texas denying Medtronic's renewed motions for judgment as a matter of law and motion for new trial and/or remittitur is unreported. App. 69a-81a.

JURISDICTION

The Federal Circuit entered judgment on January 24, 2019 (App. 1a) and denied Medtronic's petition for rehearing and rehearing *en banc* on April 29, 2019 (App. 93a-94a). On July 16, 2019, the Chief Justice extended the time for filing a petition for a writ of certiorari to September 26, 2019, and this petition is being filed on that date. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Section 102 of the Patent Act, 35 U.S.C. § 102 (2011), provides in relevant part:

> A person shall be entitled to a patent unless—
>
> * * *
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States … .
>
> * * *

Section 102 of the Patent Act, 35 U.S.C. § 102, provides in relevant part:

> (a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—
>
> > (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention … .
> >
> > * * *

INTRODUCTION

The on-sale and public-use bar of § 102(b) of the Patent Act "serves as a limiting provision, both excluding ideas that are in the public domain from patent protection and confining the duration of the monopoly to the statutory term." *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 64 (1998). The provision expresses Congress's "reluctance to allow an inventor to remove existing knowledge from public use" or to "'preserve[] the monopoly to himself for a longer period than is allowed by the policy of the law.'" *Id.* at 64-65 (quoting *City of Elizabeth* v. *American Nicholson Pavement Co.*, 97 U.S. 126, 137 (1877)).

This Court has established tests that police and enforce Congress's limits on the patent monopoly. *First*, the Court held in *Pfaff* that § 102(b) bars issuance of a patent on an invention that was on sale (or in public use) and was "ready for patenting" more than one year before the application's filing—known as the "critical date." 525 U.S. at 66-68. The "ready for patenting" criterion may be shown (though not exclusively) by "proof of reduction to practice before the critical date," *id.* at 67-68, where "reduction to practice" occurs once a claimed process is "successfully performed," *Corona Cord Tire Co.* v. *Dovan Chem. Corp.*, 276 U.S. 358, 383 (1928).

Second, though the statutory bar does not apply if the pre-critical-date use was "experimental," *Pfaff*, 525 U.S. at 64, this Court has long placed the burden on the patentee to prove experimental use with "full, unequivocal, and convincing" proof, once the challenger has established that the invention was on sale or in public use and ready for patenting before the critical date. *Smith & Griggs Mfg. Co.* v. *Sprague*, 123 U.S. 249, 264 (1887). Requiring the patentee to prove experimental use pro-

vides an additional safeguard against improper extension of the patent monopoly and removal of ideas from the public domain, by ensuring that the patentee does not dictate when his invention was on sale or in public use through self-serving testimony after the fact.[1]

The Federal Circuit, however—over a well-reasoned dissent by Chief Judge Prost—has interpreted the statutory bar in two ways contrary to this Court's precedent.

First, the Federal Circuit held that the invention claimed in the patent-in-suit was not "ready for patenting," even though there was no dispute that Respondent Dr. Mark Barry had "successfully performed" the patented process in three separate spinal surgeries on three separate patients well before the critical date. Dr. Barry further conducted a series of follow-up appointments for at least three months after the first two surgeries and for two months after the third surgery—all of which also occurred before the critical date.

In the panel majority's view, the statutory bar is not triggered by successful performance of the patented method, but additionally requires that the patentee have "'determined that the invention would work for its intended purpose,'" App. 14a, even if that "intended purpose" appears nowhere in the patent, and indeed is something the patentee ventures for the first time at

[1] Because the patent at issue was filed before March 16, 2013, it is subject to the provisions (including § 102(b)) in effect before enactment of the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011). But the issues raised in this petition remain under provisions currently in force. 35 U.S.C. § 102(a)(1); *see generally Helsinn Healthcare S.A.* v. *Teva Pharm. USA, Inc.*, 139 S. Ct. 628, 633-634 (2019) (holding that AIA's added language was "not enough of a change for us to conclude that Congress intended to alter the meaning of the reenacted term 'on sale'").

trial, defined as subjectively and narrowly as is convenient. Under that standard, Dr. Barry was allowed to prevail solely on a contention that he needed three full months of follow up after the third successful surgery—where the last surgery's three months of follow-up just happened to fall two weeks after the critical date—to determine that his invention was "ready for patenting." App. 14a-23a. As Chief Judge Prost explained in dissent, the panel majority's view "reflects some confusion in [the Federal Circuit's] case law," which that court has refused to correct. App. 57a. This Court should reaffirm that the public-use and on-sale bar applies when the invention is successfully performed, regardless of whether it separately meets some "subjective, outside-the-patent-language 'intended purpose.'" App. 59a (Prost, C.J., dissenting).

Second, the panel majority declined to place the burden of persuasion on Dr. Barry to show that his pre-critical-date use of the method was experimental, instead requiring only a burden of production, which the court deemed satisfied by Dr. Barry's self-serving testimony alone. This Court made clear over 130 years ago in *Sprague* that the patentee must shoulder the burden of proving experimental use—by "full, unequivocal, and convincing" proof—once a challenger has made a *prima facie* showing of a sale or public use before the critical date. 123 U.S. at 264. But the Federal Circuit has freed itself from that ruling, declaring it not "tenable." *TP Labs., Inc.* v. *Professional Positioners, Inc.*, 724 F.2d 965, 972 n.3 (Fed. Cir. 1984). The effect in this case was to permit Dr. Barry to prevail on his claim that otherwise-invalidating prior sales and public uses of the invention were experimental based solely on "his own after-the-fact testimony," even though he made no records of any experiments, did not report any

experimental results, and did not even inform his surgical patients that he was supposedly experimenting. App. 63a-67a (Prost, C.J., dissenting). Had the majority properly placed the burden of persuasion where this Court placed it in *Sprague*—on the patentee—there is no way Dr. Barry could have carried it.

The Federal Circuit's decision fundamentally alters the adjudication of basic constraints on the patent monopoly. The legal issues are squarely presented. And deciding these legal issues has great practical significance because "[t]he 'on sale' bar is probably the greatest source of litigation involving [§ 102] challenges to patent validity." Mueller, *Patent Law* 263 (5th ed. 2016). Clarification is also long overdue because the conflict between the Federal Circuit and this Court's precedents has long persisted, making clear that the court of appeals will continue to apply its erroneous legal standards unless this Court acts.

STATEMENT

This case involves surgical methods used to treat spinal deviation anomalies. One such anomaly is scoliosis, a condition in which the spine curves out of alignment. App. 2a. In severe cases, vertebrae also twist, and surgeons may perform procedures to "derotate" the twisted vertebrae back to a regular position. C.A.J.A. 1157-1158; C.A.J.A. 2598.

A. The '358 Patent's Claimed Surgical Technique

U.S. Patent No. 7,670,358 ("the '358 patent") is entitled "System and Method for Aligning Vertebrae in the Amelioration of Aberrant Spinal Column Deviation Conditions." App. 2a. The '358 patent was filed on December 30, 2004 and names Respondent Dr. Barry as inventor. App. 2a-3a. It claims "methods and systems

for correcting spinal column anomalies, such as those due to scoliosis." App. 2a.

The concept of "derotating" vertebrae during spinal surgery was well known to surgeons long before the '358 patent. *See* C.A.J.A. 2854-2855 ("[T]he derotation method of scoliosis … has been utilized for 40, 50 years."); *see also* C.A.J.A. 328(2:51-56) ("Over the last decade or so, more focus has been placed on the true three dimensional deformity."). After making an incision, surgeons would implant screws on both sides of a patient's vertebrae in the small bony structures known as "pedicle[s]." C.A.J.A. 2640. Surgeons would then attach metal shafts—sometimes called "derotators"—to the pedicle screws on vertebrae that had twisted out of place, pushing the shafts towards the center of the spine, thereby derotating (i.e., untwisting) the twisted vertebrae. C.A.J.A. 2642-2643. Once the desired correction was achieved, surgeons would lock rods connected to the pedicle screws in place. C.A.J.A. 2643.

Dr. Barry did not claim to have invented surgical derotation. Rather, the '358 patent's claimed improvement over prior art methods was that the surgeon would apply force to multiple vertebrae simultaneously (as opposed to one at a time) to correct (or "ameliorat[e]") the rotated vertebrae. C.A.J.A. 323(abstract); C.A.J.A. 329(3:48-59). As Dr. Barry testified at trial, "[t]he surgical correction of the rotated vertebrae" achieved by the invention, which constitutes "amelioration" of the spinal deformity, occurs during surgery and is visible immediately upon performing the derotation maneuver. C.A.J.A. 1369-1370.

While the patent describes "the amelioration of aberrant spinal column deviation conditions," the patent nowhere says anything about any follow-up time or that

its method must work in a particular set of curvatures or patients. App. 54a-56a (Prost, C.J., dissenting).

B. Dr. Barry's Pre-Critical-Date Surgeries Using The Claimed Technique

"The key facts are undisputed." App. 47a (Prost, C.J., dissenting). Although Dr. Barry filed a patent application on December 30, 2004, he admitted performing the claimed surgical method more than one year earlier (i.e., before the critical date)—indeed, he did so at least three times, on August 4, August 5, and October 14, 2003. App. 8a; App. 50a-51a (Prost, C.J., dissenting).

"It is undisputed that each of the three pre-critical-date surgeries met all the claim limitations" in the '358 patent and that Dr. Barry "charged his normal fee for them." App. 48a-49a (Prost, C.J., dissenting). Dr. Barry also knew during each surgery that he had successfully derotated the vertebrae, and he had conducted at least three months of follow-up on two of the surgeries and two months of follow-up for the third. App. 8a; App. 44a, 47a-48a, 64a-67a (Prost, C.J., dissenting). As Dr. Barry himself explained, he "correct[ed] the rotated vertebrae with a derotation maneuver [i.e., 'amelioration'] in the operating room." C.A.J.A. 1369-1370; C.A.J.A. 1426 (Dr. Barry conceding that the "crooked spine" was "derotate[d] and straighten[ed] at the end of the surgery").[2] Dr. Barry further determined that the post-operative alignment of the spine for all three patients was "[e]xcellent." C.A.J.A. 10285; C.A.J.A. 1350-1358.

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[2] *See also* C.A.J.A. 1190-1191 (Dr. Barry explaining with respect to the first surgery that he "derotate[d] [the] vertebrae into a good position"); C.A.J.A. 1193-1194 (Dr. Barry stating with respect to the second surgery that he achieved "a nice derotation and correction"); C.A.J.A. 1195 (Dr. Barry explaining with respect to the third surgery that he "perform[ed] derotation").

Although Dr. Barry claimed at trial to have been experimenting, he conceded that he "kept no records reflecting any experimental intent," "charged his normal fee for the surgeries," and "did not inform his patients that he was performing his surgical method for experimental purposes." App. 64a-66a (Prost, C.J., dissenting). Indeed, "[t]he only thing that affirmatively suggests these surgeries were experimental is that Dr. Barry said they were—after the fact, during litigation." App. 66a (Prost, C.J., dissenting).

C. District Court Proceedings

In February 2014, Dr. Barry sued Medtronic in the U.S. District Court for the Eastern District of Texas, asserting infringement of the '358 patent and two other patents. C.A.J.A. 15001-15016. With respect to the '358 patent, Dr. Barry asserted that Medtronic had induced infringement by selling devices that surgeons would use in surgeries to correct spinal deformities, allegedly using the method claimed in the '358 patent.

At a November 2016 trial, Medtronic presented undisputed evidence that Dr. Barry performed the claimed method in at least three surgeries before the December 30, 2003 critical date—on August 4, August 5, and October 14, 2003. C.A.J.A. 1190; C.A.J.A. 1193-1194; C.A.J.A. 1195; C.A.J.A. 1425. Dr. Barry's only response was his testimony—offered for the first time at trial—that he needed to perform the claimed method on three different patients with different curve types, and that he "wanted to see [his] patients at the three-month or more mark" following the surgeries (C.A.J.A. 1196), even though he acknowledged at trial that the surgeries themselves demonstrated successful derotations and nothing in the patent says anything about "follow-up time" (App. 54a-55a (Prost, C.J., dissenting)).

Despite the undisputed evidence that Dr. Barry performed the '358 patent's claimed method in at least three surgeries before the critical date, a jury found that the '358 patent was not invalid and infringed, and awarded damages of over $20 million. App. 91a; App. 84a-85a. The district court denied Medtronic's motions for judgment as a matter of law, a new trial, and remittitur, including Medtronic's motion seeking judgment that the '358 patent was invalid under the public-use and on-sale bar of 35 U.S.C. § 102(b).

D. Federal Circuit Proceedings

A panel of the Federal Circuit affirmed by a 2-1 vote. As relevant here, the majority held that Medtronic failed to show the invention was "ready for patenting" before the critical date because, in its view, an invention is not reduced to practice until it has been determined to work for an "'intended purpose,'" which "need not be stated in claim limitations" or elsewhere in the patent. App. 19a. Instead, Dr. Barry was permitted to create a new "intended purpose" through uncorroborated trial testimony that post-dated his patent application by more than a decade. Based on that testimony, the panel majority accepted Dr. Barry's claim that a "final follow-up from the [third] October surgery" was necessary at the three-month mark before Dr. Barry knew that the claimed method worked for its "intended purpose." App. 13a.

The majority separately ruled that, even if the claimed invention had been "ready for patenting" before the critical date, the pre-critical-date surgeries would still not invalidate the '358 patent because they fell within the "experimental use" exception. Placing the burden on Medtronic to prove that Dr. Barry's pre-critical-date uses and sales were not experimental, the

panel majority treated as conclusive Dr. Barry's uncorroborated testimony that he needed to perform the claimed method on three patients and conduct three months' follow-up for each one. App. 27a-28a.

Chief Judge Prost dissented, explaining that the majority's decision "perpetuate[d] the confusion" in the Federal Circuit's case law. App. 52a-53a, 57a-58a. Regarding readiness for patenting, she explained that the majority "conceive[d] of a more exacting intended purpose" than the patent required and ignored that "regardless of when his inventions were reduced to practice, Dr. Barry could have obtained a patent before the critical date." App. 50a-53a.

Chief Judge Prost further explained that the Federal Circuit precedent declining to shift the burden of proof to Dr. Barry was "questionable" in light of *Sprague*. App. 62a. But even assuming Dr. Barry had only a burden of production, she noted, he would not prevail because his evidence of experimentation was "just his own after-the-fact testimony," which was "insufficient as a matter of law to negate a bar." App. 63a-67a.

The Federal Circuit denied rehearing and rehearing *en banc*.

REASONS FOR GRANTING THE PETITION

I. THE FEDERAL CIRCUIT'S RULING THAT AN INVENTION IS NOT "READY FOR PATENTING" UNTIL THE INVENTOR DETERMINES THAT IT WORKS FOR A SUBJECTIVE "INTENDED PURPOSE" UNMENTIONED IN THE PATENT CONFLICTS WITH THIS COURT'S PRECEDENT

1. In *Pfaff* v. *Wells Electronics, Inc.*, 525 U.S. 55 (1998), this Court held that the on-sale bar under 35 U.S.C. § 102 applies "when two conditions are satisfied

before the critical date." *Id.* at 67. First, the invention "must be the subject of a commercial offer for sale." *Id.* Second, "the invention must be ready for patenting." *Id.* A party may show that an invention is "ready for patenting" in "at least two ways": (1) "by proof of reduction to practice before the critical date" or (2) "by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention."[3] *Id.* at 67-68. With respect to "reduction to practice," "[a] process is reduced to practice when it is successfully performed." *Corona Cord Tire Co.* v. *Dovan Chem. Corp.*, 276 U.S. 358, 383 (1928); *see also Coffin* v. *Ogden*, 85 U.S. 120, 125 (1874) (invention final where "complete and capable of working").

The Federal Circuit, however, has imposed an additional requirement that does not appear in the statute or this Court's case law: that an invention is not reduced to practice (and not "ready for patenting") until the inventor has "'determined that the invention would work for its intended purpose.'" App. 14a (quoting *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1373 (Fed. Cir. 2008)). That "intended purpose," the majority held, "need not be stated in claim limitations." App. 19a. Indeed, the purpose the panel majority relied on does not appear *anywhere* in the patent.

The only "purpose" recited in the patent is "the amelioration of aberrant spinal column deviation condi-

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[3] The Federal Circuit applies the same "ready for patenting" prong from *Pfaff* to the public-use bar. *See Invitrogen Corp.* v. *Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379-1380 (Fed. Cir. 2005). Medtronic therefore discusses the public-use and on-sale bar together.

tions." C.A.J.A. 330(6:7-8); App. 49a-50a, 53-56a (Prost, C.J., dissenting). Dr. Barry admitted that, during a successful surgery, he could see that a patient's aberrant spinal deviation condition had been corrected or "ameliorat[ed]" (a term the district court considered to be satisfied by some "improvement," C.A.J.A. 33). *See* C.A.J.A. 1369-1370 (Dr. Barry testifying the "surgical correction" happens in the operating room); C.A.J.A. 1158-1159 (Dr. Barry testifying that once "you have the correction that you are happy with, … you lock down the screws to the two rods," which happens "at the end of the procedure"); *see also* C.A.J.A. 1960 (Dr. Barry's expert agreeing that one knows "if there was at least some amelioration when the surgery is over"). Dr. Barry also admitted that he observed such amelioration during each of the three surgeries in question. C.A.J.A. 1190-1191, 1193-1195, 1369-1370. Thus, there can be no serious question that the patent's *recited* purpose was satisfied at the conclusion of Dr. Barry's pre-critical-date surgeries.

The panel majority moved the goal post farther. Six years after the patent issued, and 12 years after the patent application was filed, Dr. Barry claimed for the first time at trial that the intended purpose of the invention included the claimed method being performed on not one, not two, but three different types of spinal curvatures, *and* conducting at least three months of follow-up after *each surgery*. Neither supposed purpose was mentioned in the patent—or at any point, anywhere before litigation. The panel majority accepted Dr. Barry's post hoc articulation of the invention's "intended purpose" and ruled that the invention thus had not been reduced to practice before the critical date.

There are many flaws with the panel majority's approach. As Chief Judge Prost noted in dissent, even if

the patent's reference to amelioration of aberrant spinal "conditions" in the plural required the process to work on more than a single condition, Dr. Barry's invention was reduced to practice "by no later than the second surgery's completion." App. 50a & n.3; *but see* C.A.J.A. 330(6:29-36) (claim 1 requiring amelioration of "*an* aberrant spinal column deviation condition," singular (emphasis added)). Moreover, "[t]he claims say nothing about follow-up time," and "[t]he specification also says nothing relating follow-up time to the inventions' intended purpose." App. 54a-55a (Prost, C.J., dissenting). That makes sense, because the derotation *procedure* was well-known before Dr. Barry's method (*see supra* p. 7); the claimed method simply sought to make it *easier* for doctors to perform that procedure by rotating multiple vertebrae simultaneously.[4] *See* C.A.J.A. 2855 (claimed method merely "improve[d] the derotation" procedure, which had been used "for 40, 50 years").

Nonetheless, Dr. Barry asserted that he "*wanted* to see [his] patients at the three-month or more mark" following surgery. C.A.J.A. 1196 (emphasis added). And on that basis he was allowed to be the sole judge of when his invention was in the public domain. The ma-

[4] The well-established derotation procedure belies the panel majority's asserted "common-sense" belief that "for medical procedures, follow-up appointments can be necessary to determine when an invention is performing its intended purpose." App. 22a. The only thing novel about the claimed derotation method—i.e., simultaneous rotation—occurs *during the surgery*. Once the vertebrae are rotated into alignment, the remainder of the procedure (including any follow-up) proceeds as in the prior art. If Dr. Barry had thought at the time that a standard of care or three different curvature types were part of his intended purpose, he would have written that into the patent—but he did not. *See* App. 57a (Prost, C.J., dissenting).

jority acknowledged it had allowed Dr. Barry's subjective preferences to dictate the patent's validity, noting that "[a]ccording to Dr. Barry's *testimony at trial*, it was only … after the three-month follow-up for the [third] surgery that *he felt confident*" about his invention functioning for his asserted intended purpose. App. 8a (emphases added). Such subjective, uncorroborated assertions cannot exempt Dr. Barry's surgeries from the on-sale and public-use bar.

No objective evidence supports Dr. Barry's self-serving trial testimony. Each of Dr. Barry's post-operative reports indicates "[e]xcellent" post-operative alignment—which was unsurprising given that the procedure of derotating twisted vertebrae was well-known. C.A.J.A. 10285. And even if some follow-up were relevant to determining whether Dr. Barry's invention had achieved some undisclosed "intended purpose," there was no patentable reason to require follow-up appointments for all three surgeries, or that all three surgeries have three months of follow-up. As Medtronic explained, two surgeries occurred in August 2003, and three months' follow-up after that was November 2003—still well before the December 30, 2003 critical date.[5] Nonetheless, the majority accepted Dr. Barry's insistence that the intended purpose could only be assessed three months after the *third* surgery, again an issue nowhere mentioned or claimed in the patent. The majority's reliance on a *third* surgery and *three*

[5] The panel majority's suggestion that Medtronic "ha[d] not meaningfully presented" such an argument (App. 19a n.7) is demonstrably false. Chief Judge Prost summarized the relevant briefing by both sides and concluded that "[t]his straightforward argument is before us." App. 56a-57a. Notably, "[n]ot even Dr. Barry has urged otherwise." App. 57a (Prost, C.J., dissenting).

months' follow-up was utterly unsupported.[6] Thus, the panel majority upheld the patent on the bare assertion that Dr. Barry subjectively "felt confident" only after three months of follow-up on the third surgery (App. 8a), which happened to be two weeks after the critical date of December 30, 2003.

2. In a footnote, the panel majority sought to reconcile its "intended purpose" requirement with this Court's standard (App. 15a n.6), but it misread the Court's case law. The majority believed its "intended purpose" requirement is reflected in *Corona Cord Tire*'s statement that "reduction to use is shown by instances making clear that [the invention] did so work," as promised by the patent itself. 276 U.S. at 382-383. But that statement only reinforces that an invention is reduced to practice when it is successfully performed; it does not require more. A process is successfully performed—or "so work[s]" consistent with what "th[e] patent is for," *id.*—when it satisfies all the claim elements.

The majority also cited this Court's statement in *Pfaff* that an inventor's "'*bona fide* effort to bring his invention to perfection, or to ascertain whether it will answer the purpose intended,'" does not constitute an invalidating use. *Pfaff*, 525 U.S. at 64-65 (quoting *City of Elizabeth*, 97 U.S. at 137). But the Court there was

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[6] The majority's statement that "[b]oth Dr. Barry and his expert indicated" the amount of follow-up was appropriate, App. 17a, "add[ed] very little" to the analysis because that only shows "what the expert thought Dr. Barry was thinking," App. 54a n.4 (Prost, C.J., dissenting). *See* App. 56a (Prost, C.J., dissenting) ("[E]ven if I were to accept that the '358 patent's language made follow-up time relevant to the inventions' intended purpose, I would still fail to understand the legal relevance of Dr. Barry's alleged need for the third surgery's follow-up, as opposed to just the first two[.]").

explaining the separate "experimental use" doctrine, not the concept of "ready for patenting" or "reduction to practice." *See id.* at 64 (explaining "the distinction between inventions put to experimental use and products sold commercially"). Indeed, the quoted statement comes from *City of Elizabeth*, a case that addressed not reduction to practice, but experimental use. 97 U.S. at 135. To the extent the panel majority believed that *Pfaff*'s reliance on *City of Elizabeth* "reflects the intertwining, as opposed to any clean separation, of experimental use and reduction to practice standards" (App. 15a n.6), the majority is wrong for the reasons explained in Part II. The panel majority's confusion of the two doctrines itself warrants this Court's review.

The panel majority's view is also inconsistent with the statutory context. A party challenging a patent's validity under § 102(b) must make a *prima facie* showing that the patent was in public use or on sale. A *prima facie* case means "[a] party's production of enough evidence to allow the fact-trier to infer the fact at issue and rule in the party's favor." *Black's Law Dictionary* 1441 (11th ed. 2019). If "intended purpose" is part of the "reduction to practice" standard, and the "intended purpose" is whatever the patentee says he believed it was after the fact, it is difficult to see how the *prima facie* case involving such purpose could ever be made. Beyond what is stated in the patent, Medtronic could hardly have known what Dr. Barry intended. Certainly, "reduction to practice" would no longer be "the best evidence that an invention is complete" and "ready for patenting" for a party challenging the patent's validity. *Pfaff*, 525 U.S. at 66.

Not only that, but the majority's approach creates an asymmetry within the "ready for patenting" standard. As this Court made clear, "reduction to practice"

is only one way of showing "ready for patenting." *Pfaff*, 525 U.S. at 66-68. Another way is by proof of "drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention," which is based on objective evidence. *Id.* at 58, 67-68 (the "drawings Pfaff sent to the manufacturer before the critical date" were sufficient because they "fully disclosed the invention"). The same is true of the inquiry Chief Judge Prost applied based on *Pfaff*: "ready for patenting" is shown by "whether an inventor 'could have obtained a patent' on his or her invention." App. 50a-52a; *see Pfaff*, 525 U.S. at 67-68. As Chief Judge Prost explained, objective evidence in the record demonstrated that Dr. Barry could have obtained a patent by the time he performed the second surgery on August 5. App. 50a-52a. The majority's subjective "intended purpose" test highlights just how incoherent the Federal Circuit's interpretation of this Court's "ready for patenting" standard has become: whereas the inventor's preparation of qualifying drawings or descriptions or ability to obtain a patent on the invention is shown by objective evidence, reduction to practice apparently (in the Federal Circuit's view) turns on subjective evidence, namely what "intended purpose" the inventor supposedly held in his mind.

At bottom, the panel majority's holding will allow patentees to evade § 102(b)'s "limiting provision," which serves the critical purpose to "exclud[e] ideas that are in the public domain from patent protection and confin[e] the duration of the monopoly to the statutory term." *Pfaff*, 525 U.S. at 64. The panel majority permitted exactly that in this case and, through its precedential opinion, ensured the same result in all future cases. Even though Dr. Barry successfully performed the claimed method on three patients and con-

ducted three months of follow-up for two of them (and two months for the third patient) before the critical date, the panel majority made those facts irrelevant. No longer was Dr. Barry's method in the public domain (years after the sales and public uses) because, after "'abandon[ing] … his right'" to patent by all objective accounts, *Pfaff*, 525 U.S. at 64, Dr. Barry asserted later that he *subjectively* thought he needed more time to "feel confident" that his invention worked for a litigation-inspired "intended purpose," thereby improperly extending patent protection beyond the statutory term.

The Court should correct the Federal Circuit's error and reaffirm that "[a] process is reduced to practice when it is successfully performed," *Corona Cord Tire*, 276 U.S. at 383, regardless of whether a patentee could later claim that additional work was needed in order to meet some other, additional purpose.

II. THE FEDERAL CIRCUIT'S RULING THAT A PATENTEE INVOKING THE "EXPERIMENTAL USE" DOCTRINE HAS NO BURDEN OF PERSUASION CONFLICTS WITH THIS COURT'S PRECEDENT

Over 140 years ago, this Court articulated a judicially-created exception to the statutory "public use" and "on-sale" bar. In *City of Elizabeth*, this Court explained that "[t]he use of an invention by the inventor himself, or of any other person under his direction, *by way of experiment*" falls outside of the statutory bar. 97 U.S. at 134 (emphasis added); *see also Egbert* v. *Lippmann*, 104 U.S. 333, 336 (1881) ("[A] use necessarily open to public view, if made in good faith solely to test the qualities of the invention, and for the purpose of experiment, is not a public use within the meaning of the statute."). Ten years after *City of Elizabeth*, the Court further explained that although such "experi-

ment[al]" uses are "excepted out of the prohibition of the statute," upon a showing of prior use before the critical date, the patentee must establish that such a use "was for the purpose of perfecting an incomplete invention by tests and experiments" by proof that is "full, unequivocal, and convincing." *Sprague*, 123 U.S. at 256, 264.

Despite this Court's controlling precedent, the panel majority refused to "impose a (high) burden of persuasion on the patent owner to establish experimental use," applying only a burden of production and thus treating as conclusive Dr. Barry's uncorroborated testimony that he was experimenting. App. 12a-13a & n.3.[7] That ruling contradicts not only this Court's decision in *Sprague*, 123 U.S. 249, but also the rulings of other courts of appeals. Following *Sprague*, other circuits have required the patentee, upon a *prima facie* showing of prior use or sale, to prove that the use or sale was experimental. The Federal Circuit is the outlier, having rejected this Court's ruling in *Sprague* as not "tenable" in *TP Laboratories*, 724 F.2d at 971-972 & n.3. But as Chief Judge Prost pointed out in dissent, the reasoning of *TP Laboratories* was "questionable even at the time" and has "not improved with age." App. 62a.

Had the Federal Circuit followed *Sprague*, Dr. Barry's claim of experimentation would have surely failed. The panel majority's finding of experimentation rested solely on Dr. Barry's own post hoc, litigation-

[7] Medtronic presented its arguments concerning the parties' respective burdens in its petition for rehearing because it would have been "futile" to request that the panel overrule a prior panel decision. *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118, 125 (2007); *see also Robert Bosch, LLC* v. *Pylon Mfg. Corp.*, 719 F.3d 1305, 1316 (Fed. Cir. 2013) (*en banc*).

driven testimony. Those statements were "meager and bald," *Sprague*, 123 U.S. at 265, falling far short of even *TP Laboratories'* requirement that the patentee "point to or … come forward with" some evidence, 724 F.2d at 971, much less the "full, unequivocal, and convincing" proof required by *Sprague*, 123 U.S. at 264.

1. In 1887, this Court squarely placed the burden of proving experimental use on the patentee, explaining:

> In considering the evidence as to the alleged prior use … of an invention, which, if established, will have the effect of invalidating the patent, and where the defense is met only by the allegation that the use was not a public use in the sense of the statute, because it was for the purpose of perfecting an incomplete invention by tests and experiments, *the proof, on the part of the patentee, … should be full, unequivocal, and convincing.*

Sprague, 123 U.S. at 264 (emphasis added); *see also Root* v. *Third Avenue R.R. Co.*, 146 U.S. 210, 226 (1892).

Other circuits to consider the issue have followed *Sprague*, requiring the patentee—upon a *prima facie* showing that an invention was on sale or in public use—to prove that the sale or use was experimental. *See, e.g.*, *Swain* v. *Holyoke Mach. Co.*, 109 F. 154, 159-160 (1st Cir. 1901); *Aerovox Corp.* v. *Polymet Mfg. Corp.*, 67 F.2d 860, 861 (2d Cir. 1933); *Wendell* v. *American Laundry Mach. Co.*, 248 F. 698, 700 (3d Cir. 1918); *Virginia-Carolina Peanut Picker Co.* v. *Benthall Mach. Co.*, 241 F. 89, 100 (4th Cir. 1916); *In re Yarn Processing Patent Validity Litig.*, 498 F.2d 271, 286 (5th Cir. 1974); *Dunlop Co.* v. *Kelsey-Hayes Co.*, 484 F.2d

407, 413 (6th Cir. 1973); *American Ballast Co.* v. *Davy Burnt Clay Ballast Co.*, 220 F. 887, 889-890 (7th Cir. 1915); *Omark Indus., Inc.* v. *Carlton Co.*, 652 F.2d 783, 787 (9th Cir. 1980); *Manufacturing Research Corp.* v. *Graybar Elec. Co.*, 679 F.2d 1355, 1362 (11th Cir. 1982); *In re Tournier*, 17 App. D.C. 481, 489-490 (D.C. 1901); *cf. Merrill* v. *Builders Ornamental Iron Co.*, 197 F.2d 16, 19 (10th Cir. 1952). Even the Federal Circuit's predecessor—the Court of Customs and Patent Appeals—followed *Sprague*, holding that "once public use or sale before the critical date has been established, the burden is on the patentee to prove that such use was experimental by 'full, unequivocal, and convincing' proof" (which it interpreted as proof by "clear and convincing evidence"). *In re Dybel*, 524 F.2d 1393, 1400-1401 (C.C.P.A. 1975).

Despite the overwhelming authority to the contrary, in *TP Laboratories* the Federal Circuit held that "the statutory presumption of validity provided in 35 U.S.C. § 282 places the burden of persuasion upon the party attacking the validity of the patent, and that burden of persuasion does not shift at any time to the patent owner." 724 F.2d at 971. Instead, upon a *prima facie* showing of a prior public use or sale, the patentee need only "be able to point to or … come forward with convincing evidence to counter th[e] showing" of public use. *Id.* The Federal Circuit further noted that to the extent *Sprague* "impose[d] the ultimate burden of persuasion on the patent holder," it did "not believe that view is tenable in the face of the subsequently enacted statutory presumption [of validity]." *Id.* at 971 n.3.

TP Laboratories avowedly conflicts with *Sprague* by failing to place the burden of persuasion on the patentee regarding experimental use. Instead, the patentee need only satisfy a (far lower) burden of *produc-*

tion. *TP Labs.*, 724 F.2d at 971. But this Court has "consistently distinguished between burden of proof, which [is] defined as burden of persuasion, and an alternative concept, which [is] increasingly referred to as the burden of production or the burden of going forward with the evidence." *Director, Office of Workers' Comp. Program, Dep't of Labor* v. *Greenwich Collieries*, 512 U.S. 267, 274 (1994).

The primary reason the Federal Circuit gave for disregarding *Sprague* was that the presumption of validity in 35 U.S.C. § 282 somehow impliedly overruled *Sprague*. *See TP Labs.*, 724 F.3d at 971-972 & n.3. But as this Court has since held, "by the time Congress enacted § 282 and declared that a patent is 'presumed valid,' the presumption of patent validity had long been a fixture of the common law." *Microsoft Corp.* v. *i4i Ltd. P'ship*, 564 U.S. 91, 102 (2011); *see also* H.R. Rep. No. 82-1923, at 29 (1952) ("The first paragraph declares the *existing* presumption of validity of patents." (emphasis added)); *id.* at 10. There is no reason to think that enactment of § 282 shifted the ground underneath *Sprague*.

The Federal Circuit further pointed to a Sixth Circuit decision—*Austin Machinery Co.* v. *Buckeye Traction Ditcher Co.*, 13 F.2d 697 (6th Cir. 1926). *TP Labs.*, 724 F.2d at 971 n.3. In *Austin Machinery*, the Sixth Circuit stated that, due to the presumption of validity, the "burden of proof as to all the elements involved continues until the end upon one who attacks the patent grant." 13 F.2d at 700. But the Sixth Circuit appears to have abandoned that view, holding subsequently (consistent with *Sprague*) that "when an alleged infringer makes a prima facie demonstration of prior use, the inventor then has the burden of *proving* that this use 'was not of a functionally operative device, or was substantially used for experimentation or testing pur-

pose.'" *Dunlop*, 484 F.2d at 413-414 (emphasis added) (quoting *FMC Corp.* v. *F. E. Myers & Bro. Co.*, 384 F.2d 4, 10 (6th Cir. 1967)); *accord Stewart-Warner Corp.* v. *City of Pontiac*, 717 F.2d 269, 272 (6th Cir. 1983); *General Motors Corp.* v. *Toyota Motor Co.*, 667 F.2d 504, 508 (6th Cir. 1981).

The Federal Circuit's view also contradicts the general principle that the party who "claims the benefits of an exception to the prohibition of a statute" must prove the exception. *United States* v. *First City Nat'l Bank of Houston*, 386 U.S. 361, 366 (1967); *see also NLRB* v. *Kentucky River Cmty. Care, Inc.*, 532 U.S. 706, 711 (2001). As this Court observed in *Sprague*, an experimental use is a "thing implied as *excepted out of the prohibition* of the statute." 123 U.S. at 256 (emphasis added); *accord Root*, 146 U.S. at 225-226; *International Tooth-Crown Co.* v. *Gaylord*, 140 U.S. 55, 63 (1891); *see also, e.g.*, *Swain*, 109 F. at 159; *Eastman* v. *City of N.Y.*, 134 F. 844, 853 (2d Cir. 1904); *In re Yarn Processing*, 498 F.2d at 278; *American Ballast*, 220 F. at 890; *Denivelle* v. *MacGruer & Simpson*, 4 F.2d 329, 332 (9th Cir. 1925); *In re Tournier*, 17 App. D.C. at 489. The burden thus falls to the patentee to prove that the exception applies.

2. The Federal Circuit's disregard of *Sprague*'s requirement that the patentee prove experimental use by "full, unequivocal, and convincing" proof, 123 U.S. at 264, was dispositive here because Dr. Barry's evidence of experimentation (beyond his own say-so) was nonexistent. That is clear for two reasons.

First, this Court has consistently held that a patentee's uncorroborated testimony is "insufficient" to establish experimentation, *Sprague*, 123 U.S. at 265, and yet that is all Dr. Barry had. As the Court ex-

plained, a patentee's uncorroborated testimony is presumed to be "as favorable to himself as the facts will justify." *Id.* at 258; *see id.* at 265 (dismissing the patentee's uncorroborated testimony as "meager and bald, and quite insufficient" to establish experimental use). Thus, courts must "examine the circumstances" under which the invention was used to determine whether the patentee was engaged in "a *bona fide* effort to bring his invention to perfection." *City of Elizabeth*, 97 U.S. at 133, 137. And that is a high burden. App. 13a n.3. For example, in *City of Elizabeth*, the inventor had filed a caveat;[8] "[the claimed pavement] was constructed by [the inventor] at his own expense"; the inventor's testimony that he was experimenting was "corroborated by that of several other witnesses in the cause"; "the nature of a street pavement [was] such that it [could not] be experimented upon satisfactorily except on a highway, which is always public"; and the inventor "did not sell [the invention], nor allow others to use it or sell it." 97 U.S. at 133-134, 136. Those surrounding circumstances satisfied the patentee's (high) burden of proving experimentation.

By contrast, where "[t]he only witness called to prove the fact of two years' prior use was the patentee himself," such testimony should be met with skepticism, as "[i]t is to be supposed that his statement of the

[8] A "caveat" was a legal document "that the inventor could file in the Patent Office to provisionally lay claim to the invention before filing the patent application." Rooklidge & Jensen, *Common Sense, Simplicity and Experimental Use Negation of the Public Use and on Sale Bars to Patentability*, 29 J. Marshall L. Rev. 1, 9 n.34 (1995). Filing a caveat allotted inventors the time necessary "to develop their imperfections and to make the improvements necessary to their adaption to practical uses." *Id.* (quoting S. Rep. No. 24-338, at 19 (1836)). Caveats were established by the 1836 Patent Act, but abolished in 1910.

circumstances is as favorable to himself as the facts will justify." *Sprague*, 123 U.S. at 258. Accordingly, the Court—finding the patentee's testimony to be "indefinite and vague," "meager and bald," and "insufficient"—concluded that "the use of the machine was apparently for the purpose of conducting an established business," rather than for experimentation, and that the patentee's "proof [fell] far short of establishing" experimental use. *Id.* at 265-266.

Similarly, in *Root*, the Court distinguished *City of Elizabeth* based on the lack of contemporaneous corroborating evidence, noting that the patentee in *Root* "did not file a caveat" or make "any part of the structure … at his own expense," and ultimately concluded that "[i]t cannot be fairly said from the proofs that the plaintiff was engaged in good faith, from the time the road was put into operation, in testing the working of the structure he afterwards patented." 146 U.S. at 225. And in *Gaylord*, the Court again rejected an assertion of experimentation based on the patentee's testimony alone, looking instead to the surrounding circumstances and explaining that "[t]he fact that [the patentee] taught [the patented technique] to a large number of dentists throughout the country, with *no suggestion that it was an experiment*, and received pay for such instruction, precludes the defense he now sets up that all this was simply tentative." 140 U.S. at 62 (emphasis added); *cf. City of Elizabeth*, 97 U.S. at 134 ("This evidence is corroborated by that of several other witnesses in the cause.").

Had the Federal Circuit properly followed *Sprague* and required Dr. Barry to prove that his pre-critical-date uses and sales of the claimed surgical method were experimental by "full, unequivocal, and convincing" proof, 123 U.S. at 264, Dr. Barry, too, would have fallen

"far short" of meeting his burden. *Id.* at 265-266. As Chief Judge Prost noted and the panel majority did not deny, Dr. Barry "kept no records reflecting any experimental intent," "charged his normal fee for the surgeries," and "did not inform his patients that he was performing his surgical method for experimental purposes." App. 64a-67a. Nor did any witness corroborate his vague and unsupported testimony that the three pre-critical-date surgeries were experimental. App. 63a & n.7 (Prost, C.J., dissenting).

Yet the panel majority disregarded these critical (and dispositive) facts because "Dr. Barry was the only one" who actually practiced the invention such that the invention involved "a method kept within the inventor's control." App. 27a-28a, 32a. Not only does that conclusion conflict with this Court's precedent, it is contrary to basic logic and common sense. The mere fact that the inventor—rather than another—used the claimed invention prior to the critical date cannot render such use experimental where the surrounding circumstances suggest the opposite. As this Court explained in *Root*, where "[a] single sale to another of such a machine as that shown to have been in use by the complainant [before the critical date] would certainly have defeated his right to a patent, an[d] yet during that period … he himself used it for the same purpose for which it would have been used by a purchaser," "[w]hy should the similar use by himself not be counted as strongly against his rights as the use by another…?" 146 U.S. at 226 (quoting *Sprague*, 123 U.S. at 256-257). Similarly, here, absolutely nothing distinguished Dr. Barry's pre-critical-date paid surgeries from an ordinary surgery performed for commercial purposes. *See* App. 64a-67a (Prost, C.J., dissenting).

Second, even if *Sprague* and its progeny were not clear that unsupported inventor testimony alone cannot satisfy the patentee's burden of proving experimentation by "full, unequivocal, and convincing" evidence, such testimony certainly cannot do so in this case. As this Court explained in *Sprague*, "where the use is mainly for the purposes of trade and profit, and the experiment is merely incidental to that, the principle, and not the incident, must give character to its use." 123 U.S. at 256. Dr. Barry unquestionably used his surgical method "for profit in the ordinary course and conduct of his business, and for the purpose of a successful prosecution of that business"; accordingly, "it can hardly be said with propriety that such use was merely experimental," even if "during the period of its operation he was also engaged in the invention of improvements by which he hoped and expected to make [the invention] more valuable and useful." *Id.*

It is undisputed that Dr. Barry was paid for performing the pre-critical-date surgeries using the claimed method in the ordinary course of his business as a practicing surgeon. Yet the panel majority disregarded this fact because Dr. Barry "earn[ed] his normal fees from the three surgeries," and "did not 'exploit' his invention as a means to attract the three patients for those surgeries or [] charge *more* because he used his new technique." App. 27a & n.9 (emphasis added). Once again, that ruling directly conflicts with this Court's precedent. As *Sprague* confirms, Dr. Barry's receipt of his ordinary fee indicates not an experimental use, but a "use for profit in the ordinary course and conduct" of his medical practice. 123 U.S. at 256. Were it otherwise, a patentee could always evade the statutory limit on his monopoly by not charging more for use of the invention, but simply charging his usual

price. *See also Electric Storage Battery Co.* v. *Shimadzu*, 307 U.S. 5, 20 (1939) ("The *ordinary use* of a machine or the practise of a process … in the usual course of producing articles for commercial purposes is a public use." (emphasis added)); *Hall* v. *Macneale*, 107 U.S. 90, 97 (1883) (no experimental use where "[t]he safes were sold, and, apparently, no experiment and no experimental use were thought to be necessary").

Dr. Barry's assertion that experimentation was required to determine whether the claimed method would work on three different patients with different spinal curvatures rings hollow in view of this Court's precedents. Nothing in the patent requires the claimed method to work on a certain number of patients or be effective for a particular number of curve types. As discussed above, the mere fact that Dr. Barry may have been "engaged in the invention of improvements by which he hoped and expected to make [the claimed invention] more valuable and useful" cannot negate application of the statutory bar. *Sprague*, 123 U.S. at 256-257. This is particularly true here where the concept of "derotating" vertebrae during surgery to correct a spinal deviation was well known before Dr. Barry's claimed method; Dr. Barry merely sought to improve the *mechanics* for performing that procedure by rotating multiple vertebrae simultaneously—an improvement the effectiveness of which would be assessed *during the surgery*. *See supra* p. 7.

Likewise, the fact that Dr. Barry's technique may have been "capable of improvement need not be denied," and the fact that he may have practiced the claimed surgical method "with the view of devising means to meet and overcome imperfections in its operation," is irrelevant, because "this much can be said in every such case." *Sprague*, 123 U.S. at 265. Indeed,

there are few inventions "which are not susceptible of further development and improvement." *Id.* The question is whether such improvements are "vital" to the invention's operation or whether "[w]ithout them, [the invention] could and did work so as to be commercially successful." *Id.*

Here, Dr. Barry's invention "had received from its inventor every element necessary to its operation" and the invention was "commercially successful" well before the critical date. *Sprague*, 123 U.S. at 255, 265. Dr. Barry successfully performed the claimed method for pay three times, each time achieving the stated goal of the invention—"the amelioration of aberrant spinal column deviation conditions." *See* C.A.J.A. 10285 (indicating "[e]xcellent" post-operative alignment for all follow-ups for all three surgeries); C.A.J.A. 1350-1358. Dr. Barry's surgeries were thus "commercially successful," belying his claims of experimentation.

None of the circumstances surrounding Dr. Barry's pre-critical-date uses and sales of the claimed invention supports the conclusion that the three 2003 surgeries were experimental, that Dr. Barry needed to test the claimed invention on three different patients, or that Dr. Barry needed to conduct three months of follow-up on all three patients. Without any such evidence, Dr. Barry's claims of experimentation are insufficient as a matter of law, particularly when the burden of persuasion is placed where it should be, namely on Dr. Barry. *See Sprague*, 123 U.S. at 264.

III. THE QUESTIONS PRESENTED ARE EXCEPTIONALLY IMPORTANT

The Court's review is further warranted because the questions presented are exceptionally important.

Just this past Term, this Court decided whether "an inventor's sale of an invention to a third party who is obligated to keep the invention confidential qualifies as prior art" for purposes of the on-sale bar under the Leahy–Smith America Invents Act (AIA). *Helsinn Healthcare S.A.* v. *Teva Pharms. USA, Inc.*, 139 S. Ct. 628, 632 (2019). The Court concluded that the "on sale" bar enacted by the AIA retained the Court's pre-AIA interpretation of the same provision. *Id.* at 634. The issues here are in even greater need of this Court's resolution, given the Federal Circuit's longstanding conflict with both *Pfaff* and *Sprague*, and that, by virtue of this Court's decision in *Helsinn*, 139 S. Ct. at 633-634, the Federal Circuit's erroneous interpretation of the pre-AIA statutory bars will continue to be applied under the AIA.

The point at which a claimed invention is "reduced to practice" (and thus "ready for patenting") goes to the heart of the standard this Court set forth in *Pfaff* and *Corona Cord Tire*. The Federal Circuit applies the same "ready for patenting" standard to the on-sale and public-use bar, further widening its application. *See, e.g.*, *Invitrogen*, 424 F.3d at 1379-1380. Further, this Court has recognized that "burdens of proof in patent litigation" are "importan[t]," *Medtronic, Inc.* v. *Mirowski Family Ventures, LLC*, 571 U.S. 191, 196 (2014), and that generally "where the burden of proof lies may be decisive of the outcome," *Speiser* v. *Randall*, 357 U.S. 513, 525 (1958). The Federal Circuit acknowledged as much in *TP Laboratories*, noting that the district court's "shift in the burden of proof" to the patentee to prove experimental use led to what the Federal Circuit believed was "an erroneous result." 724 F.2d at 969. And all of these issues go to when a patent may be deemed valid, which has "great[] public

importance." *Sinclair & Carroll Co.* v. *Interchemical Corp.*, 325 U.S. 327, 330 (1945).

Clarification is long overdue. As then-Judge Prost explained in 2008, *Pfaff* "redefined [the] test for the on-sale bar and affected how the experimental use doctrine applies to alleged instances of invalidating prior use." *Atlanta Attachment Co.* v. *Leggett & Platt, Inc.*, 516 F.3d 1361, 1368 (Fed. Cir. 2008) (Prost, J., joined by Dyk, J., concurring). "Without considering these issues in a comprehensive manner in future cases, [the Federal Circuit] will never escape from the confused status of [its] current caselaw." *Id.* Things are no better eleven years later. The decision in this case only sharpens how far the Federal Circuit has departed from this Court's precedents. The practical significance of the Federal Circuit's errors is also not hard to see, since "[t]he 'on sale' bar is probably the greatest source of litigation involving [§ 102] challenges to patent validity." Mueller, *Patent Law* 263 (5th ed. 2016). This Court's resolution of these mature conflicts is urgently needed.

This case is the ideal vehicle to resolve these important questions. As Chief Judge Prost noted, "[t]he key facts are undisputed." App. 47a; *see* App. 44a (Prost, C.J., dissenting) ("The facts are simple."). More than one year before filing the patent, Dr. Barry successfully performed his claimed method on three different patients, charging his normal fee for each. None of the facts Dr. Barry showed at trial regarding his asserted experimental intent involved contemporaneous records or objective evidence. Indeed, the record is clear that had the Federal Circuit applied the correct legal standard, Dr. Barry would have lost. And of course, there is no need to wait for a further circuit split, since the Federal Circuit has exclusive jurisdiction over patent appeals and has long maintained its

position in the face of this Court's precedent and contrary rulings from other circuits.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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