The Experimental Use Exemption to Patent Infringement: Information on Ice, Competition on Hold

Ted Hagelin

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THE EXPERIMENTAL USE EXEMPTION TO PATENT INFRINGEMENT: INFORMATION ON ICE, COMPETITION ON HOLD

Ted Hagelin*

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* Ted Hagelin, Board of Advisors Professor of Law, Director, New York State Science & Technology Law Center and Syracuse University New Technology Law Center, Syracuse University College of Law. The views expressed in this Article are solely my own and do not represent the position of the New York State Office of Science, Technology and Academic Research or the New York State Science & Technology Law Center. I want to thank my colleague, Professor Lisa Dolak, for her excellent review of an earlier draft of this Article. I also want to thank Jeremy Swift, SUCOL third year student, for his excellent research assistance. Finally, I want to thank the SUCOL Summer Research Grant Program for support of work on this Article.

1. The title portion “Information on Ice” is a reference to Judge Newman’s dissent in Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 875 (Fed. Cir. 2003) (Newman, J., concurring in part, dissenting in part), which argued that research using patented subject matter should be facilitated as doing so serves the public interest more than placing the information “on ice.”
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I. INTRODUCTION

The U.S. patent system is built upon a delicate balance between the rights of patent owners, the rights of the public at large, and the rights of market competitors. ² The patentee is granted broad rights to exclude others from making, using, or selling the patented invention in order to reward

². Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146 (1989) ("The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'" (quoting U.S. CONST. art I, § 8, cl. 8)).
the patentee’s investment in creating the invention. In exchange for the grant of patent rights, the patentee is required to disclose the details of the invention in a patent application. This disclosure benefits both the general public by adding to the store of scientific knowledge, and market competitors by providing information about rival products and processes. In essence, the patentee’s property rights come at the expense of enabling challenges to the value of those rights through further scientific advances and increased competitor know-how. Conversely, the access by the public and market competitors to the information contained in the patent application comes at the expense of abiding by limitations upon the use of that information.

3. See Valley Drug Co. v. Geneva Pharm., Inc., 344 F. 3d 1294, 1304 (11th Cir. 2003) ("This exclusionary right is granted to allow the patentee to exploit whatever degree of market power it might gain thereby as an incentive to induce investment in innovation and the public disclosure of inventions.").

4. See Universal Oil Prods. Co. v. Globe Oil & Refining Co., 322 U.S. 471, 484 (1944) ("As a reward for inventions and to encourage their disclosure, the United States offers a seventeen-year monopoly to an inventor who refrains from keeping his invention a trade secret.").

5. In re Argoudelis, 434 F.2d 1390, 1394 (C.C.P.A. 1970) (Baldwin, J., concurring) (noting that one of the roles of the enabling provision of the Patent Act is to "provide the assurance that the public will, in fact, receive something in return for the patent grant. This consideration is, of course, the full and complete disclosure of how to make and use the claimed invention. Thus, the patent adds a measure of worthwhile knowledge to the public storehouse.").

6. See Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979) ("First, patent law seeks to foster and reward invention; second, it promotes disclosure of inventions, to stimulate further innovation and to permit the public to practice the invention once the patent expires; third, the stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public."); see also F.M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 442-43 (2d ed. 1980) (detailing the costs and benefits of the patent system).

7. See Bonito Boats, 489 U.S. at 146 ("From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy."). The Supreme Court has also observed that:

[w]hen a patent is granted and the information contained in it is circulated to the general public and those especially skilled in the trade, such additions to the general store of knowledge are of such importance to the public weal that the Federal Government is willing to pay the high price of 17 years of exclusive use for its disclosure, which disclosure, it is assumed, will stimulate ideas and the eventual development of further significant advances in the art.


8. See Fla. Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank, 527 U.S. 627, 637 (1999) ("[B]ecause courts have continually recognized patent rights as property, the fourteenth amendment prohibits a State from depriving a person of property without due process of law."). One commentator notes that:
Experimentation with patented inventions is an activity that is central to the patent system balance. On the one hand, if researchers and competitors are able to use patented inventions for their intended purposes under the guise of experimentation, then patentees are deprived of economic benefits and the incentive to invest in inventive activities is diminished. On the other hand, if the public and competitors are unable to use patented inventions for genuine experimentation, then scientific knowledge is retarded and market competition is limited. Today, there are two types of experimental use exemptions to patent infringement.

The first, the common law experimental use exemption, was developed through a long line of judicial decisions and applies to all inventions. The second, the Hatch-Waxman statutory experimental use exemption, was

upon issuance of the patent, as already discussed, the information in the patent is placed in the public domain. Since [the inventor] independently developed the process, her public disclosure of the process, via the patent, is analogous to someone independently developing and disclosing a trade secret. Such behavior would end the secret status of the trade secret and terminate its existence. Therefore, the granting of a patent to [the inventor] and the termination of [another’s] property rights in the trade secret are consistent with property theory. This result also helps to further secure for the public the benefit of the process and is consistent with an underlying policy of intellectual property law. The public disclosure that accompanies issuance of a patent provides more benefit to the public than the public benefit received if the process was maintained as a secret pursuant to trade secret law.


Under the exclusionary patent grant, the patent owner could stop a researcher’s activities if the researcher created a copy of the invention on his own and experimented with that copy. However, to the extent that free access to knowledge is a requirement for technological progress, this right of the patent owner runs directly contrary to the avowed purpose of the patent law: the encouragement of the useful arts and science.

*Id.* at 54.


11. See Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 91 (“Patent exclusivity, while promoting inventive progress by providing incentives for innovation, can slow technical progress if the best follow-on inventors are prevented from building upon the inventive idea during the patent term.”).

12. See infra Part II.

13. See infra Part II.A.
enacted by Congress in 1984 and applies only to drugs and medical devices.\textsuperscript{14}

Properly reconciling the interests of patentees, the public, and market competitors has never been more important.\textsuperscript{15} Invention of new technology is critical to the success of U.S. companies,\textsuperscript{16} the growth of the U.S. economy,\textsuperscript{17} the health and welfare of U.S. citizens,\textsuperscript{18} and U.S. competitive advantage in global trade.\textsuperscript{19} Perhaps because of its growing importance in our technology-based society, or perhaps because of its inherent interest to an array of professionals, experimental use of patented inventions has been the subject of a great deal of thoughtful scholarship. Writers have considered the development of both the common law and Hatch-Waxman experimental use exemptions, reviewed their operation in different research contexts, discussed enacted and proposed legislative changes, presented arguments in favor of expanding and contracting the scope of the experimental use exemptions and, most of all, proposed a myriad of law reform measures to shape the future development of the experimental use exemptions.\textsuperscript{20} This Article will attempt to synthesize the considerable

\begin{itemize}
\item \textsuperscript{14} See infra notes 138-39 and accompanying text.
\item \textsuperscript{15} See Bruzzone, supra note 9, at 55 ("Today, however, the ever increasing importance of technological development, the increased use of reverse engineering, and the need for common world-wide patent protection are all substantial motivations for a clearer articulation of standards.") (citations omitted).
\item \textsuperscript{16} See NAT'L SCI. BD., 1 SCIENCE AND ENGINEERING INDICATORS-2002 6-5 (2002). The report points out that "high-technology industries are driving economic growth around the world." Id. at 6-6. Within our own borders, "[d]emand for high-technology products in the United States far exceeds that in any other single country; in 1998, it was larger (approximately $768 billion) than the combined markets of Japan and the four largest European nations—Germany, the United Kingdom, France, and Italy (about $749 billion)." Id. at 6-9, 6-9 & fig. 6-7. Also, "U.S. industries that traditionally conduct large amounts of R\&D have met with greater success in foreign markets than those that are less R\&D intensive, and they have been more supportive of higher wages for their employees." Id. at 6-18.
\item \textsuperscript{17} Illustrative of this growth is the fact that from 1995 to 1998, high technology production on a global level grew at a rate three times as fast as all other manufacturing sectors. Id. at 6-6 fig. 6-1.
\item \textsuperscript{18} See id. at 6-23 ("In 1999, corporate patent activity reflected U.S. technological strengths in medical and surgical devices, electronics, telecommunications, advanced materials, and biotechnology."). These areas are obviously essential to maintaining a healthy and technologically advanced society. See id. at tbl. 6-3 (showing that the top fifteen most emphasized patent classes in the U.S. involve these areas).
\item \textsuperscript{19} Id. at 6-11 ("Throughout the 1990s, U.S. exports of advanced technology products exceeded imports in 8 of 11 technology areas."). Id. at 6-11. Those areas include advanced materials (semiconductors, optical fiber cable, etc.), aerospace, biotechnology, electronics, flexible manufacturing, nuclear technology, software products, and weapons. Id. In 1999, trade in advanced technology products accounted for 29.2% of exports, versus 17.5% of imports, and accounted for $381 billion out of $1.7 trillion involving U.S. trade in merchandise. Id.
\item \textsuperscript{20} See infra Part III. The focus of this section is on the commentary related to the common law experimental use exemption and not the Hatch-Waxman exemption. The goal of this Article
scholarship in the field, provide additional context to the debate, and propose a new statutory experimental use exemption that would treat all inventions in the same way.

Part I of this Article will discuss the common law and Hatch-Waxman experimental use exemptions to patent infringement. The discussion of the common law experimental use exemption will consider the different tests that courts have developed to distinguish between permissible and impermissible experimental uses of patented technology and the rationales that have been advanced in support of these tests. The discussion of the Hatch-Waxman experimental use exemption will describe the Hatch-Waxman Act and consider the cases that have arisen under the Act with special attention to the most recent case, which was decided by the U.S. Court of Appeals for the Federal Circuit, and later reviewed by the U.S. Supreme Court. Part II of this Article will discuss the common law experimental use exemption in the context of other U.S. and foreign patent law policies. The U.S. patent law policies considered are the policy of requiring adequate disclosure of the invention in the patent application and the policy of not allowing the lawful scope of the patent to be expanded by private contract. The foreign patent law policies considered are the policies of individual countries and international organizations that expressly allow for the experimental use of patent subject matter in a variety of circumstances. Part III of this Article will discuss and critique the various law reform measures that have been proposed to reconcile the competing interests in the experimental use of patented technology. These law reform measures will be considered in terms of three aspects of experimental use: the nature of the organization conducting the

is to revise the common law exemption in such a manner that revision or further discussion of the Hatch-Waxman amendment would not be necessary. However, for commentary relating to Hatch-Waxman, see generally Laura J. Robinson, Analysis of Recent Proposals to Reconfigure Hatch-Waxman, 11 J. INTELL. PROP. L. 47 (2003) (discussing the problems inherent in Hatch-Waxman's thirty-month stay provision, (21 U.S.C.A. § 355(j)(5)(B)(iii) (West 2003)), and concluding that greater FTC and FDA scrutiny, rather than legislative proposals, would be a far better solution to current industry abuses); Janet A. Gongola, Note, Prescriptions for Change: The Hatch-Waxman Act and New Legislation to Increase the Availability of Generic Drugs to Consumers, 36 IND. L. REV. 787 (2003) (arguing that Congress should pass the Drug Competition Act, S. 754, 107th Cong. (2001), to protect the pharmaceutical industry against anticompetitive agreements made between brand-name and generic drug manufacturers in response to Hatch-Waxman's convoluted provisions); Ned Milenkovich, Comment, Deleting the Bolar Amendment to the Hatch-Waxman Act: Harmonizing Pharmaceutical Patent Protection in a Global Village, 32 J. MARSHALL L. REV. 751 (1999) (arguing that the exemption provision of Hatch-Waxman should be eliminated in order to bring U.S. patent law in compliance with the TRIPS Agreement).

23. See infra Part II.
24. See infra Part III.
experimentation, the purpose of the experimentation, and the nature of the patented technology used in the experimentation. The discussion of the law reform proposals will be organized from the most limited proposed exemptions to the broadest proposed exemptions.

Part IV of this Article will propose a new statutory experimental use exemption. The proposed experimental use exemption would be asymmetric in nature, and differentiate the patented subject matter that could be experimentally used by corporations, small businesses, and nonprofit research organizations. For corporations, the proposed experimental use exemption would only allow the use of patented subject matter owned by other corporations. For small businesses and nonprofit research organizations, the proposed experimental use exemption would allow the use of patented subject matter owned by corporations, small businesses, and nonprofit research organizations. The proposed experimental use exemption would permit the same experimental uses of all patented subject matter for corporations, small business and nonprofit research organizations. Those allowed uses would be for the purposes of education, scientific research, evaluating patent specifications, disclosures and claims, improving upon the patented subject matter, engineering around the patented subject matter, and developing competing, non-infringing patent subject matter. Part IV will also describe a means to distinguish between permissible and impermissible uses of patented subject matter under the proposed exemption, suggest statutory language to implement the proposed exemption, and discuss the benefits of the proposed exemption.

II. THE EXPERIMENTAL USE EXEMPTIONS

A. The Common Law Experimental Use Exemption

1. Early Cases

The origin of the common law experimental use exemption to patent infringement is universally attributed to Justice Story's opinion in Whittemore v. Cutter. In Whittemore, Justice Story stated that "it could never have been the intention of the legislature to punish a man, who constructed such a [patented] machine merely for philosophical

25. See infra Part IV.
26. 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600). The origins of the experimental use exemption have been traced by several other authors. See, e.g., Bruzzone, supra note 9, at 56-57 (exploring the origins of the exemption at common law). However, the origins themselves are a
experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.” 27 At the time Justice Story wrote these words in 1813, “philosophical” referred to the field of “natural philosophy” or what we call today “science.” 28 Properly interpreted, Justice Story’s statement contained two distinct experimental use exemptions to patent infringement: an exemption for using patented subject matter in order to perform scientific experiments and an exemption for using patented subject matter in order to test its claimed utility. 29

In Whittemore, Justice Story also addressed two other important questions regarding patent infringement: the relationship between the different acts of patent infringement enumerated in the patent statute and the relationship between damages and patent infringement. 30 The Patent Act of 1800 provided that a patentee could bring an infringement action against any person who “shall make, devise, use, or sell” a patented invention without authorization. 31 It was Justice Story’s opinion that each of these activities standing alone could constitute an act of infringement. 32 On the question of whether patent infringement required proof of damages, Justice Story held that it did not. 33 In Justice Story’s opinion, “where the law gives an action for a particular act, the doing of that act imports of itself a damage to the party. Every violation of a right imports some damage, and if none other be proved, the law allows a nominal damage.” 34

Whittemore, therefore, established three fundamental principles of patent law: the use of patented subject matter for experimentation and research would be exempted from patent infringement; each individual act of making, using or selling patented subject matter would constitute patent infringement; and patent infringement could be established without showing economic harm to the patentee. 35 With respect to the third principle, it is important to note that the irrelevance of economic harm to patent infringement does not imply that economic harm is also irrelevant

27. Whittemore, 29 F. Cas. at 1121.
28. Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 874 n.8 (Fed. Cir. 2003) (Newman, J., concurring in part, dissenting in part). See also Bruzzone, supra note 9, at 60 (“Story’s original version was broader. He saw the exemption as covering ‘philosophic experiments’ which, in the nineteenth century, included what we would consider scientific experiments.”).
29. See Bruzzone, supra note 9, at 60 (distinguishing between “‘pure research’” experimentation and “‘applied science’” research primarily motivated by potential commercial application).
30. Whittemore, 29 F. Cas. at 1121.
32. Whittemore, 29 F. Cas. at 1121.
33. Id.
34. Id.
35. Id.
to the experimental use exemption to patent infringement. A patentee need not show economic harm to establish patent infringement, but a patentee’s failure to show economic harm would have relevance to a claim that the patented subject matter was used only for experimental purposes; a failure to show economic harm would be consistent with a claim of experimental use whereas a showing of economic harm would be inconsistent with such a claim.36

Justice Story elaborated on his Whittemore opinion in the case of Sawin v. Guild,37 decided in the same year. In Sawin, Justice Story contrasted the making of a patented machine with an intent to use it for profit, which would be an act of infringement, and the making of a patented machine for the purpose of a scientific experiment or to ascertain the “verity and exactness of the [patent] specification,” which would not be an act of infringement.38 Justice Story did not fully explain what he meant by using patented technology for the purpose of profit. His “for profit” test, however, can be interpreted in two ways. One interpretation of the “for profit” test would eliminate the experimental use exemption for all business organizations engaged in furtherance of their legitimate business.39 The rationale for this interpretation would be that the goal of all business organizations is profit and therefore all of the activities of business organizations, including experimentation, are in pursuit of that profit.40 A second interpretation of the “for profit” test would allow business organizations to experiment with patented technology where the immediate goal was to obtain scientific knowledge or to test patent claims, but disallow the use of patented technology for its intended purpose in

36. A patentee can show direct damages if the alleged infringer is making or using the patented subject matter for its intended commercial purpose. On the other hand, if the patentee cannot show direct damages, it is likely that the alleged infringer is not making or using the patented subject matter for its intended commercial purpose, but rather for a non-commercial purpose such as experimentation or research.

37. 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391). Sawin involved the interesting question of whether the seizure and sale of patented machines by a sheriff pursuant to the execution of a judgment on a debt would be an infringement of the machine patent. Id. Justice Story held that this was not an act of infringement, reasoning that to hold otherwise would allow debtors to place property beyond the “grasp” of creditors by investing their property in patented machines. Id. at 554-55.

38. Id. at 555.

39. See David L. Parker, Patent Infringement Exemptions for Life Science Research, 16 Hous. J. INT’L L. 615, 627 (1994). Sawin can “readily be interpreted to mean that any use that is not itself a use for profit is not an infringement, with ‘philosophical experiment’ and ‘determining the adequacy of the disclosure’ merely two examples of uses that are not considered ‘for profit.’” Id. at 627 (quoting Sawin, 21 F. Cas. at 555).

40. See Bruzzone, supra note 9, at 57 (discussing commercial competitors and noting that “[t]he very nature of [commercial] defendants undermines any argument that their motives are not profit related or that their activities will not affect the plaintiff’s potential profits.”).
direct revenue-generating activities. It is not clear which of these two interpretations Justice Story had in mind, nor is it clear how Justice Story viewed the absence of profit intent. Would a nonprofit organization always be entitled to an experimental use exemption for the use of patented subject matter in scientific research and testing? Would the lack of a profit motive exempt a nonprofit organization from patent infringement if it used patented subject matter outside of the realm of scientific research and testing? These questions raised by Justice Story’s seminal pronouncements on experimental use would be slowly, and somewhat erratically, answered over the next one hundred and ninety years.

Later nineteenth-century cases appeared to narrow the experimental use exemption to patent infringement. An 1861 case defined the experimental use exemption as the use of patented articles “for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement.” Whereas Justice Story’s conception of experimental use was utilitarian and envisioned science experiments and testing patent claims, this later definition appears to allow only for purely fanciful and idle uses of patent subject matter. Other nineteenth-century cases found that experimenting with a patented device to determine its suitability for a particular purpose and using a patented machine for the purpose of comparing and selling a competing machine were activities outside the experimental use exemption.

41. Consider WILLIAM C. ROBINSON, 3 THE LAW OF PATENTS FOR USEFUL INVENTIONS 56 (1890).

[T]he manufacture or the use of the invention may be intended only for other purposes, and produce no pecuniary result. Thus where it is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promotion of the employer’s knowledge or the relaxation afforded to his mind. But if the products of the experiment are sold, or used for the convenience of the experimentor, or if the experiments are conducted with a view to the adaptation of the invention to the experimentor’s business, the acts of making or of use are violations of the rights of the inventor and infringements of his patent.

Id. (citation omitted).

42. Poppenhusen v. Falke, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279). Poppenhusen was not decided by Justice Story; however, the language in the case would later be rephrased as “ dilettante” activity and attributed to Justice Story. See Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984).

43. See Palmer v. United States, 20 Ct. Cl. 432, 435, 438 (1885), aff’d on other grounds, 128 U.S. 262 (1888) (holding that the inventor was entitled to damages for the defendant’s experimental use of the inventor’s patented knapsack).

44. See Bonsack Mach. Co. v. Underwood, 73 F. 206, 211 (C.C.E.D.N.C. 1896) (rejecting
Three experimental use cases decided in the mid-twentieth century, however, extended the exemption well beyond "mere amusement." The first case involved a university. In the context of a complicated damages calculation, the court had to determine whether the use of infringing machine parts by a university was an act of infringement in which case the sale of the parts to the university constituted contributory infringement and would be included in the damages accounting. The court found that the university had only used the machine parts in conjunction with machines that were located in a laboratory and that these machines were used only for experiments. The court held that this was not an infringing use that could support a finding of contributory infringement. The second case involved a company that briefly experimented with a patented machine and determined that it could not yield a product of satisfactory quality. The court held that because the experimental use of the machine occurred before the company had commenced any commercial production, the use was not an act of infringement. The third case involved a competitor company that built a single patented device in order to experiment with it. Here the court found that the uncontradicted evidence showed the competitor company used the device only to experiment, never manufactured any devices for sale, and never sold any devices. The court held that under these facts the use did not infringe the rights of the patent owner.

A case decided in 1976, however, began a reversal of the trend toward liberal construction of the common law experimental use exemption. The case involved the calculation of damages in an infringement suit against the United States for the use of patented helicopter rotors and controls. The U.S. sought to exclude from the damages calculation its use of the helicopters for testing and evaluation of such factors as lift ability, vibration, flight speed, and range. The court concluded that these

an experimental use defense where the machine used for experimentation was also used for profit.

46. Id. at 702-03.
47. Id. at 703.
48. Id. at 713.
50. Id. at 333.
52. Id.
53. Id. at 230.
54. See Pitcairn v. United States, 547 F.2d 1106, 1125-26 (Ct. Cl. 1976).
55. Id. at 1110.
56. Id. at 1125.
activities were infringing and therefore compensable.57 In reaching this conclusion, the court held that testing and evaluation were “intended uses of the infringing aircraft . . . and are in keeping with the legitimate business of the using agency.”58 The first holding reversed early case law that found experimenting with patented subject matter to determine its suitability for adoption fell within the experimental use exemption.59 The second holding created an entirely new limitation on experimental use. Henceforth, use of patented subject matter for purposes related to the experimenter's legitimate business would not be allowed under the experimental use exemption regardless of whether the use was commercial or non-commercial.60 The “legitimate business” use limitation on experimental use would be applied in a case decided twenty-six years later that would nearly eliminate the common law experimental use exemption entirely.61

2. Contemporary Cases

The case that irrevocably reversed the liberalization of the experimental use exemption was Roche v. Bolar, decided in 1984.62 Roche was the owner of a patent on a drug compound contained in a successful brand-name drug product.63 Bolar was a generic drug manufacturer.64 Prior to the expiration of Roche's patent, Bolar used the patented drug compound to perform tests to establish the bioequivalency of its generic drug to Roche's brand-name drug; bioequivalency tests were necessary to obtain approval from the Food and Drug Administration (FDA) in order to market the generic drug.65 Roche argued that the use of a patented drug to obtain test data to submit to the FDA was an act of infringement under the patent laws.66 Bolar countered that the use was solely for experimental purposes and therefore exempt from infringement.67 The federal district court found for Bolar, holding that the use of a patented compound for federally mandated testing was not an act of infringement because the use

57. Id. at 1125-26.
58. Id.
60. See Parker, supra note 39, at 631 ("[E]ven if no profit motive is attached to the experimental activity, the activity will nevertheless be considered an infringement if it is within the legitimate business of the organization.").
61. See Madey v. Duke Univ., 307 F.3d 1351, 1362-63 (Fed. Cir. 2002) (finding that any use furthering a legitimate business purpose did not qualify for an experimental use defense).
63. Id. at 860.
64. Id.
65. Id.
66. Id.
67. Id. at 862.
was de minimis and experimental. The Court of Appeals for the Federal Circuit (CAFC) reversed.

In reaching its conclusion, the CAFC addressed four issues central to the experimental use exemption. First, citing to two cases that did not concern experimental use, the CAFC held that the use of a patented invention without either manufacture or sale was an act of infringement. Second, the court held that a patentee does not have to show any evidence of damage or lost sales to bring an infringement action. Third, the court held that Bolar’s experiments were conducted solely for business purposes and that unlicensed experimentation with a patented invention to adapt the invention to the experimenter’s business is a violation of the patentee’s rights. The court’s language on this point reveals just how narrowly the court viewed the experimental use exemption: “[Bolar’s experiment] is no dilettante affair such as Justice Story envisioned. We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of ‘scientific inquiry,’ when that inquiry has definite, cognizable, and not insubstantial commercial purposes.”

Finally, the court acknowledged that the result of its holding would, in effect, create a de facto extension of Roche’s patent term, but concluded that it must assume that Congress intended this result by passing both the Patent Act and the Food, Drug and Cosmetic Act. In support of this assumption, the court noted that the effective life of new drugs may be as low as seven years because of the required FDA review while the de facto extension of the patent term may be “upwards” of two years due to enjoining generic drug testing with a patented compound until the patent expires.

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68. Id. at 860-61.
69. Id. at 867.
70. Id. at 861. The first cited case, Aro Mfg. Co. v. Convertible Top Replacement Co., 377 U.S. 476 (1964), turned on whether replacement of portions of the patented item constituted infringing “reconstruction” or permissible “repair” of said item. Id. at 479. The second case, Coakwell v. United States, 372 F.2d 508 (Ct. Cl. 1967), turned on the amount of reasonable damages for direct infringement of the plaintiff’s patented invention. Id. at 510.
71. Bolar, 733 F.2d at 861.
72. Id. at 863. The court stated that “[d]espite Bolar’s argument that its tests are ‘true scientific inquiries’ to which a literal interpretation of the experimental use exception logically should extend, we hold the experimental use exception to be truly narrow, and we will not expand it under the present circumstances.” Id. (emphasis added).
73. Id.
74. Id. at 864. The court stated, “Because ‘laws are presumed to be passed with deliberation, and with full knowledge of all existing ones on the same subject’ we must presume Congress was aware that the FDCA would affect the earning potentiality of a drug patent, and chose to permit it.” Id. (quoting THEODORE SEDGWICK, THE INTERPRETATION AND CONSTRUCTION OF STATUTORY AND CONSTITUTIONAL LAW 106 (2d ed. 1874)).
75. Bolar, 733 F.2d at 864.
One can only speculate on the extent to which the court’s decision in Roche v. Bolar was influenced by the unique circumstances of the pharmaceutical industry and a concern for allowing brand-name drug manufacturers to recapture some of their lost patent terms. Whether or not that was the court’s concern, Congress moved quickly to respond to the loss of the patent term due to FDA review. However, viewed in the context outside the pharmaceutical industry, the Bolar case represented an exercise in semantics that produced a result that was neither compelled by prior case law nor consistent with other areas of patent law.

On the question of whether the use of a patented invention standing alone can constitute an act of infringement, neither the language of the statute nor the prior case law required the court to answer yes in all instances. Clearly, the use of a patented device for its intended purpose is an act of infringement regardless of whether the infringer made the device or sold the device. Likewise, the use of a patented process for its intended purpose is an act of infringement regardless of how the infringer acquired the means to implement the process. However, neither of these clear cases of infringement by using patented subject matter requires the conclusion that the use of patented subject matter for the purposes of experimentation must also constitute an act of infringement.

The CAFC also mischaracterized Justice Story’s conception of experimental use as a “dilettante” activity. Justice Story viewed the experimental use exemption as necessary to allow for scientific experimentation and to test the accuracy of patent claims—hardly dilettante activities. It was a later nineteenth-century case that defined the experimental use exemption as experiments for the sole purpose of “mere amusement” and idle “curiosity.” It is true that Justice Story contrasted experimental use and for-profit use of a patented machine; however, as discussed earlier, it is not clear whether Justice Story intended this contrast to disallow all experimental use by all for-profit organizations, or to

76. The court was also apparently concerned with “several bills that were then pending in Congress to address the regulatory delay, and to public policy issues raised by . . . Bolar.” Veronica Lanier, Note, Medical Device Eligibility for the Statutory Experimental Use Exception to Patent Infringement, 17 Hastings Comm. & Ent. L.J. 705, 711 (1995).
77. See infra Part II.B.
78. See supra notes 70-73 and accompanying text.
79. See Bolar, 733 F.2d at 863 (rejecting case law finding that experimental use does not infringe as being dicta or unpersuasive).
80. See 35 U.S.C. § 271(a) (West 2005) (stating “whoever without authority makes, uses, offers to sell, or sells any patented invention . . . infringes the patent”).
81. See id.
82. See Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600).
84. Whittemore v. Falke, 29 F. Cas. at 1121.
disallow only those uses that brought profit to the experimenter at the expense of the patentee. 85

Finally, as will be discussed in more detail later in the Article, the court’s dismissal of the argument regarding the de facto extension of the patent term can only be understood in the context of the shortened patent terms in the pharmaceutical industry. 86 This disregard for the extension of the patent monopoly is in marked contrast to many other patent law rules which seek to limit the scope of patentee rights to those clearly set forth in the Patent Act. 87

The next major experimental use case, Embrex, Inc. v. Service Engineering Corp., was decided in 2000. 88 Embrex owned a patent on a method for inoculating birds against disease by injecting vaccines into a specified region of the egg before hatching. 89 Service Engineering attempted to design around the Embrex patent by building an injection machine (not covered by the patent) and hiring two scientists to investigate the possibility of injecting chicken embryos outside the region of the egg covered by the patent. 90 The scientists used India ink to determine if injections outside the region specified in the patent would remain there and if vaccines injected outside the region specified in the patent would be effective in inoculating birds. 91 The results of the tests were negative on both counts; most injections outside the region covered by the patent penetrated into the region that was covered by the patent, and the vaccine injected outside the region covered by the patent produced little immunity to disease. 92

In the trial court, a jury found that Service Engineering had infringed the Embrex patent and Embrex was awarded $500,000 in direct damages. 93 On appeal to the CAFC, the court affirmed the finding of infringement, but remanded the case for further consideration on the question of damages. 94 The CAFC found that injecting the eggs with vaccine was done expressly for commercial purposes and therefore could not be immunized from

85. See supra notes 39-41 and accompanying text; see also Janice M. Mueller, No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools, 76 WASH. L. REV. 1, 24 (2001) (“Thus, after Roche, scientists engaged in research and development having more than negligible commercial purpose could no longer rely on the experimental use doctrine to exempt their experiments from patent infringement liability.”).

86. See infra notes 105-14 and accompanying text.
87. See infra Part III.C.
88. 216 F.3d 1343 (Fed. Cir. 2000).
89. Id. at 1346.
90. Id.
91. Id. at 1346-47.
92. Id. at 1347.
93. Id. at 1349.
94. Id. at 1352.
infringement under experimental use or de minimis use exemptions, even though Service Engineering did not sell any injection machines or commercially practice the patented method. On the question of damages, the CAFC found that Embrex was entitled to a reasonable royalty, that royalties are ordinarily computed on the basis of sales of a patented product or process, but that parties can choose other methods to calculate royalties such as "flat fees" or "milestone payments" in the case of pre-commercialization licenses. Because the record did not contain sufficient evidence to compute a reasonable royalty, the court vacated the damage award and remanded the case to the district court to determine the proper basis for calculating a reasonable royalty.

Judge Rader wrote a concurring opinion in Embrex to express his view that the experimental use and de minimis use exemptions to patent infringement should be completely eliminated. Noting that courts have sometimes addressed these "excuses" as one, Judge Rader explained the differences between the two and analyzed each separately. According to Judge Rader, experimental use is a plea based on the "character or intent" of the infringing activity whereas de minimis use is a plea based on the "amount or quantum of infringing activity." In Judge Rader's opinion, the Patent Act "leaves no leeway to excuse infringement because the infringer only infringed a little," and the damages calculation in an infringement action is fully sufficient to deal with the question of a de minimis amount of infringing activity. On the experimental use exemption, Judge Rader cited two recent cases, one from the Supreme Court and one from the CAFC, for the proposition that intent is irrelevant to infringement. Since Judge Rader had defined experimental use as a plea based on the "intent" of the infringing activity, he concluded that

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95. Id. at 1349. The court noted that "[Service Engineering's] chief commercial purpose was to demonstrate to its potential customers the usefulness of the methods performed by its in ovo injection machines. Just because [Service Engineering] was unsuccessful in selling its machines does not confer infringement immunity upon SEC for its infringing acts." Id.

96. Id. at 1350.

97. Id.

98. Id. at 1352 (Rader, J., concurring).

99. Id.

100. Id.

101. Id. at 1353 (citing Deuterium Corp. v. United States, 19 Cl. Ct. 624, 631 (1990) ("This court questions whether any infringing use can be de minimis. Damages for an extremely small infringing use may be de minimis, but infringement is not a question of degree.").)

these recent cases had eliminated the experimental use exemption completely, even in the instances of noncommercial and idle curiosity uses.\textsuperscript{103}

In both \textit{Bolar} and \textit{Embrex}, the alleged infringers used patented subject matter in an attempt to engineer around the patent claims and in both cases the CAFC held the attempts to do so constituted acts of infringement.\textsuperscript{104} This result creates a dichotomy in the use of patent information and leads to a de facto expansion in the scope of the patent claims.\textsuperscript{105} I will illustrate this result with the facts of \textit{Bolar}.

Bolar was, of course, free to spend an unlimited amount of time reading, studying, and researching the information contained in the Roche patent for any purpose whatsoever without infringing the patent rights.\textsuperscript{106} On the other hand, Bolar’s physical use of the information, no matter how minimal or non-injurious to the patentee, would constitute an act of infringement.\textsuperscript{107} This “look but don’t touch” rule regarding use of patent information results in random variations in market competition. If the information contained in the patent application is susceptible to purely mental manipulation, it can be used to produce a non-infringing substitute product and market competition will be increased. However, if the information contained in the patent application can only be fully comprehended through physical manipulation, it cannot be used to produce a non-infringing substitute product and market competition will be decreased. In the great majority of instances, this dichotomy works to benefit patentees and disadvantage competitors because few inventions can be fully understood without physical use. Thus, the prohibition of physical use encourages drafters of patent applications to provide as little information as possible without running afoul of the required enabling disclosure.

The de facto expansion in the scope of patent claims follows directly from the “look don’t touch” rule on the use of patent information. It was not possible for Bolar (or any other competitor) to develop a non-infringing substitute drug compound, or an improved drug compound, without physical use of Roche’s patented drug compound.\textsuperscript{108} To the extent Bolar was denied this opportunity, Roche’s patent claims were, in effect,
expanded to cover substitute and improved drug compounds that Roche did not, and perhaps could not, claim in its initial patent application. Stated differently, the denial of Bolar’s opportunity to experiment with Roche’s patented drug compound served to provide Roche with the same expanded scope of patent protection that Roche would have obtained, but did not obtain, through the issuance of multiple fencing patent applications.\(^{109}\)

Finally, before moving on to the next major experimental use case, a brief critique of Judge Rader’s concurring opinion is in order. Judge Rader was surely correct in distinguishing “de minimis” and “experimental use” in his assertion that there is no provision in the Patent Act exempting minor infringement, and that the damages assessment can be tailored to the quantum of infringing activity and economic harm.\(^{110}\) However, his analysis of experimental use is more problematic.\(^{111}\) Judge Rader was correct in his assertion that it is not necessary to prove intent in order to establish infringement; what is far less clear is whether intent was ever an element of experimental use.\(^{112}\) Although courts often discuss experimental use in terms of its purpose (amusement, curiosity, non-commercial), no prior experimental use case has held that the intent of the experimenter is dispositive of the question of infringement exemption.\(^{113}\) The case law in fact appears much to the contrary and strongly suggests that the objective characterization of the experimental activity, not the intent of the experimenter, is the factor that determines infringement.\(^{114}\) If intent has not been, and is not now, an element of the experimental use exemption, then the fact that intent is not required to prove infringement generally is irrelevant to the continued existence of the experimental use exemption.

The most recent, and by far the most narrow, explication of the


\(^{110}\) See Embrex, Inc. v. Serv. Eng’g Corp., 216 F.3d 1343, 1352-53 (Rader, J., concurring); see also Michelle Walters, De Minimis Use and Experimental Use Exceptions to Patent Infringement: A Comment on the Embrex Concurrence, 29 AIPLA Q.J. 509, 515 (2001) (“The de minimis use exception should be eliminated as a defense to patent infringement because the exception is judicially redundant and rarely applied. There are other mechanisms . . . which are equally capable of dealing with infringement cases of de minimis proportions.”).

\(^{111}\) See Mueller, supra note 85, at 29-30. Contrary to Judge Rader’s concurrence, the U.S. Supreme Court in Warner-Jenkinson did not create new law nor change the law with respect to the common law experimental use doctrine. The accused infringer in Warner-Jenkinson did not rely on the experimental use doctrine, nor did the case involve the use of research tools; both parties were commercial manufacturers of purified dyes. Id.

\(^{112}\) Id. at 30.

\(^{113}\) See id. ("[I]ntent plays no role in the application of the doctrine of equivalents.") (quoting Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 36 (1997)).

\(^{114}\) See supra note 103 and accompanying text.
experimental use exemption came in Madey v. Duke University. Madey was a tenured faculty member at Duke University, director of a physics research laboratory and owner of a patent on a free-electron laser (FEL) oscillator which was used as a spectroscopy research tool. Madey resigned his position at Duke after a disagreement over the management of the laboratory. Duke continued to use the FEL oscillator after Madey’s resignation. Madey then sued Duke for infringement of the FEL patent and Duke raised the defense that its use of the FEL oscillator fell within the experimental use exemption to patent infringement.

The district court found for Duke on the issue of experimental use. As defined by the district court, the experimental use defense covered uses that were "solely for research, academic, or experimental purposes." On appeal, the CAFC held that the district court’s definition of experimental use was too broad and ignored the holdings in Embrex and Roche that the experimental use defense is strictly limited to activities "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." The CAFC stated that any use which has the "slightest commercial implication" or is "in keeping with the legitimate business of the alleged infringer" cannot qualify for the experimental use defense.

In applying this stricter standard to the facts of the case, the court concluded that Duke’s use of the FEL oscillator did not fall within the experimental use exemption. First, the court held that the proper focus for experimental use analysis here should not be Duke’s nonprofit status, but rather Duke’s "legitimate business objectives." Second, the court held that Duke’s use of the FEL oscillator for research projects "unmistakably further[ed]" Duke’s "legitimate business objectives, including educating . . . students and faculty participating in these [research] projects," enhancing the status of the university, and luring

115. 307 F.3d 1351 (Fed. Cir. 2002).
116. Id. at 1352.
117. Id. at 1352-53.
118. Id. at 1353.
119. Id.
120. Id. at 1355-56.
121. Id. at 1355 (quoting Madey v. Duke Univ., 266 F. Supp. 2d 420, 425 (M.D.N.C. 2001)).
122. Id. at 1361-62 (quoting Embrex, Inc. v. Serv. Eng’g Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000)). The court also stated that "use does not qualify for the experimental use defense when it is undertaken in the ‘guise of scientific inquiry’ but has ‘definite, cognizable, and not insubstantial commercial purposes.’” Id. at 1362 (quoting Embrex, 216 F.3d at 1349).
123. Id. (quoting Embrex, 216 F.3d at 1353); see also Strandburg, supra note 11, at 99 (stating a concern that the "legitimate business" test will prove broad enough to include "almost any conceivable use" able to exploit a patentee’s potential market (quoting Madey, 307 F.3d at 1362)).
125. Id. at 1362.

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“lucrative research grants, students and faculty.” 126

The sweeping holding in Madey v. Duke would appear to preclude experimental use of patented subject matter by all nonprofit research organizations, including federal laboratories, research foundations and research hospitals. 127 Indeed, “the legitimate business objective” test as applied by the court in Madey is so open-ended that it could conceivably be interpreted to preclude experimental use of patented subject matter even by isolated individuals if the use was pursuant to any specific objective. This interpretation of the “business objective” test would morph it into the “idle curiosity” test; any experiment that had a specific purpose or goal would fail both the “idle curiosity” and the “business objective” tests.

Madey is a classic example of a case that reached the right conclusion, but for the wrong reasons. The court was forced into adopting such an extremely limited experimental use exemption—an exemption that obliterated distinctions between for-profit and nonprofit entities and activities—by its prior precedent. 128 Since the court had already held that economic loss was irrelevant to the determination of experimental use, 129 the court did not, and could not, consider the economic consequences to Madey of Duke's use of the FEL oscillator. The intended purpose of the FEL oscillator was as a research tool and this is precisely how Duke used it. 130 As a result, Madey was deprived of the licensing revenue he was entitled to receive for the use of his invention for its intended purpose. If inventors of research tools are unable to realize a fair return on their inventions, the incentive to invent research tools will be diminished, fewer research tools will be invented, and the advances in science made possible by new research tools will be retarded. 131 This result follows whether or

126. Id.; see also Strandburg, supra note 11, at 84 (noting that this result runs contrary to widespread belief within the academic research community that “purely academic research is categorically excused from patent infringement liability”).

127. See Strandburg, supra note 11, at 85 (“The court does not suggest where, outside of the halls of academe, such scientific philosophers are to be found in this modern age, but surely their ranks are thin indeed.”).

128. See Madey, 307 F.3d at 1361-62.

129. Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 861 (Fed. Cir. 1984) (“Thus, the patentee does not need to have any evidence of damage or lost sales to bring an infringement action.”). On this point, the court confused the relevance of economic harm to patent infringement and the relevance of economic harm to the experimental use exemption to patent infringement. See supra notes 82-85 and accompanying text.

130. See Madey, 307 F.3d at 1352.

131. See Mueller, supra note 85, at 39-40. Mueller argues that:

[r]esearchers are ordinary consumers of patented research tools, and if these consumers were exempt from infringement liability, the patent holder would have nowhere else to turn to collect patent royalties. An excessively broad research exemption could eliminate incentives for private firms to develop and disseminate
not the experimenter is a university or publicly traded company. The CAFC was correct, therefore, that the focus of the analysis in the case should not be on Duke’s nonprofit status. However, the court was incorrect in asserting that any use within Duke’s educational mission or beyond mere idle curiosity was outside of the permitted scope of experimental use.

The analysis in Madey should have instead focused solely on whether there was a cognizable economic harm to Madey that resulted from Duke’s use of the FEL oscillator.\textsuperscript{132} Duke used the patented FEL oscillator without authorization\textsuperscript{133} to obtain the exact research data that the FEL oscillator was designed to yield and in so doing infringed Madey’s exclusive patent right to control the use of the FEL oscillator and to receive compensation for allowing others to use it.\textsuperscript{134} The situation would have been quite different, however, if Duke had experimented with the patented FEL oscillator for the purpose of developing improvements to the FEL oscillator or of inventing a new, non-infringing oscillator. The only economic harm that Madey would suffer as a result of this latter type of use would be the loss of revenue due to the de facto extension of his patent term and the de facto expansion of his patent claims. If researchers had to await the expiration of Madey’s patent before experimenting with the FEL oscillator to develop a substitute oscillator device, then Madey’s patent term would be extended by the time it takes to perform the post-patent experimentation.\textsuperscript{135} Likewise, if researchers cannot experiment with the FEL oscillator to develop an improved oscillator or a non-infringing substitute oscillator, then the scope of Madey’s patent claims will be expanded to cover a host of competing oscillator devices.\textsuperscript{136}

In some cases, there is a fine line between the use of patented subject matter for its intended purpose, and the use of patented subject matter to develop improvements and non-infringing substitutes to the patented subject matter. For example, in the case of the FEL oscillator, a researcher experimenting with the FEL oscillator in order to develop a new, more accurate oscillator would first have to determine the accuracy of the FEL

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\textsuperscript{132} See Strandburg, supra note 11, at 96 (suggesting that the expansion of the “commercial use” concept to “legitimate business” purpose addresses the difficulty arising from not-for-profit experimentations which can cause monetary losses to the patent holder (quoting Madey, 307 F.3d at 1362)).

\textsuperscript{133} See Madey, 307 F.3d at 1353.

\textsuperscript{134} See id.

\textsuperscript{135} See supra notes 105-09 and accompanying text.

\textsuperscript{136} See id.
oscillator by using it for its intended purposes in different types of tests. Part IV of this Article will discuss this problem further and suggest a straightforward means by which a line can be drawn between proper and improper uses of all types of patent subject matter.

B. The Statutory Experimental Use Exemption

1. The Hatch-Waxman Act

Congress responded to Roche v. Bolar by adopting the Hatch-Waxman Act, an ingenious, yet convoluted, reversal of the Bolar decision. In the Hatch-Waxman Act, Congress amended § 271(e)(1) of the Patent Act to provide that "[i]t shall not be an act of infringement to make, use, offer to sell, 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." This amendment clearly allowed generic drug companies to experiment with patented brand-name drugs in order to establish the bioequivalency of generic drug substitutes and thereby obtain FDA approval of the generic drugs prior to the expiration of the brand-name patents. The immediate effect of this amendment was to eliminate the de facto patent term extension that Bolar had implicitly condoned.

However, Congress simultaneously authorized the extension of the original patent term up to a maximum of five years in order to compensate brand-name manufacturers for the time lost due to the FDA approval process, as well as the loss of the de facto patent term extension.

Congress, though, was not content with the simple quid pro quo of exempting generic manufacturers from infringement for experimenting with patented brand-name drugs and granting brand-name manufacturers an extension to their drug patent terms. Through further amendments to the Food Drug and Cosmetic Act (FDCA) and the Patent Act, Congress created an elaborate handicapping system for the pharmaceutical industry. In addition to the infringement exemption, generic drug manufacturers were allowed to use the results of a brand-name drug's clinical trials to

140. See id.
141. 35 U.S.C. § 156(g)(6).
142. See id.
establish the safety and efficacy of generic drugs and were given an incentive to challenge patents on brand-name drugs: The first generic manufacturer that successfully challenges a brand-name drug patent by establishing that the patent was either invalid or would not be infringed by the sale of the generic drug is given a 180-day period of market exclusivity.

Brand-name manufacturers were also given new rights. The Patent Act was amended to create an entirely new, and entirely artificial, act of infringement: infringement by filing with the FDA. Although generic manufacturers were allowed to experiment with patented drugs to obtain data necessary to submit to the FDA, the actual submission of the data to the FDA would constitute infringement. In addition, when brand-name manufacturers filed infringement suits against generic manufacturers, the brand-name manufacturers were granted automatic thirty-month stays on FDA approval of the generic drug. However, brand-name manufacturers could not recover monetary damages for the infringement unless there was a "commercial manufacture, use, offer to sell, or sale within the United States."

The Hatch-Waxman Act amendments to the FDCA and Patent Act spawned a complex set of cases on both procedural and substantive issues. The procedural issues dealt with such questions as what brand-name patents could be listed with the FDA, whether third parties could challenge the listing of brand-name patents, and whether brand-name manufacturers could obtain multiple thirty-month stays on FDA approval of the same generic drug. The substantive issues dealt with the subject matter covered under the Hatch-Waxman experimental use exemption and the permitted uses of this subject matter.

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144. Id. § 355(j)(5)(B)(iv).
149. See, e.g., Apotex, Inc. v. Thompson, 347 F.3d 1335, 1352 (Fed. Cir. 2003) (upholding an FDA regulation requiring that patents submitted as part of an ANDA supplement be listed in the Orange Book).
150. See, e.g., Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323, 1332 (Fed. Cir. 2001) (noting that the Hatch-Waxman Act did not create a private right of action and that only the U.S. government may bring suit for a de-listing of the Orange Book under U.S.C. § 337(m)).
2. Hatch-Waxman Cases

In *Eli Lilly & Co. v. Medtronic, Inc.*, the Supreme Court considered whether the § 271(e)(1) statutory infringement exemption covered the testing of an implantable cardiac defibrillator in order to obtain data to submit to the FDA for marketing approval. The Court held that the phrases "'patented invention'" and "'a Federal law'" used in § 271(e)(1) encompassed all inventions that were subject to regulation by the FDA under the FDCA, including medical devices.

A district court case, also involving an implantable defibrillator, considered whether the § 271(e)(1) exemption applied to the situation where the testing manufacturer intends to commercialize the device "before the expiration of the allegedly infringed patents." The plaintiff argued that Congress’s intent in enacting § 271(e)(1) was to prevent patent holders from obtaining de facto extensions of their patent monopolies. Therefore, the plaintiff urged, the only type of permissible testing was for the purpose of entering the market after the patent at issue had expired. The court found this view of § 271(e)(1) too narrow and held that Congress’s primary concern in enacting § 271(e)(1) was "to create a legal environment that would enable new, medically beneficial, cost-competitive products to reach the general marketplace" as soon as possible without infringing unexpired patents.

In yet another case involving an implantable defibrillator, the CAFC considered whether displaying the defibrillator at medical conferences to physicians and non-physicians, and also presenting the results of the clinical tests to physicians, investors, analysts, and journalists, were activities so unrelated to obtaining data for submission to the FDA that they would cause a loss of the § 271(e)(1) exemption. The court found that all of these activities involved the dissemination of data that was developed to obtain FDA approval and that nothing in the statute prohibited disseminating such data.

153. Id. at 665.
154. Id. at 666-69 (quoting 35 U.S.C. § 271(e)(1) (2000)) (holding that construction of the 1984 Act as a whole confirmed the lower court’s finding that the Act meant to include medical devices as well).
156. Id.
157. Id. The court further explained that “[i]t would be inconsistent with the positive goal of maximizing post-patent availability of lower priced new products to artificially limit the exemption only to those parties who would (or could) not enter the marketplace until after the patents expired.” Id. at 1274.
159. Id. at 1525 ("If Congress intended to make [marketplace competition] more difficult, if
3. The Federal Circuit Decision in Integra Lifesciences v. Merck

Integra Lifesciences I, Ltd. v. Merck KGaA involved a series of patents on a peptide sequence referred to as the RGD peptides or simply RGD. RGD promotes cell adhesion by stimulating the growth of new blood vessels and it was thought that it could aid in wound healing. Integra, the owner of the patents, obtained the patents from a company that was unable to develop a viable commercial product. In an unrelated research effort, a scientist, Dr. Cheresh, working at Scripps Research Institute (Scripps), discovered that blocking certain receptors on endothelial cells would inhibit the growth of new blood vessels and that this mechanism could be used "as a means to halt tumor growth by starving rapidly dividing tumor cells [of their blood supply]." Beginning in 1988, Merck funded this research and after Dr. Cheresh was successful in reversing tumor growth in chicken embryos using an RGD peptide, Merck entered into a second funding agreement with Scripps and Dr. Cheresh to perform in vitro and in vivo testing of RGD peptides to develop the information necessary for FDA approval of clinical trials. Upon learning of this research project using the RGD peptides, Integra filed an infringement suit. Merck responded, claiming that the research fell within the § 271(e)(1) research exemption. The district court determined that the research was not covered by the § 271(e)(1) research exemption and the jury awarded Integra $15,000,000 in reasonable royalty damages.

On appeal, the CAFC affirmed the infringement holding, but remanded the case for further consideration of the damages award. The court found that "the Scripps work sponsored by Merck was not clinical testing to

not impossible, by preventing competitors from using, in an admittedly non-infringing manner, the derived test data for fund raising and other business purposes, it would have made that intent clear. The statute contains no such provision.

160. 331 F.3d 860 (Fed Cir. 2003).
161. Id. at 862.
162. Id. at 862-63.
163. Id. at 873 (Newman, J., concurring in part, dissenting in part); see also George Fox, Note, Integra v. Merck: Limiting the Scope of the § 271(e)(1) Exception to Patent Infringement, 19 BERKELEY TECH. L.J. 193, 201 (2004).
164. Integra, 331 F.3d at 863.
165. Id. at 873 (Newman, J., concurring in part, dissenting in part).
166. Id. at 863 (majority opinion).
167. Id.
168. Id.
169. Id. at 863, 869.
170. Id. at 872.
supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds" and that the results of this research may or may not be submitted to the FDA, depending upon the success of the experiments.\textsuperscript{171} Although the CAFC did not specifically find that the RGD peptides were a research tool, it expressed a special concern that extending the § 271(e)(1) exemption to embrace new drug development activities such as these would "vitiate" the rights of patentees owning biotechnology research tools.\textsuperscript{172} According to the court, the Hatch-Waxman Act was simply intended to reverse the holding in Roche and "not to deprive entire categories of inventions of patent protection."\textsuperscript{173}

The majority opinion did not discuss the common law experimental use exemption at all, but did mention it in a footnote referring to Judge Newman's dissent.\textsuperscript{174} The court stated:

In her dissent, Judge Newman takes this opportunity to restate her dissatisfaction with this court's decision in Madey v. Duke Univ. . . . . However, the common law experimental use exception is not before the court in the instant case. The issue before the jury was whether the infringing pre-clinical experiments are immunized from liability via the "FDA exemption . . . ."\textsuperscript{175}

Although the court was correct that the issue before the jury was framed in terms of the § 271(e)(1) research exemption, the common law experimental use exemption was an integral part of the trial court proceedings. Merck's initial response to the patent infringement suit claimed that the activities were exempted by both the common law research exemption and the § 271(e)(1) research exemption.\textsuperscript{176} At the conclusion of trial, the district court held that all but one of the pre-1995 alleged infringing activities involving the RGD peptides were protected by the common law experimental use exemption.\textsuperscript{177} Following post-trial motions, the district court dismissed Integra's suit against Dr. Cheresh and Scripps based on the common law experimental use exemption.\textsuperscript{178} The CAFC's failure to even mention the common law experimental use

\textsuperscript{171} Id. at 866. The court noted that Merck's experiments could plainly not fall under the § 271(e)(1) exception because "[t]he FDA has no interest in the hunt for drugs that may or may not later undergo clinical testing for FDA approval." Id.
\textsuperscript{172} Id. at 867.
\textsuperscript{173} Id.
\textsuperscript{174} Id. at 863 n.2.
\textsuperscript{175} Id.
\textsuperscript{176} See Merck KGaA v. Integra Lifesciences I, Ltd., 125 S. Ct. 2372, 2379 (2005).
\textsuperscript{177} Id.
\textsuperscript{178} Id. at 2380.
exemption in its discussion of the district court proceedings is indicative of the CAFC majority's position that a common law experimental use exemption is nearly non-existent. 179

Judge Newman wrote a highly critical dissent, noting that the majority decision had held that neither the common law research exemption nor the § 271(e)(1) research exemption immunized the activities at issue. 180 Judge Newman was especially concerned with the common law research exemption, asserting that the majority holding in effect eliminated the common law research exemption altogether, that such a holding is inconsistent with well established patent law and policy, and that the elimination of the common law research exemption will serve to retard the advancement of competition, technology, and scientific knowledge. 181 In Judge Newman's view, a fundamental purpose of the patent system is to provide scientific and technological information, and, if the practical use of this information is prohibited until the expiration of a patent seventeen to twenty years later (the information is "placed on ice"), then the information disclosed in a patent would have little value. 182 It does not matter in Judge Newman's analysis whether the information is used for research to better understand the patent subject matter, to improve upon the patent subject matter, to find a new use for the patent subject matter, or to modify or engineer around the patent subject matter. 183 Judge Newman explained that if such types of research were "subject to prohibition by the patentee the advancement of technology would stop, for the first patentee in the field could bar not only patent-protected competition, but all research that might lead to such competition, as well as barring improvement or challenge or avoidance of patented technology." 184

Judge Newman also addressed the majority's suggestion that the RGD peptides were a research tool and that if the defendant were allowed to use the RGD peptides for the general purpose of drug discovery this would vitiate the rights of patentees owning research tools. 185 Judge Newman saw a fundamental distinction between research into the science and technology disclosed in patents, and the use of patented products or methods as research tools. 186 A research tool, Judge Newman explained,
is a product or method whose purpose is use in the conduct of research, whether the tool is an analytical balance, an assay kit, a laser device . . . or a biochemical method such as the PCR . . . . Use of [such a] tool in one’s research is quite different from study of the tool itself.187

Turning to the RGD peptides, Judge Newman concluded that they were not a research tool “but simply new compositions having certain biological properties.”188

4. The Supreme Court Decision in Merck v. Integra Lifesciences

On review, the Supreme Court vacated the judgment of the CAFC and remanded the case to the district court for further proceedings consistent with the Court’s decision.189 The Court defined the issue presented by the case as “whether uses of patented inventions in preclinical research, the results of which are not ultimately included in a submission to the Food and Drug Administration . . . , are exempted from infringement by 35 U.S.C. § 271(e)(1).”190

The Court began its analysis by noting that under the FDCA, there are two submissions that a drugmaker must make to the FDA.191 First, the drugmaker must obtain FDA approval to conduct clinical trials on human subjects; this approval is requested by the submission of an Investigational New Drug Application (IND).192 Second, the drugmaker must obtain FDA authorization to market a new drug; this authorization is obtained through the submission of a New Drug Application (NDA).193 The Court rejected Integra’s argument that preclinical studies are not reasonably related to an IND and therefore are outside the scope of § 271(e)(1), noting that the FDA requires an IND to include “summaries of the pharmacological, toxicological, pharmacokinetic, and biological qualities of the drug in animals.”194

The Court also rejected the CAFC’s conclusion that the Scripps-Merck experiments fell outside the § 271(e)(1) exemption because they were

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187. Id. at 878.
188. Id.
190. Id. at 2376.
191. Id. at 2377.
192. Id.
193. Id.
194. Id. at 2381. The Court also noted that the FDA approval of an IND involves an assessment of the risks and benefits associated with a proposed clinical trial and that this assessment requires that the IND include sufficient information regarding the potential risks and benefits of the drug under investigation. Id.
directed toward identifying drug candidates for future clinical trials rather than supplying information directly for submission to the FDA. 195 Under the Court's interpretation of § 271(e)(1), the use of patented subject matter in (i) experimenting "on drugs that are not ultimately the subject of an FDA submission," and in (ii) obtaining research data that is not ultimately submitted to the FDA can both be exempted from infringement. 196 The Court found that the § 271(e)(1) exemption for experimenting on drugs that are not ultimately the subject of an FDA submission was compelled by the realities of scientific research in which no one can know whether an initially promising drug candidate will prove successful until the conclusion of preclinical and clinical testing. 197 Thus, the Court found that the CAFC's interpretation of § 271(e)(1), which would fail to exempt research use of patented drugs unless an IND is ultimately submitted to the FDA, was tantamount to exempting only activities necessary to obtain approval of generic drugs because only in the case of generic drugs can one know at the outset of the testing that the active ingredient in the drug being tested will be the subject of a submission to the FDA. 198 Under the Court's interpretation:

Properly construed, § 271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval: At least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is "reasonably related" to the "development and submission of information under . . . Federal law."199

The Court similarly found that the § 271(e)(1) exemption for the use of patent subject matter to obtain research data that is not ultimately submitted to the FDA was compelled by the uncertainty at the time of the research of knowing what kinds of research data—and what amounts of research data—are necessary to include in an IND or a NDA to obtain FDA approval. 200 The § 271(e)(1) exemption would apply, the Court held,

195. Id. at 2382-83.
196. Id. at 2382.
197. Id. at 2382-83.
198. Id. at 2383.
200. Id.; 125 S. Ct. at 2382-83. The Court stated:
as long as there is a reasonable basis for believing that the experiments will produce 'the types of information that are relevant to an IND or NDA.'

The Court noted that the CAFC suggested that a narrow construction of the § 271(e)(1) exemption was necessary in order to avoid depriving research tool patentees of the entire value of their patents. The Court stated that Integra had never argued that the RGD peptides at issue were research tools and, citing to Judge Newman's dissenting opinion, that it is apparent from the record they were not. On the question of research tools, the Court concluded: "We therefore need not—and do not—express a view about whether, or to what extent, § 271(e)(1) exempts from infringement the use of 'research tools' in the development of information for the regulatory process."

Finally, unlike the CAFC, the Supreme Court explicitly acknowledged the role of the common law experimental use exemption in describing the lower court proceedings. The Court noted that Merck claimed its activities were exempt from infringement under the common law research exemption and that the district court found some of the alleged infringing activities were, in fact, exempt under the common law research exemption.

III. THE EXPERIMENTAL USE EXEMPTION IN THE CONTEXT OF OTHER PATENT POLICIES

As discussed above, the CAFC majority's current formulations of the common law and Hatch-Waxman experimental use exemptions serve both to limit scientific and technical advance, and to retard competition. These results are directly contrary to other U.S. and foreign patent law policies that have long sought to promote science, technology and competition.

Focusing now only on the discrepancies between other areas of patent law

provide only that "[t]he amount of information on a particular drug that must be submitted in an IND . . . depends upon such factors as the novelty of the drug, the extent to which it has been studied previously, the known or suspected risks, and the development phase of the drug."

Id. at 2383 (quoting 21 C.F.R. § 312.22(b) (2005)).

201. Id. at 2383-84 (quoting Brief for United States as Amicus Curiae Supporting Petitioner, at 23, Merck KGaA v. Integra Lifesciences I, Ltd., 125 S. Ct. 2372 (2005) (No. 03-1237)).

202. Id. at 2382 n.7.

203. Id. (citing Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 878 (Fed. Cir. 2003)) (Newman, J., concurring in part, dissenting in part).

204. Id.

205. Id. at 2379.

206. Id.

207. See infra Part III A. C.
and the CAFC’s majority’s formulation of the common law experimental use exemption, I will first briefly review U.S. laws that have evolved to promote innovation and competition—namely laws that are intended to enable the practice of a patented invention and laws that are intended to limit the expansion of a patent’s scope. I will then discuss foreign laws and international agreements that expressly allow for the experimental use of patented subject matter to promote science, technology, and competition. I recognize that each of these policies is subject to interpretation and debate, and do not suggest that the experimental use exemption must conform to any of these policies. The purpose instead is simply to show the marked inconsistency between the current formulation of the experimental use exemption and the general thrust of patent policy in other areas of U.S. and international law.

A. The U.S. Patent Act Section 112 Enabling Disclosure Policy

Judge Newman’s dissenting opinion in Integra discussed in general terms the contradiction between the patent system’s goal of providing scientific and technological information, and the CAFC majority’s interpretation of the experimental use exemption in a way that prohibits physical use of the information provided in the patent.\(^{208}\) The contradiction that Judge Newman noted becomes even sharper when one considers the specific statutory language and case law that has been adopted to promote the provision of scientific and technological information in patents.

Section 112 of the Patent Act provides: “The [patent] specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same . . . .”\(^{209}\) On its face, the verbs “making” and “using” in § 112 suggest that the information disclosed in the patent specification can, and should, be physically used. There are only two ways to interpret the verbs “making” and “using” in § 112 in a manner that would not allow unlicensed physical use of the information contained in the written description. Both are illogical.

One interpretation would be that the references to “making” and “using” in §112 refer only to cognitive knowledge.\(^{210}\) That is to say, the test of an adequate written description would be a question of whether the information in the written description is sufficient to provide a person

\(^{208}\) Integra, 331 F.3d at 873-75 (Newman, J., concurring in part, dissenting in part).


"skilled in the art" with the knowledge necessary to understand how to make and use the invention.\textsuperscript{211} There are two difficulties with this interpretation. In many cases, it is not possible to understand how to make and use an invention without physical use of the invention. In such cases, the written description would always fail as an enabling disclosure because the language alone would not provide the knowledge necessary to make and use the invention. The second difficulty is that the determination of whether a written description provides the requisite knowledge to make and use the invention would always be a hypothetical exercise involving a subjective inquiry when an objective inquiry is possible and preferable.\textsuperscript{212}

The second interpretation of the references to "making" and "using" in § 112 would be that they contemplate physical making and using of the invention but only after the expiration of the patent term. There are also two difficulties with this interpretation. First, as Judge Newman has observed, if the information contained in the written description cannot be physically used until the expiration of the patent term seventeen to twenty years in the future, and physical use of the information is necessary to understand the written description, then the information disclosed would have little value.\textsuperscript{213} Given the pace of innovation in many technical fields, information disclosed under these circumstances would not only be placed on ice, it would be frozen into extinction. A second difficulty lies in the contradiction between requiring the patentee to disclose the invention at the beginning of the patent term while denying the public an opportunity to use the patented invention until the end of the patent term.\textsuperscript{214}

\textsuperscript{211} See id.

\textsuperscript{212} See id. at 545-46 (discussing the difficulties of implementing the writing requirement, based on knowledge of the art, in the technologically complex biotechnical field); see also A PATENT SYSTEM FOR THE 21ST CENTURY 7 (Stephen A. Merrill, Richard C. Levin, & Mark B. Myers eds., 2004) available at http://www.nap.edu/books/0309089107/html/81.html (arguing for the modification or removal of the subjective elements of litigation as one of “the factors that increase the cost and decrease the predictability of patent infringement litigation are issues . . . that depend on the assessment of a party’s state of mind at the time of . . . patent application.”); Kevin Sandstrom, Note, How Much Do We Value Research and Development?: Broadening the Experimental Use Exemption to Patent Infringement in Light of Integra Lifesciences, Ltd. v. Merck KGaA, 30 WM. MITCHELL L. REV. 1059, 1090-91 (2004) (noting the conflict between the enablement requirement and the desire of a patentee to exclude others, and arguing that Integra should be overturned to allow use of a patented drug to create different derivative products).


\textsuperscript{214} See Eisenberg, supra note 10, at 1022. Eisenberg argues that if the public had absolutely no right to make, use, or sell the patented invention until the end of the patent term, it would be somewhat puzzling to require that the patentee give the public an enabling disclosure of the invention at the beginning of the patent term. The requirement, Eisenberg contends, of early disclosure suggests that certain uses of patented inventions during the patent term do not constitute
requirement of an invention disclosure at the beginning of the patent term suggests that some physical use of the patented invention during the patent term is allowed; otherwise, an invention disclosure at the end of the patent term would suffice.\textsuperscript{215}

On the other hand, clearly § 112 cannot be read in a way that would allow unauthorized commercial exploitation of a patented invention and thereby strip the patentee of the rights granted in § 271. The only logical way to interpret the verbs “making” and “using” in § 112 is to allow physical experimentation with a patented invention. This interpretation of § 112 would seem to be supported by the CAFC decisions on the question of enabling disclosures. The court has explicitly stated many times that enabling disclosure is fundamental to the U.S. patent system’s quid pro quo whereby an inventor is granted a patent monopoly in exchange for providing information to enrich the store of public knowledge.\textsuperscript{216} Again, as Judge Newman correctly noted, in the great majority of cases if the information disclosed in the patent specification cannot be physically used, it cannot advance scientific knowledge.\textsuperscript{217}

Moreover, the CAFC has defined an enabling disclosure as information sufficient to enable a person of ordinary skill in the art to understand the invention without the need to perform “undue experimentation.”\textsuperscript{218} Among the factors listed by the court to be considered in determining whether a disclosure would require undue experimentation are the quantity of experimentation necessary, the amount of guidance available to perform the experimentation, the presence or absence of working models, and the predictability or unpredictability of research outcomes.\textsuperscript{219} Again, it is very difficult to reconcile the CAFC cases on § 112’s undue experimentation language with its cases on the experimental use exemption to patent infringement. To do so would require a bizarre chain of reasoning: the information disclosed in the patent specification is sufficient to teach the invention if it does not have to be supplemented by undue additional experimentation, but no experimentation (undue or otherwise) can be performed because it would violate the rights of the patent holder.

B. U.S. Limits on Expanding a Patent’s Scope

I discussed earlier how the CAFC’s experimental use test results in a

\begin{itemize}
\item \textsuperscript{215} See id.
\item \textsuperscript{216} See, e.g., Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 970 (Fed. Cir. 2002).
\item \textsuperscript{217} Integra, 331 F.3d at 875-76 (Newman, J., concurring in part, dissenting in part).
\item \textsuperscript{218} See Nat’l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195 (Fed. Cir. 1999) (quoting Genentech, Inc. v. Novo Nordisk Als, 108 F.3d 1361, 1365 (Fed. Cir. 1997)).
\item \textsuperscript{219} See In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).
\end{itemize}
de facto extension of the patent term and a de facto expansion of the patent claims.\textsuperscript{220} The patent term will be extended by the time required to experiment with an invention after the expiration of the patent term in order to market a competing invention. The patent claims will be expanded by the patentee’s ability to prohibit experimentation with an invention and thereby thwart the marketing of new or improved inventions that were not claimed in the patent application. Both of these results conflict with well-established policies in other areas of patent law.

The U.S. Supreme Court held more than forty years ago that an attempt to collect license royalties beyond the period of the patent term was "unlawful per se" and constituted patent misuse rendering the license unenforceable.\textsuperscript{221} The Court was clearly concerned by the prospect of extending the patent monopoly beyond the time period specified in the Patent Act.\textsuperscript{222} Justice Douglas, writing for the Court, stated:

A patent empowers the owner to exact royalties as high as he can negotiate with the leverage of that monopoly. But to use that leverage to project those royalty payments beyond the life of the patent is analogous to an effort to enlarge the monopoly of the patent by tying [sic] the sale or use of the patented article to the purchase or use of unpatented ones.\textsuperscript{223}

Although this decision has been criticized on various grounds by commentators,\textsuperscript{224} it has never been overturned, has been acknowledged as precedent by the CAFC,\textsuperscript{225} and recently has been extended to the case of foreign license agreements.\textsuperscript{226} Recall in Bolar that the CAFC dismissed objections to the de facto extension of the patent term because this extension served to offset to some extent the loss of the effective patent term due to FDA review.\textsuperscript{227} Whether or not this rationale was supportable in the context of the pharmaceutical industry at the time Bolar was decided, it could never be supported outside of the pharmaceutical

\textsuperscript{220} See supra notes 105-09 and accompanying text.
\textsuperscript{222} See id.
\textsuperscript{223} Id. at 33.
\textsuperscript{225} See, e.g., Va. Panel Corp. v. MAC Panel Co., 133 F.3d 860, 869 (Fed. Cir. 1997) (relying on Brulotte, 379 U.S. at 33).
\textsuperscript{226} See, e.g., Admin’rs of Tulane Educ. Fund v. Debio Holding, S.A., 177 F. Supp. 2d 545, 551 (E.D. La. 2001) (recognizing that no court had ever refused to apply the Brulotte holding to foreign patent license agreements).
\textsuperscript{227} Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 864-67 (Fed. Cir. 1984).
industry and could not be supported within the pharmaceutical industry after the passage of the Hatch-Waxman Act.\textsuperscript{228}

Justice Douglas analogized the enlargement of the patent monopoly by extending the term of the patent through post-expiration royalties to the enlargement of the patent monopoly by expanding the scope of the patent claims by tying sales of a patented article to the purchase of an unpatented article.\textsuperscript{229} Earlier Supreme Court cases had held that these tying arrangements constituted patent misuse which rendered the patent unenforceable until the patent misuse was purged.\textsuperscript{230} Over the years, however, the doctrine of patent misuse has been narrowed by judicial decisions and congressional legislation to the point that today patent misuse has been largely subsumed into the field of antitrust law.\textsuperscript{231} Nonetheless, concern over arrangements in which a patent is used in a way that limits competition continues.

The most recent and most comprehensive discussion of this subject is the "Antitrust Guidelines for the Licensing of Intellectual Property" (Guidelines), jointly promulgated by the Department of Justice and the Federal Trade Commission in 1995.\textsuperscript{232} There are three areas of antitrust concern discussed in the Guidelines that are directly relevant to analysis of the experimental use exemption: limiting competition in research and development;\textsuperscript{233} limiting a licensee in dealing with technologies owned by its licensor's competitors;\textsuperscript{234} and requiring a licensee to "grantback" to its licensor improvements made by the licensee to the licensed technology.\textsuperscript{235}

The Guidelines provide that in analyzing the anticompetitive impact of licensing arrangements, the DOJ and FTC (Agencies) will consider

\textsuperscript{228} See Eyal H. Barash, Experimental Uses, Patents, and Scientific Progress, 91 NW. U. L. REV. 667, 690 (1997) (noting that the statute overruled part of Bolar by legalizing experimentation prior to patent expiration); Lanier, supra note 76, at 710-14; Mueller, supra note 85, at 25-27 (discussing the common law exemption’s state following Congress’s enactment of the act); Parker, supra note 39, at 637-41 (discussing court interpretations of the act); Walters, supra note 110, at 523-32 (discussing court applications of the exception).


\textsuperscript{230} See, e.g., Mercoid Corp. v. Mid-Continent Inv. Co., 320 U.S. 661, 665-66 (1944) (noting that such arrangements divert the patent from its statutory purpose); Morton Salt Co. v. G.S. Suppiger Co., 314 U.S. 488, 491 (1942) (noting that a "patent affords no immunity for a monopoly not within the grant").

\textsuperscript{231} See generally 35 U.S.C.A. § 271(d) (2000) (immunizing certain conduct from the charge of patent misuse); Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 200 (1980) (discussing how tying should be treated following the enactment of § 271(d)).


\textsuperscript{233} Id. § 3.2.3.

\textsuperscript{234} Id. § 5.4.

\textsuperscript{235} Id. § 5.6.
innovation markets, generally defined as research and development activities directed toward development of new or improved goods or processes, as separate markets distinct from the actual goods or processes markets. The concern here is that firms might enter into agreements that retard the pace of research and development of new technology and thereby constrain competition in the market for the current technology.

The Guidelines define “exclusive dealing” as license arrangements that prevent “licensee[s] from licensing, selling, distributing, or using competing technolog[y].” In analyzing the anticompetitive impact of exclusive dealing arrangements, the Guidelines provide that the Agencies will consider the extent to which the arrangements promote development of the licensor’s technology and foreclose development, or constrain competition, among competing technologies.

Finally, the Guidelines define “[g]rantbacks” as arrangements under which licensees agree to grant to licensors the rights to improvements made by the licensees to the licensed technologies. The principal concern here is exclusive grantbacks to licensors. Exclusive grantbacks to licensors “[limit] the licensee’s incentives to engage in research and development” because any new or improved technology yielded by the research and development can only be commercialized through the licensor. The licensee’s disincentive results in lessened competition in the research and development market and in the market for the goods or processes being licensed.

The current experimental use exemption promotes the anticompetitive practices which the Guidelines seek to restrain. The inconsistency between the current experimental use exemption and the antitrust licensing guidelines can best be illustrated by considering private arrangements among firms that would produce the same effect as the experimental use exemption. For example, assume that all the firms in a market entered

236. Id. § 3.2.3.
237. Id.
238. Id. § 5.4.
239. Id.
240. Id. § 5.6.
241. Id.
242. See id.
243. See Strandburg, supra note 11, at 82 (arguing that experimental use can circumvent anticompetitive refusals to license because it provides an exemption to infringement liability in principle). However, the current experimental use paradigm supports anticompetitive behaviors by nullifying the experimental use exemption when in pursuit of “legitimate business” objectives. See supra notes 127-31 and accompanying text.
244. See Mueller, supra note 85, at 15-16, 61-66 (suggesting researchers will more likely either neglect or forego research or conduct such research without authorization when acquisition of a research tool requires “direct license negotiations,” and discussing the benefits of reach-through royalties); Strandburg, supra note 11, at 102, 125-27 (pointing to the lack of incentive for
into an agreement in which they agreed not to pursue research and development of any technology that was under investigation by another firm. Clearly, such an agreement would retard competition in the research and development market and likely run afoul of the antitrust guidelines. However, this is exactly the result that is produced by the current experimental use exemption without the need of a private agreement. The firms in a market cannot pursue research in competition with one another without first obtaining permission if the research necessitates the use of patented technology.

The situation is the same in the case of exclusive dealing. Assume a licensor prohibited a licensee from engaging in research with the licensed technology in order to develop a non-infringing competing technology. Such a prohibition would be similar to prohibiting the licensee from dealing with technologies owned by the licensor’s competitors and would clearly limit competition both in the research and development market and in the market for the technology being licensed. Again, however, the current experimental use exemption produces this same result without the need of a private agreement. If the research required to develop a non-infringing competing technology necessitates the use of patented technology, the patentee can prohibit this research by merely failing to grant a license. If the patentee refuses to grant a license to perform the research necessary to develop a non-infringing competing technology, which is highly likely, competition is retarded in the research and development market and the patentee’s current technology is subject to lessened competition.

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245. See Strandburg, supra note 11, at 93 (noting that by making infringement dependent upon the legitimate business objectives of an unauthorized experimenter rather than commercial intent, the court has precluded the ability of third-party inventors to develop improvements to patents via follow-on innovation).

246. See id. at 102 (“Even though design-grounds and improvements are intended public benefits of the patent system, patentees have little incentive to license their competitors to experiment ‘on’ their inventions to produce such follow-on innovations.”).

247. See id.

As cases like Em brex illustrate, patentees are not primarily concerned with collecting royalties for such [experimental] uses but with impeding their competitors’ ability to use the patentees’ inventive ideas as a basis for new
Finally, the current experimental use exemption increases the possibility of anticompetitive exclusive grantbacks by giving owners of patented technology the exclusive right to control research utilizing that technology.\textsuperscript{248} Again, if the research required to develop new and improved technology necessitates the use of a patented technology which must be licensed, the owner of the patented technology has the bargaining leverage to demand a grantback of the new or improved technology as a condition of the license grant.\textsuperscript{249}

C. Foreign Experimental Use Exemptions

A number of countries have enacted a statutory experimental use exemption. These countries include the United Kingdom,\textsuperscript{250} Japan,\textsuperscript{251} Germany,\textsuperscript{252} China,\textsuperscript{253} and Mexico.\textsuperscript{254} An experimental use exemption has

inventions. Decisions such as Embrex, while indisputably correct as to the commercial intentions of the unauthorized user, are certain to have a chilling effect on this socially beneficial experimentation.

\textit{Id.} (citations omitted).

\textsuperscript{248} See \textit{id.} at 123-24 (discussing how tool patentees can "control the progress of research").

\textsuperscript{249} See \textit{id.} at 123 (suggesting that in the case of research tools the primary financial return to the research tool owners might come from exclusive control of the research results yielded by the tool rather than from the widespread use of the tool itself).

\textsuperscript{250} Patents Act, 1977, ch. 37, § 60(5)(a) (Eng.) (stating that patent protection shall not apply to an act "done privately and for purposes which are not commercial").


\textsuperscript{252} \textit{WORLD INTELLECTUAL PROPERTY GUIDEBOOK: FEDERAL REPUBLIC OF GERMANY} 2-139 (Bern & Ruster eds., 1991). The exemption covers "[a]cts carried out privately and for noncommercial purposes" and "[a]cts carried out for experimental purposes relating to the subject matter of the patented invention." Parker, \textit{supra} note 39, at 653 n.204 (citing \textit{WORLD INTELLECTUAL PROPERTY GUIDEBOOK: FEDERAL REPUBLIC OF GERMANY} 2-139 (Bern & Ruster eds., 1991)).

\textsuperscript{253} Bruzzone, \textit{supra} note 9, at 63 (citing Patent Law, adopted at the Fourth Session of the Standing Committee of the 6th National Peoples Congress on March 12, 1984, \textit{translated by} the Chinese Patent Office, Section 62(5)). The law reads: "'[W]here any person uses the patent concerned solely for the purposes of scientific research and experimentation,' that use will not be deemed to infringe." Bruzzone, \textit{supra} note 9, at 62 (quoting Patent Law, Chinese Patent Office, § 62(5)).

\textsuperscript{254} Bruzzone, \textit{supra} note 9, at 63 (citing Ley de Fomento y Protección de la Propiedad Industrial, Diario Oficial de la Federación [D.O.], § 22, 25 de Junio de 1991 (Mex.)). The pertinent section of the law provides:

\textit{[T]he right conferred by a patent "shall not have any effect against . . . a third party who, in the private or academic sphere and for noncommercial purposes, engages in scientific or technological research activities for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or a
also been included in a number of international agreements including the Convention for the European Patent for the Common Market (Community Patent Convention), the Proposed Patent Model for Developing Countries, and the World Intellectual Property Organization Draft Treaty Supplementing the Paris Convention for the Protection of Industrial Property as far as Patents are Concerned (WIPO Draft Harmonization Treaty).

Although the scope of these foreign experimental use exemptions varies, they all provide at a minimum for the use of patent subject matter for the purpose of determining whether a patented invention is feasible, useful, or technically operable. Some of the foreign experimental use exemptions are considerably broader and allow for the use of patent subject matter even when the use is clearly commercially motivated. The language in the Community Patent Convention and WIPO Draft Harmonization Treaty would appear to allow commercially motivated uses of patent subject matter if the experimentation is directly related to the patented invention. For example, the Community Patent Convention provides that patent protection does not extend to “acts done privately and for non-commercial purposes” or to “acts done for experimental purposes relating to the subject-matter of the patented invention.” Likewise, the WIPO Draft Harmonization Treaty provides that the patent owner has no right to prevent third parties from performing acts:

process identical to the one patented . . . .”

Bruzzone, supra note 9, at 63 (quoting Ley De Fomento y Protección de la Propiedad Industrial, Diario Oficial de la Federación [D.O.], § 22, 25 de Junio de 1991 (Mex.)).


256. WIPO Model Law for Developing Countries on Inventions, Commentaries on the Model Law.

257. WIPO Draft Harmonization Treaty, as reported in the “Basic Proposal” for the Treaty and the Regulations, Diplomatic Conference for the Conclusion of a Treaty Supplementing the Paris Convention as Far as Patents are Concerned, The Hague, June 3 to 28, 1991, submitted, under Rule 29(1) of the Draft Rules of Procedure, by the Director General of WIPO. (ARTICLE 19, Alternative B, Section 3(iii)).


259. See Monsanto Co. v. Stauffer Chem. Co., (1985) R.P.C. 515, 538 (C.A.) (holding that “experimental purposes” may include a commercial purpose such as determining whether a quality product can be manufactured according to the language of the patent specification); see also Smith Kline & French Labs. Ltd. v. Evans Med. Ltd., (1989) 1 F.S.R. 513, 517 (Ch. (Pat. Ct.)) (holding that experiments conducted to challenge the validity of a competitor’s patent fell within the experimental use exemption).

(ii) where the act is done privately and on a non-commercial scale or for a non-commercial purpose, provided that it does not significantly prejudice the economic interests of the owner of the patent;
(iii) where the act consists of making or using exclusively for the purpose of experiments that relate to the subject matter of the patented invention . . . .

These foreign experimental use exemptions disadvantage the United States in two ways. First, these foreign experimental use exemptions allow for the advancement of science and innovation to a much greater extent in other countries than in the United States. In an era of global technology competition, this could result in fewer jobs, larger trade deficits, and, ultimately, a lower standard of living in the United States. If this occurs, it would be an entirely self-inflicted harm that could be easily avoided through either judicial or legislative reform of the U.S. experimental use law. Second, these foreign experimental use exemptions provide scientists and engineers in other countries with research opportunities that they do not have in the United States. This could result in the migration of top researchers from the United States to other countries and deprive industry, as well as universities, of critical human resources. Again, if this were to occur, it would be an entirely self-inflicted and avoidable harm.

The purpose of this section is not to suggest that the experimental use exemption must be fully in accord with these other patent policies, and I recognize that these other patent policies are themselves subject to interpretation and debate. Nonetheless, I believe that when these other patent policies are considered together they do reveal a marked conflict between the current U.S. experimental use law and other U.S. and foreign patent law policies.

IV. EXPERIMENTAL USE LAW REFORM PROPOSALS

A number of very thoughtful articles have been written over the years on the experimental use exemption. These articles have proposed changes in the law ranging from an extremely limited research exemption to an exemption for any and all research purposes. In general, writers on the subject have analyzed the experimental use exemption in terms of

261. WIPO Draft Harmonization Treaty, supra note 257. For a discussion of foreign experimental use exemptions, see Parker, supra note 39, at 648-57 (finding that many of the world’s industrialized nations have exceptions for research related to the subject matter of a patented invention); see also Bruzzone, supra note 9, at 61-66 (providing a “brief review of the approaches some foreign states have taken”).

262. See infra Part IV.A.1-3.
distinctions within four categories of facts: the type of organization performing the experimentation, the purpose of the experimentation, the intended purpose of the patented subject matter utilized in the experimentation, and the source of funding for the experimentation. Analyses of the organization performing the experimentation have focused on distinctions between universities, small companies, and large companies; analyses of the purpose of the experimentation have focused on distinctions between research to advance science or ascertain the accuracy of patent specifications and research for the purpose of developing new commercial products or processes; analyses of the intended purpose of the patented subject matter used in the experimentation have focused on distinctions between research tools and end-user commercial products and processes; and analyses of the source of funding for the experimentation have focused on distinctions between federal funding, industry funding, and university or nonprofit funding.

In this part of the Article, the first section will describe the main law reform proposals that have been suggested for the experimental use exemption. Although each of these proposals has been advanced as an independent recommendation, there is in fact considerable overlap between the proposals, and they can best be viewed as a continuum running from limited exemptions, to qualified exemptions, to broad exemptions. The discussion of the various law reform proposals will be organized along this continuum. The concluding section in this part of the Article will critique the various law reform proposals.

A. The Law Reform Proposals

1. Limited Exemptions

Writers who advocate limited experimental use exemptions generally emphasize the loss of value to patentees that would result if patented technologies could be freely used for research to develop new or improved

263. See infra Part IV.A.
264. See infra Part IV.A.
265. I do not discuss all of the law reform proposals that have been suggested for an experimental use exemption. Two noteworthy proposals that have suggested a copyright fair use approach to an experimental use exemption that are not included in this discussion are: Maureen A. O’Rourke, Toward a Doctrine of Fair Use in Patent Law, 100 COLUM. L. REV. 1177 (2000) (concluding that “fair use, by helping to calibrate exclusive rights in a manner informed by patent policy, is a more desirable, tailored solution to new market conditions”) and Donna M. Gitter, International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption, 76 N.Y.U. L. REV. 1623 (2001) (noting that an experimental use exception would allow research for non-commercial purposes by public sector and nonprofit scientists).
competing technologies. This loss of value to patentees occurs in two ways. First, the patentee is deprived of royalties from use of the patented technology in research; that is, developers of new or improved follow-on technology benefit from the investment in the patented base technology, but escape paying for the research use of the base technology. Second, the free use of patented technology in research would increase the probability of developing new or improved competing technology. Consequently, consumers might forgo purchasing the base technology in order to purchase new or improved competing technology as it becomes available.

One of the earliest discussions of the experimental use exemption was published in 1957 by Richard Bee. Bee's ultimate conclusion is that the experimental use exception "is not warranted as a matter of law or legal theory, is not consistent with the protection otherwise given the patentee's rights by the courts, and may serve as a source of judicial confusion and mischief." Bee's interpretation of the experimental use law is similar to that of the CAFC majority: The experimental use exemption is reserved solely for the purpose of "gratifying a philosophical taste, or curiosity, or for mere amusement" and that if there is the slightest business purpose or profit motive present the exemption is no longer applicable.

266. See, e.g., Karp, supra note 244, at 2180.

[C]ommentators [supporting an experimental use exemption] fail to value the contribution that the patentee may have made to the development of his competitors' innovations. After all, but for the patentee's inventive efforts and his willingness to disclose the fruits of those efforts, competitors would not even be in a position to develop a noninfringing alternative or improvement.

Id.

267. Walters, supra note 110, at 529 ("A broad experimental use exception would weaken patent enforceability and discourage innovations because third parties would wait for someone else to conceive and make an invention. The free-rider could then copy the patented invention, improve it under the experimental use exception, and patent the improvement.").

268. Id.


270. Id. at 359.

271. Id. at 375. Bee explained:

Considering all the cases which have passed on the question of experimental use, it appears that by far the greater majority of the cases have construed the experimental use exception rather strictly and have held it to be applicable only where the experiment was for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement. Needless to say, such an occasion will rarely arise where the experiment is conducted by a business enterprise because business enterprises simply do not do things merely for amusement, etc.
A somewhat less limited proposal for an experimental use exemption, suggested by Michelle Walters, would allow the exemption only for universities and individuals, and only if they derive no monetary benefit from the research exemption.272 Walters' proposal posits five acceptable research uses of patented technology by universities: to verify patent claims, to use for comparison to a new technology, to gain scientific knowledge, to use for classroom teaching, and to develop new research tools donated to the public.273 Corporate sponsorship of university research that utilizes patented technology would not eliminate the exemption if the research results were published and available for use by the public.274 Individuals would be entitled to the experimental use exemption unless their research was funded by a corporation for commercial purposes.275

The Walters proposal would deny the experimental use exemption to all business entities because their primary objective is to make a profit and all of their activities, including research, are in pursuit of that profit objective.276 Walters also suggests that business entities do not need an experimental use exemption because they can learn about the patented technology by studying the patent specification, by purchasing the patented product and obtaining an implied right to experiment with it, or by obtaining an express license from the patentee to experiment with the patented technology.277

A similarly limited experimental use exemption has been advanced by Jordan Karp. Karp argues that a broad experimental use exemption would retard innovation because industry would be reluctant to file patents and provide invention disclosures if patented technology could be used without a license to develop new or improved competing technology.278 Karp

Id.  
272. Walters, supra note 110, at 540.  
273. Id. at 535-38.  
274. Id. at 538.  
275. Id. at 539.  
276. Id. at 523-25.  
277. Id. at 530-34. Walters suggests that a patentee might be particularly disposed to grant a license to an experimenter when the purpose of the experimenter is to develop an improvement that incorporates the original patented invention. Id. at 532. Walters' suggestion assumes that patentees welcome licensee improvements to their inventions and trust that licensees will not engineer around their patent. Both assumptions are problematic.  
278. Karp, supra note 244, at 2180.  

[A] broad experimental use exception, by discouraging inventors from relying on the patent system, would decrease the level of public disclosure of new inventions as well as reduce innovative activity in those industries that rely on patent protection. A broad exception, rather than fostering innovation, would have exactly the opposite effect.
would allow an experimental use exemption for the same general purposes as Walters: to ascertain the truthfulness and accuracy of the patent specification, to ensure that the patent disclosure complies with the requirements of § 112, to determine the novelty and non-obviousness of a subsequent invention, and for purely scientific research with no foreseeable commercial application.\textsuperscript{279} Unlike Walters, however, Karp would extend the experimental use exemption to corporations and allow the commercial use of exempted research if the patentee is paid a "reasonable royalty" for the exempted research.\textsuperscript{280} Karp describes this latter situation as a type of "limited compulsory licenses" whereby the experimenter would have to pay a royalty for the research use of the patented technology in the event that the research is used to develop a commercial product or process, regardless of whether or not the commercial product or process is non-infringing.\textsuperscript{281} In Karp's view, this arrangement would not discourage filing patent applications and making invention disclosures because the patentee would be compensated if the patented invention is used in research for commercial purposes.\textsuperscript{282}

David Parker has proposed another limited experimental use exemption. Parker believes that a broad experimental use exemption would be particularly harmful to universities and to the advancement of basic research.\textsuperscript{283} According to Parker, a significant number of university patents cover basic research subject matter that serves as building blocks for the eventual development of commercial products or processes.\textsuperscript{284} If these basic research patents can be used without a license to develop commercial products and processes, which in many cases would not infringe the basic research patent, Parker believes the return on investment

\begin{flushleft}
\textit{Id.}\textsuperscript{279} \textit{Id.} at 2179-80.
\textsuperscript{280} \textit{Id.} at 2188.
\textsuperscript{281} \textit{Id.}
\textsuperscript{282} \textit{Id.}
\end{flushleft}

An experimenter would only have to compensate the patentee when the experimental activity actually resulted in a benefit to the experimenter (thus, allowing 'pure' scientific research to continue unhindered). Because experimental use will only dissuade an inventor from utilizing patent protection to the extent that an experimenting party is able to develop a competing product, a properly administered reasonable royalty regime should strike an optimal balance between the inventor's desire to appropriate the returns on her investment in R&D and the public's desire for a steady flow of innovations.

\begin{flushleft}
\textit{Id.}\textsuperscript{283} Parker, \textit{supra} note 39, at 659.
\textsuperscript{284} \textit{Id.}
\end{flushleft}
in current basic research needed to support future basic research would be lost. Parker's proposal is similar to Karp's, but more detailed. Parker would exempt commercial and non-commercial research use of patented inventions performed by for-profit and nonprofit organizations. However, the exempted research use would retroactively become an act of infringement upon the sale of or the offer to sell any product or process developed under the research exemption. Parker would not allow the patentee to enjoin the sale of, or the offer to sell, products or processes developed under the research exemption, thus creating in essence a compulsory license to use patented inventions in research. Finally, Parker would require a separate license if the product or process developed under the research exemption would infringe the patented invention used in the research.

2. Qualified Exemptions

Probably the most thoughtful and comprehensive article on the experimental use exemption was published in 1989 by Professor Rebecca Eisenberg. Eisenberg's article is worth considering in some detail because of her analysis of the experimental use exemption in the context of the economic theories that have been advanced to explain the operation of the patent system. Eisenberg discusses four economic theories of patent law: the incentive to invent theory, the incentive to disclose theory, the

285. Id.

A significant number of patents that arise out of basic research institutes cover subject matter that is only a starting point for further development of commercial products or involve techniques or compositions whose principal value to commercial licensees is the ability to improve research capability. A statutory research exemption could thus undermine the value of these basic patents by rendering them essentially incapable of infringement.

Id. (citation omitted).

286. Id. at 659.
287. Id. at 659-60.
288. Id.
289. Id. at 660.

[If the activity results in a product or process within the scope of the patented technology, the end product or process itself would be actionable without regard to the underlying technology used in its development. In short, only the research activities would receive the 'limited-time' protection, not the end result of that research.

Id.

290. Eisenberg, supra note 10, at 1017.
incentive to innovate theory, and the incentive to invest in subsequent research theory. 291

The incentive to invent theory posits that patent protection is necessary to reward investment in research which in turn promotes the public good.292 Eisenberg does not believe that the incentive to invent theory provides clear guidance on the experimental use exemption because analyses of the theory have focused on commercial technology rather than on basic scientific research.293 The incentive to disclose theory suggests that patent protection is necessary to encourage inventors to reveal information about their inventions rather than keeping this information secret and unavailable to the public.294 Although Eisenberg questions whether secrecy is a practical strategy to protect inventions in many instances, and whether patent disclosures in fact convey enough information to be useful to the public, she appears to acknowledge that an experimental use exemption might diminish the incentive to disclose information about inventions.295 The more fundamental problem that Eisenberg notes with both the incentive to invent and incentive to disclose theories as guides to an appropriate experimental use exemption is that there is no empirical evidence on how much incentive is necessary for optimal levels of invention and disclosure, or on whether the current level of incentive is too high or too low.296

Eisenberg finds a similar problem with the incentive to innovate theory.297 The incentive to innovate theory suggests that the patent

291. Id. at 1028-38.

292. Id. at 1024-26. Eisenberg notes three criticisms of the incentive to invent theory. Id. at 1026-28. First, patent protection might restrict the use of new inventions and thereby reduce their social benefits. Id. at 1026. Second, patent protection might distort economic activity if firms race to obtain patents by means of inefficient research efforts. Id. at 1027. Third, patent protection might hinder progress by providing a disincentive to other persons to make improvements to patented inventions or to waste time and effort finding duplicative solutions to problems in order to avoid patent infringement. Id. at 1027-28.

293. Id. at 1030.

294. Id. at 1028.

295. See id. at 1028-30.

296. Id. at 1030.

One might assume that, other things being equal, reducing the strength of patents would reduce incentives to make and disclose new inventions and that, conversely, increasing the strength of patents would increase incentives to make new inventions and to patent them in lieu of protecting them as trade secrets. But the magnitude of these effects is uncertain. Moreover, it is difficult to say whether the current level of incentives is too high or too low.

297. See id. at 1037.
monopoly is necessary to promote investment in the post-invention commercial development of new technologies.\(^{298}\) Eisenberg acknowledges that the incentive to innovate theory does provide a rationale for post-invention rewards and that the loss of these rewards under an experimental use exemption could shorten the effective life of the patentee’s technology and deprive the patentee of royalties that would otherwise be collected for research use of the patentee’s technology, and that if this happened the incentive to innovate would be reduced by some degree.\(^{299}\) However, in the absence of empirical measurement of the magnitude of these effects, Eisenberg concludes that the incentive to innovate theory leads to the “same analytical dead end as the incentive to invent and incentive to disclose theories: its policy implications turn on empirical questions without clear answers.”\(^{300}\)

Finally, Eisenberg considers the incentive to invest in subsequent research theory, commonly referred to as the “prospect theory.”\(^{301}\) The prospect theory holds that patent rights promote efficiency in follow-on research by allowing the patent owner to monitor and coordinate subsequent research activity and thereby avoid duplicative and wasteful resource expenditures.\(^{302}\) Eisenberg notes a number of limitations to the prospect theory, including its criticism by economists and the incentive for follow-on researchers to obtain a license in any event if the research might

\(^{298}\) Id. Eisenberg contrasts the incentive to invent theory and incentive to innovate theory: The incentive to invent theory does not warrant strong patent protection after the point of invention while the incentive to innovate theory warrants strong patent protection throughout the patent term. Id. at 1037-38.

\(^{299}\) Id. at 1036, 1038. Eisenberg also discusses the Schumpeterian Theory that posits monopolies are conducive to innovation:

While Schumpeter does not focus exclusively on either technological innovations or the patent system, his analysis suggests how patent monopolies might promote technological innovation. He emphatically distinguishes innovation from invention, noting that invention itself produces “no economically relevant effect at all.” Innovation, on the other hand, brings about incessant revolutionary changes in the economic system through what Schumpeter calls “a process of creative destruction.”

\(^{300}\) Id. at 1038-39 (quoting JOSEPH SCHUMPETER, 1 BUSINESS CYCLES 84 (Transaction reprint, Redvers Opie trans., 1939) and JOSEPH SCHUMPETER, CAPITALISM, SOCIALISM, & DEMOCRACY 83 (3d ed. 1950)).

\(^{301}\) Id. at 1040.

\(^{302}\) Id. at 1044.
result in an improvement to the patented technology.\textsuperscript{303} In the end, however, Eisenberg does acknowledge that the experimental use exemption could arguably interfere with the efficient pursuit of follow-on research.\textsuperscript{304} She does not note, but could have noted, the lack of empirical evidence to support the prospect theory as well, and particularly the assumption that monopoly control over follow-on research activities produces superior research outcomes than can be achieved through competition.

Based on her analysis of the economic theories underlying the patent system and their implications for an appropriate experimental use exemption, Eisenberg distinguishes three experimental use situations: the researcher is using a patented research tool for its intended purpose, the researcher is using patented subject matter to test the validity of the patent claims, and the researcher is using the patented subject matter to make further advances in the technology in competition with the patent owner.\textsuperscript{305} Eisenberg believes that an experimental use exemption is not needed in the first situation because patentees of research tools will make these tools available to researchers in the ordinary course of business.\textsuperscript{306} On the other side, Eisenberg believes the case for an experimental use exemption is strongest in the second situation because patent law is intended to promote the advancement of knowledge and to allow challenges to a patent's validity.\textsuperscript{307}

\begin{itemize}
\item[\textsuperscript{303}] Id. at 1043-44.
\item[\textsuperscript{304}] Id.
\item[\textsuperscript{305}] Id. at 1074-75.
\item[\textsuperscript{306}] Id. at 1074. Eisenberg assumes that owners of patented research tools will want to extend licenses to researchers "in order to extract the full value of the patent monopoly." Id. Other writers have suggested that "[t]he primary financial return" to a research tool patentee might come from exclusive control of the results yielded by the research tool rather than from the widespread use of the tool itself. See, e.g., Strandburg, supra note 11, at 123.
\item[\textsuperscript{307}] Eisenberg, supra note 10, at 1075-76.
\end{itemize}

Free access to patented inventions for the limited purpose of permitting scrutiny of new research claims serves the policies underlying the patent law as well as the interests of research science. Indeed, patent law promotes scrutiny of the research claims embodied in patented inventions through its requirement that patent
Eisenberg sees the conflict between the interests of the patent holder and the interests of subsequent researchers as most intractable when they are competitors each seeking to develop superior technology. The compromise solution that Eisenberg proposes in this situation is to deny the subsequent researcher an experimental use exemption, but also to deny the patent owner the right to enjoin the research activity. The result of this compromise solution is that the patent owner’s only remedy would be reasonable royalty damages; or viewed in another way, the subsequent researcher would be entitled to a compulsory license to use the patented technology for research purposes upon payment of reasonable royalty damages to the patent owner.

A final noteworthy proposal for a qualified experimental use exemption has been advanced by Suzanne Michel. A major focus of Michel’s concern, similar to that of Parker, is the disadvantage to universities, research centers, and small firms that could result from a broad experimental use exemption. Michel suggests that these organizations are the source of major research advances, but they lack the resources necessary to convert these research advances into commercial technologies. If larger firms with much greater resources were able to

holders make enabling disclosures of their inventions freely available to the public.

Id.

308. Id. at 1075-76. Eisenberg notes that an experimental use exemption in the context of competitors reduces the value of the patent monopoly in two ways: First, it deprives the patentee of the royalties that might otherwise be collected from researchers; and second, it shortens the expected duration of the patent monopoly by lowering the cost to invent around the patent. Id. The loss of royalties from researchers assumes that the patentee has the right to prohibit the use of the patented invention by researchers in the first instance. The loss of value of patent monopolies assumes that patentees will not also benefit from an experimental use exemption that allows them to perform research on their competitors’ inventions just as their competitors can perform research on their inventions.

309. Id. at 1076-77.

310. Id. at 1077. Eisenberg suggests that damages would not have to be paid to the patentee for the unauthorized research use of the patented technology if the technology developed by the researcher is an improvement upon the patented technology that requires a license to commercialize. Id. However, if the researcher used the patented technology to invent around the patent, then the researcher would have to pay damages for the unauthorized research use of the patented technology. Id. at 1077-78.


312. Id. at 396-97.

313. Id. at 396.

In general, the patent system appears to be of more value in stimulating invention and innovation by small rather than large firms. Because the market position of
use this advanced research without a license, Michel believes that universities and research centers would lose the licensing revenue needed to support new research projects and that small firms would lose the investment capital needed for commercial development of early-stage research. 314

There are two parts to Michel’s experimental use proposal. The first part is similar to previously discussed proposals while the second part is novel. The first part of Michel’s experimental use proposal would grant universities and other nonprofit research centers a broad experimental use exemption; however, if a for-profit firm sought to commercialize the research undertaken by a nonprofit organization under the benefit of the experimental use exemption, the firm would have to negotiate a license with the patentee as if the firm itself had performed the research initially. 315 The second part of Michel’s experimental use exemption would allow both nonprofit and for-profit organizations to use patented technology for research purposes if the technology has been developed with federally-funded research. 316 Michel believes that this exemption is warranted because the goal of the federal government in funding research

a small firm is more vulnerable to imitation by large firms, patents do more to protect their market position. In addition, small firms will likely be slower at penetrating new markets through innovation, given their lack of distribution channels and market acceptance as compared to large firms. For these reasons, anyone proposing changes to the patent laws should be especially cognizant of their effect on small firms.

Id. (citation omitted).
314. Id. at 397.
315. Id. at 397-99. Michel claims that a broad experimental use exemption harms the incentive to invent by “allow[ing] subsequent inventors to free ride on the original inventor’s work if the subsequent inventor can use the original invention to improve on and design around the original invent[ion].” Id. at 394. There are two responses to Michel’s concerns. First, if the subsequent inventor improves upon the original invention, the subsequent inventor will require a license from the original inventor prior to commercializing the improved invention and this will provide a return to the original inventor on her investment in the original invention. Second, if the subsequent inventor is viewed as a potential free rider on the original inventor’s work, the original inventor must also be viewed as a potential free rider on the subsequent inventor’s work. A commercial experimental use exemption is a two-way street that increases the competition, as well as the risks and benefits, for all firms in a market.
316. Id. at 400. This proposal would be tantamount to a repeal of the Bayh-Dole Act, 35 U.S.C. §§ 200-212 (2000) (granting to universities the option to take title to patents resulting from federally funded research). The great majority of university patents derive from federally-funded research. If these patents can be freely used by industry for research their value to universities will be significantly reduced.

There is some inconsistency between Michel’s concern with protecting universities from unauthorized industry research under a broad experimental use exemption and her allowance of unauthorized industry research in the case of patents derived from federally-funded research, which constitute the great majority of universities’ patent portfolios. Michel, supra note 311, at 397-400.
is to encourage additional research and this goal would be undermined if federally-funded research could not be freely used. Unlike Michel's experimental use exemption for universities and research centers, however, the commercialization of federally-funded research by firms would only require a license if the resulting commercial product or process was covered by the patentee's patent claims.

3. Broad Exemptions

There are three reasons most often given in support of a broad experimental use exemption: the need to understand how patented technology works in practice in order to advance knowledge in fields of science; the need to improve upon, and invent around, patented technology in order to promote development of new technologies; and the need to limit the ability of owners of research tools to control downstream inventions in order to promote competition in technology product and process markets.

In a 1985 article, Ronald Hantman undertook the same historical review of the experimental use exemption as Bee and reached the exact opposite conclusion—that the case law supports a broad interpretation of the experimental use exemption. Under Hantman's analysis, commercially motivated research and development to find new uses and improvements for patented technology should be included within the experimental use exemption to encourage the innovation of new technology. Hantman responds directly to the argument that a broad

317. _Id._ at 402.

318. _See id._ at 407-08 (noting that a non-licensee could design around a patent thereby creating a non-infringing work that would nevertheless replace the licensee's product in the marketplace).

319. _See, e.g.,_ Barash, _supra_ note 228, at 699-700 (underscoring the need for permitting researchers to invent around patented technology); Ronald D. Hantman, _Experimental Use as an Exception to Patent Infringement_, 67 J. PAT. & TRADEMARK OFF. SOC'Y 617, 640 (1985) (arguing that research and development ought to be subject to an experimental use exemption in order to encourage innovation); Mueller, _supra_ note 85, at 11-12 (discussing the need for access to patented research tools in the field of biotechnology).

320. Hantman, _supra_ note 319, at 618.

A careful review of the case law shows that it does not support the proposition that the experimental use exception is narrow. Furthermore, an understanding of how research and development is carried on in modern industry shows that the exception is necessary for the continued technological advancement of the United States.

_**Id. Cf:**_ Bee, _supra_ note 269, at 375 (finding a strict interpretation of the experimental use exception in practice).

321. Hantman, _supra_ note 319, at 639-40 (distinguishing between experimental use on patented inventions and using patented inventions for experimental purposes). Experimental use
experimental use exemption would allow persons to use a patented technology to develop new and improved technologies that could replace the patented technology in the marketplace.\textsuperscript{322} In Hantman's opinion, "that's exactly what the [patent] system is supposed to do. In exchange for the patent monopoly given to an inventor, the inventor discloses his invention to the public and runs the risk that his invention may be made obsolete."\textsuperscript{323} The only experimental use law reform proposal that has been put forth in the form of legislation is the Research, Experimentation and Competitiveness Act of 1990 (RECA), passed by the House Judiciary Committee but withdrawn before consideration by the full House of Representatives.\textsuperscript{324} The RECA provided:

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 . . . .\textsuperscript{325}

The proposed RECA did not distinguish between for-profit and nonprofit research organizations, nor between commercial and noncommercial research purposes; in each of these instances, a third party would be allowed to make or use patented technology to perform scientific research, to improve upon patented technology, and to engineer around patented technology.\textsuperscript{326} The only distinction drawn in the RECA for the

\begin{quote}
\textit{on} patented inventions would be allowed under Hantman's proposal because it would result in improvements to patented inventions and new scientific knowledge. \textit{Id}. Using patented inventions \textit{for} experimental purposes would not be allowed under Hantman's proposal because it would not result in improvements to patented inventions and would allow the experimenter to profit at the expense of the patent owner. \textit{Id}.
\end{quote}

\textsuperscript{322} \textit{Id}. at 643.

\textsuperscript{323} \textit{Id}. Hantman defines research and development as activities "carried out to discover something new, sometimes for pure knowledge and other times for commercial application." \textit{Id}. at 640. He defines innovation as "the entire process of recognizing a problem, identifying a new solution (through research), and developing and marketing an economically attractive process or product." \textit{Id}. Hantman believes research and development "ought to be included within the experimental use exception in order to encourage and support the innovation of new technology." \textit{Id}.

\textsuperscript{324} H.R. 5598, 101st Cong. §§ 401-403 (1990).

\textsuperscript{325} \textit{Id}. § 402.


https://scholarship.law.ufl.edu/flr/vol58/iss3/1
experimental use exemption was based on the intended use of the patented subject matter; if the patented subject matter was primarily intended for use in performing research (a research tool), then it could not be made or used for its intended purpose without a license, although it could be made or used to perform scientific research outside of the research tool’s intended use, either to improve upon the research tool, or to engineer around the research tool.\textsuperscript{327} One of the proposals for a broad experimental use exemption would support the adoption of a limited version of the RECA, while other proposals would support an expanded version of the RECA.

Eyal Barash has argued for a limited adoption of the RECA exemption only for universities and nonprofit research centers.\textsuperscript{328} The focus of Barash’s concern is the risk of infringement lawsuits against universities and nonprofit research centers based on their use of patented technologies for research and experimentation purposes.\textsuperscript{329} In Barash’s view, the scope of this risk is increasing, especially for universities, due to two sets of factors. The first set of factors involves changes in the patent laws and the general way in which university researchers pursue research projects.\textsuperscript{330}

\begin{quote}
It 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 laboratory. It is equally ludicrous and burdensome if every Ph.D. research [sic] in a New Jersey pharmaceutical organization would need to have a patent attorney sitting at his side, to first opine whether his research for the day was within the scope of a third party’s patent, and then to obtain a license because he [might] tap his test tubes and precipitate out the ‘infringing’ product! (While, the fellow Ph.D. working in a sister facility in Basel, Paris or the Rhine would be totally immune from this onerous requirement.).
\end{quote}

\textit{Id.} at 8.

\textsuperscript{327} \textit{Id.} at 9 ("The easiest method of limiting and describing the ‘experimental use of research exception’ is to differentiate between experimentation on a patented invention and experimentation using a patented invention in order to accomplish another purpose, the former type of experimentation constituting the scope of the exception.").

\textsuperscript{328} Barash, supra note 228, at 697-98.

\textsuperscript{329} See \textit{id.} at 697-99.

Universities, in cooperation with industry, may find themselves embroiled in costly intellectual property litigation. . . . 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.

\textit{Id.} at 698.

\textsuperscript{330} \textit{Id.} at 697-98. "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
Congress amended the patent laws in 1984 to allow universities to license patents resulting from federally-funded research, and Barash notes that this amendment has lead to greatly increased research and patenting activity by universities. At the same time, however, university researchers continue to pursue research projects as they have in the past, taking little account of patent rights and rarely performing patent searches prior to undertaking research projects. The combination of the increased research and patenting activity coupled with the traditional neglect of patent rights, Barash believes, increases the risk of infringement lawsuits against universities.

The second set of factors Barash sees increasing the risk of infringement suits against universities involves industries’ responses to the changing university research environment. As university research becomes more valuable, Barash predicts that corporations will have an increasing commercial interest in university research—sometimes having interests aligned with the university and sometimes having interests antagonistic to the university. In either case, Barash believes industry’s growing commercial interest in university research increases the risk of infringement litigation and threatens the advancement of research activities.

Three other writers, Professors Rochelle Dreyfuss, Janice Mueller, and Katherine Strandburg, have advocated experimental use exemptions broader than the RECA. Dreyfuss, Mueller, and Strandburg are primarily concerned with the use of patented research tools to control downstream inventions and each has proposed some form of compulsory license to address this problem. Although these authors do not explicitly

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332. Barash, supra note 228, at 697.
333. Id. at 697-98 ("At the heart of the problem lies the manner in which research occurs at universities. University researchers rarely check the patent literature to determine whether their proposed research will infringe on any patents.").
334. Id. at 698.
335. Id.
336. Id.
337. Id. at 698-99 ("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.").
338. See Rochelle Dreyfuss, Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?, 46 ARIZ. L. REV. 457, 471-72 (2004) (proposing the use of waivers); Mueller, supra note 85, at 66 (discussing a “liability rule”); Strandburg, supra note 11, at 143-44 (discussing an “initial exclusivity period”).
recommend the adoption of the RECA, one would assume that if they support compulsory licenses for the use of research tools for their intended purpose they would also support the RECA exemptions for the use of research tools and nonresearch tools for the purposes of scientific research, technology improvement, and development of new, non-infringing technology.

Dreyfuss proposes an experimental use exemption similar to Barash’s proposal that would apply only to nonprofit research institutions. However, Dreyfuss articulates a far broader set of concerns than Barash, and her proposal is considerably more detailed. Dreyfuss suggests that the progress of scientific research and technology innovation, especially in the field of biotechnology, is being thwarted by a combination of three factors: a change in the character of science, a transformation in the organization of science, and a shift in public policies governing information production and sharing.

The change Dreyfuss perceives in the character of science is the growing merger of fundamental research and commercial products. She notes, for example, that in the fields of genomics and proteomics, basic scientific discoveries often have immediate commercial applications as medical diagnostic devices or disease treatments and therefore qualify for patent protection; however, these same basic scientific discoveries are also critical to innovation in a host of other technologies. Dreyfuss attributes the change in the organization of science primarily to the rapidly changing role of universities in the research enterprise. Dreyfuss describes past university research as freely available to both academic and commercial scientists under an ethos of a free and open exchange of scholarship; however, Dreyfuss suggests that today universities are “deep in the intellectual property business” and their technology transfer offices are often seen as a source of revenue to reduce tuition costs, decrease the burden on alumni and, for state-supported universities, lower the taxes on state residents. Finally, Dreyfuss believes that the public policies

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339. Dreyfuss, supra note 338, at 471.
340. Id. at 471-72; cf. Barash, supra note 228, at 697-99.
342. Id. at 462-63 (referring to the blurring of the dichotomy between fundamental and end-use work in biotechnology).
343. Id. Dreyfuss describes past science as a “linear progression from basic science, to applied science, to commercializable technology, to consumer end-products. That conception was essentially hardwired into the law. The developments at the end of that progression were patentable, the developments along the rest of the trail were not.” Id. at 462 (citation omitted).
344. Id. at 463-65.
345. Id. at 463-64. Dreyfuss is quite critical of university technology transfer offices.
governing information production and sharing have shifted from a preference for a strong public domain in which information was freely available to all to a preference for protecting all creative works as intellectual property.\textsuperscript{346} Within this milieu, Dreyfuss finds it unsurprising that faculty and universities seek intellectual property protection for their creative efforts.\textsuperscript{347}

The solution Dreyfuss proposes to resolve the conflict between intellectual property rights and the progress of scientific research and technology innovation is to replenish the public domain by allowing universities to use patented research tools for their intended purpose, but to place conditions on how universities can use the results of such research.\textsuperscript{348} Specifically, Dreyfuss would allow the unlicensed use of research tools if the research tools were not available on reasonable terms, the researcher agreed to publish the results of the research, and the researcher agreed to refrain from patenting the results of the research.\textsuperscript{349} Richard Nelson has suggested a modification of Dreyfuss's proposal. He

academic equivalent of their football teams: even if the offices aren't winning, there is cachet in fielding them. And the technology transfer offices want to win, just like the football teams do. They are judged by the number of patents granted and the value of the licenses negotiated. And so they have tremendous incentives to obtain every patent that they can get and to argue for more protection for the work that universities do, which is to say, for developments that are far more upstream.

\textit{Id.} at 464.

\textsuperscript{346} \textit{Id.} at 465 ("As Professor Jerry Reichman has so graphically put it, the classical patent and copyright systems were once islands of protection in a sea of competition. Now what we have is a sea of protection in which intrepid entrepreneurs encounter remote islands of free competition.").

\textsuperscript{347} \textit{Id.} at 466.

Put these developments together and it is clear why the issues of protecting the public domain of science and creating room to experiment have become so compelling. Patentees can now own—and many think they deserve to own—entire research opportunities, rights not only in product markets, the traditional markets that patents dominate, but rights in innovation markets as well. Patentees can exploit these innovation markets by doing research. They can license others to exploit them if they so choose. But they can also leave them unexplored.

\textit{Id.}

\textsuperscript{348} \textit{Id.} at 471.

\textsuperscript{349} Dreyfuss notes some alternative approaches to the problems she describes that do not depend upon an experimental use exemption, including redefining patentable subject matter to exclude fundamental principals of science, making patents more difficult to obtain by heightening the standards for utility and non-obviousness, changing the test for infringement by narrowing or eliminating the doctrine of equivalence, and amending the Bayh-Dole Act to make it easier for the federal government to control the use of patents derived through federal funding. \textit{Id.} at 468-70.
would allow nonprofit research institutions to patent research results obtained through the unlicensed use of research tools provided the institution agreed to license the results on a nonexclusive basis and upon reasonable terms and conditions.\textsuperscript{350}

Mueller also believes that there is a serious problem today with the availability of research tools.\textsuperscript{351} Mueller argues that Eisenberg’s position on the use of patented research tools is increasingly untenable in the current research environment.\textsuperscript{352} Recall that Eisenberg proposed that the use of research tools for their intended purpose should not be covered by an experimental use exemption because research tools were readily available to ordinary users with minimal transaction costs.\textsuperscript{353} Mueller asserts that research tools today often are not freely available for purchase by ordinary consumers and that when they are available the frequent need for multiple research tools creates a problem of royalty stacking, which greatly increases the transaction costs involved in licensing research tools.\textsuperscript{354}

Mueller also does not believe that Eisenberg’s proposed experimental use exemption for the use of research tools in order to improve upon them or to engineer around them is sufficient to address the problem of control over downstream inventions.\textsuperscript{355} Mueller agrees with Dreyfuss that technology advances in one field often spill over into other fields; Mueller gives as examples a genetically-modified mouse that might be used to screen drugs for treatment of cancers or a DNA chip that might be used to identify genetic variations associated with diseases.\textsuperscript{356} Mueller does not think that the use of patented technologies in these ways would fall within Eisenberg’s proposed experimental use exemption. However, in Mueller’s view, these activities could result in new products that are much more valuable to society than new or improved research tools.\textsuperscript{357}

Under Mueller’s proposal, patented research tools that are not “readily available for licensing on reasonable terms” could be used by third parties for their intended research purpose without a license to develop commercial products.\textsuperscript{358} In exchange for the unlicensed uses of patented

\textsuperscript{350} Id. at 471. Dreyfuss takes Nelson’s suggestion as a “friendly amendment.” Id.

\textsuperscript{351} Mueller, supra note 85, at 57.

\textsuperscript{352} Id.

\textsuperscript{353} See Eisenberg, supra note 10, at 1074.

\textsuperscript{354} Mueller, supra note 85, at 57.

\textsuperscript{355} Id.

\textsuperscript{356} Id. at 57-58.

\textsuperscript{357} Id. ("To the extent that [the users] are not improving the technology of the research tool patent itself (i.e., resulting in improved research tools of the same type), these trans-technologic uses of research tools would appear to fall outside the . . . ‘improver’ prong of Professor Eisenberg’s model.").

\textsuperscript{358} Id. at 58. Mueller does not define “readily available for licensing” or “reasonable terms.”
research tools, patentees would be entitled to 'reach-through royalty[ies]' on the products developed with the use of their research tools. Mueller believes that this arrangement would be fair to both third party product developers and to research tool patentees because the royalty payments would be linked to the commercial success of the resulting products and therefore approximate the value of the research tools to the tool users—the product developers. To implement this model, Mueller would require the third-party user to notify the research tool patentee in advance of the tool’s use. Finally, Mueller suggests alternative methods by which reach-through royalties could be determined.

Strandburg supports Mueller’s proposal, but with an important modification. Strandburg suggests a two-term system of compulsory licensing for research tool patents: During the first term, approximately three to five years, the research tool would be under the exclusive control of the research tool patentee; during the second term, the remainder of the patent’s life, the research tool would be subject to compulsory licensing by third parties upon payment of a reasonable royalty to the research tool patentee. Strandburg sees a number of benefits in this modification to Mueller’s proposal. First, the initial exclusivity period would allow patentees the opportunity to control downstream inventions developed using their research tools either by directly performing the research themselves or by collaborating with other researchers. The initial exclusivity period would also allow patentees the opportunity to recoup their investment in research tools through private market transactions before the tools become subject to compulsory license. Finally, the initial exclusivity period would provide a frame of reference for the determination of reasonable royalty rates when the compulsory license term begins.

See id.  
359. Id.  
360. Id. ("The new products [developed from the use of the research tool] would serve as the royalty base. In this manner the royalty payment to the research tool patentee would approximate the true value of the research tool to the tool user and product developer."). (citation omitted).  
361. Id. at 58-59. Mueller would not require the third-party user to disclose the nature or details of the intended use of the research tool. Id. at 59.  
362. Id. at 63-65. These methods include the "heuristic approach" rule where the licensor receives twenty-five percent of the licensee’s pre-tax profits on its sales, and the "analytical approach," which calculates the royalty as the "residual between the infringer’s anticipated net profit from practicing the infringed invention and the infringer’s normal net profit." Id. at 64-65 (quoting Richard S. Toikka, Patent Licensing Under Competitive and Non-Competitive Conditions, 82 J. PAT. & TRADEMARK OFF. SOC’Y 279, 292, 294 (2000)).  
363. Strandburg, supra note 11, at 143.  
364. Id. at 143-44.  
365. Id.  
366. Id. at 143-45.
B. Critique of the Law Reform Proposals

This Part will first consider the law reform proposals directed to end-user products and processes, and then consider the special case of research tools. The narrowest experimental use proposal (Bee) would allow infringement immunity only where the experimentation was for "mere amusement," regardless of whether the experimentation was performed by a for-profit or nonprofit organization. This is essentially the same interpretation of the experimental use exemption adopted by the CAFC in *Madey v. Duke University.* The problems that result from such a narrow interpretation of the experimental use exemption were discussed in detail in the first part of this Article. These problems include the retardation of innovation, competition, and consumer welfare, and the contradictions between such a narrow exemption and other patent law policies.

The broadest experimental use proposals (Hantman and RECA) would exempt experimentation by any organization for any purpose. These proposals would allow the use of patented subject matter by nonprofit and for-profit organizations to test the validity of patent claims, to test the accuracy of patent disclosures, to improve upon the patented subject, and to develop noninfringing substitute technology, regardless of whether the purpose was noncommercial or commercial. This experimental use "free-for-all" would undoubtedly advance innovation and competition in the private sector which would, in turn, increase consumer welfare. What is uncertain about such a broad experimental use exemption is its impact on universities and basic research.

A broad experimental use exemption would allow universities to experiment with industries' patented subject matter, for noncommercial or commercial purposes, without fear of infringement liability. This would clearly spur universities' already active research and patenting efforts and promote technology innovation and consumer welfare. However, a broad experimental use exemption would also allow industry to experiment with university-patented subject matter without infringement liability. Parker and other writers have expressed concern over this prospect. These writers believe that the majority of patents arising from university research cover basic research subject matter and that this subject matter serves as the building block for further research and development of commercial

367. See supra notes 269-71 and accompanying text.
368. See 307 F.3d 1351, 1362 (Fed. Cir. 2001).
369. See supra Part II.
370. See supra Part III.A.
371. See supra notes 320-27 and accompanying text.
372. See supra notes 283-89 and accompanying text; see also supra notes 314-17 and accompanying text.
products and processes. Their fear is that industry would be able to use university basic research patents to develop commercial products and processes not covered by the patents and that this would deprive universities of a return on their investment in basic research. If this outcome occurred, it would harm university research generally, basic research specifically, and ultimately innovation, competition, and consumer welfare.

The middle-ground experimental use proposals would generally allow non-commercial use of patented subject matter for such purposes as testing patent specifications and disclosures, determining novelty and non-obviousness, and conducting scientific research. However, these proposals would require some form of compulsory license and royalty payment in the event the exempted research was used for commercial purposes. Supporters of this compromise approach believe it allows for sufficient use of patented technology to promote public knowledge and scientific progress, while protecting patentees from two economic harms: (1) forfeiture of royalties for the research use of patented technology; and (2) loss of the competitive advantage based on the patentee’s exclusive research use of patented technology. Both of these asserted economic harms are dubious. The first rests on the circular association of royalty rights and patent rights; a patentee does not lose royalties for the research use of patented subject matter unless the patent rights are defined to cover such use. If the CAFC’s extremely narrow experimental use exemption is reversed by later cases or legislation, would the change be a deprivation of royalty rights, a taking of patent property rights, or a clarification of the scope of patent protection? The second asserted economic harm would require a determination whether the unauthorized use falls within the experimental-use exemption."

See supra note 285 and accompanying text. See supra notes 283-89 and accompanying text; see also Michel, supra note 311, at 402. See supra note 308-10 and accompanying text. See supra note 311-14 and accompanying text. See Strandburg, supra note 11, at 96 ("Thus, the 'emoluments which [a patentee] does or might receive from the practice of the invention by himself or others' are necessarily defined by the legal boundaries of the patentee's rights. To decide whether a particular unauthorized use deprives the patentee of legitimate returns, one must know whether the unauthorized use falls within the experimental-use exemption.") (quoting WILLIAM C. ROBINSON, 3 THE LAW OF PATENTS FOR USEFUL INVENTIONS 898 (1890)) (alteration in original).

See 35 U.S.C. § 154(d) (2000) ("In addition to other rights provided by this section, a patent shall include the right to obtain a reasonable royalty from any person who ... makes, uses, offers for sale, or sells ... the invention ... [in] the United States.").

See, e.g., Evan Ackiron, PATENTS FOR CRITICAL PHARMACEUTICALS: THE AZT CASE, 17 AM. J.L. & MED. 145, 175 (1991) ("In general, legislative changes that affect existing property rights may constitute a takings [sic] and thus require compensation to patentees, while measures that apply to the granting of the patent are not likely to have this effect.").

rests on the questionable proposition that a patent grants the patentee freedom from competition. It does not. A patent gives the patentee the right to exclude others from using the patented subject matter for direct commercial gain; it does not immunize the patented subject matter from competition or guarantee its commercial success. 381 Excluding commercially-motivated research from an experimental use exemption in order to protect the patentee from competition confuses monopoly over the patent subject matter with monopoly over the patent subject matter market.

More fundamentally, innovation, competition, and consumer welfare cannot be advanced if commercial research is excluded from an experimental use exemption. The inclusion of commercial research in an experimental use exemption would intensify competition in technology-based industries and force firms to invest more heavily in research and development to protect existing market share and capture new market share. It should also be noted that the inclusion of commercial research in an experimental use exemption would be a two-way street. Firms would be vulnerable to competitors who used their patented technology to develop superior, non-infringing technology, but firms would also have the opportunity to respond in kind. The likely result of these new research opportunities would be a more competitive market environment in which some firms would become more successful, some firms would become less successful, and some firms would be driven from the market. This is a natural and desirable consequence of increased competition, and it would provide consumers with higher quality goods, lower prices, and more product choices.

All of the middle-ground experimental use proposals include some form of compulsory licensing. 382 There is considerable debate over compulsory licenses in the United States and abroad, especially in the context of pharmaceutical and agricultural technologies. 383 Regardless of the outcome of this broader debate, it is highly doubtful that compulsory licenses provide a viable solution to the experimental use problem in the

While the [Patent Act] sets the basic parameters for patentability and infringement, it does not specify in detail how those basic principles are to be applied. Further, in many instances, such as application of the doctrine of equivalents or of unenforceability, judicially created doctrines play a major role in defining the scope of patent protection.

Id.

381. See, e.g., Alfred B. Engelberg, Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?, 39 IDEA 389, 393 (1999) ("Whether or not the patent owner derives a commercial benefit... is a matter that is totally divorced from the patent system.").

382. See supra Part IV.A.2.

United States. In the context of U.S. domestic patent law, compulsory license proposals are fraught with practical, policy, and political problems.

The practical problems include determining what facts would trigger the availability of the compulsory license, what terms and conditions would be included in the compulsory license, and what royalties would be paid under the compulsory license. Of these problems, the royalty determinations would be the most difficult, requiring consideration of a complex set of factors such as industry standard licensing rates, the degree of risk associated with the license, the stage of development of the licensed technology, the value of the licensed technology to the licensee, and the prospect of multiple royalty payments.

The policy problems associated with compulsory licenses arise from their implications for private property rights generally, and patent ownership rights specifically. Compulsory licenses, no matter how they

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384. For example, one commentator has noted that “In 1977, the [FTC] and DOJ had issued approximately 125 [compulsory license] decrees over thousands of patents and a wide range of technology . . . in the context of mergers, price-fixing, and the abuse of monopoly or market power.” Chien, supra note 383, at 862; see also Richard A. Epstein, Steady the Course: Property Rights in Genetic Material, 29-30 (Univ. of Chi. John M. Olin Law & Economics, Working Paper No. 152, 2003), available at http://www.law.uchicago.edu/Lawecon/index.html (noting that patent holders will be unaware that potential licensees have even begun working with the patented material unless “licensees post on some neutral site a notice of its [sic] ‘intention to use’ the covered materials of another company, and to subject that party to heavy damages in the event that they proceed without supplying the requisite notice”).

385. See Epstein, supra note 384, at 30-32 (analyzing the Harvard License Agreement and discussing the complexity of potential licensing terms, including conduct of the licensee and its affiliates, definitions (especially of “net sales”), best efforts clauses, cooperation provisions, regulatory compliance terms, international use, etc.). Epstein also points out that the terms of any compulsory license would likely need to be much more extensive than their “voluntary counterparts,” largely because under a forced licensing scheme, the parties will not share the same levels of “informal, reputational or relational sanctions to help keep each other in line,” which will in turn increase the need for “explicit monitoring.” Id. at 34.

386. Chien, supra note 383, at 869-70 (discussing the compulsory licensing terms of the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which state that “patentees are to receive ‘adequate remuneration . . . taking into account the economic value of the authorization’” (quoting Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1c, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND, vol. 31, art. 31(b) I.L.M. 81 (1994))).

387. See Epstein, supra note 384, at 32, 33 (noting that all of these variables make the selection of one “standard” rate almost impossible to determine, because if the standard were set too high without regard to the risk associated with the licensee’s particular stage of research development, then “no potential licensee will seek to exercise its rights under the compulsory scheme”; on the other hand, setting the rate too low will mean that the licensor will not be able to “recoup its expenditures with a reasonable rate of return,” which means that “the product, if made at all, will be gobbled up by a large number of nonexclusive licenses which might yield too little in revenue to encourage systematic investment over time.”).
are implemented, constitute a taking of private property.  

Although the federal government has the unquestioned authority to take private property for public purposes upon payment of just compensation, this authority is rarely exercised in the realm of personal property. Because the courts have characterized patent rights as personal property, many persons would view the creation of compulsory patent licenses as a troublesome precedent for the taking of other personal property. The same concern would exist for patent ownership rights. If compulsory patent licenses can be created for the purpose of research, why can they not also be created for the purpose of limiting firms' market dominance or lowering product prices? Finally, the political problem associated with compulsory patent licenses, which is directly related to the policy problems, is that it is highly unlikely that compulsory patent licenses could ever marshal sufficient support in either political party to be enacted into law.

Given the many problems that compulsory patent licensing would entail, one wonders why it is the preferred solution of so many law review writers, and why these writers would propose compulsory patent licensing to overcome the CAFC's elimination of the common law experimental use exemption, rather than propose a reversal of the CAFC's experimental use decisions through judicial appeals and legislative reforms. It certainly would be easier to deny patentees the right to control the use of patented technology in research and development in the first instance, than to preserve the patentees' rights and then attempt to limit them through compulsory licensing.

Finally, I turn to the law reform proposals that have been suggested for patented research tools, all of which also include some form of compulsory licensing. I will first consider the rationales advanced in support of these law reform proposals before turning to the proposals themselves. Initially, it should be noted that the concern over access to research tools is focused solely on the biotechnology industry; there is apparent agreement that research tools in other industrial settings are readily available through marketplace transactions. The evidence cited by writers to support the lack of access to research tools in the biotechnology industry, however, is almost entirely anecdotal. One article

388. See Chien, supra note 383, at 862-63. She notes that for this reason, 28 U.S.C. § 1498 (2000) was enacted to immunize the U.S. Government from liability for using inventions without the patentee's permission. Id. The statute merely provides that the government must provide "reasonable and entire compensation" for the use, and does not permit the patentee to maintain an injunctive action against the government. Id. at 863 (quoting 28 U.S.C. § 1498 (2000)).

389. See U.S. CONST. amend. V.

390. See supra note 8 and accompanying text.

391. See Mueller, supra note 85, at 11.

392. See id.
cites two examples of firms that attempted to control downstream invention through ownership of research tools, both unsuccessfully.\textsuperscript{393} Another article claims a "high percentage" of basic research tools in biotechnology are patented, but cites no factual evidence that this has caused a serious industry problem.\textsuperscript{394} The only empirical study to date concluded that although there was some indication that a problem in accessing research tools could arise in the future, there was no evidence of an existing problem even remotely warranting congressional concern.\textsuperscript{395}

The lack of hard evidence of a problem regarding access to research tools in the biotechnology industry can perhaps be explained by the special conditions that must exist in order for a research tool patentee to exercise control over downstream inventions. First, there must be no close substitutes for the patented research tool; second, there must be no close substitutes for the research projects that require the tool; third, the research tool patentee must have sufficient expertise to identify the most promising research projects; and fourth, the research tool patentee must have sufficient expertise to pursue product development independently or to select the outside researcher best able to do so.\textsuperscript{396} Because the knowledge required for development of a research tool might be very different than the knowledge required for development of a product using the research tool, even patentees that have a unique tool might be unable to control downstream inventions.\textsuperscript{397}

The lack of empirical evidence of a problem with respect to access to research tools is especially troubling because the compulsory licensing proposals in this area are the most drastic. The compulsory licensing proposals advanced for end-use product and process research do not allow for the use of products and processes for their intended purposes. These compulsory licensing proposals are solely for the purpose of allowing research to be performed upon patented technology. The compulsory licensing proposals suggested for research tools would allow for their use for the very purpose for which the tool was developed. This would have an immediate, negative financial impact upon research tool patentees that could result in diminished investment in development of research tools in the future. In light of this dire prospect, it would seem that compelling evidence of an access problem in the research tool market would be

\textsuperscript{393} See Michael A. Heller & Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, SCIENCE, May 1, 1998, at 699.

\textsuperscript{394} See Mueller, supra note 85, at 11.

\textsuperscript{395} See Dreyfuss, supra note 338, at 460 (citing John P. Walsh et al., Effects of Research Tool Patents and Licensing on Biomedical Innovation, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285 (Wesley M. Cohen et al. eds., 2003)).

\textsuperscript{396} See Strandburg, supra note 11, at 124-28.

\textsuperscript{397} Id., at 131-32.
required before proposing a compulsory licensing scheme.

V. PROPOSED ASYMMETRIC EXPERIMENTAL USE EXEMPTION

This Part of the Article will describe a proposed asymmetric experimental use exemption, discuss the patent subject matter and allowed uses included within the proposed exemption, suggest statutory language for the implementation of the proposed exemption, and discuss the benefits of the proposed exemption.

A. Description of Proposed Exemption

An experimental use exemption is essential to promote innovation, competition, and consumer welfare. The asymmetric experimental use exemption proposed here would be a statutory infringement exemption that would apply to all patent subject matter. It would be similar to the RECA experimental use bill discussed above, except in two significant respects. Similar to the RECA, the asymmetric experimental use exemption would allow for the research use of patented subject matter for commercial and noncommercial purposes, it would be available to for-profit and nonprofit organizations, and it would not include any form of compulsory licensing.399

The first major difference between the proposed asymmetric experimental use exemption and the RECA bill is that the proposed experimental use exemption would provide differential access (asymmetric access) to patent subject matter for corporations, small businesses, and nonprofit research organizations.400 The differential access to patent subject matter is necessary to protect the investment of small technology businesses and nonprofit research organizations in basic scientific research. As noted earlier, these entities are the primary source of basic scientific research, but often lack the resources necessary to convert this basic research into commercially viable technologies.401 If large firms with far greater resources were permitted to experiment with these basic scientific advances without a license, they could develop commercially viable technologies that do not infringe the basic research patents and thus deprive the small business or nonprofit research center of any return on their investment in the basic research.402 To the extent this occurs, small businesses will have a much more difficult time raising early-stage investment capital to fund further technology development,

398. See supra notes 324-25 and accompanying text.
399. See supra notes 324-25 and accompanying text.
400. See supra notes 324-25 and accompanying text.
401. See supra notes 283-89 and accompanying text.
402. See supra notes 372-74 and accompanying text.
and nonprofit research organizations will be deprived of license revenue to fund future research projects.

For non-small business corporations, the experimental use exemption would cover only patent subject matter owned by other non-small business corporations, and not patent subject matter owned by small business corporations and nonprofit research organizations. For small business corporations, the experimental use exemption would cover patent subject matter owned by non-small business corporations, nonprofit research organizations, and other small business corporations. Likewise for nonprofit research organizations, the experimental use exemption would cover patent subject matter owned by non-small business corporations, small business corporations, and other nonprofit research organizations.\textsuperscript{403} The drawing below depicts the differential access to patent subject matter under an asymmetric experimental use exemption.

\textbf{Asymmetric Access to Patent Subject Matter}

![Diagram of asymmetric access to patent subject matter]

The nonprofit research organizations would include universities, federal laboratories, research hospitals, and research institutes. The definition of small business corporations would have to be determined through legislative deliberation and could include such factors as annual sales, number of employees, research and development spending, and years since founding. An appropriate definition of small business corporations would balance the need to protect the investment in basic scientific research made by small technology businesses and the need to promote innovation and competition in technology industries.\textsuperscript{404}

\textsuperscript{403} Individual researchers would be included in the group of small business corporations and nonprofit research organizations.

\textsuperscript{404} The Small Business Administration's (SBA) definition of a "small business" could provide a starting point for discussion of the definition of a small business for purposes of the proposed experimental use exemption. See Guide to SBA's Definitions of Small Business, http://www.sba.gov/gopher/Financial-Assistance/Defin/defi4.txt (last visited Feb. 24, 2006). Although the SBA’s definition of a small business varies between different industry segments, the
In order for an asymmetric experimental use exemption to work properly, non-small business corporations must be prohibited from indirectly accessing patent subject matter that they could not directly access. There are a number of means by which non-small business corporations could seek indirect access to patent subject matter that they could not access directly, including the formation of small business corporation subsidiaries, partnerships with small business corporations, and research agreements with nonprofit research organizations. For example, a non-small business corporation (Corp. X) could enter into a research agreement with a nonprofit research organization (ResOrg. A) and by means of that agreement gain indirect access to patent subject matter owned by a small business corporation (Corp. Y). Under the asymmetric experimental use exemption, Corp. Y’s patent subject matter could be used by ResOrg. A, but could not be used by Corp. X.

The problem of indirect access to exempted patent subject matter can be solved by clearly providing in the asymmetric experimental use exemption that it is an act of infringement for a non-small business corporation to use research results obtained from exempted experimentation with patent subject matter by a small business corporation or a nonprofit research organization. If a non-small business corporation wants to use the research results obtained from exempted experimentation with patent subject matter, the corporation must obtain a license from the owner of the patent subject matter just as if the non-small business corporation sought to use the patent subject matter directly in the first instance.

The second major difference between the proposed asymmetric experimental use exemption and the RECA is that the proposed exemption would define more fully the patent subject matter included under the exemption and the purposes for which this patented subject could be used. Although the RECA is eloquent in its two-sentence simplicity, it provides little guidance in determining what patented inventions are to be characterized as research tools and what uses of research tools are to be exempted. The definitional approach of the proposed experimental use exemption is discussed below.

It should be noted that even if a statutory experimental use exemption for all patented inventions is enacted, there would still be situations in which a researcher might seek to obtain a license from a patentee prior to commencing the research. For example, if the objective of the researcher

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405. See supra notes 324-25 and accompanying text.

406. See supra note 325 and accompanying text.
is to further the development of the technology for its intended purpose, or to improve upon the technology, the researcher might well seek a license from the patentee before making a significant investment in the research project. In both of these cases, if the research is successful, the researcher will have to obtain a license to the underlying technology before she can commercialize the research. Knowing this, a researcher might decide to negotiate a license with the patentee before the research is started in order to avoid paying a higher price for the license at a later date if the research proves successful. 407

B. Definition of Patent Subject Matter and Allowed Uses Under the Proposed Exemption

The unavoidable and most difficult challenge in implementing any experimental use exemption or compulsory license is defining the patent subject matter and allowed uses covered by the exemption or license. The major challenge in defining the patent subject matter is distinguishing between end-use products and processes, and the research tools used to create end-use products and processes; as noted earlier, this distinction is necessary to foster innovation and competition in end-use products and processes while not harming investment in the creation of new research tools. 408

There have been many different attempts to define research tools. Part I of this Article discussed the disagreement on the CAFC over the


Rational licensees would prefer to negotiate a licensing amount sooner rather than later, so as to fix one more variable in their downstream research risk equation. Licensees must subtract the cost of the license from the profitability of the commercial end-product and thus will be willing to pay only if they anticipate that the cost of the license will allow a sufficient return on investment. No innovator wants to be in the position of having to pay licensing fees, however small, for the use of a patent that turned out to be a dud. And no patent holder wants to hear that it will not be receiving licensing revenues because its patent turned out to be one of the majority of patents that ultimately is not commercially viable.

Id. The situation is different, however, if the researcher is performing research as part of a scientific investigation without any intent to commercialize the research results, or if the researcher is performing research in an attempt to engineer around the patent and develop a new, non-infringing technology. In these two cases, the researcher would not be required to secure a license to the underlying technology at a later date (in the first instance because there will be no commercialization and in the second instance because commercialization will be achieved through non-infringing technology) and therefore would have no reason to negotiate a license prior to beginning the research.

408. See supra notes 185-88 and accompanying text.
definition of research tools and described the NIH definition of research tools.\textsuperscript{409} A number of writers have also attempted to define research tools. Mueller, for example, has defined research tools as "those patented tools used in development of new biotechnological or pharmaceutical products that do not themselves physically incorporate the tool."\textsuperscript{410}

Likewise, there have been many other attempts to define the allowed uses of research tools either under an experimental use exemption or compulsory license. As discussed earlier, the proposed RECA experimental use exemption would have allowed the use of research tools for the purpose of study, evaluation, and the creation of new, non-infringing research tools.\textsuperscript{411} Additionally, a number of the compulsory license proposals distinguish between non-commercial and commercial uses of research tools.\textsuperscript{412} One of the most thoughtful attempts to define the allowed use of research tools has been suggested by Strandburg. Strandburg distinguishes between ""experimenting on"" a patented research tool (using the inventive idea contained in the patent for follow-on innovation) and ""experimenting with"" a patented research tool (using the invention itself for its intended research purpose).\textsuperscript{413}

The experimental use exemption proposed here makes these definitional problems less challenging by allowing the same uses of patent subject matter whether it is classified as an end-user product or process, or as a research tool. The allowed research uses for all patent subject matter would include education, scientific research, evaluating patent specifications, disclosures and claims, improving upon the patent subject matter, engineering around the patent subject matter, and developing competing, non-infringing patent subject matter. All patent subject matter could be used for its intended purpose pursuant to these allowed uses. For example, an end-user product or process could be used for its intended purpose to evaluate the patent disclosure and a research tool could be used for its intended purpose to develop improvements to the research tool or to create a non-infringing substitute research tool. The one limitation upon the use of all patent subject matter would be that it could not be used for its intended purpose in competition with the patentee. In the case of end-user products and processes, and research tools, this means that a person

\textsuperscript{409} See supra notes 141-43 and accompanying text (detailing "the full range of resources that scientists use in the laboratory[,] including "cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools . . . methods, laboratory equipment and machines, databases and computer software").

\textsuperscript{410} Mueller, supra note 85, at 14.

\textsuperscript{411} See supra notes 324-25 and accompanying text.

\textsuperscript{412} See supra Part IV.A.2.

\textsuperscript{413} Strandburg, supra note 11, at 118-21.
could not make, use, or sell the patent subject matter in a way that results in direct financial loss to a patentee.

Whether a person's use of patent subject matter falls within the proposed experimental use exemption would be decided from the objectively determined purposes of the patent subject matter and the objectively determined purposes of the person using the patent subject matter. The objectively determined purposes of the patent subject matter would be ascertained from such sources as technical papers, and the patent specifications, disclosures and claims. In order to avoid contrived assertions of a patent's purposes, only claims enabled in the patent disclosure would be considered in ascertaining the objective purposes of the patent. The objectively determined purposes of the person using the patent subject matter would be ascertained from such sources as lab notebooks, witness testimony, and expert opinion. If the objectively determined purposes of the patent subject matter and the objectively determined purposes of the person using the patent subject matter are the same, the use would not be allowed under the proposed experimental use exemption. If the objectively determined purposes of the patent subject matter and the objectively determined purposes of the person using the patented subject matter are not the same, the use would be allowed under the proposed experimental use exemption.

I will illustrate the scope of use allowed under the proposed experimental use exemption using the facts in Madey v. Duke University and Integra Lifesciences I, Ltd. v. Merck KGaA. The objective purpose of the FEL laser at issue in Madey v. Duke University was the collection of spectroscopic research data describing the properties of different materials. Whether or not Duke’s use of the FEL laser would fall within the proposed experimental use exemption would depend upon Duke’s objective purpose in using the FEL laser. If Duke’s objective purpose in using the FEL laser was to obtain spectroscopic research data for inclusion in a research paper or grant application, the objective purpose of Duke’s use and the objective purpose of the FEL laser would be the same, and the use would not be allowed under the proposed experimental use exemption. On the other hand, if Duke’s objective purpose was to learn more about how the FEL laser worked, or to develop a new or improved laser spectrometer, the objective purpose of Duke’s use and the objective purpose of the FEL laser would not be the same, and the use would be allowed under the proposed experimental use exemption. If Duke was successful in developing a new or improved laser spectrometer and the device included elements covered in the FEL laser patent claims, Duke

414. 307 F.3d 1351 (Fed. Cir. 2002).
415. 331 F.3d 860 (Fed. Cir. 2003).
416. Madey, 307 F.3d at 1353.
would have to obtain a license to the FEL laser patent before Duke could make, use, or sell the new or improved device.

The same analysis would be used to decide whether Merck’s use of the RGD peptides at issue in Integra v. Merck would fall within the proposed experimental use exemption. The objective purpose of the RGD peptide patents was as a potential therapeutic drug to facilitate wound healing.417 Merck’s objective purpose in using the RGD peptides was to research their potential use in cancer treatment to retard tumor growth.418 Because the objective purpose of the RGD peptide patents and the objective purpose of Merck’s use of the RGD peptides were not the same, Merck’s use would be allowed under the proposed experimental use exemption. On the other hand, if the objective purpose of the RGD peptide patents was an assay to screen compounds that could stimulate the growth of new blood vessels and Merck somehow used the RGD peptides to screen compounds that could retard the growth of new blood vessels, Merck’s use would not be allowed under the proposed experimental use exemption. In this case, Merck’s objective purpose in using the RGD peptides as a research tool and the objective purpose of the RGD peptide patents as a research tool would be the same, and Merck’s use would not be allowed under the proposed experimental use exemption. In the event that Merck’s use was allowed under the proposed experimental use exemption and Merck was successful in developing a new drug to retard tumor growth, this new drug contained peptides covered by the RGD patent claims, Merck would have to obtain a license to the patents before Merck could make, use, or sell the newly developed drug.

C. Suggested Statutory Language to Implement the Proposed Exemption

There are many ways in which the language to implement the proposed experimental use exemption could be drafted. The purpose here is simply to suggest language that could provide a starting point for further drafting efforts. The following language would implement the major features of the proposed asymmetric experimental use exemption.

(1) It shall not be an act of infringement for a non-small business corporation to make or use patent subject matter owned by another non-small business corporation for the purposes of education, scientific research, evaluation of patent specifications, disclosures or claims, improvement of patent subject matter, or development of new patent subject

417. Integra, 331 F.3d at 863.
matter. It shall be an act of infringement for a non-small business corporation to make or use patent subject matter owned by a small business corporation or a nonprofit research organization, as they are defined in this section, for any purpose without authorization from the small business corporation or nonprofit research organization. It shall also be an act of infringement for a non-small business corporation to use the research results obtained from an exempted use of patent subject matter under paragraph (2) without authorization from the patent owner of the exempted patent subject matter.

(2) It shall not be an act of infringement for a small business corporation or a nonprofit research organization, as they are defined in this section, to make or use patent subject matter owned by a non-small business corporation, a small business corporation, or a nonprofit research organization for the purposes of education, scientific research, evaluation of patent specifications, disclosures or claims, improvement of patent subject matter, or development of new patent subject matter.

(3) In determining whether the use of patent subject matter is exempted from infringement under paragraph (1) or (2), a court should consider the intended purposes of the patent subject matter enabled in the patent disclosure and the intended purposes for which the patent subject matter was used. Where the intended purposes of the patent subject matter enabled in the patent disclosure and the intended purposes for which the patent subject matter was used are not the same, the use of the patent subject matter is exempted from infringement under paragraph (1) or (2). Where the intended purposes of the patent subject matter enabled in the patent disclosure and the intended purposes for which the patent subject matter was used are the same, the use of the patent subject matter is not exempted from infringement under paragraph (1) or (2).

Of course, the extent to which the proposed experimental use exemption will advance innovation, competition, and consumer welfare will depend upon the courts’ interpretation of the statutory language, perhaps many years after the enactment of the exemption. For this reason, the suggested statutory language seeks to provide courts with clear guidance on the patented subject matter and allowed uses covered by the experimental use exemption. Patented subject matter is clearly delineated between patented subject matter accessible to non-small business corporations and patented subject matter accessible to small business corporations and nonprofit research organizations. Furthermore, the exempted purposes for which patented subject matter can be used are
explicitly stated, and a simple test is provided to determine whether a given use of patented subject matter falls within the infringement exemption.

D. Benefits of the Proposed Exemption

1. Promoting Innovation, Competition, and Consumer Welfare

The proposed experimental use exemption would promote innovation, competition, and consumer welfare in the United States. Corporations would be free to experiment with one another's patented technologies for the purposes of education, scientific research, evaluating patent specifications, disclosures and claims, improving upon patented technologies, engineering around patented technologies, and developing competing, non-infringing patented technologies. This would create new threats and new opportunities for corporations. Corporations that did not diligently pursue ongoing improvement of their technology would be vulnerable to competitors' experimentation with their patented technology to develop superior technology. On the other hand, corporations that aggressively pursued improvement of their technology would be able to experiment with their competitors' patented technologies to achieve this improvement. In either case, technical innovation, market competition, and consumer welfare would be advanced.

The situation is the same for small technology businesses and nonprofit research organizations. These entities would also be able to experiment with one another's technologies and this, in turn, would create new threats and new opportunities for these entities. For example, small business corporations would be able to experiment with patented university technologies to determine what technologies might be most useful to license, while universities would be able to experiment with the patented technologies of small businesses to determine how these technologies might be improved upon or adapted to create new technologies. In this environment, the successful small businesses and nonprofit research organizations will be those which are the most able to perform, and the most committed to pursue, state-of-the-art research and development projects. Although individual small businesses and nonprofit research organizations might be more or less successful under the proposed asymmetric experimental use exemption, the overall result undoubtedly would be greater technical innovation, increased market competition, and improved consumer welfare.
2. Promoting Consistency in Patent Law and Policy

The proposed experimental use exemption would promote consistency in U.S. patent law and policy in three significant respects. First, as noted earlier, the lack of a general experimental use exemption in the United States is at odds with the Patent Act’s requirement of an enabling disclosure in the patent application. The CAFC has often stated that the § 112 enabling disclosure is fundamental to the patent system’s quid pro quo in granting a patent monopoly in exchange for information sufficient to enable one skilled in the art to understand the invention. However, as Judge Newman has recognized, in the great majority of instances it is not possible to understand a patented invention without its physical use. The adoption of a statutory general experimental use exemption would reconcile the CAFC’s conflicting decisions on enabling disclosures and the common law experimental use exemption, and would acknowledge the reality of contemporary research and development practice.

Second, the lack of a general experimental use exemption is inconsistent with the case law and regulatory guidelines limiting anticompetitive expansion of patents through licensing agreements. The Department of Justice and the Federal Trade Commission are increasingly concerned with maintaining balance between patent law and antitrust law. If firms in a market cannot freely pursue research in competition with one another, or if firms in a market can leverage ownership of existing patents to control development of new patent subject matter, competition is retarded. These are the de facto results of the current patent law without a general experimental use exemption. Enacting a general experimental use exemption would bring patent law more in line with antitrust law and lessen the tension between the two.

Third, the lack of a general experimental use exemption in U.S. law is in sharp contrast to the patent laws adopted by foreign countries and promulgated in international agreements. A general experimental use exemption would harmonize U.S. law with the prevailing international law and this, in turn, would stop vital research from being conducted outside the United States in countries that have an experimental use exemption and place researchers in the United States on an equal footing with their colleagues in other countries.

419. See supra Part III.A.
421. See Integra, 331 F.3d at 873-75 (Newman, J., concurring in part, dissenting in part).
422. See supra notes 232-42 and accompanying text.
423. See supra Part III.C.
3. Promoting Consistency in the Treatment of Patent Subject Matter

The proposed experimental use exemption would reconcile the treatment of patented drugs and medical devices and other patented subject matter, and in doing so would eliminate the complex and anomalous provisions contained in the Hatch-Waxman Act. Under the Hatch-Waxman Act, drugs and medical devices are subject to a unique form of patent infringement. 424 Although drug makers and medical device manufacturers are allowed to use patented subject matter to obtain information necessary for FDA approval of new drugs or medical devices, the filing of this information in the form of an Abbreviated New Drug Application (ANDA) or in the form of a request for Pre-market Approval (PMA) constitutes an act of infringement. 425

Drug makers and medical device manufacturers are also granted a unique form of infringement remedy: Upon filing an infringement suit, the plaintiff drug maker or medical device manufacturer is entitled to an automatic thirty-month stay of FDA approval of the alleged infringing drug or device. 426 This thirty-month stay of FDA approval is essentially a thirty-month preliminary injunction that is granted automatically to the plaintiff drug maker or medical device manufacturer without the need to prove the four elements required in all other patent infringement suits to obtain a preliminary injunction. The four elements being (i) that it is likely the plaintiff will prevail on the merits of the infringement suit, (ii) that the plaintiff will suffer irreparable harm if the preliminary injunction is denied, (iii) that the harm to the plaintiff if the preliminary injunction is denied is greater than the harm to the defendant, and (iv) that the preliminary injunction will not have serious adverse impact upon the public. 427 Another unique aspect of the infringement remedy under the Hatch-Waxman Act is that the plaintiff drug maker or medical device manufacturer cannot recover money damages in the infringement suit unless the defendant has engaged in commercial sales of the drug or device. 428

The adoption of a general experimental use exemption would abolish the differential treatment of drugs and medical devices created by the Hatch-Waxman amendments to the Patent Act and greatly simplify the

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425. Id.
427. See, e.g., Purdue Pharma L.P. v. Boehringer Ingelheim GMBH, 237 F.3d 1359, 1363, (Fed. Cir. 2001) (identifying the four factors a moving party must prove to establish the right to a preliminary injunction).
procedural and substantive law surrounding the development and commercialization of new drugs and medical devices. The adoption of a general experimental use exemption, however, would not affect the Hatch-Waxman amendments to the FDCA allowing drug makers and medical device manufacturers to use previous clinical trials to establish the safety and efficacy of a new drug or device. This provision of the Hatch-Waxman Act is necessary to avoid wasting time, money, and effort to obtain information that is already known. The adoption of a general experimental use exemption would also not affect the Patent Act amendments that restore the term of patent protection up to five years to compensate for time lost during the FDA approval process. To the contrary, the question on patent term restoration is why all inventions subject to regulatory approval prior to market entry should not receive a patent term extension for the full period of regulatory review.

4. Improving Patent Quality

The proposed experimental use exemption would lessen the problem of the issuance of poor quality patents (patents of questionable validity) by the Patent and Trademark Office (PTO), which has been noted by the Federal Trade Commission (FTC). The FTC cites three anticompetitive consequences that flow from the issuance of poor quality patents: poor quality patents slow innovation by discouraging firms from conducting research in an area; poor quality patents necessitate unnecessary licenses and royalty payments; and poor quality patents impose unnecessary litigation costs in order to challenge their validity.

To address the problem of poor quality patents the FTC has proposed a number of procedural reforms including enhanced inter partes reexamination proceedings and allowance of post-grant and pre-grant challenges to patents. Whether these proposals will ultimately be accepted, or succeed in reducing the number of questionable patents issued, is unclear. However, the proposed experimental use exemption

430. 35 U.S.C. § 156(g)(6).
432. Id. at 5-1 to -4.
433. Id. at 5-17 to -18.
434. Indeed, some commentators argue that it is inefficient to dedicate more resources to improving patent quality at the USPTO, because “most patent applications involve claims of little economic significance, and . . . therefore ‘it is much cheaper for society to make detailed validity determinations in those few cases [in which patents are challenged] than to invest additional resources examining patents that will never be heard from again.’” Id. at 5-1 (quoting Mark A. Lemley, Rational Ignorance at the Patent Office, 95 N.W. L. REV. 1495, 1497 (2001)). However,
would significantly lessen the problem of poor quality patents in two ways which could also shift the burden for patent scrutiny away from the overworked PTO examiners. First, by allowing the use of patent subject matter for the purpose of assessing patent specifications, disclosures and claims, the validity of issued patents will be subject to unprecedented public scrutiny. More importantly, that scrutiny will come from the very parties who have a stake in ensuring that their industry is not plagued by questionable patents. Corporations, which traditionally focus on late-stage research, will be able to keep each other in check by testing the validity of their competitors’ patents. Similarly, universities and small businesses, chiefly engaged in basic and early-stage research, will be able to ensure that patents covering those areas do not unduly hinder the pace of progress. Second, knowledge that the validity of patents will be scrutinized by the public at large will cause patent applicants to be far more careful in drafting and prosecuting patent applications. Patent applicants will know that resources expended in prosecuting a questionable patent application might ultimately prove fruitless if their competitors are able to experiment with the patented invention to show the invalidity of the patent’s claims or the inadequacy of the patent’s disclosure.

5. Avoiding the Anti-Commons

A number of writers have expressed concern over the “tragedy of the anti-commons” in the field of biomedical research. The tragedy of the anti-commons is alleged to arise from the high transaction costs researchers confront when they require access to multiple prior patents in order to create a single new product or process. According to the anti-commons theory, the upstream, prior patent owners act as “tollbooth[s] on the road to [new] product development, adding to the cost and slowing the

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this commentary misses the practical deterrent effect on innovation that questionable patents create, namely that innovators might forego research in an area where it is difficult to navigate the patent landscape and determine the non-infringing course. One commentator reported that, if research is to continue in the face of these “patent thickets,” “the only practical response to this problem of unintentional and sometimes unavoidable patent infringement is to file hundreds of patents each year ourselves.” id. at 3-35 (quoting statement of Robert Barr (Feb. 28, 2002), http://www.ftc.gov/opp/intellect/barrobert.doc).

435. To reveal just how overworked the examiners are, consider that the estimated time for examination of a patent application is between eight and twenty-five hours. Id. at 5-5. This involves the time necessary to “read and understand the application, search for prior art, evaluate patentability, communicate with the applicant, work out necessary revisions, and reach and write up conclusions.” Id. Further, the USPTO receives approximately 300,000 applications each year, id. at 5-4, approximately forty-five percent of which are found to be invalid when fully litigated. Id. at 5-6.

436. See, e.g., Heller & Eisenberg, supra note 393, at 698.

437. Id. at 699.
pace of downstream biomedical innovation." 438 If there is an anti-commons problem, the proposed experimental use exemption would lessen it. Corporations, small businesses, and nonprofit research organizations would be free to experiment with patent subject matter without a license in order to develop new and improved biomedical products and processes. Researchers would only have to obtain licenses if the resulting new products or processes were covered by the claims of prior patents.

6. Reducing Control of Downstream Innovations by Research Tool Patentees

Likewise, the proposed experimental use exemption would address the alleged problem of control of downstream innovations by research tool patentees. 439 One prerequisite for such control by a research tool patentee is that there does not exist a close substitute for the research tool. 440 The knowledge that other persons skilled in the field can freely experiment with a research tool to improve upon it, or to engineer around it, would motivate research tool patentees to focus on the research tool market and license their research tools rather than attempt to control new products or processes that might be developed through the use of their research tools.

VI. CONCLUSION

Adopting a statutory experimental use exemption will require difficult compromises between the rights of patentees, the rights of patentee competitors, and the rights of the public. Reaching these compromises will be difficult due to the growing role of universities in researching, patenting, and licensing new technologies, the increasing interdependence of the for-profit and nonprofit sectors in creating new technologies, and the expanding involvement of small businesses in commercializing new technologies. Nonetheless, the United States should enact a statutory experimental use exemption to patent infringement in order to promote innovation and competition, promote consistency in patent law and policy and in the treatment of patented subject matter, improve patent quality, and avoid inefficient barriers to follow-on and downstream research efforts. The asymmetric experimental use exemption proposed here would be a fair, effective, and simple way to do this.

438. Id.
439. See, e.g., Mueller, supra note 85, at 56.
440. See Strandburg, supra note 11, at 124.