Barry v. Medtronic, Inc.: The Federal Circuit Redefines Experimental Use and Patentability for Medical Procedure Inventions

I. OVERVIEW

When Dr. Mark Barry developed a new surgical procedure to properly align vertebrae on patients with common spinal column deviations, he soon found his techniques and tools replicated by others.[1] In 2002, Barry experimented with existing spinal surgery tools to create a method to move vertebrae by linking derotation components with screws.[2] This process moved misplaced vertebrae to correct spinal abnormalities like scoliosis.[3] Barry used his tool for three surgeries on patients with different, fairly common, spinal abnormalities in August and October 2003.[4] Three months after each surgery, Barry followed up with each of the three patients to confirm the success of the operations.[5] He testified that it was only after the three-month follow-up with the third patient, in January 2004, that he was certain the procedure satisfied its intended purpose and was ready to be publicized in a professional forum.[6] Shortly after, in February 2004, Barry described the development of his methods in a printed abstract for a spinal technique conference.[7]

1. Barry v. Medtronic, Inc., 914 F.3d 1310, 1316 (Fed. Cir. 2019), *cert. denied*, Medtronic, Inc. v. Barry, No. 19-414, 2020 WL 129963, at *1 (S. Ct. Jan. 13, 2020).
2. *Id.* at 1319.
3. *Id.*
4. *Id.*; *id.* at 1338 ("Dr. Barry charged his normal fee for [the surgeries].").
5. *Id.* at 1319.
6. *Id.*
7. *Id.*

Barry received two patents for methods and systems for correcting spinal column anomalies.[8] Patent 7,670,358 (the '358 patent) was issued in 2010 from an application filed on December 30, 2004.[9] Patent 8,361,121 (the '121 patent) was issued in 2013 from an application that was filed in 2010.[10]

A surgeon at Medtronic, Inc. (Medtronic) was also working on a spinal derotation project around the same time.[11] In 2006, Medtronic sold a Vertebral Column Manipulation kit, which included instructions for a procedure similar to the one claimed in Barry's patents.[12] Barry sued Medtronic in the United States District Court for the Eastern District of Texas for, among other things, direct infringement of the '121 and '358 patents.[13] Medtronic argued that Barry's patents were invalid because of the public use and on-sale statutory bars.[14] Medtronic claimed that Barry sold the patented invention and put it into public use when he charged three patients for surgeries using the method prior to the patent's critical date of December 30, 2003.[15]

Medtronic disagreed with Barry's claim of experimental use in the period leading up to the critical date for the statutory bars.[16] Specifically, Medtronic argued that Barry's spinal surgery method worked for its intended purpose after he confirmed its success upon completion of two different patient procedures.[17] However, Barry asserted that it was only after the three-month follow-up appointment for the third surgical test of the method in January 2004 that he was confident the invention worked for its intended purpose.[18] The district court rejected Medtronic's public use and on-sale invalidity defenses and awarded damages to Barry.[19] Medtronic appealed the ruling on several grounds including the public use and on-sale statutory bars.[20] On appeal, the United States Court of Appeals for the Federal Circuit *held* that when a physician determines that a certain

8. *Id.* at 1317.
9. *Id.*
10. The '121 patent was a continuation of an August 2005 application that was a continuation-in-part application of a December 30, 2004, application. *Id.*
11. *Id.*
12. *Id.* at 1319-20.
13. *Id.* at 1316-17.
14. *Id.* at 1320.
15. Both the "public use" and "on-sale" bars hinge on the critical date—a year before the patent application filing date. *Id.*
16. *Id.* at 1321.
17. *Id.* at 1321-22.
18. *Id.*
19. *Id.* at 1316.
20. *Id.*

number of procedures and follow-up appointments are required to confirm a method is fit for its intended purpose, the experimental use exception applies and prevents application of the public use and on-sale statutory bars.[21]

II. BACKGROUND

Patentability under pre-AIA 35 U.S.C. § 102 requires that a claimed invention not be "in public use, on sale, or otherwise available to the public" more than one year before the inventor filed the patent application.[22] To determine if a statutory bar applies, it is necessary to first identify the patent's critical date, the date one year prior to the date of application for a patent in the United States.[23] If an invention was in public use or on sale before the critical date, the inventor will be barred from receiving a patent or, alternatively, an already issued patent may be invalidated.

First, "[t]he public use bar is triggered where, before the critical date, the invention is in public use *and* ready for patenting."[24] Under pre-AIA 35 U.S.C. § 102(b), an invention is considered in public use for statutory bar purposes if it "(1) was accessible to the public; or (2) was commercially exploited."[25] The ready for patenting standard is met in one of two ways: a reduction to practice (RTP) of the invention or the inventor has drawings or descriptions of the invention that are detailed enough to allow a skilled individual to practice the invention.[26] RTP can be constructive or actual.[27] Constructive RTP occurs when a patent application is filed.[28] Actual RTP requires the inventor to prove construction of an embodiment or process that meets the limitations of the claim, and that the invention would work for its intended purpose.[29] Both RTP and detailed descriptions of the invention are not required to meet the ready for patenting threshold; just one of those two requirements is enough.[30] Ready for patenting and RTP are both legal concepts that depend

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21. *Id.* at 1331.
22. The patent applications at issue were filed before passage of the AIA, so the pre-AIA statutes apply in this case. 35 U.S.C. § 102(a)(1) (2018).
23. Invitrogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1379-80 (Fed. Cir. 2005).
24. *Barry*, 914 F.3d at 1320-21 (citing Polara Eng'g, Inc. v. Campbell Co., 894 F.3d 1339, 1348 (Fed. Cir. 2018)).
25. *Invitrogen*, 424 F.3d at 1380.
26. Pfaff v. Wells Elecs., 525 U.S. 55, 67 (1998).
27. Cooper v. Goldfarb, 154 F.3d 1321, 1327 (Fed. Cir. 1998).
28. *Id.*
29. *Id.*
30. *Pfaff,* 525 U.S. at 67-68.

heavily on the standards of the industry of the invention and the details of the invention.[31]

Second, "[t]o be rendered invalid under the on-sale bar, an invention 'must be the subject of a commercial offer for sale' in the United States and it 'must be ready for patenting.'"[32] The on-sale statutory bar has "been interpreted as including commercial activity even if the activity is secret" and extends to activities that include a sale, offer for sale, or other commercial activity in the United States.[33]

However, the Experimental Use Doctrine is a long-held exception to the public use and on-sale statutory bars.[34] Generally, the experimental use exception has been interpreted as a negation of the statutory bars.[35] "A use may be experimental if its purpose is: '(1) [to] test claimed features of the invention or (2) to determine whether an invention will work for its intended purpose—itself a requirement for patentability.'"[36] Experimental use is based on the totality of the surrounding circumstances and involves:

> (1) the necessity for public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether payment was made, (6) whether there was a secrecy obligation, (7) whether records of the experiment were kept, (8) who conducted the experiment, (9) the degree of commercial exploitation during testing, (10) whether the invention reasonably requires evaluation under actual conditions of use, (11) whether testing was systematically performed, (12) whether the inventor continually monitored the invention during testing, and (13) the nature of contacts made with potential customers.[37]

The Supreme Court finds it is in the public interest to let inventors fine-tune their inventions before the patent application process must begin.[38] This "bona fide effort to bring [an] invention to perfection, or to ascertain whether it will answer the purpose intended," should not be discouraged

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31. *See* Corona Cord Tire Co. v. Dovan Chem. Corp., 276 U.S. 358, 383 (1928) (describing the circumstances in which an invention for a process of vulcanizing rubber is definitively reduced to practice, compared to other types of inventions).

32. *Barry*, 914 F.3d at 1331 (citing *Pfaff*, 525 U.S. at 67).

33. *See* MPEP § 2152.02(d) (9th ed. Rev. 08.2017, Jan. 2018).

34. EZ Dock, Inc. v. Schafer Sys., 276 F.3d 1347, 1352 (Fed. Cir. 2002).

35. *Id.* at 1351.

36. *Barry*, 914 F.3d at 1328 (citing Polara Eng'g, Inc. v. Campbell Co., 894 F.3d 1339 (Fed. Cir. 2018)).

37. *Id.*

38. Pfaff v. Wells Elecs., 525 U.S. 55, 64 (1998).

by forcing the inventor to rush to apply for patenting earlier, rather than after appropriate deliberation.[39]

A. Experimental Use Background

Case law beginning with *Elizabeth v. Pavement Co.* underscores the fact-dependent nature of determining experimental use.[40] In this early case from 1877, the Supreme Court held the public use bar did not invalidate Samuel Nicholson's pavement patent even though he installed the pavement on a public roadway six years before applying for the patent.[41] Several factors contributed to the overwhelming finding that during those six years the invention was not invalidated by the public use bar. For example, the pavement was isolated to a specific area where Nicholson observed it closely in various weather conditions, he never agreed to replicate the pavement in other locations, and he never proposed selling it for use in other locations.[42] In other words, Nicholson never relinquished control of his invention. The facts of the *Elizabeth* case laid the groundwork for modern judicial interpretation of experimental use, as it relates to the public use and on-sale statutory bars for patentability.[43]

Fitness for intended purpose plays an important role in determining experimental use because it gets to the heart of the reason for the existence of the patented invention.[44] If an invention is not fit for its intended purpose, then it is not ready for patenting and neither the public use or on-sale statutory bars apply. Though fitness for intended purpose varies depending on the type of invention, it generally requires evidence of workability or utility of the invention.[45] In *Elizabeth*, the concept of intended purpose related to the pavement's durability.[46] The Court stated that if durability was a necessary part of the pavement, experimentation over "a long period, perhaps years, may be necessary to enable the inventor to discover whether his purpose is accomplished."[47] Qualities that are essential to the

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39. *Id.* at 64-65.
40. Elizabeth v. Pavement Co., 97 U.S. 126, 133 (1877).
41. *Id.* at 136.
42. *Id.* at 133-36.
43. Barry v. Medtronic, Inc., 914 F.3d 1310, 1328 (Fed. Cir. 2019), *cert. denied*, Medtronic, Inc. v. Barry, No. 19-414, 2020 WL 129963, at *1 (S. Ct. Jan. 13, 2020) (relying on *Elizabeth*, 97 U.S. at 134-35).
44. Polara Eng'g, Inc. v. Campbell Co., 894 F.3d 1339, 1348 (Fed. Cir. 2018) (citing to Clock Spring, L.P. v. Wrapmaster, Inc., 560 F.3d 1317, 1327 (Fed. Cir. 2009)).
45. Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc., 855 F.3d 1356, 1372 (Fed. Cir. 2017).
46. *Elizabeth*, 97 U.S. at 135.
47. *Id.*

function of the invention contribute to whether that invention is fit for its intended purpose.[48] Accordingly, the experimentation period should be viewed as an opportunity to achieve certainty of all the qualities that contribute to an invention's intended purpose.[49]

The Federal Circuit's interpretation of the experimental use exception has evolved.[50] There is a significant, and sometimes contradictory body of case law on the subject of readiness for patenting and how it relates to an invention's fitness for intended purpose when an inventor conducts experimentation before the critical date that obfuscates the exact date that the inventor knew the invention worked for its intended purpose.[51]

B. Public Use Exposure During the Experimental Use Phase

Public use, in its most basic sense, means that an invention (or the details necessary for making the invention) is within the public sphere and could ostensibly be made or used by those outside of the close, private circle of the inventor.[52] As previously mentioned, there are two prongs to the public use bar.[53] First, the invention must be "in public use," and second, it must be "ready for patenting."[54] The Federal Circuit focuses on three main factors to define public use: "the nature of the activity that occurred in public; the public access to and knowledge of the public use; [and] whether there was any confidentiality obligation imposed on persons who observed the use."[55] The inventor's control of the invention is a key question here.[56] When an inventor has "relinquish[ed] control of his invention," the invention is considered "accessible to the public."[57] The ready for patenting prong can be established either by RTP, or by "drawings or descriptions enabling an ordinarily skilled artisan to practice the invention."[58]

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48. *Id.*
49. *Id.*
50. Barry v. Medtronic, Inc., 914 F.3d 1310, 1321 (Fed. Cir. 2019), *cert. denied*, Medtronic, Inc. v. Barry, No. 19-414, 2020 WL 129963, at *1 (S. Ct. Jan. 13, 2020).
51. *Id.*
52. *Id.* at 1327.
53. Polara Eng'g, Inc. v. Campbell Co., 894 F.3d 1339, 1348 (Fed. Cir. 2018).
54. *Id.*
55. *Barry*, 914 F.3d at 1327 (quoting Dey, L.P. v. Sunovion Pharms., Inc., 715 F.3d 1351, 1355 (Fed. Cir. 2013)).
56. *Id.*
57. *Id.*
58. *Id.* at 1322.

Experimental use complicates this framework because there are instances where public exposure is required to determine if an invention is fit for its intended purpose.[59] The pavement in *Elizabeth* is an example of an invention that may be publicly available but is not in public use.[60] The nature of the invention that Nicholson tested, pavement for a frequently used public road, required that the pavement undergo realistic heavy use to confirm its durability.[61] The pavement's durability was necessary to ensure that the invention was fit for its intended purpose.[62] The Supreme Court held that the patent was valid and was not barred by public use because the experimental use exception allowed public use of the pavement to determine if it was fit for its intended purpose.[63]

It is clear that public exposure does not invalidate a patent where the invention must be used by the public to determine whether it is fit for its intended purpose,[64] or where the invention must be outside and exposed to weather conditions during experimentation.[65] For other types of inventions, like medical devices or procedures, public use and experimental use are not as obvious.[66] The Federal Circuit has held that, where an inventor publicly exposes their invention in some capacity, it does not trigger the public use statutory bar if they maintain a certain level of control over the invention.[67]

The Federal Circuit has reasoned that experimental use should not be viewed as an exception to public use, but rather that the public use bar is negated if it is necessary for the invention to be in public use for experimentation.[68] In *TP Laboratories, Inc. v. Professional Positioners, Inc.*, the court addressed the question of whether implantation of an orthodontal tooth-positioning device in three patients prior to the critical date invoked the public use statutory bar.[69] The court looked at the amount of time spent experimenting, whether there was payment for the invention, whether the patient agreed to secret use, whether there were records of the

59. *Polara*, 894 F.3d at 1349.
60. Elizabeth v. Pavement Co., 97 U.S. 126, 134 (1877).
61. *Id.* at 136.
62. *Barry*, 914 F.3d at 1343 (Prost, C.J., dissenting).
63. *Elizabeth*, 97 U.S. at 137.
64. *Polara*, 894 F.3d at 1349.
65. Manville Sales Corp. v. Paramount Sys., 917 F.2d 544, 550-51 (Fed. Cir. 1990).
66. TP Labs., Inc. v. Prof'l Positioners, Inc., 724 F.2d 965, 971 (Fed. Cir. 1984).
67. *See* Am. Seating Co. v. USSC Grp., Inc., 514 F.3d 1262, 1268 (Fed. Cir. 2008) ("When access to an invention is clearly limited and controlled by the inventor . . . an understanding of confidentiality can be implied.").
68. *TP*, 724 F.2d at 971.
69. *Id.* at 967-68.

experimentation process, how many patients were used for the experimentation, and more.[70] Underscoring the fact-dependent nature of this question, the court ruled that the patent owner did not put the invention into public use according to the 35 U.S.C. § 102(b) public use bar.[71] Importantly, the court found that the device needed to be tested in patients for two to six years to determine its success.[72] The court deemed the lack of confidentiality was unimportant because it was unlikely that the patients would show the device to anyone who could understand it or duplicate it.[73] Additionally, the court stated "the inventor was testing the device, not the market," because the patients were not charged an extra fee for the device.[74] *TP* sets a precedent for patent invalidity issues in the realm of medical device inventions that require experimentation in the form of patient implantation.[75]

C. The On-Sale Bar and the Pfaff Test for Readiness for Patenting

In addition to the public use bar for patentability, there is an on-sale statutory bar.[76] If an invention was commercially sold or advertised prior to the critical date, the patent may be invalidated under 35 U.S.C. § 102(a)(1).[77] The Federal Circuit uses the Supreme Court on-sale bar test from *Pfaff v. Wells Electronics, Inc.* to evaluate whether the on-sale bar applies to an invention.[78] In *Pfaff*, the Court held that there are two requirements to the on-sale bar.[79] First, before the critical date, the invention must be "the subject of a commercial offer for sale," and second, it must be ready for patenting.[80]

The sale of an invention may also constitute proof of public use.[81] The on-sale bar and the public use bar are based on the same policy considerations, and the two are similar in many ways.[82] Like the public use bar, the on-sale bar involves a two-part test—the invention must be ready for patenting and the invention must be offered for sale in a public

70. *Id.* at 971-72.
71. *Id.* at 972.
72. *Id.*
73. *Id.*
74. *Id.*
75. *Id.* at 972-73.
76. *See* 35 U.S.C. § 102(a)(1) (2018).
77. Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 59-60 (1998).
78. *Id.* at 67-68.
79. *Id.*
80. *Id.*
81. Invitrogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1382 (Fed. Cir. 2005).
82. *Id.* at 1379.

capacity.[83] The public use bar can overlap with the on-sale bar because an offer for sale (not a secret offer) makes an invention publicly accessible.[84] *Invitrogen Corp. v. Biocrest Manufacturing, L.P.* demonstrates the intersection of the public use and on-sale statutory bars.[85] There, Invitrogen sued for patent infringement and successfully argued against invalidity under the public use and on-sale bars.[86] The Federal Circuit analyzed both statutory bars and upheld the patent because Invitrogen did not sell the invention and it remained confidential within the company.[87]

The Federal Circuit has been careful to indicate that a sale of an invention is not a *per se* invalidation under the on-sale bar, particularly when there is not a public component to that sale.[88] An overriding factor in cases involving these two statutory bars is whether the inventor relinquishes control in a way that allows public access to the invention.[89] For example, a sale may not constitute public use when the seller and buyer are part of the same larger entity, so long as that sale does not allow for public access to the invention.[90] Although the on-sale bar has other public policy motives, it overlaps with the public use bar in that it serves to prevent inventors from releasing an invention into the public sphere (through public sale) before the critical date.[91]

III. COURT'S DECISION

In the noted case, the Federal Circuit reaffirmed that experimental use is a viable exception to the public use and on-sale bars to patentability.[92] First, the court relied on extensive case law for fact pattern comparisons and found that implantation into three patients and the subsequent follow-up appointments were experimental uses, and not

83. *Id.*
84. *Id.* at 1380.
85. *Id.* at 1382.
86. *Id.* at 1378.
87. *Id.* at 1382 ("Invitrogen's invention was not given or sold 'to another,' or used to create a product given or sold to another, and was maintained under a strict obligation of secrecy. Without more, these circumstances are insufficient to create a public use bar to patentability.").
88. *See* Netscape Communs. Corp. v. Konrad, 295 F.3d 1315, 1324 (Fed. Cir. 2002) ("Where . . . both parties to an alleged commercial offer for sale receive research funds from the same entity, it may be more difficult to determine whether the inventor is attempting to commercialize his invention.").
89. *Id.*
90. *Id.*
91. *Id.*
92. Barry v. Medtronic, Inc., 914 F.3d 1310, 1326-27 (Fed. Cir. 2019), *cert. denied*, Medtronic, Inc. v. Barry, No. 19-414, 2020 WL 129963, at *1 (S. Ct. Jan. 13, 2020).

public uses, of the spinal tool.[93] Second, the court carefully threaded the issues of readiness for patenting (using the *Pfaff* test) and fitness for intended purpose within the scope of experimental use.[94] Third, the court ruled that the standard payment charged for the three procedures prior to the critical date did not invalidate the patent under the on-sale bar.[95] Judge Prost's dissent disagreed with the majority's interpretation of the timeline for determining fitness for intended purpose and found that Barry's invention was ready for patenting before the critical date.[96] The dissent also rejected the majority's finding of experimental use and concluded that the opinion confused the *Elizabeth* precedent.[97]

First, the court addressed Medtronic's argument that Barry's use of the invention did not fall within the experimental use exception because it was in public use and ready for patenting.[98] Medtronic argued that the exception should not apply because Barry charged patients for the procedure and failed to inform the patients of the device's experimental status.[99] However, the court found that implantation into three patients and the subsequent follow-up appointments constituted an experimental use exception to the public use bar.[100] The court relied on cases where testing of the invention required some form of public disclosure.[101] Additionally, the court found that the invention was not ready for patenting before the critical date, refuting the possibility of public use.[102] "Medtronic relied on the August and October 2003 surgeries as reductions to practice that immediately proved that the claimed invention of the '358 patent would work for its intended purpose."[103] However, the court found "the evidence allow[ed] a reasonable finding that Dr. Barry did not know that his invention would work for its intended purpose until . . . he completed the [surgery] follow-ups."[104] The court also noted that Barry only submitted an abstract describing his spinal derotation invention *after* he confirmed the surgical method worked for its intended purpose in the three patients.[105]

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93. *Id.* at 1320.
94. *Id.* at 1322.
95. *Id.* at 1327.
96. *Id.* at 1339 (Prost C.J., dissenting).
97. *Id.* at 1340-41.
98. *Id.* at 1329.
99. *Id.*
100. *Id.* at 1319-21.
101. *Id.* at 1325-26.
102. *Id.* at 1321.
103. *Id.* at 1323.
104. *Id.*
105. *Id.*

The majority emphasized that the amount of Barry's follow-up was consistent with the standard for "peer-reviewed publications reporting new techniques."[106] The court held where an inventor tests the invention in "practical circumstances" to get a sense of the "real-world situations in which the system would be used," this valid experimental use overrides any public use.[107]

Second, the court used the *Pfaff* test to clarify readiness for patenting and fitness for intended purpose.[108] On appeal, Medtronic challenged a jury instruction that clarified a difference between experimental use in patent law versus experimentation in medicine.[109] The Federal Circuit rejected this argument, and noted that lack of informed consent, which may be legally required in the medical context, is unrelated to the experimental use exception in patent law.[110] The court deferred to Barry's judgment that it was only after the follow-up appointment for the third spinal correction surgery that the invention was fit for its intended purpose.[111] This "common-sense approach" does not require that every feature of the intended purpose be made explicit in the scope of the claim.[112] On this issue the court held that, where an invention requires experimental use to determine if it is fit for the intended purpose, it is not ready for patenting until the experimentation period ends.[113]

Third, the court rejected Medtronic's argument for invocation of the on-sale bar because the invention was not ready for patenting and the three surgeries fell within the experimental use exception. Since the court already ruled that Barry's use was not public use, but in fact experimental use, the on-sale bar did not apply.[114] Ultimately, other factors weighed toward experimental use and overwhelmed the possibility of invalidity under the on-sale bar.[115] Evidence of Barry's experimental use and the court's prior holding in *TP*, that a lack of extra fees for a device indicates there was no commercial exploitation for the purpose of the on-sale bar, contributed to the court's finding that there was no commercial exploitation.[116]

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106. *Id.*
107. *Id.* at 1326.
108. *Id.* at 1322.
109. *Id.* at 1331-32.
110. *Id.* at 1332.
111. *Id.* at 1324.
112. *Id.* at 1324-25.
113. *Id.* at 1326.
114. *Id.* at 1331.
115. *Id.* at 1328.
116. *Id.* at 1327-28.

Judge Prost's dissenting opinion first disagreed with the majority's finding that the invention was not ready for patenting before the critical date.[117] Prost insisted that the majority applied the ready for patenting standard too narrowly and argued that the timeline to determine fitness for intended purpose should be more liberally construed.[118] According to Judge Prost, "by no later than the second surgery's completion, Dr. Barry appreciated that his invention worked for its intended purposes" and that "his inventions were reduced to practice by then as a matter of law."[119] However, Judge Prost also noted that RTP is not essential for an on-sale bar to apply and "rather, the standard is whether the invention was 'ready for patenting'—that is, whether the inventor 'could have obtained a patent.'"[120] Judge Prost found Barry sufficiently outlined and described his invention to satisfy the enablement and written-description requirements of patentability.[121] Judge Prost asserted that Barry likely knew that his invention was RTP by the end of the second procedure (even before the follow-up appointment), which was enough to constitute readiness for patenting.

Second, Prost's dissent found the majority's application of the Experimental Use Doctrine incongruent with the Court's interpretation in *Elizabeth*.[122] Prost argued that experimental use occurs when the inventor's "pre-critical-date sale or public use . . . [seeks] to test an unclaimed . . . yet inherent, feature of an invention."[123] Prost rejected the third spinal surgery as part of the experimental use phase.[124] Although Prost admitted that the *Elizabeth* Court made room for a "good-faith, perfectionist inventor," she insisted that Barry's third surgery was out of scope, even for a perfectionist.[125] An aspect of an invention that is necessary to ensure fitness for intended purpose may not be made explicit in the patent claims, but Prost suggested there should be a limit to what a court will accept based solely on an inventor's subjective testimony.[126] Prost rejected the majority's application of experimental use in the noted case based on this combination of factors.[127]

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117. *Id.* at 1340 (Prost, C.J., dissenting).
118. *Id.*
119. *Id.* at 1339.
120. *Id.* (citations omitted).
121. *Id.*
122. *Id.* at 1343.
123. *Id.* at 1344.
124. *Id.* at 1342.
125. *Id.* at 1343-45.
126. *Id.* at 1341.
127. *Id.* at 1347.

IV. ANALYSIS

This Federal Circuit decision creates a convoluted standard for the *Pfaff* test for readiness for patenting where there is disputed experimental use.[128] The court's approach attempts to fit the law it wants into the fact pattern of Barry's case, rather than examining the facts within the existing legal precedent.[129] The relevance of the Experimental Use Doctrine has been questioned since passage of the America Invents Act (AIA).[130] In spite of this, the Federal Circuit applies the Doctrine broadly here. It is not evident how the court will carry forward its approach from the noted case, but there is a clear slant toward the patent applicant's claim of experimental use that does not seem to be firmly rooted in the precedential case law.[131] Judge Prost's thoughtful dissent provides a more accurate interpretation of Federal Circuit precedent and better reflects the way the court should apply the law in future cases.[132]

First, the court prioritizes certain elements of Barry's invention and experimental process in order to rule in his favor.[133] The court fixates on RTP, rather than the ready for patenting standard more broadly, leading to a focus on Barry's subjective intent and the follow-up appointments for the three surgeries.[134] Judge Prost emphasizes Barry's testimony, as well as his expert's testimony that suggested the derotation procedure was proven to work upon completion of the surgery, rather than upon follow-up three months later.[135]

Second, the significance of the legislative intent behind the Experimental Use Doctrine appears to be in decline, contrary to the holding in the noted case.[136] Since the U.S. Patent and Trademark Office (USPTO) issued narrower guidelines for the AIA public use bar, there is less of a need for experimental use exceptions.[137] Passage of the AIA in 2011 marked an enormous shift from the "First to Invent" rule to the "First

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128. *Id.* at 1340.

129. *See id.*

130. Kris J. Kostolansky & Daniel Salgado, *Does the Experimental Use Exception in Patent Law Have a Future?*, 47 COLO. LAW. 32, 32 (2018).

131. *See* Warren Woessner, Barry v. Medtronic—*Be Careful What You Use and Sell!*, PATENTS4LIFE (Jan. 28, 2019), http://www.patents4life.com/2019/01/barry-v-medtronic-careful-use-sell/.

132. *See* Kevin Noonan, *Patent Docs: When Is an Invention "Ready for Patenting"?*, DDN NEWS (Mar. 2019), http://ddn-news.com/index.php?newsarticle=13196.

133. *Barry*, 914 F.3d at 1340.

134. *Id.*

135. *Id.* at 1338-39.

136. Kostolansky & Salgado, *supra* note 130, at 36.

137. *Id.* at 34.

to File" rule.[138] In that legislation, Congress emphasized a stricter adherence to the patent application structure, creating a "race to the patent office," as some have described.[139] Importantly, the noted case was considered in the pre-AIA framework due to the timing of the patent application dates.[140] It still demands attention though, since the Federal Circuit directly contravenes the legislative purpose of the AIA in the noted case by interpreting experimental use so broadly.

Finally, Judge Prost notably mentions the necessity that fitness for intended purpose stay within the scope of the initial patent claim.[141] Here, the Federal Circuit strays too far from the *Elizabeth* Court's holding.[142] There is no evidence to suggest that the three surgeries Barry performed were all necessary to ensure the device worked for the intended purpose.[143] Barry's patent claims did not mention the three different types of spinal conditions included in the invention's intended purpose.[144] Moreover, these surgeries differed substantively and legally from Nicholson's pavement durability testing in *Elizabeth*.[145] In *Elizabeth*, the Supreme Court made a logical inference about the importance of durability in the pavement invention.[146] Here, the Federal Circuit overreaches by inferring that the three types of spinal curvature procedures are all necessary to determine fitness for intended purpose.[147]

Allowing inventors to tack on qualities that contribute to an invention's intended purpose could lead to a slippery slope for the fairness of future patent law. The noted case allows future parties bringing claims of infringement to take an overly broad approach to the intended purpose of an invention, and to take advantage of the Experimental Use Doctrine. It is possible that the court interprets the experimental use exception liberally in this case because the pre-AIA guidelines and rules apply. Although it was necessary for the court to apply these pre-AIA rules, it does not justify the expansive interpretation of experimental use.

The court will likely continue to rule on pre-AIA cases for years to come. The court's approach to experimentation goes against the USPTO's

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138. Nathan Hurst, *How the America Invents Act Will Change Patenting Forever*, WIRED (Mar. 15, 2013, 6:30 AM), http://www.wired.com/2013/03/america-invents-act/.

139. *Id.*

140. *Barry*, 914 F.3d at 1319 n.1 ("As the parties agree, the pre-AIA provisions apply here.").

141. *Id.* at 1341 (Prost, C.J., dissenting).

142. *Id.* at 1343.

143. *Id.* at 1342.

144. *Id.*

145. *Id.* at 1343-44.

146. Elizabeth v. Pavement Co., 97 U.S. 126, 136 (1877).

147. *See Barry*, 914 F.3d at 1343.

new filing guidelines that render experimental use less relevant. It would have been appropriate for the court to emphasize that its holding in this case should not encourage more inventors like Barry to construe the experimentation period so liberally. AIA's intention to spur quicker patent application filings, rather than sitting on a completed invention without patenting it, should be a serious consideration of the court in a case like this, even though the AIA did not apply. Barry and his ilk should be emboldened to file as early as possible within the realm of what is safe and appropriate for the particular industry. Therefore, the Federal Circuit should not have invoked the Experimental Use Doctrine in this case, but more deftly applied case precedent to ready for patenting and fitness for intended purpose standards.

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 J.D. candidate 2021, Tulane University Law School; B.A. 2016, Barnard College. Thank you to Professor Jeremy Bock and the executive members of the *Tulane Journal of Technology and Intellectual Property* for their assistance and advice. This Note is dedicated to my sister Sylvie, who is currently in the process of completing a formal patent application for a urological device.