The Research Exemption to Patent Infringement: The Delicate Balance Between Current and Future Technical Progress

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I. INTRODUCTION

Patents are intended to provide incentives to invest in research and development, but they can also make it more difficult to build on the inventions of others either because an improved invention falls within the claims of a prior patent or, as is the focus of this Chapter, because the research and development process for a new invention requires the practice of a prior patent. In such cases, prior patentees may be unwilling to license the research use of their inventions on reasonable terms to potential competitors. A research exemption from infringement liability might be used to skirt such prior patentee reluctance, but such an exemption raises the possibility that depriving patentees of control over the research uses of their inventions might diminish incentives to invest in developing them.

This Chapter reviews current United States law regarding research exemptions and explores proposals for broader research exemptions. The research exemption comes in two “flavors” -- a statutory exemption for research “reasonably related” to regulatory approval by the Food and Drug Administration and a traditional exemption for non-commercial research based on judicial interpretation of the scope of infringing “use.” The statutory exemption was the subject of a 2005 decision by the United States Supreme Court.
Court, while concern about judicial narrowing of the traditional exemption has been reflected in two major national reports and numerous scholarly articles.  

An important controversy exists as to whether either exemptions should be applied differently depending upon whether the research is aimed at understanding or improving upon the patented invention or uses the patented invention as a research tool.  This Chapter summarizes arguments in favor of a categorical exemption for “experimenting on” a patented invention. It then addresses the more difficult issue of an exemption for research tool use. Finally, this Chapter briefly considers the impact on the research exemption issue of paying more attention to motivations for innovation -- in particular the motives of “user innovators” --that do not stem from a desire for commercial compensation.

II. Patent Incentive Basics

The patent system is often justified by the twin theories “incentive to invent” and “incentive to disclose.” The “incentive to invent” theory is a free-rider theory based upon the assumption that investments in new ideas, unlike investments in capital equipment or materials, are appropriable by competitors at very little expense. Thus, patents are awarded lest would-be inventors be disinclined to make the investments necessary to develop new inventions. The “incentive to disclose” theory, on the other hand, is based on the notion that a patent is a quid pro quo in which an inventor teaches her invention to the public in exchange for a limited period of exclusive rights.
Though usually mentioned together, these two justifications for the patent system are in tension. The “incentive to invent” theory assumes that inventions are self-disclosing—that is, that competitors can immediately appropriate inventive ideas and begin commercial competition once an inventor brings a product to market. Many mechanical inventions fit this rubric, as do many pharmaceuticals and some business methods. The disclosure *quid pro quo* has little relevance to self-disclosing inventions. Because a self-disclosing invention is disclosed and enabled by its mere commercialization, the patent disclosure adds little to society’s store of technical knowledge.

The incentive to disclose is quite germane, on the other hand, to inventions for which trade secret protection is a viable option. For such non-self-disclosing inventions, the disclosure of the invention in the patent specification is valuable because it adds information that might have been kept secret to the store of public technical knowledge. Examples of such non-self-disclosing inventions include industrial processes or complex software programs. The free-rider “incentive to invent” theory *does not apply* to non-self-disclosing inventions. Because these inventions could have been maintained as trade secrets, an exclusive patent grant is not necessary to stimulate invention. Public benefit from patents on non-self-disclosing inventions must be secured instead through the patent system’s *disclosure* requirements. The role of the patent system for non-self-disclosing inventions is to enable more rapid follow-on invention by disclosing new technical discoveries that can be used as building blocks.

Despite their potentially beneficial impact on incentives to invent and disclose, the effect patents have on technological progress is ambiguous. Patent exclusivity can
also slow technical progress if the best follow-on inventors are prevented from building upon the inventive idea during the patent term.\textsuperscript{5}

When patents restrict research, the tension between incentives for initial invention and the progress that comes from building upon the available store of knowledge is palpable. A properly designed research exemption promises to relieve some of this tension. Because no license is required for exempted research, refusals to license motivated by private attempts to obtain unwarranted control over future innovation are avoided.

III. The Vanishing Traditional Research Exemption

The traditional research exemption\textsuperscript{6} to patent infringement has its origins in the early nineteenth century in \textit{Whittemore v. Cutter}.\textsuperscript{7} In the absence of today’s specific statutory enumeration of infringing activities,\textsuperscript{8} the defendant there objected to a jury instruction including the “making” of a machine within the realm of infringement. Justice Story upheld the instruction because it limited infringement to making the machine “with a design to use it for profit,” commenting that “it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”

Justice Story reiterated these ideas the same year in \textit{Sawin v. Guild}, where he added that an infringing use “must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.”\textsuperscript{9} These first references by Justice Story contain the seeds both of the present emphasis on whether the use is “for
“profit” or for “philosophical experiments” and of the need to “experiment on” the invention to ensure “the sufficiency of the machine to produce its described effects.” They also presage an issue that haunts the exemption to this day—the circularity in defining an exception in terms of “the lawful rewards of [the patentee’s] discovery.”

The exemption was adopted by the Robinson patent treatise of 1890. Robinson’s treatment focused on protecting the “pecuniary interests of the patentee” and failed to discuss the status of experimentation to “ascertain the verity and exactness of the specification.” This approach shaped the direction of research exemption doctrine in the United States throughout the twentieth century. Justice Story’s statement of a research exemption for “philosophical experiments” was widely cited. The second prong of his analysis, focused on experimentation to understand the operation of the patented invention more fully, was rarely discussed by the courts.

Unfortunately, a “pecuniary interests of the patentee” test is inherently circular. A patentee’s legitimate pecuniary interests are necessarily defined by the legal boundaries of the patentee’s rights. To decide whether a particular unauthorized use deprives the patentee of legitimate returns, one must know whether the unauthorized use falls within a research exemption. Thus, deprivation of “pecuniary interests” cannot define the boundaries of the exemption, which should be determined as a matter of patent policy.

The emphasis on pecuniary effects on the patentee evolved into a distinction between commercial and noncommercial users. But this distinction is itself untenable because the financial impact on the patentee is not always captured by the financial motives of the infringer. Use by a non-commercial entity might still deprive a patentee of potential revenue. As a result, courts have gradually narrowed the scope of exempted
“noncommercial use.” Thus, while in 1935 a court based a research exemption entirely on the fact that the infringing user was an academic research institution,\textsuperscript{12} by the 1970s the court in \textit{Pitcairn v. United States} rejected the government’s argument that the manufacture and use “for testing, evaluational, demonstrational or experimental purposes” of certain infringing helicopters should be permitted under the traditional research exemption.\textsuperscript{13} The court held that the tests in that case were necessary for any new helicopter and were “intended uses of the infringing aircraft manufactured for the defendant and in keeping with the legitimate business of the using agency” and not exempted. The “legitimate business” expansion of the idea of “commercial use” is an attempt to deal with unauthorized uses which, though not undertaken “for profit” by the infringer, appear to have substantial pecuniary effects \textit{on the patentee.}

In 2002, in \textit{Madey v. Duke University}, the Federal Circuit reduced the scope of the “noncommercial” category further. A Duke University professor had patented various parts of a free electron laser used for scientific research. When he and the university had a falling out, the university continued to use his patented research equipment, relying on the traditional research exemption to excuse its infringing use. The court found this university research ineligible for the traditional research exemption because it “unmistakably furthers the institution’s legitimate business objectives, including educating and enlightening students and faculty participating in these projects.”\textsuperscript{14} This outcome conflicted with widespread understanding on the part of university researchers that purely academic research was categorically excused from patent infringement liability.\textsuperscript{15} Yet in this case academic research was the primary intended use of the patented equipment. A judicial exemption of such research would
appear to threaten the core grant of exclusivity provided by the patent—the market for
direct sales or licensing to research institutions. To avoid that result, the Federal Circuit
stretched the concept of commercial use beyond recognition so that it could encompass
the university’s actions.

With the expansive understanding of “business” articulated in Madey, few
activities will be unrelated to any potential infringer’s “legitimate business.” Drawing a
strained distinction between research aimed at “enlightening students and faculty” and
research aimed at “strictly philosophical inquiry,” the court suggested that the research
exemption remains viable for experimentation “for amusement, to satisfy idle curiosity,
or for strictly philosophical inquiry.” The court did not suggest where, outside of the
halls of academe, such scientific philosophers are to be found in this modern age, but
surely their ranks are thin indeed.

Embrex v. Service Engineering Corp. illustrates the equally troubling
consequences of giving patentees complete veto power over all “commercial uses” of a
patented invention regardless of their purposes. In Embrex, the patent covered an in
ovo method for inoculating chickens against disease. Service Engineering Corp.
(“SEC”), one of Embrex’s commercial competitors, conducted experiments that were
aimed at “designing around” the patented inoculation method by injecting vaccine into a
different part of the egg than was covered by the patent claims. The experiments were
unsuccessful because the injections leaked into the areas of the egg protected by the
patent.

Despite the fact that any infringement was a literal spillover from an attempt to
invent an alternative to the patented invention and the fact that there was no evidence that
the plaintiffs lost any profits as a result of the experiments, the Federal Circuit refused to apply the traditional research exemption, emphatically reaffirming the rule that any experimentation with “definite, cognizable, and not insubstantial commercial purposes” constitutes infringement. The result is uncomfortably out of line with the policy of encouraging competitors to use the inventive ideas disclosed in a patent to design around the invention.

The upshot is that the traditional research exemption has been reduced to a mere de minimis exception that bears little relation to the implications of a particular experimental use for follow-on innovation or to effects that a specific use might have on inventor incentives. The distinction between commercial and noncommercial infringers alone is not a coherent basis to illuminate the extent to which the infringing experimental use interferes with the patentee’s ability to recoup her research and development investment or the extent to which the use is primarily aimed at follow-on invention.

In the 1990’s the proposed “Patent Competitiveness and Technological Innovation Act of 1990” avoided the pitfalls of the commercial/noncommercial distinction by focusing on exempting “experimenting on” a patented invention in the spirit of the second prong of Justice Story’s approach:

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

The proposed Act was reported favorably to Congress by the House Judiciary Committee but was never brought to a vote.¹⁷

The distinction between “experimenting on” a patented invention and using it as a “research tool” attained renewed salience during the litigation of the case of Merck KGaA v. Integra LifeSciences I, Ltd.¹⁸ involving the statutory FDA exemption, which arrived at the Supreme Court in 2005. At the Federal Circuit, the majority of the panel concluded that the traditional research exemption was not at issue in the case.¹⁹ Judge Newman disagreed and addressed it at length in her dissent. She argued strongly that the traditional exemption encompassed research aimed at studying the subject matter of patents “to understand it, or to improve upon it, or to find a new use for it, or to modify or ‘design around’ it.”²⁰ She also argued that such experimentation was necessary to effectuate the patent disclosure and distinguished “research into the science and technology disclosed in patents” from “the use in research of patent products or methods, the so-called ‘research tools’.” The issue of the traditional research exemption was not presented to the Supreme Court, so the relevance of the distinction between “experimenting on” and “experimenting with” a patented invention to the traditional research exemption remains an open question.

IV. THE STATUTORY EXEMPTION FOR RESEARCH

“REASONABLY RELATED” TO FDA REGULATION
In *Roche Products v. Bolar Pharmaceutical Co*,\(^{21}\) the Federal Circuit dealt with an issue that arises in the pharmaceutical and related industries because of regulatory requirements. The holder of a pharmaceutical patent sought to enjoin a generic drug manufacturer from using a patented ingredient to conduct testing that was required by the Food and Drug Administration (FDA) before the generic could be put on the market. The reason for testing during the patent term was to allow the generic drug to be marketed as soon as possible after the patent expired. Bolar argued that prohibiting generic testing before the expiration of a patent would result in an effective patent term extension, while Roche countered that the “extension” balanced out the fact that testing requirements for pioneer drugs shortened the patent term at the outset. Rather than consider these policy arguments, the Federal Circuit based its ruling on a categorical rejection of any exemption for experimentation with “definite, cognizable, and not insubstantial commercial purposes.”

Congress responded to the *Roche* decision by enacting specific provisions permitting generic manufacturers to perform potentially infringing tests during the patent term in preparation for sales immediately after expiration,\(^{22}\) while also providing for patent term extensions to compensate for market time lost because of testing that pioneer manufacturers were required to perform at the beginning of the patent term.\(^{23}\) The Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”) exempts those who:
make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products.24

Three questions have dominated the case law applying this exemption: 1) whether the word “solely” should be interpreted such that uses with more than one purpose would be deemed infringing; 2) whether the exemption applies to FDA-regulated items other than drugs or veterinary biological products (specifically whether it applies to regulated medical devices); and 3) what it means for a use to be “reasonably related to the development and submission of information” for FDA regulatory approval.

A. “Solely For Uses Reasonably Related . . .”

Though an early district court opinion interpreted “solely for uses reasonably related . . . .” narrowly,25 subsequent decisions have been more lenient, holding that the exemption encompasses activities such as demonstrating an infringing device at conferences and trade shows and concluding that “presenting clinical trial data at a cardiology conference, reporting clinical trial progress to investors, analysts and journalists, and describing clinical trial results in a private fund-raising memorandum fall under the category of dissemination of the data developed for FDA approval” and do not affect whether the research itself meets the “reasonably related” standard.26 There are
some limits to the expansive application of the exemption. Excessive stockpiling of a
generic drug prior to patent expiration was held to be nonexempt (though some
stockpiling was acceptable as a demonstration of commercial capacity to the FDA), as
was the making and shipment of a drug sample to a foreign regulatory agency. On the
whole, courts have interpreted the “solely” language as restricting the exemption to
research that has some reasonable relationship to FDA approval, but not to research that
has only that purpose.

B. “. . . Under a Federal Law which Regulates the Manufacture, Use or Sale of
Drugs . . . .”

In Eli Lilly and Co. v. Medtronic, Inc., the Supreme Court considered the scope
of regulated items covered by the statutory FDA exemption. The basic dispute involved
the interpretation of the phrase “a Federal law which regulates the manufacture, use or
sale of drugs . . . .” Eli Lilly argued that the exemption was limited to drugs and that
the statutory reference to “Federal law” applied only to specific provisions regulating
drugs. Medtronic contended that the term “Federal law” referred to the entirety of any
Act which contained some provision regulating drugs. The Court took the more
expansive view, based in part on its understanding that the Hatch-Waxman Act intended
to balance the term extension for patent holders (which explicitly applied to medical
devices) with the statutory research exemption. Thus, the statutory FDA exemption is
available for research relating to FDA approval not only of drugs and veterinary
biological products, but of medical devices as well.
C. How Closely Related Must “Reasonably Related” Be?

The recent case of *Merck KGaA v. Integra LifeSciences I, Ltd.*,\(^{31}\) dealt with the question of how far up the research stream the statutory research exemption was meant to extend. FDA approval of a new drug is a two-step process requiring first the submission of pre-clinical data to obtain authorization to conduct human clinical trials, then the collection and submission of data from the clinical trials for final approval. The contested research involved evaluating the drug potential of several candidates from a class of chemicals known as “RGD peptides.” The appeals to the Federal Circuit and Supreme Court concerned the applicability of the FDA exemption to pre-clinical tests of the RGD peptides, aimed at determining whether they were suitable drug candidates. The Federal Circuit majority held that the exemption did not apply to those pre-clinical tests.\(^{32}\)

The Supreme Court disagreed, rejecting arguments that the statutory exemption applied only to clinical testing; that it applied only to testing for safety (rather than for efficacy); and that it did not apply to experiments that did not comply with “good laboratory practice regulations.” It also rejected an argument that the exemption should be limited to experiments which result in information that is eventually submitted to the FDA on the grounds that it would be impossible for scientists to know *a priori*, “whether an initially promising candidate will prove successful over a battery of experiments.” Instead, the Court interpreted the exemption to apply “[a]t least where a drug-maker has a reasonable basis for believing that a patented compound may work, through a particular
biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA.”

The Court noted, however, that “[b]asic scientific research on a particular compound, performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce, is surely not ‘reasonably related to the development and submission of information’ to the FDA.”

D. Open Questions After Merck

In Merck, the Court did not address the issue of the traditional research exemption nor its relationship to the statutory FDA exemption. In her Federal Circuit dissent, Judge Newman contended that the traditional research exemption should take up where the statutory FDA exemption lets off, opining that “[i]t would be strange to create an intervening kind of limbo, between exploratory research subject to exemption, and the FDA statutory immunity, where the patent is infringed and the activity can be prohibited.” While the Supreme Court excluded basic scientific research from the statutory FDA exemption it did not address the question of continuity between the traditional and statutory exemptions and the relationship between the two exemptions remains ill-defined. Despite considerable amicus briefing on the subject of research tools, the Court specifically declined to take up the question of whether the statutory FDA exemption covers “experimenting with” a patented research tool to study a potential drugs or medical device, concluding that the case at hand did not involve a research tool
use of the patented RGD peptides. Finally, the Court’s interpretation of the “reasonably related” prong might be interpreted to inject a question of the researcher’s intent into the inquiry. It remains to be seen how the lower courts will interpret the Supreme Court’s opinion.

V. A PROPOSED EXEMPTION FOR “EXPERIMENTING ON” A PATENTED INVENTION

A categorical exception for “experimenting on” a patented invention would be consistent with the broader approach to follow-on innovation taken in U.S. law because “experimenting on” a patented invention is primarily a way of effectuating the patent disclosure to achieve its recognized purposes. Professor Rebecca Eisenberg proposed a limited form of “experimenting on” exemption in her seminal article on the research exemption in 1989.\textsuperscript{36} Several major foreign patent systems provide “experimenting on” exemptions.\textsuperscript{37} As the Federal Circuit recognized in its opinion in \textit{Roche}, “the word ‘use’ in [the infringement provision] has never been taken to its utmost possible scope.”\textsuperscript{38} It has always been anticipated that competitors will “use” the inventive idea to improve upon or design around the invention. The disclosure requirements are intended to benefit the public interest in faster-paced follow-on innovation by privileging the “use” of a patented inventive idea \textit{during the patent term}:

Designing or inventing around patents to make new inventions is encouraged. Keeping track of a competitor’s products and designing new and possibly better or cheaper functional equivalents is the stuff of which competition is made and
is supposed to benefit the consumer. One of the benefits of a patent system is its so-called “negative incentive” to “design around” a competitor’s products, even when they are patented, thus bringing a steady flow of innovations to the marketplace.39

In a perfect world, the written patent disclosure alone would be up to the task of facilitating improvements and design-arounds. However, this expectation is unrealistic. When there is no exception for “experimenting on” the patented invention, there is an incentive for patentees to provide a bare minimum of disclosure to satisfy a patent examiner whose workload and expertise may preclude a stringent enablement investigation. Moreover, there is an inherent mismatch between science and technology and verbal explanation. This fact has been recognized by the Supreme Court in the doctrine of equivalents context, where one of the primary justifications for expanding infringement beyond the literal language of the claims is the difficulty of expressing physical phenomena in words.40 The enablement doctrine also recognizes the limitations of written expression of technological matters, upholding as sufficient a patent specification that requires some experimentation to enable the practice of the invention as long as the amount of experimentation required is not “undue.”41

Even though design-arounds and improvements are intended public benefits of the patent system, however, patentees have little incentive to license their competitors to “experiment on” their inventions. A research exemption for experiments directed at understanding, designing around, and improving upon the subject matter of the invention would permit the disclosure requirement to achieve its intended result.42
A potential objection to a proposal to exempt “experimenting on” a patented invention from infringement liability is that the unauthorized use will decrease the patentee’s returns from the patent and thus decrease the incentive to make the invention in the first place. However, disclosure has an inherently greater impact on inventions that could have been maintained as trade secrets, for which the patent system’s incentive to invent is unnecessary. In non-self-disclosing cases, use of the inventive idea before the patent term expires is the only thing the public gets in exchange for the extra term of exclusivity that patenting provides to the inventor. We can strengthen the disclosure doctrine by broadly permitting experimentation aimed at follow-on innovation without substantially diminishing the patent system’s incentive to invent for those self-disclosing inventions for which it is needed.

In the United States, an “experimenting on” exemption could be enacted legislatively. But a statutory amendment may not be necessary, as explained by Judge Newman in her dissent in the Federal Circuit’s decision in Integra. The traditional research exemption is premised on judicial interpretation of the statutory prohibition of unauthorized “use” of a patented invention. An exemption for “experimenting on” a patented invention would simply extend judicial recognition of the inadequacy of written depictions of inventions from its established place in the law of the doctrine of equivalents and enablement to a more realistic interpretation of “use” of the inventive idea to produce improvements or design-arounds.43

While difficult line-drawing issues might arise in particular cases,44 the difference between “experimenting on” a patented invention to improve it and using it as a tool for other research is a factual question that can be evaluated by judges and juries without the
need for policy-driven balancing. The underlying connection between “experimenting on” and the disclosure requirements can provide guidance in applying the distinction. One way to get at this distinction is to ask whether a particular use of the invention could be replaced by a perfect disclosure of the inventive idea. Could the infringing experimentation have been avoided in principle by more information about the patented invention? If so, we are dealing with “experimenting on.”

Because the patent system anticipates that competitors will use the patent disclosure to make improvements or design-arounds, there is no reason to confine this type of experimental use to noncommercial applications. Because many commercial innovators are both patent owners and potential infringers, an “experimenting on” exception may achieve its public benefits with relatively little net cost to many of the private actors involved.

VI. “EXPERIMENTING WITH” A PATENTED INVENTION:

THE CONUNDRUM OF RESEARCH TOOLS

“Experimenting on” is the easy case. An exemption for “experimenting on” is closely tied to the historical justifications for the traditional research exemption, to patent disclosure doctrine, and to clear patent policy. It tells us nothing, however, about what to do about the conundrum of research tools. In some important cases, an exemption for “experimenting on” would not apply. BRCA1 and BRCA2 kits are used to detect genetic markers that signify an increased risk of breast cancer. Suppose that, in an attempt to discover other possible breast cancer markers, researchers use the BRCA 1 and BRCA 2
kits to exclude cancers that are explainable by the known markers so that they can study the remaining unexplained cancers. It appears that no amount of further information about BRCA1 or BRCA2 would substitute for the use of the kits to identify the unexplained tumors. In this case, researchers are “experimenting with” the kits and using them for their intended function—the identification of the BRCA1 and BRCA2 genetic markers.

Research tool inventions have a special relationship to technological progress. For ordinary inventions, the most important contribution that the invention makes to subsequent innovation is the inventive idea. Patentees have commercial incentives to supply the market demand for the inventive embodiments, while inventive progress is wide open to anyone who can make use of the inventive idea.

In contrast, when research tools are patented, the most significant “Progress [in the] . . . useful Arts”\(^46\) usually depends upon using an embodiment of the invention—the research tool itself—to produce further innovation. The questions of compensation for the invention of the tool and control of follow-on innovation (the “product” market and “innovation” market distinction\(^47\)) are entangled. An exemption for “experimenting with” a patented invention would free up the innovation market, but would seem to cut directly into the product market -- and hence the incentives to invent -- for the research tool.

\(A.\) The Problem of “Experimenting With” A Research Tool
To analyze the need for a research tool exemption, we must ask two questions. First, under what conditions does a research tool patent permit the patentee to control the direction and pace of subsequent innovation? Second, when will a tool inventor’s control over subsequent technical progress pose a problem for the public?

As Professor Janice Mueller has pointed out, there is no “research tool issue” if a patentee commercializes the research tool and sells or licenses it on the open market at a reasonable price. Even if a patentee restricts use of a tool, there are two prerequisites for a tool patentee to exercise significant control over the progress of research: there must be no close substitutes for the tool and there must be no close substitutes for the research projects that require the tool. If there are close substitutes for the tool available to researchers, then a tool patentee’s decisions about whether to commercialize or license the tool invention will not have a major impact on the progress of research. Similarly, if researchers are relatively indifferent between problems requiring a patented tool and similarly important problems for which they do not need to use the tool, then the patentee will not exercise significant power over research progress. Only when a research tool is of substantial importance to an important problem, does the potential for serious adverse public impact from a research tool patent arise. A good example of this type of research tool might be the BRCA1 and BRCA2 diagnostic kits discussed above.

From the public perspective, the important issue is not who controls the research but whether the research is performed effectively. It is in society’s interest to have the research performed by the quickest and most effective researchers. Especially where a research tool has wide application or is relevant to a particularly difficult problem, it may
also be important to have a diversity of perspectives applied to determine creative uses for the tool.

At first blush, the research tool patent would seem to be the quintessential realization of the prospect theory of patenting developed by Professor Edmund Kitch.\textsuperscript{49} Kitch argued that broad patents granted at an early stage of the inventive process can increase social value by permitting the patent holder to manage exploitation of the invention efficiently, thus avoiding wasteful duplicative effort. However, the prospect theory, especially as applied to research tools, “depends on a view that is almost antithetical to the notion about what makes progress in science—[science] depends on the view that it is good to have many people doing different types of things because different ones will see different things and different ones will be more skilled than others at doing different types of things. Trying to make orderly or rationed access to innovations is likely to be socially very costly.”\textsuperscript{50}

Developing a research tool may not always be a reasonable signal of competence to manage the difficult -- and potentially diverse -- research that employs the tool. This is especially the case when there is a relatively low standard of nonobviousness for patentability and there is a race to develop and patent relatively “easy” research tools.

Perhaps even more importantly, the holder of a research tool patent does not necessarily share society’s incentives to speed the pace of research. Employing or licensing the most efficient researchers may require sharing the profits—both monetary and reputational—of the discoveries resulting from the research in a way that is not to the private advantage of the tool patent holder. It may be in the tool patent holder’s private interest to settle for a larger share of the results of less effective research. From the point
of view of the individual research tool patentee, the social surplus associated with cooperative research may not be enough to make up for having to divide the research rewards. The twenty-year period of exclusive control granted by a research tool patent may give the patent holder such a significant head start on the relevant research as to permit him or her to slow the pace of innovation substantially in order to capture a greater proportion of the profits of the research. When the research project is aimed at addressing important societal problems, such as disease or agriculture, the societal detriment of such delay may be very severe, while the private incentives to delay so as to keep a larger share of the monetary and nonmonetary benefits of the research may be correspondingly great.

It is thus in society’s interest to encourage the inventors of research tools which are of wide and diverse use or are needed for particularly important problems to make those tools broadly available to interested researchers if the tool inventor is not able to perform the research herself in a reasonably short time.

B. Proposals for a Research Tool Exemption

A research tool exemption might play a role in accomplishing this social purpose. The difficult question is how to design such an exemption so as not to interfere with incentives to develop research tools in the first place. For this reason, proposals for research tool use exemptions have focused on limiting the effects the exemption would have on the commercial market for the tool. Three basic types of approaches have been
proposed: 1) exemptions applying only to use in nonprofit research; 2) exemptions inspired by copyright “fair use”; and 3) compulsory licensing.

1. Exemptions Applying Only to Use in Nonprofit Research

Much of the concern about research tool patents focuses around their potential effects on academic and other nonprofit research. There is concern that nonprofit researchers may be priced out of the market for lucrative research tools and that exclusive control over research tools will distort the problems to which they are applied, focusing their application on lucrative, short-term projects to the neglect of longer term research which promotes the public good. The idea that nonprofit research should be exempt from infringement liability also hearkens back to the traditional research exemption and its focus on the commercial/non-commercial distinction.

However, there are both theoretical and practical difficulties in implementing a nonprofit research exemption in today’s scientific and technological world. Professor Rochelle Dreyfuss recently articulated three developments that she correctly argues have made the need for a research exemption more pressing in modern times: 1) “the characteristics of modern science;” 2) “transformations in the organization of science;” and 3) “broader changes in the political economy of information production.”\(^5\) Unfortunately, these same developments also illustrate the difficulty in implementing a simple nonprofit research exemption.

The distinction between basic and applied research which at one time characterized thinking about science is no longer tenable. The same patent now
frequently covers a “product market,” such as a market for a diagnostic test, and an “innovation market” covering the use of this same invention in basic research. It has become far more likely that a nonprofit researcher will need to make use of a commercially important (and patented) “product” in her research, while at the same time it has become more likely that nonprofit research, even if motivated entirely by the pursuit of basic science, will produce results of immediate commercial interest.

This situation leads to what Dreyfuss characterizes as a “vicious cycle.” As research costs rise (in part due to the need to obtain patented research inputs), universities increasingly look both to licensing their own patentable inventions and to industry funding (drawn in part by the potential for patentable research results) to meet their research expenses. As universities do this, they look more and more like commercial actors and their pleas for special treatment -- whether by legal exemptions or by discounts from private actors -- become less convincing. This, of course, raises their research costs and so forth.

The increased entanglement between nonprofit and industrial research, and especially the increasing patenting by nonprofit researchers, makes it more difficult as a political matter to argue for special treatment for nonprofit actors even though industry still provides a very small fraction of their research funding. The increasing extent to which industrial players are involved in university research (and vice versa) makes it more difficult to distinguish truly nonprofit research activities from those with for-profit motivations. Nonprofit exemptions also do not solve the apparent problem, raised by Madey, of what to do about research tools for which nonprofit researchers doing fundamental research are a major part of the potential market for the tool.
Dreyfuss (with “friendly amendment” by Professor Richard Nelson\textsuperscript{53}) has made an ingenious proposal which avoids some of these difficulties. Her proposed exemption would run in favor of noncommercial research organizations, universities, and their employees if (1) the patented materials they wish to utilize were not made available on reasonable terms; (2) the researchers agreed to publish the results of their work; and (3) the researchers agreed either to refrain from patenting the results or to patent the results and then license them on a nonexclusive basis and on reasonable terms.\textsuperscript{54} The proposed waiver has the virtue of requiring nonprofit researchers to self-identify. It also selectively applies to those research programs which are least likely to compete with commercial research.

This proposal is an elegant solution to the problem of identifying truly “nonprofit” research. But the waiver proposal suffers to some extent from its very advantage -- its self-selective process will minimize its applicability to commercially significant research. It is not intended to solve the problem of excessive (from a social perspective) control over the pace and course of tool-based research with potentially lucrative applications. Moreover, as Dreyfuss recognizes, there is a question whether, in today’s atmosphere, waivers would ever be filed. Even researchers who might wish to waive their patent rights may be discouraged by university administration from doing so, especially if there is some chance of a commercially significant result.

Dreyfuss suggests an additional “carrot” for signing a waiver by permitting “buyouts” in exchange for payment of retroactive royalties.\textsuperscript{55} The “buyout” possibility would certainly make the filing of a waiver more attractive for projects which have some potential for commercially interesting results. However, it might be almost too attractive
-- rather than no one filing a waiver, perhaps everyone would, turning the waiver proposal into essentially a compulsory licensing regime for nonprofit use. Perhaps this is the point. If nonprofit research efforts rarely lead to commercially significant results, a compulsory licensing scheme which only occasionally requires royalty payments may be vastly preferable to a whole series of negotiated licenses which rarely result in significant payments.

Another approach is proposed in a National Research Council report.\(^56\) The report proposes that the Federal government might make use of its authority to avoid patent injunctions for work performed “for the Government and with the authorization and consent of the Government.”\(^57\) Under this authority, the government can authorize patent infringement and patentees can recover damages in the form of a reasonable royalty by suit in the Court of Claims. This route has rarely been taken with research grant recipients, but could presumably be employed more broadly, resulting in an effective research exemption for recipients of Federal research funding. Since the federal government funds a large share of nonprofit research, this approach could provide a significant exemption for nonprofit use. Because of the availability of damages to patentees, it would also be comparable to a compulsory licensing regime. An advantage of this approach is that it would not seem to require any new statutory or judicial action before it could be implemented. However, one may also question whether the government is likely to take the necessary steps to provide “authorization and consent” on a broad basis. Statutory authority for patent “march in” under the Bayh-Dole Act, for example, has never been exercised.\(^58\)
2. “Fair Use” Approaches to a Research Tool Exemption

Several scholars have argued that patent law should adopt an approach inspired by the copyright “fair use” defense. Though the specifics differ, the basic thrust of these proposals is that the ability to use a patented invention without authorization should be determined by a case-by-case analysis of a set of factors. Professor Maureen O’Rourke, for example, proposed that fair use be determined based on: 1) the nature of the advance represented by the infringement; 2) the purpose of the infringing use; 3) the nature and strength of the market failure that prevents a license from being concluded; 4) the impact of the use on the patentee’s incentives and overall social welfare; and 5) the nature of the patented invention. More recently, Mueller has suggested a fair use defense based on a somewhat different set of factors: 1) the availability of consensual licenses; 2) whether the challenged use amounts to experimenting on a claimed invention or experimenting with it; 3) the degree to which the alleged experimental activity is necessarily incident to subsequent commercial exploitation; and 4) the balance of harms invoked in the granting or denial of an experimental use defense under the particular facts at hand. Professor Lorelei Ritchie de Larena suggests basing a patent fair use test on an adaptation of the copyright fair use factors. All of these proposals suggest that patent fair use might, at least in some cases, be accompanied by a court-imposed fee to compensate the patent owner and preserve incentives to invent.

The advantage of a fair use approach is its flexibility and ability to take a nuanced approach to specific situations. Unfortunately, the disadvantages of a fair use approach mirror its advantages. Fair use factors are both complicated and uncertain, making it
difficult for courts to apply them and for researchers to rely on them. There is significant dissatisfaction with the fair use doctrine in copyright for these reasons. The possibility that a patent fair user might need to be charged a fee poses further complications.

3. Compulsory Licensing Proposals

Compulsory licensing schemes have also been proposed to deal with patented research tools. Compulsory licensing effectively forces a tool inventor to choose between secret research using the tool and commercialization of the tool. The option of using a patent to secure a longer period for in-house research than is possible with trade secrecy is eliminated when a compulsory license is available, yet the tool inventor is compensated by a royalty, thus preserving commercial incentives to invent.

Criticisms of compulsory licensing schemes for patents arise in part from a concern that compulsory licensing depresses the returns that a patentee may capture. In the usual case, compulsory licenses may be poor substitutes for freely negotiated arrangements. The problem of research tools is a special case, however. Where research tool patents are being used to control and delay progress in research rather than to overcome the free-rider problem of appropriable investment in developing the tool, it is precisely the goal of a research exemption to change the threat positions of the parties and force the tool patent holder to deal with those who may be better able to perform socially beneficial tool-based research. We may be willing to let the research dog wag the tool tail, removing incentives for unqualified researchers to grab control of
downstream research through tool patents and leaving incentives for effective researchers to take care of tool development as part and parcel of doing the research.

Mueller proposes compulsory licensing for “research tools not readily available for licensing on reasonable terms or via anonymous marketplace purchase.” In her proposal, availability of the compulsory license would be limited to research use of the tools and the royalty would be a “reach-through royalty” based on the ultimate commercial value of the research results. Professor Donna Gitter has endorsed a similar proposal specifically for gene sequences.

Compulsory licensing is a means of decoupling exclusive control of the research stream itself from exclusive control of the revenues from research tool sales. Elsewhere, I have proposed that patent rights for research tools might consist of two periods: a few years of complete exclusivity followed by a period to complete the patent term during which compulsory licenses would be available. The initial period of exclusivity would provide an opportunity for inventors who have sunk significant research and development investments into complex research tools with simple applications to perform the initial research their inventions made possible. By reducing the opportunities for delaying research for the patentee’s private benefit, however, the shorter exclusivity period would remove some of the opportunities for private rent-seeking. The compulsory licensing part of the patent term would permit the patentee to continue to collect royalties or higher prices to recoup tool development expenses while ensuring widespread availability of the tool.

Only if the research facilitated by the tool cannot be accomplished or coordinated by the tool inventor during the initial exclusivity period and if the tool inventor has failed
to commercialize the tool will there be much interest in the compulsory licenses when they become available. The compulsory license period would thus serve primarily as an incentive for the negotiation of voluntary licenses during the exclusive period.

C. The Important Role of Researcher Innovators in Inventing Research Tools

Despite their differences, most proposals for a research tool use exemption run up eventually against the presumed need to compensate tool patentees for most uses of their tools because of a concern that failure to do so will depress incentives to invent tools. In focusing primarily on the commercial or non-commercial character of the users of research tools, most approaches to the research tool problem have failed to look deeply into the possibility that patent incentives may or may not be significant in promoting the invention, disclosure, and widespread dissemination of research tools by particular inventors. Research tool inventors fall into four main groups: nonprofit researcher innovators, commercial researcher innovators, research tool suppliers, and commercial research tool licensing firms whose business plans revolve around inventing high-tech research tools and then licensing the resulting patents either to tool manufacturers or to tool users. A large fraction of research tools inventors are researchers rather than manufacturers. A growing body of research suggests that user innovators in general behave differently than might be anticipated from the standard patent-based model of innovation.\textsuperscript{67} Moreover, many research tool inventors are scientists working in nonprofit venues, such as universities and national laboratories. The non-commercial incentives and social norms that may motivate these researchers should be taken into account.
1. The Incentives of Nonprofit Researcher Innovators

Nonprofit researchers invent research tools because they want to use them to be more effective in their own research. Their primary focus is on obtaining research results, which provide them benefits in the form of reputation, intellectual satisfaction, the ability to obtain research funding, and the ability to participate in an ongoing community discourse. Researchers tend to devise and usually make “leading edge” tools in their own laboratories. They usually do not “out-source” the invention of these research tools to commercial manufacturers because they have significant expertise and resources available to develop their own tools. Developing a tool is just part and parcel of doing the research.

Of course there are limits to the incentives of researcher innovators. They are less likely to invest in improvements aimed at standardizing or manufacturing a tool for more general use, in things such as safety and stability, and in minor improvements that do not have large enough effects on research functionality. Researcher innovators may also be less likely than commercial tool manufacturers to invent general purpose tools which require large investments of time or money. Their incentives to invent tools are limited by the returns (whether commercial or not) they expect to receive from the results of their research, though they do sometimes collaborate to produce large-scale general purpose research tools.

Nonprofit researcher innovators have mixed incentives when it comes to disclosing their research tools. Because they can be used in a researcher’s own
laboratory, research tools may function as “non-self-disclosing” even if they would be self-disclosing if they were marketed. Nonprofit researchers compete with one another for reputational benefits and for research funding, so they are somewhat motivated to keep their research tools secret so that they can use them to advance their own research agendas.

Despite these incentives for “trade secrecy,” there are several reasons to believe that most research tools invented by nonprofit researchers will be freely revealed within a relatively short time after they are invented. Nonprofit researchers receive their primary rewards for inventing research tools through publishing the results of the research. While these scientists may be able to delay publicizing their tool inventions long enough to obtain an initial set of research results, they will eventually have to reveal what they have done in order to back up their scientific publications or to apply for research funding. Moreover, graduate students come and go, needing to publish, give presentations, and write detailed doctoral theses, and taking with them their knowledge of research methodology. The likelihood of independent invention of a particular tool by a competitor also limits the potential returns to secrecy -- particularly where publicizing the new tool provides alternative mechanisms for appropriating benefits from its invention, such as citation of the tool publication by other researchers and opportunities for collaboration resulting from expertise in a new research method. Exchange of information about research tools and methods is also part of the social currency of exchange within the research community, furthering the intellectual, reputational, and social goals of most researchers. Finally, after a new tool is used for the first “breakthrough” research and when “tinkering” with the tool begins to provide
diminishing returns, tool inventors may be happy to have a tool manufacturer take over further tool development so as to obtain a standardized tool and save researcher time. These factors conspire to make it highly unlikely that a nonprofit researcher would keep a research tool secret for very long.

Nonprofit researchers do not have natural incentives to go out and market their inventions. Indeed, this lack of incentives (and expertise) for commercial marketing is the justification for the entire field of technology transfer. The concern is that, without a concerted effort (and some incentives in the form of royalty revenues), the inventions of nonprofit researchers will simply languish in the ivory tower and not be exploited to their full socially useful potential. There are two basic reasons to suspect that this may be the case for university inventions: 1) commercial firms may lack the absorptive capacity to adopt university inventions; and 2) university inventions may tend to be “embryonic” and far from practical usefulness, thus requiring large investments to bring them to market.

The need for special efforts to disseminate surely must be at a low ebb where research tools are concerned, however. While the results of nonprofit research may tend to be “embryonic” and far from application the research tools developed by nonprofit researchers will necessarily be developed to the point at which they can be used as tools. The concern with industry absorptive capacity encompasses such things as lack of scientific expertise and know-how and search costs imposed by unfamiliarity with the scientific literature. Industry researchers, however, will have the expertise and familiarity with the literature in their fields to enable them both to find and to understand research tools developed by others. Commercial tool suppliers will also generally have substantial expertise and familiarity with the research tools that are developed in the
laboratories of nonprofit researchers (who are their customers, after all). For these reasons, even though nonprofit researchers may not have substantial incentives or expertise to promote the commercial dissemination of their research tools, dissemination of research tool inventions should follow naturally once the tools are disclosed.

Nonprofit researchers do not need patent incentives to invent or disclose the tools they invent in the course of their research. Dissemination of unpatented research tools invented by nonprofit researchers is likely to occur as a byproduct of disclosure and as a result of the complementary incentives of research tool suppliers, which will be discussed below. In some cases, patenting and licensing to a commercial tool supplier might disseminate a tool more widely, but those cases may be rare due to the many means of dissemination directly from researcher to researcher and to the incentives that tool suppliers will have to market some tools even if they are not patented by the researcher innovator. In most cases of nonprofit researcher innovation, patenting is instead likely to reduce dissemination of the tool, since researcher innovators may benefit -- at society’s expense -- from maintaining control over the tool to pursue their own tool-based research or from licensing it exclusively to for-profit firms which may pay a premium for the ability to maintain control over the commercial research stream enabled by the tool.

2. The Incentives of Commercial Researcher Innovators

Like nonprofit researcher innovators, commercial researchers are primarily motivated to invent research tools to use in their own research, which, of course, will likely be aimed at obtaining commercially valuable research results.
Commercial researchers have greater ability to maintain trade secrecy and fewer means to benefit from disclosing information about their research tool innovations than nonprofit researchers. When possible, they will probably prefer to maintain exclusive control over important research tool inventions so that they can maintain control over the related research streams. Trade secrecy is leaky, however. Other researchers may independently invent the same or substitutable research tools. In some cases commercial researchers may be working in the same areas as nonprofit researchers who have all of the incentives to disclose just discussed. Commercial researchers may also reveal some of their inventions to specific individuals as part of an informal exchange process with other researchers in the field.71

As for nonprofit researcher innovators, patents likely play a rather small role in incentivizing research tool invention by commercial researcher innovators. Because these researchers have greater ability and incentives to maintain trade secrecy than nonprofit researchers, however, patents may play a correspondingly larger role in motivating disclosure of their research tool inventions. Patents are unlikely in most cases to increase the dissemination of these research tool inventions, since commercial researcher innovators are likely to use patenting to maintain control over the research stream enabled by the tools for longer than trade secrecy would allow. The societal implications of patenting in these cases thus depend on the tradeoff between the social benefit of earlier knowledge about the research tool and the social cost of researcher control over the stream of inventive activity using the tool.

3. The Incentives of Commercial Research Tool Suppliers
Commercial research tool suppliers, like other manufacturers, will have incentives to invent new tools or improve existing tools if they can recoup their investments through commercial sales. Their inventive choices will probably be affected by the fact that researchers often invent their own tools. The suppliers’ competitive advantage likely lies in developing the types of research tool inventions less likely to be made by researchers.

Research tool suppliers may find it particularly difficult to maintain trade secrecy with respect to their inventions. Users of research tools are far more likely than consumers of products like television sets to demand a detailed understanding of a tool and how it works before purchasing it. Such knowledge may be crucial to the design and interpretation of experiments using the tool. Thus, even if the technology is not inherently self-disclosing, disclosure of its inner workings may have to be supplied as a part of marketing the tool.

For research tool suppliers, patenting plays its usual role in stemming free riding by market competitors and thus providing incentives to invent new tools or tool improvements. While in principle, patenting might also deter “user appropriation” of tool inventions, in practice patenting plays only a limited role in deterring “lab-made” versions of patented tools, since there is widespread evidence that researchers are often unaware of, and essentially indifferent to, patents and since monitoring laboratory infringement is difficult and enforcing patents against researchers would involve suing the tool supplier’s customers. Nonetheless, researchers will often purchase tools (patented or not) from commercial suppliers even if they could conceivably have made them in the lab. Researchers will make “homemade” tools only when there is an
advantage to doing so -- when commercially available tools are too expensive (a problem which is often mitigated by substantial nonprofit discounts), or when the amount of customization required makes it easier or necessary to do so, when making a tool is part of an educational process for graduate students, for example.

Research tool suppliers may also play an important role in disseminating tools invented by researcher innovators. A common path of research tool development is for tools with new functionality to emerge from the laboratories of researcher innovators, be gradually adopted and improved by researchers, and then be picked up by commercial manufacturers which standardize them and make the types of improvements in convenience, reliability, accuracy, and manufacturing techniques that are of general interest to a wide range of researchers. The ability of tool suppliers to obtain exclusive licenses to commercialize tools invented and patented by research innovators is probably much less important in the dissemination of such research tools by commercial suppliers than is often suggested, because research tools do not fit the paradigm of “embryonic” research results which will require especially large R&D investments before they can be marketed. This is not to say that there is never any inventive distance to cover between the researcher’s laboratory and the supplier’s catalog. What satisfies a graduate student rushing to complete a thesis project may not be ready for commercial sale. But there is likely to be far less technical distance between laboratory and catalog for research tools than for other types of university research results. Moreover, if commercializing a research tool created by a nonprofit researcher requires new and nonobvious improvements, the tool supplier can patent the improvements. If transfer of unpatentable
“know-how” is required it may be obtained without patenting the central invention, through consulting, collaboration, and transfer of personnel.

In the end, arguably the only socially important role of patenting for research tool suppliers is the familiar one of protecting their own appropriable investments in tool inventions against competing manufacturers.

4. The Incentives of Tool Patent Licensing Firms

Besides tool manufacturers, whose business model is to manufacture and supply research tools, there are firms whose revenues come primarily from licensing technology either to researchers themselves or to tool suppliers. These firms develop research tools in-house and either do not have the in-house capability to manufacture, market, and distribute the tools themselves or have developed research methods or techniques that are not amenable to a “tool supplier” commercial model. For these companies some disclosure of their inventions is inherent in the business model. Technology cannot be licensed without disclosing it to potential licensees.

Research tool licensing firms may or may not have incentives to disseminate their technology widely. If they license their proprietary technology non-exclusively they have incentives to maximize their royalty revenues by encouraging widespread use of their tools. If, on the other hand, they believe that their private benefit is maximized by exclusive licensing they may restrict tool dissemination.

Patents are the lifeblood of the research tool licensing business model. Since these firms are neither users nor manufacturers of research tools, they must license their
technology to obtain any revenue. While trade secrecy agreements are one means, patents lower the transaction costs of technology licensing. These firms also use patents to signal their technical competence to potential investors. For these firms, patents serve their canonical incentive to invent role, as well as facilitating the dissemination of the research tools in some cases. However, patents also may permit private rent-seeking through exclusive control of a research stream.

5. The Case of Dual-Purpose Inventions

While many research tools and methods are solely or primarily of use in doing research, some also have direct market applications. Diagnostic methods, such as the BRCA1 and BRCA2 breast cancer tests are examples of this type of invention. Since the value of such inventions is significantly located outside of their use in research, researcher innovator incentives may or may not be sufficient for their development. For this type of research tool invention in particular, it may be important to preserve the incentives to invent that arise from the ordinary consumer market. Moreover, if the tool is invented by a researcher, it may or may not be in the researcher’s private interest to market the invention for its alternative use. A researcher innovator may prefer to maintain exclusive use of the tool -- through either trade secrecy or patenting -- despite the fact that the socially optimal course might be to market it for both consumer and researcher use. If the tool is invented by a manufacturer or technology licensing firm which licenses non-exclusively, the interests of researchers in tool availability should be adequately served.
6. Summary of Benefits of Research Tool Patenting

Having analyzed the incentives of both researcher innovators and commercial producers of research tools, we now consider the ways in which patent exclusivity might be socially beneficial:

- Incentivizing disclosure by commercial researcher innovators who might otherwise rely on trade secrecy. In these cases patenting trades off longer exclusive use of the tool in favor of earlier disclosure of the tool’s characteristics.\(^74\)

- Incentivizing the development by commercial researcher innovators of research tools which require larger investments than justified by the practical availability of trade secret protection for their research.

- Incentivize inventive activity by research tool suppliers by protecting them from “free riding” competitors.

- Incentivizing inventive activity by research tool licensing companies by protecting them from “free riding” competitors and users.

- Incentivizing inventive activity for dual purpose inventions that have significant direct commercial markets.
The net social effects of the first of these effects of patent protection are ambiguous. In many active research areas, and especially where nonprofit researchers are involved, the time between invention and publication of a patent application or issued patent is comparable to the time during which trade secrecy is available. The gains from somewhat earlier disclosure of a research tool’s characteristics through patenting are unlikely to make up for the social cost of exclusive use of the research tool for the entire patent term. The second effect is most important in fields that are not significantly populated by nonprofit researchers, since nonprofit researchers can obtain upfront funding for the development of expensive research tools and reputational returns on that development by the mechanisms of attribution, collaboration, and some limited exclusivity provided by the funding process and by social norms. This reduces the importance of the patent incentive to invent such tools in these fields. The last three effects of patenting are most important for the development of research tools or improvements to research tools that are unlikely to be developed by researcher innovators. As discussed, these primarily include improvements that make existing tools more accessible for widespread use and general purpose tools the development of which is too expensive to be worth a given researcher innovator’s while. As noted, even for this latter class of tools there are sometimes alternative mechanisms for invention, such as collaborative projects.

D. An Exemption for Research Tool Use: Does User Innovation Matter?
Having taken a more detailed look at the effects of user innovation on incentives to invent, disclose, and disseminate research tool inventions, we return to the question of designing an exemption for “experimenting with” a patented invention. The researcher innovator paradigm, along with the importance of nonprofit research innovators in some fields, diminishes the importance of recouping tool development costs in many instances, and reinforces concerns that research tool patentees might pursue private gain by seeking to control the research stream beyond the point necessary to recoup their investments in tool design. Previous research exemption proposals reflected a presumed need to preserve commercial returns to research tool inventors in order to preserve incentives to invent research tools. If these commercial returns are less important than previously appreciated, perhaps an “experimenting with” exemption need be less concerned with preserving them, at least for the types of tools that are likely to be invented by researcher innovators.

Focusing on researcher incentives also highlights the fact that tool suppliers and researchers are very different kinds of potential “free riders” on the research tool inventions of others. Patents aside, researchers will choose between buying a tool from a supplier and making it in-house depending on the relative costs (including, importantly investments of time) and benefits of the two approaches. In general (though not exclusively), researchers will be more likely to “free ride” on the same kinds of tools that researchers invent. Tool suppliers have complementary incentives, being more likely both to invent and to copy the tools which researchers are less likely to invent.

This limits the extent to which a research use exemption is likely to depress incentives to invent research tools overall. The incentives of research tool suppliers and
licensing firms to invent research tools which researchers would realistically choose to purchase rather than to “bootleg” are preserved by patent exclusivity with respect to sales not use. Since researcher innovators can often gain a sufficient competitive edge through secrecy and lead time advantages (in part because research is a winner-take-all activity in which a small “head start” can have a major payoff), their incentives to invent research tools may also not be decreased much by a research tool use exemption. Moreover, since researchers are tool users as well as tool inventors, the private effects of a research tool use exemption on them might more or less wash out, while society would benefit from more rapid research.

VII. CONCLUSIONS

Any research exemption decreases the private benefits that would be available to patentees without the exemption. But considering the contributions and incentives of researcher innovators suggests that a research tool use exemption may have lower costs than previously appreciated. Since the social benefits of a research tool use exemption in freeing up tools for use in diverse and competitive research are likely to be very large, perhaps we should be less reluctant to impose research tool use exemptions.

One final point should be mentioned. The difficulties in designing a sensible and politically viable research exemption are compounded by United States obligations to comply with the international Agreement on Trade Related Aspects of Intellectual Property (“TRIPS”). TRIPS imposes substantive minimum standards of patent protection. An evaluation of the TRIPS compliance of the proposals discussed here is
beyond the scope of this Chapter. Professors Dinwoodie and Dreyfuss have analyzed the TRIPS compatibility of O’Rourke’s “fair use” approach and of Dreyfuss’s nonprofit waiver proposal, concluding that these proposals might withstand TRIPS scrutiny depending upon how the relevant provisions are interpreted. An “experimenting on” exemption might be expected to fare at least as well as those proposals, in part because such exemptions are so common in national laws as to make it unlikely that TRIPS was intended to eviscerate them. Broader exemptions for research tool use are likely to run into more serious objections.

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1 This chapter is based in part on my earlier article, Katherine J. Strandburg, What Does the Public Get? Experimental Use and the Patent Bargain, 2004 Wis. L. Rev. 81.


6 The traditional research exemption goes by several names, including “common law exemption” or simply “experimental use” exemption.

7 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).


9 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391).

10 3 WILLIAM C. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* § 898 (1890)


12 13 F. Supp. at 697.

13 547 F.2d 1106, 1125 (Ct. Cl. 1976).


16 Embrex, Inc. v. Serv. Eng’g Corp., 216 F.3d 1343 (Fed. Cir. 2000).

17 H.R. REP. NO. 101-960, PT. 1, AT 55–56, 65–66 (1990). The National Institutes of Health Working Group also took the position that the distinction between “experimenting on” and “experimenting with” a patented invention is a “sensible distinction.” *NAT’L


(Newman, J., concurring in part and dissenting in part)


28 NeoRX, 877 F. Supp. at 207.

29 496 U.S. 661 (1990)


32 Integra Life Scis. I, Ltd. v. Merck KGaA, 331 F.3d 860 (Fed. Cir. 2003)

33 125 S. Ct. at 2382-83.

34 331 F.3d at 877.

35 125 S. Ct. at 2381 n7.

36 Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989). Proposing an exemption for: “(1) Research use of a patented invention to check the adequacy of the specification and the validity of the patent holder's claims about the invention should be exempt from infringement liability. (2) Research use of a patented invention with a primary or significant market among research users should not be exempt from infringement liability when the research user is an ordinary consumer of the patented invention. (3) A patent holder should not be entitled to enjoin the use of a patented invention in subsequent research in the field of the invention, which could potentially lead to improvements in the patented technology or to the development of alternative means of achieving the same purpose. However, it might be appropriate in some cases to award a reasonable royalty after the fact to be sure that the patent holder receives an adequate return on the initial investment in developing the patented invention.”

37 Generally, western European nations exempt from infringement experiments directed at the subject matter of the invention. *See, e.g.*, VI C. INTELL. PROP., tit. 1, art. L613-5(2) (France), available at Legifrance, http://lexinter.net/ENGLISH/intellectual_property_code.htm (last visited Apr. 15, 2004);

38 *Roche Prods.*, 733 F.2d at 861.


41 *See, e.g.*, *In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988); *see also* Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CAL. L.
REV. 1, 18–19 (2001) (noting that reverse engineering would be unnecessary if disclosure were fully enabling).

42 See Integra, 331 F.3d at 875 (Newman, J., concurring in part and dissenting in part) (stating “there would be little value in the requirement of the patent law that patented information must be removed from secrecy in consideration of the patent right to exclude, if the information is then placed on ice and protected from further study and research investigation”).

43 Integra, 331 F.3d at 875–76 (Newman, J., concurring in part and dissenting in part) (“The patentee’s permission is not required whenever a patented device or molecule is made or modified or investigated. Study of patented information is essential to the creation of new knowledge, thereby achieving further scientific and technological progress.”).


46 U.S. CONST. art. I, § 8, cl. 8.

47 Graeme B. Dinwoodie and Rochelle Cooper Dreyfuss, WTO Dispute Resolution and the Preservation of the Public Domain of Science under International Law, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, K.E. Maskus and J. H. Reichman, eds. (Cambridge University 2005).

48 See Mueller, supra note 45, at 15.


52 See, e.g., John P. Walsh, Charlene Cho, and Wesley M. Cohen, Patents, Material Transfers and Access to Research Inputs in Biomedical Research, FINAL REPORT TO THE NATIONAL ACADEMY OF SCIENCES’ COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS IN GENOMIC AND PROTEIN-RELATED INVENTIONS (2005) at 11, available at tigger.uic.edu/~jwalsh/NASReport.html (industry funding accounts for about 7% of total university research funding).

Dreyfuss, supra note 51 at 471

Id. at 472.

National Research Council, supra note 3 at 115-17.


Lorelei Ritchie de Larena, What Copyright Teaches Patent Law about “Fair Use” and Why Universities are Ignoring the Lesson, 84 OR. L. REV. 779 (2005)


64 Mueller, supra note 60, at 58.

65 See generally Gitter, supra note 62.

66 Strandburg, supra note 1.

67 See, e.g., ERIC VON HIPPEL, DEMOCRATIZING INNOVATION (2005) and references therein.


69 VON HIPPEL, supra note 67 at 70-71.


71 See, e.g., VON HIPPEL, supra note 67 at 77-91 (discussing reasons for free revealing by users).

72 See Walsh et al, supra note 52 at 2.


74 Strandburg, supra note 1 at 131-35.

75 Dinwoodie and Dreyfuss, supra note 47 at 868-78.