No. 19-414

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

## REPLY BRIEF FOR PETITIONER


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

SETH P. WAXMAN
*Counsel of Record*
BRITTANY BLUEITT AMADI
CLAIRE H. CHUNG
WILMER CUTLER PICKERING HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006
(202) 663-6000
seth.waxman@wilmerhale.com

**TABLE OF CONTENTS**

## TABLE OF AUTHORITIES

### CASES

**TABLE OF AUTHORITIES—Continued**



**STATUTES AND RULES**



**OTHER AUTHORITIES**

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## REPLY BRIEF FOR PETITIONER

Dr. Barry's brief in opposition only intensifies the need for review of the two questions presented.

Regarding the first question, Dr. Barry mashes together two doctrines that he admits are "separate" (Opp. 2, 25): (1) the principle that the on-sale and public use bar is triggered when the invention is "ready for patenting" before the critical date, *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 67-68 (1998); and (2) the experimental use exception, *City of Elizabeth* v. *American Nicholson Pavement Co.*, 97 U.S. 126, 134 (1877). Dr. Barry's conflation of the two doctrines mirrors the panel's errors below. Pet. App. 11a-32a. Neither the statute nor this Court's case law supports the Federal Circuit's nonstatutory ruling that an invention is not ready

for patenting unless the invention meets some litigation-inspired "intended purpose" advanced long after the patent issues.

Regarding the second question, Dr. Barry does not deny that the Federal Circuit's ruling conflicts with *Smith & Griggs Manufacturing Co.* v. *Sprague*, 123 U.S. 249 (1887), and several decisions of other circuits. He may well think the Federal Circuit knows best, but that is a decision this Court should make.

Finally, Dr. Barry nowhere denies that both questions presented are of major importance to the patent law. Pet. 30-33. Square divisions in authority on critical issues of patent validity are ample grounds for review, particularly given that "[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). The petition should be granted.

## I. THE COURT SHOULD CORRECT THE FEDERAL CIRCUIT'S ERRONEOUS RULING THAT A PATENTED METHOD THAT IS "SUCCESSFULLY PERFORMED" IS NONETHELESS NOT READY FOR PATENTING

Dr. Barry is flatly wrong in contending (Opp. 18)—without citation—that it was "established law" that an invention is not ready for patenting unless "the inventor was convinced the invention worked for its intended purpose." Dr. Barry reaches that conclusion only by conflating the "ready for patenting" inquiry with the question whether a use or sale is "experimental." Yet, as Dr. Barry concedes (Opp. 2, 25), those are two "separate" inquiries. Dr. Barry's attempted obfuscation merely confirms the need for this Court to clarify the law governing these two doctrines.

1. Dr. Barry begins with a half-hearted waiver argument (Opp. 13-15), which fails upon inspection. Both questions presented were raised in Medtronic's petition for rehearing and rehearing en banc in the Federal Circuit—the first stage at which the Federal Circuit's erroneous precedent could have been overruled. Pet. 20 n.7. And both the panel majority and dissent addressed them, citing precedential decisions making clear that the Federal Circuit's positions are longstanding and settled. Pet. App. 13a-15a & nn.3, 6; Pet. App. 46a, 53a-54a, 60a-63a (Prost, C.J., dissenting). Thus, this is not a case where the question presented "'was not pressed or passed upon below,'" *United States* v. *Williams*, 504 U.S. 36, 41 (1992). *See also Yee* v. *City of Escondido*, 503 U.S. 519, 534-535 (1992) ("Once a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they made below."). Dr. Barry's suggestion that Medtronic was required to raise futile objections at trial (Opp. 14-15) is meritless; the district court (like the Federal Circuit panel) was powerless to do anything but follow binding Federal Circuit precedent.

2. An invention is shown to be "ready for patenting" by (as relevant here) "proof of reduction to practice before the critical date." *Pfaff*, 525 U.S. at 67-68. This Court held long ago that "[a] process is reduced to practice when it is successfully performed"—a holding Dr. Barry fails to acknowledge, let alone dispute. *Corona Cord Tire Co.* v. *Dovan Chem. Corp.*, 276 U.S. 358, 383 (1928). As Medtronic explained (Pet. 7-8)—and as Dr. Barry apparently agrees—Dr. Barry successfully performed all steps of his claimed method during at least three surgeries before the critical date. *See* Opp. 7 ("Those notes indicate the procedures were success-

ful."). That should end the matter: Dr. Barry's "successful[] perform[ance]" of his patented method reduced it to practice (and thus made it ready for patenting) under *Corona Cord* before the critical date.

Dr. Barry strains to conjure support for the Federal Circuit's additional requirement that the invention work for a later-devised "intended purpose." But his primary authority is *City of Elizabeth*, which did not even mention "ready for patenting" or "reduction to practice," and instead involved the separate experimental use doctrine. 97 U.S. at 135; *see also* Pet. 16. Contrary to Dr. Barry's assertions (Opp. 26-28), this Court has never held that *City of Elizabeth* governs both "the question of whether an invention was publicly used or sold … and the question of ready for patenting."[1]

Dr. Barry's other cited decisions are not to the contrary. *Sinko Tool & Manufacturing Co.* v. *Automatic Devices Corp.*, 157 F.2d 974 (2d Cir. 1946), undermines his position. The Second Circuit ruled that Sinko had reduced the invention to practice in 1933 because "he might have filed an application" then and skilled artisans in the field were satisfied "that it was ready for production." *Id.* at 976-977. The Second Circuit rejected the defendant's argument—indistinguishable from Dr. Barry's here—that the invention was not reduced to practice until tested in an automobile, holding that "a

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[1] As Dr. Barry acknowledges (Opp. 28), the invention in *City of Elizabeth* was "fully described." 97 U.S. at 129. That description alone rendered the invention "ready for patenting." *Pfaff*, 525 U.S. at 67-68 ("ready for patenting" may be established through "drawings or *other descriptions* of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention" (emphasis added)).

test under service conditions" is not required for reduction to practice. *Id.* at 977. On the contrary, the invention "was ready for manufacture in 1933" and later "changes do not postpone the date of 'reduction to practise.'" *Id.* at 978. The Second Circuit certainly did not rule that reduction to practice is delayed until the invention works for some later-defined "intended purpose" not mentioned in the patent.[2]

*Pfaff* does not help Dr. Barry either, as the passage he cites merely recites the "experimental use" test. *See* 525 U.S. at 64-65 (quoting *City of Elizabeth*, 97 U.S. at 137). When addressing the separate question of readiness-for-patenting, *Pfaff* emphasized the need for certainty, not subjectivity. *Id.* at 65 (requiring "a definite standard for determining when a patent application must be filed"). Dr. Barry's proposed standard—which subjectively turns on "what the inventor *believed* he was working toward" (Opp. 17 (emphasis added))—would only inject ambiguity into a statutory bar designed "to fix a period of limitation which should be certain," *Pfaff*, 525 U.S. at 65.

Just as the simple and objective facts led to an invalidating prior sale in *Pfaff* (525 U.S. at 68-69), Dr. Barry's performance of all of the claimed steps of his patented method in three successful surgeries (for which he was paid) meant his invention was ready for patenting. Dr. Barry concedes that those "procedures were successful." Opp. 7. He admitted that he could see each patient's aberrant spinal deviation condition being corrected or "ameliorat[ed]" during each surgery, and noted in post-operative reports that each patient's

[2] The decisions of the Court of Customs and Patent Appeals that Dr. Barry cites (Opp. 19) merely confirm the longstanding conflict with *Corona Cord*.

post-operative spinal alignment was "[e]xcellent," C.A.J.A. 10285. *See* Pet. 12-13; *see also* C.A.J.A. 1190-1191, 1193-1195, 1369-1370. That "successful[] perform[ance]" of the patented method made it ready for patenting. *Corona Cord*, 276 U.S. at 383. Dr. Barry cannot delay that moment by contriving a litigation-inspired "intended purpose" years later.

3. Continuing his confusion of ready-for-patenting and the separate experimental use doctrine, Dr. Barry claims that the Federal Circuit's required "intended purpose" need not "be claimed or expressly stated in the patent." Opp. 21. That proposition again finds no support in the statute or this Court's decisions.

Neither *City of Elizabeth* nor the Federal Circuit cases Dr. Barry cites justifies importing into the ready-for-patenting inquiry a subjective "intended purpose" requirement divorced from the patent and ventured for the first time in litigation. All of his cited cases involve experimental use which—once again—is a separate doctrine. And *Honeywell International Inc.* v. *Universal Avionics Systems Corp.*, 488 F.3d 982, 997 (Fed. Cir. 2007), simply restates the erroneous Federal Circuit rule challenged here; it does not justify it or reconcile it with this Court's jurisprudence.

Apparently recognizing the flaws in the Federal Circuit's analysis, Dr. Barry now seeks to recast his invention as directed to the "treatment of patients." Opp. 23. But the only portion of Dr. Barry's '358 patent that discusses "treatment" is the background of the invention, which describes what was known in the *prior art*. C.A.J.A. 328. That is unsurprising, given that treating spinal abnormalities by "derotating" vertebrae during spinal surgery (along with any associated patient follow-up) was known long before Dr. Barry's patent.

C.A.J.A. 2854-2855. The patent nowhere suggests that the claimed method is aimed at treating patients *after* the surgical derotation procedure ends.

To the contrary, the '358 patent's only claimed improvement over prior art derotation methods is the application of force to multiple vertebrae simultaneously (as opposed to one at a time) to derotate the vertebrae together *during surgery*. C.A.J.A. 323(abstract); C.A.J.A. 329(3:48-59). Nothing in the patent turns on *post-operative* treatment. Indeed, Dr. Barry admitted that he conducts follow up on all patients, regardless of whether he used the patented surgical technique or not. *See* C.A.J.A. 1196.

Dr. Barry's reference to the claim step requiring that the surgeon "secure said vertebrae in their respective and relative positions and orientations" is equally misplaced. Opp. 23. Dr. Barry admitted that that step also occurs *during surgery*. C.A.J.A. 1159(159:2-7), 1190-1191, 1193-1195. And although Dr. Barry claims otherwise (Opp. 23-24), there was no evidence that the purported "three months of follow-up" was needed to ensure that the vertebrae were secured in place. *See* C.A.J.A. 1196; *see also* Pet. App. 53a (Prost, C.J., dissenting). Only by allowing Dr. Barry to create a new, *post hoc* "intended purpose" outside the four corners of the patent could the Federal Circuit rule as it did.

Dr. Barry's arguments only reinforce that the Federal Circuit majority has collapsed readiness-for-patenting and the experimental use exception together, thus "render[ing] the experimental-use doctrine superfluous." Pet. App. 58a (Prost, C.J., dissenting). This Court should grant certiorari and clarify that the Federal Circuit's counterintuitive conclusion is incorrect.

## II. THE COURT SHOULD CONFIRM THAT THE PATENTEE BEARS THE BURDEN OF PROVING THE EXPERIMENTAL USE EXCEPTION

On the second question presented, Dr. Barry fails to confront this Court's recognition over a century ago that the patentee bears the burden to prove that an otherwise invalidating prior use or sale "was for the purpose of perfecting an incomplete invention by tests and experiments" with proof that is "full, unequivocal, and convincing." *Sprague*, 123 U.S. at 264. And he does not meaningfully engage with the overwhelming authority from other circuits following *Sprague*. Dr. Barry instead again muddles the admittedly "separate inquiries" (Opp. 2) of "ready for patenting" and "experimental use" in a manner that confirms "the confused status of [the Federal Circuit's] current caselaw." *Atlanta Attachment Co.* v. *Leggett & Platt, Inc.*, 516 F.3d 1361, 1368 (Fed. Cir. 2008) (Prost, J., concurring).[3] Dr. Barry's aim is clear—to justify his evasion of the statutory bar through reliance on uncorroborated inventor testimony ventured for the first time in litigation. But as Medtronic explained (Pet. 23-26), *Sprague*'s placement of the burden on the patentee to prove experimentation (by "full, unequivocal, and convincing" proof,

[3] Chief Judge Prost's *Atlanta Attachment* concurrence did not—as Dr. Barry claims (Opp. 31)—"acknowledge" conflation of the "ready for patenting" and "experimental use" inquiries. Rather, Chief Judge Prost acknowledged that "the experimental use doctrine … is not pertinent" to readiness for patenting, which "must concern *claimed* aspects of the invention, because those aspects control whether the invention is ready for patenting or not." *Atlanta Attachment*, 516 F.3d at 1370 (Prost, J., concurring) (emphasis added); *see also* Pet. App. 58a-60a (Prost, C.J., dissenting).

123 U.S. at 264) renders Dr. Barry's uncorroborated testimony "insufficient" as a matter of law, *id.* at 265.[4]

1. Dr. Barry does not deny that the Federal Circuit's decision in *TP Laboratories, Inc.* v. *Professional Positioners, Inc.*, 724 F.2d 965, 973 n.3 (Fed. Cir. 1984), not only decreed *Sprague* "untenable," but also departed from the precedents of numerous other circuits; he says only that "the majority of the cases … pre-date the statutory placement of the ultimate burden on the challenger." Opp. 33. But as Medtronic explained (Pet. 22), "by the time Congress enacted [35 U.S.C.] § 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). That the Federal Circuit "has been the nationwide appellate court for patent matters since 1982" (Opp. 33) merely underscores the need for this Court's intervention. If left unchecked, the Federal Circuit will continue to apply its erroneous burden-of-proof allocation. The Federal Circuit's divergence from the holdings of this Court in *Sprague* and numerous other circuits is ample reason to grant certiorari. S. Ct. R. 10(a), (c).

Dr. Barry seeks (Opp. 34) to exempt the judicially-created experimental use doctrine from the general principle that the burden of proof lies with the party who "claims the benefits of an exception to the prohibition of a statute," *United States* v. *First City Nat'l Bank of Houston*, 386 U.S. 361, 366 (1967); *see* Pet. 23. But he provides no authority for his assertion. If anything, the experimental use exception's judicial origin

[4] Despite Dr. Barry's vague suggestions (Opp. 31, 34), *Pfaff* neither overruled nor questioned *Sprague* (or even addressed burden of proof at all).

warrants *narrowing* its applicability, not broadening it. *Cf. United States* v. *Rutherford*, 442 U.S. 544, 559 (1979) ("Whether, as a policy matter, an exemption should be created is a question for legislative judgment, not judicial inference.").

The burden-shifting framework of Title VII does not suggest otherwise. Evidence of a "legitimate, nondiscriminatory" basis for an employment decision can "rebut" the prima facie case of discriminatory intent. *St. Mary's Honor Ctr.* v. *Hicks*, 509 U.S. 502, 507 (1993). But experimental use does not "rebut" the fact of a prior sale or public use; the sale and use happened regardless. Rather, an experimental use is a "thing implied as *excepted out of the prohibition* of the statute," *Sprague*, 123 U.S. at 256 (emphasis added). In other words, a showing of experimental use establishes that the otherwise-invalidating sale or use will not trigger the statutory bar. Thus, the party invoking the experimental exception must prove its applicability, as *Sprague* held. *See* Pet. App. 58a-59a (Prost, C.J., dissenting)

2. As Medtronic explained (Pet. 24-29), the Federal Circuit's dismissal 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 had no evidence of experimentation. Dr. Barry scarcely attempts to dispute this fact. Nor does he deny that this Court's precedents demand much more than a patentee's self-serving assertion at trial that he was experimenting.

Dr. Barry points to scattered "facts" he contends demonstrated experimentation. None remotely approaches *Sprague*'s high standard.

Dr. Barry first references "invoices demonstrating work done in modifying the tools" used in performing

the claimed method. Those invoices predate the August and October 2003 surgeries by months. C.A.J.A. 10278-10280. And the surgical device representative "helping Dr. Barry" (Opp. 7) testified that as of *July 2003*—long before the three supposedly "experimental" surgeries—"the system worked to everyone's satisfaction," "worked to manipulate the spine in a way that corrected the scoliosis to Dr. Barry's satisfaction," "seemed to be a success," and rendered Dr. Barry "satisfied at that time." C.A.J.A. 1706-1707. Similarly, Dr. Barry's "surgical notes" (Opp. 7)—generated after-the-fact during litigation (C.A.J.A. 1253-1254)—indicated "[e]xcellent" post-operative alignment for all follow-ups for all three surgeries," without any indication that the surgical procedures were experimental. C.A.J.A. 10285.

The allegedly corroborating testimony Dr. Barry cites (Opp. 8) fares no better. *See* Pet. App. 63a & n.7 (Prost, C.J., dissenting). Dr. Barry's wife, Dr. Yvonne Barry, who assisted in the 2003 surgeries, actually admitted that "[n]one of those procedures were experimental." C.A.J.A. 2854. And Dr. Barry's anesthesiologist could not recall which surgeries she participated in or when she learned of a "patent pending project," let alone anything indicating that the three surgeries at issue were experiments. C.A.J.A. 1733-1734.

Dr. Barry's decision to share his technique in a conference presentation (Opp. 8)—just two weeks after he claims to have been "experimenting"—sheds no light on whether the three surgeries at issue were experimental. Dr. Barry reported on *21 separate procedures* (C.A.J.A. 10009)—19 before the critical date, each resulting in "[e]xcellent" post-operative alignment (C.A.J.A. 10281-10285)—suggesting that the three surgeries at issue here were merely exemplary of many

more invalidating prior uses and sales of his claimed invention.

None of these purported "facts" 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. Indeed, much of Dr. Barry's evidence supports the opposite conclusion: he performed the claimed derotation method for profit, without disclosing or recording any experimental intent or results, and without telling his patients or their families that he was experimenting, in full confidence that each surgery worked as well as any prior art derotation. That renders his patent invalid as a matter of law, particularly when the burden of persuasion is placed (as it should have been) on Dr. Barry. *See Sprague*, 123 U.S. at 264. The Court should bring the Federal Circuit's jurisprudence back into line.

## CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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

SETH P. WAXMAN
*Counsel of Record*
BRITTANY BLUEITT AMADI
CLAIRE H. CHUNG
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006
(202) 663-6000
seth.waxman@wilmerhale.com

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