No. 19-414

IN THE

Supreme Court of the United States

MEDTRONIC, INC.,

Petitioner,

v.

MARK A. BARRY,

Respondent.

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

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

The Court in *Pfaff v. Wells Elecs., Inc.*, created a two-part test for whether a patent is barred because the invention was sold or publicly used too early. 525 U.S. 55, 67 (1998). The fact-finder is asked whether the challenger demonstrated (1) the invention was sold or publicly used and (2) the invention was ready for patenting. *Id.* Under the ready for patenting prong, the challenger can show reduction to practice or that the inventor had prepared drawings or descriptions sufficient to enable a person of ordinary skill in the art to practice the invention. *Id.*

To show reduction to practice, the challenger must show the inventor knew that his invention worked for its intended purpose. This has not, nor should it be, a purely objective question. In *Corona Cord Tire Co. v. Dovan Chem. Corp.*, the Court emphasized the priority inventor *knew* the invention functioned as intended. 276 U.S. 358, 382 (1928).

Similarly, the question of whether an invention was sold or publicly used under *Pfaff*'s first prong involves determining whether the activity was experimental. The Court in *Pfaff* expressly confirmed that an activity conducted with a *bona fide* intent to experiment would not be a barring activity. 525 U.S. at 64. The *bona fide* intent of an inventor in the question of experimentation has been the standard inquiry since the Court's decision in *City of Elizabeth v. American National Pavement Co.*, 97 U.S. 127 (1877). Whether a sale or public use occurred will also take into consideration whether the inventor had a *bona fide* intent to perfect his invention.

The questions presented are thus:

1. Whether the record supports the finding that Dr. Barry's invention was not ready for patenting until

January 2004 because Dr. Barry needed to test his novel method on the three most common curve types of scoliosis and determine that the method would achieve treatment of those conditions, including, for example, that the implants would remain in their proper position as observed at clinically appropriate follow-up.

2. Whether 35 U.S.C. Section 282, which specifies that the burden of proof on showing invalidity lies with the challenging party, should be ignored in place of an entirely separate question as to whether an inventor was experimenting despite *Pfaff*'s express recognition that experimental use was part of the on-sale question.

STATEMENT OF RELATED CASES

- *Barry v. Medtronic, Inc.*, 1:14-cv-00194-RC, U.S. District Court for the Eastern District of Texas. Judgment entered on May 16, 2017.

- *Barry v. Medtronic, Inc.*, 2017-2463, U.S. Court of Appeals for the Federal Circuit. Judgment entered on January 24, 2019.

- *Medtronic, Inc. v. Barry*, 2017-1169, 2017-1170, U.S. Court of Appeals for the Federal Circuit. Judgment entered on June 11, 2018.

- *Medtronic, Inc. v. Barry*, IPR 2015-00780, IPR 2015-00783, United States Patent Trial and Appeal Board. Final written decision entered September 7, 2016.

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INTRODUCTION

The Petition should be denied. The Petition seeks reexamination of the Federal Circuit's affirmance that Dr. Barry's patent is not invalid under 35 U.S.C. § 102(b). The jury found, and the Federal Circuit agreed, that Dr. Barry's invention was not "ready for patenting" under *Pfaff v. Wells Electronics., Inc.*, 525 U.S. 55 (1998), more than one year before filing his patent application. That finding alone disposes of Petitioner's validity challenge because Petitioner needed to prove the invention was both (1) on-sale or publicly used more than a year for applying for the patent *and* (2) ready for patenting. *Id.* at 67-68. Because the Federal Circuit affirmed Dr. Barry's invention was not "ready for patenting," and its affirmance correctly applied settled law to the unique facts of this case, nothing here justifies a grant of certiorari.

Petitioner, however, asserts that when considering "ready for patenting," the jury, through its instructions, improperly considered evidence of whether the inventor was working to determine if his invention worked for its *intended* purpose. But Petitioner never before argued this was improper. It never objected to the instruction on ready for patenting nor did it argue to the Federal Circuit anything other than a critique of the factfinder's determination of the weight of the evidence. Petitioner also, and again for the first time, challenges the underlying burden of persuasion for the question of experimental use. Yet Petitioner never objected to the relevant jury instructions; nor did it argue to the Federal Circuit for a change in the law. Petitioner's arguments are waived.

Petitioner's arguments also ignore or contradict well-settled precedent. *Pfaff* held "ready for patenting"

can be shown in at least two ways: (1) proof of reduction to practice or (2) proof that the inventor had drawings or other descriptions that would enable a person of skill to practice the invention. *Id.* By the time the Court decided *Pfaff*, it had long been the law—going back to *City of Elizabeth v. American National Pavement Co.*, 97 U.S. 127 (1877)—that whether an invention has been reduced to practice or was the subject of experimentation depends on whether the inventor was engaged in a *bona fide* effort to perfect or determine if his invention worked for its intended purpose.

This is not, and has never been interpreted as, a wholly objective inquiry. Rather, the invocation of "*bona fide* effort" means determining whether the inventor *knew* his invention worked as he intended will involve consideration of the inventor's objectives, methods, and perceived results. These questions depend heavily on judging the entirety of record evidence—the quintessential province of the factfinder. Thus, the Federal Circuit's "ready for patenting" analysis correctly considered evidence of whether Dr. Barry was working to determine if his invention worked as intended.

As for Petitioner's effort to restructure the burden of persuasion, the Court need not consider this because the question of experimental use is part of *Pfaff*'s on-sale or public use prong, not the ready for patenting prong. 525 U.S. at 67-68. While underlying facts may apply to both, a point *Pfaff* also acknowledged, they are separate inquiries. As such, and as the Federal Circuit noted, Chief Judge Prost's dissent opining that patentees ought to carry the burden of persuasion on the experimental use issue would not affect the outcome of this case, as Dr. Barry's invention was not ready for patenting.

Separately, the Court established that experimental use by the inventor means an alleged activity is neither a sale nor a public use under the first prong of *Pfaff*, and thus evidence of experimental use is considered for this prong. Petitioner, however, seeks to make experimental use an entirely separate inquiry—one which would shift the challenger's ultimate burden of persuasion to the patent owner. Petitioner's proposed burden-shift ignores the statute and this Court's controlling interpretation of it. Congress declared that a patent is presumed valid and that "[t]he burden of establishing invalidity . . . shall rest on the party asserting such invalidity." 35 U.S.C. § 282. This Court has declared the statute means the challenger's burden of persuasion "is constant and never changes and is to convince the court of invalidity by clear evidence." *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 97 (2011). As such, while Petitioner suggests the Federal Circuit has strayed from the *Pfaff* decision, it is Petitioner that suggests a fundamental shift diverging from the statute and the Court's precedent.

Ultimately, the Petition is simply a re-write of Chief Judge Prost's dissent. Petitioner ignores, however, that the dissent garnered no support from the full Federal Circuit[1] and was dismissed by the majority, which noted after reviewing the record that "we see nothing in the dissent's proposed changes that would alter our § 102(b) result—at least on the sufficient ground that Medtronic failed to establish readiness for patenting." Pet. App. 12a-13a & n.3. Indeed, the facts of this case fully support the Federal Circuit's application of "ready for patenting"

1. The Federal Circuit denied rehearing and rehearing *en banc* without requiring Dr. Barry to respond.

as set forth in *Pfaff*. The Federal Circuit's decision analyzed the law in detail, and is entirely consistent with the case law applying the on-sale and public-use statutory bar. Pet. App. 11a-20a.

STATEMENT

I. The Factual Record

Dr. Barry invented methods and systems for three-dimensional correction of spinal deformities, such as scoliosis, using linked derotation instruments. C.A.J.A. 328. Scoliosis is abnormal curvature of the spine presenting as a side-to-side curve. C.A.J.A. 1773-75. In more severe cases, the individual vertebrae rotate around the spinal cord resulting in a rib hump. *Id.* Before Dr. Barry's invention, surgeons treated these conditions by either rotating individual vertebra one at a time or rotating multiple vertebrae using unlinked instruments. C.A.J.A. 1156-61. These procedures had drawbacks, such as requiring multiple assistants and producing inconsistent results. C.A.J.A. 1156-61. Dissatisfied with the current tools and procedures, Dr. Barry invented improved methods and systems making treatment of scoliosis safer for the patient and easier for the surgeon. C.A.J.A. 1169-71.

A. Dr. Barry's Development of the Method Claimed in the '358 Patent

In 2002, Dr. Barry had been exposed to segmental derotation—manipulating individual vertebrae in a one-at-a-time manner. C.A.J.A. 1161-63. This required implanting screws into pedicles of the spine and placing a

lever onto the screw head to move the vertebra. C.A.J.A. 1156. Dr. Barry was unsatisfied with that technique and by March 2003 began to envision ways to link multiple levers attached to pedicle screws along the length of the spine. C.A.J.A. 1169-71.

At that time, however, surgical tools useable for the technique Dr. Barry was considering did not exist. C.A.J.A. 1171. He considered modifying tools offered by two device companies. C.A.J.A. 1176-77. Those tools were unsatisfactory and Dr. Barry then considered tools offered by a third device company. C.A.J.A. 1177-79. After working with a machine shop for months (C.A.J.A. 1182-90), Dr. Barry finally had tools that might work for his envisioned linked derotation technique. C.A.J.A. 1190-91.

Correcting spinal deformities is a medical treatment that differs across patients. C.A.J.A. 1192-93. The procedures are invasive, requiring implantation of many screws and rods while subjecting the spine and implants to considerable force. C.A.J.A. 1194. Medical treatment is not simply what happens during or at the end of a surgical procedure; rather, it is treatment of a human patient. C.A.J.A. 1191. Scoliosis, specifically, is a disorder of a large range of curve types and severities and because of the potentially wide range of applications, Dr. Barry aimed to ensure his inventive technique of derotating multiple, linked vertebrae would work in such real-world varieties of treatments. C.A.J.A. 1192-93.

Dr. Barry's claimed invention addressed "[a] method for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions . . . ." C.A.J.A. 330. To account for the nature of treating the multiple "deviation

conditions" found across multiple patients with different deformities, follow-up patient evaluations were necessary to ensure successful treatment of the various aberrant spinal conditions encountered amongst diverse patients. C.A.J.A. 1159-60. Follow-up at various intervals was necessary to see that correction had taken hold and the implants remained where they should. C.A.J.A. 1195-96. Specifically, follow-up is necessary because surgeons "want to make sure that this patient recovers well, there is[*sic*] no complications, that, you know, all these new forces and corrections that we're putting on the spine are holding, you know, no issues of implants shifting or moving out of position and dislodging . . . ." C.A.J.A. 1194.

Such follow-up is not only common in practice, but the Scoliosis Research Society, the preeminent organization and journal society in the art, "will not even let you publish a paper that has less than two years of follow-up . . . ." C.A.J.A. 2899-2901. For this invention, a minimum of three months of follow-up was believed necessary to ensure the claimed invention worked as intended and the surgical results were holding. C.A.J.A. 1196.

Dr. Barry conducted three surgeries using his inventive method in August and October of 2003. C.A.J.A. 1190-97. These procedures were scoliosis treatments and Dr. Barry was compensated for such treatment, not the performance of his novel technique. C.A.J.A. 1430. Each procedure was done in the confidence of the operating room (C.A.J.A. 2905), the intricacies unknown to patients under anesthesia, and involved a team of professionals under implied or contractual confidentiality understandings. C.A.J.A. 1303-13, 2388-89.

The first surgery in August 2003 did not, by itself, demonstrate the method would work for a range of treatments of various deformities because it was simply one surgery treating one of many curve types. C.A.J.A. 1190-93. Two other procedures, another in August and one in October, presented opportunities to see if the new method would work as conceived on different patients with different spinal deformities. C.A.J.A. 1193-95. It was after the three month follow-up to the October 2003 procedure, in January 2004, when Dr. Barry observed his novel technique resulted in safe, effective, and lasting corrections addressing the multiple aberrant spinal deviation conditions found in a diverse patient population, such that Dr. Barry was convinced he successfully treated the "three most common[] curve types of scoliosis." C.A.J.A. 1195-96.

B. Evidence of Dr. Barry's Experimentation

The record includes numerous other facts showing the three treatments that began in August 2003 through January 2004 were experimental.

First, invoices demonstrated the work done in modifying the tools ultimately used in surgical methods as claimed. C.A.J.A. 10278-80. Dr. Barry's device sales representative testified about helping Dr. Barry in having serial modifications made to tools while Dr. Barry worked on his invention. C.A.J.A. 1697-1706.

Second, Dr. Barry had surgical notes generated as part of work with his then-exclusive licensee of the technology covered by his patents to aid further development of his concepts. C.A.J.A. 1183-96, 10281-92. These notes indicate the procedures were successful. C.A.J.A. 10285.

Third, Dr. Barry's anesthesiologist, Dr. Stephanie Davidson, testified she knew Dr. Barry was working on an inventive scoliosis technique in the 2003 time period. C.A.J.A. 1733-35, 1739. Dr. Barry's device sales representative confirmed the evolving work done on the tools. C.A.J.A. 1697-1707. Similarly, Dr. Yvonne Barry, one of Dr. Barry's surgical assistants, testified that, while the concept of derotation was not experimental, the equipment Dr. Barry was using to improve derotation was experimental. C.A.J.A. 2854-55. Moreover, the record contained extensive testimony that operating rooms are, as one would expect, places of confidence. C.A.J.A. 2904-05, 1730.

Fourth, and perhaps most telling, was that Dr. Barry published to his peers the results of his experiments—"*the evolution of his technique*." C.A.J.A. 5282 ("This technique evolved with a design of linked multiple derotation levers mounted on a cluster of fixed head screws . . . ."); C.A.J.A. 1197-98. After submitting the abstract on February 1, 2004, two weeks after the three-month follow-up to the third surgery, it was accepted for presentation at a July 2004 conference. C.A.J.A. 1202. Dr. Barry presented his results at that meeting (C.A.J.A. 10001-32) where he was complemented on his study by Dr. Lenke, the meeting's chair and Petitioner's alleged prior inventor. C.A.J.A. 1226-28, 2595.

II. The District Court Proceedings

Petitioner did not object to instructions on the on-sale bar and prior public use. For example, as to the on-sale bar, the jury was instructed:

On-Sale Bar:

> A patent claim is invalid if, more than one year before the filing date of the patent, an embodiment of the claimed invention was both:
>
> 1. ready for patenting; and also
>
> 2. the subject of a commercial sale or offer for sale in the United States.

C.A.J.A. 161. The jury was instructed that

> An invention is "**ready for patenting**" either when:
>
> 1. it is reduced to practice; or
>
> 2. the inventor has prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person of ordinary skill in the art to practice the invention.
>
> In either case, the claimed invention is ready for patenting when there is reason to believe it would work for its intended purpose.

C.A.J.A. 159. The jury was further instructed that

> An invention is "**reduced to practice**" either when:
>
> 1. The invention has been constructed, used, or tested sufficiently to show that it will work for its intended purpose; or

> 2. The inventor files a patent application with the Patent and Trademark Office.

C.A.J.A. 158.

As to Dr, Barry's purported "public use" of his experimental method in an operating room, the jury was instructed that a claim is invalid if, more than a year before the patent application, "the claimed invention was both: 1. ready for patenting; and also 2. accessible to the public." *Id.* The jury was instructed on what "accessible to the public" meant and specifically on considering "whether or not a use is an 'experimental use'":

> Patent law recognizes that an inventor must be given the opportunity to develop his invention through experimentation. Activities are experimental if they are a legitimate effort to test the claimed features of an invention or to determine if the invention will work for its intended purpose. So long as the primary purpose is experimentation, it does not matter that use of the invention was accessible to the public or that the inventor incidentally derived benefit from the use, for example a nominal surgical fee.

C.A.J.A. 159-60. The jury received multiple factors to consider regarding whether a use or sale was experimental (C.A.J.A. 160-61), and was told that, as to Petitioner's claim of prior invention, Dr. Barry would need *corroborated* evidence of reduction to practice and diligence between conception and reduction to practice. C.A.J.A. 165-66. As the reduction to practice inquiry

is the same between on-sale bar, public use, and prior invention, the jury was instructed to determine whether the corroboratory evidence was reliable. *Id.* Petitioner did not object to these aspects of the instructions.[2] C.A.J.A. 2974-76.

On these instructions, the jury considered the evidence summarized above and weighed it under the clear and convincing standard against Petitioner's evidence and arguments.[3] Petitioner asserted Dr. Barry conceded he could tell he had achieved some correction during the 2003 procedures. C.A.J.A. 1369-70 ("The surgical correction of the rotated vertebrae back to the midline, yeah, happens with that maneuver"); C.A.J.A. 1426 ("At the time of surgery, yes, I see a crooked spine that I derotate and

2. While Petitioner objected to informing the jury of the difference between medical experimentation vis-à-vis informed consent and experimentation in the patent law, that objection is not at issue in the Petition.

3. Notably, the Petition cites the dissent over the record more often than not. This is noteworthy because Chief Judge Prost's dissent contains as much analysis of the weight of the facts as legal critique. For example, in disagreeing with the jury's acceptance that Dr. Barry needed to see his invention in at least three different surgical contexts with follow-up, Chief Judge Prost states, "I am unpersuaded." Pet. App. 54a. Similarly, the dissent (Pet. App. 63a-67a) reweighs the evidence, crediting Petitioner's spin on the evidence as opposed to Dr. Barry's, which is unwarranted given the underlying appeal was for review of denial of judgment as a matter of law. *See, e.g.*, *Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 573–74 (1985) ("If the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently.").

straighten at the end of the surgery."). The fact-finder was thus free to accept the evidence as set forth by Petitioner and find the invention was "ready for patenting" or that Dr. Barry was not experimenting, but rather found the opposite.

As explained above, Dr. Barry's invention was aimed at treating spinal disorders including scoliosis. As claimed, "amelioration of aberrant spinal column deviation condition" was given its plain and ordinary meaning by the district court, which made several notable findings regarding that term. First, that "[i]mprovement of an aberrant spinal condition like scoliosis to a 'near normal' configuration provides some standard for measuring the improvement and provides a [person of skill] reasonable certainty regarding the scope of the invention." C.A.J.A. 33. Second, that "it is impossible to predict the results of a surgery or to guarantee perfect results." *Id* (citing Petitioner's expert). Without objection, the jury was instructed that if a construction for a term was not given, its understanding to a skilled artisan would be its plain and ordinary meaning. C.A.J.A. 145. Accordingly, the jury heard the above testimony and argument concerning what persons of skill in the art would view as acceptable practice in surgical arts regarding evaluating the readiness of an invention.

The jury was free to weigh Petitioner's selectively quoted record against testimony that Dr. Barry's invention of "amelioration of aberrant spinal column deviation conditions" was treatment of a patient and not simply straightening the spine. For example Dr. Barry explained "when I treat a patient, you know, I consider treatment of the entire patient, the whole patient; and treatment doesn't

end with what happens at the end of a surgical procedure." C.A.J.A. 1191. This includes ensuring implants hold considering the new forces applied by his inventive tools (C.A.J.A. 1194) and ensuring successful implementation in patients with varying conditions. C.A.J.A. 1192. Dr. Wallid Yassir corroborated these points by explaining that, while a surgeon may see correction by the conclusion of surgery, overall determination of correction is not known immediately. C.A.J.A. 2899-2901.

Based on the undisputed instructions and record, the jury found Petitioner had not demonstrated by clear and convincing evidence that the inventions were "ready for patenting" or sold or publicly used before the critical date. The Federal Circuit affirmed the denial of judgment as a matter of law giving proper deference to the jury's findings on proper instruction.

REASONS TO DENY THE PETITION

I. Petitioner Waived Its Current Challenges.

"[A]ppellate courts ordinarily abstain from entertaining issues that have not been raised and preserved in the court of first instance." *Wood v. Milyard*, 566 U.S. 463, 473 (2012). That practice applies with added force when a party intentionally relinquishes or abandons a waivable position at trial. *United States v. Olano*, 507 U.S. 725, 733 (1993). Waiver applies with full force to jury instructions, which district courts enjoy wide latitude to fashion and which appellate courts review for abuse of discretion. *See, e.g.*, *i4i P'ship Ltd. v. Microsoft Corp.*, 598 F.3d 831, 841 (Fed. Cir. 2010), *aff'd*, 564 U.S. 91 (2011); 9C Charles Alan Wright & Arthur R. Miller, *Federal Practice*

and Procedure: § 2558 (3d ed. 2008). An objection to a jury charge "must be sufficiently specific to bring into focus the precise nature of the alleged error." *Palmer v. Hoffman*, 318 U.S. 109, 119 (1943). On pain of forfeiture, a party must show not only a specific, timely objection to the supposedly erroneous instruction, but also that "it requested alternative instructions that would have remedied the error." *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1311-12 (Fed. Cir. 2005); *see also Microsoft*, 564 U.S. at 111-12 (holding that Microsoft waived a claim of instructional error by failing to propose alternative instructions at district court). This Court has stated "[t]here would be considerable prudential objection to reversing a judgment because of instructions that petitioner accepted, and indeed itself requested." *Springfield, Mass. v. Kibbe*, 480 U.S. 257, 259 (1987).

These well-established principles are fatal to Petitioner's certiorari request.

In the district court, Petitioner did not challenge the instructions related to the "ready for patenting" standard it now claims stand contrary to this Court's decision in *Sprague* and other circuits. Pet. 20 & n.7. Nor did it argue Dr. Barry should have borne the burden of persuasion on the question of experimental use. *Id.* On appeal, Petitioner argued exclusively the jury's verdict was not supported by sufficient evidence, leading the court—after briefing and oral argument—to affirm the district court's judgment.

Given Petitioner's waiver and lack of any decision below, this case is a particularly inappropriate candidate for certiorari. *Cf. Microsoft Corp.*, 564 U.S. 91 (Microsoft proposed the analysis at the root of its certiorari review at

trial and maintained its challenge throughout appeal). This is "a Court a court of review, not of first view." *McLane Co. v. EEOC*, 137 S. Ct. 1159, 1170 (2017).

Petitioner contends otherwise, citing *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007). In *MedImmune*, the Petitioner raised its issue before the Federal Circuit, even if only in passing. *Id.* at 125. Petitioner here did not. Petitioner did not object to, and in fact agreed to, the jury instructions for "ready to patenting," and subsequently did not challenge the instructions on appeal. The notion of applying a different test for "ready for patenting" was only first introduced by the dissent, and was dismissed by the majority in a footnote. Pet. App. 14a n.4. Similarly, Petitioner did not object to the instructions regarding "experimental use" despite now proposing it as a separate question where the burden to show a use was experimental is shifted to the patentee. Again, it was not until the dissent suggested these changes to the law that Petitioner seized on the arguments at the heart of its Petition.

Parroting Chief Judge Prost's dissent in a petition for rehearing is not a timely advancement of argument. Likewise, citing *Robert Bosch, LLC v. Pylon Manufacturing Corp.*, 719 F.3d 1305, 1316 (Fed. Cir. 2013) (*en banc*), does not remedy waiver at every stage of the case. At best, *Bosch* merely stands for the proposition that *en banc* Federal Circuit decisions control over panel decisions. It certainly does not suggest presenting an argument for the first time after appellate review is proper. Petitioner waived the questions presented and its Petition should be denied.

II. This Case Does Not Warrant Supreme Court Review.

The Petition's two questions are unworthy of review. First, contrary to Petitioner's assertion, the Federal Circuit did not misread the Court's precedent regarding the "ready for patenting" standard, and thus its decision does not reflect "confusion" in its case law. Removed of its rhetoric, the Petition improperly attempts to revisit denial of judgment as a matter of law based on the *bona fide* efforts of an inventor. It assumes Petitioner's facts are true and Dr. Barry's facts insufficient even though weighing that evidence is the province of the factfinder.

Second, the Federal Circuit's decision correctly applies the statutory requirement that the burden of establishing invalidity always rests on the party asserting it. *See* 35 U.S.C. § 282. In its second question on the burden of persuasion, the Petition asks the Court to ignore the statutory requirement.[4] That is improper.

A. The Federal Circuit Properly Applied the "Ready for Patenting" Standard Set Forth in *Pfaff*'s to the On-Sale/Public Use Inquiry.

In Part 1 of the Petition regarding "ready for patenting," Petitioner argues against the weight of the evidence regarding *what* the intended purpose of the

4. Petitioner argues the Federal Circuit has diverged from the Court's precedent through the decision in *TP Laboratories, Inc. v. Professional Positioners, Inc.*, 724 F.2d 965 (Fed. Cir.), *cert. denied*, 469 U.S. 826 (1984). In that case, the Court denied certiorari on this very issue.

invention is. In Part 2, Petitioner argues against the Court's decision in *Pfaff*, which makes clear that facts regarding experimentation apply to both prongs of the *Pfaff* analysis, to circumvent the Federal Circuit's correct analysis of the record regarding experimentation in determining Dr. Barry's invention was not "ready for patenting."

1. The Federal Circuit Properly Considered Evidence That Dr. Barry Was Working to Determine His Invention Worked for Its Intended Purpose.

To avoid the findings that Dr. Barry's invention was not "ready for patenting," the Petition suggests the Federal Circuit's analysis added a requirement unsupported by law. Petitioner urges that, despite this Court's adoption of reduction to practice as one way to show "ready for patenting," it is improper to consider whether the patentee determined the invention works for its "intended purpose." Pet. 12. Petitioner ignores, however, the Court consistently recognized the public use/on-sale bar inquiry is not divorced from what the inventor believed he was working toward, *i.e.*, the invention's "intended purpose."

i. The "reduction to practice" analysis includes consideration of the invention's "intended purpose."

"Ready for patenting" can be shown in at least two ways: (1) proof of pre-critical date reduction to practice and (2) proof of pre-critical date drawings or other descriptions of the invention prepared by the inventor that would enable a skilled artisan to practice the invention.

Pfaff, 525 U.S. at 67-68. This case involves only the first type of proof and, by the time the Court decided *Pfaff*, it was established law that whether an invention had been reduced to practice involved considering whether the inventor was convinced the invention worked for its intended purpose.

Petitioner posits that assessing facts concerning the intended purpose was improper and the test for ready for patenting cannot concern itself with the intentions of the inventor. Petitioner's argument contradicts *City of Elizabeth v. American Nicholson Pavement Co.*, which held that a use in experiment "pursued with a *bona fide* intent of testing the qualities of the machine" is not a public use. 97 U.S. 126, 135 (1877). Black's Law Dictionary defines "bona fide" as "in good faith; honestly, openly, and sincerely . . . ." *Bona Fide*, Black's Law Dictionary (11th ed. 2019). *City of Elizabeth* plainly dictates assessing the inventor's intent to experiment, as buttressed or refuted by surrounding facts bearing on its good faith.

Likewise, after *City of Elizabeth,* courts long considered reduction to practice in relation to whether the invention worked for its intended purpose under the relevant conditions dictated by the art. As Learned Hand wrote,

> The doctrine to be drawn from the books, as we read them, is this—and incidentally it is the only doctrine that can find support in reason: a test under service conditions is necessary in those cases, and in those only, in which persons qualified in the art would require such a test before they were willing to manufacture and sell the invention, as it stands.

Sinko Tool & Mfg. Co. v. Automatic Devices Corp., 157 F. 2d 974, 977 (2d Cir. 1946). Judge Hand was not alone in recognizing these points. Numerous cases explained that, when considering reduction to practice, "the inquiry is not what kind of test was conducted, but whether the test showed that the invention would work as intended in its contemplated use." *E. Rotorcraft Corp. v. United States*, 384 F.2d 429, 431 (Ct. Cl. 1967); *see also Gaiser v. Linder*, 253 F.2d 433, 436 (C.C.P.A. 1958) (inferring the necessary attributes for a test from the real-world application); *Elmore v. Schmitt*, 278 F.2d 510, 512-13 (C.C.P.A. 1960) ("[d]etermining the sufficiency of laboratory tests to effect a reduction to practice must necessarily depend on the circumstances of the particular case under consideration including, inter alia, the simplicity or complexity of the device . . . as well as the conditions to which the device is subjected when in practical use.").

Pfaff itself recognized and reaffirmed these points. *Pfaff* first noted that "[t]he law has long recognized the distinction between inventions put to experimental use and products sold commercially." 525 U.S. at 64. *Pfaff* then approvingly cited *City of Elizabeth*'s reasoning that "'delay . . . occasioned by a *bona fide* effort to bring [an] invention to perfection, or to ascertain whether it will answer the purpose intended,'" does not unduly extend the monopoly period for "'it is the interest of the public, as well as [the inventor], that the invention should be perfect and properly tested, before a patent is granted for it.'" *Id.* (quoting *City of Elizabeth*, 97 U.S. at 137). In light of these considerations, *Pfaff* squarely recognized "[t] he patent laws therefore seek both to protect the public's right to retain knowledge already in the public domain and the inventor's right to control whether and when he may

patent his invention." *Id.*; s*ee also id.* at 67 (concluding that "[a]n inventor can both understand and control the timing of the first commercial marketing of his invention" and recognizing that "[t]he experimental use doctrine … has not generated concerns about indefiniteness….").

Pfaff also, in reaching its holding, assessed both inventor testimony and surrounding facts and circumstances in finding the invention had been reduced to practice in view of the relevant art. The Court noted Pfaff "did not make and test a prototype of the new device" before sale, citing testimony that the way he did business was to go "from the drawing to the hard tooling" and that he knew from the drawings that "it works." *Id.* at 58 & n.3. Likewise, in affirming the "invention was ready for patenting," the Court highlighted "[t]he fact that the manufacturer was able to produce the socket using his detailed drawings." *Id.* at 68.

The Court's precedent thus repeatedly has acknowledged the inquiry requires assessment of the *bona fide* intentions and efforts of the inventor in light of the relevant art. Otherwise, the balance *Pfaff* insists upon—protection of public domain knowledge versus the inventor's control over experimentation—would be upset. The inquiry requires assessing what the inventor knew or was working to determine, and the inquiry into "bona fide" intent and efforts, means that, in addition to the inventor's testimony, evidence of the surrounding circumstances is relevant. *EZ Dock v. Schafer Sys., Inc.*, 276 F.3d 1347, 1355 (Fed. Cir. 2002) (Linn, J., concurring).

Contrary to Petitioner's contention, *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358 (1928), confirms

this Court's repeated declarations that the inventor's effort to confirm the invention works for its intended purpose remains relevant. That case dealt with prior invention and found the first inventor had reduced the invention to practice for the purpose of establishing priority when the claimed product—an effective accelerant—worked as an effective accelerant *and was known to do so by the alleged prior inventor*. *Id.* at 382 (noting the inventor knew of the novel property because the evidence collectively "show[ed] undoubtedly that he *knew* the existence of [D.P.G.] as an accelerator") (emphasis added). Express there is that the priority inventor *knew* it worked.

Under this framework, the Federal Circuit properly considered Dr. Barry's testimony that he did not know his invention worked for its intended purpose until performing three surgeries, on three differing curve types, and following up on all three patients when assessing whether his invention was "ready for patenting." *See supra* at I.A The record also included evidence corroborating the three procedures and follow-ups were experimental. *See supra* at I.B.

ii. The record demonstrates Dr. Barry was working to determine if his invention works for its "intended purpose."

Petitioner alternatively attempts to change the inquiry to require "intended purpose" be claimed or expressly stated in the patent. Pet. 12. That requirement has never existed.

In *City of Elizabeth*, the Court found the inventor's use was not public or a sale despite being in the open as a

toll road. The record showed the inventor was testing for durability, likelihood of decay, whether people liked the pavement, and use by "rich and poor." 97 U.S. at 133-34. The Court held the use was experimental and reached that conclusion despite the claims not reciting a single word about use, durability, and long-term resistance to decay. *Id.* at 128 (reproducing claims). This makes sense as the Court stated "bring his invention to perfection," not bring his *claimed* invention to perfection. Thus, Petitioner's suggestion the patents must recite *in hac verba* the intended purpose ignores precedent.

Rather than requiring legal formalism, *City of Elizabeth* simply assessed the logical relation between the invention—a road paving system—and the character of the experiment—assessing its durability. The Federal Circuit has similarly and appropriately inferred intended purpose on numerous occasions. *See Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 550-551 (Fed. Cir. 1990) ("When durability in an outdoor environment is *inherent* to the purpose of an invention, then further testing to determine the invention's ability to serve that purpose will not subject the invention to a section 102(b) bar.") (emphasis added); *see also Polara Eng'g Inc. v. Campbell Co.*, 894 F.3d 1339, 1349 (Fed. Cir. 2018) ("The jury heard testimony that Polera needed to test the claimed invention at actual crosswalks of different sizes and configurations . . . to ensure that the invention would work for its intended purpose. The jury also heard testimony *underscoring the importance of such testing* of the invention as 'a life safety device.'") (emphasis added); *see also Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 996-97 (Fed. Cir. 2007) ("to test its new system with human pilots in a *genuine* cockpit setting.") (emphasis added).

As in *City of Elizabeth*, and later applications of that case, here, the Federal Circuit properly considered the evidence, including the patent, in reviewing the record of Dr. Barry's intended purpose for his invention. And the record evidence supported that three surgeries, on three different conditions, with follow-up for each were conducted for Dr. Barry to determine whether his invention worked as intended.

Even as claimed, the invention is a novel method of treating spinal disorders through medical treatment—amelioration of aberrant spinal column deviation conditions.[5] *See supra* at I.A. At trial, that phrase received, without challenge, its plain and ordinary meaning to a person of skill. *See supra* I.C. The jury heard the invention was treatment of patients, not simply correcting scoliotic curves, which includes the common-sense need for patient follow-up to ensure the treatment took. *Supra*, at I.A.

Likewise, the jury heard evidence regarding a limitation in claim 1 of the '358 patent specifying the inventive method would "secure said vertebrae in their respective and relative positions and orientations . . . ." C.A.J.A. 330. More specifically, the jury heard a minimum of three months of follow-up was necessary for Dr. Barry to determine whether the method used during the procedures worked to "secure said vertebrae in their

5. Petitioner contends the claim reads "*an* aberrant spinal column deviation condition" in the singular, but that argument contradicts established law. *See KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2000) ("This court has repeatedly emphasized that an indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more' in open-ended claims . . . .").

respective and relative positions and orientations" for each of the three patients with different curve types. *Supra*, at I.A. This evidence also supports determining the purpose of the invention was the treatment of patients, not simply correction during surgery.

But even if the claim language alone was insufficient, as Petitioner suggests, the intended purpose here can be inferred. It is undisputed the claims are to a surgical method of treating spinal disorders and Dr. Barry intended to develop a surgical technique to treat various spinal disorders, work in various real-world situations, and hold up over time. *Supra*, at I.A. It is also precisely the kind of evidence used for the analysis of whether an invention works as intended routinely upheld based on jury findings like those at present.

The jury heard Dr. Barry needed to make sure his invention worked in various types of scoliosis conditions. C.A.J.A. 1192-93. Dr. Barry needed to make sure it worked in real-world situations by performing more than one or two surgeries. C.A.J.A. 1193-95. And finally, Dr. Barry needed to make sure that the new forces being applied from his inventive technique permitted the correction to take hold and the implants to remain in the proper place. C.A.J.A. 1195-96. This testimony was unrebutted. And further evidence supported that Dr. Barry was engaged in experimentation to determine if his invention would work as intended. *Supra* at I.A and I.B. When all is considered, not simply Petitioner's selective recitation of the evidence, a reasonable fact-finder could find in Dr. Barry's favor. *TP Labs v. Prof. Positioners, Inc.*, 724 F.2d 965, 973 (Fed. Cir. 1984).

The Petition and Chief Judge Prost's dissent merely argue for judgment as a matter of law based on reweighing the record. There has never been, nor should there be, a prescribed method to the process of invention or a requirement that testing rationale be spelled out in the specification or claims. Rather, the factual nature of determining whether an inventor possessed a *bona fide* intent to perfect or confirm the invention works as intended is properly an issue resolved by the factfinder. That factfinders can resolve issues of credibility and intent and analyze those issues under a legal framework is common to our laws. *Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 574 (1985).

Here, the record supports finding Dr. Barry's invention was not "ready for patenting." As such, the inquiry ends because it would not matter if the 2003 surgeries were experimental if the invention was not "ready for patenting."

2. The Federal Circuit Properly Recognized that Facts Supporting "Ready for Patenting" Are Also Relevant to "Experimental Use."

For Petitioner to succeed in overturning the verdict, it must make two separate but equally improper revisions to the application of the relevant bars. First, it must re-write *Pfaff* to ignore that "reduction to practice" is predicated on the inventor knowing the invention works as intended—the "ready for patenting" prong. Such analysis will often include the same facts which underpin the separate *Pfaff* question of whether an allegedly barring activity was done for experimental purposes—the sale or use prong.

Second, it must extricate analysis of experimentation from the question of whether an activity was a barring sale or use and make such an analysis a separate question with burdens of persuasion contrary to the Patent Act.

Neither of these revisions to the Section 102(b) bars are supported by precedent.

As the Court recognized in *Pfaff*, the questions of whether a sale occurred, whether it was experimental and thus not a sale, and whether the invention was ready for patenting are intertwined:

> [T]he product must be the subject of a commercial offer for sale. An inventor can both understand and control the timing of the first commercial marketing of his invention. The experimental use doctrine, for example, has not generated concerns about indefiniteness, and we perceive no reason why unmanageable uncertainty should attend a rule that measures the application of the on-sale bar of § 102(b) against the date when an invention that is ready for patenting is first marketed commercially.

525 U.S. at 67 (footnoted omitted).

The Federal Circuit likewise has acknowledged the interplay:

> [T]he Supreme Court and this court apply the experimental use negation without conflict with the 'ready for patenting' prong of the new on-sale bar test. Indeed . . . the Supreme

> Court acknowledged that a litigant may show readiness for patenting with evidence of reduction to practice. Like evidence of experimentation sufficient to negate a bar, reduction to practice involves proof that an invention will work for its intended purpose. *Even beyond this overlap of the experimental use negation and the ready for patenting standard, however, the Supreme Court explicitly preserved proof of experimentation as a negation of statutory bars.*

EZ Dock, 276 F.3d at 1352 (emphasis added) (citation omitted).

Thus, the question of whether an invention worked for the inventors' intended purpose, as articulated in *City of Elizabeth*, applies to both the question of whether an invention was publicly used or sold, as opposed to being used experimentally, and the question of ready for patenting. Chief Judge Prost acknowledged this in her concurrence in *Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1351, 1370 (Fed. Cir. 2008) ("While the experimental use doctrine, as such, is not pertinent to the second *Pfaff* prong [ready for patenting], an inventor's experimentation may have relevance to that prong"). *See also supra* at II.A.1.i.

Interplay between experimental use and reduction to practice makes sense given the many holdings, unchallenged by Petitioner, that there is no experimental use once the invention has been reduced to practice. *See, e.g.*, *New Railhead Mfg. LLC v. Vermeer Mfg Co.*, 298 F.3d 1290, 1299 (Fed. Cir. 2002); *RCA Corp. v. Data Gen. Corp.*,

887 F.2d 1056, 1061 (Fed. Cir. 1989); *Pennwalt Corp. v. Akzona Inc.*, 740 F.2d 1573, 1581 (Fed. Cir. 1984). The question of experimental use is simply part and parcel of whether an activity is a sale or public use. *Clock Springs LP v. Wrapmaster, Inc.*, 560 F.3d 1317, 1326 (Fed. Cir. 2009); *EZ Dock*, 276 F.3d at 1357-58 (Linn, J., concurring).

The Petition suggests the statutory bar ignore the Court's prior decisions and ask only whether at the time of the alleged barring activity a person of ordinary skill in the art "could have" obtained a patent. Pet. 17-18. Under the Petition's approach, a challenger would put forward evidence of an allegedly barring sale or public use and then simply ask whether a person of ordinary skill could have written a patent application.

Petitioner's approach effectively overrules *City of Elizabeth* and disposes of the balance established there and reaffirmed in *Pfaff*.

In *City of Elizabeth*, the patent specified two ways of making pavement, one of which was "to set square blocks on end arranged like a checker-board" with small spaces in between for gravel or the like over which tar or pitch was placed. 97 U.S. at 128. The claims encompassed both this method and an alternative. *Id.* Before experimentation began, the inventor "filed a *caveat* in the Patent Office in August, 1847, in which the checker-board pavement is fully described" and experiments later commenced in 1848 involving both kinds of pavement. *Id.* at 129. A *caveat* was similar to a patent application with a description of an invention and drawings, but without claims or examination for patentability. Patent Act of 1836, ch. 357, 5 Stat. 117 (repealed 1870). Stated simply, the *caveat*

demonstrated the invention could have been described in a patent application even before the experiments began; the inventor could have written his claims—which did not recite durability properties—long before observing its real-world performance.

But far from finding the patent barred, this Court instead found "[i]t is perfectly clear from the evidence that he did not intend to abandon his right to a patent. He had filed a *caveat* in August, 1847, and he constructed the pavement in question by way of experiment, for the purpose of testing its qualities." 97 U.S. at 133. The Court instead focused on the *bona fide* intent of the inventor and did so with a particular purpose in mind—balancing the inventor's and public interest in seeing inventions perfected and properly tested, versus concerns about undue patent term extension. *Id.* at 137.

Petitioner proposes to reverse *City of Elizabeth* and upset that balance, as reaffirmed in *Pfaff*. Petitioner's focus on whether a patent could have been written or whether a process is successfully performed (Pet. 17-18) renders *bona fide* experimentation a dead-letter. Indeed, Petitioner's proposal is similar to, but more aggressive in upsetting the balance this Court has achieved, than proposed in *Pfaff*. There, the Solicitor General proposed barring a patent "'if the sale or offer in question embodies the invention for which a patent is later sought,'" and the sale or offer is "'primarily for commercial purposes.'" 525 U.S. at 68 n.14 (citation omitted). This proposal preserved some inquiry into the commercial nature of the sale, yet the Court rejected it because "the possibility of additional development after the offer for sale in those circumstances counsels against" such a rule. *Id.* Under Petitioner's

proposal, post-sale experimentation is likewise rendered irrelevant and no inquiry into the commercial versus experimental nature of the sale is made.

Petitioner's attempt to remove intended purpose from both whether an invention was "ready for patenting" and the factually related question of experimental use finds no basis in this Court's carefully crafted and balanced decisions. Petitioner's effort destroys the balance the Court set allowing inventors room to experiment and perfect their inventions in real world conditions to the benefit of both the inventor and the public.

B. The Statutory Burden of Persuasion on Invalidity Based on Sale or Public Use, Which the Court Has Confirmed Includes the Experimental Use Inquiry, Must Control.

At the outset, the burden-of-proof question is worth considering only if the record fails to establish the 2003 surgeries were performed for Dr. Barry to determine if his invention worked for its intended purpose, thus showing his invention was not ready for patenting. *Pfaff*, 525 U.S. at 67. Petitioner's objective is clear. By making "ready for patenting" unrelated to determining the invention worked as the inventor intended, and by making experimental use a separate question from whether the activity was a barring sale or use, Petitioner seeks to avoid its statutory burden of persuasion to prove invalidity under *Pfaff*.

However, Petitioner offers no compelling reason to support its assertion the Court should ignore the statutory placement of the burden of establishing invalidity always on the party asserting it. The Petition argues the Federal

Circuit strayed from this Court's decision in *Smith & Griggs Manufacturing Co. v. Sprague*, 123 U.S. 249 (1887). Pet. 20. But as explained below, Petitioner's argument mischaracterizes law and precedent.

In *TP Laboratories*, the Federal Circuit addressed this issue in relation to whether an alleged use was an invalidating public use:

> Under this analysis, it is incorrect to impose on the patent owner, as the trial court in this case did, the burden of proving that a "public use" was "experimental." These are not two separable issues. It is incorrect to ask: "Was it a public use?" and then, "Was it experimental?" *Rather, the court is faced with a single issue: Was it public use under § 102(b)?*

724 F.2d at 971 (emphasis added). This is precisely what the Court in *Pfaff* suggested when it made sure experimental use was still part of the public use inquiry. *See supra*, at II.A.1. Experimental use is not a separate question from public use or on-sale bar, a point even Chief Judge Prost has acknowledged. *Atlanta Attachment*, 516 F.3d at 1370 (concurring).

As part of that formulation—entirely consistent with the Court's pronouncement of the two-part test in *Pfaff*—the Federal Circuit addressed the argument that the Court's *Sprague* decision compelled placing the ultimate burden of persuasion on the patent owner. The Federal Circuit explained:

> [T]he [trial] court should have looked at all the evidence put forth by both parties and

> should have decided whether the entirety of the evidence let to the conclusion that there had been "public use." This does not mean, of course, that the challenger has the burden of proving that the use was not experimental. Nor does it mean that the patent owner is relieved of explanation. It means that if a *prima facie* case is made of public use, the patent owner must be able to point to or must come forward with convincing evidence to counter that showing.

TP Labs., 724 F.2d at 971 (footnoted omitted).

The Federal Circuit specifically explained the Court's decision in *Sprague* must be read in light of the subsequent statutory codification placing the burden of proving invalidity on the challenger:

> We do not read [*Sprague*] as contrary to [the previous block quote], as urged by appellees. However, assuming that in [*Sprague*], the Court intended to impose the ultimate burden of persuasion on the patent holder rather than merely the burden of going forward with countering evidence, we do not believe that view is tenable in the face of the subsequently enacted statutory presumption.

Id. at 971 n.3 (further citing and quoting *Austin Mach. Co. v. Buckeye Traction Ditcher Co.*, 13 F. 2d 697, 700 (6th Cir. 1926)).

The statutory codification of the burden of proof is at 35 U.S.C. § 282. This Court has affirmed that the burden

laid out there controls and is not adjusted based on factual nuances specific to the type of validity challenge. *See Microsoft*, 564 U.S. at 108-09 (holding that the burden of persuasion is not lower just because specific prior art was not before the examiner). Further, the Court has been aware of the Federal Circuit's analysis in *TP Laboratories* since issuance. *See* n.4, *supra*. Similarly, the Court in *Pfaff* cited the same publication from which most of the Petition's analysis comes from.[6] Thus, Petitioner's attempt to format the inquiry under § 102(b) as separate from experimental use cannot stand.

Petitioner also argues the Federal Circuit's view diverges from that of other circuits. Pet. 21-22. But the majority of the cases cited by Petitioner pre-date the statutory placement of the ultimate burden on the challenger, and the remainder do not come from the Federal Circuit, which has been the nationwide appellate court for patent matters since 1982.

Petitioner argues the Federal Circuit's predecessor court—Court of Customs and Patent Appeals—explicitly followed *Sprague*. Pet. 22. But, in the case it cites, the burden of proof was not at issue. In *In re Dybel*, 524 F.2d 1393 (C.C.P.A. 1975), the court addressed an ex parte examination where a third-party petitioned the Patent

6. *Compare Pfaff*, 525 U.S. 67, n.15 *with* Pet. 25, n.8. The Court cited the Rocklidge paper as recognition that experimental use can make a sale not subject to the statutory bar even though Rocklidge argued the burden of persuasion for experimental use should be borne by the patentee. William C. Rocklidge & Stephen C. Jensen, *Common Sense, Simplicity and Experimental Use Negation of the Public Use and On Sale Bars to Patentability*, 29 J. Marshall L. Rev. 1, 45-46 (1995).

Office to consider public use. *Id.* at 1396. Thus, to the extent the Court of Customs and Patent Appeals held that it was a separate inquiry—"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"—it has been overruled by *TP Laboratories* and, more importantly, the Court in *Pfaff.*

Petitioner also asserts the Federal Circuit's approach in *TP Laboratories* is contrary to the Court's holding where a party carries both a burden of production and persuasion to qualify for an exception from a statutory prohibition. Pet. 24. But Petitioner ignores that, in those cases, the exception to the statutory prohibition is provided by statute and must therefore be established separately. *See Javierre v. Cent. Altagracia, Inc.*, 217 U.S. 502, 507-508 (1910); *see also United States v. First City Nat'l Bank of Hous.*, 386 U.S. 361, 365-66 (1967) (analyzing the statutory exception *within* the Clayton Act that created the defense to anticompetitive mergers).

That is not the case here. Rather, whether an allegedly invalidating activity is a sale or public use, and not an experimental one, is better analogized to cases where there are shifting burdens of production following a *prima facie* showing. For example, in cases of unlawful employment practices under Title VII of the Civil Rights Act, the Court has held that meeting the *prima facie* case of showing discriminatory conduct creates a presumption of unlawful conduct and thus "places on the defendant the burden of producing an explanation to rebut the prima facie case—*i.e.*, the burden of 'producing evidence' that the adverse employment actions were taken 'for a legitimate, nondiscriminatory reason.'" *St. Mary's Honor Center v.*

Hicks, 509 U.S. 499, 506-507 (1993) (*quoting Tex. Dep't of Cmty Affairs v. Burdine*, 450 U.S. 248, 254 (1981)).

In *St. Mary's*, Justice Scalia summarized that where the ultimate burden lies with a party but facts potentially negating the finding lie with the opposing party, this kind of burden shift is both consistent with the Federal Rules of Evidence and not uncommon to the law. *Id.* at 507. The Court explained that "[t]he factfinder's disbelief of the reasons put forward by the defendant (particularly if disbelief is accompanied by suspicion of mendacity) may, together with the elements of the prima facie case, suffice to show intentional discrimination." *Id*. at 511. Thus, there is no need for a separate question regarding experimental use, which will consider the evidence of whether the inventor intended to perfect his invention, just as there is no need for a separate question of whether there was a nondiscriminatory reason for a Title VII plaintiff to have been passed over.

Thus, Petitioner's attempt to extract the facts of experimentation from the *Pfaff* test asking whether a barring activity occurred and create a separate question such to shift the burden of persuasion to the patent owner is unfounded. Moreover, Petitioner's argument that under such a rubric, it would be entitled to judgment as a matter of law is incorrect. Petitioner supplants the factual record before the jury, and the inferences drawn from those facts, with its own theory of the facts. Pet. 24-27. At most, the remedy would be remand for trial consistent with a never before seen articulation of the experimental use doctrine.

CONCLUSION

The petition should be denied.

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