

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

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This article examines the evolution and current status of the experimental use exception in patent law.

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)¹ 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.²

The Experimental Use Doctrine

The experimental use exception is a judge-made doctrine that provides protection for experimental uses of an invention.³ 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).⁴ 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.⁵ 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.⁶ This give and take between the inventor and the public is called the “patent bargain” or “quid pro quo.”⁷

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.”⁸ The drafters believed that the Constitution needed this clause to promote science and literature.⁹ 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*."¹⁰ 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."¹¹ The next two laws, the Patent Act of 1836 and Patent Act of 1839, codified the modern form of the ban against public use by prohibiting inventors from receiving a patent on an invention that they used in public more than two years before filing the application.¹²

Today, the public use prohibition is governed by two statutes. For patent applications filed on or after March 16, 2013, the AIA § 102(a)(1) governs and prohibits inventors from receiving a patent on an invention that was in public use before the filing date of the patent application.¹³ For patent applications filed before March 16, 2013, pre-AIA § 102(b) governs and prohibits inventors from receiving a patent on an invention that was in public use more than one year before filing an application for the invention. Section 102(b) provides a one year grace period for an inventor to file a patent within one year of her first public use of the invention. Under pre-AIA §102(b), the public use test is whether the use was (1) accessible to the public or (2) commercially exploited.¹⁴ This test includes consideration of "the nature of the activity that occurred in public; public access to the use; confidentiality obligations imposed on the members of the public who observed the use; and commercial exploitation."¹⁵

Also, "public use" under pre-AIA §102(b) does not include a "public knowledge" requirement.¹⁶ In other words, the public does not need to know that the invention is being used in public for the use to be public use. For example, suppose you invent and install a small device in your smartphone that greatly improves the screen resolution without impacting the phone's battery life. The device is perfected and does not need any additional improvements or experimentation. You may use the device on your phone for years and show the phone's impressive screen resolution to friends and colleagues without disclosing the device's existence within the phone. Although the public was not aware of the device and did not have knowledge of it, your use of the device would still constitute 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.¹⁷ Congress believed that such quick disclosures in the public domain helped promote the progress of science and literature.¹⁸ 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.¹⁹ Some inventions, by their nature, must be tested and perfected in public.²⁰ 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."²¹ 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*.²² In *City of Elizabeth*, inventor Samuel Nicholson received a patent on a new and improved

wooden pavement.²³ He sued the City of Elizabeth for infringement of his patent when the city installed wooden pavement in Elizabeth, New Jersey.²⁴ 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.²⁵ 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.²⁶ The city alleged that Nicholson tested his invention by laying the wooden pavement down on a public road in Boston in 1848.²⁷ The City of Elizabeth argued that the Boston public used the invention for six years before Nicholson filed his patent application,²⁸ and that this use should bar Nicholson from obtaining a patent on his wooden pavement invention.²⁹

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.³⁰ 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.³¹ These teams had to stop to pay a toll at a nearby toll-house.³² The teams' constant stopping and starting made the location "as severe a trial to the pavement as it could be put to."³³ 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.³⁴

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.³⁵ It compared his use to the experimental testing of a traditional machine invention.³⁶ This type of invention may be tested and tried in a building, away from the view of the public.³⁷ The inventor may alter it, improve it, and conduct experiments to see what additional alterations may be necessary.³⁸ If the inventor is attempting to improve durability, the inventor may need to test this quality over long periods

of time.³⁹ After that period, the inventor may find out that no changes are necessary.⁴⁰ 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.⁴¹ 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.⁴² Therefore, the Court concluded that experimental use of an invention has never been regarded as public use.⁴³ Thus, Nicholson’s use was experimental and could not be public use.⁴⁴ 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.⁴⁵

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,⁴⁶ 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.⁴⁷ 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,

- whether there was a secrecy obligation,
- whether records of the experiment were kept,
- who conducted the experiment,
- the degree of commercial exploitation during testing,
- whether the invention reasonably requires evaluation under actual conditions of use,
- whether testing was systematically performed,
- whether the inventor continually monitored the invention during testing, and
- the nature of the contacts made with potential customers.⁴⁸

With these factors established in case law, inventors were free to rely on the experimental use exception and experiment with their inventions in public without fear of falling within the scope of the public use bar. However, the changes to patent law under the AIA may have narrowed the scope of public use. Even more severe, the AIA may also have eliminated the experimental use doctrine altogether as a defense against public use.

AIA Changes to Public Use

The AIA was signed into law on September 16, 2011, and its central provisions went into effect on September 16, 2012 and March 16, 2013.⁴⁹ The AIA is the most significant reform to the U.S. patent system since 1952.⁵⁰ Among its many changes, the AIA significantly altered § 102 to provide that “[a] person shall be entitled to a patent unless the claimed invention was patented, described in a printed publication, or in *public use*, on sale, or *otherwise available to the public* before the effective filing date of the claimed invention.”⁵¹ The residual clause, “otherwise available to the public,” is an addition that has led to conflicting interpretations of its effect on the definition of public use. One interpretation is that the clause does not have any impact, and the substantive scope of public use remains unchanged post-AIA.⁵² Proponents of this view argue that Congress adopted the same statutory definition of public use, and when Congress reenacts the same statutory language, there is a strong presumption that the language continues to have the same meaning it had previously.⁵³ The other interpretation is the

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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.”⁵⁴ 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, 2013.⁵⁵ 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*.”⁵⁶ 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.⁵⁷

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.*⁵⁸ 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.⁵⁹ 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.”⁶⁰ According to the court, the legislative history did not reveal an intent to make such a change.⁶¹ 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.”⁶²

This holding suggests that the “otherwise available to the public” language does not substantively change the categories of prior art

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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.⁶³ 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.⁶⁴

[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 these⁶⁵

The court stated, “[a]t most the floor statements show an intent ‘to do away with precedent under current [§ 102] law.’”⁶⁶ That precedent appears to be cases that govern secret uses under the public use prong.⁶⁷ Senator Kyl explicitly listed public use cases and stated that “new section 102(a) precludes extreme results such as these.”⁶⁸ 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.”⁶⁹ However, the court refused to address the scope of public use because the issue was not before it.⁷⁰

Helsinn filed a petition for rehearing en banc in June 2017.⁷¹ 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.⁷² 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 *Whittemore 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 patented 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

Story's early-19th century image of a scientist driven by idle curiosity.¹⁰⁸

Madey v. Duke

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.¹⁰⁹ In *Madey*, the inventor, Dr. John M.J. Madey, was a professor at Duke, where he directed the free electron laser (FEL) research lab.¹¹⁰ He had sole ownership of two patents practiced by some of the equipment in the FEL lab.¹¹¹ After nearly 10 years at Duke, Madey resigned.¹¹² Duke continued to use the equipment in the FEL lab, and Madey sued Duke for infringement of his two patents.¹¹³

Duke argued that its use of Madey's patents was not infringement because the use fell within the experimental use exception.¹¹⁴ The district court agreed, holding that the defense was available for "experimental, non-profit purposes."¹¹⁵ However, the Federal Circuit overturned this ruling, stating that the district court's interpretation of the experimental use defense was too broad.¹¹⁶ 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."¹¹⁷ 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."¹¹⁸ In this case, the research activities of Duke and other major research universities "unmistakably further the institution's legitimate business objectives."¹¹⁹ These business objectives include education and enlightening students, increasing the status of the institution, and luring lucrative research grants, students, and faculty.¹²⁰ The profit or nonprofit status of the user is not determinative.¹²¹

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."¹²² Universities can no longer freely rely on the experimental use exception to protect them in their research.

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Some commentators believe that *Madey* will inhibit research and innovation.¹²³ 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.¹²⁴ 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."¹²⁵ 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.¹²⁶ This includes lawsuits that fall within federal jurisdiction either through diversity or federal question jurisdiction.¹²⁷ 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 1992.¹²⁸ 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."¹²⁹ In 1999, the Supreme Court struck down the Patent Remedy Act as unconstitutional in *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*.¹³⁰ 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.¹³¹ Florida Prepaid moved to dismiss the action on the grounds of sovereign immunity and argued that the Patent Remedy Act was unconstitutional.¹³² The Court agreed, stating that state sovereign immunity can only be abrogated under the Fourteenth Amendment, not under Congress' Article I powers.¹³³ Congress failed to provide sufficient justification under the Fourteenth Amendment to support the abrogation of state sovereign immunity in the Patent Remedy Act.¹³⁴ Without sufficient justification, the law is unconstitutional.¹³⁵

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.¹³⁶ 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.¹³⁷ This legislation was passed in response to the Federal Circuit decision *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*¹³⁸ 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.¹³⁹ Roche argued that Bolar's use of the patented drug for the federally mandated tests was infringement of its patent.¹⁴⁰ Bolar argued that its use of the patented drug fell under the experimental use exception.¹⁴¹ The Federal Circuit disagreed, holding that

Bolar's experiments "were conducted with a view to the adaption of the patented invention" to its business.¹⁴² 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.¹⁴³ The Federal Circuit refused to extend the doctrine to include experimental uses required to get FDA approval.¹⁴⁴

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.¹⁴⁵ 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.¹⁴⁶ The manufacturers wanted to market their generic substitutes for patented drugs on the day after the patent expired.¹⁴⁷ 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.¹⁴⁸

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."¹⁴⁹ The Supreme Court increased the breadth of the Hatch-Waxman Act in *Merck KGaA v. Integra Lifesciences I, Ltd.*,¹⁵⁰ 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.¹⁵¹ 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 *Madey* 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 not have preserved 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. CL



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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.
3. Baluch, "Relating the Two Experimental Uses in Patent Law: Inventor's Negation and Infringer's Defense," 87 *B.U. L.Rev.* 213, 216-18 (2007), www.bu.edu/law/journals-archive/bulr/volume87n1/documents/baluchv2.pdf.
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.").
6. Baluch, *supra* note 3 at 215.
7. *Id.*
8. U.S. Const. art. 1, § 8, cl. 8.
9. George Washington even addressed Congress in January 1790 to support passage of the clause, stating, "there is nothing which can better deserve your patronage than the promotion of science and literature." Constitutional Rights Foundation, *The Origins of Patent and Copyright Law* (Winter 2008), www.crf-usa.org/bill-of-rights-in-action/bria-23-4-a-the-origins-of-patent-and-copyright-law.
10. Patent Act of 1790 § 1 (emphasis added).
11. Patent Act of 1793 § 1.
12. See Patent Act of 1836 § 7; Patent Act of 1839 § 7.
13. See AIA 35 USC § 102(a)(1).
14. *Invitrogen Corp. v. Biocrest Mfg. L.P.*, 424 F.3d 1374, 1380 (Fed. Cir. 2005).
15. *Id.*
16. Manual of Patent Examining Procedure (MPEP) § 2133.03(a)II ("Mere knowledge of the invention by the public does not warrant rejection under pre-AIA 35 U.S.C. 102(b). Pre-AIA 35 U.S.C. 102(b) bars public use or sale, not public knowledge.") (citing *TP Labs., Inc. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 970, 220 USPQ 577, 581 (Fed. Cir. 1984)), www.uspto.gov/web/offices/pac/mpep.
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 experimented upon satisfactorily except on a highway, which is always public.").
21. Matthews, Jr., 3 *Annotated Patent Digest* § 17:156 (Thomson Reuters 2017).
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. When the subject of invention is a machine, it may be tested and tried in a building, either with or without closed doors. In either case, such use is not a public use, within the meaning of the statute, so long as the inventor is engaged, in good faith, in testing the operation.").
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.* . . . which is the starting place for analysis of any case involving experimental use.").
47. *Petrolite 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.");
48. *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1120 (Fed. Cir. 1996) ("To determine whether a use is 'experimental,' 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.").
49. MPEP § 2133.03(e)(4). See also *Electromotive Div. of General Motors Corp. v. Transp. Sys. Div. of General Elec. Co.*, 417 F.3d 1203, 1213 (Fed. Cir. 2005).
50. *Id.*
51. 35 USC § 102(a)(1) (emphasis added).
52. Lemley, "Does 'Public Use' Mean the Same Thing It Did Last Year?," 93 *Tex. L.Rev.* 1119, 1126-28 (2015), www.texaslrev.com/wp-content/uploads/2015/08/Lemley-93-5.pdf; Merges, "Priority and Novelty Under the AIA," 27 *Berkeley Tech. L.J.* 1023, 1034-35 (2012), <http://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?article=2893&context=facpubs>.
53. See Lemley, *supra* note 52 at 1126-28. See Merges, *supra* note 52 at 1034-35.
54. See Armitage, "Understanding the America Invents Act and Its Implications for Patenting," 40 *AIPPLA Q.J.* 1, 54 (2012), www.uspto.gov/sites/default/files/aia_implementation/armitage_pdf.pdf; Matal, "A Guide to the Legislative History of the America Invents Act: Part I of II," 21 *Fed. Cir. B.J.* 435, 471-75 (2012).
55. USPTO, Examination Guidelines for Implementing the First to File Provisions of the Leahy-Smith America Invents Act (2013), www.uspto.gov/sites/default/files/aia_implementation/FITF_Final_Guidelines_FR_2-14-2013.pdf.
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.").
58. *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017).
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-

- tently-O (Sept. 24, 2017), patently.com/patent/2017/09/helsinn-banc-status.html.
72. *Id.*
73. USPTO, *supra* note 55 at 11063.
74. In *Dzinesquare, Inc. v. Armano Luxury Alloys, Inc.*, the patent owner invoked the experimental use exception under AIA § 102(a)(1), but the court did not address it because the patent owner did not provide evidence to support its assertion. *Dzinesquare, Inc. v. Armano Luxury Alloys, Inc.*, No. CV1401918JVSJCGX, 2014 WL 12597154, at *6 (C.D. Cal. Dec. 22, 2014).
75. Lemley, *supra* note 52 at 1135; Lemley, "Ready for Patenting," 96 *B.U. L.Rev.* 1171, 1183 (2016); Kelly, "Is the Prototypical Small Inventor at Risk of Inadvertently Eliminating Their Traditional One-Year Grace Period Under the America Invents Act?—Interpreting 'Or Otherwise Available to the Public' per New §102(a) and 'Disclosure' per New § 102(b)," 21 *Tex. Intell. Prop. L.J.* 373, 400 (2013), www.tiplj.org/wp-content/uploads/Volumes/v21/v21p373.pdf.
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.").
78. *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002).
79. *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1149 (Fed. Cir. 2004).
80. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 35 (1997).
81. Baluch, *supra* note 3 at 229–30.
82. Strandburg, "What Does the Public Get? Experimental Use and the Patent Bargain," 2004 *Wis. L.Rev.* 81, 82 (2004) ("Patents . . . can . . . make it more difficult to build on the inventions of others.").
83. *Madey*, 307 F.3d at 1361 (citing *Roche Prod., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 862 (Fed. Cir. 1984)).
84. *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000).
85. *Roche*, 733 F.2d at 863.
86. *Id.* at 862.
87. *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).
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.")).
92. *Ruth v. Stearns-Roger Mfg. Co.*, 13 F.Supp. 697 (D.Colo. 1935), *rev'd on other grounds*, 87 F.2d 35 (10th Cir. 1936).
93. Rowe, "The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?," 57 *Hastings L.J.* 921, 928 (2006), <http://scholarship.law.ufl.edu/faculty-pub/91>.
94. *Ruth*, 13 F.Supp. at 699.
95. *Id.* at 703.
96. Rowe, *supra* note 93 at 928.
97. *Id.* at 934.
98. *Id.*
99. *Id.*
100. Eisenberg, "Patent Swords and Shields," 299 *Science* 1018, 1018 (2003).
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 ("[Critics] 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.*
128. Patent and Plan Variety Protection Remedy Clarification Act, Pub. L. No. 102-560, § 2(a)(2), 106 Stat. 4230 (1992) (codified at 35 USC § 296 (2000)).
129. *Florida Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 640 (1999) ("the underlying conduct at issue here is state infringement of patents and the use of sovereign immunity to deny patent owners compensation for the invasion of their patent rights.").
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.*
145. *Eli Lilly and Co. v. Medtronic, Inc.*, 872 F.2d 402, 404–05 (Fed. Cir. 1989).
146. *Id.* at 405.
147. *Id.*
148. 35 USC § 271(e)(1).
149. See Rowe, *supra* note 93 at 932.
150. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).
151. *Id.* at 206–07 ("At least where a drugmaker 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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