Research Tools and User Innovation

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I. INTRODUCTION

We award patents, as the Constitution requires, "To promote the Progress of . . . useful Arts."[1] 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. The difficulty may arise either because an improved invention still falls within the claims of a prior patent, necessitating a license from the prior patentee for implementation of the improvement or, as is the focus of this Article, because the research and development process for a new invention requires the practice of a prior patent. In such cases, there has been considerable concern that prior patentees may be unwilling to license the experimental use of their inventions on reasonable terms to potential competitors or that non-profit researchers might be unable to afford even a commercially reasonable license fee. A research exemption from infringement liability might be used to skirt such prior patentee reluctance, but such an exemption raises another specter—the possibility that depriving patentees of control over the research uses of their inventions might diminish incentives to invest in developing the initial invention.

In the United States, the research exemption comes in two "flavors" -- a broad statutory exemption for research "reasonably related" to regulatory approval by the Food and Drug Administration and an increasingly narrow general exemption for non-commercial research based on judicial interpretation of the prohibition on infringing "use" of patented inventions. Both exemptions have received considerable attention in recent years. The statutory exemption was the subject of a 2005 decision by the United States Supreme Court, while two major national reports, along with numerous scholarly and news media articles reflect the concern about the vanishing exemption for non-commercial research.

An important controversy exists as to whether either research exemption should be applied differently depending upon whether the research is aimed at understanding or improving upon the patented invention -- "experimenting on" the invention -- or uses the patented invention as a research tool -- "experimenting with" the invention. Internationally, major patent systems have distinguished between these two types of unauthorized uses of patented inventions, though the distinction has yet to be effectuated in United States law. This Article addresses the more complex question of research exemptions for use of a patented invention as a research tool or method. It goes beyond the previous literature on research tool exemptions by focusing on motivations for innovation -- in particular the motives of "user innovators" --that do not stem from a desire for financial reward based on commercial sales or royalties.

The case for a research tool exemption is considerably strengthened when these motivations are taken into account. I propose two approaches alternatives that would be consistent with the "user innovation" analysis: a complete exemption for all research

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[1] U.S. CONST. art. I, § 8, cl. 8.

uses of patented inventions (not extending to sales or other uses) and a narrower "double-edged sword" proposal permitting both nonprofit use of research tools patented by others and use by any researcher of tools patented by nonprofit researchers. The proposed exemptions are confined to research use and, importantly, would not exempt sales of patented research tools from liability.

Section II addresses the theoretical underpinnings for research exemptions for infringement liability and explains why the case of research tools use is considerably more troubling than the case of "experimenting on" a patented invention to understand or design around it. Section III provides a brief overview of the current United States research exemptions: an exceedingly narrow general exemption based on judicial interpretation of the statutory term "use" in the infringement statute and a broadly interpreted statutory exemption for patented inventions regulated by the Food and Drug Administration. Section IV describes and assesses previous proposals for a research tool exemption, including a previous proposal by this author. Section V explores the impact on the research tool exemption analysis of the fact that researchers themselves invent many research tools. Section VI proposes that the consideration of research innovator incentives provides support for a broad "research tool use" exemption and discusses two specific proposals for such an exemption. Section VII briefly evaluates whether these proposals are likely to be deemed TRIPS-compliant. Section VIII concludes.

II. WHY A RESEARCH EXEMPTION?

Patents are intended as incentives to invent new technologies and to disclose inventions that might otherwise have been kept as trade secrets. The exclusive rights they award provide a defense against the likelihood that competitors will "free ride" on the investments that patentees have made in developing their inventions. From a social perspective, however, patents are double-edged swords; they provide incentives to initial inventors, but they also impose costs on those who seek to build on their work.

Research is a primary path for technological and scientific progress. Because patents can restrict research, there is a palpable tension between incentives for initial invention and the progress that comes from building upon the available store of knowledge.. Research exemptions aim to relieve some of this tension. Under a research exemption, some unauthorized "experimental uses" of patented inventions are exempted from infringement liability.[2] Because no license is required for exempted research, anticompetitive refusals to license can, in principle, be overcome. Unlike more general modifications of the terms of the patent grant that might be accomplished by judicial adjustment of doctrines such as nonobviousness or equivalents or by legislative adaptation of the patent term, research exemptions are targeted at those activities that contribute most directly to technological progress.

I have argued in detail in earlier work that some of this tension can be alleviated by distinguishing between use of *embodiments* of a patented invention in research

[2] *See* 35 U.S.C. § 271(e) (stating "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within 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"); 5 DONALD S. CHISUM, CHISUM ON PATENTS, § 16.03 (1997); 3 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 898 (1890).

("experimenting with" the invention) and "experimenting on" a patented invention to study or design around it, which facilitates the use of the *inventive idea* in follow-on innovation.[3] Professor Rebecca Eisenberg proposed a limited form of an "experimenting on" exemption in her seminal article on the research exemption in 1989.[4] Several major foreign patent systems provide "experimenting on" exemptions.[5] A research exemption for "experimenting on" a patented invention is clearly justified as it is consistent both with other aspects of U.S. patent doctrine, which separate control over embodiments of inventions from control of the inventive idea and with an economic analysis that distinguishes between "self-disclosing" and "non-self-disclosing" inventions.

While "experimenting with" a patented invention as a research tool cuts directly into patentees' commercial incentives to invent, "experimenting on" a patented invention is primarily a means of effectuating the disclosure of the inventive idea which the patent system already requires. The distinction between use of embodiments of the invention and use of the inventive idea during the patent term is well rooted in current law. The patent system grants a period of exclusive rights in embodiments of the invention but simultaneously requires that patentees provide immediate public access to inventive ideas by disclosing them in published patents.[6] Other inventors are permitted, and even encouraged, to avoid patent infringement by "designing around" patented inventions using the patent disclosure as a springboard.[7] Similarly, the system permits patents on

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[3] Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81.

[4] 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."

[5] 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); German Patent Act, § 11(2); U.K. Patents Act of 1977, § 60(5)(b). For cases interpreting the experimental-use exemption, see *Monsanto Co. v. Stauffer Chemical Co.*, [1985] R.P.C. 515 9 (Eng. C.A.); *Klinische Versuche (Clinical Trials) I*, [1997] R.P.C. 623, 639 (BGH); *Klinische Versuche (Clinical Trials) II*, [1998] R.P.C. 423, 432 (BGH). Likewise, the statutory schemes of several other European nations, including Spain, Italy, Belgium, the Netherlands, and Ireland, permit experimentation relating to the subject matter of the invention. *See* ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 1015 (3d ed. 2002). Western Europe is by no means alone in permitting experimental use relating to the subject matter of a patented invention. *See, e.g.*, Brazil Indus. Prop. Law art. 43(2); Japanese Patent Act, § 69(1); Korean Patent Law art. 96(1). Canada, like the United States, has no statutory experimental-use exemption, but their judicially created exception exempts "experimenting on" a patented invention. *See* Micro Chems. Ltd. v. Smith Kline & French Inter-American Corp., [1972] S.C.R. 506, 519–20; Dableh v. Ontario Hydro [1996] 3 F.C. 751, 781–82.

[6] Eisenberg, *supra* note 4, at 1021.

[7] Westvaco Corp. v. Int'l Paper Co., 991 F.2d 735, 745 (Fed. Cir. 1993) (citing London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1538 (Fed. Cir 1991)); State Indus., Inc. v. A.O. Smith Corp., 751 F.2d 1226, 1236 (Fed. Cir. 1985) (describing one of the patent system's primary goals as insuring competition through

improvements even when they incorporate the patented inventive ideas of others. Third-party inventors are free to build upon patented inventions in these ways during the patent term without any authorization whatsoever from the original patentee. The permission of the original patentee is required only when a follow-on inventor seeks to use or sell an improved product or process that actually embodies the original invention. This distinction between the effects of "experimenting on" a patented invention and using it as a research tool, recognized in other jurisdictions internationally, was advocated vigorously by Judge Newman of the Federal Circuit Court of Appeals in her dissent in the case of *Integra v. Merck*,[8] to which we will return shortly.

As a theoretical matter, the distinction between "experimenting on" and "experimenting with" may be rooted in the differential incentives applicable to self-disclosing inventions (for which the incentive to invent is important, but the incentive to disclose is not) and non-self-disclosing inventions (for which the incentive to disclose is important, but the incentive to invent is not). Because "experimenting on" is a means of facilitating disclosure it does not affect incentives to invent self-disclosing inventions. For non-self-disclosing inventions, an "experimenting on" exemption merely effectuates the disclosure quid pro quo. Thus, a broad "experimenting on" exemption -- which can be applied equally to commercial and non-commercial research -- is well justified as a matter of patent policy and theory.

In the United States, such 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 v. Merck*. An "experimenting on" exemption could be premised on judicial interpretation of the statutory prohibition of unauthorized "use" of a patented invention.[9] The prohibition of "use" is already interpreted to permit use of the inventive idea as disclosed in the specification during the patent term for the purpose of improving upon or designing around the patent. The disclosure law requires that the patent teach a person of ordinary skill in the relevant art to understand the patented invention.[10] The intention is that this understanding will be sufficient to provide the public benefits of design-arounds and improvements on the patented invention.[11] 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.[12] Because a research exemption for "experimenting on" a patented invention could be a judicial gloss on the statutory

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the "'negative incentive' to 'design around' a competitor's products, even when they are patented, thus bringing a steady flow of innovations to the marketplace"); *see also* Craig Allen Nard, *Certainty, Fence Building, and the Useful Arts*, 74 IND. L.J. 759, 759–60 (1999) (discussing competition between patented technologies by "designing around").

[8] Integra Life Scis. I, Ltd. V. Merck KGaA, 331 F.3d 860, 872-78 (Fed. Cir. 2003) (Newman, J., concurring in part and dissenting in part).

[9] 35 U.S.C. § 271.

[10] *Id.* § 112.

[11] *Westvaco Corp.*, 991 F.2d at 745.

[12] *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.")

prohibition of unauthorized "use," no legislation would be required to effectuate the distinction. Moreover, as an extension and effectuation of the disclosure requirement, the exemption should apply to commercial and non-commercial research alike.

As a practical matter, if legislation is required to implement a research exemption, it is far more likely to succeed if the proposal stands to promote faster innovation in both the commercial and nonprofit sectors. Indeed, 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 the private actors involved. This kind of even-handed legislative exemption -- possibly of even greater scope than "experimenting on" a patented invention -- has been advocated by the American Intellectual Property Law Association ("AIPLA"), a bar association which is certainly not an opponent of strong patent protection.[13]

The question of whether, and how, to exempt unauthorized research tool uses of a patented invention is a far more difficult conundrum, however. Unlike the situation with "experimenting on" a patented invention, where public use of a patented invention's contribution to further innovation -- its inventive idea -- can be separated from the patentee's ability to recoup the costs of developing the invention through sales and licensing, the research tool question appears to put the two goals of incentivizing development of the tool and promoting maximal progress based on the tool directly at loggerheads. Whether this is in fact the case is the main topic of this Article, to which we will return after a brief look at current United States law regarding research exemptions from patent infringement liability.

III. THE CURRENT STATE OF RESEARCH EXEMPTIONS IN UNITED STATES PATENT LAW

United States law contains two separate types of research exemption: a statutory exemption aimed at products regulated by the Food and Drug Administration and a general exemption based on judicial interpretation of the infringement statute. These two exemptions differ in both goals and scope. The statutory exemption relates to issues in public health and regulatory delay, while the general exemption is based more broadly in the role that research plays in technical progress.[14]

A. The Vanishing General Research Exemption

U.S. courts have oscillated between providing a meaningful general research exemption and taking a mere *de minimis* approach in attempting to define the circumstances under which unlicensed use of patented inventions should generally be permitted.[15] The history of the U.S. general research exemption has been reviewed in

[13] **[CITE to AIPLA proposal and quote]**

[14] The general research exemption goes by many names, including "common law exemption" or simply "experimental use" exemption. The exemption is judge-made and premised on an interpretation of the statutory prohibition on unauthorized "use" and "making" of a patented invention.

[15] This history may be contrasted with the law's longstanding recognition of the need for a "fair-use" exemption in copyright law. See Maureen A. O'Rourke, Toward a Doctrine of Fair Use in Patent Law, 100 Colum. L. Rev. 1177, 1177 (2000).

numerous articles, and I do not attempt to reproduce an extensive review here, focusing instead on the current state of the law.[16]

The case law on the general research exemption has focused on the distinction between commercial and noncommercial use, with commercial use categorically ineligible for the general research exemption.[17] Unfortunately, the commercial versus noncommercial distinction has not proved stable and recent decisions by the U.S. Court of Appeals for the Federal Circuit have shrunk the definition of noncommercial use, pushing the general research exemption nearly to extinction.[18] For example, in *Madey v. Duke University*, a 2002 Federal Circuit case, the court found university research ineligible for the research exemption because it "unmistakably furthers the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects."[19] This outcome conflicted with the widespread understanding on the part of university researchers that purely academic research was categorically excused from patent infringement liability.[20] With the expansive understanding of "business" articulated in *Madey*, few activities will be unrelated to any potential infringer's "legitimate business." The research exemption remains viable, according to the court, for experimentation that is "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[21] The court thus drew a strained distinction between research aimed at "enlightening students and faculty" and research aimed at "strictly philosophical inquiry."[22] The court does not suggest where, outside of the halls of academe, such scientific philosophers are to be found in this modern age; surely their ranks are thin indeed.

Recent trends have also served to blur the distinction between commercial and noncommercial uses. Since passage of the Bayh-Dole Act,[23] which was intended to

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[16] *See generally* Richard E. Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. PAT. OFF. SOC'Y 357 (1957); Eisenberg, *supra* note 4; O'Rourke, *supra* note 15.

[17] *See* Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000) (finding that tests performed "expressly for commercial purposes" did not qualify as experimental use); Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984), *overridden on other grounds by* 35 U.S.C. § 271(e) (2000) (same).

[18] Madey v. Duke Univ., 307 F.3d 1351, 1362–63 (Fed. Cir. 2002) ("On remand, the district court will have to significantly narrow and limit its conception of the experimental use defense."); *Embrex*, 216 F.3d at 1349 ("While the SEC tries to cloak these tests in the guise of scientific inquiry, that alone cannot immunize its acts."); *Roche Prods.*, 733 F.2d at 863 (holding that courts should not "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"); *see also* Integra Life Scis. I, Ltd. v. Merck KGaA, 331 F.3d 860, 872–78 (Fed. Cir. 2003) (Newman, J., concurring in part and dissenting in part) (disputing recent Federal Circuit interpretations of the common-law experimental-use exemption).

[19] *See Madey*, 307 F.3d at 1362.

[20] *See, e.g.*, John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, PATENTS IN THE KNOWLEDGE-BASED ECONOMY 324–28, 334–35 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) (providing evidence that researchers presume a relatively broad "informal research exemption" and noting the potential of the *Madey* case to undercut reliance on such an assumption).

[21] *Madey*, 307 F.3d at 1362 (citing *Embrex*, 216 F.3d at 1349). The exemption for "philosophical experiments" dates back to the inception of the experimental-use exemption in a nineteenth-century opinion by Justice Story. *See* Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600).

[22] *Madey*, 307 F.3d at 1362.

[23] .*See generally* Bayh-Dole University and Small Business Patent Procedures Act, Pub. L. No. 96-517, 94 Stat. 3019 (Dec. 12, 1980) (codified at 35 U.S.C. §§ 200–211).

encourage technology transfer between federally funded university researchers and the private sector, universities have become increasingly involved in patenting and licensing their own discoveries, while university researchers have become increasingly involved in technology start-up companies. Moreover, in some technical disciplines, basic research has increasing relevance to technological applications.[24] The blurring of the boundary between commercial and noncommercial research also provides opportunities for strategic behavior, such as firms' placing of particular research projects into the nonprofit sector so as to gain access to the patented technology of competitors.[25]

The upshot is that the general research exemption has been reduced to a mere *de minimis* exception that bears little relation to the implications of a particular experimental use for the public benefits of follow-on innovation or to specific effects that the use might have on inventor incentives. Continued reduction in scope of the general research exemption seems inevitable if the courts stay on the course outlined by *Madey*. However, it is possible that the Federal Circuit will recognize a broader general exemption for "experimenting on" a patented invention to understand or design around it. Though the issue was not framed in those terms, *Madey* dealt with the use of a patented invention as a research tool, rather than research concerned with understanding the patented invention.

In a later case focusing primarily on the statutory FDA exemption discussed below, Judge Newman argued strenuously in dissent that the experimentation in that case was exempted from infringement liability under the general judge-made exemption. She distinguished "research into the science and technology disclosed in patents" (what here has been called "experimenting on") from "the use in research of patent products or methods, the so-called 'research tools'" (what here has been called "experimenting with"). She argued that the general 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."[26] She also argued that such experimentation was necessary to effectuate the patent disclosure. The majority, however, declined to address the applicability of the general research exemption, holding that only the statutory exemption was before it in the case.[27] The case eventually came before the Supreme Court[28] in 2005 for consideration of a question of interpretation of the statutory exemption discussed below. The issue of the general research exemption was not dealt with by the Supreme Court either, so any distinction in the judge-made general research exemption between "experimenting on" a patented invention and using it as a research tool remains an open question.[29]

B. The Broad Statutory Exemption for Research "Reasonably Related" to FDA Regulation

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[24] *See, e.g.*, Philippe Ducor, *Are Patents and Research Compatible?*, NATURE, May 1, 1997, at 13 (discussing the blurring between commercial and noncommercial research).
[25] *See, e.g.*, Walsh et. al., *supra* note 20, at 326.
[26] 331 F.3d 860 at 42.
[27] *Id.* at _
[28] Merck KGaA v. Integra Life Scis. I, Ltd., 125 S. Ct. 2372 (2005).
[29] Note that in the earlier *Embrex* case the Federal Circuit applied the commercial-non-commercial rubric to find no exemption in a case that clearly involved "experimenting on" the invention, but the "experimenting on" distinction was not actually raised, so it is still possible that the Federal Circuit will adopt it in a future case.

Passage of the statutory exemption for research related to the fulfillment of FDA regulations was driven by the Federal Circuit's decision in *Roche Products v. Bolar Pharmaceutical Co.*[30] In *Roche*, the holder of a pharmaceutical patent sought to enjoin a generic drug manufacturer from using a patented ingredient during the term of the patent to conduct testing that was required by the Food and Drug Administration (FDA) before the generic could be put on the market.[31] The purpose of the testing was to allow for marketing of the generic drug as soon as possible after the patent term expired.[32] The district court held that the testing was excusable experimental use, but the Federal Circuit reversed, deeming it infringing.[33]

In response, Congress enacted specific provisions to deal with the patent term problems posed by FDA drug regulations, permitting generic manufacturers to perform potentially infringing tests during the patent term in preparation for sales immediately after expiration,[34] while also providing for patent term extensions to drug patentees to compensate for market time lost because of testing they were required to perform at the beginning of the patent term.[35] The statutory FDA exemption was part of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), which was substantially motivated by Congressional interest in getting generic drugs into the hand of patients as soon as possible after the expiration of a drug patent. The Act also created an exemption to patent infringement liability for 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.[36]

The idea was to allow the research necessary for FDA approval to be done prior to the expiration of the patent on a regulated item. It is worthy of note that this exemption, is broader then an "experimental use exception" because it excuses more than the *use* of patented inventions in FDA-related research; the whole range of actions usually constituting infringement -- including sales and importation -- is exempted.

Three basic interpretative issues have dominated the case law applying the statutory exemption: 1) whether the word "solely" should be interpreted to apply independently to each use 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. The Supreme Court has considered the latter two questions and taken an expansive approach to interpreting the

[30] *See* 733 F.2d at 863.
[31] *Id*. at 860.
[32] *Id.*
[33] *Id.* at 861.
[34] *See* 35 U.S.C. § 271(e)(1).
[35] *See id.* § 156(a).
[36] *See id.* § 271(e)(1).

exemption. Lower courts have also generally given the exemption a broad scope with respect to the first. As a result, the statutory exemption may apply to uses for which the development and submission of information to the FDA is one of several uses; the exemption applies broadly to medical items regulated by the FDA (including medical devices); and some pre-clinical research and research aimed at identifying new drugs candidates can be "reasonably related" to FDA approval so as to qualify for the exemption.[37]

The recent case of *Merck KGaA v. Integra LifeSciences Ltd.*,[38] dealt with the question of how far back in the research chain the statutory research exemption extends. What does it take for a research project to be "reasonably related to the development and submission of information" to the FDA? 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 showing safety and efficacy for final approval. *Merck* involved attempts to inhibit "angiogenesis," considering several drug candidates of a class of chemicals known as "RGD peptides."

The Federal Circuit (over an extensive dissent by Judge Newman) took a narrow view of the statutory exemption and held that it did not apply to the pre-clinical tests of the RGD peptides at issue in the case. The Supreme Court, however, rejected 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."[39] It also rejected an argument that the exemption should be limited to experiments which actually result in information that is 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."[40] Instead, the Supreme 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."[41] The fact that the results of a particular set of experiments are not included in an eventual FDA submission does not remove them from the protection of the statutory exemption, "as long as there is a reasonable basis for believing that the experiments will produce 'the types of information that are relevant to [an FDA submission]."[42] 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

[37] For a somewhat more detailed review of the case law interpreting the FDA exemption, see Katherine J. Strandburg, *The Research Exemption to Patent Infringement: The Delicate Balance Between Current and Future Technical Progress*, in INTELLECTUAL PROPERTY AND INFORMATION WEALTH, Peter Yu, ed., in press.
[38] 125 S. Ct. 2372 (2005).
[39] Id.
[40] Id. at 2383.
[41] Id.
[42] Id.

researcher intends to induce, is surely not 'reasonably related to the development and submission of information' to the FDA."[43]

The Supreme Court's opinion in *Merck* did not address the issue of the general research exemption, nor its relationship to the statutory FDA exemption. It remains unclear whether there can be a "gap" between very early stage basic research covered by the general exemption and research "reasonably related to FDA regulation" and thus exempted by statute. The Court also specifically declined to take up the question of whether the statutory FDA exemption protects the unauthorized use of a patented invention when it is used as a research tool to study a potential drug or medical device, because in its view the case did not involve a research tool use of the patented RGD peptides.[44]

While no court decision concerning either the general judge-made research exemption or the statutory FDA exemption has yet turned on the research tool issue, the question has become increasingly salient. The increasing public concern with the research tool question is evident from the number of *amicus* briefs filed in the Merck case addressing the issue -- even though the research tool issue was not mentioned in the questions presented to the Court and was not considered by the Court. The interest of some Federal Circuit judges in the issue is evident not only from Judge Newman's *Integra* dissent, but also from the fact that Judge Rader focused his questioning in the oral argument following remand of the *Merck* case from the Supreme Court on the research tool issue despite the fact that both parties contended (correctly, as I read the Supreme Court's opinion) that the issue was not presented on remand. The remaining parts of this Article discuss the research tool issue, first explaining how previous scholarly commentary has approached it, and then arguing that the concept of "user innovation" may provide us with a way out of the conundrum the research tool question presents.

IV. "EXPERIMENTING WITH" A PATENTED INVENTION: THE CONUNDRUM OF RESEARCH TOOLS

An exemption for "experimenting on" is closely tied to the historical justifications for the general research exemption, to patent disclosure doctrine, and to well-established patent policy. Separating out the disclosure-related instances of "experimenting on" a patented invention from "experimenting with" a patented invention as a research tool takes us only part of the way, however. It tells us nothing about what to do about the conundrum of research tools. The research tool patent question has generated at least as much scholarly concern -- and controversy among commercial actors -- as the issue of patentee control over experimentation aimed at improving a patented invention.[45] This concern is due to the obvious fact that 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,

[43] Id. at 2382.
[44] Id. at n7.
[45] *See generally* Eisenberg, *supra* note 4; O'Rourke, *supra* note 15; Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L. Rev. 1 (2001).

while inventive progress is wide open to anyone who can make use of the inventive idea. During the patent term, the public benefits by widespread availability of both the embodiments of the invention (through commercialization by the patent holder and licensees) and the inventive idea (through self-disclosure or the patent document).[46] As long as disclosure is complete (and "experimenting on" is permitted), the inventor cannot use her exclusive control over the primary invention to slow the pace of follow-on innovation.

In contrast, when research tools are patented, the most significant "Progress [in the] . . . useful Arts"[47] usually depends upon using an embodiment of the invention—the research tool itself—to make a further, and often patentable, innovation. The primary financial (or, in the case of non-profit researchers, reputational) return may flow from exclusive control of the research *results* rather than from widespread commercial use of an embodiment of the research tool. Thus, to determine whether a research exemption should apply to patented research tools, the effects of patenting on subsequent innovation *using the tool*—not just the idea—must be considered. When a patented invention is used as a research tool, the questions of compensation for the initial invention and control of follow-on innovation (the "product" market and "innovation" market distinction, as explained by Dinwoodie and Dreyfuss[48]) are entangled. A research tool exemption intended to free up the innovation market has the potential to cut directly into the product market -- and hence the incentives to invent -- for the research tool.

A. Why a Research Tool Exemption?

Given the potential impact on incentives for tool inventions, why consider a research tool exemption at all? The concern with patented research tools arises from the fear that a research tool may give the tool inventor the ability to block technological progress by controlling the research that may be performed using the tool so as to maximize the return to the tool patentee at the expense of society. To determine under what circumstances this concern is justified, we must ask two questions. 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.[49] Even if a patentee restricts use of the tool, there are two prerequisites

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[46] Patentees are not required to commercialize their inventions, of course. Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1547 (Fed. Cir. 1995). However, the incentive theory assumes that they generally will if they can. Thus, ordinarily, if an invention is not commercialized, it is reasonable to assume that there is not a sufficient market for the invention to justify society's "reimbursing" the inventor for her research efforts. Because society's interest in the availability of improved commercial products and processes is generally aligned with the inventor's interest in recouping investment, there is generally little reason to police whether inventors commercialize their inventions. As discussed herein, however, the research tool case may be an exception to this generally felicitous alignment.

[47] U.S. CONST. art. I, § 8, cl. 8.

[48] 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).

[49] *See* Mueller, *supra* note 44, at 15. This is an oversimplification, of course, because a patented research tool will presumably still be more expensive than it would be if not patented. But this kind of price increase is an unavoidable and necessary result of patenting any type of invention. The important

for a tool patentee to exercise significant control over the progress of research in the applicable field: there must be no close substitutes for the tool and there must be no close substitutes for the research projects requiring 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 using the tool.[50] Likewise, if researchers are relatively indifferent between problems requiring a patented tool and a whole host of similarly important problems for which they do not need to use the tool, then the patentee will not exercise significant power over research progress.[51] Only when the research tool is of substantial significance to an important problem, does the potential for serious adverse public impact from a research tool patent arise.[52] A good example of this type of research tool might be the BRCA1 and BRCA2 diagnostic kits for breast cancer.

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. It may also be important to have a diversity of perspectives applied to determine creative uses for a research tool, especially where the tool has wide application or is relevant to a particularly difficult problem.

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.[53] Kitch analogized patents to mineral claims, arguing that 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.[54] 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."[55]

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characteristic of widespread commercial availability is that it decouples control over research using the tool from recovering the toolmaker's investment.

[50] For this reason, the tool inventor is also likely to make the tool commercially available or otherwise to ensure access by the most effective researchers because the alternative is not to profit from the eventual research at all.

[51] For an exploration of these issues in the molecular biology context and some case studies of research tools that are and are not made broadly available, see NATIONAL RESEARCH COUNCIL, INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY (1997), *at* Nat'l Academy Press, http://books.nap.edu/html/property/ (analyzing case studies in chapter five).

[52] For a similar discussion of the conditions under which problems with access to research tools can arise, see John P. Walsh et al., *supra* note 20, at 332–33.

[53] *See Edmund W. Kitch, The Nature and Function of the Patent System, 20 J.L. & Econ. 265 (1977)* (arguing that the patent system performs a function not previously noted: to increase the output from resources used for technological innovation); *see also* Yoram Barzel, *Optimal Timing of Innovations*, 50 REV. ECON. & STAT. 348, 349 (1968).

[54] Kitch, *supra* note 52, at 276.

[55] Richard D. Nelson and Roberto Mazzoleni, *Economic Theories About the Costs and Benefits of Patents,* in INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY (Nat'l Academies Press (1997).

Developing a research tool may not always be a reasonable signal of competence to mange the difficult -- and potentially diverse -- research that employs the tool. This is especially the case when there is a relatively low standard of obviousness for patentability and there is a race to develop and patent "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 more 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 do the research in house, settling 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.[56]

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. For research projects 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 to be able to keep a larger share of the benefits of the research may be correspondingly great.[57]

At this point, a judgment call must be made. The question is whether society is most likely to benefit from competitive (and hence potentially duplicative) research or from coordinated (and hence potentially delayed by private rent-seeking or ineptitude) research. Economic arguments have been advanced for both positions.[58] We have, as a society, generally presumed that competition fosters innovation. This presumption is echoed by the scientific community, which views research as an activity that is not susceptible to central planning.[59]

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, at least if the tool inventor is not able to perform the research herself in a reasonably short time. There are many ways to accomplish this -- through patenting and commercial supply of the tool; through widespread non-exclusive licensing; or by publication or other free revealing without

[56] A related problem arises when the patentee or an improver undervalues the social benefits created by an invention because those benefits do not inure to the patentee or improver. *See* Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 Tex. L. Rev. 989, 993–95, 1056-58 (1997).

[57] *See id.* at 1059–61 (discussing other noneconomic incentives).

[58] For the classic expositions of these arguments, see JOSEPH A. SCHUMPETER, CAPITALISM, SOCIALISM, AND DEMOCRACY 106 (3d ed. 1942) (arguing in favor of monopoly as promoting innovation); Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention* (1962), *reprinted in* 5 KENNETH J. ARROW, COLLECTED PAPERS OF KENNETH J. ARROW: PRODUCTION AND CAPITAL 104, 115 (1985) (arguing that competition best promotes innovation).

[59] Eisenberg, *supra* note 4, at 1059–65. Of course, there have been notable successes of highly focused large scientific enterprises such as the space program and the Manhattan Project. But projects involving such great expense or such national security ramifications are the exception rather than the rule. The scientific norm calls for bottom-up proposals for research projects, evaluated by shifting groups of peer reviewers, and performed by fluid collaborations of globetrotting researchers.

patenting.[60] Since tool inventors often have private incentives to control the research stream by not making the tool widely available, a research tool exemption might play a role in accomplishing this social purpose.

B. Previous Proposals for a Research Tool Exemption

In approaching the research tool issue, the difficult question has been how to design such an exemption so as not to interfere with incentives to develop research tools in the first place. Proposals for research exemptions for research tool use (including my own earlier proposal) have therefore focused on limiting the effects the exemption would have on commercial incentives for developing research tools. Three basic types of approaches have been proposed: 1) exemptions applying only to nonprofit research;[61] 2) exemptions inspired by copyright "fair use";[62] and 3) compulsory licensing.[63] Each of these proposals attempts to deprive a tool patentee of some degree of control over research using the tool while maintaining incentives for invention through a market for research tools. Each has also assumed that a primary incentive for tool development is the ability to recoup investment through sales and licensing of the tool. This assumption is scrutinized in subsequent Parts of this Article. Before proceeding to that analysis, this Part reviews previous proposals for exemptions for research tool use.

1. Exemptions Applying Only to 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 these patents may impose a tax on basic research and research devoted to the public interest, and that nonprofit researchers may be priced out of the market for lucrative research tools. There is also a concern that exclusive control over research tools will distort the problems to which they are applied, focusing their application on lucrative short-term projects, resulting in the neglect of longer-term research which may better promote the public good. It is thus natural that exempting nonprofit research is a major focus in proposals for a research tool exemption to infringement liability.[64] The idea that nonprofit research

[60] This choice is also supported by the likelihood that, given the option to license a research tool, mainly those researchers who have a reasonable chance of success will take licenses and make the investment necessary to perform the research. While some researchers may be susceptible to erroneous assessments of their own research abilities, they have many advantages over the research tool patentee in performing this self-selection. They have more accurate information about their own abilities to perform the research and, because they do not have exclusive rights to the tool, have no capacity to delay the research for strategic reasons.

[61] See, e.g., Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense arrived?*, 46 Ariz. L. Rev. 457, 462-63 (2004).

[62] See O'Rourke, *supra* note 15; Janice M. Mueller, The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development, 56 Baylor L. Rev. 917 (2004).

[63] See Mueller, supra note 44; Strandburg, supra note 3.

[64] Proposals for a research exemption for nonprofit research often do not distinguish between "experimenting on" and "experimenting with" a patented exemption as I do here. Because I believe that the arguments for an "experimenting on" exemption are convincing for all patents, I focus on the

should be exempt from infringement liability also hearkens back to the "general" research exemption and its focus on the commercial/non-commercial distinction. This history makes a nonprofit exemption attractive as a strategic matter as well, since it suggests a return to "what has always been done."

As a number of scholars have recognized, however, there are both theoretical and practical difficulties in implementing a nonprofit research exemption in today's scientific and technological world. Rochelle Dreyfuss recently articulated three developments which she 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." Unfortunately, these same three developments also illustrate the difficulty in implementing a simple nonprofit research exemption. Even as a theoretical matter, the distinction between basic and applied research which at one time dominated thinking about science policy is no longer tenable.[65] 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 the same invention in basic research. This change in the relationship between science and technology (and in how that relationship is perceived) has implications for both the inputs and outputs of the research stream of a nonprofit institution. It has become far more likely that a nonprofit researcher will need to make use of a commercially important "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. Thus, university and other nonprofit researchers have become more likely to need to make use of a patented invention (which is one reason for the increasing need for a research exemption) and more likely to produce patentable inventions in their research.

This situation leads to what Professor Dreyfuss characterizes as a "vicious cycle." As research costs rise due in part 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. Finally, Professor Dreyfuss points out a larger societal shift to a more propertized view of the outputs of creative activity. That shift arguably affects university research in two ways: it changes the social expectations of individual scientists as to the "ownership" of their research results and changes the expectations of the larger society as to whether those whose primary output is knowledge should be expected to "fend for themselves" in the market.

These changes result in both a political and a practical problem in defining a research exemption for nonprofit research. The increased entanglement between nonprofit and industrial research, and, even more so, the increasing patenting by nonprofit researchers, makes it more difficult as a political matter to argue for special treatment of nonprofit actors. As a practical matter, the increasing extent to which

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applicability of these proposals to the more difficult research tool case but those who are not convinced may take a broader view of these proposals.

[65] *See, e.g.*, Dreyfuss, *supra* note 60 at 462-63 (2004)

industrial players are involved in university research (and *vice versa*) makes it more difficult to distinguish nonprofit research activities from those with for-profit motivations.[66]

Professor Dreyfuss[67] (with "friendly amendment" by Professor Richard Nelson[68]) has made an ingenious proposal which avoids some of these difficulties. The 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.[69] The proposed waiver has the virtue of requiring nonprofit researchers to self-identify using a certification with some of the flavor of an open source license of the "non-viral" variety. It also selectively applies to those research programs that are least likely to compete with commercial research.

This proposal is an elegant solution to the problem of identifying truly "nonprofit" research. However, there are remaining concerns. First, the waiver proposal suffers to some extent from its very advantage -- its self-selective process will preclude (or at least limit) its applicability to commercially significant research. It will likely not (and was not intended to) solve the problem of the potential for inventors of research tools to have excessive (from a social perspective) control over the pace and course of tool-based research with potentially lucrative applications, whether that research takes place in the nonprofit or for-profit sectors. Moreover, as Professor Dreyfuss recognizes, there is a question whether, in today's atmosphere, waivers would ever be filed. The proposed waiver is in some tension with the Bayh-Dole Act since it requires the researcher to forego any exclusive licensing of research results. The Bayh-Dole Act was intended to promote technology transfer from universities to the private sector precisely through the mechanism of exclusive patent licensing. Those who are skeptical as to the extent to which university patenting is necessary or successful as a mechanism of technology transfer (and I count myself among them) may not be much bothered by this, but university officials may be, especially if there is some chance of a commercially significant result. It is thus possible that even researchers who might wish to waive their patent rights will be discouraged by university administration from taking advantage of a nonprofit exemption that requires such a waiver.

Professor Dreyfuss suggests an additional "carrot" for signing a waiver by permitting "buyouts" in which a waiver can be rescinded in exchange for payment of retroactive royalties. The "buyout" possibility would certainly make the filing of a waiver more attractive, especially for those projects that have some potential for commercially interesting results. However, it might be almost too attractive -- now rather than no one filing a waiver, perhaps everyone would, turning the waiver regime into

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[66] These entanglements also increase the potential for a number of agency problems with respect to the university's public mission. See, e.g., Patrick L. Jones and Katherine J. Strandburg, *Technology Transfer and An Information View of Universities: A Conceptual Framework For Academic Freedom, Intellectual Property, Technology Transfer and the University Mission* (working paper).

[67] *See generally* Dinwoodie & Dreyfuss, *supra* note 47; Dreyfuss, *supra* note 60.

[68] Richard Nelson, *The Market Economy and the Scientific Commons* (Nat'l Bureau of Econ. Research, Summer Inst. Working Paper, 2003), *at* http://www.nber.org/~confer/2003/si2003/papers/pripe/nelson.pdf.

[69] *See id.* at 8–10.

essentially a compulsory licensing proposal for nonprofit entities. Perhaps this is the point. If nonprofit research efforts rarely lead to commercially significant results, a compulsory licensing scheme that only occasionally requires royalty payments may be socially preferable to a whole series of negotiated licenses which rarely result in significant payments.

Another approach is proposed in a National Research Council report.[70] 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."[71] 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 would provide a significant nonprofit exemption. Because of the availability of damages to patentees, it would also amount in essence 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 implementation. 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.[72]

Another approach, which targets recipients of federal funding as inventors and users of research tools, is exemplified by Principles and Guidelines for grant recipients that were adopted by the National Institutes of Health ("NIH").[73] These Principles and Guidelines seek to "promote utilization, commercialization, and public availability of [NIH funded] inventions" and note that research tools for which "further research, development and private investment are [not] needed to realize their primary usefulness," the goals of technology transfer "can be met through publication, deposit in an appropriate databank or repository, widespread non-exclusive licensing, or any other number of dissemination techniques. Restrictive licensing of such an invention, such as to a for-profit sponsor for exclusive internal use, is antithetical to [these goals]." These Principles and Guidelines are to be taken into account when NIH funding recipients consider their own intellectual property approaches and when they enter into contracts with for-profit companies. The Principles and Guidelines also address the types of agreements into which NIH funding recipients might enter with for-profit companies to acquire the use of research tools, and attempts to restrict the use of certain licensing provisions that might "interfere with the open dissemination of research tools." More recently, the NIH has adopted "Best Practices for the Licensing of Genomic Inventions" which state that funding recipients should "consider whether significant further research

[70] See NAT'L RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY (2004).
[71] Id. at 115-17. See also 28 U.S.C. 1948(a)]
[72] 35 U.S.C. § 203. *See also* David C. Hoffman, *Note: A Modest Proposal: Toward Improved Access To Biotechnology Research Tools By Implementing A Broad Experimental Use Exception,* 89 CORNELL L. REV. 993, 1008 (2004).
[73] National Institutes of Health, *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice*, 64 FED. REG. 72090 (December 23, 1999).

and development by the private sector is required to bring the invention to practical and commercial" fruition and when this is not the case "best practices dictate that patent protection rarely should be sought."[74] The Best Practices also urge the pursuit of non-exclusive licensing whenever possible. Because nonprofit researchers with federal funding are the inventors of many important research tools, this approach, if successfully implemented, has great potential to increase the availability of research tools. It is, of course, limited to those tools invented with NIH funding (though other agencies could adopt similar guidelines) and is limited by the extent to which it is enforced by the agency.

The NIH guidelines are notable more generally, however, because of their focus on the incentives of particular classes of inventors of research tools, rather than only on the status of potential users. Part VI of this Article returns to this point.

2. "Fair Use" Approaches to a Research Tool Exemption

Several scholars have argued that patent law should adopt a "fair use" approach inspired by the copyright "fair use" defense.[75] Though the specifics differ, the basic thrust of the fair use 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. Because of their case-by-case approach, these proposals do not generally make categorical distinctions between "experimenting on" and "experimenting with" a patented invention, though this distinction may factor in to the fair use analysis.

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.[76] More recently, Professor Janice 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' or 'with' a claimed invention; 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.[77] Professor Lorelei Ritchie de Larena suggests basing a patent fair use test on an adaptation of the copyright fair use factors.[78] All of these proposals suggest that, in some cases, a court-imposed fee to compensate the patent owner and preserve incentives to invent should accompany patent fair use.

The advantage of a fair use approach is its ability to take a nuanced approach to specific situations, along with the fact that it can be applied to both commercial and noncommercial research tool use. Unfortunately, the disadvantages of a fair use

[74] National Institutes of Health, *Best Practices for the Licensing of Genomic Inventions: Final Notice*, 70 FED. REG. 18413 (April 11, 2005).
[75] See O'Rourke, *supra* note 15; Mueller, *supra* note 61; 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).
[76] O'Rourke, *supra* note 15.
[77] Janice M. Mueller, supra note 61.
[78] De Larena, supra note 82.

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. Analogous problems with fair use are a focus of extensive discussion in the copyright arena and there is significant dissatisfaction with the doctrine. Moreover, a fair use analysis may have a tendency to replicate the instability of the commercial/non-commercial distinction because proposed tests rely in one way or another on the extent to which the use is commercial in nature. Moreover, most of the patent fair use proposals envision a *post hoc* fee in some cases. Research tool use is likely to be subject to a fee because of the way in which unauthorized use of a research tool patent affects potential direct sales of the patented invention. The possibility of charging a fee for a patent fair use poses further complications, though perhaps not many more than are presented in a typical patent infringement damages case.

3. Compulsory Licensing Proposals

Compulsory licensing authorizes some potential infringers to use a patented invention without authorization, but requires that the patentee be compensated for the use. Generally, the compensation takes the form of a government-determined royalty. Like litigation, the availability of a compulsory license often serves as an incentive for parties to negotiate to avoid the uncertainties of a governmental determination of the terms of the license. Compulsory licensing schemes have also been proposed to deal with patented research tools. [79] For example, Mueller has made a detailed proposal for compulsory licensing of research tools, in which she suggests compulsory licensing for "research tools not readily available for licensing on reasonable terms or via anonymous marketplace purchase."[80] 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.[81] Professor Donna Gitter has endorsed a similar proposal specifically for gene sequences.[82] Compulsory licensing provides compensation to the tool inventor (thus maintaining commercial incentives to invent) but frees others to perform tool-based research. Because compulsory licensing requires payment from the user, it can apply to all researchers, whether commercial or noncommercial. It effectively forces a tool inventor to choose between researching in secret and broadly commercializing the tool. Having a compulsory license available eliminates the option of using a patent to secure a longer period for in-house research than is possible with trade secrecy (control over the "innovation market").

Criticisms of compulsory licensing schemes for patents arise from an underlying concern that compulsory licensing depresses the returns that a patentee may capture. [83] In

[79] *See, e.g.*, Tom Arnold & Paul Janicke, *Compulsory Licensing Anyone?*, 55 J. PAT. OFF. SOC'Y 149, 149 (1973); Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1628 (2001); Cole M. Fauver, Comment, *Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come*, 8 NW. J. INT'L L. & BUS. 666, 668 (1988).
[80] Mueller, *supra* note 44, at 58.
[81] *Id*.
[82] *See generally* Gitter, *supra* note 78.
[83] See, e.g., Richard A. Epstein, *Steady the Course: Property Rights in Genetic Material*, in PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 153–56 (F. Scott Kieff ed., 2003).

most situations, a compulsory license may be a poor substitute for a freely negotiated arrangement. Dreyfuss, however, has pointed out several practical reasons why research tools are a special case where compulsory licensing could be particularly successful.[84] But the more fundamental response to criticisms of compulsory licensing is that, where research tool patents are being used to control the "innovation market" rather than to recoup development investments through the "product market," it is precisely the goal of a research exemption to change the threat positions of the parties and to force the tool patent holder to deal with those who may be better able to perform socially beneficial tool-based research. As discussed in subsequent Parts of this Article, for most tools, we need not even be too concerned that the administrative costs or reduced royalties associated with compulsory licensing might deter some potential tool developers. Incentives for researchers to take care of tool development as part and parcel of doing the research are left intact.

Compulsory licensing is a means of decoupling exclusive control of the research stream itself from exclusive control of 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.[85] 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 supra-competitive 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.

V. THE IMPORTANT ROLE OF RESEARCHER INNOVATORS IN INVENTING RESEARCH TOOLS

Despite their differences, all of the proposals for research tool infringement exemption thus far run up eventually against the presumed need to compensate the tool patentee for most uses of the tool 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 (with the primary exception of the NIH Principles and Guidelines) have failed to look deeply into whether patent incentives are significant in promoting the invention,

[84] Rochelle Cooper Dreyfuss, *Varying the Course in Patenting Genetic Material: A Counter-Proposal to Richard Epstein's Steady Course* (N.Y.U. Law School, Pub. L. & Legal Theory, Research Paper Series 2003).
[85] Strandburg, supra note 3 at 142-45.

disclosure, and widespread dissemination of particular types of research tools.[86] There are two reasons to take a more careful look at the incentives of research tool inventors. First, for reasons that will be discussed in more detail below, a large fraction of inventors of research tools are research tool users rather than research too 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.[87] Second, a large fraction of research tool inventors are researchers working in nonprofit venues, such as universities and national laboratories. A growing body of research also emphasizes the non-commercial incentives and social norms that may motivate these researchers.[88] Because nonprofit researchers and researcher innovators (a partially overlapping group) play such an important role in research tool invention, a closer look at the incentives of different potential tool inventors may help to devise a more effective research tool exemption.

Research tool inventors fall into four main groups: nonprofit researcher innovators, commercial researcher innovators, research tool suppliers, and commercial research tool licensing firms (companies whose business plans revolve around inventing high-tech research tools and then licensing the resulting patents either to tool manufacturers or to tool users). Researcher innovators face different incentives both to invent and to disclose the invention of research tools than commercial tool manufacturers or tool "licensers."

A. The Incentives of Nonprofit Researcher Innovators

1. Incentives to Invent Research Tools

Many research tools are invented by nonprofit researcher innovators. These researchers, many of whom are university faculty, postdoctoral researchers, and graduate students, invent research tools to use to be more effective in their own research. Indeed, the question of why they invent research tools would probably strike most researchers as somewhat inane -- inventing research tools and methods is a large part of what many of these researchers do. These researchers are likely not motivated to invent research tools by the prospect of commercial sales or licensing of the tool. Instead, like user innovators more generally, they benefit directly from their own innovative activity. Their primary focus is on obtaining research results, which provide them with benefits in the form of professional reputation, intellectual satisfaction, ability to obtain their own funding, and

[86] This is not to say that none of the analyses to date have taken any account of the fact that many research tools are invented by researchers. Dreyfuss's waiver proposal implicitly treats nonprofit tool inventors differently if the tool inventions result from research that employs other research tools on the basis of the nonprofit waiver. My own earlier work assumes that research tool inventors may choose to perform the research "in-house" using trade secrecy and thus implicitly assumes that some tool inventors are also tool users. But the effects of different types of incentives and rewards for different types of tool inventions have not been systematically considered.

[87] *See, e.g.*, Eric von Hippel, Democratizing Innovation (2005) and references therein.

[88] *See, e.g.*, Katherine J. Strandburg, *Curiosity-Driven Research and University Technology Transfer*, *in* Gary D. Libecap, ed., Advances in the Study of Entrepreneurship, Innovation, and Economic Growth (2005) and references therein.

the ability to participate in an ongoing social discourse which they enjoy.[89] 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 generally have significant expertise and resources available to develop their own tools. On the leading edge, research tools are often heterogeneous (specialized to a particular researchers attack on a problem) and ex ante there is often no guarantee of a broad enough market for the tool to warrant commercial interest. The unpredictability of research and the hands-on nature of science also favor tool innovation by the researchers themselves. Researchers may often be hard-pressed to describe their needs to a commercial manufacturer. They may have know-how about their particular experimental needs that is difficult and costly to transfer to a tool manufacturer. Commercial manufacturers may be too removed from the research to perceive exactly what tool is needed. Even when a researcher sends out "specs" to a custom manufacturer for a piece of equipment, for example, the inventive activity may be primarily or entirely that of the researcher. The pace of research also militates against relying on a commercial R&D process to provide leading edge tools. Researchers often prefer the flexibility of "tinkering" with a tool as the research progresses to obtain better understanding of how the tool is working and to make needed changes "on the fly." Developing a tool is often 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 a tool for more general use, in things such as safety and stability, and in minor improvements that do not have significant effects on research functionality.[90] Researcher innovators may also be less likely than commercial tool manufacturers to invent general-purpose tools that 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. This does not mean that research innovators never produce this kind of general-purpose tools. On the contrary, academic scientists have demonstrated an immense ability to cooperate on projects that are advantageous to the group as a whole. Academic scientists have done this with collaborative grant proposals for large facilities that are made available to all. High energy particle accelerators, supercomputing facilities, and the Human Genome Project are examples of this type of researcher innovation. Part of the reason that nonprofit researchers are motivated to collaborate on this type of large-scale project is that the rewards they get from research are not only reputational, but also intellectual and social. Theirs is not a strictly competitive game; they benefit individually when the whole field advances.

To summarize, nonprofit researcher innovators have intrinsic incentives to invent "leading edge" research tools that increase the speed and effectiveness of their research. They are motivated to develop specialized tools and methods that are adapted to their particular projects. They may also be motivated in some circumstances to pool their resources to produce large-scale tools that advance the entire field. They are considerably less motivated to produce the kind of inventions that involve standardizing a tool, making it cheaper or easier to manufacture, making it easier to use, or adapting a tool for more general uses. The traditional patent "incentive to invent" will have little

[89] *Id.*
[90] See Hippel, *supra* note 86 at 70-71.

force for nonprofit researcher innovators as long as they are able to obtain funding for their research from government grants and so forth.

2. Incentives to Disclose Research Tool Inventions

Nonprofit researcher innovators have mixed incentives when it comes to disclosing their research tools. The usual categories of "self-disclosing" and "non-self-disclosing" based on the nature of the invention do not matter to researcher innovators because they intend not to market the tools, but to use them. Because they can be used in a researcher's own laboratory, research tools may easily function as "non-self-disclosing" in use 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 they can use them to advance their own research agendas.

Despite these incentives for research tool "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 future research funding. For these researchers, frequent publication is the key means to obtain professional status and rewards, limiting their ability to keep research tools secret. Graduate students come and go, needing to publish, give presentations, and write detailed doctoral theses, and taking with them their knowledge of research methodology (of which they are often joint inventors). Scientific norms and competition between universities preclude saddling graduate students with the type of "non-compete" agreements common in industry. Moreover, scientific publication of a new research method ensures that the authors of the publication receive credit for developing the new technique. They may gain opportunities for collaboration through their expertise in a new and useful research method. The likelihood of independent invention of a particular tool by a competitor also limits the potential returns to secrecy -- particularly where publication and collaboration provide alternative mechanisms for appropriating benefits from the invention of a research tool. Exchange of information about research tools and methods is also part of the social currency of exchange within the research community; membership in this community is important to obtaining 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, there may be a desire to "outsource" further tool development to a tool manufacturer in order 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 more than a few years at most.

3. Incentives to Disseminate Research Tools

Standard discussions of patenting stop at the incentives to invent and disclose. When the inventor is a commercial actor, there is an implicit assumption that the inventor of a new product will seek to ensure dissemination of the product to consumers one way or another, for that is how the rewards for invention are obtained. Nonprofit researchers do not have the same 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. Without a concerted effort (and some incentives in the form of royalty revenues), the concern is that the inventions of nonprofit researchers will simply languish and not be exploited to their full, socially beneficial, potential.

As a general matter, the need for special technology transfer efforts to disseminate university inventions is a matter for debate and no doubt depends upon the particular invention. However, the need for such special efforts to disseminate (beyond disclosing) must surely be at a low ebb where research tools are concerned. The general assumption underlying the patent system is that knowledge that is already in the public domain is "ripe for the picking" and will be brought to market without special incentives. There are basically two types of reasons to suspect that this may not be the case for university inventions: 1) commercial firms may lack the absorptive capacity to adopt university inventions;[91] and 2) university inventions may tend to be "embryonic" and far from practical usefulness, thus requiring large investments to bring them to market. The concern with absorptive capacity encompasses such things as lack of scientific expertise and know-how, as well as search costs imposed by unfamiliarity with the scientific literature. One would expect that these concerns would be largely absent in the research tool context for several reasons. First of all, while the *results* of nonprofit research may tend to be "embryonic" and far from application, at least in some fields, the research *tools* developed by nonprofit researchers will obviously be developed to the point at which they can be used as tools. Since the users of these tools are other researchers, the concerns with absorptive capacity are also significantly lessened, as researchers 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. Moreover, to the extent that use of a particular research tool requires "know-how" which is not imparted by publication, the social structure of scientific research facilitates dissemination through collaboration and movement of research personnel (particularly graduate students and postdoctoral researchers) between nonprofit laboratories, and between the nonprofit sector and industrial laboratories. Indeed, upon disclosure of a research tool, researcher innovators can benefit from widespread dissemination of their research methods through attribution and collaboration.

For some research tools, the time will come when there will be a market for a commercial version of the tool. While the incentives of tool manufacturers will be discussed below, for now, it is sufficient to note that research tool suppliers will generally have substantial expertise and familiarity with research tools that are developed in the laboratories of nonprofit researchers (who are their customers, after all). They also have the ability to hire university faculty as consultants and university graduates as employees as a means to transfer "know-how."

[91] *See, e.g.*, W. Cohen and D. Levinthal, *Absorptive Capacity: A New Perspective on Learning and Innovation*, 35 ADMIN. SCI. Q., 128 (1990).

For these reasons, even though nonprofit researchers may not have substantial incentives or the expertise to promote the commercial dissemination of their research tools, it is likely that dissemination of research tool inventions will occur rather easily and naturally once the researcher discloses the tool.

4. The Role of Patents for Nonprofit Researcher Innovators

Patents are unlikely to play a significant role in the incentives of nonprofit researchers to invent and disclose research tools unless those researchers are strapped for funding and driven to select research projects likely to lead to widely marketable tools.[92] As argued above, 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. Of course, patenting may affect the dissemination of these research tools. In some cases, patenting may make research tools more widely available through licensing to a commercial tool supplier, but those cases may be rare due to the many means of dissemination directly from researcher to researcher and due to the incentives that tool suppliers will have to market these tools even if the researcher innovator does not patent them. In most cases of researcher innovation, patenting is likely to reduce dissemination of the tool, since nonprofit 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 that may pay a premium for the ability to maintain control over the commercial research stream that the tool enables. Note again that the situation is different here than it is for the *results* of nonprofit research, which may be so embryonic as to require significant incentives for commercial investment.

B. The Incentives of Commercial Researcher Innovators

1. Incentives to Invent Research Tools

Like nonprofit researcher innovators, commercial researchers are primarily rewarded based on the results of their research. Indeed, some commercial researchers publish their research in scientific journals and are motivated by many of the same types of reputational rewards as nonprofit researchers, while only the possibility of obtaining commercially viable results will motivate other commercial researchers. Either way, commercial researcher innovators, like nonprofit researcher innovators, are motivated to invent by their own expected use of the tools. One might expect that commercial researchers would be less likely than nonprofit researchers to pool their resources to create general-purpose tools. While this is probably true, there is increasing recognition of the importance of such collaborative efforts in the commercial sector. Standards-

[92] See, e.g., Strandburg, supra note 87; Brett M. Frischmann, *Commercializing University Research Systems in Economic Perspective: A View From the Demand Side, in* Gary D. Libecap, ed., ADVANCES IN THE STUDY OF ENTREPRENEURSHIP, INNOVATION, AND ECONOMIC GROWTH (2005); Jerry G. Thursby and Marie C. Thursby, *Who is Selling the Ivory Tower: The Sources of Growth in University Licensing*, MGMT. SCIENCE (January 2002) for discussions of the relationship between patenting and the research projects chosen by university researchers.

setting bodies, groups like the SNP Consortium, and industry participation in open source software projects provide examples of commercial participation in collaborative efforts.

2. Incentives to Disclose Research Tool Inventions

Commercial researchers who do not seek to publish their results would certainly have fewer incentives to reveal their research tool inventions were it not for patenting. Commercial researchers have greater ability to maintain trade secrecy and fewer means to appropriate the benefits of disclosing information about their research tool innovations than nonprofit researchers. Trade secrecy is leaky in general, however, for several reasons. Even in the commercial context, there is evidence of considerable free revealing.[93] Other researchers may independently invent the same or substitutable research tools. And there is always the danger of industrial espionage or theft of trade secrets by present or former employees. Moreover, the research context adds some special limitations on trade secrecy. In some cases commercial researchers may be working in the same areas as nonprofit researchers who have all of the incentives to disclose we have just discussed. Commercial researchers may also benefit from the reputational boost that generally flows from developing a cutting edge research method. For example, firms may encourage their researchers to disclose research tools to enhance the reputation of a firm's research within the industry, which may play a key role in attracting new employees.

The extent to which the patent "quid pro quo" is needed to incentivize disclosure of research tool inventions by commercial researcher innovators is thus variable, but certainly lessened in fields with substantial nonprofit research.

3. Incentives to Disseminate Research Tools

Commercial researcher innovators are less likely than nonprofit researcher innovators to disclose their research methods, but, if the tools are disclosed, commercial researchers are more likely than their non-profit counterparts to disseminate them through commercial licensing or commercial tool manufacture. They may also reveal some of their inventions as part of an informal exchange process with other researchers in the field.[94] However, commercial researcher innovators are likely, when they can through trade secrecy or patenting, to maintain exclusive control over important research tool inventions so that they can maintain control over the related research streams.

4. The Role of Patents for Commercial Researcher Innovators

Because commercial researchers have greater ability and incentives to maintain trade secrecy than nonprofit researchers, patents may play a correspondingly larger role in the disclosure of their research tool inventions. As for nonprofit researcher innovators, patents likely play a rather small role in incentivizing research tool invention by these researchers. Patents are also unlikely in most cases to increase the dissemination of these research tool inventions, since commercial researcher innovators are likely to use

[93] See von Hippel, supra note 86 at 77-91 (discussing reasons for free revealing by users).
[94] Id.

patenting to maintain control over the research stream enabled by the tools. The societal benefit from patenting is arguable in this case and depends 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.

C. The Incentives of Commercial Research Tool Suppliers

1. Incentives to Invent Research Tools

Commercial research tool suppliers are ordinary commercial producers. They will have incentives to invent new tools or improve existing tools if they can recoup their investments through commercial sales. Their incentives to invent will be affected by how expensive it is to develop a particular tool, whether or not the tool is self-disclosing to competitors, what kind of market lead time they get by introducing a new or improved tool, and so forth. The inventive choices of research tool suppliers will probably be affected by the fact that researchers often invent their own tools. Their competitive advantage likely lies in the types of research tool inventions less likely to be made by researchers -- inventions relating to standardizing tools for more general application, making them more convenient and safer to use, making them cheaper and easier to manufacture, and so forth. Tool suppliers also have incentives to invent general-purpose research tools which require investments that are too large (relative to the usefulness of the tool) to be worth it for researcher innovators to invent. For some research tools, tool suppliers' incentives to invent may be affected more than in most other markets by the propensity of researchers to make "home-made" versions of some tools (those which are particularly easy and cheap to make relative to their price). Researcher propensity to make rather than buy a tool is a direct outcome of the balance between expenditure of financial resources and resources of time and attention.

2. Incentives to Disclose Research Tool Inventions

Research tool suppliers' incentives to disclose their inventions through patenting will depend on the usual trade-offs between the possibility of trade secrecy and the length of the patent term, which depend in part on the extent to which a research tool is inherently self-disclosing or easily reverse engineered. However, research tool suppliers may find it particularly difficult to maintain trade secrecy with respect to their inventions. A difference between research tools and ordinary consumer products is that the users of research tools are far more likely than consumers of products like television sets to demand a detailed understanding of the tool and how it works before purchasing the tool. Such knowledge may be crucial to the design and interpretation of experiments using the tool. Research tool inventions are thus more likely than other commercial products to be self-disclosing as marketed, since if the technology is not inherently self-disclosing, research tool suppliers may have to disclose its inner workings in the course of marketing the tool.

3. Incentives to Disseminate Research Tools

Research tool suppliers have every incentive, of course, to disseminate their own tool inventions via commercial sales. But it is worth emphasizing that research tool suppliers also play an important role in disseminating the tool inventions made by researcher innovators. There will be many tools that researchers will purchase from commercial suppliers rather than making them in-house. Researchers will purchase tools from commercial providers for the same reasons that consumers purchase commercial versions of anything they could make themselves -- the commercial provider will develop supply chains, expertise in tool manufacture, economies of scale, and so forth, which will make it more efficient and cost-effective for the researcher to purchase the commercial version than to make the tool herself. This is the case for many pieces of standard equipment, standard chemicals, and so forth, but it is also often true for more complex and specialized equipment (such as scanning tunneling microscopes, SQUID magnetometers, and the OncoMouse). Researchers will "make" tools in their own laboratories only when there is an advantage to doing so -- when commercially available tools are too expensive (a problem often mitigated by substantial nonprofit discounts), 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, or when making the tool is part of a learning process for the researcher. A common path of research tool development (probably the most common path, though empirical studies are limited) is for tools with new functionality to emerge from researcher innovators' laboratories, be gradually adopted and improved by researchers, and then be picked up by commercial manufacturers, who standardize them and make the types of improvements in convenience, reliability, accuracy, safety, and manufacturing techniques that are of general interest to a wide range of researchers.

4. The Role of Patenting for Commercial Research Tool Suppliers

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. In principle, patenting should also deter "user appropriation" of tool inventions, but in practice, because researchers are often unaware of, or essentially indifferent to, patents,[95] and because monitoring laboratory infringement is difficult and enforcing patents against researchers would involve suing the tool supplier's customers, patenting plays only a limited role in deterring "lab-made" versions of patented tools. Research tools suppliers deal with these issues to some extent through price discrimination -- offering lower prices to nonprofit researchers, for example. Patenting's "incentive to disclose" likely plays a relatively minor role for commercial research tool suppliers, who will usually have to disclose their tool inventions in order to sell them.

The ability of tool suppliers to obtain exclusive licenses to commercialize tools invented and patented by research innovators is probably much less important in motivating the dissemination of research tools by commercial suppliers than is often suggested.[96] One common model for such firms is the technology transfer firm, which may be a start-up spun off to commercialize university technology, or an existing firm which licenses a university invention. The Bayh-Dole Act, which standardized the ability

[95] See Walsh, *supra* note 20 at 334–35

[96] The NIH Principles and Guidelines implicitly recognize this point. See supra note 72 and associated text.

of nonprofit entities to patent federally-funded inventions, was motivated by concerns that the fruits of federally-funded research were languishing untapped by the commercial market because companies were reluctant to invest in the research and development necessary to bridge the gap between upstream university research and commercial viability.[97]

There are reasons to be skeptical of this "incentive to commercialize" justification. The general assumption underlying the patent system is that no patent incentives are necessary to incentivize the commercialization of public domain technologies since free rider issues do not arise. It is not at all clear that this reasoning is inapplicable to the fruits of nonprofit research. The argument is that the results of nonprofit research will be highly "embryonic," thus requiring larger and more risky investments in development than are common in the commercial sector and, thus, requiring patent exclusivity to attract investment. While this may sometimes be the case, improvement patents are designed for precisely this type of situation, in which improvements on prior advances are themselves significant innovations. Substantial investments in the development of "embryonic" inventions will likely result in patentable improvements. Additionally, some of the most lucrative university patents are licensed non-exclusively, which may be applauded for providing widespread access to the technology, but seems to belie the suggestion that exclusivity is needed to attract commercial interest. Moreover, there are alternative explanations for any failures to bridge the gap from university laboratory to commercial marketplace. Rather than a fear of free riding, such failures could arise out of search failures[98] or lack of absorptive capacity on the part of commercial firms.[99] While these are important issues of technology transfer, it is not at all clear that patents are the optimal way to solve them.[100]

In any event, whatever one concludes about the general applicability of the "incentive to commercialize" story, it is clearly at a low ebb in the context of research tools. The extent to which the fruits of nonprofit research are "embryonic" in today's world of technology-based science and science-based technology is certainly variable,[101] but research tools are bound to be among the least "embryonic" of the lot. Unlike research *results*, which may be of purely scientific interest and far from practical application, researchers design research *tools* specifically for practical application in the laboratory. If they were "embryonic," they would not do what researchers need them to do. Indeed, many chemical and biological research tool inventions may be technologically complete, but that is not to say that there is never any inventive distance covered 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. What should be recognized is that there is likely to be far less technical distance

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[97] See D. MOWERY, R.R. NELSON, B.N. SAMPAT AND A.A. ZIEDONIS, IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT, (2004) for a discussion of hte history of the Bayh-Dole Act.

[98] See, e.g., Thomas Hellmann, *The Role of Patents for Briding the Science to Market Gap* (working paper), arguing that the primary role of patents in university technology transfer is to reduce search costs.

[99] See Cohen and Lenvinthal, supra note 90.

[100] See Jones and Strandburg, supra note 65, discussing the role that should be played by university technology transfer. See also Thursby and Thursby, supra note 91, noting the importance of inventor involvement in successful university-based startup firms.

[101] Dreyfuss, *supra* note 60.

between laboratory and catalog for research tools than for other types of university research results. Moreover, the absorptive capacity and search problems faced by other types of university research results are likely to be minimal for research tools. It is, after all, the very researchers most likely to adopt inventive research tools and methods who read the scientific literature in which nonprofit research results are published. These researchers are generally in close contact with tool suppliers as well. To the extent that transfer of unpatentable "know-how" is required, it may be obtained without patenting the central invention, through consulting, collaboration, and transfer of personnel. There is little need for technology transfer "outside of the scientific community" in the context of research tools.

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

D. The Incentives of Tool Patent Licensing Firms

Just as there are two main types of researcher innovators, there are two types of commercial players in the research tool arena. Besides tool manufacturers, whose business model is to manufacture and supply research tools to researchers, there are firms whose revenues come primarily from technology licensing either to researchers themselves for tools and methods they can make and use in the laboratory or to tool suppliers. These firms develop research tools 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.

1. Incentives to Invent Research Tools

Tool patent licensing firms invent research tools with the intention of licensing their inventions either to manufacturers or directly to users. To have incentives to invention they must be able to recoup their research and development expenses and avoid free riding copying of their inventions by either manufacturers or users. Because these firms must disclose their proprietary research tools and methods in order to license them, trade secrecy is of limited value even if a tool is inherently non-self-disclosing. Though trade secret licensing is possible, it is difficult to enforce, which often makes patents a better option for protecting against free riding and preserving incentives to invent for tool patent licensing firms.

2. Incentives to Disclose Research Tool Inventions

The incentive to disclose for these companies stems from the business model. Technology licensing cannot occur without disclosing the technology to potential licensees. While confidentiality agreements are a means of limiting disclosure, patents lower the transaction costs of technology licensing in comparison to trade secrecy.

3. Incentives to Disseminate Research Tools

Research tool licensing firms may or may not have incentives to disseminate tool technology widely. If they license their proprietary technology non-exclusively they have incentives to maximize their royalty revenues by encouraging widespread use of the tool. If, on the other hand, they believe that exclusive licensing maximizes their private benefit, they may, like some commercial researcher innovators, fail to license socially useful research in favor of private rent-seeking through control of the research stream.

4. The Role of Patenting for Tool Patent Licensing Firms

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 either as trade secrets or through patents in order to obtain any revenue. They also use patents to signal their technical competence to potential investors.[102] For these firms, patents serve their canonical incentive to invent role and facilitate the dissemination of the research tools.

E. 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 significant outside of their use in research, user 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 non-research-consumer market. There are several potential scenarios that might arise. 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 a manufacturer or technology licensing firm that licenses in a way that promotes broad commercial availability invents the tool, then the interests of researchers in tool availability should be adequately served, particularly if price discrimination makes it possible to provide discounts to nonprofit researchers.

F. Summary of Benefits of Research Tool Patenting

Having analyzed the incentives of both researcher innovators and commercial producers, we now summarize the ways in which patent exclusivity for research tool inventions provides a social benefit. Patents are socially beneficial primarily when they:

[102] Clarisa Long, *Patent Signals*, 69 U. Chi. L. Rev. 625, 628–35 (2002).

- Incentivize disclosure by commercial researcher innovators who might otherwise rely on trade secrecy. In these cases patenting trades off longer exclusive use of the tool for earlier disclosure of the tool's characteristics.[103]

- Incentivize the development by commercial researcher innovators of some research tools that require larger investments than justified by the practical availability of trade secret protection for their in-house research.

- Incentivize research tool supplier's inventive activity by protecting them from "free riding" competitors.

- Incentivize research tool licensing companies' inventive activity by protecting them from "free riding" competitors and users.

- Incentivize inventive activity for dual purpose inventions that have significant direct commercial markets.

The net social effects of the first of these results of patent protection are ambiguous and depend on the particular technology involved. 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 effectively available. The gains from somewhat earlier disclosure of a research tool's characteristics 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. The reasons for this are that 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 researcher innovators are unlikely to develop. 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 time and effort. As noted, even for this latter class of tools there are sometimes alternative mechanisms for invention, such as collaborative projects. While these collaborative projects are more common in the nonprofit sector, there are some examples of them in the for-profit sector as well.

VI. AN "EXPERIMENTING-WITH" EXEMPTION FOR RESEARCH TOOL USE: DOES USER INNOVATION MATTER?

[103] Strandburg, supra note 3. Note that inventors will not patent their inventions unless trade secrecy is likely to provide less protection than patenting. Thus it is highly unlikely that patenting will lead to an earlier relinquishment of exclusivity in the "product" market for the invention than trade secrecy.

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 research innovator paradigm and the importance of nonprofit research innovators in some fields, diminishes the importance of recouping investment costs in most instances, and reinforces concerns that research tool patentees might pursue private gain by seeking to control research using the tool beyond the point necessary to recoup their investments in tool design. It also shifts the focus for many types of research tool from incentives to invent the tools to incentives to disclose and disseminate them. Limitations on previous proposals for "research tool use" exemptions have been primarily concerned with preserving the commercial returns on research tool inventions in order to preserve incentives to invent research tools. If these commercial returns are, as has been argued above, less important than previously appreciated, then an "experimenting with" exemption need be less concerned with preserving them. What should the parameters of a broader research tool exemption be in light of these considerations?

First, any research tool exemption should preserve the incentives of research tool suppliers and tool licensing firms to invent those tools which researcher innovators are less likely to invent because for one reason or another they provide insufficient returns to an individual researcher. This consideration counsels against any exemption for infringing sales. The broadest exemption one might reasonably consider is thus an exemption for making and using patented research tools without authorization. Returning to the primary social functions of research tool patenting which we identified above, we can consider the effects of a broad research tool use exemption on each:

- *Incentivizing disclosure by commercial researcher innovators who might otherwise rely on trade secrecy.* In the face of a "research tool use" exemption, commercial research innovators would be more likely to choose trade secrecy to permit them to maintain control of a research stream. As already mentioned, because the patent term is long relative to the pace of research in many areas, the choice of trade secrecy over patenting may be of net benefit to society because of the potential for developers of relatively easily invented research tools to control the pace of difficult and important research. Moreover, a commercial researcher innovator might still choose to patent in order to exercise the option of commercial manufacture of the research tool. Depending upon the research tool, other researchers may choose not to exercise a "research tool use" exemption if a reasonably priced commercial option is available.

- *Incentivizing the development by commercial researcher innovators of some research tools that require larger investments than justified by the practical availability of trade secret protection for their research.* For the most part patenting would still perform this function in the face of a "research tool use" exemption. The option of licensing the commercial manufacture of research tools may allow the researcher innovator to obtain returns greater than those that secret research might provide. However, commercial sales would not be an option for all "research tool" inventions. Patented research methods could not be "sold" on the open market in the face of a "use" exemption except through trade secrecy methods, which would almost certainly give rise to additional "leakiness" of the trade secrecy protection. Researchers

would also choose to make rather than buy some patented research tools if there were a "research tool use" exemption. The net effect would likely be some reduction in the development of expensive research tools by commercial researcher innovators.

- *Incentivizing research tool suppliers' inventive activity by protecting them from "free riding" competitors.* A "research tool use" exemption would not lessen the protection of patents in this regard.

- *Incentivizing research tool licensing companies' inventive activity by protecting them from "free riding" competitors and users.* Research tool licensing companies would retain their ability to license their technology to tool suppliers. They would also retain the ability to provide services, such as training and customization in conjunction with their patented technology. They would lose the ability to license their research tool technologies directly to researchers and thus would probably direct their efforts toward developing tools that researchers would purchase commercially rather than making in-house.

- *Incentivizing inventive activity for dual purpose inventions that have significant direct commercial markets.* Patents would retain their ability to incentivize the invention and disclosure of dual purpose inventions. Any use or sales for non-research purposes would not be exempted.

Tallying up the likely social costs and benefits of a broad "research tool use" exemption, one sees that the primary benefit of such an exemption is to wrest control of the research stream from research innovators after whatever period of secret use of the tool the circumstances, which include the competing inventive efforts of other researchers, allow. The primary social cost would be a reduction in commercial incentives to invest in developing the research tools that researchers would choose to make in their laboratories rather than buy. Research methods are an obvious example of this category, but laboratory production of other tools might also be relatively easy.

This reduction may be less significant than one might at first expect. Difficulties in enforcement of patents being what they are, commercial tool suppliers and licensing companies may already be focused on tools that are not easily duplicated in the laboratory, even without a formal research exemption. Moreover, one might expect a substantial overlap between tools researchers would choose to make rather than buy and those they would be likely to invent in the course of their research activities. Indeed a "research tool use" exemption might perform the socially beneficial function of directing the efforts of commercial research tool suppliers or licensing firms toward general-purpose tools, which researcher innovators are less likely to invent. There is, of course, one potentially significant "hole" in this protection -- it is possible that there are general-purpose research tools that are expensive to invent but easy to copy. An exemption for "research tool use" will lessen the incentives of commercial tool manufacturers to invest in developing such tools.

To the extent that this subset of research tools is significant, the reduced incentives for tool providers might be mitigated by collaborative efforts among researchers themselves. While such collaborations are susceptible to free rider problems,

since by hypothesis all researchers would be able to use the collectively developed tool whether or not they contributed to developing it, social norms within some research communities may demand contribution. In addition, as has been recognized in other areas of collective user innovation such as open source software, contributors may receive greater benefits than free riders, such as reputational advantages and the ability to tailor the tool for their particular research. In the nonprofit sector, large collaborative grant proposals are a means of facilitating the development of expensive general-purpose research tools, with research funding being one of the benefits of participation in the project. Standards-setting bodies, groups like the SNP consortium, and the Human Genome project are some examples of such collaborative projects.

A broad exemption for research tool use would mesh well with the proposed exemption for "experimenting on" a patented invention, alleviating the need to distinguish "experimenting on" from "experimenting with." Such a proposal would, of course, likely encounter significant opposition, as is evident from the extensive briefing on the subject of research tools that was provoked by the Supreme Court's consideration of the scope of the statutory exemption in *Merck v. Integra*. A more moderate (but still likely controversial) proposal would be to consider an out-and-out exemption for research tool use when either the inventor's employer or the researcher user is a nonprofit entity.[104] Commercial researchers would then be precluded from making or using research tools invented by their competitors, but nonprofit entities would be able to use tools invented by anyone and anyone would be able to use tools invented by nonprofit entities.

As discussed above, nonprofit researchers have substantial incentives to invent, disclose, and disseminate research tools without any need for patent exclusivity. But it is worth reiterating that such an exemption would not entirely preclude nonprofit entities from benefiting from the commercial licensing of tools they invented. They could still license their research tool inventions to commercial tool suppliers to supply the market for those researchers who prefer to buy rather than make the tool. Moreover, since nonprofit researchers are research tool users as well as research tool inventors, the financial effects of a 'research tool use' exemption might more or less wash out if research tool use by nonprofit researchers is also covered by the exemption.

The effects of an exemption for nonprofit research tool use on commercial researcher innovators would also be mixed. These researchers would benefit from the ability to use the research tool inventions of nonprofit researchers without compensating them, but would be less able both to control the streams of research conducted with their own tool inventions and to collect revenue from licensing their tools to nonprofit researchers. On the other hand, they would maintain the ability to exclude their commercial competitors from using their patented tools.

Finally, a nonprofit research tool use exemption would have similar effects on tool suppliers and tool licensing firms as a complete research tool use exemption, except that the effects would be lessened by the fact that commercial firms could still be precluded (to the extent enforceable) from making and using patented research tools in their laboratories.

[104] *E.g.*, Dreyfuss, *supra* note 60, at 8–11; *see also* O'Rourke, *supra* note 15, at 1208–10 (arguing for a fair-use defense in patent law to address problems of market failure).

While a nonprofit research tool use exemption of this type might be politically more palatable than a complete research tool use exemption, their remains the question of how to determine to whom the exemption would apply. With respect to determining whether a particular patent is subject to a research tool use exemption, a simple rule based on whether any of the inventors is employed by a nonprofit entity could be used. With respect to determining whether a particular user is entitled to a nonprofit research tool exemption, a similar rule could be used, exempting any research in which one of the collaborators is employed by a nonprofit entity, as could an alternative rule based on whether the research is funded in part by a nonprofit entity. Having established that the potential incentive effects of a research tool use exemption are less than we might have imagined, we may perhaps be less concerned about getting the line in exactly the right place and opt instead for a bright line erring on the side of exemption.

VII. CONCLUSIONS

Previous discussions of the research exemption from patent infringement liability have focused on preserving commercial incentives to invent. This focus has made it difficult to devise a workable exemption for research tool use, since use of a patented research tool without the patentee's authorization seems to cut directly into the market for the patented tool. As a result, most proposals have involved some kind of retroactive fee or compulsory license royalty to be paid to the patent owner, with all the concomitant administrative difficulties that such systems would pose. This Article argues that, for research tools, these concerns with preserving commercial incentives are overblown. The incentives of research innovators to invent research tools for their own use and then to disclose and disseminate them are taken into account, along with the fact that researchers will purchase many tools from commercial suppliers regardless of whether they are patented, raise the possibility that a broad, general research use exemption may be socially beneficial for "experimenting on" and "with" a patented invention. If such a broad exemption is not feasible, the Article proposes an alternative "double-edged sword" exemption which excuses nonprofit researcher use of any and all patented research tools as well as use by anyone (whether for commercial or noncommercial purposes) of research tools invented by nonprofit researchers.