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COMMENTS

Experimental Uses, Patents, and Scientific Progress

Eyal H. Barash

I. INTRODUCTION

The patent system is designed to stimulate progress in "[s]cience and useful [a]rts."[1] The Supreme Court explicitly stated that "the patent monopoly [is] . . . a reward, an inducement, to bring forth new knowledge."[2] The United States Court of Appeals for the Federal Circuit explained that "[t]he reason for the patent system is to encourage innovation and its fruits: new jobs and new industries, new consumer goods and trade benefits."[3] Patents are monopolies granted to inventors that enable them to make, use, sell or offer to sell their inventions to the exclusion of all others for a limited amount of time. Although the patent system may act as an incentive for innovators to advance the progress of science, it does not follow that individual patents always contribute to that progress. This Comment argues that in order to fulfill its constitutional mandate to promote progress in science, the patent law should reflect the important contributions to technological progress made by academic and other non-profit research.

This Comment seeks to accomplish this goal by broadening and altering the application of two distinct doctrines that have virtually identical names. What this Comment will refer to as "inventor" experimental use provides a safe haven for inventors to experiment with their inventions without fear of forfeiting their patent rights. This Comment will refer to the other experimental use doctrine as "third-party" experimental use. This doctrine permits third parties to experiment with the patented inventions of others without infringing those patents. Each of these similarly-named legal tools should be applied more rationally in order to better represent the way scientific research operates today.

In basic science, many researchers publish their newest achievements in scientific publications, not in the patent literature. This is because a patent in the basic sciences is not written for a scientific

1 U.S. CONST. art. I, § 8, cl. 8.
2 Graham v. John Deere Co., 383 U.S. 1, 9 (1966).
3 Paulik v. Rizkalla, 760 F.2d 1270, 1276 (Fed. Cir. 1985).

audience.[4] Rather, because judges and juries have the power to determine the validity of the patent and whether it has been infringed, patents are written for them.[5] Moreover, the arcane language found in patent claims is often more confusing than elucidating.[6] Inventors in research institutions are usually professors, post-doctoral researchers, and graduate students. Their patent applications are reviewed by patent examiners whose training and expertise are often not as sophisticated.[7] By contrast, peer reviewed publications are examined by scientists with sophistication and knowledge comparable to the inventors.[8] In addition, there can be a significant time lag between the time a patent is filed and when it is issued. This time lag is substantially longer than a delay for a scientific publication. For instance, a biotech patent often takes more than three years from filing to issuance.[9] In comparison, a typical research report for the journal *Science* is published within five months of submission.[10]

Although university researchers sometimes publish their results in the patent literature, their primary vehicle for disseminating information is through the many available academic journals. Nevertheless, patents are potentially more commercially lucrative than

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[4] Jeffrey G. Sheldon, *Preparing and Prosecuting a Patent to Win in Litigation*, *in* WINNING STRATEGIES IN PATENT LITIGATION 1995, at 69, 79 (PLI Patents, Copyrights, Trademarks, and Literary Course Handbook Series No. G4-395).

[5] *Id.*

[6] For instance, the following language is used in a claim for a soap dispenser:

> 1. A dispensing apparatus of the type usable to dispense gel detergent to a washing apparatus, the gel dispensing apparatus comprising in combination:
> (a) a uniformly dissolvable detergent gel concentrate;
> (b) means for containing the gel concentrate;
> . . .
> (f) means for receiving fluid and gel solution from the valve outlet when the fluid delivering means delivers fluid under pressure into the fluid inlet, the gel delivering means delivers gel concentrate to the gel inlet, and the valve means mixes the fluid with the gel concentrate.

United States Patent No. 4,998,850, at 11 (1991).

[7] One is eligible to become a patent examiner in one of three ways: (1) obtain a bachelor's degree in one of twenty-nine disciplines, such as physics or chemistry; (2) earn a minimum number of credit hours in undergraduate scientific disciplines; or (3) pass the Engineer-in-training Test. Advanced degrees are not necessary. Michelle J. Burke & Thomas G. Field, Jr., *Promulgating Requirements for Admission to Prosecute Patent Applications*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 369, 373 (1995).

[8] Scientific journals are typically peer-reviewed, meaning that the author's peers study and review an author's work before allowing it to be published. The author's peers in the scientific community have a similar educational background as the author. In the university environment the formal educational background of such authors is at the Ph.D. level. *See* Tammy L. Lewis & Lisa A. Vincler, *Storming the Ivory Tower: The Competing Interest of the Public's Right to Know and Protecting the Integrity of University Research*, 20 J.C. & U.L. 417, 421, 441-42 (1994).

[9] *See* Robert A. Armitage, *U.S. Patent Laws Change*, CHEMICAL & ENGINEERING NEWS (June 12, 1995) at 30, 31.

[10] Telephone Interview with the publications staff at the American Association for the Advancement of Science (Aug. 28, 1996).

scientific publications because they grant the user a legal monopoly. For this reason, there has been an explosion in recent years in the number of patents issued to universities.[11] This number is still small in comparison to the number of non-patent university publications, but the trend towards patenting inventions is accelerating. Because universities and other non-profit organizations disseminate knowledge in different forums and generally for different reasons, the patent law should reflect those differences in order to ensure that these institutions will continue to serve the public good in their research.[12]

This Comment argues that scientists and engineers are better suited than judges and juries to evaluate the best way to introduce their inventions into the marketplace. The patent law should, therefore, reflect how research is organized and performed in this country while also recognizing the importance of patents themselves. Patents are potentially powerful tools because they can be profitable and restrict competition. Pure academic research, on the other hand, depends on the free dissemination of knowledge. This dissemination, unfortunately for universities, stands in conflict with patent law, because an inventor who makes her invention available to the public for more than one year prior to filing a patent application, is statutorily barred from patenting it. This is the so-called "public use" bar of section 102(b).[13] This bar can be devastating to university researchers who routinely publish and discuss their research results without even knowing such a bar exists until it is too late. Moreover, as this Comment discusses later, it is remarkably easy to demonstrate public use.[14]

The doctrine of "experimental use" effectively bridges the gap between law and technology. Experimental use is a specific judicially-created doctrine that gives limited freedom to inventors to use their inventions publicly.[15] Part II of this Comment analyzes the scope of the experimental use doctrine, examines its evolution in the Federal Circuit, and provides guidelines for determining how to apply this doctrine. The Part advocates that inventors, not judges, should be able to decide whether a use is experimental or is barred by section 102(b). Courts examining this question should rely on objective evidence surrounding the inventor's claim of experimental use instead of

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11 *See infra* notes 219-20 and accompanying text.

12 There are numerous examples of important university sponsored research. For instance, the 1995 Nobel Prize in Chemistry went to two university researchers who discovered that CFCs damaged the ozone layer. *Trio Share Nobel Prize in Chemistry Ozone Layer Research Honored; 2 Americans Get Physics Award*, CHI. TRIB., Oct. 12, 1995, at 10.

13 Section 102(b) reads, "A person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b) (1994).

14 *See infra* Part II.

15 *See infra* Part II.

second-guessing the inventor's scientific methodology. This doctrine can be particularly useful for universities since it has the potential of encouraging researchers to consult their peers for technical advice before filing a patent application. This benefits the public because it encourages inventors to perfect their inventions before patenting them.

Part III discusses a separate and distinct experimental use doctrine which will be called the "third-party" experimental use doctrine. This doctrine allows potential infringers to experiment with patented inventions without procuring prior approval from the patent owners. This Part focuses on the most significant use of this exception: the use of patented drugs by generic pharmaceutical manufacturers in anticipation of patent expiration.[16] This is a much more controversial topic than the §102(b)-linked experimental use doctrine because this doctrine erodes the value of the monopoly granted to inventors by Congress. Nevertheless, important policy reasons centering on the goals and needs of university and other non-profit research warrant such an "erosion." Part III ends with a recommendation to expand the scope of the third-party experimental use for non-profit research only. Unlike for the inventor experimental use doctrine, this Comment recommends changes in the third-party experimental use doctrine that are specifically aimed at universities and other non-profit research organizations. Part III argues that the doctrine of third-party experimental use should be expanded in conjunction with the unenacted Patent Competitiveness Act of 1990,[17] but its scope should not include commercial research by profit-oriented companies.

Finally, Part IV analyzes how changes in the inventor and third-party experimental use doctrines will benefit both society and academic research.[18] By modifying the inventor and third-party experimental use doctrines to grant non-profit and university researchers a license to experiment with patented inventions and processes, the government will promote progress in "[s]cience and useful [a]rts."[19]

II. Experimental Use under Section 102(b)

Inventor experimental use permits an inventor to perfect her creation without losing patent protection. Ordinarily, section 102(b) of the patent code establishes a bar to patentability for inventions that have been in public use for more than one year. The common-law experimental use doctrine negates the effect of this bar, permitting inventors to experiment with their inventions without fear of losing

16 *See infra* Part III. This statute is codified at 35 U.S.C. § 271(e)(1) (1994) and was enacted as part of the Drug Price Competition and Restoration Act of 1984.

17 H.R. Rep. No. 960(I), 101st Cong., 2d Sess. (1990).

18 *See infra* Part IV for a hypothetical example used as a template for this discussion.

19 U.S. Const. art. I, § 8, cl. 8.

rights to their inventions under section 102(b). However, courts often apply the provisions of this doctrine narrowly, denying patent protection to arguably deserving inventions. As university researchers come to use and rely on patents to a greater extent, a broader reading of the inventor experimental use doctrine becomes imperative.

Subpart A of this Part examines the public use bar to patentability under section 102(b). Subpart B explains the experimental use exception to this prohibition and traces its genesis in the Supreme Court. Subpart C examines the application of the experimental use doctrine in the United States Court of Appeals for the Federal Circuit.[20] This subpart argues that the Federal Circuit should apply the experimental use doctrine more broadly than it has. It also asserts that the court should give greater weight to evidence from the inventors themselves, rather than adhere to judicially created legal tests.

A. Public Use

Section 102(b) specifically forbids an inventor from obtaining a patent if her invention was "in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States."[21] The term "public use" has been defined as "any use of [an] invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor[s]."[22] The origin of the public use bar dates to the passage of the Patent Act of 1790, in which Congress limited inventions to those that had not been in prior use.[23] The Act of 1793 clarified the language of the prior Act by stating that the invention could not be "known or used" before the "application" of the patent seeker.[24] In 1836, Congress added the "on sale" prohibition and a qualifier to the "public use" prohibition that limited the bar to uses and sales made with the inventor's "consent and allowance."[25] The Act of 1839 granted inventors a two-year window in which to file a patent application after the onset of public use, and this window was subsequently reduced to one year in 1939.[26]

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20 This court was created in 1982 and has appellate jurisdiction over all patent cases. *See* 35 U.S.C. § 1295(a) (1994).

21 35 U.S.C. § 102(b) (1994).

22 In re Smith, 714 F.2d 1127, 1134 (Fed. Cir. 1983).

23 The Act stated:

> That upon the petition of any person or persons to the Secretary of State, the Secretary for the Department of War, and the Attorney General of the Untied States, setting forth that he, she, or they, hath or have invented or discovered any useful art . . . not before known or used.

Patent Act of 1790, 1 Stat. 109, 109-110 § 1 (1790) (repealed 1793).

24 Patent Act of 1793, 1 Stat. 318, 319 § 1 (1793) (repealed 1836).

25 Patent Act of 1836, 5 Stat. 117, 119, § 6 (1836).

26 Patent Act of 1839, 5 Stat. 353, 354, § 7 (1839); 35 U.S.C. § 102(b) (1994).

The general purpose of the public use bar is to encourage inventors to file their patents as soon as practical.[27] The Federal Circuit has identified four basic policy considerations in analyzing questions of both "public use" and "on sale" as they apply to section 102(b).[28] Three of these policies work against the inventor: (1) protecting the public's use of an invention when the use commenced prior to the application date; (2) encouraging inventors to promptly disclose new and useful innovations; and (3) preventing inventors from obtaining a effective patent term longer than statutorily allowed.[29] A fourth policy that favors inventors states that public interest is served when inventors are given time to perfect their inventions by public experimentation.[30]

B. Experimental Use Origins in the Supreme Court

Experimental use by inventors is not public use; therefore, under such circumstances, section 102(b) does not apply. The doctrine of experimental use began in the Supreme Court in *Elizabeth v. Pavement Co.*[31] In that case, an inventor, the plaintiff, had patented an improved wooden pavement, and the defendant, the city of Elizabeth, New Jersey, put this pavement into use without securing permission from the patent owner. In the ensuing legal battle over infringement, the city argued that the patent was invalid because the inventor had publicly used the pavement on a street in Boston for six years before he applied for a patent, and consequently, that this use constituted an abandonment of the invention.[32] The Supreme Court disagreed, holding that upon examination of "the circumstances under which this pavement was put down," it was clear that the inventor had not abandoned the invention.[33] These circumstances included the subjective intent of the inventor and the objective evidence of the test in Boston; both indicated that the use of the pavement was experimental.[34] The Court reasoned that, although the inventor experimented with the pavement on a public street, this did not constitute a public use be-

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27 DONALD S. CHISUM, PATENTS § 6.01 (1996).

28 TP Lab., Inc. v. Professional Positioners, Inc., 724 F.2d 965, 968 (Fed. Cir.), *cert. denied*, 469 U.S. 826 (1984).

29 *Id.*

30 *Id.*

31 97 U.S. 126 (1877).

32 *Id.* at 129.

33 *Id.* at 133.

34 *Id.* The circumstances included the manner in which the inventor, Mr. Nicholson, had constructed the pavement. The pavement had been constructed at Nicholson's own expense, he had examined the pavement daily, and he had asked numerous questions concerning the wear and use of the pavement. *Id.*

cause he tested the pavement's operation in good faith, kept a log of his measurements, and maintained control over the entire operation.[35]

Over the next few years, the Supreme Court examined the experimental use doctrine several more times and rejected its application each time a commercial use or sale occurred.[36] The Court developed a standard to determine the presence of experimental use that asked whether the invention in question had been completed or "reduced to practice."[37] If the invention had been reduced to practice, no further experimentation was necessary, and therefore the statutory bars of public use and sale applied. On the other hand, if the invention had not been reduced to practice, the invention was not complete, and therefore the experimental use doctrine was a possible defense to the section 102(b) bars.

The Supreme Court examined the experimental use doctrine most recently in *Electric Storage Battery Co. v. Shimadzu*,[38] in which it held that "[a] mere experimental use is not . . . [a] public use, but a single use for profit, not purposely hidden is such."[39] In other words, although an inventor may claim her public use of an invention was experimental, if that public use resulted in a profit, she is no longer protected by the experimental use doctrine. The Court found that the process in question—a method for manufacturing lead oxide powder—had not been concealed from plant employees, no efforts had been made to conceal the method from outsiders, and the method had been used for profit. The patents in question, therefore, were ultimately declared invalid.[40] Some commentators have noted that since inventors used their inventions for profit prior to the "critical date,"[41] the Supreme Court invalidated the patents. Therefore, they argue

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35 *Id.* at 134-35.

36 Root v. Third Ave. R.R. Co., 146 U.S. 210 (1892) (construction and operation of a railway costing $400,000 not experimental); International Tooth-Crown Co. v. Gaylord, 140 U.S. 55 (1890) (public demonstrations of tooth crowning for profit went beyond experimental needs); Smith & Griggs Mfg. Co. v. Sprague, 123 U.S. 249 (1887) (a primary purpose of manufacturing for an invention preempts incidental and secondary experimental purposes); Hall v. Macneale, 107 U.S. 90 (1882) (the sale of safes unconditionally was not experimental); Egbert v. Lippman, 104 U.S. 333 (1881) (holding that the use cannot be experimental if no limitations were placed on the wearing of a corset and if there were no tests or experiments).

37 William C. Rooklidge & W. Gerard von Hoffmann, III, *Reduction to Practice, Experimental Use, and the "On Sale" and "Public Use" Bars to Patentability*, 63 ST. JOHN'S L. REV. 1, 1-3 (1988).

38 307 U.S. 5 (1939).

39 *Id.* at 20.

40 *Id.*

41 Public use prior to the critical date statutorily bars an inventor from obtaining a patent. Under section 102(b), that date occurs exactly one year before the patent is filed. 35 U.S.C. § 102(b) (1994).

that the Court does not weigh experimental motive, but rather looks at whether the use resulted in profit.[42]

C. *The Evolution of the Inventor Experimental Use Doctrine in the Federal Circuit*

This subpart discusses the Federal Circuit's changing approach to the experimental use doctrine. First, it analyzes the elements that comprise the experimental use doctrine. Second, it examines the kind of evidence the Federal Circuit finds most persuasive in determining experimental use. Finally, it discusses procedural aspects of an experimental use doctrine.

1. Elements.—The elements of the experimental use doctrine can be divided into three main categories: (1) whether the use in question was primarily for the purpose of experimentation or commercial exploitation;[43] (2) how much control the inventor exercised over the use;[44] and (3) to what extent the invention needs further experimentation or testing in order to be complete.[45] These elements do not comprise any sort of judicial test for experimental use, but rather are subjective factors that courts analyze when confronted with experimental use arguments. However, some elements are more likely to invalidate the protection of the experimental use doctrine than others. For example, selling an invention at a profit for commercial purposes will most likely destroy any hope of avoiding the §102(b) bar.[46]

a. Purpose: experimental or commercial.—In determining the purpose of the use, the Federal Circuit has consistently ruled that the defense of experimental use will not succeed unless commercial exploitation has been minor and subservient to an experimental purpose.[47] Determining whether the primary focus of the use was commercial or experimental will not always be difficult. For example, when a manufacturer ships thousands of copies of its invention to customers in a usual commercial fashion, it is clear that, absent any objective evidence to the contrary, the engaged use is commercial rather than experimental.[48]

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42 *See, e.g.,* William K. West, Jr. & Nancy J. Linck, *The Law of "Public Use" and "On Sale": Past, Present and Future*, 72 J. PAT. & TRADEMARK OFF. SOC'Y 114, 134-35 (1990).

43 *In re* Smith, 714 F.2d 1127, 1134 (Fed. Cir. 1983).

44 *In re* Hamilton, 882 F.2d 1576, 1580 (Fed. Cir. 1989).

45 RCA Corp. v. Data Gen. Corp., 887 F.2d 1056 (Fed. Cir. 1989).

46 *See* Electric Storage Battery Co. v. Shimadzu, 307 U.S. 5 (1939).

47 *See, e.g.,* Baker Oil Tools, Inc. v. Geo Vann Inc., 828 F.2d 1558, 1564 (holding use must be "substantially for purposes of experiment" in order to avoid the section 102(b) bar).

48 *See In re* Brigance, 792 F.2d 1103, 1108 (Fed. Cir. 1986) (holding that an exam used for measuring student skills was barred by public use of 2500 copies of the exam where the inventor failed to meet the burden of showing experimental use).

In *In re Smith*,[49] the court invalidated a patent for "Carpet Fresh," a carpet cleaner and deodorizer. It held that because the appellant's tests of the compound in private homes in and around St. Louis thirteen months prior to applying for a patent were primarily commercial, these tests initiated the section 102(b) bar.[50] The court's holding was based in large part on its opinion that the testing could have been performed in the inventor's laboratory. Some commentators have supported the court's decision, arguing that the main purpose of the test was to determine whether potential customers would purchase the product.[51]

Although the holding in *Smith* may have been appropriate, the court should not have interjected its opinion as to how the functional features of Carpet Fresh should have been analyzed. The dissent in *Smith* stated the dangers of favoring a court's interpretation of appropriate experimentation over that of inventors.[52] It argued that inventors, not judges, are most adept at determining the scope, number, and type of experiments needed to perfect an invention. By placing unnecessary restrictions on inventors, the court "thwart[s] and nullif[ies], in the consumer product category, the experimental use exception itself."[53]

While it was clear that at least some of the tests in *Smith* were market oriented, others were not. For example, the court found unpersuasive the appellant's arguments that a test of powdered versus granular versions of Carpet Fresh was for technical purposes. It stated, "this evidence [a memorandum written by the inventor] suggests that the test was a determination as to which particle size was more marketable and not a determination as to which particle size was technically superior."[54] However, analysis of those parts of the inventor's memoranda the court itself chose to publish yields the opposite conclusion. One memorandum, written before consumers were interviewed, stated that the powdery version had several technical advantages over the granular one: better deodorization, anti-static and anti-soil properties, easier vacuuming attributes and manufacturing methods, and was less costly.[55] A later memorandum observed that the consumer tests confirmed the belief that the powder blend "vacuumed

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49 714 F.2d 1127 (Fed. Cir. 1983).

50 *Id.* at 1137.

51 *See, e.g.*, Douglas W. Wyatt, *Current Developments in Patent Law 1985: The Burden of Proof Regarding "Experimental Purpose", in Connection with a Potential "On Sale", or "Public Use" Statutory Bar to Patentability Under 35 U.S.C. Section 102(b)*, 213 PRACTICING LAW INST. PAT. 257 (1985).

52 *In re Smith*, 714 F.2d at 1138-39 (Nichols, J., dissenting).

53 *Id.* at 1138.

54 *Id.* at 1135.

55 *Id.* at 1130.

up the best."[56] These qualities are primarily technical features of a product and not subjective marketing factors.

The Federal Circuit recently reexamined its position on market studies and clarified the *Smith* ruling in *Tone Bros. v. Sysco Corp.*[57] In *Tone Bros.*, the court held that a limited marketing study used to determine the shape of a spice container for manufacture and sale could constitute experimental use.[58] Unlike those in *Smith*, the inventors in *Tone Bros.* had applied for a design patent.[59] Design patents, by definition, must be ornamental—the opposite of functional.[60] The court here, unlike the *Smith* court, did not find the use of a marketing study fatal to an experimental use claim. Ultimately, the court reversed the district court's grant of summary judgment against the inventors. The court held that the marketing study was focused on both functional and ornamental aspects of the container and thus, fit under the umbrella of the experimental use doctrine.[61] Interestingly, the court distinguished the marketing studies from those in *Smith* not because of the commercial aspects of the study, but rather because of the degree to which the inventors actually controlled the tests and the samples.[62] In neither *Smith* nor *Tone Bros.* were members of the test group required, or even asked, to sign confidentiality agreements. However, the court stated that in the Carpet Fresh study the inventors did not exercise as much control over the test samples as the inventors in *Tone Bros.* had.[63] The court did not discuss whether it could analyze experimental data, but considered objective evidence and concluded that the inventors were involved in legitimate experimentation.[64]

In 1996, the Supreme Court affirmed that judges, not juries, must interpret the meaning of patent claim language.[65] The judge is supposed to limit herself, if possible, to the patent claims, the specification, and the prosecution history when determining the meaning of the claims.[66] If the meaning of the claims is still unclear, the judge can

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56 *Id.*

57 28 F.3d 1192 (Fed. Cir. 1994), *cert. denied*, 115 S. Ct. 1356 (1995).

58 *See id.* at 1200.

59 A successful application for a design patent must show the design to be "new, original and ornamental." 35 U.S.C. § 171 (1994).

60 PAUL GOLDSTEIN, COPYRIGHT, PATENT, TRADEMARK AND RELATED STATE DOCTRINES 880 n.2 (3d ed. rev. 1993).

61 *Tone Bros.*, 28 F.3d at 1200. Specifically, the court stated "[w]e . . . hold that experimentation directed to functional features of a product also containing an ornamental design may negate what otherwise would be considered a public use within the meaning of section 102(b)." *Id.*

62 *Id.* at 1200 n.8.

63 *Id.*

64 *See* Jonathan Bloom et al., *Experimental Use May Save Design Patent*, 6 J. PROPRIETARY RTS. 29 (1994).

65 Markman v. Westview Instruments, Inc., 116 S. Ct. 1384 (1996), *aff'g* 52 F.3d 967, 979 (Fed. Cir. 1995).

66 Vitrionics Corp. v. Conceptronics, Inc., 90 F.3d 1576 (Fed. Cir. 1996).

then rely on extrinsic evidence, such as expert testimony, to elucidate the meaning of ambiguous claim language.[67] This gives the judge an enormous amount of power, for after interpreting the claims, she may rule as a matter of law for or against a party without submitting the case to a jury. While judges have broad powers with regard to interpreting claim language, they should not translate that power into areas best left to the inventors, such as telling them where to perform experiments.[68] Experimental use cases, by their very nature, are vulnerable to an active judiciary. It is at this juncture that what is appropriate for law and what is best for science and technology diverge.

Simply put, courts are ill-suited to analyze the technical value of experimental data. A jurist lacking proper discipline, education, and experience cannot possibly tell an inventor what the optimal experimental conditions should be. What she can do, however, is judge whether the inventor has accumulated enough evidence of experimentation to circumvent the section 102(b) bar.

Some standards and guidelines are available to help guide courts in properly weighing and evaluating experimental use evidence. In *Electric Storage Battery Co. v. Shimadzu*,[69] the Supreme Court ruled that a single commercial use for profit, not kept intentionally secret, cannot be an experimental use.[70] The same outcome can occur when an inventor, claiming experimental use, sells her invention for a loss. In *U.S. Environmental Products Inc. v. Westall*,[71] the court held a patent invalid under section 102(b) even though the sale of the product did not yield a profit because the primary purpose of the sale was nevertheless commercial. Clearly, the experimental use doctrine should not be based on commercial success. Whether a product is marketed effectively is irrelevant in light of a policy that encourages inventors to perfect their inventions before seeking patent protection. Had the inventor's primary purpose been experimental, then the sale would not have barred the defense.

In *TP Laboratories v. Professional Positioners, Inc.*,[72] doctors tested an orthodontic device on their patients. Although the patients were not charged for the implantation, the court in dicta said that even if the doctors had charged their patients for the fitting, then such a charge is "itself . . . not critical."[73] The court concluded that the presence of a commercial sale or use was just one factor to consider in the entire experimental use analysis. This rule is reasonable because it

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67 *Id.* at 1583.

68 *See supra* notes 49-56 and accompanying text.

69 307 U.S. 5 (1939).

70 *Id.* at 20.

71 911 F.2d 713, 717 (Fed. Cir. 1990).

72 724 F.2d 965, 971-72 (Fed. Cir.), *cert. denied*, 469 U.S. 826 (1984).

73 *Id.* at 973.

gives the inventor the freedom to sell prototypes to potential customers and to receive potentially valuable data which can later be used to perfect the invention.[74] This decision recognizes the importance of determining an inventor's reasons for experimenting with an invention beyond the one year section 102(b) time frame, and thereafter resolving whether sufficient evidence exists to support the experimentation claim.

b. Control.—The second major element in evaluating whether a use is experimental, commercial, or public is the degree of control that the inventor exercised over her invention. Control includes, for example, confidentiality agreements. Other aspects of control concern the degree of supervision the inventor exercises over the potentially public use. The notion is that an inventor who is truly experimenting with her invention will exercise greater control over the "public" use of the invention than an inventor who is no longer experimenting. In *In re Hamilton*,[75] the Federal Circuit rejected a patent claim based primarily on evidence that the inventor did not have adequate control over his invention to claim experimental use. The inventor appealed a Patent and Trademark Office decision rejecting his patent application for the production of perforated business forms and the devices used to make those forms. The inventor, James Hamilton, was an employee of Western Printing Machinery Company, a manufacturer of rotary die systems. Western was unable to test the production of business forms itself so it contacted Uarco, Inc., a manufacturer of these types of forms, to make them. Uarco made tens of thousands of these forms for commercial use in what was termed a "test order."[76] A patent for this process was filed more than one year after the completion of the test run, and the patent examiner rejected the patent under section 102(b). An appeal to an administrative board yielded a similar result, and the case was appealed directly to the Federal Circuit.[77] The inventor claimed that, because the test order was actually an experimental use, section 102(b) did not apply.[78]

Although the court stated that control was not the "'lodestar' test in all cases involving experimental use,"[79] it asserted that if an inventor does not control experimental tests either directly or through another party, she cannot rely upon the experimental use doctrine to

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74 The question of what evidence the court will consider when making this evidentiary determination will be discussed *infra* at section II.C.2.

75 882 F.2d 1576 (Fed. Cir. 1989).

76 *Id.* at 1578.

77 Under 35 U.S.C. § 141 (1994), an inventor can appeal a board's decision directly to the Federal Circuit.

78 *Hamilton*, 882 F.2d at 1580.

79 *Id.* at 1581.

avoid the statutory bar of section 102(b).[80] In *Hamilton*, the lack of involvement by either Hamilton or his employer and assignee, Western, eliminated Hamilton's experimental use claim. The court reasoned that the lack of control "tend[ed] to show that [Hamilton's and Western's] motivation was not in fact experimental."[81]

Other means of court-approved control include formal confidentiality agreements,[82] doctor-patient relationships,[83] and physical control over testing conducted by third parties.[84] Control need not, however, be formalized by a written contract between the inventor and another party.[85] The true test of control is not the presence of an agreement, but whether the confidential information was in fact transmitted to other parties.[86] However, this "effects" test leaves open the possibility that a breach of a written confidentiality agreement by another party may bar an innocent inventor from claiming experimental use under section 102(b).[87] Presumably, the court did not intend to punish an inventor who, in good faith, gave valuable and confidential information to another party who then inadvertently or intentionally leaked that secret information to the public. Nevertheless, the Federal Circuit recently ruled that third parties not in a confidential relationship with the inventor can activate the section 102(b) bar even after the invention is reduced to practice.[88] In *Baxter Int'l v. Cobe Laboratories, Inc.*, the patentee had invented a sealless centrifuge for separating blood components. He had filed a patent application on May 14, 1976, thereby making May 14, 1975, his critical date. Before the critical date, scientists at the National Institutes of Health (NIH) used the invention for studying heart preservation via perfusion. The scientists discovered that the sealless centrifuge worked better than

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80 *Id.*

81 *Id.* at 1583.

82 *See* Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 550 (Fed. Cir. 1990) (finding the presence of a confidentiality agreement between a manufacturer and the state even more compelling when state law forbids officials from disclosing confidential information to the public).

83 *See* TP Labs., Inc. v. Professional Positioners, Inc., 724 F.2d 965, 972 (Fed. Cir.) (asserting that a pledge of confidentiality can be established inherently by a dentist-patient relationship), *cert. denied*, 469 U.S. 826 (1984).

84 *See* Allied Colloids Inc. v. American Cyanamid Co., 64 F.3d 1570, 1575 (Fed. Cir. 1995) (finding that "[i]t was undisputed that Colloids maintained strict control over the test samples").

85 The Federal Circuit recently asserted that the absence of a written promise "does not make a use 'public' as a matter of law." *Id.* at 1576.

86 *Id.*

87 An inventor who has strict control over her invention and utilizes a third party to help test the invention will be able to prevent that party from releasing information publicly. In *Allied Colloids*, for instance, the inventors of a sludge treatment process performed tests at a public sewage plant and did not allow the plant employees to view the tests. The public employees did not perform the tests nor did they even know what products were being tested. Therefore, they would have been incapable of telling third parties about the nature of the tests. 64 F.3d at 1575.

88 Baxter Int'l v. Cobe Labs., Inc., 88 F.3d 1054 (Fed. Cir. 1996).

standard centrifuges. The trial court concluded that the scientists' use of the invention was public and therefore the patent was invalid. On appeal, the Federal Circuit adopted the plaintiff's policy argument that "the most applicable policy underlying the public use bar here is discouraging removal from the public domain of inventions that the public reasonably has come to believe are freely available."[89] The Federal Circuit found the lack of control between the inventor and the third-party scientists dispositive in holding the use to be public.[90] This ruling further cements the Federal Circuit's belief that control of information really is the most important factor dividing experimental from public use.

In her dissent, Judge Newman criticized the majority for ruling that "unpublished laboratory use after reduction to practice is public use" as it creates "a new and mischievous category of 'secret' prior art."[91] Judge Newman's comments are particularly appropriate in the university context. University laboratories, like the particular laboratories discussed above in NIH, are relatively open environments compared to corporate research laboratories. It is much easier, for example, for a visitor to randomly inspect a university lab in which security is notoriously lax as compared with an industrial research facility. In fact, the NIH researchers acknowledged that their laboratory was in a public building where people were "flowing" into the lab.[92] This ruling makes it even more difficult for academic researchers to obtain patents because it requires them to police their laboratories in case a third party might see and then use an invention. Given the university culture encouraging shared information, this decision could limit the patentability of university inventions.

One of the major problems of imposing legal limits on experimental use is that inventors spend little or no time reading legal opinions to determine the scope of the law. Whereas large industrial concerns maintain their own patent counsel, universities often do not. The Federal Circuit's decision in *Lough v. Brunswick Corp.*[93] illustrates this problem. In *Lough*, the inventor created a clever device to prevent corrosion of upper seal assemblies for stern drives used in marine motors. He made six prototypes and had them installed on various craft including his own boat, friends' boats, and the owner of the marina's boat, where Lough worked. Lough did not ask nor did he receive comments on the motors for over a year, and he did not attempt to sell any of his assemblies. Two years after constructing the seal assemblies, he filed a patent application, and he received a patent

89 *Id.* at 1058.
90 *Id.*
91 *Id.* at 1061 (Newman, J., dissenting).
92 *Id.* at 1059.
93 86 F.3d 1113 (Fed. Cir. 1996).

about a year after that. Lough subsequently sued Brunswick for patent infringement in 1993, and Brunswick counterclaimed for a declaratory judgment that, inter alia, the patent was invalid because of public use before the critical date. A jury, however, found infringement, and Brunswick appealed.

The Federal Circuit reversed, holding that Lough's use of the prototypes was not an experimental use. The court stated that experimental use was a matter of law and held that because Lough lacked control over the prototypes and never inquired about how well they were performing, his use was not experimental. The court said that "control is critically important, because, if the inventor has no control over the alleged experiments, he is not experimenting. If he does not inquire about testing or receive reports concerning the results, similarly, he is not experimenting."[94] The court concluded, therefore, that there was no legal basis for the jury's conclusion.

In dissent, Judge Plager chastised the majority for not holding that the use was experimental. His sarcastic opinion noted that although it would have been better for Mr. Lough to have read the court's opinions on experimental use and studied their application, a common sense approach reveals that he was "more likely than not . . . testing and perfecting his device, rather than simply making it available gratis to members of the general public for what the law calls 'public use.'"[95]

Judge Plager's dissent is particularly applicable to university researchers. It is a manifest waste of resources to have scientists read legal opinions in order to make sure that they can exploit their inventions without being barred under section 102(b). Rather, it is a better use of resources and better for the progress of science to let inventors develop the standards under which experimental use can apply. Whereas Mr. Lough did not perform the *legally* required steps showing experimental use, it appeared that his use was nevertheless experimental. He did not sell any of the seal assemblies nor did he widely distribute them. The fact that he did not closely monitor the assemblies is irrelevant if he knew that his friends owning the prototypes would only contact him if there was a problem.[96] The majority's opinion is an unwarranted intrusion into the innovative process. Its narrow application of "control" further illustrates why judges should not be telling inventors how to operate their experiments.

c. Reduction to practice.—The third major element in the experimental use doctrine is whether an invention has been "reduced to practice." Section 102(b) states that one may not obtain a patent

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94 *Id.* at 1120.
95 *Id.* at 1124 (Plager, J., dissenting).
96 *Id.*

on an "invention" that was in "public use or on sale" in the United States more than a year prior to the filing date.[97] Therefore, until a device has reached the status of "invention," the statutory bar of section 102(b) does not apply. Once it has reached this stage, it has become reduced to practice. This may mean that once an invention becomes operable, an inventor can no longer rely upon the experimental use doctrine to save her from the scope of section 102(b).[98]

Commencing with *Baker Oil Tools Inc. v. Geo Vann, Inc.*,[99] however, the court has increasingly expanded the availability of experimental use to inventors who wish to improve an invention that is already arguably marketable.[100] Later, in *Allied Colloids, Inc. v. American Cyanamid Co.*, for example, the court down-played reduction to practice as a distinct element in determining experimental use and instead focused on whether "the inventor was in fact testing the invention."[101] Experimental use is governed by the philosophy that the inventor needs breathing room to test and experiment with her invention in order to provide the public with the best possible invention.[102] The inventor is in the best position to determine whether the invention is finished. No court can better analyze an inventor's data than the inventor herself. What the court can do, however, is evaluate the objective evidence surrounding the test and determine whether that information supports a conclusion that the test was done for the purpose of experimentation. Therefore, a critical factor in the court's analysis should be the evaluation of experimental use evidence.

2. Experimental Use Evidence.—Evidence of experimental use can be classified as either objective or subjective.[103] An inventor who argues solely that she meant a use to be experimental is relying on subjective evidence to convince a court to waive the section 102(b) bar. An inventor's claims at trial that she intended commercial activity to be secondary to experimental activities will not persuade absent other evidence.[104] In *LaBounty Manufacturing v. United States Inter-*

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97 35 U.S.C. § 102(b) (1994).

98 In Harrington Mfg. Co. v. Powell Mfg. Co., 815 F.2d 1478, 1481 (Fed. Cir. 1986), the court declared that "[a]ll that is necessary is that the invention be commercially operable" for the public use or on sale prohibition to apply.

99 828 F.2d 1558 (Fed. Cir. 1987).

100 The court said that the district court had erred in holding that reduction to practice automatically barred an experimental use defense. *See id.* at 1564.

101 Allied Colloids Inc. v. American Cyanamid Co., 64 F.3d 1570, 1577 (Fed. Cir. 1995).

102 *See supra* note 30 and accompanying text.

103 Subjective evidence refers strictly to the inventor's intent. *See In re* Smith, 714 F.2d 1127, 1135 (Fed. Cir. 1983). Objective evidence of experimental use comprises records, logs, confidentiality agreements and other similar evidence that is not based merely on intent. *In re* Brigance, 792 F.2d 1103, 1107-08 (Fed. Cir. 1986).

104 *See* Labounty Mfg., Inc. v. United States Int'l Trade Comm'n, 958 F.2d 1066, 1071 (Fed. Cir. 1992).

national Trade Commission,[105] the court stated that an inventor's protestation of intent "is of little evidentiary value" when initially expressed at litigation.[106] *LaBounty* involved the sale of industrial shears to its customers in which there was no attempt to keep the shears secret, no records were kept, and the transactions were typical of ordinary commercial deals.[107] There was no objective evidence of experimental purpose. The entire body of evidence rested solely on the inventor's subjective intent that the activities were experimental. This was insufficient to negate a section 102(b) bar. Inventors need to provide substantial objective evidence of experimental use in order to escape the section 102(b) bar. For example, the appellant in *Grain Processing Corp. v. American Maize-Products*[108] successfully avoided the section 102(b) statutory bar by presenting the court with sufficient objective evidence of experimental use. Grain Processing Corporation (GPC) had invented a carrier—a starch hydrolysate—for synthetic sweeteners and for bulking agents in synthetic creams and whiteners.[109] More than one year prior to applying for a patent, GPC's predecessor had sent samples of the hydrolysate to several different food manufacturers. The lower court found that this practice was in accordance with industry customs in ascertaining products' utility.[110] GPC argued that the testing was necessary to ensure the hydrolysate's stability with the food manufacturers' products. Moreover, GPC sent out only small samples to the manufacturers, the testing period did not take very long, and GPC did not charge for the samples.[111] The court relied upon these objective indicia of experimental use to rule that GPC's use of the hydrolysate was experimental.[112] The court did not address any factors involving GPC's subjective intent.

More recently, the court has focused on the record-keeping aspect of objective evidence. For example, in *Allied Colloids*, the court stated that record keeping was "highly relevant" since detailed records are a "routine indicium of the experimental mode."[113] These records are important because if they are properly kept they "indicate the inventor was testing the device, not the market."[114]

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105 958 F.2d 1066 (Fed. Cir. 1992).

106 *Id.* at 1071.

107 *Id.* at 1074.

108 840 F.2d 902 (Fed. Cir. 1988).

109 *Id.* at 904.

110 *Id.* at 906.

111 *Id.*

112 *Id.*

113 *Allied Colloids*, 64 F.3d at 1576.

114 *Id.* (quoting TP Lab., Inc. v. Professional Positioners, Inc., 724 F.2d 965, 973 (Fed. Cir.), *cert. denied*, 469 U.S. 826 (1984)).

An inventor who wishes to experiment publicly with a device and avoid the public use statutory bar should be certain to have objective evidence supporting an experimental use claim. The Federal Circuit has listed numerous evidentiary factors it considers as objective evidence of experimental use: (1) whether a user agreed to use the invention secretly; (2) whether records were kept of progress; (3) whether persons other than the inventor conducted the asserted experiments; (4) how many tests were conducted; and (5) the length of the testing period in relation to tests of similar devices.[115] In other words, a decision on whether there has been a "public use" can only be made upon consideration of all of the factors.[116]

3. Procedural Aspects of Section 102(b).—As an introductory matter, the Federal Circuit has ruled that both public and experimental use are matters of law.[117] Nevertheless, as discussed above, whether a use is experimental or public is a fact-specific question involving the "totality of the circumstances." Because the court has declared such use a matter of law, it can review ultimate jury or bench conclusions de novo.[118] Parties litigating section 102(b) must understand their respective burdens of persuasion and proof.[119] Once a patent has been issued, a party seeking to have the patent declared invalid has the burden of proof.[120] If that party attempts to have the patent invalidated based on prior public use, then it has the burden of showing prima facie evidence of such use.[121] Furthermore, the standard of persuasion is clear and convincing evidence.[122] Once the patent challenger has met this burden, then the patent holder has the burden of presenting convincing evidence to counter the public use argument.[123] These situations often arise on summary judgment where a prima facie case of public use has been presented and the court examines whether the actions of the patent holder constitute experimental use.[124] This provides a further incentive for the inventor

115 William C. Rooklidge, *The On Sale and Public Use Bars to Patentability: The Policies Re-examined*, 1 FED. CIR. B.J. 7, 35-36 (1991).

116 *TP Lab.*, 724 F.2d at 972.

117 *Baxter*, 88 F.3d at 1058 ("Whether a public use has occurred is a question of law."); *Lough*, 86 F.3d at 1120 (explaining that experimental use, as a question of law, involves examining evidence too).

118 *Lough*, 86 F.3d at 1120.

119 *See* Wyatt, *supra* note 51, at 268.

120 *See, e.g.*, Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534 (Fed. Cir. 1983).

121 *See* Sinskey v. Pharmacia Opthalmics, Inc., 982 F.2d 494, 498 (Fed. Cir. 1992), *cert. denied*, 508 U.S. 912 (1993).

122 Tone Bros. v. Sysco Corp., 28 F.3d 1192, 1197 n.4 (Fed. Cir. 1994), *cert. denied*, 115 S. Ct. 1356 (1995).

123 *Id.*; U.S. Envtl. Prods. v. Westall, 911 F.2d 713, 716 (Fed. Cir. 1990) (quoting *TP Lab.*, 724 F.2d at 971).

124 *Sinskey*, 982 F.2d at 498.

to keep detailed records and collect objective evidence to prove that the questionable use was experimental.

4. Experimental Use and University Research.—The experimental use doctrine will become increasingly important to universities who seek to patent their inventions as federal research funding declines.[125] Since research at a university is by its very nature public, research resulting in patents is particularly vulnerable to the section 102(b) bar. Abandoning rigid application of tests such as the dogmatic emphasis on inventor control in favor of evaluating objective evidence of experimental use will further advance the progress of science and the useful arts in general and in universities in particular. As research grows increasingly complicated, it becomes imperative that researchers collaborate with each other to solve daunting scientific challenges. This drive, coupled with the ever-increasing exploitation of university-owned intellectual property, requires a broader application of the experimental use doctrine to continue to allow universities and other non-profit institutions to maintain high scientific standards and contribute to the progress of science.

The experimental use doctrine evolved in recognition of public benefits that would result from allowing inventors to experiment with their inventions before applying for patent protection. When applied properly, this doctrine gives inventors the freedom to perfect their creations so long as they are diligent in documenting and demonstrating their bona fide experimentation. The goal of this doctrine is for the inventor to ultimately patent her invention if she deems it is reasonable to do so.

III. The Experimental Use Allowance for Infringers: Third-Party Experimental Use

A second experimental use doctrine, distinct and separate from inventor experimental use, allows third parties to experiment with a patented invention without permission. Like inventor experimental use, third-party experimental use would benefit from a broader reading by courts. This would help stimulate non-profit research and promote the policy that underlies the Patent Clause. This Part discusses the development of this doctrine, how it is applied today, and how it should be applied in the future. Subpart A discusses the origins of the doctrine in the common law and subpart B analyzes the major pre-Federal Circuit decisions invoking the doctrine. Subpart C examines the modern treatment of this doctrine, including the statutory exceptions to infringement specifically allowing for experimental use in cer-

125 Charles Petit, *Huge Cuts on Horizon for Science*, S.F. Chron., Aug. 29, 1995, at A5.

tain situations.[126] Subpart D lists recommendations, which include adopting a modified version of the Patent Competitiveness and Technological Innovation Act of 1990.[127]

A. Origins of Third-Party Experimental Use in the Common Law

The origins of the third-party experimental use doctrine can be traced to the dicta of Justice Story in 1813 in the cases of *Whittemore v. Cutter*[128] and *Sawin v. Guild*.[129] Because numerous publications have examined these cases, there is no detailed discussion of them here.[130] It is sufficient to note that the doctrine created by Justice Story allows third parties to use inventions for "philosophical experiments, or for the purpose[s] of ascertaining the sufficiency of the machine[s] to produce [their] described effects."[131] Story also explicitly stated that in order to qualify for this exemption on either the philosophical or verification grounds, the use could not be commercial.[132]

One commentator claims that this two-step purpose and commercial use test is too broad a reading of Justice Story's rationale for creating the exception.[133] He suggests that Story's test is truly only a one-part test that asks whether a "use for profit" was evident by the third party, and that the philosophical and verification inquiries were given merely as examples of two instances where there was no such use.[134] Regardless of Justice Story's intent, the development of this exception in the common law has focused primarily on the extent to

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126 At least three statutes allow parties to experiment with patented inventions legally and without getting permission from the inventors in advance. These are 35 U.S.C. § 271(e)(1) (1994), allowing generic drug manufacturers to experiment with patented drugs prior to patent expiration in order to meet FDA approval guidelines, 7 U.S.C. § 2544 (1988), specifically exempting research and experimentation on plant breeding from patent infringement, and 17 U.S.C. § 906(a)(1) (1994), allowing researchers to experiment with semiconductor masks.

127 H.R. REP. NO. 960(I), 101st Cong., 2d Sess. (1990).

128 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

129 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391).

130 *See, e.g.*, Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1074-75 (1989); Ned A. Israelsen, *Making, Using, and Selling Without Infringing: An Examination of 35 U.S.C. Section 271(E) and the Experimental Use Exception to Patent Infringement*, 16 AM. INTELL. PROP. L. ASS'N. Q. J. 457, 458-59 (1989); David L. Parker, *Patent Infringement Exemptions for Life Science Research*, 16 HOUS. J. INT'L L. 615, 626-36 (1994); Steven J. Grossman, Comment, *Experimental Use or Fair Use as a Defense to Patent Infringement*, 30 J.L. & TECH. 243, 256-57 (1990); Suzanne T. Michel, Comment, *The Experimental Use Exception to Infringement Applied to Federally Funded Inventions*, 7 HIGH TECH. L.J. 369, 371-72 (1992); Jordan P. Karp, Note, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169, 2170-72 (1991).

131 *Whittemore*, 29 F. Cas. at 1121.

132 *See Sawin*, 21 F. Cas. at 555 (noting in dicta that the unauthorized use of a patent with the intent of making a profit constitutes infringement).

133 Parker, *supra* note 130, at 627.

134 *Id.*

which the potentially infringing action has had a commercial element.[135]

B. Third-Party Experimental Use Before the Creation of the Federal Circuit

The exception created by Justice Story limits third-party experimental use to non-commercial activity.[136] The experimental use argument has succeeded only in circumstances where courts are certain that the use was not tainted with commercial overtones. In *Finney v. United States*,[137] the United States government was sued for allegedly infringing the patent for Velcro. The plaintiff in *Finney* claimed that NASA had used Velcro by putting a Velcro glove on a mannequin for display in a showroom and also that Apollo astronauts had used Velcro during training for a lunar landing.[138] The court quickly dismissed the claim, applying "the doctrine of de minimis non curat lex."[139]

In another case against the government, *Chesterfield v. United States*,[140] the plaintiff accused the government of infringing a patent for metal alloys used in high-speed cutting tools. The court placed great weight on evidence that some of the alloy samples procured by the government were used "only for testing and for experimental purposes" and that none of the evidence suggested that the remaining samples were used any differently.[141]

Courts have found governmental infringement where use was linked to a commercial end. For instance, in *Deuterium Corp. v. United States*,[142] the plaintiff corporation, an inventor of a process to remove hydrogen sulfide from geothermal streams, sued the Department of Energy (DOE) and EIC Laboratories for allegedly testing the patented process on a stream at a Pacific Gas & Electric power plant. The court was not impressed with DOE's protests that its use was experimental and instead relied on a statement by DOE's own project manager, who stated that the purpose of the project was "to explore the technical and economic feasibility of controlling and eliminating the hydrogen sulfide emissions."[143] The court further held that since infringement was not a matter of degree, the de minimis argument did not carry much weight.[144]

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135 *See infra* subpart III.B.

136 *See* Israelsen, *supra* note 130, at 459.

137 188 U.S.P.Q. (BNA) 33 (Ct. Cl. 1975), *aff'd*, 538 F.2d 347 (Ct. Cl. 1976), *cert. denied*, 431 U.S. 905 (1977).

138 *Id.* at 35.

139 *Id.*

140 159 F. Supp. 371 (Ct. Cl. 1958).

141 *Id.* at 375.

142 19 Cl. Ct. 624 (1990).

143 *Id.* at 634 (internal quotation marks omitted).

144 *Id.* at 631.

Some courts have expanded the commercial use test to include governmental activity as potentially infringing. Since the government usually does not operate with an eye toward profit, courts have expanded the scope of liability to hold that normal governmental activity can fall outside of experimental use even if there is no commercial goal. For instance, in *Douglas v. United States*,[145] the court held that "[a]t no time were the accused devices used for amusement, to satisfy idle curiosity, or for philosophical inquiry; to the contrary, each use was in keeping with the legitimate business of the using agency and served a valuable governmental and public purpose."[146] This ruling and others similar to it significantly narrowed the scope of what could constitute experimental use since many governmental functions involve experimental research.[147] In effect, the court equated governmental use and commercial use in determining the scope of third-party experimental use protection.

In *Pitcairn v. United States*,[148] the court found that the government could not claim an experimental use exemption for "testing, evaluational, demonstrational or experimental purposes."[149] The patent in *Pitcairn* covered rotor structures and control systems on helicopters made for the military by the plaintiff.[150] The government claimed that its use of the invention was necessary to test the helicopters for "lifting ability, for the effect of vibration on installed equipment, flight speed and range, engine efficiency, and numerous other factors."[151] The court held these were intended uses of the infringing patent since they were "in keeping with the legitimate business of the using agency," and thus the experimental use exception could not be used as a defense.[152]

C. Experimental Use Treatment in the Federal Circuit

1. Roche v. Bolar.—The only significant ruling in the Federal Circuit on the issue of common-law third-party experimental use is

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145 181 U.S.P.Q. (BNA) 170 (Ct. Cl. 1974), *modified*, 510 F.2d 364 (Ct. Cl.), *cert. denied*, 423 U.S. 825 (1975). In *Douglas*, the military used the inventor's novel jet engine designs without his permission.

146 *Id.* at 177.

147 For instance, in 1995, the National Institute of Health provided over $11 billion for health-related research. Curt Suplee, *Health and Foreign Policy Agencies Brave for Budget Ax; Long-term Spending Freeze Would Leave Viability of Medical Research Agency in Doubt, Director Says*, WASH. POST, May 18, 1995, at A29.

148 547 F.2d 1106 (Ct. Cl. 1976), *cert. denied*, 434 U.S. 1051 (1978).

149 *Id.* at 1125.

150 *Id.* at 1110-11.

151 *Id.* at 1125.

152 *Id.* at 1125-36.

Roche Products, Inc. v. Bolar Pharmaceuticals Co.[153] Roche Products owned the patent to the sleeping pill manufactured under the brand name Dalmane. The defendant had imported five kilograms of flurazepam hydrochloride (HCl), the active and patented ingredient in Dalmane, from a foreign supplier located in a nation not subject to the patent law of the United States.[154] Bolar's actions were based on commercial, not philosophical interests, therefore Justice Story's experimental use exception did not apply. Bolar argued, however, that its actions were only minimally infringing. The trial court accepted the de minimis argument, stating that Bolar obtained no benefit from using flurazepam HCl for experimental purposes.[155] The court held that experiments for a commercial purpose do not constitute infringement when there was no "profit, manufacture, or sale during the patent term."[156]

Bolar also argued that a denial of its right to experiment with flurazepam HCl would effectively extend the life of Roche's patent due to the regulatory delay Bolar would have to face in getting FDA approval for its generic version of Dalmane.[157] The trial court accepted this argument and as a result it denied Roche's motion for a permanent injunction.[158]

On appeal, the Federal Circuit reversed the trial court. The court held, in an invocation of *Pitcairn*,[159] that Bolar's intended use was "for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[160] Although Bolar argued that public policy demanded that the court create an exception for this kind of experimentation, the court disagreed, stating that creating exceptions was an activity better left for Congress.[161]

2. Statutory Experimental Exemptions.—Partly in response to *Roche*, Congress passed The Drug Price Competition and Patent Restoration Act of 1984 (the Act), which specifically validated certain

153 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984). This is the only case in which the Federal Circuit has discussed the doctrine of experimental use at length. *See* Michel, *supra* note 130, at 374.

154 Roche Prods., Inc. v. Bolar Pharm. Co., 572 F. Supp. 255, 256 (E.D.N.Y. 1983), *rev'd*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

155 *Id.* at 257.

156 *Id.* at 258.

157 *Id.* at 257. Prior to the passage of the Drug Price Competition and Patent Term Restoration Act in 1984, the FDA approval process could not begin until the patent on the original drug expired. *See* James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433 (1986).

158 *Roche*, 572 F. Supp. at 258.

159 547 F.2d at 1125-26.

160 *Roche*, 733 F.2d at 863.

161 *Id.* at 864.

kinds of otherwise infringing activity.[162] The Act had two main parts. First, it attempted to create new incentives for "pioneer" drug manufacturers to invest in research and development, and second, it sought to provide low cost generic drugs to the public as soon as practical.[163]

Prior to the passage of the Act, pioneer drug manufacturers had complained that the lengthy FDA approval process for new drugs was decreasing the value of their pharmaceuticals.[164] For example, in 1980, twelve drugs that were approved by the FDA for patient use came onto the market. However, by that time they had an average of only 7.5 years left on their respective patents.[165] This distortion of patent law, which was intended to grant a seventeen-year monopoly, prompted Congress to amend the patent laws to return some of that lost time to inventors who suffered at the hands of regulatory delay.[166] The Act adds up to five years to the life of a patent if unavoidable testing and regulatory approval delayed marketing the invention.[167]

The second major purpose of the Act was to make it easier for generic drug manufacturers to get their drugs to market after the pioneer drug patent expired. This was accomplished by establishing an explicit research exemption that stated, "[i]t shall not be an act of infringement to make, use, . . . or . . . sell 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."[168] The statute overruled part of *Roche* by legalizing experimentation with patented pioneer drugs prior to patent expiration.[169]

Generic pharmaceutical manufacturers can take advantage of section 271(e)(1)'s safe haven through the use of Abbreviated New

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162 35 U.S.C. §§ 156, 271(e)(1) (1994).

163 Amy Stark, Comment, *The Exemption from Patent Infringement and Declaratory Judgments: Misinterpretation of Legislative Intent?*, 31 SAN DIEGO L. REV. 1057, 1059 (1994). A pioneer drug is the patented drug. A generic is the non-patented version of the pioneer drug. *See* Abbott Lab. v. Zenith Lab., 36 U.S.P.Q.2d (BNA) 1801, 1805 (N.D. Ill. 1995).

164 *See* Marjorie Sun, *Study Says U.S. Drug Firms Falling Behind; but Academy Study Contrasts with Earlier Findings by OTA That the Drug Industry Is Healthy*, 221 SCIENCE 1157 (1983).

165 *Shortening 'Drug Lag' at the FDA*, CHEMICAL WK., Apr. 22, 1981, at 26.

166 KENNETH J. BURCHFIEL, BIOTECHNOLOGY AND THE FEDERAL CIRCUIT 376-77 (1995).

167 *Id.* On June 8, 1995, the Uruguay Round Agreement Act (URAA) became law and changed the method of calculating patent terms. Prior to that date, patents lasted seventeen years from the time they were issued. Now, they expire twenty years from the time they are filed and take effect when issued. The Federal Circuit recently ruled in Merck & Co. v. Kessler, 80 F.3d 1543 (Fed. Cir. 1996), that patents in force as of June 8, 1995 can get the restoration extension added to the end of the new recalculated twenty year term. However, patents that were in force on June 8, 1995, only because they were already in the midst of a patent term extension, do not get the advantage of the new twenty year term and expire once the extension ends. *Id.* at 1550.

168 35 U.S.C. § 271(e)(1) (1994).

169 *See* Veronica Lanier, Note, *Medical Device Eligibility for the Statutory Experimental Use Exception to Patent Infringement*, 17 HASTINGS COMM. & ENT. L.J. 705, 713 (1995).

Drug Applications (ANDAs) as administered by the FDA.[170] If a generic manufacturer wishes to begin experimentation on a patented drug prior to expiration, it must file one of four categories of ANDAs.[171] If a generic manufacturer files a Category IV certification, then it is claiming that the pioneer patent is invalid or that the introduction of the generic product into the market before its expiration will not constitute infringement.[172] The Act states that the mere filing of this ANDA constitutes a technical act of patent infringement.[173] Upon filing this class of ANDA, the generic manufacturer must submit its intent to produce the generic in writing to the pioneer patent owner. The owner then has forty-five days upon receipt to institute a patent infringement suit.[174]

In the Act, Congress recognized a public need to exempt drug manufacturers by inducing them to lower the cost of pharmaceuticals.[175] The Act also sought to stimulate innovation in pharmaceutical research by providing incentives to pioneer inventors by reimbursing them for up to five years for time lost to the FDA bureaucratic process. In this respect, the Act eases the tension between pioneer inventors on the one hand and the community of "generic infringers" or experimenters on the other. Pioneers try to expand their monopolistic powers whereas the experimenters wish to limit those powers and introduce their own inventions. Although the Act itself is limited to pharmaceuticals, recent case law has broadened its scope.

3. Cases Examining 35 U.S.C. § 271(e)(1): Validation of Third-Party Experimental Use.—The Supreme Court extended the scope of the Drug Price Competition and Patent Term Restoration Act to include medical devices in *Eli Lilly & Co. v. Medtronic, Inc.*[176] Med-

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170 21 U.S.C. § 355(j) (1994).

171 *See* Abbott Lab. v. Zenith Lab., 36 U.S.P.Q.2d (BNA) 1801, 1805-06 (N.D. Ill. 1995). Category I certifies that there is no patent information regarding the pioneer drug. Category II certifies that the pioneer patent has already expired and that the FDA can approve the generic form immediately upon satisfaction of health and safety requirements. Category III means that the pioneer patent is currently active and the generic producer plans to introduce the generic as soon as the pioneer patent expires. *Id.*

172 *Id.*

173 The statute states:

> It shall be an act of infringement to submit—
> (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or use of which is a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before expiration of such patent.

35 U.S.C. § 271(e)(2) (1994).

174 21 U.S.C. § 355(j)(4)(B)(iii) (1994).

175 H.R. REP. NO. 857, 98th Cong., 2d Sess. (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647.

176 496 U.S. 661 (1990).

tronic developed an implantable cardioverter defibrillator based on patented defibrillators made by Eli Lilly. Medtronic argued that section 271(e)(1) permitted experimentation of their generic defibrillator because, under section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA), Medtronic was required to obtain governmental approval prior to marketing the device.[177] Prior to *Eli Lilly*, section 271(e)(1) had only been applied to pharmaceuticals.[178] In accordance with this precedent, the trial court held that section 271(e)(1) did not apply to medical devices.[179] On appeal, the Federal Circuit held that it was possible for section 271(e)(1) to apply to medical devices, but also stated that it was possible that Medtronic, nevertheless, had violated the statute by pursuing its experimentation for uses not "solely for purposes reasonably related to submission of information" to the FDA.[180]

The Supreme Court affirmed, holding that section 271(e)(1) provides a safe harbor for activities that would otherwise be infringing, if the purpose of those activities was to submit information to the FDA in order to obtain approval to sell a medical device.[181] In ruling that section 271(e)(1) applied to medical devices in addition to drugs, Justice Scalia rejected the argument that legislative history could meaningfully unravel this debate, and instead relied on other sections of the patent code to support his opinion. Specifically, he ruled that the definition of "invention" in section 271(e)(1) applied to any invention, not just drugs.[182] Moreover, Justice Scalia compared the language of section 271(e)(1) to the language of section 156(f)—the part of the Act that extended the life of certain patents whose effective lifetime had been shortened by regulatory delay—in which medical devices are specifically mentioned.[183] Justice Scalia ignored legislative history and

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177 *Id.* at 684.

178 *Eli Lilly* was the first case where medical devices were held to fall under section 271(e)(1) protection.

179 Eli Lilly & Co. v. Medtronic, Inc., 5 U.S.P.Q.2d (BNA) 1760, 1762 (1987).

180 Eli Lilly & Co. v. Medtronic, Inc., 872 F.2d 402, 406 (Fed. Cir. 1989), *aff'd*, 496 U.S. 661 (1990).

181 *Eli Lilly*, 496 U.S. at 663.

182 *Id.* at 665. The Court cites to 35 U.S.C. § 100(a) (1994), which states that "[w]hen used in this title unless the context otherwise indicates . . . [t]he term 'invention' means invention or discovery." Justice Scalia expanded the scope of section 271(e)(1) and shifted the focus of attention to other language in section 271(e)(1) which Eli Lilly argued limited the section's application to drugs. Specifically, the language that the otherwise infringing activity had to be for "development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 496 U.S. at 664 (citing 35 U.S.C. § 271(e)(1) (1994)). This, in turn, eventually led to his conclusion that the "law" that section 271(e)(1) referred to also encompassed section 156(f) which specifically contemplated medical devices falling under the terms of patent restoration. 496 U.S. at 672-73.

183 *Eli Lilly*, 496 U.S. at 674. 35 U.S.C. § 156(f) (1994) states, "[f]or purposes of this section . . . [t]he term 'product' means . . . a drug product . . . [or] . . . [a]ny medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act."

instead assembled the different sections of the patent code, relying upon the vague language in section 271(e)(1) to synthesize the conclusion that medical device experimentation is permitted under section 271(e)(1).[184]

Prior to the Supreme Court's decision in *Eli Lilly*, the lower courts' examination of section 271(e)(1) had focused on the "solely for purposes reasonably related to submission of information" language found in the statute when ruling on third-party experimental use.[185] One of the most important cases involving this language was *Scripps Clinic & Research Foundation v. Genentech*,[186] in which the court refused to allow Genentech to use section 271(e)(1) to escape liability for infringing Scripps's patent.

The patent at issue in *Scripps* was for the purification and concentration of Factor VIII:C—a naturally occurring biological compound that promotes blood clotting by initiating interactions between proteins responsible for clotting.[187] The Scripps method of obtaining this agent involved attaching monoclonal antibodies of another agent to a solid surface, such as one composed of small beads. These antibodies are known to attach to Factor VIII:C; therefore, by pouring large amounts of human or porcine blood plasma over these antibodies, the Scripps scientists were able to separate Factor VIII:C from the rest of the plasma.[188]

Scientists at Genentech developed an improved synthetic technique to manufacture Factor VIII:C that did not require copious amounts of blood plasma.[189] Scripps sued Genentech for patent infringement, and one of Genentech's defenses was section 271(e)(1).[190] Genentech argued that "all [of] its uses of Factor VIII:C, though not solely for purposes related to FDA testing, bear some reasonable relationship to such purposes and hence are noninfringing under § 271(e)(1)."[191] The court rejected this argument, stating that if it were to grant Genentech's request, it would be eliminating the "solely for" language in section 271(e)(1).[192]

Although technically correct, the court's holding unduly limits Congress's ability to promote "[s]cience and useful [a]rts."[193] First,

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184 *Eli Lilly*, 496 U.S. at 669 ("Both parties seek to enlist legislative history in support of their interpretation, but that sheds no clear light.").

185 *See, e.g.*, Scripps Clinic & Research Found. v. Genentech, 666 F. Supp. 1379 (N.D. Cal. 1987), *vacated*, 927 F.2d 1565 (Fed. Cir. 1991).

186 666 F. Supp. 1379 (N.D. Cal. 1987), *vacated*, 927 F.2d 1565 (Fed. Cir. 1991).

187 666 F. Supp. at 1383.

188 *See id.*

189 *Id.* at 1384.

190 *Id.* at 1382.

191 *Id.* at 1396.

192 *Id.*

193 U.S. CONST. art. I, § 8, cl. 8.

the Genentech technology was not merely a copy of the Scripps technique; it was an advancement that had significant advantages over its predecessor.[194] In that respect, it truly was an improvement over the Scripps method and was based on a distinctly different process. Second, the court's actions prevented the public from obtaining another source of an invaluable product. Scripps held a monopoly over Factor VIII:C, and the court's decision effectively prevented the development of a non-infringing alternative.[195] Third, the court misapplied the use-purpose distinction of section 271(e)(1). The court attacked Genentech's purpose for making Factor VIII:C but did not address its actual use.[196] It failed to recognize that section 271(e)(1) addresses only a party's use of a patented invention, not its purpose in doing so.[197]

However, soon after, in *Intermedics, Inc. v. Ventritex, Inc.*,[198] the Federal Circuit identified the distinction between purpose and use and retreated from its position in *Scripps*. *Intermedics* was decided after the Supreme Court's decision in *Eli Lilly* and concerned the patent of a similar medical device—an implantable defibrillator.[199] In this case, the defendant had begun testing its version of a defibrillator that it eventually planned to market.[200] The plaintiff claimed that the defibrillator infringed its patent, and that the defendant's use of the defibrillator did not fall under section 271(e)(1) because of the defendant's inherent commercial motives.[201] The court responded by expanding the scope of the experimental use exception of section 271(e)(1) to allow the defendant, Ventritex, to experiment with its version of the defibrillator.[202] As a result, the court developed a two-part test as a guideline for detecting the presence of experimental use.[203]

The first prong of the *Intermedics* test is to determine whether the defendant committed any acts that would be infringing under a sec-

194 One disadvantage of the Scripps techniques was the possibility of transmitting blood-borne pathogens through the collection process. The Genentech synthetic approach eliminated this possibility. *See* Scripps Clinic & Research Found. v. Genentech, 666 F. Supp. 1379, 1401 (N.D. Cal. 1987), *vacated*, 927 F.2d 1565 (Fed. Cir. 1991).

195 *See* Karp, *supra* note 130, at 2186.

196 *See* Parker, *supra* note 130, at 637.

197 Nowhere in section 271(e)(1) is the word "purpose" mentioned.

198 775 F. Supp. 1269 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993) (unpublished opinion).

199 *Intermedics*, 775 F. Supp. at 1276.

200 *Id.*

201 *Id.* at 1273.

202 *Id.* at 1278.

203 *Id.* at 1281.

tion 271(a) analysis.[204] If none of the acts constitute infringement under section 271(a), then there is no need to advance to analysis under the 271(e)(1) exception and the inquiry ends. If, however, a use is infringing under section 271(a), the next step is to resolve whether the safe harbor of section 271(e)(1) applies. Once a defendant reaches this stage, the inquiry focuses on what the defendant has done with the invention, not what she intends to do with it in the future.[205] Some commentators argue that this kind of exception undermines the delicate incentive system that stimulates research and development,[206] whereas others support the expansion as necessary for continued innovative progress.[207] The court's decision to focus on use instead of purpose benefits those engaged in academic research. Many researchers have projects that have commercial purposes or ends. However, before those ends can be met, a substantial amount of time and energy is often needed for experimentation. Simply put, protecting academic experimental use under a section 271(e)(1) analysis protects and promotes scientific progress.

4. The Proposed Patent Competitiveness and Technological Innovation Act of 1990.—In 1990, Congress attempted, but failed, to radically change the patent law of the United States by implementing a statute that it hoped would "promote the progress of science by improving this country's patent law."[208] The broad-reaching titles of the Act cover inventions made aboard spacecraft and patents on transgenic animals, and calls for a significant expansion of the breadth of allowable experimental use.[209] The proposed broadening of experimental use stated:

> It shall not be an act of infringement to make or use a patented invention solely for research or experimentation purposes unless the patented invention has a primary purpose of research or experimentation. If the patented invention has a primary purpose of research or experimentation, it shall not be an act of infringement to manufacture or use such invention to study, evaluate, or characterize such invention or to create a

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204 *Id.* 35 U.S.C. § 271(a) (1994) states, "[e]xcept as otherwise provided in this title, whoever without authority makes, uses, . . . or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent."

205 *Intermedics*, 775 F. Supp. at 1280. The court defines "use" to mean a physical act whereas a "purpose" is an intention to do an act. Under the court's analysis, the defendant may intend to infringe the pioneer patent but so long as it does not do so, there is no infringement under section 271(e)(1). *Id.*

206 *See, e.g.*, Thomas F. Poche, *The Clinical Trial Exemption from Patent Infringement: Judicial Interpretation of Section 271(E)(1)*, 74 B.U. L. REV. 903, 920-25 (1994) (arguing that the *Intermedics* decision undermines social welfare by decreasing the incentives to invest in research).

207 *See, e.g.*, Parker, *supra* note 130 (supporting the expansion of the experimental use exception to patent infringement).

208 H.R. REP. 960(I), 101st Cong., 2d Sess. 1 (1990).

209 *Id.* at 1-2.

> product outside the scope of the patent covering such invention. This subsection does not apply to a patented invention to which subsection (e)(1) applies.[210]

Commentators, not surprisingly, are split on the utility and appropriateness of this Act. Some argue that it would erode the country's carefully crafted incentive system and would be disastrous.[211] Others counter that, at the very least, a research exemption for university research is warranted.[212] This Comment welcomes the proposed Act's broadening of the experimental use infringement exception, but cautions that, as written, the Act's breadth should be altered to reflect university and non-profit uses.

D. Recommendations.—As stated earlier, scientists engaged in basic research at universities publish their innovations in the scientific literature. Furthermore, scientists read this literature to advance their knowledge and skills.[213] Any broadening of the safe harbor provisions of the third-party experimental use doctrine needs to recognize that a significant portion of scientific innovation occurs in university, government, and private non-profit environments where patents are not used as often as they are in private industry. For example, since 1990, General Electric and IBM have been issued about the same number of patents as all academic institutions put together.[214]

However, universities publish significantly more than their industrial counterparts in scientific journals. For example, in *Science*, a preeminent journal, university researchers far outproduce their industrial counterparts. In a random selection of four *Science* publications, university authors outpublished their industrial counterparts more than five to one.[215] Any proposed changes in patent law should reflect how those changes will impact this important avenue of research. In addition, the fast paced growth of patent publication in academic research

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210 H.R. REP. 960(I), 101st Cong., 2d Sess. 65-66 (1990).

211 *See, e.g.*, Karp, *supra* note 130, at 2188.

212 *See, e.g.*, Parker, *supra* note 130, at 660-61.

213 *See infra* note 8 and accompanying text.

214 I base this statement on research conducted on WESTLAW's Patents-90 database. On September 28, 1996, there were 6,104 hits where General Electric was a patent assignee and 7,533 for IBM. For universities and other academic institutions, I combined the search results for each patent assignee that was classified as a "university," "school," "college," "institute of technology," or "research foundation." This resulted in 12,205 hits.

215 Issues of *Science* from Sept. 15, 1995; Aug. 11, 1995; July 10, 1987; and Sept. 25, 1987 were chosen at random from the stacks at the Northwestern University School of Law library. Only the *Reports* section of each journal was tabulated. Multiple university authors for the same paper were counted only once. Papers that had both university and corporate authors were counted once under each heading. Over thirty reports had at least one university author, whereas only six reports had authors from industrial laboratories. The AAAS, publishers of *Science*, do not record the number of university and corporate authors. However, they confirmed that the majority of their authors come from universities. Telephone Interview with the Publications Staff at the American Association for the Advancement of Science (Aug. 28, 1996).

communities will impact this analysis. The scope of the proposed Patent and Competitiveness Innovation Act would provide protection to university researchers who experiment with patented inventions so long as those inventions are not meant for university research. For example, the Act does not protect a researcher wishing to utilize the Harvard mouse[216] since that invention's market is solely for the research community. Nevertheless, the Act would protect university researchers from potential patent infringement lawsuits for using many other patented inventions. Some have argued that in the university context, this statute fixes a problem that does not exist.[217] Representative Moorhead, in attacking the experimental exception provision, wrote "[i]f the existing patent law is harming universities or interfering with their research, I believe they should come forward and explain the nature of the problem."[218] However, the nature of the problem is not what has happened in the past, but what is happening in the present and will happen in the future.

For example, during the 1970s, academic institutions published only about 2400 patents.[219] In the 1980s, that number rose to about 7000. Between 1990 and September 1996, these institutions published over 12,000 patents.[220] The trend in the way universities go about the business of research suggests that a change in the law will be needed to protect educational and similar centers of research.

In 1980 and again in 1984, the patent laws of the United States were changed so that universities could keep the titles to patents issued based on federally-funded research projects.[221] This may explain the recent increase in patents being filed by universities.[222] Patents issued to universities are often licensed to industry in the hope of developing commercially useful products and processes.[223] For instance, the Massachusetts Institute of Technology received about $5.5 million in licensing fees in 1991.[224] These licenses could potentially be a liability in the future if the current trend of patent development among universities continues. At the heart of the problem lies the manner in

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216 H.R. REP. 960(I), 101st Cong., 2d Sess. 65 (1990).

217 "The stated purpose of this title is to protect university research activity. I fail to understand what universities are being protected from. There has never been a case, to my knowledge, where a university has been sued for patent infringement for carrying on research on a patented invention." H.R. REP. 960(I), 101st Cong., 2d Sess. 69 (1990).

218 *Id.*

219 WESTLAW search on Patents-70 & Patents-80 on Sept. 28, 1996. See *supra* note 214 for a description of the search procedure.

220 WESTLAW search on Patents-90 on Sept. 28, 1996. See *supra* note 214 for a description of the search procedure.

221 *See* Michel, *supra* note 130, at 377-81.

222 *Id.* at 377-79.

223 *Id.* at 379-80.

224 *Id.* at 380 n.59.

which research occurs at universities. University researchers rarely check the patent literature to determine whether their proposed research will infringe on any patents. As the value of university licenses continues to increase and as federal funds become harder to get, university researchers may face increasing opposition from corporations who may vehemently attempt to prevent their intellectual property from being used or sold.[225] Universities, in cooperation with industry, may find themselves embroiled in costly intellectual property litigation. In recent months, two universities have sued corporations for infringement of valuable patents. Both the University of California and the Johns Hopkins University are involved in large and expensive patent litigation.[226] As plaintiffs, they were able to carefully analyze the costs and benefits of the litigation prior to filing suit. A more problematic scenario arises when universities—especially those without the substantial resources of the University of California or Johns Hopkins—find themselves as unexpected defendants in expensive patent infringement suits. The effect of this type of litigation could be disastrous for academic research.

The effect of extensive patent litigation against universities may chill many research activities, not just those in which an invention may be patented, by requiring researchers to investigate whether their proposed laboratory research infringes any known patent. While corporations have legal departments geared towards answering potential legal quagmires, universities do not have the infrastructure to render routine opinion work to researchers. One commentator noted to Congress that "[i]t is ludicrous to expect every researcher to obtain a license in advance of conducting a simple experiment, each time he sees a newly issued patent and attempts to duplicate the efforts in his

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225 For instance, the Cohen-Boyer gene splicing patent, invented by University of California and Stanford researchers, is worth $100 million. Michel, *supra* note 130, at 379.

226 *See* Johns Hopkins Univ. v. Cellpro, 894 F. Supp. 819 (D.Del. 1995); The Regents of the Univ. of Cal. v. Eli Lilly & Co., 777 F. Supp. 779 (N.D. Cal. 1991).

A recent Supreme Court decision may affect the ability to sue state universities in the future. In Seminole Tribe of Fla. v. Florida, 116 S. Ct. 1114, 1123 (1996) (citing Green v. Mansour, 474 U.S. 64, 68 (1985)), the Supreme Court limited the ability of private plaintiffs to sue states. The court ruled that the Seminole tribe could not sue the state of Florida in federal court under the Indian Gaming Regulatory Act. The Court ruled that in this instance, Congress lacked the authority to abrogate the states' sovereign immunity. Similarly, Congress has specifically included states as potential patent defendants. 35 U.S.C. § 271(h) (1994). Whether Congress has this authority under *Seminole Tribe* remains unanswered. In his dissent, Justice Stevens argued that this would also prevent parties from suing states for intellectual property infringement. *Id.* at 1134 n.1 (Stevens, J., dissenting). In fact, one court stated, in dicta, that *Seminole Tribe* would apply to patent law. Gen-Probe, Inc. v. Amoco Corp., 926 F. Supp. 948, 954 n.6 (S.D. Cal. 1996). Nevertheless, *Seminole Tribe* does not apply to private institutions and the question as to whether so-called public institutions are really arms of the State is not obvious. *See, e.g., id.* at 953 (citing a five-factor test to determine whether a state entity is an arm of the State for Eleventh Amendment purposes).

laboratory."[227] Litigation between industry and universities may cause researchers to obtain legal advice prior to using university facilities, which may lead to the abandonment of some research activities. This would affect university publications in both the patent and, more importantly, the scientific literature. This would certainly controvert the constitutional mandate of promoting progress in science. Therefore, universities and other non-profit research organizations that freely and publicly disseminate their research should be absolutely exempt from section 271(a) infringement for making or using a patented invention so long as the fruits of that labor do not result in commercial activity by the university.[228]

A potential problem lies in the area of industry-sponsored research. A company may try to avoid its own section 271(a) bar by funding non-exempt universities to conduct the formerly prohibited research. This problem can be remedied by defining this kind of activity as willful infringement on the part of the corporation, and place the burden on it to ensure that the proposed academic research will not infringe any patents. This is not an onerous requirement since corporations must do these searches now anyway whenever they engage in research activities.

For public policy reasons, universities that engage in developing commercial products that are distinct from, but are based on, patented inventions, should also be exempt from suit. This provision is discussed in the proposed 1990 Act.[229] The Act's design around provision allows inventors to use patented inventions to develop new inventions that, although not identical to the patented invention, rely on them.[230] Under this Comment's proposal, patent owners would

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227 H.R. REP. 960(I), 101st Cong., 2d Sess. 44 (1990).

228 As stated earlier, it is unlikely that a corporation will spend valuable resources suing a university for a de minimis infringement. Nevertheless, by exempting researchers from infringement actions, universities will not have to develop a costly infrastructure to monitor research activities for potential patent infringement. This will provide a "safe harbor" for infringing research that does not lead to commercial development, thereby focusing potential litigation only on those infringing activities that are used commercially.

229 The Act would have codified this protection by exempting from infringement "product[s] outside the scope of the patent covering such invention." H.R. REP 960(I), 101st Cong., 2d Sess. 66 (1990).

230 It is important to note that this proposal is unrelated to the doctrine of equivalents. The doctrine of equivalents "prevents a copyist from evading patent claims with insubstantial changes." Valmont Indus. Inc. v. Reinke Mfg. Co., 983 F.2d 1039, 1043 (Fed. Cir. 1993). The purpose of the doctrine is to protect a patent owner from a copyist who tries to make, use, offer to sell, or sell an invention that is similar to the patented one but does not fall literally within the claim language. The doctrine extends the reach of the patent to similar inventions so long as the distinguishing feature "add[s] nothing of significance to the claimed invention." *Id.*

In contrast, this Comment proposes that an inventor should be allowed to use patented inventions as "intermediates" in developing new inventions. The new inventions would not be "equivalent" to the original ones in any manner. Part IV discusses a hypothetical situation that illustrates this concept.

not be permitted to prevent any experimentation with patented inventions regardless of the ultimate purpose or outcome so long as the experimenter is in an academic or other non-profit research institution. Given the growth in university patent development, however, it is possible that that experimentation may lead to a patented invention.[231] In this situation, the underlying patent owner should be compensated through a compulsory license.

Compulsory licenses are generally thought of as a state mandated allowance permitting infringers to make, use, or sell patented inventions without obtaining consent so long as the infringers pay reasonable royalties to the patent owner.[232] Their theoretical basis relies on either the theory of lack of adequate supply or public policy or both.[233] Under the adequate supply theory, compulsory licenses are granted when a "patentee is unable to meet the demand for its product under an exclusive right to manufacture and sell" a product.[234] Public policy reasons include areas important to public health. For instance, the Environmental Protection Agency has the statutory right under the Clean Air Act to implement a compulsory license for inventions necessary for emissions limitations.[235] These licenses prevent inventors from suppressing their inventions when their use would be in the public's best interest. In his dissent in *Special Equipment Co. v. Coe*,[236] Justice William Douglas provided a philosophical framework for preventing patent owners from suppressing their inventions:

> It is difficult to see how that use [suppression] of patents can be reconciled with the purpose of the Constitution "to promote the Progress of Science and the useful [A]rts". . . . Take the case of an invention or discovery which unlocks the doors of science and reveals the secrets of a dread disease. Is it possible that a patentee could be permitted to suppress that invention for seventeen years . . . and withhold from humanity the benefits of the cure? But there is no difference in principle between that case and any case where a patent is suppressed because of some immediate advantage to the patentee.[237]

A university researcher who develops a commercially-patented invention should pay reasonable royalties to the owners of any patent she used in making her design. Moreover, those owners should not be

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231 *See infra* Part IV.

232 *See* Charles Pfizer & Co. v. Federal Trade Comm'n, 401 F.2d 574, 577 (6th Cir. 1968) (holding that the FTC has authority to require compulsory licensing of tetracycline and aueromycin patents on a reasonable royalty basis), *cert. denied*, 394 U.S. 920 (1969).

233 *See, e.g.*, Cole M. Fauver, Comment, *Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come*, 8 NW. J. INT'L L. & BUS. 666 (1988).

234 *Id.* at 668-69.

235 42 U.S.C. § 7608 (1994).

236 324 U.S. 370 (1945).

237 *Id.* at 383 (Douglas, J., dissenting).

allowed to suppress the researcher's patent thereby stifling an important avenue of innovation.[238]

IV. A Comparison of the Two Experimental Use Doctrines as They Act to Stimulate Innovation

The interaction between inventor experimental use of the section 102(b) variety and third-party experimental use that allows infringers to use patented inventions can be illustrated by considering a hypothetical situation. Several years ago, an enormous amount of publicity was focused on the *Taxus Brevifolia* yew tree in the Pacific Northwest. Researchers discovered that the bark of the tree contained a potent anti-cancer agent called taxol that could be separated and purified only at great expense.[239] There was great interest in developing a synthetic method of producing taxol because this yew tree is not in abundant supply.[240] Researchers found a method to synthesize the drug without reliance on yew trees.[241] Unfortunately, the complexity of the target molecule required a very long and complex synthesis that would be very costly to produce on a commercial scale.[242] The following hypothetical involving the experimental use doctrines is based around the discovery of a novel and inexpensive method of producing taxol.

A researcher discovering an inexpensive method of producing a highly-prized pharmaceutical would undoubtedly confer with colleagues and peers to gain their input and advice concerning the synthesis. Under the present system of section 102(b) experimental use, a researcher discussing a successful synthesis with a colleague may inadvertently activate the public use clock.[243] Under current law, the in-

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238 Commentators are split on the applicability of compulsory licensing. *Compare* Paul Gormley, Comment, *Compulsory Patent Licenses and Environmental Protection*, 7 Tul. Envtl. L.J. 131 (stating that compulsory licensing is an excellent device for promoting the development of beneficial technology in the area of environmental science) *with* Alan M. Firsch, Comment, *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem*, 34 Jurimetrics J. 295 (arguing compulsory licensing lowers company revenues and that ultimately leads to lower levels of research and development). Neither author addresses the issue of design-around compulsory licenses that this Comment proposes. In addition, this Comment does not propose a system whereby any invention has an implicit compulsory license attachment. Rather, compulsory licensing would be limited to those few instances where a university or other research oriented non-profit institution would develop a commercially viable product or process whose components or elements may infringe a patent.

239 A single treatment can cost more than $1250. Richard Saltus, *TAXOL New Drug Playing Wider Role*, Boston Globe, July 17, 1995, at 25.

240 Ann Thayer, *Firms Dispute Cancer Drug Patent Rights*, 73 Chemical & Eng'g News 8 (1995).

241 *Id.*

242 Chris Schaller, *No Easy Cure for Drug Costs*, Grand Rapids Press, April 17, 1994, at 2.

243 "It does not take much to trigger the 'public use' statutory bar to a patent." National Research Dev. Corp. v. Varian Assocs., Inc., 822 F. Supp. 1121, 1129 (D.N.J. 1993), *aff'd*, 17 F.3d

ventor has the burden of showing experimental use.[244] The current system places an undue emphasis on the control aspect of experimentation, and as a result, the researcher and society are at the mercy of court reevaluation of substantive research. By focusing too heavily on control, the court retains the power to usurp the inventor's ability to analyze the invention. In *Smith*, this was taken to an extreme when the court actually dictated where experimentation should have been done.[245] Under the proposed system, however, where inventors have the ability to show a balance of experimental use factors, the inventor would have the burden of producing documents, records, and expert testimony to prove that the advice of colleagues was necessary and crucial to fine tune the synthesis. Letting the inventor control when an invention is no longer experimental affords her the power to perfect her invention. This way, the inventor has the opportunity to prove her subjective experimental intent without undue legal interference.

Let us assume that the novel and creative method of synthesizing taxol involved producing a novel intermediate compound. Let us also assume that a researcher files patents for both the synthesis and the intermediate, while simultaneously submitting her research to a prestigious journal. Another researcher in a completely different field reading the journal realizes that the intermediate could be used to make a completely different product, such as a polymer, and immediately sets out trying to duplicate the synthesis. Once the patents are issued, any use of the intermediate by the second researcher would constitute patent infringement.[246] The Patent Term Restoration Act of 1984 only allows experimentation with a small number of inventions and, even then, only under circumstances in which the inventions are being prepared for FDA approval.[247] No such mechanism exists for preliminary research. The proposed Act of 1990, however, would have protected such research.[248] If the original patent holder was a pharmaceutical corporation zealously guarding its patented intermediate, it might consider this subsequent research to be an infringement.[249] Under the present system, the second researcher could be forced to halt her research—under section 271(a)—if she had tried to develop anything commercially that relied upon the intermediate.

1444 (Fed. Cir. 1994). In *Varian*, a handful of scientists observed a complex laboratory instrument that triggered the public use bar. *Id.* at 1130.

244 *See* TP Lab., Inc. v. Professional Positioners, Inc., 724 F.2d 965, 971 (Fed. Cir. 1991).

245 *In re* Smith, 714 F.2d 1127, 1135-36 (Fed. Cir 1983).

246 35 U.S.C. § 271(a) (1994).

247 *See supra* section III.C.2.

248 H.R. REP. No. 960(I), 101st Cong., 2d Sess. 65-66 (1990).

249 A similar situation has already occurred. Johnson & Johnson recently informed university researchers that use of its patented cell line may constitute infringement. Michel, *supra* note 130, at 385-86.

Moreover, the university may be liable for damages. Under the proposed system, the researcher would not have to fear that her innovative use of the intermediate would be infringing. Her academic research would be absolutely exempt from suit. If her research led to a different commercial application, then the patent owner would be compensated by receiving royalties. This situation is not to be confused with one where the university is trying to commercialize an invention that is similar to the patented one. For instance, the university and the researcher would not have a safe harbor if they attempted to market the patent intermediate themselves.[250] Similarly, universities under the proposed system would still be able to sue for patent infringement, as Johns Hopkins and the University of California have already done.[251]

V. Conclusion

A challenging new era confronts the patent law system. New technologies are changing the way patent law is being conceived and practiced. In the past thirty years, the law has been forced to respond to rapid advances in technology ranging from the computer revolution to dramatic developments in biotechnology. Universities have played a key role in these advancements. Universities now pose new challenges to the law as they emerge as active participants in the patent race. What makes the university and its researchers interesting is the seemingly disparate functions of promoting scientific endeavors through freely accessible publication in the scientific literature and the increasing reliance on patents as way to replace dwindling federal research dollars. The experimental use exceptions should be based on the philosophy that science is best conducted by scientists. In the inventor based experimental use doctrine, scientists should be given the benefit of the doubt as they determine when experimentation ends. By granting them such leeway, society encourages innovation. In the third-party experimental use exception, the law should recognize both the important contributions non-profit research makes to society and the precarious future it faces as federal research funds diminish.

Law should provide a framework where the public can best be served by the achievements of scientific prowess. Letting researchers engage in experimental pursuits—either as inventors or infringers—will ultimately better promote progress in science.

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250 *See supra* note 231 and accompanying text.

251 *See supra* note 226 and accompanying text.