Does the Experimental Use Exception in Patent Law Have a Future?

BY KRIS J. KOSTOLANSKY AND DANIEL SALGADO

The experimental use exception, part of U.S. patent law for nearly two centuries, is becoming obsolete. Recent court decisions and changes under the America Invents Act (AIA) have raised doubts about the continued viability of the doctrine. Additionally, other legal provisions that offer protections similar to those of the experimental use doctrine and reduce the need for its use have gained prominence. This article explores the development and current state of the experimental use exception and its place in patent law.

**The Experimental Use Doctrine**

The experimental use exception is a judge-made doctrine that provides protection for experimental uses of an invention. The doctrine is primarily invoked as protection against (1) the “public use” bar under 35 USC § 102, and (2) claims of patent infringement under 35 USC § 271(a). Courts created the experimental use exception in these contexts to align with the underlying policies of U.S. patent law.

Patent law in the United States is a “carefully crafted bargain” that balances the competing interests of the inventor and the public. An inventor receives a limited-time monopoly to exploit his innovations and, in exchange, the public receives the full disclosure of the invention and the right to practice it when the patent term expires. This give and take between the inventor and the public is called the “patent bargain” or “quid pro quo.”

The patent bargain reflects the policy of the U.S. Constitution’s Patent and Copyright clause, which seeks to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” The drafters believed that the Constitution needed this clause to promote science and literature. This ultimate goal of promoting science and art laid the foundation for creation of the experimental use exception.

**The Public Use Bar**

In one context, the experimental use exception is a defense against the public use bar under 35 USC § 102. Historically, patent statutes have contained provisions that prevent an inventor from receiving a patent on an invention that she used in public before filing a patent application. This prohibition placed a burden on the inventive
process because it limited inventors’ ability to test the qualities of their inventions in public before filing a patent. Courts addressed this issue by creating an exception for public uses that were experimental. However, changes under the AIA may have eliminated the experimental use exception in this context.

Public Use Prohibitions

Since their earliest iterations, patent statutes have included some form of prohibition against the “public use” of an invention before filing a patent application for that invention. The first patent statute, the Patent Act of 1790, stated that an inventor can receive a patent on “any useful art, manufacture, engine, machine, or device, or any improvement therein not before known or used.” The next statute, the Patent Act of 1793, elaborated on this language and more explicitly stated that the inventor could not receive a patent on an invention “known or used before the application.” The next two laws, the Patent Act of 1836 and Patent Act of 1839, codified the modern form of the ban on public use under pre-AIA §102(b).

The limitations on public use encouraged inventors to file their patents quickly and to disclose their inventions to the public. Congress believed that such quick disclosures in the public domain helped promote the progress of science and literature. But limiting public use also conflicts with the underlying policies of patent law. As part of the patent bargain, the public receives the disclosure of the invention, but the public benefits more from the disclosure of an invention that has been properly perfected and tested before it is patented. Some inventions, by their nature, must be tested and perfected in public. Such public testing may constitute public use under pre-AIA §102(b) and thus bar the inventors from obtaining patents on their inventions. To address this issue, courts recognized that a public use may avoid the pre-AIA §102(b) bar to patentability “if the use was done primarily to experiment with the claimed invention by testing it to improve its qualities before the invention is completed.” The experimental use exception was born from this recognition.

The Public Use Exception

One of the first cases to recognize experimental use as an exception to public use was the U.S. Supreme Court case City of Elizabeth v. American Nicholson Pavement Company. In City of Elizabeth, inventor Samuel Nicholson received a patent on a new and improved wooden pavement. He sued the City of Elizabeth for infringement of his patent when the city installed wooden pavement in Elizabeth, New Jersey. The city countered by arguing that Nicholson’s patent was invalid because his invention was in public use for six years before he applied for a patent. At the time Nicholson obtained his patent, the Patent Acts of 1836 and 1839 prohibited the public use of an invention more than two years before an application. The city alleged that Nicholson tested his invention by laying the wooden pavement down on a public road in Boston in 1848. The City of Elizabeth argued that the Boston public used the invention for six years before Nicholson filed his patent application, and that this use should bar Nicholson from obtaining a patent on his wooden pavement invention.

As discussed in the Court’s opinion, Nicholson laid the pavement on the road at his own expense to test the durability of his invention. He chose this location because it was a well-traveled road in Boston and frequently used by teams of horses having a load of five or six tons. These teams had to stop to pay a toll at a nearby toll-house. The teams’ constant stopping and starting made the location “as severe a trial to the pavement as it could be put to.” In addition, the local toll-collector testified that Mr. Nicholson was there almost daily, and when he came he would examine the pavement, would often walk over it, cane in hand, striking it with his cane, and making particular examination of its condition. . . . I have heard him say a number of times that this was his first experiment with this pavement, and he thought that it was wearing very well.

The Court acknowledged that Nicholson’s use of the pavement was public, but questioned whether its public nature alone was sufficient to deem it public use. It compared his use to the experimental testing of a traditional machine invention. This type of invention may be tested and tried in a building, away from the view of the public. The inventor may alter it, improve it, and conduct experiments to see what additional alterations may be necessary. If the inventor is attempting to improve durability, the inventor may need to test this quality over long periods...
of time. After that period, the inventor may find out that no changes are necessary. Regardless of the final outcome of the experiments, this “bona fide intent of testing the qualities of the machine” would not be deemed a public use. It should not make any difference if the nature of an invention, such as street pavement, forces the inventor to test and perfect the invention in public. Therefore, the Court concluded that experimental use of an invention has never been regarded as public use. Thus, Nicholson’s use was experimental and could not be public use.

The Court summarized the experimental use exception as use:

- under the surveillance of the inventor, and
- for the purpose of enabling him to test the machine, and ascertain whether it will answer the purpose intended, and make such alterations and improvements as experiment demonstrates to be necessary, it will still be a mere experimental use, and not a public use, within the meaning of the statute. This holding laid the foundation for the experimental use exception to the public use bar.

Using City of Elizabeth as a starting point, courts continued to build and refine the experimental use exception, and consistently held that whether a public use was experimental presents a question of law to be analyzed based on the totality of the circumstances. Courts also established a set of factors to consider in determining whether the inventors engaged in experimentation. These factors include but are not limited to:

- the necessity for public testing,
- the amount of control over the experiment retained by the inventor,
- the nature of the invention,
- the length of the test period,
- whether payment was made,
clause indicates that the preceding categories of prior art set forth in the statute—patents, publications, public use, and sales—must also be “available to the public.” Under this view, the residual clause appears to add a public knowledge requirement, which did not exist before the AIA. In other words, the public must know about the public use for it to fall within the scope of the public use bar. For example, use of the hypothetical smartphone device discussed in the previous section would not be public use because the use of the device does not disclose the invention to the public. This interpretation narrows the field of prior art that would fall under the public use bar.

The U.S. Patent and Trademark Office (USPTO) adopted the narrower view of public use in its AIA Examination Guidelines issued on February 14, 2013. The Examination Guidelines stated that “the Office views the ‘or otherwise available to the public’ residual clause of the AIA's 35 U.S.C. § 102(a)(1) as indicating that secret sale or use activity does not qualify as prior art.” This statement declares that public uses that are unknown to the public do not fall within the scope of the public use bar. Generally, USPTO guidelines are not binding on courts, but they can be persuasive.

Recently, the Federal Circuit addressed the impact of the “otherwise available to the public” language on the “on-sale” bar of § 102 in Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc. In this case, Helsinn argued that the “otherwise available to the public” clause limits the scope of the on-sale bar, and it no longer applies unless the sale discloses the details of the invention to the public. The Federal Circuit disagreed and stated that “[r]equiring such disclosure as a condition of the on-sale bar would work a foundational change in the theory of the statutory on-sale bar.” According to the court, the legislative history did not reveal an intent to make such a change. Thus, the Federal Circuit held that “after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale.”

This holding suggests that the “otherwise available to the public” language does not substantively change the categories of prior art listed in § 102. However, in dicta, the Helsinn court suggested that the AIA legislative history may indicate an intent to narrow the scope of public use. It looked at the following floor statements made by Senators Patrick Leahy and Jon Kyl:

[S]ubsection 102(a) was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the United States that result in a product or service that is then made public may be deemed patent-defeating prior art. That will no longer be the case.

[T]he current on-sale bar imposes penalties not demanded by any legitimate public interest. There is no reason to fear ‘commercialization’ that merely consists of a secret sale or offer for sale but that does not operate to disclose the invention to the public. . . . The present bill’s new section 102(a) precludes extreme results such as these . . . .

The court stated, “[a]t most the floor statements show an intent ‘to do away with precedent under current [§ 102] law.’” That precedent appears to be cases that govern secret uses under the public use prong. Senator Kyl explicitly listed public use cases and stated that “new section 102(a) precludes extreme results such as these.” The court acknowledged that all of the cases listed by Senator Kyl “involved a public use where the invention was not, as a result of the use, disclosed to the public.” However, the court refused to address the scope of public use because the issue was not before it.

Helsinn filed a petition for rehearing en banc in June 2017. Its petition is supported by several amicus briefs filed by the American Intellectual Property Law Association (AIPLA), Biotechnology Innovation Organization (BIO), Pharmaceutical Research and Manufacturers of America (PhRMA), and others. As of the date of this article, the Federal Circuit has not ruled on the petition.

Although the Federal Circuit’s discussion appears in dicta, Helsinn may have laid the foundation for a future holding limiting the scope of public use to exclude uses that are not disclosed to the public. If courts conclude that public use is narrower under the AIA, there would be less need to invoke the experimental use exception. Such a holding would further erode the significance of the doctrine.

**AIA Changes to the Experimental Use Exception**

In addition to possible changes to the scope of public use, it is not clear whether the experimental use exception will continue to exist at all under the AIA. In the AIA Examination Guidelines, the USPTO stated:

Neither the AIA nor its legislative history expressly addresses whether the experimental use exception applies to public use under AIA 35 U.S.C. 102(a)(1), or to a use that makes the invention available to the public under the residual clause of AIA 35 U.S.C. 102(a)(1). Because this doctrine arises infrequently before the Office, and is
case-specific when it does arise, the Office will approach this issue when it arises on the facts presented.73

As of the date of this article, neither the USPTO nor any district court has addressed a case invoking the experimental use exception under AIA § 102(a)(1).74 Commentators appear to believe that the experimental use exception should continue under the AIA.75 If courts conclude that the scope of “public use” remains the same, it should follow that all case law interpreting “public use,” including the experimental use case law, should remain valid.76 And even if courts construe “public use” more narrowly, the public policy of allowing experimentation to perfect an invention before patenting will remain.77 The USPTO’s decision to address the issue when it arises likely means that the exception will remain viable in cases where it truly applies.

Experimental Use as Defense Against Infringement

Experimental use is also used as a defense against allegations of infringement under 35 USC § 271(a). Ordinarily, a patent grants the inventor the right to exclude others from making or using her invention. However, courts have recognized that inventors may not exclude others from using their inventions in experimental activities. Although the experimental use exception in the infringement context was established independently from the public use exception, it was guided by the same policies of encouraging experimentation and innovation to “promote the progress of science and arts.” But a recent court decision has eroded the strength of the experimental use doctrine as a defense against infringement, placing this branch of the doctrine’s future in question.78

Infringement

The U.S. Code, at 35 USC § 271(a), states that “whoever without authority makes, uses, offers to sell, or sells any patented invention . . . infringes the patent.” “Infringement requires that every limitation of a claim be met, either literally or equivalently, by the accused device.”79 Infringement is a strict liability offense regardless of whether the user knew about the patent.80

Like the prohibition against public use, § 271(a) both supports and contradicts the patent law goals of “promot[ing] the progress of science and useful arts.” It supports patent law policy goals by offering a monopoly to incentivize the time and expense of innovation.81 It inhibits patent law policy goals by preventing others from applying the patented invention to new and different areas.82 For example, a researcher may be prevented from using a new compound in his work because that compound is patented by another.

To help alleviate this strain on innovation, courts have recognized experimental use as an exception to infringement.83 The courts define experimental use in this context as any actions performed “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.”84 The actions cannot be in the “guise of ‘scientific inquiry,’ when that inquiry has definite, cognizable, and not insubstantial commercial purposes.”85 This exception, although narrow, created some flexibility for the public to tinker with patented inventions without being liable for infringement.

The experimental use exception to patent infringement was first recognized in Whitemore v. Cutter, an opinion written by Supreme Court Justice Story while on circuit in Massachusetts.86 In dicta, Justice Story wrote, “it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”87 Although not legally binding precedent, Justice Story’s dicta led to the creation of the experimental use exception to patent infringement.88 It was firmly entrenched in patent law when it was recognized in the famous and influential treatise The Law of Patents for Useful Inventions § 898 (1890),89 which stated:

Thus where it is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promotion of the employer’s knowledge or relaxation afforded to his mind.90

The establishment of the experimental use exception to patent infringement proved important for research universities. The doctrine led to the widespread belief that purely academic research was categorically excused from patent infringement liability.91 This widespread belief was also buttressed by the 1935 District of Colorado case Ruth v. Stearns-Roger Manufacturing Co.92 This was the first case that examined the experimental use exception in the context of academic research.93 In Ruth, the defendant sold parts for a patented inflation device to the Colorado School of Mines.94 The district court found the defendant liable for contributory patent infringement, but ruled that Colorado School of Mines’ use was exempt from infringement because it used the flotation device as an instrument in conducting research.95 Academic institutions interpreted this decision as providing broad protection from patent infringement for academic research activities.96

Additionally, Congress passed the Bayh-Dole Act in 1980, which allowed private ownership of patents on inventions derived from research funded by the federal government.97 Previously, the federal government owned all rights to research conducted by universities but sponsored by federal funds.98 Now, universities could own patents on the inventions from federally funded research.99 This legislation and the widespread belief of broad protection under the experimental use doctrine allowed universities “to assume that they could enforce patents on their own inventions while avoiding liability for using the patented inventions of others.”100

This combination allowed universities to become major players in the patent system.101 In 1981, universities were awarded 436 patents.102 By 2001, they received 3,203 patents.103 In 1997, universities earned approximately $500 million in gross revenues from patents.104 In 2005, a survey of 156 colleges and universities found that institutions earned almost $1 billion from patent revenues.105 Universities also aggressively enforced their patents. For example, the University of California sued Genentech and settled for $200 million.106 The University of Minnesota sued Glaxo Wellcome and settled for $300 million.107 This state of university research presents a much different picture than Justice
The universities’ growing role in the patent system was scaled back in the Federal Circuit case Madey v. Duke. This case was the first infringement decision by the Federal Circuit that held an academic research institution liable for infringement for using a patented technology during its research. In Madey, the inventor, Dr. John M.J. Madey, was a professor at Duke, where he directed the free electron laser (FEL) research lab. He had sole ownership of two patents practiced by some of the equipment in the FEL lab. After nearly 10 years at Duke, Madey resigned. Duke continued to use the equipment in the FEL lab, and Madey sued Duke for infringement of his two patents.

Duke argued that its use of Madey’s patents was not infringement because the use fell within the experimental use exception. The district court agreed, holding that the defense was available for “experimental, non-profit purposes.” However, the Federal Circuit overturned this ruling, stating that the district court's interpretation of the experimental use defense was too broad. The Federal Circuit emphasized that the experimental use defense is “very narrow and strictly limited” to actions performed “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.” It “clearly does not immunize use that is in any way commercial in nature” or “immunize any conduct that is in keeping with the alleged infringer’s legitimate business.” In this case, the research activities of Duke and other major research universities “unmistakably further the institution’s legitimate business objectives.” These business objectives include education and enlightening students, increasing the status of the institution, and luring lucrative research grants, students, and faculty. The profit or nonprofit status of the user is not determinative.

Although this holding did not eliminate the experimental use exception, it is seen as eviscerating it “to the point that it is essentially useless to research universities.” Universities can no longer freely rely on the experimental use exception to protect them in their research. Some commentators believe that Madey will inhibit research and innovation. Regardless of its overall impact on promoting research and innovation, Madey weakened the experimental use defense. Its diminished state suggests that the doctrine has an uncertain future. However, experimenters may find similar protections in the legal provisions discussed below, thus reducing the need for an experimental use exception.

## Alternatives to the Experimental Use Exception

In the face of a fading experimental use defense to infringement, some researchers can rely on other legal provisions for protection. These provisions include state sovereign immunity under the Eleventh Amendment of the U.S. Constitution and the Hatch-Waxman Act. For certain researchers, these alternatives reduce the need to rely on the experimental use exception, further eroding the doctrine’s place in the future of patent law.

### State Sovereign Immunity

Sovereign immunity under the Eleventh Amendment provides some protection for public research universities to experiment with patented technologies. The Eleventh Amendment states that “[t]he judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any foreign state.” The Supreme Court has stated that the Eleventh Amendment confirms that states cannot be subject to federal lawsuits of an individual without the state’s consent. This includes lawsuits that fall within federal jurisdiction either through diversity or federal question jurisdiction. As state entities, public universities fall under the protections of the Eleventh Amendment. This protection would prohibit patent owners from filing patent lawsuits against universities for using the patent owner’s patents in the university’s research activities.

Recognizing the impact of state sovereign immunity in patent infringement cases, Congress attempted to undercut this protection by passing the Patent and Plant Variety Protection Remedy Clarification Act (Patent Remedy Act) in 1992. This legislation explicitly abrogated the sovereign immunity of states and state entities in patent infringement cases by stating: “States, instrumentalities of States, and officers and employees of States acting in their official capacity, are subject to suit in Federal court by any person for infringement of patents.” In 1999, the Supreme Court struck down the Patent Remedy Act as unconstitutional in Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank. In Florida Prepaid, College Savings Bank, a New Jersey savings bank, brought an infringement suit against...
the Florida Prepaid Postsecondary Education Expense Board (Florida Prepaid), a Florida state entity that administers tuition prepayment contracts to Florida residents. Florida Prepaid moved to dismiss the action on the grounds of sovereign immunity and argued that the Patent Remedy Act was unconstitutional. The Court agreed, stating that state sovereign immunity can only be abrogated under the Fourteenth Amendment, not under Congress’ Article I powers. Congress failed to provide sufficient justification under the Fourteenth Amendment to support the abrogation of state sovereign immunity in the Patent Remedy Act. Without sufficient justification, the law is unconstitutional.

Florida Prepaid preserved state sovereign immunity protection against patent infringement for public universities. The state sovereign immunity protection can be used as a tool to help promote the progress of science and useful arts, thus filling the void of a strong experimental use defense. Although it does not protect private research universities such as Duke, its impact is still significant. In 2001, approximately 60% of patents issued to universities in 2001 went to public universities. This substantial impact helps offset the need for the experimental use exception.

The Hatch-Waxman Act

Another legal doctrine that provides some protection for experimental use of a patented invention is the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. This legislation was passed in response to the Federal Circuit decision Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc. In Roche, the pharmaceutical company Roche Products, Inc. filed suit against a manufacturer of generic drugs, Bolar Pharmaceutical Co., Inc., to enjoin Bolar from taking FDA regulatory steps necessary to market a generic version of Roche’s patented drug after the patent term expires. Roche argued that Bolar’s use of the patented drug for the federally mandated tests was infringement of its patent. Bolar argued that its use of the patented drug fell under the experimental use exception. The Federal Circuit disagreed, holding that Bolar’s experiments “were conducted with a view to the adaption of the patented invention” to its business. Because of the underlying commercial purpose of the experimental testing, Bolar’s use did not fall within the scope of the traditional experimental use exception. The Federal Circuit refused to extend the doctrine to include experimental uses required to get FDA approval.

Based on Roche, investigational testing of an infringing medical device would be infringement, even though the testing is required to obtain FDA approval to market such a device. Drug manufacturers pushed Congress to act, arguing that if they had to wait until the patent term expired to begin FDA testing, this would effectively extend the patent term and prevent the public from receiving lower-cost drugs as soon as possible. The manufacturers wanted to market their generic substitutes for patented drugs on the day after the patent expired. The Hatch-Waxman Act satisfies this objective, particularly 35 USC § 271(e)(1), which states in part:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention… solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

This section provides a safe harbor for experimental uses of patented pharmaceuticals and medical devices that are conducted to obtain results needed for FDA approval. One commentator referred to § 271(e)(1) as “a codified version of the experimental use exception for the pharmaceutical industry.” The Supreme Court increased the breadth of the Hatch-Waxman Act in Merck KGaA v. Integra Lifesciences I, Ltd., in which it interpreted the § 271(e)(1) phrase “reasonably related” broadly to encompass all activity where drug manufacturers have a “reasonable basis” for believing the information may be included in a submission to the FDA. It does not matter whether the results from the experiments ultimately end up in the FDA submission.

The Court’s expansive reading of the Hatch-Waxman Act § 271(e)(1) provides protection for experimental uses of pharmaceuticals and medical devices that need approval from the FDA. This ruling helps offset the limitations imposed on the experimental use exception as a defense against infringement by the Maday decision. As a result, researchers have another viable option to protect them against infringement. This alternative, along with state sovereign immunity, reduces the need for an experimental use exception.

Conclusion

After nearly two centuries of providing protection for inventors and researchers, the experimental use exception is losing significance. Inventors may have less need to rely on the experimental use exception as a defense against public use because the AIA may have narrowed the definition of public use. Moreover, the USPTO has acknowledged the possibility that the AIA may have less need to rely on the experimental use exception as a defense against public use. In addition, recent cases have weakened the experimental use doctrine as a defense against infringement. However, certain researchers have been able to turn to other legal doctrines for protection against alleged infringement claims. As a result, researchers likely will rely less on the experimental use exception. With these recent changes, the experimental use doctrine is marching toward extinction, but it is not there yet.

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NOTES

1. Pub. L. No. 112-29, 125 Stat. 284 (codified at 35 USC §§ 100 et seq.).
2. This article focuses on U.S. patent law; it does not explore the experimental use exception in foreign jurisdictions.
4. Experimental use can also be used as a defense against the on-sale bar of 35 USC § 102. This article focuses only on experimental use as a defense against the public use bar and against infringement.
5. Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150–51 (1989) (“The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years.”).
7. Id.
15. Id.
17. Allied Colloids Inc. v. Am. Cyanamid Co., 64 F.3d 1570, 1574 (Fed. Cir. 1995) (“The public use bar serves the policies of the patent system, for it encourages prompt filing of patent applications after inventions have been completed and publicly used.”). See also City of Elizabeth v. Am. Nicholson Pavement Co., 97 U.S. 126, 137 (1877) (“It is sometimes said that an inventor acquires an undue advantage over the public by delaying to take out a patent, inasmuch as he thereby preserves the monopoly to himself for longer period than is allowed by the policy of the law.”).
18. See Pennock v. Dialogue, 27 U.S. 1, 19 (1829) (“[T]he main object [of the patent laws] was to promote the progress of science and useful arts; and this could be done best, by giving the public at large a right to make, construct, use, and vend the thing invented, at as early a period as possible . . . .”).
19. City of Elizabeth, 97 U.S. at 137.
20. E.g., id. at 134 (“[T]he nature of a street pavement is such that it cannot be experimentally used upon satisfactorily except on a highway, which is always public.”).
22. City of Elizabeth, 97 U.S. at 126.
23. Id. at 127.
24. Id. at 128.
25. Id. at 129.
26. Id. at 133.
27. Id. at 129.
28. Id.
29. Id.
30. Id.
31. Id. at 134.
32. Id.
33. Id.
34. Id. at 133–34.
35. Id. at 134 (“That the use of the pavement in question was public in one sense cannot be disputed. But can it be said that the invention was in public use?”).
36. Id. at 134–35.
37. Id. at 135.
38. Id.
39. Id.
40. Id.
41. Id.
42. Id. at 134–35 (“[T]he nature of a street pavement is such that it cannot be experimented upon satisfactorily except on a highway, which is always public.”).
43. Id. at 134.
44. Id. at 136 (“The proprietors of the road alone used the invention, and use it at Nicholson’s request, by way of experiment. The only way in which they could use it was by allowing the public to pass over the pavement.”).
45. Id. at 135.
46. See, e.g., TP Labs., Inc. v. Prof’l Positioners, Inc., 724 F.2d 965, 970 (Fed. Cir. 1984) (“The above quotation is from City of Elizabeth v. American Nicholson Pavement Co. . . . the starting place for analysis of any case involving experimental use.”).
47. Petroleo Corp. v. Baker Hughes Inc., 96 F.3d 1423, 1426 (Fed. Cir. 1996) (“Experimental use is a question of law to be analyzed based on the totality of the surrounding circumstances.”).

Lough v. Brunswick Corp., 86 F.3d 1113, 1120 (Fed. Cir. 1996) (“To determine whether a use is ‘experimental use’ as a question of law, the totality of the circumstances must be considered . . . .”); Tone Bros., Inc. v. Sysco Corp., 28 F.3d 1192, 1197 n.3 (Fed. Cir. 1994) (“Whether or not an invention was in public use within the meaning of section 102(b) is a question of law, which is based upon underlying issues of fact.”).
50. Id.
51. 35 USC § 102(a)(1) (emphasis added).
53. See Lemley, supra note 52 at 1126–28. See Merges, supra note 52 at 1034–35.
56. Id. at 11062 (emphasis added).
57. See Litton Sys., Inc. v. Whirlpool Corp., 728 F.2d 1423, 1439 (Fed. Cir. 1984) (“The MPEP has no binding force on [Federal Circuit], but is entitled to notice so far as it is an official interpretation of statutes or regulations with which it is not in conflict.”).
59. Id. at 1369.
60. Id.
61. Id. at 1371.
62. Id.
63. See id. at 1368–69.
64. Id. at 1368 (citing 157 Cong. Rec. 3415 (2011) (remarks of Sen. Leahy)).
65. Id. (citing 157 Cong. Rec. 3424 (2011) (remarks of Sen. Kyl)).
66. Id.
67. Id.
68. Id.
69. Id.
70. Id. at 1368–69.
71. Crouch, “Helsinn En Banc Status,” Pa-
72. Id.
73. USPTO, supra note 55 at 11063.
76. See generally Lemley, supra note 52 at 1135. 77. See Kelly, supra note 75 at 400 (“[T]he passage of the AIA had no bearing on the continued need for this exception because certain inventions will inevitably require extensive, open experimentation before the public to ready the invention for patenting. Thus, this exception should continue under the AIA for policy reasons that transcend the AIA’s passage.”).
83. Madey, 307 F.3d at 1361 (citing Roche Prod., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 862 (Fed. Cir. 1984)).
85. Roche, 733 F.2d at 863.
86. Id. at 862.
88. See Strandburg, supra note 82 at 94.
89. Roche, 733 F.2d at 862.
90. Id. (citing Robinson, The Law of Patents for Useful Inventions § 898 (Boston, Little, Brown and Co. 1890)).
91. Strandburg, supra note 82 at 84 (citing Walsh et al., Effects of Research Tool Patents and Licensing on Biomedical Innovation, Patents in the Knowledge-Based Economy 324–28, 334–35 (National Academies Press 2003) (providing evidence that researchers presume a relatively broad “informal research exemption.”)).
95. Id. at 703.
96. Rowe, supra note 93 at 928.
97. Id. at 934.
98. Id.
99. Id.
101. Id. (“[U]niversities have become layers in the patent system in a way that could hardly have been imagined before the Bayh-Dole Act.”).
102. Rowe, supra note 93 at 936.
103. Id.
104. Id.
105. Id.
106. Id. at 936–37.
107. Id.
108. See Eisenberg, supra note 100 at 1018.
109. Rowe, supra note 93 at 922.
110. Madey, 307 F.3d at 1352.
111. Id.
112. Id. at 1353.
113. Id.
114. Id. at 1355.
115. Id.
116. Id. at 1361.
117. Id. at 1361–62.
118. Id. at 1362.
119. Id.
120. Id.
121. Id.
122. Eisenberg, supra note 100 at 1019 (“Although the Madey decision did not extinguish the experimental use defense entirely, it eviscerated it to the point that it is essentially useless to research universities.”).
123. Rowe, supra note 93 at 922 (“[C]ritics fear that the courts’ ‘narrowing’ of the experimental use exception will stifle research and innovation.”).
124. Rowe, supra note 93 at 944–45.
125. U.S. Const. amend. XI.
126. Seminole Tribe of Fla. v. Florida, 517 U.S. 44, 54 (1996) (“Although the text of the Amendment would appear to restrict only the Article III diversity jurisdiction of the federal courts, we have understood the Eleventh Amendment to stand not so much for what it says, but for the presupposition . . . which it confirms.’ That presupposition . . . has two parts: first, that each State is a sovereign entity in our federal system; and second, that ‘[i]t is inherent in the nature of sovereignty not to be amenable to the suit of an individual without its consent.’”) (internal citations omitted).
127. Id.
130. Id. at 647–48.
131. Id. at 630–32.
132. Id. at 633.
133. Id. at 636–37 (“While reaffirming the view that state sovereign immunity does not yield to Congress’ Article I powers, this Court in Seminole Tribe also reaffirmed its holding in Fitzpatrick v. Bitzer, 427 U.S. 445, 96 S.Ct. 2666, 49 L.Ed.2d 614 (1976), that Congress retains the authority to abrogate state sovereign immunity pursuant to the Fourteenth Amendment.”).
134. Id. at 639–41.
135. Id. at 647–48.
136. Rowe, supra note 93 at 945.
137. Id. at 932.
138. Rowe, supra note 93 at 932.
139. Roche, 733 F.2d at 860.
140. Id.
141. Id. at 862.
142. Id. at 863.
143. Id.
144. Id.
146. Id. at 405.
147. Id.
148. 35 USC § 271(e)(1).
149. See Rowe, supra note 93 at 932.
151. Id. at 206–07 (“At least where a druggaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is ‘reasonably related’ to the ‘development and submission of information under . . . Federal law.’”).
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An Interactive CLE with Judges and Attorneys

Hosted by the Colorado Judicial Institute and Sherman & Howard L.L.C.

March 1, 2018

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5:00 p.m. - 6:00 p.m.

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