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The Experimental Use Exception to Infringement Applied to Federally Funded Inventions

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COMMENT

THE EXPERIMENTAL USE EXCEPTION TO INFRINGEMENT APPLIED TO FEDERALLY FUNDED INVENTIONS

SUZANNE T. MICHEL †

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I. INTRODUCTION

With one minor exception1 the patent statutes do not suggest any instance in which use of a patented invention is not infringement. According to 35 U.S.C. § 154, "[e]very patent shall contain . . . a grant to the patentee . . . of the right to exclude others from making, using or

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1. 35 U.S.C. § 271(e) provides that it is not an act of infringement to make, use, or sell a patented invention for purposes reasonably related to obtaining FDA approval of drugs.
sells the invention throughout the United States." Section 271(a) provides that "whoever without authority makes, uses or sells any patented invention ... infringes the patent."

In spite of the seemingly unyielding dictate of the statutes, courts have recognized experimental use as an exception to infringement. Use of a patented invention "for the mere purpose of philosophical experimentation, or to ascertain the verity and exactness of the specification" is exempt from infringement. ² While it is well settled that a patented invention may be made and used to test the verity and exactness of the specification, the scope of the "philosophical experimentation" prong of the exception is much less clear. The Federal Circuit has called this prong "truly narrow." ³ To be deemed philosophical experimentation, the experiment must be "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." ⁴ The exception does not "allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable and not insubstantial commercial purposes." ⁵ Part II of this Comment describes the history and current scope of the experimental use exception.

In view of this narrow interpretation of the "philosophical experiment" prong of the experimental use exception, several commentators have called for a legislative broadening of the exception to encompass all activity short of commercialization. ⁶ A House bill, the Research, Experimentation and Competitiveness Act of 1990, also proposed broadening the exception. ⁷

Those proposing the broad exception point to two key problems which they contend the broad exception would either clarify or solve. First, it is unclear whether university and other non-profit research done under contract with industry or with a purpose to patent the results is "strictly for philosophical inquiry." The uncertain limits of the doctrine might chill research or lead to litigation. Second, when a patent owner controls important information, that control might prevent a subsequent researcher from building on the information in a way that benefits society. The broad exception would allow subsequent research on patented inventions and would clarify the position of non-profit

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⁴ Id.
⁵ Id.
researchers. Part III describes the conditions which caused these two problems.

The task at hand is to find the wisest limits for the exception while providing a workable solution to the problems of foreclosed research and the uncertain position of non-profit researchers. Any proposal must take into account the economics and incentives of the patent system. Part IV critiques the wisdom of the proposals for a generally applicable broad exception. Part IV also argues that a generally applicable broad experimental use exception weakens the incentives to invent, to develop and to disclose provided by the patent system to too great an extent when applied to patents resulting from private research efforts.

Instead, this Comment proposes in Part V that the experimental use exception (extending up to commercialization) be made applicable only in the special circumstances in which its harm to patent incentives is minimal compared to the resulting benefits. First, university and other non-profit researchers should be allowed the advantage of the broad exception. This first proposal clarifies the position of non-profit researchers with minimal harm to the patent holder. Second, any party should be allowed to use a patented, federally funded invention in research and development. This second proposal provides a number of benefits without the disincentives which result when a broad experimental use exception is applied to privately funded patents. For instance, federally funded inventions will not foreclose subsequent research, but federal grantees will not lose their incentive to invent and disclose because those incentives come from outside the patent system.

II. BACKGROUND OF EXPERIMENTAL USE EXCEPTION

Understanding how the critique and proposals presented by this Comment fit into the framework of the patent laws first requires understanding the judicially created experimental use exception.

A. Creation and Early Development

The experimental use doctrine as a defense to patent infringement originated in 1813 in Whittemore v. Cutter, an opinion written by Justice Story while sitting on the Massachusetts Circuit Court. The defendant in that case challenged a jury instruction that “the making of a machine fit for use, and with a design to use it for profit, was an infringement of the patent right.” Justice Story approved the instruction on the grounds that “it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiment, or

9. Id. at 1121.
for the purpose of ascertaining the sufficiency of the machine to produce its described effects."^{10}

Justice Story referred to this exception again in *Sawin v. Guild*.^{11} In holding that the defendant's use of patented machines constituted patent infringement, he noted that the machines had been used for profit rather than "for the mere purpose of philosophical experimentation, or to ascertain the verity and exactness of the specification. . . . In other words, that the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery."^{12} Even though experimental use was not an issue in either case, meaning that the exception originated in dicta, by 1861 the law on this subject was deemed "well-settled."^{13}

Very few early cases applied the experimental use doctrine created by Justice Story to excuse use of a patented invention that would otherwise constitute infringement.^{14} Even so, the second prong of Justice Story's test which allows activity for "ascertaining the verity and exactness of the specification" does appear to be "well settled." A party may wish to challenge a patent as invalid for not being enabling or useful and therefore must use the invention without a license to assemble proof of this invalidity. A party may also wish to test a patent before taking a license. Although there is little case law on the point, most commentators agree that this sort of activity is and should be protected by the exception.^{15}

The scope of the "philosophical experiment" prong is much less clear. The cases that applied this prong simply concluded that the use in question was "experimental" without offering an elaboration of that term.^{16} The commercial character of a use or the commercial intent of a user usually forfeited the protection of the doctrine in other early cases.^{17} Overall, these early cases provide little guidance in setting the contours of the exception today.

Two more recent cases developed the "philosophical experiment" prong more fully, but neither found the doctrine to be applicable. In *Pitcairn v. United States*, the Court of Claims considered whether

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10. *Id.*
11. 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391).
12. *Id.* at 555 (citation omitted) (citing Whitemore).
14. The history of the experimental use exception from its creation to its application by the Federal Circuit is described elsewhere. See Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PA T. & TRADEMARK OFF. So c'Y 617 (1985). Accordingly, this Comment presents only a summary.
15. Eisenberg, *supra* note 6, at 1074.
16. See *Israelsen, supra* note 6, at 460 n.11.
17. See *id.* at 460 n.14.
helicopters produced under contract for the United States infringed patents that had been previously declared valid by that court. The court rejected the government's argument that the helicopters were purchased for testing and experimental purposes and therefore did not infringe. The court held that "[t]ests, demonstrations and experiments of such nature are intended uses of the infringing aircraft manufactured for the defendant and are in keeping with the legitimate business of the using agency." The helicopters were not built solely for experimental purposes and thus were excluded from the exception.

In Pfizer, Inc. v. International Rectifier Corp., a federal district court held International Rectifier (IR) in contempt of court for violating an injunction which ordered IR to cease manufacture, use and sales of doxycycline, a pharmaceutical compound patented by Pfizer. In spite of the injunction, IR had continued to manufacture doxycycline in order to conduct various tests such as bioequivalency and serum level tests. IR also shipped doxycycline to laboratories in and out of the United States accompanied by a notice that the compound constituted laboratory samples for experimental purposes only.

IR defended its activities on the grounds that they were solely experimental, and that the compound was never sold in the United States after the injunction. The court held these arguments to be "utterly without merit." The court interpreted the history of the experimental use doctrine to suggest that "the underlying rule of permissible experimental use demands there must be no intended commercial use of the patented article, none whatsoever, if the exception is to be recognized at all." Because IR's activities were for the purpose of competing with Pfizer after its patent expired, the court held IR in contempt. In addition, the court ordered IR to destroy all the doxycycline it possessed as well as all data it illicitly acquired regarding doxycycline.

Both Pitcairn and Pfizer make clear that when a use is consistent with the "legitimate business" of the infringer or has an ultimate commercial purpose, the use is not "philosophical experimentation" and falls outside of the exception.

19. Id. at 1124-25.
20. Id. at 1125-26.
22. These tests are required for FDA approval of generic drugs.
23. Id. at 158-59.
24. Id. at 160.
25. Id. at 161.
26. Id. at 163.
B. The Federal Circuit

In Roche Products, Inc. v. Bolar Pharmaceutical Co., the only Federal Circuit case discussing at length the scope of the experimental use doctrine, the court interpreted the doctrine narrowly. Bolar had imported five kilograms of Roche's patented compound flurazepam hydrochloride which Roche sold as a sleeping pill, Dalmane. Bolar used the compound to conduct the bioequivalency studies required for FDA approval with an eye toward marketing a generic version of the drug when Roche's patent expired a year later. Roche argued that this use constituted infringement, but the district court held that the use of a patented drug for testing related to FDA drug approval during the last six months of the patent term was de minimis, experimental and noninfringing.

The Federal Circuit reversed, calling the experimental use exception "truly narrow." The court's analysis first addressed the statute, noting that "[s]ection 271(a) prohibits, on its face, any and all uses of a patented invention," but admitted that the definition of "use" is a matter of judicial interpretation. The court cited Pitcairn for both the proposition that experimental use may be a defense to infringement and as setting forth the controlling law. The court quoted Pitcairn's statement that "'[t]ests, demonstrations, and experiments . . . [which] are in keeping with the legitimate business of the . . . [alleged infringer]' are infringements for which '[e]xperimental use is not a defense.'"

Bolar did not come within the exception because its use was "not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." The court explained:

[U]nlicensed experiments conducted with a view to adaption of the patented invention to the experimenter's business is a violation of the rights of the patentee to exclude others from using his patented invention . . . 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.

30. Roche, 733 F.2d at 863.
31. Id. at 861, 863.
32. Id. at 863 (quoting Pitcairn v. United States, 547 F.2d 1106, 1125-26 (Ct. Cl. 1976), cert. denied, 434 U.S. 1051 (1978)).
33. Id.
34. Id.
Nor did the court consider the use *de minimis* even though the quantity used was small, because the testing could have had a significant economic impact on Roche if Bolar released the generic drug on the market earlier than it would have absent the infringement.\(^{35}\)

1. **THE OVERRULING OF ROCHE V. BOLAR**

Shortly after the *Roche v. Bolar* decision, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984\(^ {36}\) which legislatively overruled that decision. That law exempts from infringement activity which is "reasonably related" to seeking FDA approval for a generic drug. The portion of the bill codified as 35 U.S.C. § 271(e)(1) states that "[i]t shall not be an act of infringement to make, use, or sell a patented invention . . . solely for purposes reasonably related to the development and submission of information under a federal law which regulates the manufacture, use or sale of drugs."

The scope of the exemption is fairly narrow. The legislative history indicates that only a limited amount of testing to establish the bioequivalency of a generic drug substitute is permitted.\(^ {37}\) Whether an activity is "reasonably related" to seeking FDA approval has been narrowly interpreted in the case law.\(^ {38}\)

The legislation is interesting because it demonstrates a Congressional attitude which is willing to allow exceptions to infringement under some circumstances. The committee report states that the exemption did not substantially interfere with the rights of the patent holder because "[t]he patent holder retains the right to exclude others from commercial markets during the life of the patent."\(^ {39}\) In spite of this statement, Congress concurrently enacted a law which extended the patent grant for human drugs and other products which must undergo federal approval before marketing to compensate patentees for the time lost in which they can monopolize the market.\(^ {40}\) Patent owners essentially receive an extension of the patent term in exchange for their toleration of infringing use which enables a competitor to market a product as soon as the pertinent patent expires. This trade-off implies

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35. *Id.* at 866.
38. Scripps Clinic v. Genentech, Inc., 666 F. Supp. 1379, 1396 (N.D. Cal. 1987) (a multiple purpose use of a patented invention is not exempted where only one purpose is reasonably related to FDA testing). However, the Supreme Court's decision in *Eli Lilly v. Medtronic* affirms a Federal Circuit decision to extend the scope of 271(e) to include the testing of medical devices. 872 F.2d 402 (Fed. Cir. 1989), aff'd, 496 U.S. 661 (1990).
that Congress may have conflicting views as to whether the harm to the patentee caused by the exempted experimental testing is as insubstantial as the legislative history suggests. The nature of an experimental use exception’s interference with the patent right is discussed below in Section IV.C.

III. PROBLEMS WITH COMMON LAW DOCTRINE

Although the holding of *Roche* was overruled through legislation, that case is illustrative of the Federal Circuit’s attitude toward the experimental use exception as a defense to infringement. The rationale of *Roche* remains the common law of experimental use in contexts other than the limited conditions of section 271(e). Given the narrow limits which that case places on the doctrine, any activity with a long-range profit motive or with any profit potential is unlikely to fall within the exception. Corporate research will nearly always be “in keeping with the legitimate business of the alleged infringer.”

This narrow interpretation of the “philosophical experiment” prong of the experimental use exception engenders two related problems. First, it is unclear whether university research done under contract with industry or with a purpose to patent the results is “strictly for philosophical inquiry.” Second, when a patent owner controls important information, that control might prevent a subsequent researcher from building on the information in a way that benefits society. The uncertain limits of the doctrine might chill research or lead to unnecessary litigation.

A. Uncertainty for Universities and Federal Laboratories

The extent to which use of a patented invention is permissible noninfringing experimentation when conducted by nonprofit researchers such as universities and federal labs remains unclear. Only one 1935 case, *Ruth v. Stearns-Roger Manufacturing Co.*, has addressed the issue of whether university use can be infringement. The district court in that case held that use of an infringing machine by the Colorado School of Mines was experimental and exempt from infringement because the machines were used in a laboratory and were cut up and changed from day to day. The school used the machines in furtherance of its educational purpose.41

Whether all research conducted in universities and federal laboratories today can be categorized as “philosophical experiments” is extremely problematic given the Federal Circuit’s narrow interpretation

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of that term. To understand how university research, which would appear to epitomize "philosophical experimentation," could fall outside the exception, we must examine the trend toward patenting and licensing university research and the relationships universities have forged with industry. It is through the universities' own attempts to monopolize research results and collaborate with the commercial sector that they have potentially lost claim to the experimental use exception. Part I through Part III below describe the current landscape of industry-university, industry-federal laboratory relationships. Part IV explains why these relationships make application of the experimental use exception uncertain.

1. PATENTING AND LICENSING BY UNIVERSITIES

Prior to the 1980 and 1984 amendments to the patent laws, patents resulting from federally funded research belonged to the government, who often licensed them on a royalty-free, non-exclusive basis, although policies varied depending on the granting agency. The government had a poor record for advancing the development of its patents. For instance, in 1976, less than four percent of the twenty-eight thousand patents held by the federal government were commercially developed.

The perceived need for the 1980 and 1984 amendments was prompted in part by the concern that federally funded research was not being efficiently commercialized because a company wishing to use that research confronted "a bewildering array of 26 different sets of agency regulations governing their rights to use such research." In response, the amendments created a single, uniform national policy. Non-profit research institutions and small businesses now retain the rights to patents resulting from federally funded research which they perform. The amendments also give universities the right to own inventions made in federally owned research facilities run by the university under contract with the government.

The amendments encourage government-funded researchers to patent resulting inventions by simplifying the bureaucratic obstacles to licensing and by allowing the patent holder to keep the royalties. Private industrial firms can exclusively license these patents from the

university or another government contractor for specific uses they intend to commercialize.46

Congress designed the amendments to encourage private industry to commit the capital necessary to develop government-funded inventions to the point of commercial application. Supporters of the amendments argue that without the profit incentive provided by exclusive rights, commercial development lags and research results do not become socially useful. The Secretary of Commerce stated, “Direct access to the university and the university’s right to transfer the results of its research on an exclusive basis is an important incentive for business to invest in the further development and commercialization of new technologies.”47

Thus, the patent system accomplishes the policy goal of transferring the products of university research to the public by allowing a university to license its inventions.48 However, the license must be exclusive before companies will invest in development. Inventions arising from university research are often at an early stage of development and the licensee may need to do further development simply to identify a commercial product. Because biotechnology products in particular require expensive regulatory approval, it is difficult to find a licensee who is willing to make the required investment without receiving an exclusive license.49

In the past the university scientific community viewed private ownership of discoveries as contrary to the university’s mission and the public interest.50 Especially in the biomedical fields, some researchers held a belief that new knowledge should be made as widely available as possible to serve humanity.51 This attitude has changed for several reasons, making universities increasingly likely to patent publicly and privately funded research.

First, the view that basic research should be freely available to everyone was predicated on the assumption that the work being done

46. 35 U.S.C. § 202(c)(7) (1988). The government retains a royalty-free worldwide license to practice the invention or have it practiced for the government. Id. § 202(c)(4). In addition, the government has march-in rights that terminate the rights of the contractor if the contractor does not effectively attempt to apply the invention. Id. 35 U.S.C. §§ 202(c)(8), 203.
48. Phyllis S. Lachs, University Patent Policy, 10 J.C. & U.L. 263, 276-77 (1983). Of course, this argument assumes that the private sector would not commercially develop the university invention absent an exclusive license.
had no immediate commercial value. When this premise broke down in fields like molecular genetics, and laboratories produced results with commercial value, various entrepreneurial interests insisted that results be privatized. Consequently, patent protection for basic research discoveries with potential commercial value has become more commonplace. This is especially true in biotechnology-related fields where the dividing line between basic and applied research is not clear. Academic and industrial scientists often work on the same or closely related problems.

Second, universities had little incentive to pursue patent rights before the 1980 amendments because the common practice of government agencies supporting the research was to require that the patent be assigned to the government and then freely licensed.

Because the amendments allow the universities to keep royalties, they are looking to licenses as a way to supplement government money for research. As government support of university research has decreased in terms of constant dollars, the cost of scientific research has rapidly escalated. Erich Bloch, then director of NSF, testified before a Senate Committee that the federal government is unable to meet all research needs of the universities and, therefore, the universities have a continuing need for additional funding.

Allowing universities to patent and license faculty inventions has produced a number of success stories for different universities. The Cohen-Boyer gene-splicing patent which forms the basis of the biotechnology industry is expected to bring more than $100 million in royalties to the University of California and Stanford. The Massachusetts Institute of Technology registers more patents than any other university, over one hundred per year, and licenses up to 53% of

52. Id. at 107.
53. DICKSON, supra note 49, at 75-76.
54. Id. at 74-75; see David Blumenthal et al., Industrial Support of University Research in Biotechnology, 231 SCIENCE 242 (1986).
55. Dobkin, supra note 42, at 568-84, 591-607.
56. Lachs, supra note 48, at 268.
57. National Science and Technology Issues: Hearing Before the Senate Committee on Commerce, Science and Transportation, 101st Cong., 2nd Sess. 22 (1990) (statement of Erich Bloch, Director, National Science Foundation) [hereinafter Technology Issues Hearing]. For instance, the NIH budget has been rising rapidly, from $3.2 billion in 1980 to $7.5 billion in 1990. However, the soaring cost of doing research, the fact that more money is tied up in long-term grants, and the increasing number of scientists applying for grants have created a money drought, especially for younger scientists. NIH research grants account for about 75% of all biomedical research funds provided by the federal government and private nonprofit sources. Gina Kolata, Beginning Scientists Face a Research Fund Drought, N.Y. TIMES, June 5, 1990, at C1.
those. In 1991, M.I.T. grossed $5.5 million from its licensing activities.\(^{59}\) Some forty companies employing more than one thousand people have been started based on M.I.T.-licensed technology.\(^{60}\)

Third, the requirement of the 1980 amendments that universities share royalties with inventors gives researchers an incentive to be alert to patent rights.\(^{61}\) Universities generally include a patents rights clause in employment contracts with faculty so that the patent must be assigned to the university. Often the university awards between one third and one half of any resulting royalty to the inventor, with the remainder going to the university.\(^{62}\) Consequently, the inventor profits from any licensing.

2. UNIVERSITY-INDUSTRY RELATIONSHIPS

For universities, patents provide more than just royalty income. Patents are also a means of strengthening ties with industry and gaining private support for academic research.

Universities are contracting with industry to conduct specific research with the understanding that the industrial firm receives the right to license and commercially develop the results.

In the past, university-industry agreements were generally of a small scale and seldom controversial.\(^{63}\) The situation began to change in the mid-1970s at a time when universities experienced economic pressures from rising operating costs coupled with federal funding that failed to keep pace with the expanding number of scientists. In this atmosphere, university faculty and administrators welcomed increased collaboration with and funding from industry.\(^{64}\) Industrial support of academic research made up only 3.8\% of the total university research budget in 1980 but has been generally increasing since then.\(^{65}\) A 1984 study reveals that industry may be funding as much as one fourth of all biotechnology research in universities.\(^{66}\) Fueling industry’s increased

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\(^{59}\) M.I.T. netted only $500,000 from the $5.5 million it grossed from royalty licenses in 1991 due to the costs associated with filing and licensing patents and the $1 million it distributed to hundreds of individual scientists. Shaffer, \textit{supra} note 58, at 10.

\(^{60}\) \textit{Id.}


\(^{62}\) Lachs, \textit{supra} note 48, at 281, 285-86 (recommending that universities include a patent rights clause in their employment contracts).

\(^{63}\) DOROTHY NELKIN, SCIENCE AS INTELLECTUAL PROPERTY 18 (1984).

\(^{64}\) \textit{Id.} Universities are partially motivated to accept the corporate sponsorship in order to keep their best scientists, who may move to another university or to industry if denied the corporate funding. \textit{Kenney, supra} note 51, at 62.


\(^{66}\) Blumenthal et al., \textit{supra} note 54, at 244.
funding is the fact that the gap between basic research and commercial interest has "dramatically narrowed."\textsuperscript{63}

University-industry relationships take a variety of forms ranging from contributions\textsuperscript{68} to contract research to long-term agreements. Contract research requires that a university laboratory conduct specific experiments, such as testing the safety of new chemical, for a fee. In another type of contract arrangement, the university provides continuing education for the industrial personnel.\textsuperscript{69}

In some long term university-industry agreements the corporation directs a grant to a specific investigator. In others, a review board consisting of university and corporate members selects the projects to be funded. Alternatively, a research institute may be organized to be distinct from the university.\textsuperscript{70}

Businesses see the long-term university-corporate contract as a means to purchase access to university scientists. In exchange for funding, the corporation receives the research skill of the principal investigator and her entire laboratory staff, including graduate students and postdoctoral researchers. The company often expects to be intimately familiar with ongoing research, giving the company tremendous opportunities for access to the researcher's ideas.\textsuperscript{71}

Companies fund university research to enhance their competitive position and this requires that research results be patented.\textsuperscript{72} The 1980 and 1984 patent amendments are a cornerstone of university-industry cooperation.\textsuperscript{73} (Since projects may be both publicly and privately funded, the amendments will apply.) Cooperative arrangements between an industry sponsor and a university usually provide that the sponsor acquires either patent rights, patent ownership or, more commonly, an

\textsuperscript{67} DICKSON, supra note 49, at 74.

\textsuperscript{68} A corporation may simply make a contribution to the university, either an undirected contribution which the university may use as it sees fit or a directed contribution which targets a substantive research area or supports a specific professor. These relatively small grants do not provide the corporation with any unique claim on research results though they may provide a personal relationship with the professor. KENNEY, supra note 51, at 37-38.

\textsuperscript{69} Id. at 39-40.

\textsuperscript{70} Lachs, supra note 48, at 279.

\textsuperscript{71} KENNEY, supra note 51, at 68, 240. The long-term one university-one corporation agreement has been more common in biotechnology than in other fields. The early development of biotechnology took place in universities rather than commercial laboratories and a significant portion of cutting-edge research remains in universities. Id. at 55. For example, in 1982 Yale University announced a $1,100,000 research contract with Celanese Corporation which mandated that Yale conduct specific research for the company on the composition and synthesis of enzymes. Lachs, supra note 48, at 280. Other specific agreements are described elsewhere. See, e.g., Kenney, supra note 51, at 58-72.

\textsuperscript{72} Id. at 61.

\textsuperscript{73} DICKSON, supra note 49, at 89.
exclusive license, to all inventions made in connection with the project agreement.\textsuperscript{74}

Universities are not always on the receiving end in a university-industry relationship. Universities like Harvard, Johns Hopkins and the University of Texas have formed or invested in for-profit venture capital companies to develop their researchers' work. Universities may also "accept stock in startup companies instead of a licensing fee," hoping to "benefit when a company becomes successful."\textsuperscript{75}

University-industry relationships may also involve only individual faculty members, rather than the university as an entity. Faculty consulting\textsuperscript{76} for corporations can grow into a more intimate relationship, such as a position on a scientific advisory board for which the advisor receives stock. An important factor in convincing professors to affiliate with a company has been the provision of equity interest, giving the professor a stake in the success of the company.

Professors may also start firms in partnership with venture capital. While retaining their faculty status, university faculty have acted as founders and consultants for new ventures hoping to commercialize the practical applications of their research.\textsuperscript{77} In some cases professors who are heavily involved in company management leave the university completely, especially in the electrical engineering and computer science fields.\textsuperscript{78} Many biology professors, however, retain their university connection. All of the earliest genetic engineering companies were founded by professors who completed the initial research in university laboratories. For instance Genentech, co-founded by Herbert Boyer to exploit the Cohen-Boyer gene splicing patent, did not have a laboratory in its early stages, so Boyer's campus laboratories at UCSF were used. The company granted Boyer $200,000 to perform specific research.\textsuperscript{79}

3. \textit{FEDERAL LABORATORY-INDUSTRY RELATIONSHIPS}

The 1984 amendment to the patent laws works with the Federal Technology Transfer Act (FTTA) to promote a greater flow of technology from federal laboratories to the private sector by giving the laboratories the authority and incentive to work with the private sector. The 1984

\textsuperscript{74} \textbf{KENNEY, supra} note 51, at 58, 63, 64, 65.
\textsuperscript{75} \textbf{Shaffer, supra} note 58, at 10.
\textsuperscript{76} \textbf{KENNEY, supra} note 51, at 101-03. Faculty consulting for government and corporations has long been a part of the academic world. Within the traditional limits which dictate that consulting should not interfere with academic responsibilities, consulting alone has had little effect upon the university. \textit{Id.} at 91.
\textsuperscript{77} \textbf{Brinton, supra} note 49, at 480; see also \textbf{Lachs, supra} note 48, at 289-90.
\textsuperscript{78} \textbf{KENNEY, supra} note 51, at 100.
\textsuperscript{79} Id. at 94-95. For a list of professors having both university and lucrative industry connections, see \textbf{Morgenson, supra} note 65, at 208.
amendments require federal laboratories to identify and seek patents for inventions with commercial potential and authorize laboratories to negotiate and issue patent licenses on those inventions. The FTFA establishes a mechanism and offers incentives for government laboratories to enter into cooperative research and development agreements (CRADAs) with industry. The Act allows the over 700 federal laboratories to accept funds, services, and property from a private firm in exchange for an exclusive license to any patent rights resulting from the cooperation. In addition, federal employees whose inventions are commercially developed receive a percentage of the royalties.

Federal laboratories had previously been generally unsuccessful in transferring research results to the private sector. Although an agency supporting research in federal laboratories could allow a private company to develop a patented invention, agencies were often so slow in doing so that companies lost interest. For example, between 1977 and 1985, the Department of Energy received 135 requests to use patent rights to inventions made at contractor-operated facilities, but by December 1985 had responded to only fifty-five of them.

The importance of federal laboratories having the authority to grant exclusive licenses was emphasized by Ronald Hart, director of the National Center for Toxicological Research. He stated that the inability to grant exclusive licenses in the past has meant the research “was everybody’s property and so nobody’s product.” Hart contends that “many inventions that could have improved public health simply languished.”

4. UNCERTAINTY UNDER THE EXPERIMENTAL USE EXCEPTION

The activities and relationships described above raise the issue of what circumstances constitute infringement when a university researcher uses a patented invention without a license. When will that use be exempted as “philosophical inquiry,” and when will that use be deemed commercial so that the use falls outside the narrow experimental use

82. 15 U.S.C. § 3710(b) (1988); Technology for Sale, supra note 81. When Oak Ridge National Laboratory was designated as a guinea-pig laboratory in 1984 to test the incentives, laboratory employees sought 30% more patent applications in two years. Id.
84. Technology for Sale, supra note 81.
exception? (Research in federal laboratories raises the same concerns and
difficulties as research in universities and is not referred to separately.)

In some cases, non-licensed research use of a patented invention
will lead to another invention which the university may patent and
license. By generating funds from licensing, the university imparts a
profit motive to the research work. Of course, the university can argue
that because any license fees it receives are not distributed as profits, but
instead are used to support its educational and research missions, the use
of the original patented invention was an exempted experimental use.

But when industry licenses a university owned invention with a
view towards commercializing the invention, the university research
takes on a "definite, cognizable and not insubstantial commercial
purposes." Although the university does not itself participate in the
commercialization, the subsequent industry use taints the university
research with a commercial purpose. University research most likely
loses its status as an experimental use once the results of that research are
licensed to a commercial organization. This is especially true when an
industrial firm contracts with a university with an understanding that the
industrial sponsor will receive an exclusive license on any patented
results. Any different conclusion would allow industry to easily
circumvent the patent laws when it wanted to conduct research on a
patented invention by contracting with a university lab to do the work.

If universities insist that industrial firms license their patented
inventions, even for experimental purposes, it will not be surprising if
industrial firms eventually demand equal, reciprocal treatment for their
own inventions. Thus, industrial firms may begin raising the issue of
whether university use is truly experimental.

Universities apparently do expect industrial firms to license their
technologies for experimental use. To generate royalties, Joyce Brinton,
Director of Harvard University's Office for Patents, Copyrights and
Licensing, suggests a licensing strategy which clearly contemplates that
industry must license technology it wishes to research, even when no
specific commercial application has yet been identified. Brinton suggests
that the university set financial terms that encourage licensees to
experiment with the invention. For example, Brinton suggests that the
university could charge a small initial fee for time-limited research
followed by a larger fee to continue R&D. The hope is that a licensee will
find the invention useful and sufficiently inexpensive so that the
company will not search for an alternative.

In another example, Stanford announced in 1985 that seventy-three companies had taken licenses under the Cohen-Boyer patents\(^7\) for recombinant DNA technology. As of that time however, only about ten companies had reportable sales using the technology. It logically follows that a substantial number of licensees were using the technology on an experimental basis.\(^8\)

Scientists working in a university or federal laboratory setting are likely to be concerned with both the traditional rewards of the scientific community and the incentives provided by the patent system.\(^9\) The patent incentive may cause individual scientists to choose experiments with a profit motive rather than strictly for philosophical inquiry. This individual profit motive can also cause the research in question to lose its status as an experimental use.

By profiting directly from any licensing of their inventions,\(^10\) individual university scientists may lose their status as pure experimental researchers entitled to the exception. But the profit motive may have an even deeper effect on research choices. It is now accepted practice for university researchers to profit directly from the results of academic research through various types of commercial ventures. University scientists may have equity interests in companies sponsoring or developing their work.\(^11\) In this case, the scientist's and the company's objectives will be closely aligned, tempting the scientist to ensure the company's success by tilting her academic research agenda. This can lead to a conflict of interest for the researcher. For instance, the scientist may use students and university equipment for private gain, divide work time in a way that slights the university, shift research to commercial goals, transfer patent rights from the university to the company and suppress research results.\(^12\) Certainly, this type of activity has a commercial purpose and cannot be characterized as an experimental use.

As research use of patented inventions by non-profit institutions becomes more of a threat to the interests of patent holders, the patentees may either demand licensing fees or attempt to enjoin the research. For instance, Johnson & Johnson sent letters to researchers at universities and government laboratories warning them that research use of the company's patented cells may infringe the company's patent rights. Johnson & Johnson's position was that using the patented invention to

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87. Hantman, supra note 14, at 643.
88. Id.
89. Rebecca S. Eisenberg, Proprietary Rights and the Norms of Science in Biotechnology Research, 97 YALE L.J. 177, 195 (1987).
90. The amendments to the patent laws require that the inventor receive a share of the royalties when any university invention is licensed. 35 U.S.C. § 202(c)(7)(C) (1988).
91. Nelkin, supra note 53, at 20; Blumenthal et al., supra note 54.
make a commercial improvement would be an infringement, even if made in a university. The licensing and contracting activities described above increase the uncertainty of the outcome of this type of threat to the universities and the federal labs.

B. Foreclosure of New Inventions When A Basic Technique is Patented

Occasionally the subject of a patent is a basic technique or piece of information which lays the foundation for further discovery and developments. The consequences of patenting discoveries that are significant to both basic and applied research are not well understood. Patents present a difficult dilemma for the progress of science. Patenentees can retard further scientific progress by prohibiting the use of their patented invention in subsequent research. For instance, patent holders can prohibit the research use of their inventions in order to prevent subsequent researchers from developing non-infringing substitutes which would of course undermine the value of the patent.

Subsequent researchers might obtain licenses, but as explained below, this is problematic in a non-profit research institution conducting basic research. Of course, holders of patents on basic techniques might not enforce their rights against subsequent researchers. The patent holder may not be aware of the research or may not object. Furthermore, the amount of damages available from research-oriented infringement may make a suit financially unsound, especially if the research does not threaten the commercial interests of the patent holder.

This problem is related to the uncertain situation in which non-profit researchers find themselves. A basic technique is precisely the type of invention that a university researcher would wish to investigate further. Again, the patent holder may not object as suing a university would undoubtedly create adverse publicity. However, the university is in an uncertain situation due to the confused scope of the experimental use exception, especially if it wishes to patent and license the results of the subsequent research.

95. Id. at 742; Eisenberg, supra note 89, at 177.
96. See infra notes 147-50 and accompanying text.
97. Eisenberg, supra note 94, at 742-43.
98. Id. at 743. In Roche, however, the Federal Circuit noted that the financial harm to the patentee from even the minimal use at issue there would not be inconsequential. Roche Prods., Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858, 866 (Fed. Cir.), cert. denied, 469 U.S. 856 (1984).
C. Polymerase Chain Reaction Example

The actions of Hoffmann-LaRoche controlling the use of the polymerase chain reaction (PCR) demonstrate how a patented invention can cause uncertainty for non-profit researchers and foreclose scientific progress if other researchers are not allowed to use the invention.

The polymerase chain reaction amplifies minute amounts of genetic material into measurable quantities, enabling scientists to identify and study extremely small traces of genetic material. For instance, if the procedure is repeated twenty times, one million copies of DNA are produced from a single original piece of DNA. The technique has been analogized to taking a needle in a haystack and using it to generate a whole stack of needles.

PCR is having a revolutionary impact in the biomedical sciences. It is crucial to the human genome project and has great potential for the examination of genetic defects and the identification of infections, viruses and cancers. For instance, PCR plays an increasingly major role in the study and detection of AIDS. PCR can also be used in forensic criminal investigations to obtain DNA fingerprints from blood, semen or hair samples.

Dr. Kary Mullis, then at Cetus Corporation, invented PCR in 1983. In 1991, Hoffmann-LaRoche paid $300 million to acquire the patented technology from Cetus. The invention is unusual in that it was made by a biotechnology company but is now in wide use for both academic research and commercial purposes. Roche has not attempted to block any basic research, but the company only recently agreed to relax its hold on PCR rights for certain applications after lobbying by genetic-testing laboratories and researchers, including James Watson. The company dropped the idea of demanding an up-front licensing fee and an annual minimum payment by academic and non-profit institutions. However, the very fact that Roche considered the plan demonstrates the company's attitude that academic research does constitute infringement. Although

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99. The first step in using PCR is to heat the DNA so that the two strands of the double helix come apart. Primers, short pieces of DNA, are attached to each strand to identify the portion of DNA to be copied and to provide chemical instructions for the next step. In the next step, the enzyme DNA polymerase assembles a matching strand of DNA along each original strand, thereby producing two new double helices of the target DNA. Kary B. Mullis, The Unusual Origin of the Polymerase Chain Reaction, Sci. Am., Apr. 1990, at 56; Harold M. Schmeck Jr., New Test That Finds Hidden AIDS Virus Is a Sleuth With Value in Many Fields, N.Y. Times, June 21, 1988, at C1.

100. Schmeck, supra note 99.


adverse publicity may often force a company to relent in similar circumstances, the uncertain position of academic and non-profit research institutions indicates a potential for future problems.

Roche also considered but abandoned requiring its licensees to report back any new technology based on PCR. Biotechnology companies warned that the requirement would impede improvements by others in PCR techniques, discouraging commercial laboratories from developing new genetic tests since they would be competing directly with Roche's own PCR based products. The proposal shows how a patentee can influence subsequent research.

IV. PAST PROPOSALS AND CRITIQUE

A serious problem results when a patent prevents subsequent research by others. This is especially problematic when basic techniques and information are patented. Although the common law experimental use exception answers this concern in some instances, its scope is limited. Moreover, the full reach of the exception is unclear, especially as it applies to research at universities and federal labs when the ultimate goal is to patent and license research results.

As a solution, commentators and legislators have suggested broadening the experimental use exception to allow any research use short of commercialization. The broad exception would allow subsequent research on patented inventions and would clarify the position of non-profit researchers.

A. Proposals For a Broad Exception

The House Committee on the Judiciary reported favorably on the Patent Competitiveness and Technological Innovation Act of 1990 (H.R. 5598) and recommended that the bill pass in September 1990. Title IV of the bill entitled "The Research, Experimentation and Competitiveness Act of 1990" proposed a broad experimental use exception. The proposed legislation would add section 271(j) to the patent code, which would state:

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

104. Id. at 46-47.
such invention or to create a product outside the scope of the patented invention to which subsection (e)(1) applies.\textsuperscript{106}

The Committee Report describes the amendment as a clarification of case law, although this description is inaccurate as explained below. The Report states, "It is a central tenet of American patent law that there is a right to use scientific information to create new and better inventions in competition with the patented invention."\textsuperscript{107} The Report delineates several acts which do not constitute infringement under the proposed legislation:

(1) testing an invention to determine its sufficiency or to compare it to prior art; (2) tests to determine how the patented invention works; (3) experimentation on a patented invention for the purpose of improving on it or developing a further patentable invention; (4) experimentation for the purpose of "designing around" a patented invention; (5) testing to determine whether the invention meets the tester's purposes in anticipation of requesting a license; and (6) academic instructional experimentation with the invention.\textsuperscript{108}

Business testing is clearly not an experimental use.\textsuperscript{109} Examples 1, 2 and 5 fall under Justice Story's second prong of experimental use, that of testing the verity of the specification. Example 6 is arguably a "philosophical experiment." However, examples 3 and 4, when performed with an ultimate commercial motive, are excluded from the experimental use exception as interpreted in \textit{Roche v. Bolar}. Using a patented invention to improve or design around the invention is infringement when the effort is in keeping with the legitimate business of the user.\textsuperscript{110} Thus, the legislative proposal presents a broadening, rather than a codification of the current experimental use doctrine.

The report justifies the broad exception partly on the grounds that it clarifies that university research use of a patented invention is an experimental use and not infringement.\textsuperscript{111} Government and university scientists should not be confused about the permissible boundaries of their research because the confusion may chill research and

\textsuperscript{106} \textit{Id.} at 55-56. The research exemption does not apply to research tools (like microscopes and mice) except to allow study of an invention to create a second invention that falls outside the scope of the original patent. In other words, if an invention's primary use is as an aid or tool in research, so that the research use is not directed towards improving the tool, the use should not fall under the exemption. \textit{Id.} at 56. The legislative overruling of \textit{Roche Products, Inc. v. Bolar Pharmaceutical Co.}, 35 U.S.C. § 271(e), is not altered by the proposed amendment. \textit{Id.}

\textsuperscript{107} \textit{Id.} at 41.

\textsuperscript{108} \textit{Id.} at 44-45.

\textsuperscript{109} \textit{Id.} at 45-46.


\textsuperscript{111} In addition, supporters of a broad exception worry that legitimate scientific activities are driven outside the U.S. where the work is exempt from U.S. patent laws. \textit{H.R. Rep. No. 960, supra note 105, at 44.}
experimentation. If university research were clarified as experimental, then researchers could work with patented materials without paying a licensing fee. Almost all university research could be described under examples 3 and 4 as improving or designing around the invention if it could not be described as academic instructional experimentation according to example 6. As long as the university refrained from "business testing" it would not infringe.

A broad experimental use exception would also lessen the foreclosure of subsequent research when a basic technique or information is patented. A subsequent researcher could improve on or design around the base patent without risking infringement.

Commentators have made recommendations which generally correspond to the proposed legislation broadening the exception by allowing experimentation on a patented invention for the purpose of improving or "designing around" it, even with the long term goal of an eventual business use. Given the support for a broad experimental use exception voiced by practitioners, scholars and Congress, it is likely that Congress will eventually enact a bill similar to the one quoted above. The task at hand is to find the wisest limits for the exception while providing a workable solution to the problems of foreclosed research and the uncertain position of non-profit researchers. Any proposal must take into account the economics and incentives of the patent system. Accordingly, the following Part describes those incentives before attempting a critique of the proposals for a broad experimental use exception.

112. *Id.* at 43-44.
113. *Id.* at 43.
114. One commentator argues that the case law supports a position that the experimental use exception applies to testing a patented invention for adaptation to the experimenter's business provided that the experimental use does not result in a "use for profit." He contends that, based on case law and the policies behind the patent system, the exception ought to apply to infringement while developing new uses and improvements for the patented technology if the infringer does not make or attempt to make a monetary profit during the infringement. Hantman, *supra* note 14, at 644. Given the language in *Roche v. Bolar*, however, it is doubtful that the Federal Circuit will follow this interpretation. See *supra* notes 27-35 and accompanying text; see also Irving N. Feit, *Biotechnology Research and the Experimental Use Exception to Patent Infringement*, 71 *J. PAT. & TRADEMARK OFF. SOC'Y* 819, 835-37 (1989). Accordingly, any proposals on the scope of the experimental use exception are best viewed as suggestions for changes to the patent laws.

B. Incentives of the Patent System

Invention and innovation\textsuperscript{118} contribute to the public good and should be encouraged. However, a free enterprise economy underinvests in research because it is risky and sometimes unrewarded.\textsuperscript{119} Moreover, when something of value is discovered in a free enterprise economy, competitors may quickly appropriate the innovation, thus decreasing the inventor’s profits by driving down prices. Thus, underinvestment in research and development is expected because the social returns on these activities are greater than the private returns. Therefore, society must promote invention and innovation because profit-maximizing firms would often choose to be imitators rather than innovators.\textsuperscript{120} The goal of the patent system is to make the level of investment in R&D closer to its social value.

The patent system advances this goal in three ways; by promoting invention, by encouraging the development and commercialization of the invention and by encouraging public disclosure of the invention.\textsuperscript{121} The patent system promotes invention that might not occur otherwise by granting the inventor an exclusive right in her invention and presumably the ability to exploit monopoly profits.\textsuperscript{122} The lure of monopoly profits stimulates the invention of new products and processes. A patent enables an inventor to capture returns from her investment by preventing others from appropriating the invention and driving down the price of the final product. In this way the patent system curtails free-riding that would otherwise discourage research and development activities.\textsuperscript{123}

The incentive provided by the patent system to develop an invention to the point of commercialization is as important as the

\textsuperscript{118} As a matter of definition, “invention” will be used to refer to the first implementation of the inventor’s idea, but not necessarily a commercial product. An “innovation” is the commercially practical form of the invention. An innovation may significantly differ from an invention due to the changes necessary to turn the invention into a commercial product. Robert P. Merges, Commercial Success and Patent Standards: Economic Perspectives on Innovation, 76 CAL. L. REV. 803, 807 (1988).


\textsuperscript{120} See Morton I. Kamien & Nancy L. Schwartz, Market Structure and Innovation 112-13 (1982).

\textsuperscript{121} F.M. Scherer, Industrial Market Structure and Economic Performance 440 (2d ed. 1980).

\textsuperscript{122} A patentee’s actual power over price varies widely from case to case depending on the availability of substitutes and elasticity of demand for the patented product. Id. at 449.

incentive to invent. The first patentable invention is frequently discovered years before the first significant commercial product is marketed. In many cases, an invention requires extensive development before any commercial application is possible. For example, this was the case with the laser, the transistor, nylon and xerography. The patent system furnishes an incentive to develop early inventions by allowing an innovator to recoup development costs through monopoly profits and by protecting an innovator's central ideas during the development process. In the modern industrial world, development accounts for more than three fourths of all industrial R&D expenditures. Developing an invention to the point of commercial applicability is both costly and risky. To recoup their development costs plus a premium for risk, developers must be able to sell the product at a price which exceeds production costs. The patent system prohibits imitation of the new product which would otherwise drive down the price in a competitive market, thereby allowing the innovator to recoup development costs.

Because most inventors apply for patents at the beginning of a long process leading from invention to innovation, the incentive to develop can be characterized as an incentive to complete the project. The incentive stems from the knowledge that the exclusive rights granted by the patent protect the inventor from appropriation of the invention's central ideas while the inventor converts the invention to an innovation. Through the patent the inventor carves out an area which she exclusively is allowed to develop.

124. By enacting the 1980 Amendments to the Patent Act, which allow small businesses and universities to own and license patents resulting from federally funded research, Congress recognized the importance of patent protection as an incentive to invest in development. See supra notes 45-49 and accompanying text.

125. Inventors file patent applications before an invention is marketable because the laws and rules governing the patent system encourage early filing in three ways. First, the inventor can obtain a patent before the invention is commercially practical because she need not actually construct the invention to file the application, she need only supply instructions that enable one skilled in the art to make it. 35 U.S.C. § 112 (1988). Second, although a patent is awarded to the first to invent rather than the first to file, late filers carry the burden of proving they were the first to invent in an interference proceeding to determine the first to invent between parties having filed applications on the same invention. 35 U.S.C. § 102 (1988). Third, publication or other public disclosure of the invention bars a patent after one year. 35 U.S.C. § 102(b) (1988). If an inventor wishes to make an invention public she has only one year to file the application.


127. SCHERER, supra note 121, at 440.

128. Id. at 444. Of course, the patent owner has an incentive to make the required investment in development and maximize the value of the patent only if the patent will cover the commercial embodiment. Otherwise, the development investment may produce information as to product manufacture and design that would be appropriable by competitors. Kitch, supra note 123, at 276-77.

129. Merges, supra note 118, at 840.
In exchange for the exclusive grant, society gains the resources that cost-saving innovations release for alternative uses and the introduction of superior products and more efficient processes which would not otherwise have been made or made much later. In addition, society may freely use the invention once the patent expires.130

The patent system also offers the important incentive to disclose the invention. By offering protection from appropriation by others, even after the invention becomes public, patent protection leads inventors to make public what they might otherwise keep secret.131 The inventors' other major method of protecting inventions from appropriation, trade secrets, are risky because once the information is disclosed, even unintentionally or without consent, proprietary protection is no longer possible. Moreover, the inventor has no protection if another party independently creates the invention.132

An issued patent is public so other firms can direct their work so as not to duplicate work already done by the patent holder. When trade secrets protect the research, however, a competing firm striving for the same result will likely duplicate efforts made by others.133 Thus, it is reasonable to assume that research which was kept secret due to a lack of patent protection would also be duplicated by competitors hoping to achieve the same product. Accordingly, trade secret protection arguably leads to more duplication than patent protection.

Another benefit of the patent system is that it generates R&D activity by creating a desire to design around another firm's patent to avoid infringement and royalty payments. Sometimes design around the patent yields a superior product or process.134 In addition, companies may conduct R&D to guard against being foreclosed from an area of technology by the patent rights of another. A company's own patents give it a bargaining chip in negotiating with firms holding complementary patents.135

130. Scherer, supra note 121, at 442.

131. Id. at 441. A successful patent application must disclose a novel and nonobvious invention in a way that enables one skilled in the art to which the invention pertains to practice the invention. 35 U.S.C. §§ 102, 103, 112 (1988).


133. Kitch, supra note 123, at 278.

134. Scherer, supra note 121, at 446-47. However, some commentators have criticized the competitive and duplicative research devoted to design around activity as being, on the whole, wasteful. See William S. Comanor, Research and Competitive Product Differentiation in the Pharmaceutical Industry in the United States, 31 Economica 372, 381-84 (1964). Scherer concludes that it is impossible to determine whether the benefits of design around research exceed the cost of the duplication. Scherer, supra note 121, at 446. This criticism overlooks the importance of the incentive to disclose.

135. Scherer, supra note 121, at 446. Cross-licensing is a common way to bargain with patents.
C. A Critique of the Broad Exception

1. THE HARM TO THE PATENT INCENTIVE

The broad experimental use exception, which would allow any person to use a patented invention in research and development up to the point of commercialization, does clarify the position of non-profit researchers and partially alleviate the foreclosure of subsequent inventions. Unfortunately the broad exception will also discourage inventors from using patent protection in the future. If a broad exception discourages use of the patent system, it decreases public disclosure of new inventions and reduces the incentive to invent and develop in industries where patent protection is especially important. For these reasons the Patent and Trademark Office opposes legislation creating a research exemption.

The broad exception harms the incentive to invent. Allowing an experimental use exception in a commercial setting allows 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 inventor's crude models. This free riding can make it impossible for the original inventor to appropriate returns on early R&D investment. A broad experimental use exception could lead to less R&D rather than more if inventors refuse to invest in inventive activity due to free riding.

The broad exception also harms the incentive to develop already patented inventions to the point of commercialization. As discussed above, a patentable invention often requires extensive development before any commercial application is possible. In this situation the patent serves as an incentive to complete the project because it guards against appropriation of the inventor's central idea while she converts the invention to a marketable innovation. A commercial experimental use exception destroys this important control over the patented idea. If others can use the patented invention to design around, improve and ultimately supersede the invention with a superior alternative, the use contributes another degree of uncertainty to the profitability of the final product. Therefore, the patentee has less reason to develop and commercialize the invention. But without commercialization the patentee

137. H.R. REP. NO. 960, supra note 105, at 8 n.25 ("It could diminish the strong incentive provided by the patent system.").
cannot recoup her investment in researching and developing the invention, discouraging both invention and innovation.

The proposal for a broad experimental use exception amounts to an unlicensed appropriation of the patent during the research and development stages. At a minimum the appropriation deprives the patentee of royalties for the research use even though the patentee is clearly contributing something of value to the infringer's work. Even if an attempt to design around or improve a patent is unsuccessful, the infringer would have used the patented invention with an eye toward future profit without compensating the patent holder. The patentee loses some of the reward of the patent monopoly that encourages invention and development. Allowing a competitor to benefit from a patentee's inventive activity without any payment lessens the patentee's economic return on the inventive investment. The result may be to reduce inventive activity in industries that rely heavily on patent protection.139

Because a broad experimental use exception encourages design around and improvement activity it also harms the incentive to disclose and encourages secrecy. Inventors may choose secrecy as an alternative to patent protection if their patent disclosure can make the invention and eventual innovation less valuable. The extent to which the patent disclosure facilitates designing around the patent influences the choice between obtaining a patent and maintaining the invention as a trade secret.140

Disclosure through patenting is preferable to secrecy for at least two reasons, even if the patented invention cannot freely be used in research. First, the patent avoids duplication of the same work by competitors by informing them of the results. Second, the patent informs competitors of what technology is available for licensing and cross-licensing.

Firms have significant incentives to enter licensing and cross-licensing agreements.141 A patentee may license an invention that it

139. The differences among innovation processes in different industries and the differences in the importance of patents to these industries makes the incentives provided by the patent system more relevant in some cases than in others. Merges, supra note 118, at 846 n.181 and references therein. For instance, patents constitute a critical dimension of product differentiation in the pharmaceutical industry, but are less important in the mechanical and electronic industries. See Edwin Mansfield, Patents and Innovation: An Empirical Study, 32 MGMT. SCI. 173 (1986).

140. Richard C. Levin et al., Appropriating the Returns from Industrial Research and Development, 1987 BROOKINGS PAPERS ON ECON. ACTIVITY (Special Issue on Microeconomics) 783, 805.

cannot develop and commercialize itself or that the licensee can develop more efficiently. Royalty-free cross-licensing schemes can increase efficiency of industry-wide R&D. Cross-licensing agreements also provide a constructive way to avoid stalemates between complementary patent portfolios. Many firms may cross-license or license because they are risk-averse and prefer to preserve a delicate balance of relations within an industry or to assure future licensing by rivals. Some firms would rather risk losing monopoly profits from their own invention by cross-licensing than be excluded from the market by a competitor's important innovation.

The prevalence of licensing and cross-licensing agreements also indicates that in many cases a patent holder will not in fact foreclose further development and improvements on the patent. If the patent holder licenses the invention, the licensee can proceed. Thus, disclosure through the patent system promotes more innovation than does secrecy.

2. THE HARM TO SMALL FIRMS

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 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.

The broad exception would be especially harmful to small firms, research centers and universities that invent important advances but do not have the resources to develop the advance into a commercial product. In this case the patent holder may license the invention to an entity that can develop a commercial product. Licensing can be a

Cooperation Between Rivals: Informal Know-How Trading, 16 Res. Pol'y 291 (1987) (licensing allows research and development costs to be split between firms); Merges, supra note 118, at 868-69; Yu, supra note 138, at 234-36 (licensing can be used to reduce litigation and preserve industry relations).

143. Scherer, supra note 121, at 452.
144. Merges, supra note 118, at 868.
145. Karp, supra note 136, at 2185.
146. Scherer, supra note 121, at 449.
147. For a description of a university's expectations that industrial firms will license a university's patents in order to experiment with and develop those inventions, see supra notes 85-86 and accompanying text.
148. Note, supra note 141, at 1200, 1226 n.166.
central part of a firm's innovation policy, crucial to the firm's survival and growth.\textsuperscript{149} If the developer can claim it is experimenting by improving on the original patent, it will not have to take a license unless the final product infringes the original patent.

The patent portfolio of a start-up company is often its major asset, enabling it to raise venture capital for highly speculative R\&D before the company has a product ready for market. If larger, better funded companies were able to use the patented inventions of start-ups to design their own commercial alternatives, the smaller companies' patent portfolio would be less attractive and less able to attract funding. Overall, this scenario would have an important dampening effect on innovation because small firms contribute significantly toward the creation of new products and processes.\textsuperscript{150}

V. NEW PROPOSALS

A generally applicable broad experimental use exception weakens the incentives to invent, to develop, and to disclose provided by the patent system to too great an extent when applied to patents resulting from private research and development efforts. If the disclosure of a patented invention can be used to make the patent less valuable, inventors will have less incentive to make risky investments in groundbreaking research. Inventors may also choose secrecy over patents. The broad exception does, however, provide a solution for the uncertain position of non-profit researchers and the foreclosure of subsequent research based on a patented invention.

In response to these conflicting values this Comment proposes that the broad experimental use exception (extending up to commercialization) be made applicable in the special circumstances in which the harm to the patent incentive is minimal compared to the resulting benefits. First, university and other non-profit researchers should be allowed the advantage of the broad exception. Second, the broad exception should be applied to all patented, federally funded inventions so that any party can use these inventions in research and development.

A. Non-profit Researchers Allowed Broad Exception

Because one of the problems with the common law experimental use exception is that the status of non-profit researchers such as universities is uncertain due to their patenting and licensing activities, a simple remedy is to grant these researchers the benefit of a clarified

\textsuperscript{149} Lowe & Crawford, supra note 141, at 45.
\textsuperscript{150} Scherer, supra note 121, at 416-17; Karp, supra note 136, at 2183.
experimental use exception, which would exempt them from infringement when studying and improving a patented invention.\textsuperscript{151}

The exemption should extend only to research use and not to commercialization of a product. However, the exemption will provide the certainty that non-profit researchers seek because they do not engage in commercialization anyway. Most importantly, the exempted work cannot harm the patentee because the research institution cannot commercialize a non-infringing design-around.

Although researchers could theoretically license the patents used in their research, in reality licensing patented inventions used in basic research poses special problems. The need to obtain licenses would add significant administrative and financial burdens to researchers in fields where patent protection is widespread.\textsuperscript{152} Most research builds on many prior discoveries. If a significant number of these are patented, obtaining licenses on each would generate mounting royalty and transaction costs. Society should question whether paying royalties to further basic research is the best use of scarce resource funds. Licensing would add another expense to conducting research at a time when funding is not keeping pace with needs.\textsuperscript{153}

The unpredictable nature of basic research may make it impossible to determine significantly in advance what patents will be needed, leading to delays if the researcher must negotiate a license in the midst of a project. In addition, the contribution of that patent to the research (and, therefore, a fair royalty rate) may also be impossible to determine in advance.\textsuperscript{154} More likely, the scientist without astute legal advice will not realize that she is using a patented invention. She risks a law suit when she makes public her methods and results.\textsuperscript{155}

1. **A LIMITATION ON THE EXEMPTION**

The close relationships between industry and universities require that the proposed exemption be subject to a key limitation. A university's exempted research does not directly harm the patentee because the university cannot commercialize any results. However, those results could be patented and exclusively licensed to the original patentee's competitor. An industrial firm could simply move any work that it

\textsuperscript{151} The exemption would not cover routine laboratory use of patented research tools. For instance, patented microscopes are routinely used in certain types of research and their main purpose is to serve as a research tool. To exempt these tools from infringement would make those patents worthless without furthering technical progress.

\textsuperscript{152} Eisenberg, supra note 94, at 743.

\textsuperscript{153} See supra notes 56-57 and accompanying text.

\textsuperscript{154} Eisenberg, supra note 89, at 217.

\textsuperscript{155} These issues will be of less concern for the industrial scientist with legal advice and working on more predictable development projects.
wished to do on a patented invention to a university setting. The firm would support the university research and if a patentable design-around resulted, the firm would take a license from the university. The end result would be that university experimental use would be generating the same disincentive that corporate experimental use generates. Industries with university ties could easily circumvent the spirit of the special university exemption.

A reasonable limitation can prevent this easy circumvention. When university (or other non-profit) research takes advantage of the exemption by using a patented invention, the results should be used by industry only under specific circumstances. The industry must operate as though it wished to conduct itself the research done by the university. If work done by the university would have infringed if conducted by a private firm, then the firm must negotiate a license with the patent holder before the firm can use the university results. This license should be required whether or not the research results infringe. Of course if the results do infringe, the firm must also request a license for use of the results. Requiring a license even for use of non-infringing results insures that industry will not tempt university laboratories into creating a design-around which the industrial firm then commercializes.

It is possible that the patent holder will refuse to grant a license in this situation. That does not mean, however, that the university research can never be put to practical use. The holder of the patent on which the research was based may use the results. If the university patents its results, the original patent holder may take a license from the university in order to commercialize those results. This proposal is easily implemented given the university-industry relationships described above.156

The openness required in a university means that any infringement can be detected and monitored by the patentee. The detection prevents the scenario described above in which infringing research is set in a university and later moved to industry for commercialization. Universities encourage the publication and free sharing of research results.157 Traditionally, the scientific community has operated on a principle of communal ownership of research results rather than private ownership. According to the norms that guide the scientific community, all discoveries build on previous work and contribute to further discoveries. To extend knowledge, scientists must dedicate their scientific findings to the scientific community.158

156. See supra notes 63-78 and accompanying text.
157. Dickson, supra note 49, at 89.
In exchange for dedicating discoveries to the public, the scientific community offers professional recognition and esteem to those who make original contributions to the store of knowledge.\textsuperscript{159} Scientists will publish results as quickly as possible to avoid being scooped by researchers doing competing work, making sure the first disclosure will be original.\textsuperscript{160} Thus, the traditional reward structure of science encourages original research and prompt disclosure.\textsuperscript{161} Although university researchers are influenced by the rewards available from privatization of results, the forces supporting openness are also very strong.

To summarize this first proposal, university researchers will be allowed to conduct research using patented inventions without being subject to infringement. However, any company that wishes to use the results of this exempted research must obtain a license on the underlying patent, even if the university results do not infringe.

\textbf{B. Government-Funded Inventions Subject to a Broad Exception}

The first proposal clarifies the position of university and other non-profit researchers by exempting them from the restrictions of the patent system. However, it is inequitable to allow an institution to gain from the existence of the patent system without submitting to the restrictions that are necessary for the system to exist in the first place. This is especially true given that individual university members can personally profit from their university work, either through royalty payment or through equity interest in a company benefiting from university research.

For this reason, the first proposal should be implemented only in tandem with the second. The second proposal applies the broad experimental use exception to patents resulting from federally funded research so that the patent can be used without liability for infringement up to the point of commercialization. The proposal exempts any researcher, whether for profit or not, from infringement when using a federally funded invention.


\textsuperscript{161} Competition among scientists for recognition is intense and can lead to temporary secrecy, but the norms of science place limits on that secrecy. \textit{Kenney}, supra note 51, at 108-10. For instance, in 1971 James Watson, then director of Cold Spring Harbor Laboratory, pressured an NIH researcher into delivering a viral strain to Cold Spring Harbor researchers which the NIH team was withholding for competitive reasons. Watson threatened to report the withholding to the director of NIH, the journal \textit{Science} and Congress (on the grounds that results from publicly funded research was not being made available). This threat alone was enough. \textit{Id.} at 109.
This proposal provides a number of benefits without the disincentives which result when a broad experimental use exception is applied to every patent. For instance, federally funded inventions will not foreclose subsequent research, but federal grantees will not lose their incentive to invent and disclose.\(^\text{162}\)

1. **ISSUES IN FEDERALLY FUNDED RESEARCH.**

In spite of the advantages which supported passage of the 1980 patent law amendments, private ownership of federally funded work is not without critics. Critics point out that the government does not own any proprietary rights resulting from the research it funds, despite the fact that federal funds account for about half of the over $100 billion dollars spent each year on research and development in the United States.\(^\text{163}\) The federal government provides two-thirds of the funds for basic research in most years\(^\text{164}\) and spends between $12 and $14 billion a year on research at universities alone.\(^\text{165}\)

In dissenting from the House report recommending passage of the 1980 amendments, Rep. Jack Brooks articulated the major flaws in the amendments. He criticized the government patent policy as giving away rights that properly belonged to the taxpayers who funded the research. He argued that there was no reason to assume the new policy would spur productivity since the federal government was already funding half the research and development in the United States. Companies and institutions were accepting the money and producing results without the lure of patents and exclusive licensing rights. Making technological advances available to all offers a greater potential for increased productivity than does offering exclusive rights. Granting exclusive rights to the developer of federally funded research only restricts the number of potential producers.\(^\text{166}\)

Rep. Brooks acknowledged that when a private company takes risks in developing new products it deserves the exclusive rights and profits that may result. However, when the government risks the taxpayers' money, the rewards should go to all people. Granting a monopoly privilege is justified when a private entity risks considerable sums on research and development because it allows the developer to recapture the investment through commercialization and monopoly profits. But

\(^{162}\) See supra notes 157-61 and accompanying text.


\(^{165}\) Shaffer, supra note 58.

when the taxpayer bears the financial risk, the justification for granting a monopoly does not exist. Moreover, the new policy creates a disincentive for private investment whenever federal money is available, since exclusive rights would still be available, but without the financial risk.\textsuperscript{167}

Critics outside Congress made similar claims. Consumer activist Ralph Nader wrote that the new patent laws represented a “massive giveaway” of property which was contrary to the public interest.\textsuperscript{168} By allowing federally funded research to be patented by the grantee and exclusively licensed to private firms for commercial development, the government forces the public to pay twice for that research, once through the federal funds and once when purchasing the product. However, without an exclusive license, a company will not invest the capital necessary to commercially develop a product and research results are never made useful.\textsuperscript{169}

While the private sector should certainly be encouraged to develop government-funded basic inventions, it would be incongruous with the purpose behind public funding of research to allow that development to foreclose further basic research. Much of the research funded by the federal government is basic research which lays the foundation for further discovery and developments. Federal funding by the National Institutes of Health (NIH) and the National Science Foundation (NSF) built the basic scientific knowledge from which commercial biotechnology developed. Funding of basic research was meant to create the technical base necessary to understand and cure diseases.\textsuperscript{170} For instance, information concerning human DNA sequences, the discovery of which is funded as part of the human genome project, is vital to the future course of basic research in the biomedical sciences.\textsuperscript{171} Allowing this information to be patented and exclusively licensed can retard further scientific progress by prohibiting its use in subsequent research. The problem is less acute with regard to privately funded patents since these tend to cover applied inventions rather than basic information.\textsuperscript{172}

In the future the government may fund more industry research and allow the firms doing the work to keep any resulting patent rights. This allocation of rights raises the same concerns discussed above when universities keep patent rights in work sponsored by the government.

\begin{itemize}
\item[167.] Id. at 30-31, reprinted in U.S.C.C.A.N. at 6489.
\item[168.] DICKSON, supra note 49, at 92.
\item[169.] See supra notes 47-49 and accompanying text.
\item[170.] KENNEY, supra note 51, at 241.
\item[171.] Eisenberg, supra note 94, at 780. Most biotechnology research makes use of patented inventions. See Fox, supra note 93.
\item[172.] Although a few industries devote 10\% of their research and development budgets to basic research, most corporations routinely spend about 3.8\%. Barfield, supra note 164.
\end{itemize}
Concern over foreign competition\textsuperscript{173} and the United States' leadership role in technology\textsuperscript{174} have prompted calls for the federal government to increase participation with the private sector in research and development activities.\textsuperscript{175} For instance, Erich Bloch, former director of the National Science Foundation, encouraged Congress to provide partial support for research on generic technologies at the pre-competitive stage. Generic technologies are those that promise to benefit a wide range of industries. Precompetitive R&D lies between laboratory discoveries, on the one hand, and proprietary product development, on the other. Technical work at this stage focuses on overcoming basic engineering obstacles and barriers which threaten to slow the commercialization and production of new technologies.\textsuperscript{176} In a hearing before the Senate Committee on Commerce, Science and Transportation, Mr. Bloch stated:

Investments [in generic technologies] are often too high and too risky for private companies because the technologies are evolving too quickly, or as in some important industries, U.S. companies have lost the necessary technology base or cannot afford to compete with foreign competitors that are funded by their Governments in these endeavors. The federal government must provide the kind of support often available to our foreign competitors in these critical technologies essential to entire industries and the industrial sectors.\textsuperscript{177}

In response to this type of sentiment, Congress passed the Technology Competitiveness Act of 1988\textsuperscript{178} which created the Advanced

\textsuperscript{173} In a report entitled "Gaining New Ground: Technology Priorities for America's Future," the private Council on Competitiveness partly blamed U.S. industry's loss of market share in technology-intensive products on programs sponsored by the governments of other major industrialized countries. Those programs have used R&D funding, public-private technology consortia, infrastructure programs and tax policy to improve the technological competitiveness of their industries. S. REP. No. 157, 102d Cong., 1st Sess. 4 (1991).

\textsuperscript{174} Critics of U.S. policy point to a 1990 Department of Commerce study identifying 12 key emerging technologies: advanced materials, biotechnology, digital imaging technology, superconductors, advanced semiconductor devices, high-density data storage, high-performance computing, medical devices and diagnostics, optoelectronics, sensor technology, artificial intelligence and flexible computer-integrated manufacturing. The study concluded that the United States is losing relative to Europe in 3 of the 12 technologies, remaining steady in 6 and gaining in 3. The United States is also losing relative to Japan in all but two technologies—flexible computer-integrated manufacturing and artificial intelligence. Id. at 4.

\textsuperscript{175} The federal government spends relatively little to support industry-led technology projects. In 1988 only 0.2% of the federal R&D budget promoted industrial development. Id. at 5.

\textsuperscript{176} Id. at 3.

\textsuperscript{177} Technology Issues Hearing, supra note 57, at 6 (statement of Erich Bloch, Director, National Science Foundation).

Technology Program (ATP) to assist industry-led precompetitive R&D projects in developing new generic technologies. Proposed amendments to the Technology Competitiveness Act, the American Technology Preeminence Act, seek to strengthen the ATP. The amendments state that any intellectual property rights arising from work done under an ATP grant will belong to the company doing the work to avoid deterring participation by private companies.

It is possible that in the future, the federal government will be funding more industrial research and allowing the firms to own patent rights in the results of that research. However, exclusive ownership defeats the purpose of government funding research for generic technologies which are meant to benefit a range of industries. Others must be allowed to build on that work.

2. BENEFITS OF THE PROPOSAL

The exception proposed here softens the blow of having the public pay twice for research by ensuring that the research will stimulate rather than foreclose further inventions. To the extent that prior researchers might otherwise charge royalties, free access provides a subsidy for subsequent research. It is fitting that publicly funded research should continue providing a subsidy for subsequent research since the point of government-funded research is to stimulate further research.

Society gains no benefit in exchange for granting a patent when an invention would be conceived and developed without patent protection. As discussed below, federal grantees have incentives to invent and disclose outside the patent system. If an inventor secures patent protection on the invention anyway, society pays the monopoly costs without the corresponding trade-off of an invention that would not have been available otherwise. The suggested changes to the patent laws decrease the social costs of federally funded inventions that would have been created without the patent incentive.

Since federally funded inventions would be created without patent protection, one could argue that they should not be patented. However, patents are also important for providing an incentive to develop an invention, and the ability to grant exclusive licenses on government-funded, patented inventions is necessary to encourage licensees to further

180. Id. at 17.
181. Eisenberg, supra note 6, at 1057.
182. SCHERER, supra note 121, at 443-47.
183. See supra notes 157-61 and accompanying text.
184. SCHERER, supra note 121, at 443.
develop and commercialized those inventions.\textsuperscript{185} The patent laws need only protect the incentive to develop, and not the incentive to invent federally funded inventions. Thus, the weaker patent incentive suggested here should suffice.

The proposed exception also helps resolve a conflict in the scientific community on how best to promote scientific progress. The university scientist's interest in both traditional scientific rewards and patent rewards presents a conflict between the free contribution of knowledge to the community and the private ownership of that knowledge. The fundamental conflict occurs because disclosure through traditional publication marks the end of exclusivity whereas disclosure through patents marks the beginning of exclusivity. Through publication, a researcher contributes the knowledge to the whole community whereas through a patent a researcher stakes a claim in the right to exclude others from using the invention.\textsuperscript{186} The conflict arises from the divergent views of how to best promote scientific progress.\textsuperscript{187} The patent laws are based on the theory that exclusive rights will provide an incentive to create. The traditions of the scientific community derive from the assumption that free access to discoveries best promotes further progress.\textsuperscript{188} The proposal allows free access for federally funded inventions for research purposes while still allowing exclusive ownership for commercial development purposes. Since most academic, basic research is federally funded, the proposal here solves the most perplexing branch of the conflict.

Finally, allowing private industry to freely research with results that will mostly come from universities and other non-profit researchers equitably balances the proposal above which exempts non-profit researchers from infringement in the usual course of their work.

3. \textit{EFFECT ON FEDERAL GRANTEES}

The broad exception proposed here would not affect the incentive to invent and to disclose provided by the patent system when federal funds are involved. Because university and other non-profit researchers have significant incentive to invent and publish outside the patent system, weakening their patent rights will not effect their productivity.

\textsuperscript{185} See Kitch, \textit{supra} note 123, at 287.
\textsuperscript{186} Eisenberg, \textit{supra} note 89, at 217.
\textsuperscript{187} Scientists seeking patent protection may delay publication of research discoveries that are ripe for reporting to the scientific community but are not ripe for patent protection. \textit{Id.} at 216.
\textsuperscript{188} Merton, \textit{supra} note 158, at 273; Merton, \textit{supra} note 160, at 346-52; Barber, \textit{supra} note 50, at 197, 198-206; Eisenberg, \textit{supra} note 6, at 1048-49.
The proposed exception will probably not affect federal grantees' incentive to invent. University researchers' major incentive to invent comes from their professional reward structure. Tenure, awards and other forms of professional recognition are based on the researcher's inventiveness. For example, Dr. Jonathan King, a biology professor at the Massachusetts Institute of Technology, has stated, "The extraordinary development of genetic engineering was the fruit of 40 years of public investment in university research by the federal government. The whole notion that you need the profit motive for scientific innovation is spurious. Biotechnology grew up without patenting or proprietary knowledge."  

Small businesses which receive federal funds but keep any resulting patent rights incur less risk than firms which provide sole support for risky research. It is unlikely that a company would turn down federal grants due to this exception. Thus, weakening the patent rights of these small businesses should not affect their incentive to invent.

Weakening the patent will not discourage university scientists from disclosing their research results because universities can use secrecy to only a limited extent. As discussed above, the reward structure of science places a high value on openness and the disclosure of research results. Moreover, universities will not be forced to choose between secrecy and inadequate patent protection because universities worry much less than private industry about whether a subsequent researcher designs around or improves on its patent. This is true because it cannot commercialize the patent in any event.

This proposal to apply the broad exception to federally funded patents is consistent with the policies of the major scientific funding organizations. NSF guidelines state that the policy allowing awardees to retain intellectual property rights does not reduce the responsibility of researchers and institutions to make results, data, and collections available to the research community. The NSF expects significant findings from research it supports to be promptly submitted for publication. It expects investigators to share with other researchers within a reasonable time, the data, samples, physical collections, and other supporting materials created or gathered in the course of the work. It also encourages awardees to share software and inventions, once appropriate protection for them has been secured, or otherwise act to make the innovations they embody widely useful and usable.

189. Shaffer, supra note 58.
190. See supra notes 157-61 and accompanying text.
192. Id. at 14.
Usually, the financial impact of this proposal on the non-profit research institution will be insignificant. Some universities may be currently licensing their patented technologies to industries conducting research and development with the invention. This proposal will cause the universities to lose that source of funding. However, the loss of funds will rarely be significant. Licensing fees for this type of use are generally lower than fees for a commercial use.\textsuperscript{193}

Moreover, most patent programs are actually not financially successful. John Preston, head of M.I.T.'s technology licensing office, warns that universities should not count on a large amount of funds from patent licenses. M.I.T. netted only $500,000 from the $5.5 million it grossed from royalty licenses in 1991 due to the costs associated with filing and licensing patents and the $1 million it distributed to hundreds of individual scientists. Most universities and government laboratories license as few as one percent of their issued patents.\textsuperscript{194} In fact, few universities have made or expect to make any significant money from their patents, and some are losing money from their programs.\textsuperscript{195}

4. **EFFECT ON EXCLUSIVE LICENSEES**

Companies which exclusively license patents resulting from federally funded research present a less clear picture because the broad exception may affect the incentive to develop. The licensee hopes to have an exclusive market position after developing the patented invention to the point of commercialization. The broad exception supports this goal by not allowing any other firm to commercialize the patent. However, the exception may allow other researchers or firms to design around the patent and create a noninfringing product which replaces the licensee's product in the marketplace.

If the experimental work by a non-licensee results in a product which designs around the basic research and does not infringe the original patent, then federal funds spurred more development at the private level, which is the point of government supported research. A licensee will be forced to accept the possibility of increased design around activity.

In response, the licensee and licensor can account for the added risk through decreased royalty rates. By licensing technology for which it did not have to risk capital to invent, at a rate which accounts for market risks, the licensee is in a better position than if it had been forced to make the original invention itself. Presumably, once the invention is made, development, though expensive, will be less risky than invention. The

\textsuperscript{193} Brinton, *supra* note 49, at 487.
\textsuperscript{194} Shaffer, *supra* note 58.
\textsuperscript{195} DcKSON, *supra* note 49, at 91.
incentive to develop should still be strong enough to motivate the technology transfer from the government contract researcher to the marketplace.

Alternatively, the experimental research by a non-licensee may lead to an improvement that still infringes the underlying patent. Because research in universities is heavily supported by public funds, a university must always consider the public interest in its licensing activities.\textsuperscript{196} Thus, the university should certainly license the patent to the developer of the improvement so that the improvement can be marketed. If the university refuses the government can exercise its march-in rights.\textsuperscript{197} A problem arises when the base patent has already been exclusively licensed to another firm. The first licensee can block the improvement, but the problem can be resolved through purchase of the improvement patent or through a cross-licensing agreement under which the exclusive licensee and the holder of the improvement patent are both allowed to use the improved technology.\textsuperscript{198}

Alternatively, the original patent holder, the university, might plan ahead for such an occurrence and incorporate a provision into the exclusive licensing agreement mandating cross-licensing in the event of a significant improvement. A university may view this as part of its responsibility for acting in the public interest.

5. PRACTICAL POINTS

A research project may be funded by both federal and private sources. Therefore it is necessary to set a minimum amount of government funding before the exception becomes applicable, perhaps 50%. Implementing this proposal will not be difficult. Government grant applications require that the applicant report all other sources of funding for a project, and thus the total funding for any project is a matter of public record. For instance, whenever Department of Energy grantees issue any document describing projects funded in whole or in part with DOE money, the document must state the percentage of the total cost financed with DOE money.\textsuperscript{199} Thus, mechanisms for keeping track of percent funding have been designed and must be in place for some non-profit research.

A grant application must include a detailed description of the proposed project, including the objectives of the project and the applicant's plan for carrying it out. Applications must also include a

\textsuperscript{196} Brinton, \textit{supra} note 49, at 483.
\textsuperscript{198} \textsc{Scherer, supra} note 121, at 444.
\textsuperscript{199} \textsc{Office of Energy Research, Department of Energy, No. DOE/ER-0249, Application and Guide for the Special Research Grant Program} 32.
detailed budget, with supporting written justification sufficient to evaluate the costs of the proposed project.\textsuperscript{200} Awardees must report on their progress to the funding agency\textsuperscript{201} and clear any major changes in the research plan with the government funding agency.\textsuperscript{202} Consequently, even if the research does not go as planned it is possible to track which results were funded by which grant.

To facilitate full use of the exception, the pertinent regulations should require that patent applicants disclose the percent of government support for the invention when the application is filed. The disclosure of government funding should be subject to rules of candor before the Patent Office to insure compliance by patentees. If the application issues, a statement on the patent cover will notify interested parties that this patent is available for experimental use.

VI. CONCLUSION

The proposals laid out here attempt to strike a balance between maintaining a strong patent incentive, answering the concerns of non-profit researchers, and ensuring that the patent system forecloses a minimum of new inventions.

Arguably, society might gain new products through a generally applicable broad experimental use exception by allowing infringing design around activity that would not occur otherwise. But society would also sacrifice some level of inventive activity by allowing the broad exception. No patent system can exist without foreclosing some subsequent work; short-term inefficiencies must be traded for long-term progress. Economist Joan Robinson described the paradox inherent in the patent system:

A patent is a device to prevent the diffusion of new methods before the original investor has recovered profit adequate to induce the requisite investment. The justification of the patent system is that by slowing down the diffusion of technical progress it ensures that there will be more progress to diffuse. . . . Since it is rooted in contradiction, there can be no such thing as an ideally beneficial patent system, and it is bound to produce negative results in

\textsuperscript{200} Id. at 35; \textit{National Science Found.}, supra note 190, at 3.

\textsuperscript{201} NSF grantees must submit an annual technical progress report, which summarizes activity during the past year, identifies any scientific developments and describes any problems encountered. After the expiration of the grant, the investigator submits a Final Project Report which contains the results of the supported activity. \textit{National Science Found.}, supra note 190, at 14. The Department of Energy has identical requirements. \textit{Office of Energy Research}, supra note 198, at 31.

\textsuperscript{202} \textit{Office of Energy Research}, supra note 198, at 35; \textit{National Science Found.}, supra note 190, at 13.
particular instances, impeding progress unnecessarily even if its general effect is favorable on balance.203

Proponents of the broad experimental use exception can point to instances in which negative results produced by the patent system would have been alleviated by a broad exception. It is important to keep the “contradiction” of the patent system in mind, however, when judging any proposed weakening of the patent system. For instance, Scherer concludes that “society gains unambiguously from inventions and innovations induced or hastened by the grant of patent rights.”204 We must look beyond the particular negative instances to the generally favorable effect of the entire system.

204. SCHERER, supra note 121, at 443.