WHAT DOES THE PULIC GET? EXPERIMENTAL USE AND THE PATENT BARGAIN

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I. Introduction

We award patents, as the Constitution requires, to "promote the progress of . . . the useful arts." ¹ According to the conventional wisdom, patents are needed to promote the progress of the useful arts because inventive ideas can easily be appropriated by competitors once they are developed.² Because inventions often cannot be developed without significant upfront investment, the law must step in to provide a way to recoup such investments or else inventors (or their financial backers) will have insufficient incentive to make research and development investments. Patents, which have a term of twenty years from the date the application is filed, provide a period of exclusivity in the market in which to recover such investments.

The effect patents have on technological progress is complicated because, in principle, most inventions have the potential to benefit society in two ways: through their direct utility to the users or consumers of embodiments of the invention and through the use of the inventive idea as a springboard to further innovation. Patent exclusivity, while

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¹ U.S. CONST. art. I, § 8, cl. 8.

promoting inventive progress by providing incentives for innovation, can slow technical progress if the best follow-on inventors are prevented from building upon the inventive idea during the patent term.³ Considerable effort has gone into analyzing the ways in which characteristics of the patent grant, such as scope and term, might be optimized to balance these effects, but, as a recent extensive review of the literature by Professors Nancy Gallini and Suzanne Scotchmer concludes, "the jury is still out" as to the optimal design to achieve cumulative invention.⁴

Because inventive results are also inventive inputs, the most rapid technological progress will result if the law provides a patentee the opportunity to recoup investments in appropriable research and development by commercializing her invention, while at the same time preventing the patentee from obtaining a stranglehold over technological progress that may flow from the invention. This principle is well rooted in current law. The patent system grants a period of exclusive rights to inventions, but simultaneously requires that patentees provide immediate public access to inventive ideas by disclosing them in published patents.⁵ Other inventors are not only permitted, but encouraged, to avoid patent infringement by "designing around" patented inventions using the patent disclosure as a springboard.⁶ Similarly, the system permits patents on improvements

² See, e.g., Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1024-30 (1989) (discussing the "incentive to invent" theory) [hereinafter Eisenberg, *Patents and the Progress of Science*].

³ See, e.g., Robert Merges & Richard Nelson, On the Complex Economics of Patent Scope, 90 COLUM. L. REV. 839 (1990) [hereinafter Merges & Nelson, Economics of Patent Scope]; Roberto Mazzoleni and Richard R. Nelson, The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate, RESEARCH POLICY 27 273 (1998).

 ⁴ Nancy Gallini and Suzanne Scotchmer, *Intellectual Property: When Is It the Best Incentive System?*, *INNOVATION POLICY AND THE ECONOMY, VOL 2*, 51, 69, Adam Jaffe, Joshua Lerner and Scott Stern, eds, MIT Press (2002) [hereinafter Gallini and Scotchmer, *Best Incentive System*].
 ⁵ Eisenberg, *Patents and the Progress of Science* at 1021.

⁶ Westvaco v. Int'l Paper Co., 991 F.2d 735, 745 (Fed. Cir. 1993); State Indus., Inc. v. A.O. Smith Corp., 751 F. 2d 1226, 1235-36 (Fed. Cir. 1985) (describing one of the patent system's primary goals as insuring

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 if and when a follow-on inventor seeks to use or sell an improved embodiment that actually embodies the original invention. These patent doctrines reflect the principle of separating a patentee's ability to recoup research and development investment from her ability to control (and perhaps hamper) further progress.

Professors Gallini and Scotchmer emphasize the key role that private licensing agreements can play in allocating profits so as to provide balanced incentives for original and follow-on invention.⁷ However, as pointed out by Professors Michael Heller and Rebecca Eisenberg and others, efficient licensing arrangements may not always be concluded for a variety of reasons including the transaction costs of coordinating multiple licenses, the inability of inventors to agree upon the appropriate division of rewards for original and follow-on inventions, and the possibility of anti-competitive behavior resulting in licensing failure or in collusive licensing practices.⁸

The experimental use or research exception is a patent law doctrine that at first glance seems well suited to help reconcile the role of patents as incentive for invention with the need to provide a robust public domain from which new inventions may spring.

competition through 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 (1999) (discussing competition between patented technologies by "designing around").

⁷ Gallini and Scotchmer, *Best Incentive System* at 64-65, 67-68, 71-72

⁸ Michael Heller & Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998) [hereinafter Heller and Eisenberg, *Anticommons*]; Gallini and Scotchmer, *Best Incentive System* at 65, 67-69, 71-72 and references therein (discussing the issues posed by licensing).

Under the experimental use exception, which is based on a judicial gloss on the infringement provision of the patent statute,⁹ unauthorized "experimental uses" of patented inventions are permitted.¹⁰ Experimentation is a primary path toward technological and scientific progress. When patents restrict experimentation, the tension between incentives for initial invention and the progress that comes from "standing on the shoulders of giants" is palpable.¹¹ A properly designed experimental use exception promises to relieve some of this tension. Because no license is required for exempted experimental uses, anti-competitive 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, the experimental use exception is targeted at the activities that contribute most directly to technological progress.

As discussed in this Article, there are general reasons to believe that a welldesigned exemption from infringement liability for unauthorized experimental use of patented inventions would promote faster technological progress with little diminution of incentives to invest in the original invention. As explained below, this distinction is possible because of the different impact that different types of experimental use have on inventions that are easily copied from their commercial embodiments (what I call selfdisclosing inventions) and on inventions that can be marketed without revealing the

⁹ 35 U.S.C. §271(a).

¹⁰ See generally WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 898 (1890), DONALD S. CHISUM, CHISUM ON PATENTS, §16.03, 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.").

¹¹ Eisenberg, *Patents and the Progress of Science* at 1055 (quoting Isaac Newton's famous epigram).

inventive ideas behind them (non-self-disclosing inventions). Such a well-crafted exception would distinguish unauthorized experimental uses that hamper a patentee's ability to recoup her appropriable research and development investment from those that primarily result in further technological progress.

Unfortunately, the experimental use exemption in current United States law is not formulated to distinguish between recouping appropriable investment and controlling technological progress. Instead, it has focused on the distinction between commercial and non-commercial use, with commercial use categorically ineligible for the "experimental use" exemption.¹² Because this distinction does not "line up" with the incentive-based structure of patent law it has not been sustainable and recent Federal Circuit decisions threaten to shrink the exemption to extinction.¹³ This recent precedent demonstrates the difficulty of producing reasonable results in individual cases while maintaining the commercial/non-commercial rubric.¹⁴

Thus, in the most recent Federal Circuit opinion on the subject, *Madey v. Duke University*, university research was placed on the commercial side of the divide because it "unmistakably furthers the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects."¹⁵ With

¹² Roche Products, Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858, 863 (Fed. Cir. 1984), *superceded on other grounds by* 35 U.S.C. § 271(e); Embrex, Inc. v. Service Engineering Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000).

¹³ *Roche Products*, 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"); *Embrex*, 216 F.3d at 1349 (finding that tests performed "expressly for commercial purposes" did not implicate the 35 U.S.C. § 271(e) exception); Madey v. Duke University, 307 F.3d 1351, 1362-1363 (Fed. Cir. 2002). *See also* Integra Life Sciences, Ltd. v. Merck KGaA, No. 02-1052 (Fed. Cir. June 6, 2003) (Newman concurring in part and dissenting in part) at 21-33 (disputing recent Federal Circuit interpretations of the common law experimental use exception).

¹⁴ *Embrex*, 216 F.3d at 1349; *Madey*, 307 F.3d at 1362-1363.

¹⁵ *Madey*, 307 F.3d at 1362-63.

this expansive understanding of "business," few activities will be unrelated to any potential infringer's "legitimate business." Moreover, the exemption remains viable, according to the court, for experimentation that is "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."¹⁶ Thus, apparently, research aimed at "enlightening faculty" is not exempted, while research aimed at "strictly philosophical inquiry" is.

Why has the Federal Circuit been reduced to such linguistic gymnastics? A quick look at the facts of the *Madey* case provides some insight. In *Madey*, a Duke University physics professor had patented various parts of a free electron laser used for scientific research.¹⁷ When he and the university had a falling out, the university continued to use his patented research equipment without his authorization.¹⁸ The university then tried to invoke the experimental use exception to excuse its infringing research.¹⁹ It is easy to understand the court's dilemma in this situation. The patented laboratory equipment was designed specifically for basic research, or "strictly philosophical inquiry," in a non-profit research laboratory. Because this type of research as "non-commercial" experimental use would have gutted the core grant of exclusivity supposedly provided by the patent – the market for direct sales or licensing of embodiments of the patented invention. Rather than approve that result, the Federal Circuit stretched the concept of

¹⁶ Madey, 307 F.3d at 1362 (citing *Embrex*, 216 F.3d at1349).

¹⁷ *Madey*, 307 F.3d at 1351.

¹⁸ *Madey*, 307 F.3d at 1351.

¹⁹ *Madey*, 307 F.3d at 1355.

commercial use beyond recognition so that it could encompass the university's actions and protect Professor Madey's core exclusive rights.²⁰

Because of cases like *Madey*, involving patented inventions designed primarily for non-commercial use, the focus on the commercial/non-commercial distinction leads inexorably to the withering away of the experimental use exception.²¹ The upshot is that the experimental use exception is reduced to a mere *de minimis* exception which bears little relation to the effects of a particular use on follow-on innovation. This happens because the commercial/non-commercial distinction is not a coherent basis to distinguish between a patentee's "just deserts" and the benefit due to the public under the patent bargain. It does not tell us the extent to which the alleged infringer is interfering with the patentee's ability to recoup her research and development investment or the extent to which the use is primarily aimed at follow-on invention.

The problem with the commercial/non-commercial distinction is not confined to the non-commercial end of the spectrum. Another recent Federal Circuit case, *Embrex v*. *Service Engineering Corp.*, illustrates the equally troubling consequences of giving patentees complete veto power over all "commercial uses" of a patented invention regardless of the purpose of the use.²² In *Embrex*, the patent covered an *in ovo* method for inoculating chickens against disease.²³ Embrex was the exclusive licensee of the

²⁰ See also Integra, No. 02-1052 (Fed. Cir. June 6, 2003) at 32-33 n.10 (Newman, concurring in part and dissenting in part, taking a similar view of the *Madey* case, agreeing with the decision on its facts, but disagreeing with its "sweeping dictum" about the narrowness of the experimental use exception).

²¹ See Eisenberg, Patents and the Progress of Science at 1024 (noting that the basing of the experimental use defense on lack of any commercial motivation makes the exemption both too narrow, because even much non-profit research has commercial motivations and too broad because it would deprive holders of patents with significant markets among "strictly philosophical" researchers of a large number of their potential customers).

²² *Embrex*, 216 F.3d at 1343.

²³ *Embrex*, 216 F.3d at 1346.

patent rights.²⁴ Service Engineering Corp. ("SEC"), one of Embrex's commercial competitors, conducted experiments that were aimed at designing around the patented inoculation method.²⁵ The patented method involved injecting vaccines into a particular region of a chicken egg.²⁶ SEC's experiments were intended to design around the patent by injecting a different part of the egg than was covered by the patent claims.²⁷ The experiments were unsuccessful because the injections leaked into the areas of the egg protected by the patent.²⁸ Despite the fact that any infringement was a literal "spillover" from an attempt to design around the patent and the fact that there was no evidence that the plaintiffs lost any profits as a result of the experiments, the Federal Circuit refused to apply the experimental use exception, basing the refusal on the commercial intentions of the experimenters.²⁹ *Embrex* presents an almost trivial application of the commercial rubric of the current experimental use test. Yet the result is uncomfortably out of line with the law's encouragement to competitors to use the inventive ideas disclosed in a patent to design around the invention.³⁰

This Article suggests that it is possible to extricate experimental use from the mess it is currently in by stepping back and refocusing attention away from the commercial/non-commercial distinction and on to the basic incentive structure of patent

²⁴ *Embrex*, 216 F.3d at 1346.

²⁵ *Embrex*, 216 F.3d at 1346.

²⁶ *Embrex*, 216 F.3d at 1346.

²⁷ *Embrex*, 216 F.3d at 1346.

²⁸ *Embrex*, 216 F.3d at 1347.

²⁹ *Embrex*, 216 F.3d at 1349.

³⁰ *Integra*, No. 02-1052 (Fed. Cir. June 6, 2003) at 5 n.2 (declining to discuss the applicability of the common law experimental use exception to the research on improved pharmaceutical compounds involved there). In her opinion concurring in part and dissenting in part, however, Judge Newman took issue with the strict commercial use test for common law experimental use exemption. She opined that "an ultimate goal or hope of profit from successful research should not eliminate the exemption." In Judge Newman's view the research in *Integra* was aimed at improving upon the patented compound and should fall under the experimental use exemption. *Id.* at 29.

law – providing means to recoup appropriable investment (the "incentive to invent") while permitting continued technological progress based on the inventive idea (the "incentive to disclose"). This work builds upon and incorporates many of the insights in the pioneering work of Ronald Hartman³¹ and Professor Rebecca Eisenberg³² on the experimental use exception and is in agreement with many of their conclusions.³³ However, while Professor Eisenberg reaches outside of patent theory to justify her proposals because she concludes that "[n]either the incentive to invent theory nor the incentive to disclose theory offers any clear guidance in formulating a research exemption,"³⁴ this Article contends that considerable progress can be made by considering more fully the conventional incentive justifications for patents.

In its focus on the internal logic of the patent law, this analysis also differs from the work of Professor Maureen O'Rourke, in which she advocates adoption of a multifactor test modeled on copyright law's fair use exception.³⁵ While acknowledging the relevance of many of the factors Professor O'Rourke identifies, this analysis seeks a more practical regime which will not require judges and juries to make complicated assessments of market failure, patentee incentives, and so forth. Instead, many of the factors identified by Professor O'Rourke are relevant in devising the experimental use exceptions proposed here.³⁶

³¹ Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. TRADEMARK OFF. SOC' Y 617 (1986) [hereinafter Hantman, *Experimental Use as an Exception*].

³² See Eisenberg, Patents and the Progress of Science, supra note Error! Bookmark not defined. and accompanying text.

³³ See generally Hantman, Experimental Use as an Exception at 639-40, 44 and Eisenberg, Patents and the Progress of Science at 1078.

³⁴ Eisenberg, Patents and the Progress of Science at 1031.

³⁵ Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000) [hereinafter O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*].

³⁶ Unlike Professor O'Rourke's proposal, however, the proposals in this article would not apply if a competitor markets a directly infringing product. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*

The distinction between recouping investment in appropriable invention and controlling follow-on innovation is a well-defined and meaningful criterion that can be used to evaluate proposals for unauthorized research use and to design a robust experimental use exception.³⁷ Concentrating attention on this distinction highlights two distinct types of experimental use of patented inventions. Experimentation aimed at verifying, designing around, or improving upon a patented invention (as in the *Embrex* case) plays essentially the same role as patent disclosure.³⁸ As discussed below, because of differences between self-disclosing and non-self-disclosing inventions that have not been widely recognized, such "experimenting on" a patented invention has relatively little impact on the incentive to invent and should be broadly permitted – without regard to the commercial or non-commercial nature of the user. Such a broad exemption for "experimenting on" patented inventions is already available in many countries, including Germany, the United Kingdom, and Japan.³⁹ The United States would do well to follow these countries' example.⁴⁰

http://wuesthoff.de/0897.htm (last visited July 12, 2003), U.K. Patent Act of 1977 §60(5)(b) (stating "[a]n act which, apart form this subsection, would constitute an act of infringement of a patent for an invention

at 1206. Professor O'Rourke advocates the possibility of such an exemption when the infringing product constitutes a major advance over the initial invention, but is still subject to patent blocking. *Id.* The analysis of such situations is beyond the scope of this Article, though it bears superficial similarity to the research tool problem discussed below. The potential for blocking patents differs from that problem, however, in that it can arise only after an improvement is made. Once the improvement is made, both patentees have incentives to come to an agreement that would allow the improvement to be marketed. Further investigation of this issue is clearly warranted. However, I do not think it is sufficient reason to abandon the relatively straightforward approach to experimental use advocated in this Article in favor of a multi-factor test that will be extremely difficult to apply in practice.

³⁷ See generally Graeme B. Dinwoodie & Rochelle Cooper Dreyfuss, *Preserving the Public Domain of Science Under International Law* (forthcoming) [hereinafter Dinwoodie & Dreyfuss, *Preserving the Public Domain of Science*] (distinguishing between patents giving power in product markets and patents giving power over innovation markets). As an aside, I might note that the distinction between recouping appropriable investment and exercising control over subsequent innovation might prove useful in defining "normal exploitation" of a patent as it is used in Article 30 of TRIPS. *See id.* at 15-26.

³⁸ *Integra*, No. 02-1052 (Fed. Cir. June 6, 2003) at 26-7 (Newman concurring in part and dissenting in part) (discussing the relationship between disclosure and experimentation on patented subject matter).

³⁹ See, German Patent Act \$11(2) (stipulating "that the effects of a patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention) *at*

The second type of "experimental use," in which a patented invention is used (as in the *Madey* case) as a research tool is more difficult to analyze because it is harder to separate the exclusivity a patentee needs to recoup research and development investments from the counterproductive use of a research tool patent to control research so as to maximize the tool patentee's profits at the expense of slower technological progress.⁴¹ As Professor Eisenberg pointed out, "[a]n experimental use exemption seems most likely to undermine critical patent incentives when the researcher is an ordinary consumer of an invention with a primary or at least significant market among research users."⁴² Yet a number of scholars, notably Professor Janice Mueller, have raised concerns that patentees of certain important research tools may delay research progress by restricting the access that "ordinary consumers" of the tools would normally anticipate.⁴³

In the research tool case, the analysis in this Article supports Professor Mueller's proposal for a limited use exemption for "experimenting with" research tools designed to provide the patentee with adequate compensation for use of the tool through a compulsory licensing requirement.⁴⁴ However, an analysis of how best to separate a patentee's need to recoup investment from a socially detrimental attempt to maintain a stranglehold on research results, along with consideration of some criticisms of

shall not do so if . . . it is done for experimental purposes") at

http://www.patent.gov.uk/patent/reference/mpp/s60_71.pdf (last visited July 12, 2003), *and* Japanese Patent Act §69(1) (stating "[t]he effects of the patent right shall not extend to the working of the patent right for the purposes of research or experiment.") *at http://*www.jpo.go.jp/shoukaie/patent.htm (last visited July 12, 2003).

⁴⁰ Indeed, Professor John Duffy has argued that the availability of this research exemption overseas will simply provide an incentive to move "experimenting on" research activities to one of the many countries that already recognize such an exemption. *See* John F. Duffy, *Symposium: Patent System*

Reform: Harmony and Diversity In Global Patent Law, 17 Berk. L. Tech J. 685, 718-719 (2002). ⁴¹ See generally Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L. Rev. 1 (2001) [hereinafter Mueller, *Rethinking the Experimental Use Exception] and* Eisenberg, *Patents and the Progress of Science*. ⁴² Eisenberg, *Patents and the Progress of Science* at 1074.

compulsory licensing proposals, leads to a proposal for a two-term system for research tool patents: a period of complete exclusivity followed by a period of compulsory licensing.

Section II provides background on the United States' experimental use exception and compares it to the different approach taken by many other nations. Section III of this Article analyzes the patent system's incentive to invent and incentive to disclose and explains why a broad exception for "experimenting on" a patented invention bolsters the benefits of disclosure without significantly lessening the incentives to invent. Section IV analyzes the more difficult research tool problem and concludes that a more limited form of experimental use exemption – a compulsory licensing provision that kicks in after a period of complete exclusivity -- will best promote technological progress. Section V offers conclusions and summarizes the comprehensive approach to experimental use suggested by the analysis of this Article.

II. The Failure of the Current Experimental Use Doctrine To Support the Patent Incentive Structure

While copyright law has long recognized the need to permit certain types of unauthorized, uncompensated use of copyrighted material under the fair use doctrine,⁴⁵ United States courts have oscillated between a true experimental use exception and a mere *de minimis* approach, in attempting to define the circumstances, if any, under which unlicensed use of patented inventions should be permitted. As the *Madey* and *Embrex* cases make clear, the beleaguered "experimental use exception" defined for use "solely

⁴³ Mueller, *Rethinking the Experimental Use Exception* at 10-17.

⁴⁴ Mueller, *Rethinking the Experimental Use Exception* at 59-60.

⁴⁵ O'Rourke, *Toward a Doctrine of Fair Use in Patent Law* at 1177.

for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry"⁴⁶ is simply not up to the task of determining whether an unauthorized use serves to "promote the progress of the useful arts."

The commercial/non-commercial distinction which has evolved as the ostensible litmus test for experimental use is fundamentally flawed when applied to either type of experimental use: "experimenting on" a patented invention, as in *Embrex*, in hopes of developing an improvement or design-around or "experimenting with" a patented invention by using it as a research tool, as in *Madey*.

The history of the United States common law experimental use exception has been reviewed in numerous articles and I do not attempt to reproduce an extensive review here.⁴⁷ Rather, this brief reprise focuses on how the exception has evolved to lose track of the need for an exception to permit "experimenting on" the invention and become mired in an all-encompassing focus on the commercial/non-commercial distinction.

The experimental use defense to patent infringement has its origins in the jurisprudence of Justice Story, in his days riding circuit in the early nineteenth century. In *Whittemore v. Cutter*, Justice Story first addressed the issue in an aside while discussing a jury instruction describing infringement as the "making of a machine fit for use, and with a design to use it for profit."⁴⁸ In the absence of today's specific statutory enumeration,⁴⁹ the defendant objected to including the making of a machine within the realm of infringement. Justice Story upheld the instruction, commenting that it was, in

⁴⁶ See supra note ____ and accompanying text.

⁴⁷ See generally Richard E. Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. PAT. OFF. SOC'Y 357 (1957), Hantman, *Experimental Use as an Exception*, Eisenberg, *Patents and the Progress of Science*, and O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*.

 ⁴⁸ Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).
 ⁴⁹ 35 U.S.C. § 271(e).

fact, favorable to the defendant because of its recognition that "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."⁵⁰ This observation was the germ of the experimental use exception to infringement liability.

Justice Story elaborated on experimental use later the same year in *Sawin v*. *Guild*, where he reiterated his statements and added that an infringing use "must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery."⁵¹ Interestingly, these first references by Justice Story contain the seeds both of the emphasis on whether the use is "for profit" or "for philosophical experiments" and of the need to protect unauthorized uses to ensure the functional availability of the patent disclosure to the public ("the sufficiency of the machine to produce its described effects").⁵² They also presage an issue that continues to haunt the exemption to this day – the circularity in defining an exception in terms of "the lawful rewards of [the patentee's] discovery."⁵³

Few judicial opinions addressed the incipient experimental use exception during the rest of the 19^{th} century.⁵⁴ The exception was given renewed legitimacy – and a *de minimis* direction – when it was adopted by the famous Robinson patent treatise of 1890.

⁵⁰ Whittemore at 1121.

⁵¹ Sawin v. Guild, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813).

⁵² Sawin, 21 F. Cas. at 555.

⁵³ Sawin, 21 F. Cas. at 555.

⁵⁴ See, e.g., Poppenhusen v. Falke, 19 F. Cas. 1048, 1049 (C.C. S.D.N.Y. 1861) (stating that "an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee"), *and* Byam v. Bullard, 4 F. Cas. 934, 935 (C.C.D. Mass. 1852) (interpreting the experimental use exception as founded on an assumption of *de minimis* injury).

Robinson interpreted the exception as based entirely on the pecuniary interests of the

patentee:

§ 898. No Act an Infringement unless it Affects the Pecuniary Interests of the Owner of the Patented Invention.

The interest to be promoted by the wrongful employment of the invention must be hostile to the interest of the patentee. The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others. These, though not always taking the shape of money, are of a pecuniary character, and their value is capable of estimation like other property. Hence acts of infringement must attack the right of the patentee to these emoluments, and either turn them aside into other channels or prevent them from accruing in favor of any one. An unauthorized sale of the invention is always such an act. But the manufacture or the use of the invention may be intended only for other purposes, and produce no pecuniary result. Thus where it is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promotion of the employer's knowledge or the relaxation afforded to his mind. But if the products of the experiment are sold, or used for the convenience of the experimentor, or if the experiments are conducted with a view to the adaptation of the invention to the experimentor's business, the acts of making or of use are violations of the rights of the inventor and infringements of his patent. In reference to such employments of a patented invention the law is diligent to protect the patentee, and even experimental uses will be sometimes enjoined though no injury may have resulted admitting of positive redress. [Footnotes omitted. Emphasis added.155

Robinson's still-influential treatise, with its exclusive focus on pecuniary effects on the patentee, its failure even to mention the social goal of trading exclusivity for enhanced progress, and its failure to discuss the category of experimental uses aimed at "experimenting on" the invention to "ascertain the verity and exactness of the specification,"⁵⁶ shaped the direction of experimental use doctrine in the United States

⁵⁵ WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 898 (1890).

⁵⁶ Sawin, 21 F. Cas. at 555.

throughout the twentieth century. Thus, Justice Story's statement of an experimental use exception for "philosophical experiments"⁵⁷ is widely cited, while the second prong of his analysis, focused on experimentation to understand the operation of the patented invention more fully, is rarely discussed by the courts and remains essentially undeveloped.

As the courts attempted to apply the Robinson formulation of the doctrine, the emphasis on pecuniary effects on the patentee evolved into a distinction between commercial and non-commercial users.⁵⁸ Some such evolution was perhaps inevitable because of the inherently circular character of a "pecuniary interests of the patentee" test.⁵⁹ The question whether a particular unauthorized use affects the pecuniary interests of the patentee is, of course, answered by the judicial determination of the legal rule that determines the scope of the patentee's exclusive rights. If the use in question is deemed "experimental," the patentee has no right to royalties or other pecuniary benefits from the use. If the use is not "experimental," the patentee's pecuniary rights are clearly affected since no consideration was paid for the unauthorized use.⁶⁰

The pecuniary interests approach cannot tell us which unauthorized uses, if any, should be excused. Thus, the "emoluments which [a patentee] does or might receive from the practice of the invention by himself or others"⁶¹ are necessarily defined by the legal boundaries of the patentee's rights. To decide whether a particular unauthorized use

⁵⁷ Whittemore, 29 F. Cas. at 1121.

⁵⁸ Ruth v. Stearn-Roger Mfg. Co., 13 F. Supp. 697 (D. Colo. 1935), *rev'd on other grounds*, 87 F.2d 35 (10th Cir. 1936).

⁵⁹ See Eisenberg, Patents and the Progress of Science at 1034-35.

⁶⁰ Alternatively, one could view the pecuniary interests test as encompassing any use for which the law *could* provide compensation to the patentee. Interpreted in this way, a pecuniary interests test is simply a *de minimis* exception.

⁶¹See supra note _ and accompanying text.

deprives the patentee of legitimate returns, one must know whether the unauthorized use falls within the experimental use exception. A more well-defined test is needed.

The commercial/non-commercial distinction is an attempt to capture the pecuniary effects idea but it has not been entirely successful in doing so because, as the *Madey* and *Embrex* cases illustrate, the financial impact on the *patentee* is not always captured by the financial motives of the *infringer*.⁶² The "legitimate business" expansion of the idea of "commercial use" is an attempt to deal with unauthorized uses which, though not undertaken "for profit" by the infringer, appeared to have substantial pecuniary effects *on the patentee*. Thus, while in 1935 a district court based an experimental use exception entirely on the fact that the infringing user was an academic research institution, ⁶³ by the 1970's the Court of Claims, in *Pitcairn v. United States*, rejected the United States government's argument that the manufacture and use "for testing and experimental purposes" of certain infringing helicopters should be permitted under the experimental use doctrine.⁶⁴

Though the government clearly had no "commercial" motive for its use, the court held that the tests in that case were necessary for any new helicopter and were "intended uses of the infringing aircraft manufactured for the defendant and [were] in keeping with the legitimate business of the using agency" and not exempted.⁶⁵ The *Pitcairn* court apparently did not consider whether the disputed tests of "lifting ability, effect of vibration on installed equipment, flight speed and range, engine efficiency, and numerous

⁶² Eisenberg, *Patents and the Progress of Science* at 1035 (recognizing that "the difference between commercial and noncommercial research in fact often has little to do with the financial interests of patent holders.").

⁶³ See supra note _____ and accompanying text.

⁶⁴ Pitcairn v. United States, 547 F.2d 1106, 1124-1126 (Ct. Cl. 1976).

⁶⁵*Pitcairn*, 547 F.2d at 1125-26.

other factors"⁶⁶ might be "for the purpose of ascertaining the sufficiency of the machine to produce its described effects."⁶⁷ The important point, as in the later *Madey* case, was that the government's use was in keeping with the primary use for which the helicopters were marketed.

The commercial/non-commercial focus of the experimental use exception was enshrined in present-day law by the Federal Circuit's decision in *Roche Prods. v. Bolar Pharmaceutical Co.*⁶⁸ *Roche* concerned an infringement case brought by the holder of a pharmaceutical patent 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 before the generic could be put on the market. The purpose of the testing, of course, was to allow the generic drug to be marketed as soon as possible after the patent term – the Congressionally-determined period for recouping appropriable research and development investment – expired. The district court held that the testing was excusable experimental use, but the Federal Circuit reversed. Though quoting Justice Story's "sufficiency to produce the described effects" test, the court did not consider whether the FDA testing might fall into this category.⁶⁹

Nor did the court rely, as it might have, on the overall impact of FDA testing requirements on the patentee's ability to recoup R&D investments. While Bolar had argued that failing to permit generic testing before the expiration of a patent would result in an effective patent term extension, Roche had countered that the even more extensive testing requirements for pioneer drugs shortened the patent term at the outset so that the

⁶⁶ *Pitcairn*, 547 F.2d at 1125-26.

⁶⁷ *Pitcairn*, 547 F.2d at 1125-26.

⁶⁸ 733 F.2d 858 (Fed. Cir. 1984).

⁶⁹ *Roche*, 733 F.2d at 862.

effective "extension" was necessary to preserve invention incentives. Rather than grapple with these policy issues, the court went out of its way to emphasize that the experimental use exception is "truly narrow." ⁷⁰ Quoting Robinson's prohibition of "unlicensed experiments conducted with a view to the adaptation of the patented invention to the experimentor's business,"⁷¹ the court based its ruling on a categorical rejection of any exemption for experimentation with "definite, cognizable, and not insubstantial commercial purposes."⁷²

The Federal Circuit's reluctance to engage the issues of patent policy presented in *Roche* was largely due to the fact that Congress was then engaged in considering the same issues.⁷³ Congress eventually enacted specific provisions to deal with the patent term problems posed by FDA drug regulations. The legislation aimed to ameliorate the effects of FDA testing requirements at both ends of the patent term, by permitting generic manufacturers to perform potentially infringing tests during the patent term in preparation for sales immediately after expiration,⁷⁴ while also providing for patent term extensions to drug patentees compensate for market time lost due to testing they were required to perform at the beginning of the patent term.⁷⁵

In addition to the legislation that overturned the specific holding of *Roche*, some have advocated a broader statutory reform to the experimental use exception, more in line with Justice Story's second, "ascertaining the sufficiency," prong and with the foreign

⁷⁰ *Roche*, 733 F.2d at 863.

⁷¹ *Roche*, 733 F.2d at 863.

⁷² *Roche*, 733 F.2d at 863.

⁷³ *Roche*, 733 F.2d at at 863-65.

⁷⁴ 35 U.S.C. § 271(e).

⁷⁵ 35 U.S.C. § 156.

exemption for "experimenting on" patented inventions.⁷⁶ In 1990 Congress considered the "Research, Experimentation, and Competitiveness Act of 1990", which included the following language:

It shall not be an act of infringement to make or use a patented invention solely for research or experimentation purposes unless the patented invention has a primary purpose of research or experimentation. If the patented invention has a primary purpose of research or experimentation, it shall not be an act of infringement to manufacture or use such invention to study, evaluate, or characterize such invention or to create a product outside the scope of the patent covering such invention.⁷⁷

The proposal was favorably reported to Congress by the House Judiciary Committee, but was never brought to a vote.⁷⁸ Had it been enacted, it might have been read to have adopted the "experimenting on"/ "experimenting with" distinction.⁷⁹

Because the legislation that eventually superseded the specific holding of *Roche* was directed primarily to the pharmaceutical industry, it left the *Roche* opinion's more general discussion of the common law experimental use exception intact. Any doubts about the Federal Circuit's continued commitment to the commercial /non-commercial distinction were erased by the court's *Embrex* ruling in 2000.⁸⁰ In *Embrex*, the court relied heavily on *Roche*, despite the legislative supersedence of its specific holding, and emphatically reaffirmed the rule that any experimentation with "definite, cognizable, and

⁷⁶ Eisenberg, *Patents and the Progress of Science* at 1078 (recommending that "[a] patent holder should not be entitled to enjoin the use of a patented invention in subsequent research in the filed 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").

⁷⁷ H.R. REP. NO. 101-960. pt. 1 (1990).

⁷⁸ H.R. REP. No. 101-960. pt. 1, at 1 (1990). More recently, the National Institutes of Health Working Group has taken the position that the distinction between "experimenting on" and "experimenting with" a patented invention is a "sensible distinction." Report of the National Institutes of Health Working Group on Research Tools, Appendix D (June 4, 1998), available at http://www.nih.gov/news/researchtools/appendd.htm.

⁷⁹ Though it is not entirely clear how the provision would have been interpreted since it purported simply to clarify, and not to change, existing law. H.R. REP. NO. 101-960. pt. 1, at 27 (1990). Also, the exemption

not insubstantial commercial purposes" constituted infringement.⁸¹ The court appeared to give no weight to the fact that the infringement occurred during an attempt to design around the patent.⁸²

With *Madey*'s disqualification even of non-profit experimental use when it is in keeping with the alleged infringer's "legitimate business," the Federal Circuit's reading of the experimental use exception is confirmed to be "very narrow" indeed.⁸³ Only use that is "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry" without any connection to the infringer's legitimate business is currently exempted.⁸⁴ Yet it seems unlikely that even this "very narrow" exemption can survive for long since, as *Madey* demonstrates, the "legitimate business" concept can (and inevitably will) be expanded to cover almost any conceivable use that could cut into the patentee's potential market for the invention.

While the United States currently embraces a *de minimis* interpretation of the exemption, elsewhere in the world, as noted above, national patent law has recognized the distinction between "experimenting on" (experimental use aimed at understanding the invention itself) and "experimenting with" (using an invention as a tool for research into another matter) and provided an exemption for "experimenting on."⁸⁵

for use "to create a product outside the scope of the patent covering such invention" might sweep in some instances of "experimenting with" a patented research tool.

 $^{^{80}}_{*1}$ *Embrex*, 216 F.3d at 1343.

⁸¹ *Embrex*, 216 F.3d at 1349 (citing *Roche*, 733 F.2d 858 at 863).

⁸² *Embrex*, 216 F.3d at 1346.

⁸³ *Madey*, 307 F.3d at 1362.

⁸⁴ *Madey*, 307 F.3d at 1362.

⁸⁵ Generally, western European nations exempt from infringement experiments directed at the subject matter of the invention. *See, e.g.*, Article 613-5(2) (France), German Patent Act §11(2), U.K. Patent Act of 1977 §60(5)(b). *See* cases interpreting the experimental use exception, Monsanto Co. v. Stauffer Chemical Co. *and* [1995] RPC 515, Klinische Versuche I (Clinical Trials I), GRUR Int. 1996, 58, Klinische Versuche I (Clinical Trials II), xx. 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

For example, the Court of Appeal in the United Kingdom case, *Monsanto Co. v. Stauffer Chemical Co.*,⁸⁶ explained that the exemption would apply to experiments to discover something unknown, to test a hypothesis, or to evaluate an invention's workability in conditions different than those contemplated by the inventor, even if the experimentation was carried out with a commercial motive.⁸⁷ Similarly, the German Supreme Court interpreted its statutory experimental use provision⁸⁸ to exempt experimentation with a patented invention that "served to gain information and thus to carry out scientific research into the subject matter of the invention"⁸⁹ even if an additional commercial purpose was involved.⁹⁰ Though Canada has no statutory experimental use exception, the Supreme Court of Canada has upheld an experimental use exception very similar to that found in European statutes:

... no doubt if a man makes things merely by way of bona fide experiment, and not with the intention of selling and making use of the thing so made for the purpose of which a patent has been granted, but with the view of improving upon the invention the subject of the patent, or with the view of seeing whether an improvement can be made or not, that is not an invasion of the exclusive rights granted by the patent. Patent rights were never granted to prevent persons of ingenuity exercising their talents in a fair way.⁹¹

The United States' current de minimis approach, which virtually untethers

"experimental use" from its origins in the connection between experimentation and

the invention. Western Europe is by no means alone in permitting experimental use relating to a patented invention's subject matter. *See, e.g.*, Brazil Industrial Property Law, Article 43(2). Japanese Patent Act §69(1), Korean Patent Law Art. 96(1). Closer to home, Canada, like the United States, has no statutory experimental use exception; the exception in Canada is a creature of the judicial system. *See* Micro Chemicals Ltd. et al. v. Smith Kline & French Inter-American Corp., 2 C.P.R. (2 Md) 193 (1971), *quoting* Frearson v. Loe, 9 Ch. D. 48 (1878), *and* Dableh v. Ontario Hydro, [1996] 3 F.C. 751.

⁸⁶ Monsanto Co. v. Stauffer Chemical Co. and another, [1995] RPC 515.

⁸⁷ Monsanto, RPC 515 at ___.

⁸⁸ German Patent Act §11(2).

⁸⁹ Klinische Versuche I (Clinical Trials I), GRUR Int. 1996, 58.

⁹⁰ Klinische Versuche II (Clinical Trials II), xx

technological progress, should be reconsidered. A focus on experimentation and its role in achieving technological progress is crucial to devising an exception that can serve the public interest in providing incentives for invention while maintaining a robust public domain. The purpose of an experimental use exception should be to protect the patentee's ability to recoup her research and development investment while preventing her from using her exclusive rights to exercise unwarranted control over subsequent innovation.

- III. "Experimenting On" a Patented Invention is Consistent With the Patent Incentive Structure and Disclosure Doctrine
 - A. The Relation Between Patent Disclosure Doctrine and Follow-On Innovation

As we saw in Section II, the sole emphasis in the development of United States experimental use doctrine on preventing any diminution of the circularly defined "pecuniary rights of the inventor"⁹² is leading to the demise of the experimental use exception. The line between commercial and non-commercial purposes on the part of the infringer also fails to capture the distinction between recouping R&D investment and monopolizing subsequent innovation. On the other hand, a rule that treats "experimenting on" a patented invention, as in *Embrex*, differently from "experimenting with" an invention, as in *Madey*, can begin to sort out these effects. As will be discussed in Sections III and IV, these two types of experimental use have very different effects on the incentives for current and follow-on innovation. The distinction between the two types of experimentation is recognized in many foreign jurisdictions and has been noted

⁹¹ Micro Chemicals Ltd. et al. v. Smith Kline & French Inter-American Corp., 2 C.P.R. (2d) 193 (1971), quoting Frearson v. Loe, 9 Ch. D. 48 (1878); followed by Dableh v. Ontario Hydro, [1996] 3 F.C. 751.
⁹² See supra notes _____ and ____ and accompanying text.

by scholars, ⁹³ yet the two types of experimental use have been conflated in United States case law.⁹⁴ Without explicitly recognizing the distinction, it has been impossible for United States courts to devise a reasonable standard for either type of experimental use.

An exception for "experimenting on" a patented invention would be consistent with the broader approach to follow-on innovation taken in United States law because "experimenting on" a patented invention is primarily a way of effectuating the patent disclosure to achieve its recognized purposes. As the Federal Circuit recognized even in its opinion in *Roche*, "the word 'use' in [the infringement provision] has never been taken to its utmost scope."⁹⁵ It has always been anticipated that competitors will "use" the inventive idea to improve upon or design around the invention.⁹⁶ Though Judge Rader stated emphatically in his concurrence in *Embrex* that he would prefer to "lay to rest permanently [the defendant's experimental use] infringement excuses which find no support in the Patent Act,"⁹⁷ he has recently provided a clear explication of the importance of using the inventive idea during the patent term:

Enablement already requires inventors to disclose how to make (reproduce, replicate, manufacture) and how to use the invention (by definition rendering it a "useful art"). Therefore, because the competitor

⁹³ See, e.g., Mueller, Rethinking the Experimental Use Exception at 39.

⁹⁴ The notable exception to this conflation is Judge Newman's *Integra* opinion (concurring in part and dissenting in part), where she notes the "fundamental distinction between research into the science and technology disclosed in patents and the use in research of patented products or methods, the so-called research tools." *Integra*, No. 02-1052 (Fed. Cir. June 6, 2003) (Newman concurring in part and dissenting in part) at 11. *See also Integra*, No. 02-1052 (Fed. Cir. June 6, 2003) at 20 (majority opinion citing the National Institutes of Health definition of research tools as "tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines," Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts, 64 Fed. Reg. 72,090, 72092 n.1 (Dec. 23, 1999), but declining to discuss the common law experimental use exception).

⁹⁵ *Roche*, 733 F.2d at 861.

⁹⁶ The Telephone Cases, 126 US 1, 533 (1888) ("Other inventors may compete with him for the ways of giving effect to the discovery, but the new art he has found will belong to him and those claiming under him during the life of his patent.").

⁹⁷ *Embrex*, 216 F.3d at 1353.

can make the invention, it can then acquire the DNA sequence or any other characteristic whenever it desires. Meantime the competitor can use, exploit, commercialize (outside the patent term) or *improve upon and design around (within the patent term)* as much of the invention as it cares to make. In other words, the statutory standard for sufficiency of disclosure serves masterfully the values of the patent system.⁹⁸ (Emphasis added.)

As Judge Rader explains, the disclosure requirements already serve to benefit the

public interest in faster-paced follow-on innovation by privileging the "use" of a patented

inventive idea in developing improved or alternative follow-on inventions during the

patent term.⁹⁹ No license or authorization is required for this activity, which is

indisputably a form of use. Moreover, a follow-on innovation can be patented, published,

or discussed – even if it incorporates the original inventive idea – as long as no one

makes an embodiment of the follow-on invention that incorporates an infringing

embodiment of the original invention.

Similarly, the Federal Circuit stated in Westvaco v. International Paper Co.:

Designing or inventing around patents to make new inventions is encouraged. Keeping track of a competitor's products and designing new and possibly better or cheaper functional equivalents is the stuff of which competition is made and is supposed to benefit the consumer. One of the benefits of a patent system is its so-called "negative incentive" to "design around" a competitor's products, even when they are patented, thus bringing a steady flow of innovations to the marketplace. (Citations and internal quotation marks omitted.)¹⁰⁰

While design-arounds and improvements are intended public benefits of the patent system, patentees have little incentive to license their competitors to experiment "on" their inventions to produce such follow-on innovations. As cases like *Embrex*

⁹⁸ Enzo Biochem v. Gen-Probe, Inc., 42 Fed. Appx. 439, 450 (Rader, J., dissenting) (rejecting the need for a heightened written description standard).

⁹⁹ *Enzo Biochem*, 42 Fed. Appx. at 450.

¹⁰⁰ Westvaco Corp. v. International Paper Co., 991 F.2d 735, 745 (Fed. Cir. 1993).

illustrate,¹⁰¹ patentees are not primarily concerned with collecting royalties for such uses, but with impeding their competitors' ability to use the patentees' inventive ideas as a basis for new inventions. Decisions like *Embrex*, while indisputably correct as to the commercial intentions of the unauthorized user, are certain to have a chilling effect on this socially beneficial experimentation.

In a perfect world, perhaps the written patent disclosure alone would be up to the task of facilitating improvements and design-arounds. For a variety of reasons, however, this is an unrealistic expectation. First, when there is no exception for experimentation aimed at a more complete understanding of the patented invention, there is an incentive for patentees to provide a bare minimum of disclosure to satisfy the legal requirements. Indeed, the inability of competitors to "experiment on" a patented invention makes it difficult even to unmask such obfuscation.

Second, there is an inherent mismatch between science and technology and verbal explanation. This fact has been recognized by the Court in the doctrine of equivalence context, where one of the primary justifications for expanding infringement beyond the literal language of the claims is the difficulty of expressing physical phenomena in words.¹⁰² Enablement doctrine also recognizes the limitations of written expression of technological matters, upholding as sufficient a patent specification that requires some experimentation to enable the practice of the invention as long as the amount of experimentation required is not "undue."¹⁰³

¹⁰² See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd., 535 U.S. 722, 731 (2002).

¹⁰¹ *Embrex*, 216 F.3d at 1350 (noting that the infringing tests "were not shown to cause any loss of profits to Embrex" and remanding for computation of a reasonable royalty rate.).

¹⁰³ See, e.g., In re Wands, 858 F.2d 731, 736-737 (Fed. Cir. 1988). See also Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CALIF. L. REV. 1, 18-19 (2001) (noting that reverse engineering would be unnecessary if disclosure were fully enabling).

As these legal doctrines already recognize, for scientists and engineers,

"understanding" is often, if not virtually always, a "hands-on" experience. Published results are reproduced by those seeking to build on them not only, or necessarily even primarily, to "verify" them, but to understand them – to see in detail how they were obtained and to explore their limitations and features not presented in the published description. As *Embrex* vividly illustrates, the attempt to build on what has been established will almost unavoidably touch upon the previous results.¹⁰⁴ An experimental use exception for experiments directed at understanding, designing around, and improving upon the subject matter of the invention would permit the disclosure requirement to achieve its intended result.¹⁰⁵ Because the patent system anticipates that competitors will use the patent disclosure to make improvements or "design-arounds" there is no reason to confine this type of experimental use to non-commercial applications.

A potential objection to a proposal to exempt "experimenting on" a patented invention from infringement liability is that the unauthorized use will decrease the patentee's returns from the patent and thus decrease the incentive to make the invention in the first place. However, as Section III.B shows, a close examination of the

¹⁰⁴ *Embrex*, 216 F.3d at 1346-1347.

¹⁰⁵ See Integra, No. 02-1052 (Fed. Cir. June 6, 2003) at 27 (Newman, concurring in part and dissenting in part) (stating "[t]here would be little value in the requirement of the patent law that patented information must be removed from secrecy in consideration of the patent right to exclude if the information is then placed on ice and protected from further study and research investigations."). See also Eisenberg, Patents and the Progress of Science at 1022 (stating that "[I]f the public had absolutely no right ot sue the disclosure without the patent holder's consent until after the patent expired, it would make little sense to require that the disclosure be made freely available to the public at the outset of the patent term. The fact that the patent statute so plainly facilitates unauthorized uses of the invention while the patent is in effect suggests that some such sues are to be permitted.") and Ned A. Israelsen, Making, Using, and Selling Without Infringing: An Examination of 35 U.S.C. Section 271(e) and the Experimental Use Exception to Patent Infringement, 16 AIPLA Q.J. 457 (1989) [hereinafter Israelsen, Making, Using, and Selling Without Infringing] (stating "[i]t could not have been the intent of Congress that once an invention is patented, and

relationship between disclosure and the patent system's incentive to invent shows that increasing the effectiveness of disclosure will be unlikely to have a significant impact on incentives to invent because disclosure has an inherently greater impact on inventions that could have been maintained as trade secrets, for which the patent system's incentive to invent is unnecessary.

- B. The Relation Between the Patent Incentive Structure and Follow-On Innovation
 - 1. Overview of the Distinction Between the Incentive to Invent and the Incentive to Disclose

Over and over, scholars and courts have explained that the patent system is justified by the twin theories: "incentive to invent" and "incentive to disclose."¹⁰⁶ In most scholarly and judicial expositions, the incentive to invent is featured, while the incentive to disclose is mentioned in passing and then set aside as though it merely supplements the free rider analysis of the incentive to invent.¹⁰⁷ What seems to go unnoticed in these discussions is that these two theories are not parallel justifications, but alternatives that apply quite differently to different types of inventions.

the public has received the 'early disclosure' of the invention, all progress that requires investigation of the discovery claimed in the patent should cease for 17 years.").

¹⁰⁶ See, e.g., Robert Merges, Commercial Success and Patent Standards: Economic Perspectives on Innovation, 76 CALIF. L. REV. 805 (1988), Suzanne Scotchmer & Jerry Green, Novelty and Disclosure in Patent Law, 21 RAND J. ECON. 131 (1990), Merges & Nelson, Economics of Patent Scope, Mark A. Lemley, The Economics of Improvement in Intellectual Property Law, 75 Tex. L. Rev. 989 (1997) [hereinafter Lemley, The Economics of Improvement in Intellectual Property Law], Seymour v. Osborne, 78 U.S. 516, 533-534 (1871), Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484 (1974), Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989). In this Article, I primarily take what Professor Clarisa Long has called the "simple view" of patent rights, (Clarisa Long, Patent Signals, 69 U. CHI. L. REV. 625 (2002)), assuming that the benefit to the patentee takes the form of additional profit resulting from the exclusive market for the patented invention, though I note in several places how a signaling function might be incorporated into the analysis.

¹⁰⁷ See, e.g., Kurt Saunders, *Patent Nonuse and the Role of Public Interest as a Deterrent to Technology Suppression*, 15 HARV. J. LAW & TECH. 389, 397-398 (2002) and Eisenberg, *Patents and the Progress of Science* at 1028 (stating that the incentive to disclose argument is "more popular with the courts than with commentators").

The "incentive to invent" theory is a classic "free rider" theory based upon the observation that ideas are non-excludable public goods, "peculiarly and benevolently designed by nature, when she made them, like fire, expansible over all space, without lessening their density in any point, and like the air in which we breathe, move, and have our physical being, incapable of confinement or exclusive appropriation."¹⁰⁸ The production of patentable inventions is understood to be different from other commercial activity because the investment in new ideas, unlike the investment in capital equipment or materials, is assumed to be appropriable by competitors at very little expense. Thus, the theory goes, patents must be awarded "as an encouragement to men to pursue ideas which may produce utility"¹⁰⁹ lest would-be inventors be disinclined to make the necessary investment in developing an invention for fear that, once an embodiment of the invention is available in the marketplace, competitors can easily copy the invention and begin competitive commercial production without having to pay the costs of research and development. The "incentive to disclose" theory, on the other hand, is based on the notion that a patent is a "quid pro quo" in which an inventor teaches her invention to the public in exchange for a limited period of exclusive rights to the invention.¹¹⁰

Though usually mentioned in the same breath, these two justifications for the patent system are actually in tension. The "incentive to invent" theory assumes that inventions are self-disclosing, *i.e.*, that competitors can immediately appropriate inventive ideas and begin commercial competition almost as soon as an inventor brings a patented product to market. Many mechanical inventions, for example, fit this rubric

¹⁰⁸ Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), in THOMAS JEFFERSON, THE LIFE AND SELECTED WRITINGS OF THOMAS JEFFERSON 577 (Adrienne Koch & William Peden eds., 1972). ¹⁰⁹ Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), in THOMAS JEFFERSON, THE LIFE

AND SELECTED WRITINGS OF THOMAS JEFFERSON 577 (Adrienne Koch & William Peden eds., 1972).

perfectly. The free rider "incentive to invent" analysis is eminently reasonable for such inventions, suggesting that without the patent system such inventions will be underproduced. For such inventions the societal tradeoff is clear: the higher consumer prices presumably resulting from the grant of exclusivity during the patent term are compensated (at least in theory and on average) by "progress in the useful arts" in the guise of inventions that would not otherwise have been made.

Note, however, that while the incentive to invent is highly pertinent to such selfdisclosing inventions, the disclosure "quid pro quo" has little relevance. Because the invention free rider theory assumes that an invention is disclosed and its reproduction enabled by its mere commercialization, the patent disclosure can add little to society's store of technical knowledge and serves almost exclusively to define the "metes and bounds" of the invention.

The patent system incentive to disclose is quite germane, on the other hand, to another category of inventions – those for which trade secret protection is a viable option. Such inventions are non-self-disclosing and not easily copied. For such non-selfdisclosing inventions, the disclosure of the invention in the patent specification is valuable to society over and above merely defining the scope of the grant, because it adds something the inventor could have kept secret to the store of public technical knowledge. Examples of such non-self-disclosing inventions include industrial processes or complex software programs.

The free rider incentive to invent theory *does not apply* to non-self-disclosing inventions. Because these inventions could have been maintained as trade secrets for a

¹¹⁰ See Kewanee Oil Co., 416 U.S. at 484.

sufficient time after commercialization to recoup the costs of their development, an exclusive patent grant is not necessary to stimulate invention. Because these inventions can be commercialized and still kept secret, they can, and will, be invented and then commercialized if an appropriate market for them exists whether or not they are patentable.

If any public benefit is to be had from patents on non-self-disclosing inventions, then, it must be obtained through the patent system's *disclosure* requirements. Patent disclosure serves the public good because it enhances the potential for follow-on inventions by releasing into the public domain technical information upon which other inventors can build.¹¹¹ Disclosure of non-self-disclosing inventions also steers others away from duplicative efforts to reinvent the patented invention. Technological progress is enhanced when society's creative resources can be focused on unsolved problems.

The role of the patent system for non-self-disclosing inventions is therefore not to encourage primary invention (for which trade secret protection is sufficient) but to enable more rapid follow-on invention by disclosing new technical discoveries that can be used as building blocks and by providing notice of work that has already been completed.

As discussed in Section III.D of this Article, this distinction between inventions makes it possible to devise an experimental use exception that, to a great extent, resolves the "tension" between society's interest in promoting improvements and design-arounds and the patent system's incentive to invent.¹¹² A key insight gained by focusing on the different functions patenting serves for different inventions is that we can strengthen the

¹¹¹ See, e.g., Hantman, *Experimental Use as an Exception* at 643 (stating "in exchange for the patent monopoly given to an inventor, the inventor discloses his invention to the public and runs the risk that his invention may be made obsolete").

¹¹² See Eisenberg, Patents and the Progress of Science at 1035-36 for a discussion of this "tension."

disclosure doctrine by broadly permitting experimentation aimed at follow-on innovation without substantially diminishing the patent system's incentive to invent in those cases where it counts.

2. Theoretical Analysis of the Incentive to Invent and the Incentive to Disclose

To probe the likely effects of an "experimenting on" exemption similar to the exemption provided by many foreign patent systems, a somewhat more detailed look at the distinction between self-disclosing and non-self-disclosing inventions is helpful. That distinction, while a useful heuristic, is not black and white, of course. There is a gray scale between the simple screw and the trade secret formula for Coca-Cola. A useful way to characterize this scale is by what might be called the "trade secret return," T -the extra amount that an inventor can recoup from commercializing the invention because the inventor can maintain exclusivity in the market for the invention for a period of time (without obtaining a patent). The trade secret return can be used to define the extent to which an invention is self-disclosing. Inventions that can be easily copied (selfdisclosing inventions) will have low values for T while inventions that must be invented independently (non-self-disclosing inventions) will have higher values. T is strictly capped by the possibility of independent invention by a third party. Other factors, such as the difficulty of reverse engineering and the costs of maintaining secrecy, can reduce T further by limiting the time during which the inventor can maintain an exclusive market.¹¹³ Because the focus of this analysis is on the effect of appropriable disclosure of

¹¹³ The theoretical analysis presented here does not distinguish between "invention" and "innovation," where innovation is understood to include any necessary non-patentable, but appropriable, investment needed to commercialize an invention once it has been invented. *See* Eisenberg, *Patents and the Progress of Science* at 1036-40 for a discussion of the distinction between invention and innovation. Invention and innovation both are accounted for by the trade secret return, however, since it includes any extra income

the invention to the public, T does not include any extra income generated by market "lead time" that is not due to appropriable investment in technical knowledge. Other investment -- such as investment in equipment, generating sales leads, or personnel training -- though some of it might be protected by trade secret law, is not exclusive to intellectual property and does not depend on whether the inventive idea has been disclosed.

In the absence of a patent system, the simplest analysis suggests that an invention will be brought to market if the extra income needed to recoup the appropriable investment in developing and commercializing the invention, which I will call R, is less than the trade secret return, T. ¹¹⁴ Thus, all other things being equal, the invention can

¹¹⁴ Here again a distinction between invention and innovation is not necessary to the analysis because both can be absorbed in the appropriable investment, R, which should be understood to include whatever investment in technical knowlege is unique to the first comer in the market and appropriable by others once the invention is fully disclosed, including any part of the investment in commercialization that is subject to free riding by competitors. Where appropriate, R should also be interpreted to include investments in related research that did not bear fruit. In other words, a prospective inventor will consider the possibility that some research efforts are unsuccessful when comparing expected returns to expected investment.

generated by the ability to maintain secrets. Focusing on the trade secret return also permits us to distinguish between disclosure of the technical idea to the *public*, which is the goal of the incentive to disclose, and disclosure to *potential investors*, which is sometimes necessary for commercialization. Any needed disclosure to potential investors will be reflected in the trade secret return. If an inventor needs to attract outside capital to commercialize the invention, various scenarios are possible. For example, it may be possible for the inventor to disclose the invention privately to potential investors under confidentiality agreements. In such a case, the trade secret return for the invention is largely unaffected by the disclosure to investors and depends only on the properties of the commercialized inventive product or process. On the other hand, there may be inventions which will attract sufficient capital only if information about the invention is "leaked" to produce a "buzz" of excitement about its potential. In such cases, the trade secret return may be affected by the amount of information about the invention that must be leaked. In the extreme case, the need to attract investors may require releasing so much information that a technically non-self-disclosing invention is effectively transformed into a "self-disclosing" invention. See Id. at 1029-30. The analysis here is based on the trade secret return, which can be defined for all of the possibilities described. (I am grateful to Professor Justin Hughes for pointing out the need to consider the case in which a "buzz" about the invention is necessary to attract investors.) Moreover, Professor Clarisa Long has argued in her recent discussion of patent "signaling," that it is also possible that patenting itself (as distinct from the information about the invention disclosed in a patent) is used by investors as a signal of potential commercial success so that the private returns from patenting should include returns from signaling. See Long, Patent Signals at 639-43. The analysis here is based on the trade secret return and patent return, which can be defined for all of the possibilities described.

profitably be made if T>R and will not be made if T < R.¹¹⁵ (See Fig. 1.) When T > R, trade secrecy provides a sufficient "incentive to invent" and a patent is not needed to induce invention.

When a patent on the invention is available, the time of exclusivity in the market can in some cases be increased by obtaining a patent, thus increasing the amount that the inventor can recoup over and above what would be available without patent protection. We can define the patent return, P, as the amount that an inventor can recoup from commercializing the invention if she chooses the market exclusivity available from patenting.¹¹⁶ Thus, we would expect that the invention will be made if either the patent return, P, or the trade secret return, T, is sufficient to recoup the research and development investment, R. (See Fig. 2a.) On the other hand, if both P and T are less than R, the inventor cannot expect to recover her research and development investment either by obtaining a patent or by keeping a trade secret. Thus, the potential inventor will not make the investment necessary to the invention and neither trade secrecy nor patenting provides sufficient incentive to invent. (See Fig. 2b.)

¹¹⁵ This way of putting it is a slight over-simplification. It is always possible that there will be no investment in an invention even if T > R simply because some other investment is more attractive. More precisely, the point at which T = R is the point at which secrecy is sufficient to "level the playing field" between the invention and other potential investments that do not involve intellectual property. The analysis here implicitly assumes, as does the free rider theory, that this is the goal of the patent system. One might, of course, argue that investment in research and development should be encouraged by giving rewards that will tilt the playing field toward such investment. It is not necessarily clear why this should be the goal. Once the playing field is leveled, the success of the commercialized invention will presumably be determined by its societal value. There may be no obvious reason to encourage investment in patentable inventions if the result is less valuable than non-inventive alternatives. Long-term research, which does not produce results that are attractive in the short-term perspective of investors, is generally not patentable and generally publicly funded. Government-funded research produces a different spectrum of problems and potential solutions. *See generally* Brett Frischmann, *Innovation and Institutions: Rethinking the Economics of U.S. Science and Technology Policy*, 24 VT, L, REV, 347 (2000).

¹¹⁶ Just as the trade secret return depends on the cost of maintaining secrecy, the patent return can be defined to take into account the costs of obtaining and enforcing the patent.

If either the patent return or the trade secret return is greater than the R&D expenditures, the incentive to invent is sufficient. The inventor will decide whether to patent the invention based on a comparison of P, T, and R. Thus, if the trade secret return is insufficient to enable the inventor to recover the investment in research and development, (T < R), the inventor will have to obtain a patent simply to justify making the invention. (See Fig. 3a.) A small trade secret return correlates with a shorter period of market exclusivity, signifying that the invention is relatively easily copied by competitors once it is commercialized – in other words, the invention is "self-disclosing." (See Fig. 3b.) For such self-disclosing inventions, where T < R, the primary function of the patent system is to increase the period of market exclusivity enough to provide a sufficient patent return to give an "incentive to invent."

On the other hand, inventions for which the trade secret return is sufficient to offset the research investment, (*i.e.*, T > R), are different. These are the "non-self-disclosing" inventions. (See Fig. 3b.) Because these inventions can be successfully commercialized as trade secrets, the patent system is not needed to level the playing field to stimulate invention in these cases. In these cases the primary public benefit of the patent system is to provide an "incentive to disclose" the invention rather than keep it secret.¹¹⁷

An inventor will decide whether to obtain a patent on such a non-self-disclosing invention by comparing the expected patent return, P, with the expected trade secret

¹¹⁷ Throughout this discussion "disclosure" refers to everything that is disclosed in the patent specification – including the disclosure meeting each of the written description, enablement, and best mode requirements of 35 U.S.C. 112. There is no attempt to isolate the effects of these different types of disclosure, any of which may assist a third party researcher in coming up with a follow-on invention. Moreover, since each of these aspects of disclosure may affect the ability to reproduce an invention, a self-disclosing invention

return, T. If the trade secret return is greater (*i.e.*, T > P) (most likely because the invention can be kept secret for longer than the patent term), the inventor has no incentive to obtain a patent and will be expected simply to keep the invention a trade secret. (See Fig. 4.) From the inventor's perspective, obtaining a patent would only force a premature disclosure of the invention. The inventor can maintain market exclusivity longer by eschewing the patent system in favor of trade secret protection. Such inventions, in a sense, are beyond the reach of the patent system unless patent return is increased by changes in patent scope or term.

The most interesting case for our purposes is the situation in which the trade secret return is larger than the inventor's research investment, (T > R) but less than the patent return (T < P). (See Fig. 4.) Because T > R, the inventor does not need a patent as an incentive to invent. However, because T < P, the inventor may wish to obtain a patent to increase his or her return from market exclusivity. On the other hand, the inventor may prefer to keep the invention secret to avoid disclosing information to competitors that could be used for follow-on innovation.

In such a case, illustrated in Figure 4, the inventor faces a choice. The inventor can choose not to patent the invention, thus avoiding the required patent disclosure, but settling for a lesser return from the current invention. Alternatively, the inventor can patent the invention, make the required disclosure, and obtain the benefit of a greater return from commercializing the current invention (usually because the patent will provide a longer period of market exclusivity for this invention). Here we see the "quid pro quo" of patent disclosure in operation. Because there is no free rider problem to

presumably discloses whatever aspects are necessary to permit another to compete in the marketplace for
overcome, society's "payment" for the extra return that the patent provides to the inventor is the disclosure itself.¹¹⁸ It is in this set of circumstances, and this set of circumstances alone, that the so-called "quid pro quo of patent disclosure" operates.

Thus, to sum up the analysis so far (see Figure 4): The "incentive to invent" is active for "self-disclosing" inventions for which a patent is necessary to stimulate invention because the research investment is greater than the trade secrecy return (*i.e.*, T < R < P). The patent disclosure plays a relatively minor role for this category of inventions, since the ineffectiveness of trade secrecy demonstrates that the inventive idea is relatively quickly appropriated once the invention is commercialized. The patent disclosure adds little to the disclosure inherent in commercializing the invention. On the other hand, the "incentive to disclose" is central for those inventions for which the grant of a patent is not necessary to compensate for the ability of free riders to appropriate the inventive idea (*i.e.* R < T < P). In such non-self-disclosing cases, the patent disclosure is *the only thing the public gets* in exchange for the extra return that patenting provides to the inventor.¹¹⁹

Once we focus on the different regimes in which the "incentive to disclose" and "incentive to invent" operate there are numerous questions to ponder. In particular, it

the invention.

¹¹⁸ In some sense, the existence of this class of inventions reflects the law's inability to calibrate the patent term to the invention. If the patent term were adjusted precisely to offset the research investment, there would be no inventions for which the disclosure quid pro quo was predominant. One way to view patent disclosure is as compensation for a "one-size-fits-all" patent term. Alternatively, the public benefits of disclosure provide a rationale for a relatively long patent term.

¹¹⁹ This is the case for non-self-disclosing inventions even if the mere existence of a patent performs a signaling function according to Professor Long's theory. *See generally* Long, *Patent Signals*. Depending upon the accuracy of the signal sent by patenting, (*see id.* at 659-64), the signaling function may benefit the public by increasing the patent return for a self-disclosing invention enough to cover the research and development investment and thus provide an incentive to invent. However, by definition, trade secrecy is sufficient to recoup the R&D costs for non-self-disclosing inventions. In such cases the patent signal may not provide a public benefit.

becomes crucial to consider whether the doctrines of patent law are designed to ensure that the public actually benefits from patent disclosure in non-self-disclosing cases. If there is insufficient public benefit from disclosure then a patent may be simply a windfall for the patentee.

3. The Relationship Between Disclosure and Follow-On Innovation

To begin analyzing the effectiveness of the patent system for non-self-disclosing inventions, we must ask in what way the patent disclosure advantages the public. There are two basic possibilities: First, it may be that the patent disclosure is useful to the public after the patent expires. Indeed, it is often assumed that the patent quid pro quo is satisfied by the availability of the inventive idea at the end of the patent term.¹²⁰ However, this assumption is generally incorrect. Unless there are very substantial costs related to trade secret protection, an inventor's choice to patent will ordinarily signify that patenting gives a longer period of exclusivity than trade secret protection. Since this is the case, the choice to patent will ordinarily be made only if the inventive idea would have "leaked out" before the end of the patent term. Thus, for most inventions that will be patented (and thus for which T < P), the patent disclosure has no value to the public by the end of the patent term, because competitors would have uncovered the patentee's

¹²⁰ See, e.g., Donald Chisum, Comment: Anticipation, Obviousness, Enablement: An Eternal Golden Braid, 15 AM. INTELL. PROP. L. ASS'N Q.J. 57 (1987).

¹²¹ There can be rare situations in which the patent return is larger than the trade secret return even if the optimal trade secret time is shorter than the patent term. For this to occur, two conditions must be satisfied: $P > T(t^*)$ and $t^* > p$. Here, $T(t^*)$ signifies that the trade secret return is maximized at the trade secret term, t*. The patent term is p. The time for independent third party invention, t_i , limits the trade secrecy term. The condition that $p < t^*$ thus requires, at least, that $p < t_i$. There are relatively few modern-day research fields in which independent invention of a patentable invention would take longer than the twenty-year patent term. Of course, the optimal trade secret term, t*, may be even shorter than t_i due to the possibility of reverse engineering or industrial espionage. Also, since the income from an invention strictly increases with time, the only way for $P > T(t^*)$ and $t^* > p$ is for the costs of the optimal term of trade secrecy to be

The public benefit of patent disclosure must therefore generally result from some kind of use of the disclosure *during* the patent term. Such "use" can be of two types: use as a warning against wasteful and duplicative efforts to develop (or steal) what the patentee has already invented,¹²² or as a direct input to follow-on innovation.¹²³ Either way, the patent disclosure advances the "progress of the Useful Arts" by permitting societal resources to be put to their best use in advancing more quickly beyond the patentee's contribution. To summarize: in general the patent disclosure provides a benefit to the public only if it steps up the pace of follow-on innovation.¹²⁴

Disclosure can speed up follow-on innovation only if there are third parties who can make better use of the information than the patentee would if she maintained exclusive control of the information. When the disclosure quid pro quo functions properly for non-self-disclosing inventions, both sides make tradeoffs: the inventor gives up some control of follow-on innovation in exchange for a bigger return from the original invention while the public accepts less competition in the market for the original invention in exchange for faster follow-on innovation by a third party.

Thus, for non-self-disclosing inventions, unless the patent disclosure leads to faster or broader follow-on innovation than the original inventor would produce, the public has in general not been compensated for the patent grant, since it results in a longer period of exclusivity than necessary to recoup the appropriable R & D investment

substantially larger than the costs of patent enforcement. But those costs are limited by the requirement that $T(t^*)$ be a maximum. For these reasons, the cases where $t^* < p$ are likely to be rare.

¹²² See, e.g., Mark Grady & Jay Alexander, Patent Law and Rent Dissipation, 78 VA. L. REV. 305, 307-311 (1992).

¹²³ See Eisenberg, Patents and the Progress of Science at 1055-1060.

¹²⁴ As I use the term in this Article, follow-on innovation may include either improvements or alternatives to a prior invention. Any socially useful innovation that is inspired by the patent disclosure is a public benefit of patenting.

for those inventions. Indeed, there might be adverse public effects from disclosure if it leads third parties to waste resources attempting to come up with improvements that the patentee could more quickly discover. The law should seek to ensure that the public gets the benefit of the patent bargain for non-self-disclosing inventions by encouraging these tradeoffs when it is possible to do so without significantly decreasing the incentives to make the original invention in the self-disclosing case.

The situation with respect to follow-on innovation is illustrated in Fig. 5. As do the earlier diagrams, Fig. 5 shows the trade secret return on the vertical axis. Now, however, the horizontal axis illustrates the effect of disclosure on follow-on innovation. The horizontal axis, labeled I, is the time the original inventor would take to come up with a follow-on invention.¹²⁵ Superimposed on the diagram are lines indicating the time lag before a third party would come up with a follow-on.

The bold line corresponds to the time for independent third party follow-on innovation if there is no patent disclosure. The bold line shifts toward longer times as the trade secret return increases because it is reasonable to assume that, without the aid of the patent disclosure, third parties will take relatively longer to come up with follow-on inventions when there is a larger return to trade secret protection, indicating that the invention is more difficult to reverse engineer or invent independently.

The dashed line illustrates what is likely to happen to third party follow-on innovation when a patent is obtained and disclosure is made. The ability of third parties to create follow-on innovations will be relatively unaffected by the patent disclosure if the original invention is self-disclosing (small T). This is just another way of saying that

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the patent disclosure adds little to the public store of information about those inventions. Disclosure will have an increasingly greater impact on third party innovation time as the trade secret return increases. Again, this is another way of saying that the patent disclosure is more valuable to the public the longer it would have taken the public to unravel the secret on its own. The position of the dashed line (*i.e.*, the extent to which disclosure speeds up third party follow-on innovation) will depend on how extensive the patent disclosure is - a point to which we shall return in discussing the experimental use exception.

Given the analysis illustrated in Figure 5, we can make some general prescriptions for beneficial disclosure requirements. Consider the region in Fig. 5 in which the potential trade secret return, T, is greater than the research and development expenditure, R, but less than the potential patent return, P (*i.e.* focus attention on the non-selfdisclosing inventions to which the disclosure quid pro quo potentially applies). The third party innovation time lines divide this region into three pieces:

To the left of the dashed line representing the third party innovation time in the presence of patenting is a region, (marked I in Fig. 5), in which the original inventor will be the winner of the follow-on innovation race *in spite of the patent disclosure*. In this situation, patenting does not affect the pace of follow-on innovation because the patent disclosure does not add enough to the state of the art to permit another inventor to win the follow-on innovation race. In such cases there is no quid pro quo – the inventor is in a win-win situation. By patenting the invention, the inventor generally benefits from both a period of market exclusivity longer than needed to recoup her research investment and

¹²⁵ More accurately, I represents the time for follow-on innovation coordinated by the original inventor,

from maintaining control of the follow-on innovation. The public, on the other hand, generally gains nothing by awarding a patent in Region I -- losing out on a period of beneficial competition in the market for the original invention, but seeing no faster progress in follow-on innovation.¹²⁶ In this region, the patentee will very likely choose to patent the invention – but the public may well be worse off than if the invention had been maintained as a trade secret for a shorter period of time.

To the right of the bold line in Fig. 5, which represents the third party innovation time without patent disclosure, is another region (marked III) in which the original inventor faces no tradeoffs. In this region a third party will win the follow-on innovation race regardless of whether the original invention is disclosed in a patent. Because the original inventor will lose the follow-on innovation race whether or not the invention is patented, there is no reason from the inventor's perspective not to patent the invention and gain the extra period of market exclusivity. Region III differs from Region I from the public's perspective, however. Though the patent disclosure is immaterial to the inventor, the public may gain a substantial benefit from the disclosure, since it will enable third parties to quicken the pace of follow-on innovation (as reflected in the difference between the bold and dashed lines in Fig. 5.).

Between the bold line and the dashed line is a more complicated region (marked II in Fig. 5). In this region, the public gains from patent disclosure (since the patent disclosure permits third parties to beat the inventor's follow-on innovation pace), while the patentee is forced to relinquish her hold on the follow-on innovation. Conversely, the

whether or not the original inventor actually performs the follow-on research.

¹²⁶ As discussed in note ___, there may be an occasional case in which P > T even though the optimal trade secrecy term is longer than the patent term. In those cases, patenting allows earlier, rather than later, competition in the market for the original invention, but these cases are not typical.

patentee gains a period of exclusivity because the patent term is generally longer than the trade secret term, while the public loses the advantages of market competition during that period. The inventor must make a trade-off in this region, deciding whether the extra exclusivity or the chance to control follow-on innovation is more valuable. Importantly, the public benefits in this region *whichever choice the inventor makes*.

Based on these observations, we can make a general prescription. Region I is a set of inventions for which the patent system is ordinarily a giveaway to inventors. Inventors get a greater return from patenting than necessary to recoup research and development expenditures but the patent disclosure does not serve its purpose of speeding up the pace of follow-on innovation. In Region II, on the other hand, there is a quid pro quo -- the public gets the benefit of the patent bargain. Therefore, it is generally in the public's interest to reduce the size of Region I by increasing Region II, even though the inventors of some of the inventions thus pushed into region II may choose trade secret protection over patenting. Because patenting produces neither a necessary increase in incentives for primary invention nor a faster pace of follow-on innovation in Region I it is not necessarily preferable to trade secret protection.

One way to move the dividing line between Region I and Region II is to modify the disclosure requirements. More stringent disclosure requirements will tend to shrink Region I by speeding up third party follow-on innovation. Before concluding that more stringent disclosure requirements will provide an overall benefit, however, we need to consider the effect of more stringent disclosure requirements on the incentives to invent self-disclosing inventions

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Referring again to Figure 5, we may consider the effects of increased patent disclosure for self-disclosing inventions. Here, because the trade secret return is insufficient to compensate for the research investment needed for invention, the potential inventor faces a choice between inventing with the expectation of patent protection and not inventing at all. Trade secret protection is not an option. How does disclosure affect the potential patentee's choices? We can expect minimal effects for two reasons.

First, because these inventions are self-disclosing, the patent disclosure is much less likely to have an appreciable effect on third party innovation than it is for non-selfdisclosing inventions. (This point is illustrated in the shape of the bold and dashed lines in Fig. 5.) Second, the only undesirable action that the inventor of a self-disclosing invention might reasonably take in response to an increased disclosure requirement would be to delay commercial introduction and patenting of the primary invention until the follow-on is in hand. (There would seem to be no particular reason for the inventor to give up on making a self-disclosing invention because of stiffer disclosure requirements, since patenting guarantees that research expenses can be recouped from commercializing the original invention alone.)¹²⁷

¹²⁷ Another way to describe the effects of more and less stringent disclosure requirements is by looking at an effective patent return defined to include returns from follow-on innovation. Increasing disclosure requirements can result in decreased returns to the patentee if third parties can appropriate the increased disclosure. But there are three situations in which increased disclosure requirements will have little impact on patent returns: (1) if disclosure requirements do not add significantly to the available public knowledge (i.e. for self-disclosing inventions); (2) if the additional disclosure adds significant knowledge but the original inventor is still able to capture most of the returns from follow-on innovation by virtue of being the fastest inventor (i.e., Region I of Figure 5); and (3) if the additional disclosure adds significant public knowledge but the original inventor would not have captured the returns from follow-on innovation in any event (i.e., Region III of Figure 5). Only if the additional disclosure adds sufficient knowledge to the public domain to permit a third party to appropriate returns that the patentee would otherwise have obtained can the disclosure affect the patentee's incentives regarding invention and patenting (i.e., in Region II). Because the extent to which additional disclosure adds usable knowledge to the public domain is related to the efficacy of trade secret protection, additional disclosure tends to decrease the patentee's returns preferentially for those inventions for which patents provide returns in excess of what would be needed to recoup research and development investments. (The ability of third party follow-on innovation to restrict

Because the effects of disclosure are inherently targeted at inventions for which patenting already provides excessive returns, it seems safe to conclude, therefore, that there is an overall public benefit to be gained by imposing stringent disclosure requirements to increase the size of the region (region II in Figure 5) in which a true disclosure quid pro quo exists so that the public is ensured the benefit of the patent bargain.

C. "Experimenting On" A Patented Invention as a Means of Effectuating Disclosure

With the above framework in mind, we can draw some inferences about the effect an exception for "experimenting on" might have on the incentives of potential patentees. First, we should note that there are many patented inventions – those self-disclosing inventions available for anonymous purchase in the market – for which an "experimental use exception" of this type may be irrelevant. If the follow-on researcher can obtain the necessary information by using a purchased product (which comes with an implied license to use it), there is no need for a special exception. Even when this type of use is unauthorized, it is unlikely, for a commercially successful invention, that such research use will make much of a dent in the prior inventor's income stream from marketing the invention. The primary effect on a patentee of others "experimenting on" her invention is thus the effect of the research on the likelihood that the patentee will win the follow-on innovation race. Thus, an exception for "experimenting on" a patented invention is the equivalent of more thorough disclosure of the inventive idea.

patent returns is related to the concept of effective patent life explored by Scotchmer and others. *See* Gallini and Scotchmer, *Best Incentive System?* at 68, *citing* Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law,* Symposium on Intellectual Property Law, JOURNAL OF ECON. PERSP. 5, 29 (1991) and Ted O'Donoghue, Suzanne Scotchmer, and Jacques-Francois Thisse,

Referring back to Figure 5, when the patent disclosure is made more complete and effective by allowing follow-on researchers to perform experiments on the subject matter of the patent, the third party follow-on time is decreased (*i.e.*, the dotted line in Fig. 5 moves further to the left). As discussed above, increasing the effectiveness of the disclosure is generally advantageous because it has little effect on self-disclosing inventions, for which the incentive to invent dominates, and a salutary effect on non-self-disclosing inventions, for which the public's primary compensation for the award of a patent is a faster pace of follow-on invention.

To summarize, when the commercial-non-commercial distinction is dropped and the focus is returned to the underlying goals of the patent system, the analysis of experimentation "on" the subject matter of an invention shows that it is essentially a species of enabling disclosure. Such disclosure enhancement promises to have beneficial effects on the pace of follow-on innovation for non-self-disclosing inventions with minimal effects on the invention incentives for self-disclosing inventions. Moreover, because the patentee of a non-self-disclosing invention has already been compensated by society for the disclosure of her invention with the award of a greater patent return than necessary to recoup her investment in invention, such disclosure-based experimental use need not be separately compensated.

D. A Proposed Exemption for "Experimenting On" a Patented Invention

An exception for "experimenting on" a patented invention could be legislatively enacted, perhaps by reviving the Research, Experimentation, and Competitiveness Act of 1990 proposal. But statutory amendment might not be necessary. Any common law

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experimental use exception is premised on judicial interpretation of the statutory prohibition of unauthorized "use" of a patented invention.¹²⁸ As already discussed, the prohibition of "use" is already understood to permit use of the inventive idea 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.¹²⁹ And the intention is that this understanding will be sufficient to provide the public benefit of "design-arounds" and improvement on the patented invention.¹³⁰ A common law exemption for "experimenting on" a patented invention to produce an improved or alternative version 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 the prohibition of infringing "use."¹³¹

The proposal of a categorical exemption for "experimenting on" a patented invention may be compared with other proposed approaches to the experimental use question. In addition to being theoretically grounded in the distinction between recovering R&D investment and controlling subsequent innovation, a rule permitting "experimenting on" patented inventions has the advantage of relative clarity and

STRAT. 7, 1 (1998). ¹²⁸ 35 U.S.C. § 271.

¹²⁹ 35 U.S.C. § 112.

¹³⁰ Westvaco Corp., 991 F.2d at 745.

¹³¹ Integra, No. 02-1052 (Fed. Cir. June 6, 2003) at 27-8 (Newman concurring in part and dissenting in part) (stating that "[t]he 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.") See also Israelsen, Making, Using, and Selling Without Infringing at 475-76 (arguing that the goals of the patent system are served by permitting comparison, development of improvements, and designing around patented inventions and suggesting that making, using or selling be considered to occur "only if the patent is practiced primarily to secure the benefits thereof.") While Israelsen's identification of activities that serve the goals of the patent

simplicity of administration. Unlike proposals that echo copyright's "fair use" analysis and require courts or juries to make complicated multi-factor analyses.¹³² the proposal for a categorical "experimenting on" exception reduces the question to an objective analysis of the nature of the research in question.¹³³ While difficult line-drawing issues may still arise in particular cases,¹³⁴ the difference between "experimenting on" a patented invention to improve it and using it as a tool for other research is a factual question that can be evaluated by judges and juries without the need for policy-driven balancing. Also, because there is no need to determine whether a potential infringer is commercial or nonprofit, or whether the research is part of its "legitimate business" there is a greatly reduced incentive for strategic attempts to disguise commercial ventures as university research and so forth.

As a practical matter, if legislation is required to implement the exemption, it is far more likely to succeed if the proposal stands to promote faster innovation in both the commercial and non-profit sectors. Indeed, since 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.

IV. "Experimenting With" A Patented Invention: The Problem of Research Tools

system is consistent with the analysis here, his proposed "secure the benefits" test seems to have the same potential pitfalls as the "pecuniary effects" test. *Id.* ¹³² *See supra* notes _____ and accompanying text.

¹³³ Richard A. Epstein, Steady the Course: Property Rights in Genetic Material at 1-9, available at http://www.law.uchicago.edu/lawecon/index.html (last visited July 14, 2003) [hereinafter Epstein, Property *Rights in Genetic Material* (discussing the advantages of "all-or-nothing" rules).

¹³⁴ Council of the Royal Society, *Keeping Science Open: The Effects Of Intellectual Property Policy* On The Conduct Of Science (April 2003), Para. 3.23 (discussing research tools and the ambiguities in interpreting the European exemption for 'acts done for experimental purposes' (Community Patent Convention 1975, Art 31 (b)); noting "doubtful ground" between the "two extremes" of exempted "experiments to establish the scope and application of a patented invention, including experiments to discover an improvement to it" and prohibited "experiments simply to prepare to duplicate and sell what is already on the market.")

Once we separate out the disclosure-related instances of "experimenting on" a patented invention from the more problematic "experimenting with" a patented invention -i.e. using a patented invention as a research tool – we can hope to address the more complicated research tool issue more clearly.

Indeed, once we distinguish the two types of "experimental use" it may seem that they have little besides a name in common. "Experimenting on" a patented invention is focused on gaining a better understanding of the inventive idea to facilitate further innovation. The embodiment of the idea is ancillary. It merely supplements the written patent disclosure and would have been unnecessary if the written disclosure had been completely effective. "Experimenting with" a research tool involves using an embodiment of the invention for its intended purpose. It is not an extended form of patent disclosure. Indeed, though as a practical matter unauthorized experimentation employing a research tool will usually require an understanding of the patented invention, it need not in principle. For example, laboratory use of an unauthorized copy of the computer object code embodying a patented software invention might not rely at all on the experimenter's understanding of how the software functions.

In the "experimenting on" context, because of the distinction between selfdisclosing and non-self-disclosing inventions, the public interest in disclosure can be advanced by an expansive exception with little adverse impact on the public interest in encouraging invention. "Experimenting on" an invention, like any form of disclosure, has only an indirect impact, through potentially competitive follow-ons, on the market for embodiments of the original invention. In contrast, unauthorized use of a research tool has a direct impact on the market for the tool. Thus, uncompensated "experimenting

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with," like garden variety patent infringement, directly implicates the incentive to invent by letting some of the free riders back into the marketplace. Analysis of the potential benefits of any exception for "experimenting with" a research tool is thus fraught with much greater uncertainty than the "experimenting on" inquiry.

Nonetheless, "experimenting with" a research tool bears closer scrutiny because, as many commentators have recognized, it shares with "experimenting on" a patented invention the potential for significant impact on scientific and technological progress. Indeed, the research tool patent question has generated at least as much scholarly concern as the problems with prohibiting experimentation aimed at improving a patented invention.¹³⁵ This is because of 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*. When ordinary inventions are patented, the inventor's market for embodiments of the primary invention is protected, while disclosure allows follow-on inventors to use the inventive idea to make technological progress by improving upon or designing around the original invention. During the patent term, 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) are generally available for the public benefit.¹³⁶ Thus, as long as disclosure is complete, the inventor cannot use her exclusive market in the primary invention to slow the pace of follow-on innovation.

¹³⁵ See generally Eisenberg, Patents and the Progress of Science, Hantman, Experimental Use as an Exception, O'Rourke, Toward a Doctrine of Fair Use in Patent Law, and Mueller, Rethinking the Experimental Use Exception.

 ¹³⁶ Patentees are not required to commercialize their inventions, of course. Rite-Hite Corp. v. Kelley Co.,
56 F.3d 1538, 1547 (Fed. Cir. 1995) (stating that patentees are not required to commercialize their inventions). However, the incentive theory assumes that they generally will if they can. Thus, ordinarily,

In contrast, when research tools are patented, the most significant "progress in the useful arts" usually depends upon using an embodiment of the invention – the research tool itself – to make a further (often patentable) innovation. The primary financial return may flow from exclusive control of the research *results* rather than from widespread commercial use of an embodiment of the invention. Thus, to determine whether an experimental use exemption should apply to patented research tools, the effects of patenting on subsequent innovation *using the tool* (not just the idea) must be considered.

To begin the inquiry, we must examine what is meant by a "research tool." For the purposes of this discussion, a research tool is an invention the primary function of which is to facilitate scientific or technological progress.¹³⁷ 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 in a way that maximizes the return to the tool patentee at the expense of society. To determine under what circumstances (if any) this concern is justified, we must ask two questions: (1) Under what conditions does a research tool patent permit the patentee to control the direction and pace of subsequent innovation? (2) When, if ever, will a tool inventor's control over subsequent technical progress pose a problem for the public? Only after considering these questions can we determine whether a well-crafted infringement exception for "experimenting with" can or should be devised.

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if a research tool 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.

A. When Can a Tool Patentee Control the Progress of Research?

There are two prerequisites 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 that require the tool. As Professor Janice Mueller has pointed out, there is no "research tool issue" if the patentee commercializes the research tool and sells or licenses it on the open market.¹³⁸ If there are close substitutes for the tool available to researchers, 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 for which the tool might be used. (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 since the alternative is not to profit from the eventual research at all.) Similarly, if researchers are relatively indifferent between problems requiring a patented tool and a whole host of interesting problems for which they do not need to use the tool, the patentee will not exercise significant power over research progress.

Unless these two prerequisites are satisfied a patentee is likely to market the tool widely, in an attempt to recoup the investment in developing it, rather than to refuse to license it in an attempt to control forthcoming research. Only when the research tool is of

¹³⁷ See Mueller, *Rethinking the Experimental Use Exception* at 10-17*and Integra*, No. 02-1052 (Fed. Cir. June 6, 2003) at 32 (Newman concurring in part and dissenting in part) (stating that a "research tool is a product or method whose purpose is use in the conduct of research").

¹³⁸ See Mueller, *Rethinking the Experimental Use Exception* at 15. This is an over-simplification, of course, since 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 characteristic of widespread commercial availability is that it decouples control over research using the tool from recovering the toolmaker's investment.

unique importance to a uniquely important problem, does the potential for serious adverse public impact from a research tool patent arise.

B. When Is an Inventor's Control Over Research Use of a Patented Tool Cause For Concern?

From the public perspective, the important issue is not who controls the research, but whether the research is performed effectively. 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.¹³⁹ Kitch analogized patents to mineral claims, arguing that patents -- especially broad patents granted at an early stage of the inventive process -- can increase social value by permitting the patent holder to manage exploitation of the invention efficiently, thus avoiding wasteful duplicative effort.¹⁴⁰ Patents on research tools for which no close substitutes are available are "broad" in the sense that they give the patent holder exclusive control over the development of the research (which will presumably lead to some kind of commercially useful result) is performed.¹⁴¹ Research tool patents also may avoid, at least to some extent, one of the principal criticisms of the explanatory power of the prospect theory, which is that the ability of others to obtain improvement patents that can potentially block further development of

¹³⁹ Edmund Kitch, *The Nature and Function of the Patent System*, 20 J. L. & ECON. 265 (1977) [hereinafter Kitch, *The Nature and Function of the Patent System*]. See also Yoram Barzel, *Optimal Timing of Innovations*, 50 REV. ECON. & STAT. 348, 349 (1968).

¹⁴⁰ Kitch, *The Nature and Function of the Patent System* at 276.

¹⁴¹ They are also frequently "early" in the sense that development of the tool may require significantly less investment than the subsequent research.

the patented technology casts doubt on the claim that patent holders are actually able to coordinate exploitation of the technology within the scope of the patent.¹⁴²

While patentable improvements are likely to stem from the broad pioneer patents traditionally associated with the Kitch theory, a research tool patent may be much more specific (and less susceptible to patentable improvements) yet still control access to a relatively broad scope of tool-based research.¹⁴³ As already discussed, where research tool patents can easily be designed around or where they have close substitutes, they do not exert special control over research progress and do not warrant special treatment. Where research tools do not have close substitutes, they really may provide the control over exploitation of the patent that the prospect paradigm assumes.

The Supreme Court has opined that "a patent is not a hunting license."¹⁴⁴ However, a research tool patent may, in the absence of close substitutes, be exactly that.¹⁴⁵ The question then becomes whether there is any reason to be concerned about the award of an exclusive "license to hunt" the solutions to important research problems to the first one to develop the research tool.

Because research tool patents fit so well into the prospect theory, they are also particularly susceptible to criticisms of that theory that have been made.¹⁴⁶ Criticisms

¹⁴³ See generally Rochelle Cooper Dreyfuss, Varying the Course in Patenting Genetic Material: A Counter Proposal to Richard Epstein's Steady Course, available at http://www.ssrn.com/abstract_id=394000
[hereinafter Dreyfuss, Varying the Course in Patenting Genetic Material]
¹⁴⁴ Brenner v. Manson, 383 U.S. 519, 536 (1966).

¹⁴² See, e.g., Merges, 76 CAL. L. REV. 805 (1988), John F. Duffy, *Rethinking the Prospect Theory: A Neo-Demsetzian View, available at* http://_____ (citing and discussing authorities) [hereinafter Duffy, *Rethinking the Prospect Theory*]. Indeed, critics of the prospect theory have argued that the current patent system seems inconsistent with the prospect theory because it does not eliminate the potential for inefficient races to produce patentable improvements within the scope of a broad, early patent.

 ¹⁴⁵ See Dreyfuss, Varying the Course in Patenting Genetic Material at 4.

¹⁴⁶ See generally Merges & Nelson, *Economics of Patent Scope* at 872-873, Lemley, *The Economics of Improvement in Intellectual Property Law*, at 1048-1052, Heller and Eisenberg, *Anticommons, and* Eisenberg, *Patents and the Progress of Science* at 1040-44.

that are particularly relevant to research tools focus on the differences between research, which depends critically and somewhat unpredictably on the expertise and creativity of the researcher, and mineral prospecting, which is a fairly straightforward task that requires coordination but no flashes of insight.¹⁴⁷

These criticisms are particularly appropriate where, as is often the case, obtaining a research tool patent may be relatively "easy," with many potential inventors competing to stake out a claim, in comparison to the research using the tool, which may be relatively "hard," requiring creativity, specialized expertise, and substantial resources. In fact, as I discuss below, this "tail wagging the dog" aspect of research tool patenting underlies much of the skepticism about whether the inventor will exploit the patents to best effect.¹⁴⁸

It is in society's interest, of course, to have the research performed by the quickest and most effective researcher. The pace of research is important not only to "promote progress in the useful arts" but also, at least for some research problems, because of the threats to health and safety that inspire the research (as though the hunting license is a license to hunt a man-eating tiger). It is also, of course, in the interest of the patent holder to solve the research problem so as to obtain the rewards of exclusive control of the research results. But do the patentee's incentives align with those of the public at large? Not necessarily. Several factors may prevent the research tool patent holder from

¹⁴⁷ See generally Eisenberg, Patents and the Progress of Science, Merges & Nelson, Economics of Patent Scope, and Julie E. Cohen & Mark A. Lemley, Patent Scope and Innovation in the Software Industry, 89 CALIF. L. REV. 1 (2001).

¹⁴⁸ As discussed further below, however, the case of a research problem that is easily solved once the appropriate tool is developed is also not uncommon. Any proposed research use exemption must account for both types of research tool.

making the tool available (through license or employment) to the most effective researcher.

First, the tool patent holder may not necessarily have the expertise necessary to correctly identify the best researcher – even if it is possible to determine in advance who that researcher may be. Unlike the process of working a mine claim, which may be largely a matter of organized searching, research may require a unique combination of expertise and luck. Depending on the tool in question, the knowledge and skills relevant to tool development may not be cognate with those relevant to performing the research. Indeed the concept of a "tool" carries with it the connotation, as already discussed, of a device that is simpler than, and supplemental to, the primary work at hand.¹⁴⁹ And while obtaining the broad pioneer patents generally considered in the context of the prospect theory may be a reasonably good signal of competence to make further developments in the field, developing an "easy" research tool may not be a reasonable signal of competence to mange the difficult research that employs the tool. For the same reasons, the tool patent holder may not be best qualified to identify the research problems to which the tool might be fruitfully applied.¹⁵⁰

Most importantly, however, the holder of a research tool patent does not necessarily share society's incentives to speed the pace of research. Employing (or licensing) the most efficient researchers may require sharing the profits (both monetary and reputational) of the discoveries resulting from the research in a way that is not to the private advantage of the tool patent holder. In this respect, research tool patents may be

¹⁴⁹ Again, it is important that this connotation is not always accurate in the research context. Developing a complicated piece of research equipment may be a very good indicator of competence to use it in research.

significantly different from mining claims. Because mining is performed primarily by hired workers who are in plentiful supply, it could be a reasonable assumption for mining prospects that the claim holder's incentives to maximize profits will align with society's interest in efficient exploitation of the claim. Both claim holder and society have an interest in mining in a cost-effective way.

Patent prospects may be quite different, however, especially when the patented invention is a relatively easily-developed research tool. Exploiting the research tool efficiently may require the cooperation of expert researchers, who may reasonably insist on a substantial share in the profits from the eventual research results.¹⁵¹ While a profit-sharing arrangement with the most effective researcher might be quite sufficient to address the free rider problem by reimbursing the tool patentee for her investments in tool development, it may be in the tool patent holder's interest to settle for a larger share of the results of less effective research. In other words, the holder of the tool patent may not be able to internalize the benefits of cooperative research and may thus not have incentives to exploit the patent in the most socially beneficial way.¹⁵²

¹⁵⁰ Offhand, this might be expected to be less of a problem than the incapacity to identify the best researchers, since proposals to license the tool for use on various problems should find their way to the patentee.

¹⁵¹ See Gallini and Scotchmer, *Best Incentive System?* at 65-66 (discussing and citing authorities regarding the problem of dividing profits between cumulative innovators). Gallini and Scotchmer point out that inventors of research tools, for which all of the social value resides in the results of the research, must be able to claim some of the profit from research using the tool or they will have insufficient incentives to invent. This is true, but only in the sense that any manufacturer of raw materials or other components of a product depends upon income from the eventual sales of the marketed product. The profit to the research tool inventor can come in the form of a purchase price for the tool. It need not take the form of a reach-through royalty on the research results. More important to the research tool problem is the issue, also highlighted by Gallini and Scotchmer and the researchers they cite, of "dividing the profit between innovators in a way that respects their costs." (*Id.* at 66.) Such a division is the goal of a research tool exemption.

¹⁵² A related problem arises where 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* Lemley, *The Economics of Improvement in Intellectual Property Law* at 1056-1058.

Professor Duffy has argued that the primary benefit of early, broad patenting is a race for earlier invention (and corresponding earlier patent expiration.¹⁵³ He argues that the prospect theory should be modified to emphasize the incentives to speed the pace of invention that result from early, broad patenting. According to Duffy's analysis, broad, early patenting produces a socially beneficial tradeoff of rent dissipation in duplicative research (which has no social benefits) and rent dissipation in a race for earlier innovation, which benefits society.¹⁵⁴ As Duffy explains, "policies that permit patenting of embryonic research results -i.e., that allow patenting prior to the bulk of the investment needed to bring the innovation to market – increase the efficiency of the competition by ensuring that the predominant private cost of earlier patenting is the earlier expiration of the patent right (which has a private but not a social cost), not the premature expenditure of resources on innovation or the duplication of innovative efforts (both of which are private costs and social costs)."¹⁵⁵ Unlike the race to obtain the earliest patent that Duffy describes, which speeds the pace of innovation and leads to earlier patent expiration,¹⁵⁶ the grant of a research tool patent, despite its seeming fit with the prospect theory, may in some circumstances have the opposite effect. This is because the most important question for society may be the incentive for rapid research using the tool rather than the incentive for earlier tool development.

If a research tool has no effective substitutes and is not made widely available, the relatively long period of exclusive control of the tool granted by a patent may give the patent holder such a significant head start on the relevant research as to permit him or her

¹⁵³ Duffy, *Rethinking the Prospect Theory* at 5.

¹⁵⁴ Duffy, *Rethinking the Prospect Theory* at 33-34

¹⁵⁵ Duffy, *Rethinking the Prospect Theory* at 7-8.

¹⁵⁶ Duffy, *Rethinking the Prospect Theory* at 33-34.

to slow the pace of innovation substantially so as to capture a greater proportion of the profits of the research. While the race to patent the tool may lead, as in Duffy's analysis, to earlier expiration of the tool patent, it need not lead to earlier expiration of the more important eventual patent on the research results since the successful tool patentee need not "race" to those results. When the research project is aimed at addressing important societal problems, such as disease or agriculture, the societal detriment of such delay may be very severe while the private incentives to delay so as to keep a larger share of the monetary and non-monetary benefits of the research may be correspondingly great.¹⁵⁷

Duffy also identifies the prospect of third party improvement patents as an incentive for the original inventor to continue developing the invention as quickly as possible. In the research tool context, while there may be continuing incentives to improve the tool, these need not necessarily translate into incentives to speed the pace of research using the tool.

Thus, when there are a limited number of highly valuable research projects that can be performed with a patented tool (and the tool has no close substitutes) there are two possibilities. It is possible that, as in Kitch's prospect theory, the patent holder may perform the socially useful function of limiting wasteful and duplicative expenditures by many researchers.¹⁵⁸ Alternatively, though, the patent holder may, either by mistake or

¹⁵⁷ See Lemley, *The Economics of Improvement in Intellectual Property Law* at 1059-1061 (discussing other noneconomic incentives).

¹⁵⁸ See generally Kitch, *The Nature and Function of the Patent System*. It should be noted that, to the extent competing researchers share information or explore different approaches to the problem, their efforts may be neither duplicative nor wasteful. In principle, the holder of a research tool patent could take such effects into account in organizing the research effort. In practice, the holder of a research tool patent may lack the necessary expertise to do this or be unable to internalize the benefits of doing so.

by design, significantly slow the progress of research by excluding the best researchers from the project or failing to license the optimum number of researchers.¹⁵⁹

At this point there is a judgment call to 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. We have, as a society, generally presumed that competition fosters innovation. This intuition is echoed by the scientific community, which views research, unlike mining, as an activity that is not susceptible to central planning.¹⁶⁰ Moreover, as discussed, there are good reasons to suspect that the private incentives of tool patent holders are not aligned with the best interests of society. For these reasons the analysis that follows assumes that it is in society's interest to encourage the inventors of "easy" research tools to commercialize their inventions so as to make them broadly available to interested researchers rather than to award control of the research to the one who happens to get the patent on the tool.¹⁶¹ This approach focuses the competitive (though potentially duplicative) efforts on the more difficult problems and places more control in the hands of those who are capable of performing the more difficult research tasks.

C. The Potential For an Experimental Use Exception To Alleviate Problems From Research Tool Patenting

Now that we have identified the circumstances under which problems may arise from research tool patenting, we may consider whether some kind of experimental use

¹⁵⁹ Lemley, *The Economics of Improvement in Intellectual Property Law* at 1052-1062.

¹⁶⁰ Eisenberg, Patents and the Progress of Science at 1059-1065.

¹⁶¹ 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,

exception to infringement liability is a useful antidote. The commercial/non-commercial distinction, here as in the "experimenting on" context, is not necessarily focused on the potentially problematic circumstances. As noted by Janice Mueller in her article on experimental use of "research tools," there are many patented research tools, including chemical reagents, laboratory equipment such as lasers and microscopes, and certain genetically modified mice that are widely available on the market from parties whose business consists in selling such items.¹⁶² There is no immediately obvious reason that non-profit research laboratories should avoid paying the going rate (or an appropriately discounted rate based on the patentee's ability to price discriminate) for such inventions, just as they do for patented copy machines, computers, and staplers.¹⁶³

If it is desirable to modify the incentive structure in some instances to encourage commercialization of a research tool, we must consider whether it is possible to do so without unduly discouraging the development of such tools or driving tool inventors to keep the tools secret so that they can control the pace of research. An analysis similar to that in Section III.B can help to sort out the options.

Having developed a research tool, an inventor has two basic options: commercialize the tool by making it widely available on the market or use the tool to perform in-house research.¹⁶⁴ Depending on whether the tool is self-disclosing in the sense of Section III, the inventor may commercialize the tool with or without patenting it.

because they do not have exclusive rights to the tool, have no capacity to delay the research for strategic reasons.

¹⁶² Mueller, *Rethinking the Experimental Use Exception* at 12-15.

¹⁶³ Mueller, *Rethinking the Experimental Use Exception* at 33-35, Eisenberg, *Patents and the Progress of Science* at 1084-85.

¹⁶⁴ Of course there are actually intermediate options, involving licensing the tool exclusively to a limited number of researchers. For present purposes, I have lumped all of these options which maintain control of the research process in the hands of the tool inventor together under the "in-house" umbrella. It is to be

Likewise, the inventor may perform in-house research either by patenting the tool or by keeping it as a trade secret during the research period.

To analyze the research tool question, a plot similar to those used in Section III.B can be used. (See Fig. 6.) The vertical axis of the diagram represents the secrecy time, S, during which the inventor of the tool can perform research using the tool in secret without competition from others.¹⁶⁵ S will be the shorter of the time it takes for a third party to invent the tool independently and the time it takes for a third party to reproduce the tool using information obtained from the tool inventor through industrial espionage or by other means.¹⁶⁶ The horizontal axis represents the time, I_R, it will take for the research tool inventor to perform successful research using the tool. Because S depends on expenditures on secrecy by the researcher, we expect generally $S <~ I_R$ since there is no point in investing in keeping the tool secret longer than necessary to complete the research project. Thus, the most interesting part of Figure 6 is the region below the line S = I_R ¹⁶⁷

In the absence of a patent on the research tool, the time for a third party to complete the research project, denoted I_3 , is the sum of the time it takes the third party to obtain the tool and the time it takes the third party to use the tool to obtain research results, which we will denote I_{3R} . If the tool is commercialized, the third party will be able to begin research almost immediately, thus $I_{3C} = I_{3R}$. If the third party must develop

¹⁶⁵ S is similar to, but not the same as, a trade secrecy term. S can be longer than a trade secrecy term because the tool is not available on the market for reverse engineering.

assumed that, if permitted, the tool inventor will choose whichever combination of such options maximizes private benefit, taking into account the non-monetary rewards of being the successful researcher.

¹⁶⁶ S may depend on secrecy expenditures by the patentee. It is assumed that the patentee will optimize her total anticipated return from the research in choosing the amount to spend on secrecy.

¹⁶⁷ Assuming that the costs of maintaining tool secrecy are minimal compared to the expected payoff from successful research, the tool inventor will invest as necessary to keep the tool secret until the important research is completed, but not substantially longer. Thus, S will usually be close to or less than I_R

(or steal) the tool, the time for third party invention will be lengthened by the secrecy time, S. Thus, if the tool is not commercialized, $I_{3S} = I_{3R} + S$.

As long as the tool is commercialized, patenting will not affect the third party research time, which will be $I_{3C} = I_{3R}$. On the other hand, if the tool is not commercially available during the patent term, third parties may begin using the tool only *after the patent expires*. Third party research will be substantially delayed in this situation, with $I_{3P} = I_{3R} + p$, where p is approximately the patent term.¹⁶⁸

To analyze the research tool problem, we first focus on cases in which tool development is much easier than tool-based research. In figure 6, this is the region where $S \ll I_R$ (because S is limited by the time required for independent tool invention, which is assumed to be much less than the time required for research).

The various possibilities depicted in Figure 6 can be understood as follows:

Region A: $I_R < I_{3R}$. In these cases the tool inventor is also the most effective researcher (or the tool inventor has been able to identify and license the most effective researcher). When this is the case, the tool inventor may commercialize the tool or not, patent it or not, without affecting the pace of research using the tool. There is no public benefit to commercializing the tool, since a commercially available tool can only induce competitors to waste resources on duplicative (and ultimately ineffective) research. The social value of patenting is ambiguous in these cases, since patenting can be used either to monopolize tool-based research (thus eliminating ultimately unfruitful duplicative efforts) or to commercialize the tool (thus inducing duplicative and unfruitful research).

¹⁶⁸ Actually p may be somewhat less than the patent term since there may be some delay between patenting the tool and being able to use it and we have set our "zero" at the time the tool is available for use.

Region B: $I_{3R} < I_R < I_{3S}$. In these cases the tool developer is not the most effective researcher but can maintain control of tool-based research through secrecy (or, in most such cases, by patenting). Though commercializing the tool would make it available to the most effective researcher, the tool inventor has no incentive to give up control of the lucrative research by commercializing the invention.¹⁶⁹ An experimental use exception cannot help in these cases because the tool inventor can perform her research in secret rather than patenting the tool. Because the tool inventor can keep control of the research, tool-based research will be delayed. However, as long as research tools are relatively easily developed, S is small and the delay in these cases will not be substantial. Recall that $I_{3S} = I_{3R} + S$. Thus, $I_{3R} < I_R < I_{3S}$ only if $0 < I_R - I_{3R} < S$. Because S is short relative to I_R , this condition implies that $(I_R - I_{3R})/I_R << 1$. In other words, these are cases in which the tool inventor can perform the ultimate research almost as effectively as any other researcher.

Region C: $I_{3R} < I_{3S} < I_R < I_{3P}$. In these cases, as in region B, the tool developer is not the most effective researcher. Here, though, the tool inventor cannot keep the tool secret long enough to "catch up" to the fastest researcher either because someone else will discover the tool independently or because word of the tool will leak out. The tool inventor thus prefers to patent the tool (but not to commercialize it) so that she can obtain the profits from tool-based research.¹⁷⁰ Unless the tool inventor is spurred by some kind of experimental use exception to commercialize the tool, she is in a position to delay

¹⁶⁹ We have already assumed that we are dealing with a case in which the tool inventor's private benefit is maximized by controlling the research using the tool, rather than by commercializing the tool, because the payoff from research is very high. ¹⁷⁰ These tool patentees will face choices about how to exploit their control to maximize their private

¹⁷⁰ These tool patentees will face choices about how to exploit their control to maximize their private benefit. They may, of course, choose to give the license to the best researcher rather than invest in their

significantly the societal benefits of tool-based research. The potential delay in these cases is limited only by the patent term, since $I_{3S} < I_R < I_{3P}$ implies that $S < I_R - I_{3R} < P$. Thus, in these cases there may be significant public benefit to be gained if the tool developer can be persuaded to commercialize the tool.

Region D: In this region, not only is $I_{3R} < I_R$, indicating that the tool developer is not the most effective researcher, but $I_{3P} < I_R$, indicating that the tool inventor is more than twenty years slower at getting the research done than a third party researcher! Tool inventors in this presumably unusual situation can benefit from inventing the tool only if they commercialize it. They will never win the research race. They may choose to patent tools that are self-disclosing in the sense of Section III, but they gain nothing by delaying the research race since they cannot win it in any event. In this region, if the tool has sufficient market value (according to the analysis in Section III) it can be developed and made available to third party researchers (presumably including the fastest researcher).

Before considering the implications of this analysis for a potential experimental use exception for research tools, it is important to see how the analysis differs if we consider the case of complex research tools with relatively easy research application. In such cases we can no longer assume that $S \ll I_R$. Instead, we expect $S \sim I_R$, where I_R itself is relatively short because the research applications are relatively easy. In fact, we would normally anticipate that I_R is substantially less than p in these cases. Finally, there are good reasons to anticipate that $I_R \sim I_{3R}$, where I_{3R} is the research time for the fastest third party researcher.

own slower research. There is no guarantee, however, that the maximum private benefit to the tool holder coincides with the public interest in faster research.

There are several reasons to expect a narrow spread in research times for relatively simple research projects. For one thing, in contrast to the developer of a "simple" research tool, who may not have the expertise for carrying out the tool-based research, the inventor of a complex piece of research equipment is likely to have the necessary expertise to carry out the research. Even if the tool inventor does not have the expertise herself, she has every incentive, having already made the lion's share of the necessary investment, to contract for quick performance of the research. Because the research is relatively "easy", the choice of researcher should not be critical and there should be a reasonable supply of research "labor." Thus, the region of Figure 6 most relevant for complex tool inventions is the region where $I_R \sim I_{3R}$, $S \sim I_R$, and I_R is considerably less than p. Thus, complex research tools do not raise the same concerns for potential research delay as simple research tools. There is little reason to encourage the transaction costs and potential duplicative effort of commercialization or licensing in these cases.

Having laid out this basic framework, we can now consider how patent policy might be shaped to encourage inventors of "easy" research tools to commercialize their inventions when they are not the most effective tool-based researchers (and particularly in region C, where tool-based research may be significantly delayed if the tool is not commercialized). In considering whether and how to formulate an experimental use exception, we consider whether any proposed exemption would be effective in disentangling the incentives for tool inventions from the ability to control the outcome of research using the tool. We also analyze the impact of any proposed exception on the development of complex tools.

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D. Proposed Experimental Use Exemption for Research Tools

Two types of proposals have generally been made for experimental use exemptions for research tools.¹⁷¹ One type of proposal contemplates an exception for non-profit institutions,¹⁷² while another type suggests a compulsory licensing scheme (or the equivalent) for research tool inventions.¹⁷³ Let us consider each of these proposals in light of the above analysis.

1. Compulsory Licensing

Commentators, most notably Professor Mueller, have suggested some sort of compulsory licensing for experimental use of a patented research tool invention.¹⁷⁴ Because compulsory licensing provides compensation to the tool inventor, but frees others to perform tool-based research, it is a possible mechanism to separate recovery of investment in tool development from "tail wagging the dog" control of tool-based research. Compulsory licensing effectively forces a tool inventor to choose between researching in secret and commercializing the tool. The option of using a patent to secure a longer period for in-house research is eliminated when a compulsory license is available.

Thus, referring to Figure 6, we can see that compulsory licensing of a research tool will have little impact in cases in region A, where the tool inventor can win the race regardless of whether the tool is available to other researchers, and region D, where the tool inventor can never win the research race and will thus does not need a compulsory

¹⁷¹ For the most part, it must be recognized that "experimental use" in this context means "use." Research tools are generally used for experimentation. However, there are inventions, such as certain medical diagnostic tests, that have both commercial and research applications. The proposed exemptions are targeted at research uses of such inventions.

¹⁷², Dreyfuss, Varying the Course in Patenting Genetic Material at 9-11.

¹⁷³ See, e.g., Mueller, Rethinking the Experimental Use Exception at 52-9.

license incentive to make the tool available on the market to recoup her development expenses. In region B, tool inventors subject to a compulsory licensing regime will resort to secrecy since they are able to maintain control of the tool-based research in that way. But, as discussed earlier, for research tools that are relatively easy to develop, the delay occasioned by secrecy will be correspondingly small because the ability to perform secret research is limited by the ease with which third party researchers can develop the tool independently. There is also little societal detriment if the inventor of a complex research can complete the research in secret since there is likely to be little difference in the pace at which different researchers can perform "easy" research.

In region C, secrecy is insufficient to protect the tool inventor's lead in tool-based research and, if compulsory licensing is imposed, the tool inventor will have to patent and commercialize her tool to reap any benefits from its invention. In this region, compulsory licensing would have a significant positive impact on the inventors of relatively "easy" tools because it precludes research delays which can range up to twenty years.

The effect of compulsory licensing for *complex* research tools whose inventors cannot finish their research in secret is much less positive, however. If such inventors cannot count on the royalty rate being high enough to offset their large investments in tool development they will be disinclined to invest in tool development. Perhaps equally important in many cases is the inability of compulsory licenses to allocate reputation rewards from research. Reputational rewards will tend to accrue to the one who performs the final research. This is a reasonable outcome for easily-developed tools, since the final

¹⁷⁴ See, e.g., Mueller, Rethinking the Experimental Use Exception at 52-9.

researcher actually has performed most of the difficult work. But this inability to allocate reputational rewards is a significant drawback of compulsory licensing for developers of complex tools. Moreover, as already noted, licensing (perhaps especially compulsory licensing) has transaction costs. These costs may be worthwhile to avoid significant research delay, but they are unlikely to be justified in the complex research tool context.

Even for easily developed tools, because compulsory licensing limits the tool inventor in Region C to recovery of a royalty payment, rather than offering the potential rewards from the research results, it will, of course decrease the incentives for those who are not fast researchers to develop tools. In some circumstances, depending on how the royalty is determined, the commercial market for the tool might not be sufficient to induce the fastest potential tool developer to develop the tool.

Even if the specter of compulsory licensing deters some potential tool developers, however, the combined effectiveness of tool development and tool-based research for simple tools is still likely to improve in region C under a compulsory licensing regime. When tool development is relatively easy compared to tool-based research there are strong incentives for good researchers to engage in in-house tool development efforts because they can win the research race even if other researchers gain access to the tool. The public benefits from compulsory licensing as long as it results in a more effective combination of tool development and tool-based research. Ironically, such benefits can arise despite compulsory licensing having its feared effect of deterring some potential tool inventors. As long as the tools are relatively easy to develop, compulsory licensing tends to put the tool-based research in the hands of the most effective researchers.

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Compulsory licensing has long been proposed as a solution to perceived excesses of patentee exclusivity.¹⁷⁵ More specifically, a detailed proposal for compulsory licensing of research tools has been made by Professor Mueller.¹⁷⁶ She proposes compulsory licensing for "research tools not readily available for licensing on reasonable terms or via anonymous marketplace purchase."¹⁷⁷ 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.¹⁷⁸ Professor Donna Gitter has endorsed a similar proposal specifically for gene sequences.¹⁷⁹

Critics of compulsory licensing schemes for patents, of whom Professor Richard Epstein is a recent example,¹⁸⁰ raise a litany of criticisms of such proposals ranging from philosophical objections to forced transfers of property rights to a parade of administrative horribles. As Professor Epstein recognizes,¹⁸¹ and as emphasized by Professor Rochelle Dreyfuss in a response to Epstein's paper, "the core significance of compulsory licensing requirements is that they act as credible threats, not as actual business deals."¹⁸² Professor Dreyfuss points to the experience of other countries in this regard, noting that "developed counties that have compulsory licensing requirements in

¹⁷⁵ See, e.g., Tom Arnold & Paul Janicke, Compulsory Licensing Anyone?, 55 J. PAT. & TRADEMARK OFF. SOC'Y 149 (1973), Cole M. Fauver, Compulsory Licensing in the United States: An Idea Whose Time Has Come, 8 NW. J. INT'L L. & BUS. 666 (1988), and Donna M. Gitter, International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption, 76 N.Y.U. L. REV. 1623 (2001) [hereinafter Gitter, International Conflicts Over Patenting Human DNA Sequences].

¹⁷⁶ Mueller, Rethinking the Experimental Use Exception at 58.

¹⁷⁷ Mueller, Rethinking the Experimental Use Exception at 58.

¹⁷⁸ Mueller, *Rethinking the Experimental Use Exception* at 58.

¹⁷⁹ See generally Gitter, International Conflicts Over Patenting Human DNA Sequences.

¹⁸⁰ Epstein, Property Rights in Genetic Material.

¹⁸¹ Epstein, Property Rights in Genetic Material.

¹⁸² Epstein, Property Rights in Genetic Material.

their laws find that potential research licensees rarely need to resort to court to enforce them."¹⁸³

Epstein complains that, besides being likely to "fail as an administrative matter,"¹⁸⁴ compulsory licensing provisions do more than bring parties to the bargaining table. He argues that they "change the threat positions of the parties to any negotiation," "deny a patent holder the right to choose the parties with whom he will do business in the first place," and "make exclusive licenses a dead letter."¹⁸⁵ As Professor Dreyfuss comments, these criticisms arise from an underlying concern that compulsory licensing depresses the returns that a patentee may capture.¹⁸⁶

One might agree that, in the usual case, compulsory licenses are a poor substitute for freely negotiated arrangements. The problem of easily developed research tools is a special case, however, to which Epstein's criticisms have questionable application. Professor Dreyfuss has pointed out several practical reasons to expect compulsory licensing to be more successful in the research tool context than Professor Epstein predicts.¹⁸⁷ But the more basic response to criticisms of compulsory licensing is that, in the context of research tool patents that are being used to control (and delay) progress in research rather than to overcome the free rider problem of appropriable investment, some

¹⁸³ Dreyfuss, Varying the Course in Patenting Genetic Material at 6 (quoting Gianna Julian-Arnold, International Compulsory Licensing: The Rationales and the Reality, 33 IDEA: J.L. & TECH. 349 (1993). Even Robert Merges, a classic transactional optimist, concedes that the "visible hand' of government" may sometimes be needed "to prod or force parties into [pooling] transactions," Robert P. Merges, *Institutions* for Intellectual Property Transactions: The Case of Patent Pools, in EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY at 123, 165. See also Mueller, Rethinking the Experimental Use Exception at n.319.

¹⁸⁴ Epstein, *Property Rights in Genetic Material* at 33.

¹⁸⁵ Epstein, Property Rights in Genetic Material at 26-7.

¹⁸⁶ Dreyfuss, Varying the Course in Patenting Genetic Material at 7.

¹⁸⁷ Dreyfuss, Varying the Course in Patenting Genetic Material at 9.

of the purported disadvantages of compulsory licensing are precisely the point of the proposals.

Because the research tool patent holders in question are trying to "game the system," 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 beat her in the tool-based research race. To put an even finer point on it, when we are dealing with tools that are mere tails in comparison to the research dogs they control, we are not even too concerned that the administrative costs or reduced royalties associated with compulsory licensing might deter some potential tool developers. If necessary, we are willing to let the dog wag the tail, removing incentives for unqualified researchers to grab control of downstream research through tool patents and leaving incentives for effective researchers to take care of tool development.

Of course these responses to criticisms of compulsory licensing are only convincing if a compulsory licensing proposal finds a way to identify the research tool patents to which they should apply. Here, I share with Professor Epstein a preference for "all-or-nothing" rules that do not impose too many complicated judgment calls on judges and juries in these cases.¹⁸⁸ The viability of a research tool exemption depends on having some sensible and reasonably mechanism for applying it. The characteristics of problematic research tool patents identified above were: i) no close substitutes; ii) developing the tool is much easier than doing the tool-based research; and iii) the tool patentee (in conjunction with her employees and exclusive licensees) is not the most effective researcher. While this list of factors is fine as a theoretical matter, it would

¹⁸⁸ Epstein, Property Rights in Genetic Material at 2.
clearly be preferable to avoid incorporating them into jury instructions. The question is whether there is a simpler rule that can serve as a reasonable proxy for these requirements.

Extant proposals for research tool exemptions confine them to tools that have not been commercialized.¹⁸⁹ Failure to commercialize a research tool may very well indicate that there are no close substitutes for the tool. The availability of close substitutes eliminates the possibility of controlling tool-based research by controlling the tool and provides an incentive to commercialize the tool. But relying on failure to commercialize as a test for compulsory licensing has some important drawbacks.

First, failure to commercialize cannot identify the cases in which the tool inventor is the most effective researcher (region A in Figure 6). In those cases, commercializing the tool would be wasteful and failing to commercialize is not indicative of a problem. Second, a commercialization test does not distinguish the true research tool cases discussed here, in which development of the tool is relatively trivial compared to the research, from the case of a very complicated research instrument which can be used easily to solve important research problems. Third, a commercialization requirement begs the question of timing. At what point is it reasonable to assess whether an invention has been commercialized? Finally, a commercialization test will often be difficult to assess, the question whether a tool is "readily available for licensing on reasonable terms" being open to significant (and inevitable) dispute.

In light of these complications, I would like to float an "all-or-nothing" proposal that I believe might be effective in addressing the research tool issue. Looking at Figure

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6, we can see that any difficulties that arise in the research tool case stem from the length of the patent term, which in principle permits tool patent holders to delay research by as much as twenty years. The twenty-year patent term performs two functions for research tool patents. As for ordinary inventions, it limits the time period over which a patentee can collect royalties (or higher prices) to recoup her investment in appropriable intellectual property. For research tools, however, it may also provide an excessive opportunity to delay important research for an inventor who has made a relatively minor contribution.

Compulsory licensing is a way of decoupling these two time periods. And there is no *a priori* reason that compulsory licensing must kick in at the beginning of the patent term. Instead, patent rights for research tools might consist of two periods: a few years (perhaps three to five) of complete exclusivity followed by a period to complete the patent term during which compulsory licenses would be available.

Such an approach would encourage early commercialization and voluntary licensing. It would give the tool patentee an opportunity to maintain control of the toolbased research either by demonstrating her own research skills or by making socially beneficial bargains with more effective researchers so as to preserve the opportunity to capture at least some portion of the rewards of the eventual research. By reducing the opportunities for delay it would remove some of the opportunities for private rentseeking. The initial exclusivity period would also provide an opportunity for inventors who have sunk significant research and development investments into complex research

¹⁸⁹ See, e.g., Mueller, *Rethinking the Experimental Use Exception* at 58 (proposing compulsory licensing for tools "not readily available for licensing on reasonable terms or via anonymous marketplace purchase.").

tools with simple applications to perform the research their inventions have made possible.

The initial exclusivity period would implicitly sort out whether there are close substitutes for the tool, whether the tool inventor can effectively manage the tool-based research, and whether the tool development was a trivial precursor for the tool-based research. 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 will serve primarily as an incentive for the negotiation of voluntary licenses during the exclusive period. Because the compulsory license would be available only after a substantial delay there would be incentives for both sides to come to an agreement rather than let the compulsory provisions kick in.

The exclusivity period would also provide some reference for the determination of a reasonable compulsory license.¹⁹⁰ While royalty determination is notoriously difficult,¹⁹¹ it may make sense to defer royalty determination to a compulsory licensing proceeding.¹⁹² By the time the compulsory licensing period kicks in the experience with

¹⁹⁰ It would be possible to simplify this proposal further by completely exempting research tool use after the exclusivity period. This would remove some of the potential administrative difficulties of compulsory licenses, but might pose the problem of too little incentive for tool development and could even conceivably delay the eventual research if third parties find it possible just to wait out the exclusivity period. On balance, and given the experience of other countries with compulsory license regimes, it seems better to require a royalty payment during the balance of the patent term.

¹⁹¹ Mueller, *Rethinking the Experimental Use Exception* at 58-66

¹⁹² International obligations require that some other determinations be made at the time of application for compulsory licensing in any event. TRIPS Article 31(b) permits compulsory licenses only if "prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time." *Id.* While this requirement may reintroduce some of the complexity of the commercialization requirement, it is specific to a particular licensee and thus more amenable to determination in a licensing

the tool during the exclusivity period should provide evidence of how much the tool invention contributes to the research process. Leaving this type of flexibility in the backup compulsory license will help promote voluntary licensing since neither party will be able to count on a slam-dunk win at the compulsory licensing stage. Experience elsewhere suggests that the potential complication (and expense) of administrative proceedings will be offset by the incentives to come to voluntary resolutions.¹⁹³

The remaining issue is how to determine whether a given patent is subject to the research tool provisions. There are a couple of options. There could be an administrative designation (which could be challenged in the courts) of research tool patents at the time of patenting. The difficulty with this approach is that some patented inventions are dual-purpose, with uses, for example, both as clinical tests and in the laboratory. The better approach is probably to defer the determination to the point of application for a compulsory license when the specific proposed use can be considered. Because I would anticipate very few actual applications for compulsory licenses at the end of the exclusivity period, there should be relatively few disputes about whether a particular use is a "research use" left to be resolved by the administrative proceeding.

The approach suggested here is similar to the "working requirement" in the patent law of the United Kingdom, for example.¹⁹⁴ It is also similar to the proposal made by Molly Holman and Stephen Munzer for the express sequence tags (ESTs) used in genetic

proceeding. An evaluation of TRIPS-compliance is beyond the scope of this article (For a complete discussion on the implications of TRIPS, *see* Dinwoodie & Dreyfuss, *Preserving the Public Domain of Science*).

¹⁹³ See generally Mueller, Rethinking the Experimental Use Exception, and Dreyfuss, Varying the Course in Patenting Genetic Material.

¹⁹⁴ See U.K. Patent Act of 1977 §§48, 48A, 48B.

research,¹⁹⁵ though the proposal differs from their proposal in that it does not incorporate a separate or weaker patentability requirement for research tools. The proposal affects only infringement liability and not any patentability requirements.

There remains, of course, the question of the length of the initial exclusivity period. Here, of course, as for the patent term, there is no one right answer and one could argue for different periods for different areas of research. However, the patent law deals with average public benefit and we need not get the answer exactly right to make a significant improvement over the status quo. What is clear is that twenty years is too long a delay for any research field. One or two years is probably not enough time for the commercialization issues to shake out. Something somewhat longer – say four or five years – is probably about right.

2. Exemption for Non-Profit Institutions

While some have advocated compulsory licenses, others have proposed an outand-out exemption for non-profit experimental use of patented inventions or at least have advocated that non-profit status be considered a factor favoring an experimental use exception.¹⁹⁶ Indeed, prior to the Federal Circuit's *Madey* decision, many may have assumed that a non-profit research exception was implicit in the common law experimental use exception. As discussed above, there are compelling reasons to exempt any "experimenting on" a patented invention from infringement liability, whether or not

¹⁹⁵ Molly A. Holman & Stephen R. Munzer, *Intellectual Property Rights In Genes and Gene Fragments: A Registration Solution for Expressed Gene Tags*, 85 IOWA L. REV. 735 (2000). Professor Justin Hughes has made a somewhat related suggestion in relation to the copyright fair use doctrine in *Fair Use Across Time*, 50 UCLA L. REV. 775, 778 (2003).

¹⁹⁶ See generally, Dreyfuss, Varying the Course in Patenting Genetic Material and O'Rourke, Toward a Doctrine of Fair Use in Patent Law.

it is commercially motivated. Should non-profit institutions receive an additional exemption for use of research tools? In fact, non-profit institutions often do receive deep discounts on research necessities, such as computers or laboratory supplies, which are widely marketed. These discounts seem a reasonable form of price discrimination reflecting the disparate ability to pay of the non-profit and private sectors. But it is a different question whether a non-profit exemption would solve the issues raised by nonsubstitutable research tools targeted at particular high impact research problems.

Looking again at Figure 6, one can ask whether a non-profit exemption can solve the problems of potential research delay without an unacceptable negative impact on tool development incentives. A non-profit exemption will have little impact on the incentives of tool inventors if non-profit institutions are not among the most competitive researchers who might use the tool. By "most competitive" here is meant "most likely to obtain a commercially valuable result." Thus, if non-profit researchers are most likely to use the tool for projects that do not compete with the primary commercial project, a non-profit exemption has much to recommend it. However, in such cases a formal non-profit exemption may not be necessary since non-profit researchers will probably be able to negotiate discounted licenses or simply infringe without repercussions. Empirical evidence suggests that this often happens, either because the infringement is not detected or because there is a norm disfavoring suits in such cases.¹⁹⁷ Indeed, until governmentfunded researchers were given the right to patent their inventions and universities began partnering with commercial entities in technology transfer ventures, this kind of benign

¹⁹⁷ See, e.g., Ashish Arora, Marco Ceccagnoli & Wesley M. Cohen, *R&D and the Patent System available at* http://www.nber.org.papers/w9431 (last visited July 14, 2003).

neglect of potential infringement by both patent holders and non-profit researchers was undoubtedly the rule.

Recently Professor Rochelle Dreyfuss¹⁹⁸ and, with modification, Professor Richard Nelson,¹⁹⁹ have proposed a form of non-profit research exemption that would serve primarily to "restore" what many had assumed existed before *Madey* was decided -an exemption for non-profit research aimed at projects unlikely to result in significant short-run commercial value.²⁰⁰ Their 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 researcher agreed to publish the results of the work; and 3) the researcher agreed to refrain from patenting the results, or to patent the results and then license them on a nonexclusive basis and on reasonable terms.²⁰¹ The proposed waiver functions almost like a certification that the researcher will not pre-empt the tool inventor in commercially significant research.

While the waiver proposal may restore part of the commercial market for the tools, since it removes exempted researchers from the competition for commercially significant research, it simultaneously renders the exemption ineffective to solve the primary problem considered here – the potential for inventors of relatively simple research tools to have undue influence over the pace and course of tool-based research with potentially lucrative applications.

¹⁹⁸ See generally, Dreyfuss, Varying the Course in Patenting Genetic Material, and Dinwoodie & Dreyfuss, Preserving the Public Domain of Science.

¹⁹⁹ Richard Nelson, *The Market Economy and the Scientific Commons*, RESEARCH POLICY (forthcoming). ²⁰⁰ Drevfuss, *Varying the Course in Patenting Genetic Material* at 15.

²⁰¹ Dreyfuss, Varying the Course in Patenting Genetic Materials at 8-10.

The case of interest for solving this problem is one in which the non-profit researcher has a good chance of beating the tool inventor to a commercially interesting research result if given access to the tool. In this kind of case, a non-profit exemption, like any other experimental use exemption, will increase incentives for secrecy where it is possible (as in Region B of Fig. 6). As already discussed, though, region B is small for relatively easily developed research tools. The more important question is the effect of a non-profit exemption on region C. Here there are serious implications for tool development incentives. If there is a non-profit exemption and any non-profit is a more effective research unit than the tool developer is able to assemble, the tool developer will be unable to maintain control of the results of the tool-based research. The tool developer who patents her invention will thus need to commercialize the tool if she hopes to recoup her investment. But the tool developer cannot obtain any revenue from the use of the tool by any non-profit entity if these entities are exempted from infringement liability. To recoup her tool development investment, the tool patentee may still make the tool commercially available to for-profit researchers. But the commercial research market is smaller and it may shrink further if commercial entities are unwilling to pay as much for a tool license (or even to take one at all) when they must compete with non-profit researchers who get to use the tool for free. Because it may cut out a substantial part of the market for a commercialized tool, a non-profit exemption seems more likely than a compulsory license to decrease incentives to develop and patent research tools for commercialization. Moreover, a non-profit exemption will not do anything to solve any problem of research delay in fields dominated by the private sector.

It is also unclear whether any non-profit exemption can adequately solve the problem (which may have been posed by *Madey v. Duke*) of research tools that are difficult to develop. Concern is usually focused on making available to the non-profit sector research tools (EST's being a prototypical example²⁰²) that are relatively trivially developed and can then be patented and used to lock up access to much more difficult and extensive research. But, as discussed above, there are also examples (in fact, such examples are common in the basic research context) of research projects in which development of a complex new piece of equipment is the most difficult and important phase of the research. The inventor of such a tool may justifiably wish to limit the ability of others (even if they are non-profit researchers who are willing to forego patenting their results) to free ride on her inventive efforts by performing the final -- and in this case relatively trivial -- application of the equipment to obtain results. This issue is not limited to commercially important results because non-profit researchers are highly sensitive to reputational rewards – which may be significant for results that no one wishes to patent.

For such cases, a non-profit exemption (even with a waiver requirement) both reduces incentives to develop the equipment and increases incentives to work in secret – neither of which are desirable outcomes in the non-profit context. The two-tiered compulsory licensing scheme proposed in the previous section handles this type of situation relatively well, however. The inventor of a complex piece of laboratory equipment can publish the workings of the equipment in a patent while at the same time having a period of exclusivity to obtain the first research results employing it. Such a

²⁰² See generally Mueller, Rethinking the Experimental Use Exception at 10-17, and Epstein, Property Rights in Genetic Material at 46-52.

scheme preserves both the incentive to develop complicated equipment and to place its workings into the public domain.

In sum, while a non-profit exemption of the type proposed by Dreyfuss and Nelson may have the important public benefit of restoring the ability for non-profit researchers to perform research without significant commercial implications, a two-tiered compulsory licensing solution has broader application to the problem of delay in research into problems of commercial significance and better protects the investments of inventors of complex equipment used primarily in the non-profit sector.

V. Conclusions

The goal of any experimental use exception should be to distinguish between a patentee's reasonable efforts to recoup her investment in appropriable intellectual property and a patentee's attempts to exert undue control over follow-on innovation. This distinction is already enshrined in many aspects of the patent law, including the disclosure requirement.²⁰³ An analysis of the differing roles played by the incentive to invent and the incentive to disclose in the development of different inventions indicates that experimental use aimed at understanding, designing around, or improving a patented invention is merely an extension of disclosure. Such "experimenting on" has little direct effect on the free rider problems that the patent system's incentive to invent is designed to solve. "Experimenting on" a patented invention can, and should, be broadly permitted, regardless of commercial intent, as a means of ensuring that the public receives the benefit of its patent bargain with respect to follow-on innovation.

²⁰³ *Integra*, No. 02-1052 (Fed. Cir. June 6, 2003) at 7 (Newman concurring in part and dissenting in part) (stating "the patent system both contemplates and facilitates research into patented subject matter, whether the purpose is scientific understanding or evaluation or comparison or improvement. Such activities are integral to the advance of technology.").

Experimentation "with" patented inventions – the case of research tools – is a more difficult question because the patentee's ability to recoup tool development investments is entangled with her ability to exert undue control over tool-based research. After considering proposals for research tool exemptions based on the non-profit status of the researcher, I conclude that a more effective scheme for speeding the pace of commercially significant research while preserving incentives to invest in tool development is a two-tiered compulsory licensing scheme. In the proposed scheme a research tool patentee would be entitled to a limited period of complete exclusivity during which she would have an opportunity to perform research or to commercialize or license the patented tool voluntarily. After the expiration of this period, compulsory licenses would be that the availability of such licenses would serve primarily as an incentive to voluntary solutions.

Finally, the proposals here may illustrate the possibility of a middle ground in the broader dispute between those who believe that the heterogeneity of subject matter covered by the patent laws demands specialized treatment for different types of inventions²⁰⁴ and those who advocate an "all-or-nothing" approach.²⁰⁵ The proposals here demonstrate that it may be possible in some instances to have the best of both worlds by designing rules of uniform applicability that inherently discriminate between types of

²⁰⁴See, e.g., Pamela Samuelson and Suzanne Scotchmer, *The Law and Economics of Reverse Engineering*, 111 YALE L.J. 1575 (2002) (providing an economic analysis suggesting that restrictions on reverse engineering ought to be imposed only if justified in terms of the specific characteristics of the industry, a specific threat to that industry, and the economic effects of the restriction); Gallini and Scotchmer, *Best Incentive System?* at 71-72 (discussing the need to design IP regimes to deal with economic heterogeneity and arguing that "each IP regime should cover subject matter with similar needs for protection").

rules.²⁰⁶

²⁰⁵ See, e.g., Epstein, *Property Rights in Genetic Material*] (discussing the advantages of "all-or-nothing" rules).

²⁰⁶ For a proposal with a similar spirit, *see* Dan L. Burk and Mark A. Lemley, Is Patent Law Technology-Specific?, available at <u>http://ssrn.com/abstract_id_349761 (2002</u>) (arguing that modifications to the PHOSITA standard will differentiate between technologies in a useful way).