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THE EXPERIMENTAL USE EXEMPTIONS
TO PATENT INFRINGEMENT

NYSTAR RESEARCH REPORT

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I. Introduction

The objective of this paper is twofold. First, to inform university researchers and technology transfer professionals on the state of the law regarding the experimental use exemption to patent infringement under which patented subject matter can be used without a license for research purposes. Second, to stimulate debate among university, industry and government officials on whether an experimental use exemption is desirable, and, if so, on the appropriate scope of such an experimental use exemption.

The U.S. patent system is built upon a delicate balance between the rights of patent owners, the rights of the public at large, and the rights of market competitors.¹ The patentee is granted broad rights to exclude others from making, using or selling the patented invention in order to reward the patentee's investment in creating the invention.² In exchange for the grant of patent rights, the patentee is required to disclose the details of the invention in the patent application.³ This disclosure benefits the public generally by adding to the store of scientific knowledge⁴ and benefits market competitors specifically by providing information about rival products and processes.⁵ In essence, the patentee's property rights come at the expense of enabling challenges to the value of those rights through further scientific advances and increased competitor know how;⁶ and the access by the public and market competitors to the information

¹ See *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) (“The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the ‘Progress of Science and useful Arts.’”).

² See *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294, 1304 (11th Cir. 2003) (“This exclusionary right is granted to allow the patentee to exploit whatever degree of market power it might gain thereby as an incentive to induce investment in innovation and the public disclosure of inventions.”).

³ See *Universal Oil Products v. Globe Oil & Refining*, 322 U.S. 471, 484 (1944) (“As a reward for inventions and to encourage their disclosure, the United States offers a seventeen-year monopoly to an inventor who refrains from keeping his invention a trade secret.”).

⁴ *Application of Argoudelis*, 434 F.2d 1390, 1394 (C.C.P.A. 1970) (Baldwin, J. concurring) (noting that one of the roles of the enabling provision of the Patent Act is to “provide the assurance that the public will, in fact, receive something in return for the patent grant. This consideration is, of course, the full and complete disclosure of how to make and use the claimed invention. Thus, the patent adds a measure of worthwhile knowledge to the public storehouse.”). *Id.*

⁵ See *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979) (“First, patent law seeks to foster and reward invention; second, it promotes disclosure of inventions, to stimulate further innovation and to permit the public to practice the invention once the patent expires; third, the stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public.”). See also F. M. Scherer, *INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE* 442 (2d ed. 1980).

⁶ See *Bonito Boats*, *supra* note 2 at 146 (“From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.”). See also *Kewanee Oil Co.*

contained in the patent application comes at the expense of abiding by limitations upon the use of that information.⁷

Experimentation with patented inventions is an activity that is central to the patent system balance.⁸ On the one hand, if researchers and competitors are able to use patented inventions for their intended purposes under the guise of experimentation, then patentees are deprived of economic benefits and the incentive to invest in inventive activities is diminished.⁹ On the other hand, if the public and competitors are unable to use patented inventions for genuine experimentation, then scientific knowledge is retarded and market competition is limited.¹⁰ Today, there are two types of experimental use exemption to patent infringement. The first, the common law experimental use exemption, developed through a long line of judicial decisions and applies to all inventions.¹¹ The second, the Hatch-Waxman experimental use exemption, was enacted by Congress in 1984 and applies only to drugs and medical devices.¹²

v. Bicon Corp., 416 U.S. 470, 481 (1974) (“When a patent is granted and the information contained in it is circulated to the general public and those especially skilled in the trade, such additions to the general store of knowledge are of such importance to the public weal that the Federal Government is willing to pay the high price of 17 years of exclusive use for its disclosure, which disclosure, it is assumed, will stimulate ideas and the eventual development of further significant advances in the art.”).

⁷ See Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank, 527 U.S. 627, 637 (1999) (“[B]ecause courts have continually recognized patent rights as property, the fourteenth amendment prohibits a State from depriving a person of property without due process of law.”). See also, Andrew Beckerman-Rodau, *Are Ideas Within the Traditional Definition of Property?: A Jurisprudential Analysis*, 47 ARK. L. REV. 603, 648 (1994).

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

⁸ See Lauren C. Bruzzone, *The Research Exemption: A Proposal*, 21 AIPLA Q.J. 52, 53-54 (1993).

Under the exclusionary patent grant, the patent owner could stop a researcher's activities if the researcher created a copy of the invention on his own and experimented with that copy.

However, to the extent that free access to knowledge is a requirement for technological progress, this right of the patent owner runs directly contrary to the avowed purpose of the patent law: the encouragement of the useful arts and science.

⁹ See Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1038-40 (1989) [hereinafter Eisenberg] (discussing Joseph Schumpeter's notion that “monopolies are conducive to innovation.”).

¹⁰ See Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 91 [hereinafter Strandburg] (“Patent exclusivity, while promoting inventive progress by providing incentives for innovation, can slow technical progress if the best follow-on inventors are prevented from building upon the inventive idea during the patent term.”).

¹¹ See Section I.A. *infra*.

¹² See Section I.B. *infra*.

Properly reconciling the interests of patentees, the public and market competitors has never been more important.¹³ Invention of new technology is critical to the success of U.S. companies,¹⁴ the growth of the U.S. economy,¹⁵ the health and welfare of U.S. citizens¹⁶ and U.S. competitive advantage in global trade.¹⁷ Perhaps because of its growing importance in our technology based society, or perhaps because of its inherent interest to an array of professionals, experimental use of patented inventions has been the subject of a great deal of thoughtful scholarship. Writers have considered the development of both the common law and Hatch-Waxman experimental use exemptions, reviewed their operation in different research contexts, discussed enacted and proposed legislative changes, presented arguments in favor of expanding and contracting the scope of the experimental use exemptions and, most of all, proposed a myriad of law reform measures to shape the future development of the experimental use exemptions.¹⁸ This paper will discuss the development of the experimental use exemptions and

¹³ See Bruzzone, *supra* note 9 at 55 (“Today, however, the ever increasing importance of technological development, the increased use of reverse engineering, and the need for common worldwide patent protection are all substantial motivation for a clearer articulation of standards.”) (internal citations omitted).

¹⁴ See NATIONAL SCIENCE BOARD, 1 SCIENCE AND ENGINEERING INDICATORS 6-6. The report highlights the importance of technology-intensive industries, pointing out that “high technology industries are driving economic growth around the world.” Within our own borders, “[d]emand for high-technology products in the United States far exceeds that in any other single country; in 1998, it was larger (approximately \$768 billion) than the combined markets of Japan and the four largest European nations—Germany, the United Kingdom, France, and Italy (about \$749 billion). *Id.* at 6-9 and fig. 6-7. Also, “U.S. industries that traditionally conduct large amounts of R&D have met with greater success in foreign markets than those that are less R&D intensive, and they have been more supportive of higher wages for their employees.” *Id.* at 6-18.

¹⁵ Illustrative of this growth is the fact that from 1995 to 1998, high technology production on a global level grew at a rate three times as fast as all other manufacturing sectors. *Id.* at fig. 6-1.

¹⁶ “In 1999, corporate patent activity reflected U.S. technological strengths in medical and surgical devices, electronics, telecommunications, advanced materials, and biotechnology.” *Id.* at 6-23 and tbl. 6-3. These areas are obviously essential to maintaining a healthy and technologically advanced society.

¹⁷ In the 1990’s, “U.S. exports of advanced technology products exceeded imports in 8 of 11 technology areas.” *Id.* at 6-11. Those areas include advanced materials (semiconductors, optical fiber cable, etc.), aerospace, biotechnology, electronics, flexible manufacturing, nuclear technology, software products, and weapons. *Id.* In 1999, trade in advanced technology products accounted for 29.2 percent of exports, versus 17.5 percent of imports, and accounted for \$381 billion out of \$1.7 trillion involving U.S. trade in merchandise. *Id.*

¹⁸ See Part III, *infra*. The focus of this section will be on the commentary related to the common law experimental use exemption and not the Hatch-Waxman exemption. For commentary relating to Hatch-Waxman, see generally Janet A. Gongola, Note: *Prescription for Change: The Hatch-Waxman Act and New Legislation to Increase the Availability of Generic Drugs to Consumers*, 36 IND. L. REV. 787 (2003) (arguing that Congress should pass the Drug Competition Act (S. 754, 107th Congress (2001) to protect the pharmaceutical industry against anticompetitive agreements made between brand-name and generic drug manufacturers in response to Hatch-Waxman’s convoluted provisions); Ned Milenkovich, Comment: *Deleting the Bolar Amendment to the Hatch-Waxman Act: Harmonizing Pharmaceutical Patent Protection in a Global Village*, 32 J. MARSHALL L. REV. 751 (1999) (arguing that the exemption provision of Hatch-Waxman should be eliminated in order to bring U.S. patent law in compliance with the TRIPS Agreement); Laura J. Robinson, *Analysis of Recent Proposals to Reconfigure Hatch-Waxman*, 11 J. INTEL. PROP. L. 47 (2003) (discussing the problems inherent in Hatch-Waxman’s thirty-month stay provision (21

review the considerable scholarship in the field. The discussion and review are particularly timely because of the sweeping patent reform bill (the Patent Act of 2005) introduced in Congress on June 8, 2005;¹⁹ and because of the important Supreme Court decision on experimental use decided on June 15, 2005.²⁰

Part I of the paper will discuss the common law and Hatch-Waxman experimental use exemptions to patent infringement. The discussion of the common law experimental use exemption will consider the different tests that courts have developed to distinguish between permissible and impermissible experimental uses of patented technology and the rationales that have been advanced in support of these tests. The discussion of the Hatch-Waxman experimental use exemption will describe the Hatch-Waxman Act and consider the cases that have arisen under the Act with special attention to the most recent case, which was decided by the U.S. Court of Appeals for the Federal Circuit and later reviewed by the Supreme Court. Part I will also briefly discuss the case of hybrid technologies which might fall within the common law and Hatch-Waxman experimental use exemptions. Part II of the paper will discuss the various law reform measures that have been proposed to reconcile the competing interests in the experimental use of patented technology. These law reform measures will be considered in terms of three aspects of experimental use -- the nature of the organization conducting the experimentation, the purpose of the experimentation, and the nature of the patented technology used in the experimentation. The discussion of the law reform proposals will be organized from the most limited proposed exemptions to the broadest proposed exemptions.

U.S.C. § 355(j)(5)(B)(iii)) and concluding that greater FTC and FDA scrutiny, rather than legislative proposals, would be a far better solution to current industry abuses.).

¹⁹ Patent Act of 2005, H.R. 2795, 109th Congress (2005). Although the proposed Patent Act of 2005 does not currently include an experimental use exemption to patent infringement, a group of prominent university associations, including the Association of American Universities, the American Council on Education, the Association of American Medical Colleges, and the Council on Government Relations, has urged Congress to include an experimental use exemption in the reform bill. *See* AAU/ACE/AAMC/CORG Comments on H.R. 2795 submitted to Lamar Smith, Chairman, H. Judiciary Subcomm. on Courts, the Internet and Intellectual Property, June 23, 2005 at 6, *available at* <http://www.acenet.edu/AM/Template.cfm?Section=Search>.

²⁰ *See infra*, note 140 and accompanying text.

II. The Experimental Use Exemptions

A. The Common Law Experimental Use Exemption

1. Early Cases

The origin of the common law experimental use exemption to patent infringement is universally attributed to Justice Story's opinion in *Whittemore v. Cutter*.²¹ In *Whittemore*, Justice Story stated that "it could never have been the intention of the legislature to punish a man, who constructed a [patented] machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."²² At the time Justice Story wrote these words in 1813, "philosophical" referred to the field of "natural philosophy" or what we call today "science."²³ Properly interpreted therefore Justice Story's statement contained two distinct experimental use exemptions to patent infringement; an exemption for using patented subject matter in order to perform scientific experiments and an exemption for using patented subject matter in order to test its claimed utility.²⁴

In *Whittemore*, Justice Story also addressed two other important questions regarding patent infringement; the relationship between the different acts of patent infringement enumerated in the patent statute and the relationship between damages and patent infringement.²⁵ The Patent Act of 1800 provided that a patentee could bring an infringement action against any person "who should make, devise, use or sell" a patented invention without authorization.²⁶ Justice Story held that each of these activities standing alone could constitute an act of infringement.²⁷ On the question of whether patent infringement required proof of damages, Justice Story held that it did not.²⁸ In Justice Story's opinion: "[W]here the law gives an action for a particular act, the doing of that act imports of itself a damage to the party. Every violation

²¹ *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C. D. Mass.1813) (No. 17,600). The origins of the experimental use exemption have been traced by several other authors. However, the origins themselves are a requisite starting point for any discussion in this area.

²² *Id.* at 1121.

²³ *Integra Lifesciences v. Merck*, 331 F.3d at 875 (Newman, J., dissenting). *See also* Bruzzone, *supra* note 9 at 60 ("Story's original version was broader. He saw the exemption as covering 'philosophic experiments' which, in the nineteenth century, included what we would consider scientific experiments.").

²⁴ *See infra* note 32.

²⁵ *Whittemore* 29 F. Cas. at 1121.

²⁶ 2 Stat. 37 (1880).

²⁷ *Whittemore* at 1121.

²⁸ *Id.*

of a right imports some damage, and if none other be proved, the law allows a nominal damage."²⁹

Justice Story elaborated on his opinion in *Whittemore* in the case of *Sawin v. Guild* decided in the same year.³⁰ In *Sawin*, Justice Story contrasted the making of a patented machine with an intent to use it for profit, which would be an act of infringement, and the making of a patented machine for the purpose of a scientific experiment or to ascertain the "verity and exactness of the [patent] specification," which would not be an act of infringement.³¹ Justice Story did not fully explain what he meant by using patented technology for the purpose of profit. His "for profit" test, however, can be interpreted in two ways. One interpretation of the "for profit" test would eliminate the experimental use exemption for all business organizations.³² The rationale for this interpretation would be that the goal of all business organizations is profit and therefore all of the activities of business organizations, including experimentation, are in pursuit of that profit.³³ A second interpretation of the "for profit" test would allow business organizations to experiment with patented technology where the immediate goal was to obtain scientific knowledge or to test patent claims, but disallow the use of patented technology for its intended purpose in direct revenue generating activities.³⁴ It is not clear which of these two interpretations Justice Story had in mind, nor is it clear how Justice Story viewed the absence of profit intent. Would a non-profit organization always be entitled to an experimental use

²⁹ *Id.*

³⁰ 21 F. Cas. 554 (1813) (C.C. D. Mass. 1813) (No. 12,391). *Sawin* involved the interesting question of whether the seizure and sale of a patented machine by a sheriff pursuant to the execution of a judgment on a debt would be an infringement of the machine patent. Justice Story held that this was not an act of infringement reasoning that to hold otherwise would allow debtors to place property beyond the "grasp" of creditors by investing their property in patented machines. *Id.* at 554-555.

³¹ *Id.* at 555.

³² See David L. Parker, Symposium, *Patent Infringement Exemptions for Life Science Research*, 16 HOUS. J. INT'L L. 615, 627 (1994) [hereinafter Parker] (*Sawin* can be "readily interpreted to mean that any use that itself is not a use for profit is not an infringement, with 'philosophical experiment' and 'determining the adequacy of the disclosure' merely two examples of uses that are not considered 'for profit.'").

³³ See Bruzzone, *supra* note 9 at 57 (discussing commercial competitors, she notes that "[t]he very nature of such defendants undermines any argument that their motives are not profit related or that their activities will not affect the plaintiff's potential profits.").

³⁴ Consider 3 William C. Robinson, *The Law of Patents for Useful Inventions* § 898 (1890)

[T]he manufacture or the use of the invention may be intended only for other purposes, and produce no pecuniary result. Thus where it is made or used as an experiment, whether for 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 experimenter'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 experimenter, or if the experiments are conducted with a view to the adaptation of the invention to the

exemption for the use of patented subject matter in scientific research and testing? Would the lack of a profit motive exempt a non-profit organization from patent infringement if it used patented subject matter outside of the realm of scientific research and testing? These questions raised by Justice Story's seminal pronouncements on experimental use would be slowly, and somewhat erratically, answered over the next one hundred and ninety years.

Later nineteenth century cases appeared to narrow the experimental use exemption to patent infringement. An 1861 case defined the experimental use exemption as the use of patented articles "for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement."³⁵ Whereas Justice Story's conception of experimental use was utilitarian and envisioned science experiments and testing patent claims, this later definition appears to allow only for purely fanciful and idle uses of patent subject matter. Other nineteenth century cases found that experimenting with a patented device to determine its suitability for a particular purpose³⁶ and using a patented machine for the purpose of comparing and selling a competing machine were activities outside the experimental use exemption.³⁷

Three experimental use cases decided in the mid-twentieth century, however, extended the exemption well beyond "mere amusement." The first case involved a university.³⁸ In the context of a complicated damages calculation, the court had to determine whether the use of infringing machine parts by a university was an act of infringement in which case the sale of the parts to the university constituted contributory infringement and would be included in the damages accounting.³⁹ The court found that the university had only used the machine parts in conjunction with machines that were located in a laboratory and that these machines were used only for experiments.⁴⁰ The court held that this was not an infringing use that could support a finding of contributory infringement.⁴¹ The second case involved a company that briefly experimented with a patented machine and determined that it could not yield a product of

experimenter's business, the acts of making or of use are violations of the rights of the inventor and infringements of his patent.

³⁵ *Poppenhusen v. Falke*, 19 F. Cas. 1048, 1049 (C.C.N.Y. 1861) (No. 11279). *Poppenhusen* was not decided by Justice Story; however, the language in the case would later be rephrased as "dilettante" activity and attributed to Justice Story. See *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F. 2d 858, 863 (Fed. Cir. 1984).

³⁶ *Palmer v. United States*, 20 Ct. Cl. 432 (1885), aff'd on other grounds, 128 U.S. 262 (1888).

³⁷ *Bonsack Machine Co. v. Underwood*, 73 Fed. 206 (C.C.N.C. 1896).

³⁸ *Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697 (D. Colo. 1935).

³⁹ *Id.* at 702.

⁴⁰ *Id.* at 703.

⁴¹ *Id.* at 713.

satisfactory quality.⁴² The court held that because the experimental use of the machine occurred before the company had commenced any commercial production the use was not an act of infringement.⁴³ The third case involved a competitor company that built a single patented device in order to experiment with it.⁴⁴ Here the court found that the uncontradicted evidence showed the competitor company used the device only to experiment, never manufactured any devices for sale, and never sold any devices.⁴⁵ The court held that under these facts the use did not infringe the rights of the patent owner.⁴⁶

A case decided in 1976, however, began a reversal of the trend toward liberal construction of the common law experimental use exemption.⁴⁷ The case involved the calculation of damages in an infringement suit against the United States for the use of patented helicopter rotors and controls.⁴⁸ The U.S. sought to exclude from the damages calculation its use of the helicopters for testing and evaluation of such factors as lift ability, vibration, flight speed and range.⁴⁹ The court concluded that these activities were infringing and therefore compensable.⁵⁰ In reaching this conclusion, the court held that testing and evaluation were "intended uses of the infringing aircraft...and are in keeping with the legitimate business of the using agency."⁵¹ The first holding reversed early case law that found experimenting with patented subject matter to determine its suitability for adoption fell within the experimental use exemption.⁵² The second holding created an entirely new limitation on experimental use. Henceforth, use of patented subject matter for purposes related to the experimenter's legitimate business would not be allowed under the experimental use exemption regardless of whether the use was commercial or non-commercial.⁵³ The "legitimate business use" limitation on

⁴² *Akro Agate Co. v. Master Marble Co.*, 18 F. Supp. 305, 315 (1937).

⁴³ *Id.* at 333.

⁴⁴ *Dugan v. Lear Avia, Inc.*, 55 F. Supp. 223, 229 (1944).

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Pitcairn v. United States*, 547 F.2d 1106 (1977).

⁴⁸ *Id.* at 1110.

⁴⁹ *Id.* at 1125.

⁵⁰ *Id.*

⁵¹ *Id.* at 1125-26.

⁵² *See Agro Agate Co.* 18 F. Supp. at 333.

⁵³ *See Parker, supra* note 33 at 631 (“[E]ven if no profit motive is attached to the experimental activity, the activity will nevertheless be considered an infringement if it is within the legitimate business of the organization.”).

experimental use would be applied in a case decided twenty-six years later that would nearly eliminate the common law experimental use exemption entirely.⁵⁴

2. Contemporary Cases

The case that irrevocably reversed the liberalization of the common law experimental use exemption was *Roche v. Bolar*, decided in 1984.⁵⁵ Roche was the owner of a patent on a drug compound contained in a successful brand name drug product.⁵⁶ Bolar was a generic drug manufacturer.⁵⁷ Prior to the expiration of Roche's patent, Bolar used the patented drug compound to perform tests to establish the bioequivalency of its generic drug to Roche's brand name drug; bioequivalency tests were necessary to obtain approval from the Food and Drug Administration (FDA) in order to market the generic drug.⁵⁸ Roche argued that the use of a patented drug to obtain test data to submit to the FDA was an act of infringement under the patent laws.⁵⁹ Bolar countered that the use was solely for experimental purposes and therefore exempt from infringement.⁶⁰ The federal district court found for Bolar holding that the use of a patented compound for federally mandated testing was not an act of infringement because the use was de minimus and experimental.⁶¹ The Court of Appeals for the Federal Circuit (CAFC) reversed.⁶²

In reaching its conclusion, the CAFC addressed four issues central to the experimental use exemption. First, citing to two cases that did not concern experimental use, the CAFC held that the use of a patented invention without either manufacture or sale was an act of infringement.⁶³ Second, the court held that a patentee does not have to show any evidence of damage or lost sales to bring an infringement action.⁶⁴ Third, the court held that Bolar's experiments were conducted solely for business purposes and that unlicensed experimentation

⁵⁴ *Madey v. Duke*, 307 F.3d 1351 (Fed. Cir. 2002).

⁵⁵ 733 F.2d 858 (Fed. Cir. 1984).

⁵⁶ *Id.* at 860.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.* at 862.

⁶¹ *Id.* at 860-61.

⁶² *Id.* at 867.

⁶³ *Id.* at 861 The first cited case, *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 484 (1964), turned on whether replacement of portions of the patented item constituted infringing 'reconstruction' or permissible 'repair' of said item. *Id.* at 479. The second case, *Coakwell v. United States*, 372 F.2d 508, 510 (1967), turned on the amount of reasonable damages for direct infringement of the plaintiff's patented invention. *Id.*

⁶⁴ *Bolar* at 861.

with a patented invention to adapt the invention to the experimenter's business is a violation of the patentee's rights.⁶⁵ The court's language on this point reveals just how narrowly the court viewed the experimental use exemption: "[Bolar's experiment] ...is no dilettante affair such as Justice Story envisioned. We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry', when the inquiry has definite, cognizable, and not insubstantial commercial purpose."⁶⁶

Finally, the court acknowledged that the result of its holding would, in effect, create a de facto extension of Roche's patent term, but concluded that it must assume that Congress intended this result by passing both the Patent Act and the Food, Drug and Cosmetic Act.⁶⁷ In support of this assumption, the court noted that the effective life of new drugs may be as low as seven years because of the required FDA review while the de facto extension of the patent term may be "upwards" of two years due to enjoining generic drug testing with a patented compound until the patent expires.⁶⁸

One can only speculate on the extent to which the court's decision in *Roche v. Bolar* was influenced by the unique circumstances of the pharmaceutical industry and a concern for allowing brand name drug manufacturers to recapture some of their lost patent terms.⁶⁹ Whether or not that was the court's concern, Congress moved quickly to respond to the loss of the patent term due to FDA review.⁷⁰

The next major common law experimental use case, *Embrex v. Service Engineering Corp.* (SEC), was decided in 2000.⁷¹ Embrex owned a patent on a method for inoculating birds against disease by injecting vaccines into a specified region of the egg before hatching.⁷² SEC attempted to design around the Embrex patent by building an injection machine (not covered by

⁶⁵ *Id.* at 863. The court stated that "[d]espite Bolar's argument that its tests are 'true scientific inquiries' to which a literal interpretation of the experimental use exception logically should extend, we hold the experimental use exception to be *truly narrow*, and we will not expand it under the present circumstances." *Id.* (*emphasis added*).

⁶⁶ *Id.*

⁶⁷ *Id.* at 864. The court stated, "because 'laws are presumed to be passed with deliberation, and with full knowledge of all existing ones on the same subject' ...we must presume Congress was aware that the FDCA would affect the earning potentiality of a drug patent, and chose to permit it." *Id.* (citing T. Sedgwick, *THE INTERPRETATION AND CONSTRUCTION OF STATUTORY AND CONSTITUTIONAL LAW* 106 (2d ed. 1874)).

⁶⁸ *Id.*

⁶⁹ The court was also apparently concerned with "several bills that were then pending in Congress to address the regulatory delay, and to public policy issues raised by...Bolar." Veronica Lanier, *Medical Device Eligibility for the Statutory Experimental Use Exemption to Patent Infringement*, 17 HASTINGS COMM. & ENT. L.J. 705, 711 (1995) (citing *Bolar* at 865).

⁷⁰ See Section B, *infra*.

⁷¹ 216 F.3d 1343 (2000).

the patent) and hiring two scientists to investigate the possibility of injecting chicken embryos outside the region of the egg covered by the patent.⁷³ The scientists used India ink to determine if injections outside the region specified in the patent would remain there and if vaccines injected outside the region specified in the patent would be effective in inoculating birds.⁷⁴ The results of the tests were negative on both counts; most injections outside the region covered by the patent penetrated into the region that was covered by the patent, and the vaccine injected outside the region covered by the patent produced little immunity to disease.⁷⁵

In the trial court, a jury found that SEC had infringed the Embrex patent and Embrex was awarded \$500,000 in direct damages.⁷⁶ On appeal to the CAFC, the court affirmed the finding of infringement, but remanded the case for further consideration on the question of damages.⁷⁷ The CAFC found that injecting the eggs with vaccine was done expressly for commercial purposes and therefore could not be immunized from infringement under experimental use or de minimus use exemptions, even though SEC did not sell any injection machines or commercially practice the patented method.⁷⁸ On the question of damages, the CAFC found that Embrex was entitled to a reasonable royalty, that royalties are ordinarily computed on the basis of sales of a patented product or process, but that parties can choose other methods to calculate royalties such as "flat fees" or "milestone payments" in the case of pre-commercialization licenses.⁷⁹ Because the record did not contain sufficient evidence to compute a reasonable royalty, the court vacated the damage award and remanded the case to the district court to determine the proper basis for calculating a reasonable royalty.⁸⁰

Judge Rader wrote a concurring opinion in *Embrex* to express his view that the experimental use and de minimus use exemptions to patent infringement should be completely eliminated.⁸¹ Noting that courts have sometimes addressed these "excuses" as one, Judge Rader

⁷² *Id.* at 1346.

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.* at 1347.

⁷⁶ *Id.* at 1349.

⁷⁷ *Id.* at 1352.

⁷⁸ *Id.* at 1349. The court noted that "SEC's chief commercial purpose was to demonstrate to its potential customers the usefulness of the methods performed by its *in ovo* injection machines. Just because SEC was unsuccessful in selling its machines does not confer infringement immunity upon SEC for its infringing acts." *Id.*

⁷⁹ *Id.* at 1350.

⁸⁰ *Id.*

⁸¹ *Id.* at 1352 (Rader, J., concurring).

explained the differences between the two and analyzed each separately.⁸² According to Judge Rader, experimental use is a plea based on the "character or intent" of the infringing activity whereas de minimus use is a plea based on the "amount or quantum of infringing activity."⁸³ In Judge Rader's opinion, the patent act "leaves no leeway to excuse infringement because the infringer only infringed a little," and the damages calculation in an infringement action is fully sufficient to deal with the question of a de minimus amount of infringing activity.⁸⁴ On the experimental use exemption, Judge Rader cited two recent cases, one from the Supreme Court and one from the CAFC, for the proposition that intent is irrelevant to infringement.⁸⁵ Since Judge Rader had defined experimental use as a plea based on the "intent" of the infringing activity, he concluded that these recent cases had eliminated the experimental use exemption completely, even in the instances of noncommercial and idle curiosity uses.⁸⁶

The most recent, and by far the most narrow explication of the common law experimental use exemption came in *Madey v. Duke* decided in late 2002.⁸⁷ Madey was a tenured faculty member at Duke University, director of a physics research laboratory and owner of a patent on a free-electron laser (FEL) oscillator which was used as a spectroscopy research tool.⁸⁸ Madey resigned his position at Duke after a disagreement over the management of the laboratory.⁸⁹ Duke continued to use the FEL oscillator after Madey's resignation, Madey then sued Duke for infringement of the FEL patent and one of the defenses which Duke raised to the infringement action was that its use of the FEL oscillator fell within the experimental use exemption to patent infringement.⁹⁰

The district court found for Duke on the issue of experimental use. As defined by the district court, the experimental use defense covered uses that were solely for research, academic,

⁸² *Id.*

⁸³ *Id.*

⁸⁴ *Id.* at 1353 (citing *Deuterium Corp. v. United States*, 19 Cl. Ct. 624, 631 (1990) ("This court questions whether any infringing use can be *de minimis*. Damages for an extremely small infringing use may be *de minimis*, but infringement is not a question of degree."))

⁸⁵ *Id.* ("Application of the doctrine of equivalents, therefore, is akin to determining literal infringement, and neither requires proof of intent.") (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 34 (1997); ("Intent is not an element of infringement.") (citing *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.* 62 F.3d 1512, 1519, (Fed. Cir. 1995)).

⁸⁶ *Id.* Judge Rader thought that "these recent cases should dispose of the intent-based prong of SEC's (or anyone else's) argument" against patent infringement. *Id.*

⁸⁷ 307 F. 3d 1351.

⁸⁸ *Id.* at 1352.

⁸⁹ *Id.* at 1352-53.

⁹⁰ *Id.*

experimental and non-profit purposes.⁹¹ On appeal, the CAFC held that the district court's definition of experimental use was too broad and ignored its holdings in *Embrex* and *Roche* that the experimental use defense is strictly limited to activities performed "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."⁹² The CAFC stated that any use which has the "slightest commercial implication" or is "in keeping with the legitimate business of the alleged infringer" cannot qualify for the experimental use defense.⁹³ In applying this stricter standard to the facts of the case, the court concluded that Duke's use of the FEL oscillator did not fall within the experimental use exemption.⁹⁴ First, the court held that the proper focus for experimental use analysis here should not be Duke's non-profit status, but rather Duke's "legitimate business objectives."⁹⁵ Second, the court held that Duke's use of the FEL oscillator for research projects unmistakably furthered Duke's legitimate business objectives, including educating students and faculty participating in the research projects, enhancing the status of university, and luring lucrative research grants, students and faculty to the university.⁹⁶

The sweeping holding in *Madey v. Duke* would appear to preclude experimental use of patented subject matter by all non-profit research organizations, including federal laboratories, research foundations and research hospitals.⁹⁷ Indeed, the "the legitimate business objective" test as applied by the court in *Madey* is so open-ended that it could conceivably be interpreted to preclude experimental use of patented subject matter even by isolated individuals if the use was pursuant to any specific objective. This interpretation of the "business objective" test would morph it into the "idle curiosity" test; any experiment that had a specific purpose or goal would fail both the "idle curiosity" and the "business objective" tests.

⁹¹ *Id.* at 1355.

⁹² *Id.* at 1362. The court stated also that "use does not qualify for the experimental use defense when it is undertaken in the 'guise of scientific inquiry' but has 'definite, cognizable, and not insubstantial commercial purposes.'" *Id.* (citing *Embrex* at 1349).

⁹³ *Id.* See also Strandburg, *supra* note 11 at 99 (stating a concern that the "legitimate business" test will prove broad enough to include "almost any conceivable use" able to exploit a patentee's potential market.)

⁹⁴ *Madey* at 1362.

⁹⁵ *Id.*

⁹⁶ *Id.* See Strandburg, *supra* note 11 at 84 (noting that this result runs contrary to widespread belief within the academic research community that "purely academic research is categorically excused from patent infringement liability.").

⁹⁷ See Strandburg, *supra* note 11 at 84 ("The court does not suggest where, outside the halls of academe, such scientific philosophers are to be found in this modern age, but surely their ranks are thin indeed.").

B. The Statutory Experimental Use Exemption

1. The Hatch-Waxman Act

Congress responded to the CAFC decision in *Roche v. Bolar* by adopting the Hatch-Waxman Act; an ingenious, yet convoluted, reversal of the *Bolar* decision.⁹⁸ In the Hatch-Waxman Act, Congress amended section 271(e)(1) of the Patent Act to provide that "it shall not be an act of infringement to make, use, offer to sell, or sell...a patented invention...solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products."⁹⁹ This amendment clearly allowed generic drug companies to experiment with patented brand name drugs in order to establish the bioequivalency of generic drug substitutes and thereby obtain FDA approval of the generic drugs prior to the expiration of the brand name patents. The immediate effect of this amendment was to eliminate the de facto patent term extension that *Bolar* had implicitly condoned. However, Congress authorized the extension of the original patent term up to a maximum of 5 years, an amendment intended to compensate brand name manufacturers for the time lost due to the FDA approval process, as well as the loss of the de facto patent term extension.¹⁰⁰

Congress, however, was not content with the simple quid pro quo of exempting generic manufacturers from infringement for experimenting with patented brand name drugs and granting brand name manufacturers an extension to their drug patent terms. Through a further set of amendments to the Food Drug and Cosmetic Act (FDCA) and the Patent Act, Congress created an elaborate handicapping system for the pharmaceutical industry. In addition to the infringement exemption, generic drug manufacturers were allowed to use the results of a brand name drug's clinical trials to establish the safety and efficacy of generic drugs¹⁰¹ and were given an incentive to challenge patents on brand name drugs; the first generic manufacturer that successfully challenged a brand name drug patent by establishing that the patent was either invalid or would not be infringed by the sale of the generic drug was given a 180 day period of market exclusivity.¹⁰² Brand name manufacturers were also given new rights. The Patent Act was amended to create an entirely new, and entirely artificial, act of infringement -- infringement

⁹⁸ Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act), PL 98-417, 98 Stat 1585 (1984).

⁹⁹ Patent Act, 35 U.S.C. § 271(e)(1) (1984).

¹⁰⁰ *Id.* § 156(g)(6).

¹⁰¹ Food Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(iv) (1984).

by filing with the FDA. Although generic manufacturers were allowed to experiment with patented drugs to obtain data necessary to submit to the FDA, the actual submission of the data to the FDA would constitute an act of infringement.¹⁰³ In addition, when brand name manufacturers filed infringement suits against generic manufactures, the brand name manufacturers were granted automatic thirty-month stays on FDA approval of the generic drug.¹⁰⁴ However, brand name manufacturers could not recover monetary damages for the infringement unless there was a commercial manufacture, use, offer to sell, or sale in the United States.¹⁰⁵

The Hatch-Waxman Act amendments to the FDCA and Patent Act spawned a complex set of cases on procedural and substantive issues.¹⁰⁶ The procedural issues dealt with such questions as what brand name patents could be listed with the FDA,¹⁰⁷ whether third parties could challenge the listing of brand name patents¹⁰⁸ and whether brand name manufacturers could obtain multiple thirty-month stays on FDA approval of the same generic drug.¹⁰⁹ The substantive issues dealt with the subject matter covered under the Hatch-Waxman experimental use exemption and the permitted uses of this subject matter.

2. Hatch-Waxman Cases

A Supreme Court case considered whether the section 271(e)(1) infringement exemption covered the testing of an implantable cardiac defibrillator in order to obtain data to submit to the FDA for marketing approval.¹¹⁰ The Court held that the phrases "patented invention" and "Federal law" used in section 271(e)(1) encompassed all inventions that were subject to

¹⁰² *Id.* § 355(j)(5)(B)(iv).

¹⁰³ 35 U.S.C. § 271(e)(2)(A) (2004).

¹⁰⁴ 21 U.S.C. § 355(j)(5)(B)(iii) (2004).

¹⁰⁵ 35 U.S.C. § 271(e)(4)(C) (2004).

¹⁰⁶ *See generally*, Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, July 2002.

¹⁰⁷ *See generally*, *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003) (court upheld an FDA regulation that patents submitted as part of an ANDA supplement must be listed in Orange Book).

¹⁰⁸ *See e.g.*, *Mylan Pharmaceutical, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001) (no suits for de-listing of Orange Book allowed under 21 U.S.C. § 337(a) except those brought by the United States, Hatch-Waxman did not create private right of action either).

¹⁰⁹ *See generally*, *SmithKline Beecham Corp. v. Apotex Corp.*, 2004 U.S. Dist. Lexis 20348 (E.D. Pa. 2004) (noting that prior case law allowing NDA holders to obtain multiple thirty-month stays was statutorily overruled by 21 U.S.C. § 355(c)(3)(C)).

¹¹⁰ *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990).

regulation by the FDA under the FDCA including medical devices.¹¹¹ A district court case, also involving an implantable defibrillator, considered whether the section 271(e)(1) exemption applied in the situation where the testing manufacturer intends to commercialize the device before the expiration of the allegedly infringed patents.¹¹² The plaintiff in the case argued that Congress' intent in enacting section 271(e)(1) was to prevent patent holders from obtaining de facto extensions of their patent monopolies and therefore the only type of permissible testing was for the purpose of entering the market after the patent at issue had expired.¹¹³ The court found this view of section 271(e)(1) too narrow and held that Congress' primary concern in enacting 271(e)(1) was "to create a legal environment that would enable new, medically beneficial, cost-competitive products to reach the general marketplace" as soon as possible without infringing unexpired patents.¹¹⁴

In yet another case involving an implantable defibrillator, the CAFC considered whether displaying the defibrillator at medical conferences to physicians and non-physicians, and also presenting the results of the clinical tests to physicians, investors, analysts and journalists were activities so unrelated to obtaining data for submission to the FDA that they would cause a loss of the 271(e)(1) exemption.¹¹⁵ The court found that all of these activities involved the dissemination of data that was developed to obtain FDA approval and that nothing in the statute prohibited disseminating such data.¹¹⁶

3. *The Federal Circuit Decision in Integra Lifesciences v. Merck*

Integra involved a series of patents on a peptide sequence referred to as the RGD peptides or simply RGD.¹¹⁷ RGD promotes cell adhesion by stimulating the growth of new

¹¹¹ *Id.* at 666-69 (court stated that construction of the 1984 Act as a whole indicates that the Act meant to include medical devices as well). *Id.* at 669.

¹¹² *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269 (N.D. Cal. 1991).

¹¹³ *Id.* at 1273.

¹¹⁴ *Id.* at 1273-74 ("[I]t would be inconsistent with the positive goal of maximizing post-patent availability of lower priced new products to artificially limit the exemption only to those parties who would (or could) not enter the marketplace until after the patents expired."). *Id.* at 1274.

¹¹⁵ *Teletronics Pacing Systems, Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1521-22 (Fed. Cir. 1992).

¹¹⁶ *Id.* at 1523-24 ("If Congress intended to make [marketplace competition] more difficult, if not impossible, by preventing competitors from using, in an admittedly non-infringing manner, the derived test data for fund raising and other business purposes, it would have made that intent clear. The statute contains no such provision."). *Id.* at 1525.

¹¹⁷ *Integra*, 331 F.3d at 862.

blood vessels and it was thought that it could aid in wound healing.¹¹⁸ Integra, the owner of the patents, however, was unable to develop a viable commercial product.¹¹⁹ In an unrelated research effort, a scientist, Dr. Cheresh, working at Scripps Research Institute (Scripps) discovered that blocking certain receptors on endothelial cells would inhibit the growth of new blood vessels and that this mechanism could be used as a means of halting tumor growth by starving rapidly dividing tumor cells of their blood supply.¹²⁰ Beginning in 1998, Merck funded this research and in 1994 Dr. Cheresh was successful in reversing tumor growth in chicken embryos using an RGD peptide. In 1995, Merck entered into a second funding agreement with Scripps and Dr. Cheresh to perform *in vitro* and *in vivo* testing of RGD peptides to develop the information necessary for FDA approval of clinical trials.¹²¹ Upon learning of this research project using the RGD peptides, Integra filed an infringement suit.¹²² Merck responded claiming that the research fell within the common law and 271(e)(1) research exemptions.¹²³ The jury in the case did not consider the common law research exemption, but found the research was not covered by the 271(e)(1) research exemption and awarded Integra \$15,000,000 in reasonable royalty damages.¹²⁴

On appeal, the CAFC affirmed the infringement holding, but remanded the case for further consideration of the damages award.¹²⁵ The majority opinion found that “the Scripps work sponsored by Merck was not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds” and that the results of this research may or may not be submitted to the FDA, depending upon the success of the experiments.¹²⁶ Although the CAFC did not specifically find that the RGD peptides were a research tool, it expressed a special concern that extending the 271(e)(1) exemption to embrace new drug development activities such as these would vitiate the rights of patentees owning

¹¹⁸ *Id.* at 863.

¹¹⁹ *Id.* at 873 (Newman, P., dissenting); *see also* George Fox, Note, *Integra v. Merck: Limiting the Scope of the 271(e)(1) Exemption to Patent Infringement*, 19 BERKELEY TECH. L.J. 193, 201 (2004).

¹²⁰ *Integra*, 331 F.3d at 863.

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.* at 863, 869.

¹²⁵ *Id.* at 872.

¹²⁶ *Id.* at 866. The court noted that Merck’s experiments could plainly not fall under the Section 271 exception because “[t]he FDA has no interest in the hunt for drugs that may or may not later undergo clinical testing for FDA approval.” *Id.*

biotechnology research tools.¹²⁷ According to the court, the Hatch-Waxman Act was simply intended to reverse the holding in *Roche* and not to deprive an entire category of inventions of patent protection.¹²⁸

The majority opinion did not discuss the common law experimental use exemption at all referring to it only in a footnote reference to Judge Newman's dissent. The court stated:

In her dissent, Judge Newman takes this opportunity to restate her dissatisfaction with this court's decision in *Madey v. Duke University*. However, the common law experimental use exception is not before the court in the instant case. The issue before the jury was whether the infringing pre-clinical experiments are immunized from liability via the "FDA exemption."¹²⁹

Judge Newman wrote a highly critical dissent. In Judge Newman's opinion, the majority decision had held that neither the common law research exemption nor the 271(e)(1) research exemption immunized the activities at issue.¹³⁰ Judge Newman was especially concerned with the common law research exemption, asserting that the majority holding in effect eliminated the common law research exemption altogether, that such a holding is inconsistent with well established patent law and policy, and that the elimination of the common law research exemption will serve to retard the advancement of competition, technology and scientific knowledge.¹³¹ In Judge Newman's view, a fundamental purpose of the patent system is to provide scientific and technological information and if the practical use of this information is prohibited until the expiration of a patent seventeen to twenty years later (the information is "placed on ice") then the information disclosed in a patent would have little value.¹³² It does not matter in Judge Newman's analysis whether the information is used for research to better understand the patent subject matter, or to improve upon the patent subject matter, or to find a new use for the patent subject matter, or to modify or engineer around the patent subject matter.¹³³ Judge Newman explained that if such types of research were subject to prohibition by the patentee "the advancement of technology would stop, for the first patentee in the field could

¹²⁷ *Id.* at 867.

¹²⁸ *Id.*

¹²⁹ *Id.* at 863.

¹³⁰ *Integra*, 331 F.3d at 873.

¹³¹ *Id.* at 875.

¹³² *Id.*

¹³³ *Id.*

bar not only patented-protected competition, but all research that might lead to competition, as well as barring improvement or challenge or avoidance of patented technology.”¹³⁴

Judge Newman also addressed the majority’s suggestion that the RGD peptides were a research tool and that if the defendant were allowed to use the RGD peptides for the general purpose of drug discovery this would vitiate the rights of patentees owning research tools.¹³⁵ Judge Newman saw a fundamental distinction between research into the science and technology disclosed in patents and the use of patented products or methods as research tools.¹³⁶ A research tool, Judge Newman explained,

is a product or method whose purpose is use in the conduct of research, whether the tool is an analytical balance, an assay kit, a laser device or a biochemical method such as the PCR. . . . Use of [such a] tool in one’s research is quite different from study of the tool itself.¹³⁷

Turning to the RGD peptides, Judge Newman concluded that they were not a research tool and that the defendant’s experimentation with the RGD peptides was for the purpose of developing new compositions having certain biological properties.¹³⁸

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

On review, the Supreme Court vacated the judgment of the CAFC and remanded the case to the district court for further proceedings consistent with the Court’s decision.¹³⁹ The Court defined the issue presented by the case as “whether uses of patented inventions in preclinical research, the results of which are not ultimately included in a submission to the Food and Drug Administration. . . , are exempted from infringement by 35 U.S.C. § 271(e)(1).”¹⁴⁰

The Court began its analysis by noting that under the FDCA, there are two submissions that a drugmaker must make to the FDA.¹⁴¹ First, the drugmaker must obtain FDA approval to conduct clinical trials on human subjects; this approval is requested by the submission of an Investigational New Drug Application (IND).¹⁴² Second, the drugmaker must obtain FDA authorization to market a new drug; this authorization is obtained through the submission of a

¹³⁴ *Id.*

¹³⁵ *Integra*, 331 F.3d 860, 877-78.

¹³⁶ *Id.* at 878

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. at 2384.

¹⁴⁰ *Id.* at 2376.

¹⁴¹ *Id.* at 2377.

¹⁴² *Id.*

New Drug Application (NDA).¹⁴³ The Court rejected Integra's argument that preclinical studies are not reasonably related to an IND and therefore are outside the scope of the 271(e)(1), noting that the FDA requires an IND to include "summaries of the pharmacological, toxicological, pharmacokinetic, and biological qualities of the drug in animals."¹⁴⁴

The Court also rejected the CAFC's conclusion that the Scripps-Merck experiments fell outside the 271(e)(1) exemption because they were directed toward identifying drug candidates for future clinical trials rather than supplying information directly for submission to the FDA.¹⁴⁵ Under the Court's interpretation of 271(e)(1), the use of patented subject matter in (i) experimenting on drugs that are not ultimately the subject of a FDA submission and in (ii) obtaining research data that is not ultimately submitted to the FDA can both be exempted from infringement.¹⁴⁶ The Court found that the 271(e)(1) exemption for experimenting on drugs that are not ultimately the subject of a FDA submission was compelled by the realities of scientific research in which no one can know whether an initially promising drug candidate will prove successful until the conclusion of preclinical and clinical testing.¹⁴⁷ The Court found that the CAFC's interpretation of 271(e)(1), which would not exempt research use of patented drugs unless an IND is ultimately submitted to the FDA, is tantamount to exempting only activities necessary to obtain approval of generic drugs because only in the case of generic drugs can one know at the outset of the testing that the active ingredient in the drug being tested will be the subject of a submission to the FDA.¹⁴⁸ Under the Court's interpretation:

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

¹⁴³ *Id.*

¹⁴⁴ *Id.* at 2381. The Court also noted that the FDA approval of an IND involves an assessment of the risks and benefits associated with a proposed clinical trial and that this assessment requires that the IND include sufficient information regarding the potential risks and benefits of the drug under investigation. *Id.*

¹⁴⁵ *Id.* at 2382.

¹⁴⁶ *Id.* at 2382.

¹⁴⁷ *Id.* at 2382-83.

¹⁴⁸ *Id.* at 2383.

“reasonably related” to the “development and submission of information under ... Federal law.”¹⁴⁹

The Court similarly found that the 271(e)(1) exemption for the use of patent subject matter to obtain research data that is not ultimately submitted to the FDA was compelled by the uncertainty at the time of the research of knowing what kinds of research data, and what amounts of research data, are necessary to include in an IND or a NDA to obtain FDA approval.¹⁵⁰ The 271(e)(1) exemption would apply, the Court held, “as long as there is a reasonable basis for believing that the experiments will produce ‘the types of information that are relevant to an IND or NDA.’”¹⁵¹

The Court noted that the CAFC suggested that a narrow construction of the 271(e)(1) exemption was necessary in order to avoid depriving research tool patentees of the entire value of their patents.¹⁵² The Court stated that Integra had never argued that the RGD peptides at issue were research tools and, citing to Judge Newman’s dissenting opinion, that it is apparent from the record they were not.¹⁵³ On the question of research tools, the Court concluded: “We therefore need not -- and do not -- express a view about whether, or to what extent, § 271(e)(1) exempts from infringement the use of ‘research tools’ in the development of information for the regulatory process.”¹⁵⁴

Finally, unlike the CAFC, the Supreme Court explicitly acknowledged the role of the common law experimental use exemption in describing the lower court proceedings.¹⁵⁵ The Court noted that Merck claimed its activities were exempt from infringement under the common

¹⁴⁹ *Id.*

¹⁵⁰ *Id.* The Court stated:

This is especially true at the preclinical stage of drug approval. FDA regulations provide only that “[t]he amount of information on a particular drug that must be submitted in an IND ... depends upon such factors as the novelty of the drug, the extent to which it has been studied previously, the know or suspected risks, and the development phase of the drug.”

Id. (citing 21 C.F.R. § 312.22(b)).

¹⁵¹ *Id.* at 2383-84 (citing Brief of United States as *Amicus Curiae* 23).

¹⁵² *Id.* at 2382 n.7.

¹⁵³ *Id.*

¹⁵⁴ *Id.* Another fact situation which the Court was not required to consider at this time, but will likely be required to consider in the not too distant future, involves the research use of a technology that might have both FDA-related and non-FDA-related applications. For example, the same DNA technology might have an application as a medical diagnostic test used by physicians in hospitals and as a research kit used by researchers in laboratories. Under the first application, the DNA technology would constitute a medical device that would require FDA pre-market approval and therefore fall within the safe harbor research exemption of 35 U.S.C §271(e)(1). Under the second application, the DNA technology would be a research kit that would not require FDA pre-market approval and therefore would not fall within the safe harbor research exemption of 35 U.S.C. §271(e)(1).

¹⁵⁵ *Id.* at 2379.

law research exemption and that the district court found some of the alleged infringing activities were, in fact, exempt under the common law research exemption.¹⁵⁶

C. Hybrid Technologies

As the above discussion illustrates, current law on experimental use exemption to patent infringement draws a sharp distinction between patented subject matter that is subject to FDA pre-market approval and all other patented subject matter. However, some technology might be subject to FDA pre-market approval in one application, but not in another application. For example, a technology to detect the presence of target DNA sequences in samples could be used as a diagnostic test in medical settings to detect DNA markers associated with genetic diseases and viral infections. This diagnostic application of the technology would clearly be classified as a medical device and subject to FDA approval prior to public sale. However, the same technology could also be used as a research kit in laboratories for such purposes as ascertaining the presence of induced infection in animal subjects and determining the DNA traits of genetically engineered mice. This research kit application of the technology would clearly not be classified as a medical device and would not be subject to FDA approval.

The use of patented subject matter to develop a new, non-infringing diagnostic medical device would fall squarely under the provisions of the Hatch-Waxman Act and would be exempt from patent infringement. On the other hand, the use of the same patented subject matter to develop a DNA laboratory research kit would fall outside of the Hatch-Waxman Act and, under the current common law experimental use exemption, would constitute an act of patent infringement. The hybrid nature of the technology, and the use of patented subject matter during the course of its development, are further complicated by the fact that the research required to develop the technology for use as medical diagnostic device and for use as a laboratory research kit might not be separable at certain points of time during the research project.

III. Experimental Use Law Reform Proposals

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

¹⁵⁶ *Id.*

general, writers on the subject have analyzed the experimental use exemption in terms of distinctions within four categories of facts--the type of organization performing the experimentation, the purpose of the experimentation, the intended purpose of the patented subject matter utilized in the experimentation, and the source of funding for the experimentation. Analyses of the *organization performing the experimentation* have focused on distinctions between universities, small companies, and large companies; analyses of the *purpose of the experimentation* have focused on distinctions between research to advance science or ascertain the accuracy of patent specifications, and research for the purpose of developing new commercial products or processes; analyses of the *intended purpose of the patent subject matter* used in the experimentation have focused on distinctions between research tools and end-user commercial products and processes; and analyses of the *source of funding* for the experimentation have focused on distinctions between federal funding, industry funding and university or non-profit funding.

A. Limited Exemptions

Those writers advocating limited experimental use exemptions generally emphasize the loss of value to patentees that would result if patented technologies could be freely used for research to develop new or improved competing technologies. There are two prongs to this analysis. First, that the patentee is deprived of the royalties that would otherwise be paid for use of the patented technology in research and that this would constitute a market failure since the new or improved follow-on technology would benefit from the investment in the patented base technology but not pay for the research use of the base technology.¹⁵⁷ Second, that the free use of patented technology in research would increase the probability of developing new or improved competing technology and that this would in turn decrease the value of the patented base technology because consumers might forgo current purchases of the base technology in order to purchase the new or improved competing technology when it becomes available.¹⁵⁸

¹⁵⁷ Jordan Karp, Note, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exemption*, 100 YALE L.J. 2169, 2180 (1991).

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

¹⁵⁸ Michelle Walters, *De Minimus Use and Experimental Use Exemptions to Patent Infringement: A Comment on the Embrex Concurrence*, 29 AIPLA Q.J. 509, 529 (2001) ("A broad experimental use exception would weaken patent enforceability and discourage innovations because third parties would wait for someone else to conceive and make

One of the earliest discussions of the experimental use exemption was published in 1957 by Richard Bee.¹⁵⁹ Bee's ultimate conclusion is that the experimental use exception "is not warranted as a matter of law or legal theory, is not consistent with the protection otherwise given the patentee's rights by the courts, and may serve as a source of judicial confusion and mischief."¹⁶⁰ Bee's interpretation of the experimental use law is similar to that of CAFC majority: the experimental use exemption is solely for the purpose of "gratifying philosophical taste, or curiosity or for mere amusement" and that if there is the slightest business purpose or profit motive present the exemption is no longer applicable.¹⁶¹

A somewhat less limited proposal for an experimental use exemption, suggested by Michelle Walters, would allow the exemption only for universities and individuals and only if they derive no monetary benefit from the research exemption.¹⁶² The Walters' proposal posits five acceptable research uses of patented technology by universities; use to verify patent claims, use for comparison to a new technology, use to gain scientific knowledge, use for classroom teaching and use to develop new research tools donated to the public.¹⁶³ Corporate sponsorship of university research that utilizes patented technology would not eliminate the exemption if the research results were published and available for use by the public.¹⁶⁴ Individuals would be entitled to the experimental use exemption unless their research was funded by a corporation for commercial purposes.¹⁶⁵

The Walters' proposal would deny the experimental use exemption to all business entities because their primary objective is to make a profit and all of their activities, including research, are in pursuit of that profit objective.¹⁶⁶ Walters also suggests that business entities do not need

an invention. The free-rider could then copy the patented invention, improve it under the experimental use exception, and patent the improvement.").

¹⁵⁹ Richard E. Bee, *Experimental Use as an Act of Patent Infringement*, 34 J. PAT OFF. SOC'Y 357 (1957).

¹⁶⁰ *Id.* at 359.

¹⁶¹ *Id.* at 375

Considering all the cases which have passed on the question of experimental use, it appears that by far the greater majority of the cases have construed the experimental use exception rather strictly and have held it to be applicable only where the experiment was for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement. Needless to say, such an occasion will rarely arise where the experiment is conducted by a business enterprise because business enterprises simply do not do things merely for amusement, etc.

Id.

¹⁶² Walters, *supra* note 159 at 540.

¹⁶³ *Id.* at 536-38.

¹⁶⁴ *Id.* at 538.

¹⁶⁵ *Id.* at 539.

¹⁶⁶ *Id.* at 523-26.

an experimental use exemption because they can learn about the patented technology by studying the patent specification, or by purchasing the patented product and obtaining an implied right to experiment with it, or by obtaining an express license from the patentee to experiment with the patented technology.¹⁶⁷

A similarly limited experimental use exemption has been advanced by Jordan Karp.¹⁶⁸ Karp argues that a broad experimental use exemption would retard innovation because industry would be reluctant to file patents and provide invention disclosures if patented technology could be used without a license to develop new or improved competing technology.¹⁶⁹ Karp would allow an experimental use exemption for the same general purposes as Walters: to ascertain the truthfulness and accuracy of the patent specification; to ensure that the patent disclosure complies with the requirements of section 112; to determine the novelty and non-obviousness of a subsequent invention; and for purely scientific research with no foreseeable commercial application.¹⁷⁰ Unlike Walters, however, Karp would extend the experimental use exemption to corporations and allow the commercial use of exempted research if the patentee is paid a reasonable royalty for the exempted research.¹⁷¹ Karp describes this latter situation as a type of “limited compulsory license” whereby the experimenter would have to pay a royalty for the research use of the patented technology in the event that the research is used to develop a commercial product or process, regardless of whether or not the commercial product or process is non-infringing.¹⁷² In Karp’s view, this arrangement would not discourage filing patent applications and making invention disclosures because the patentee would be compensated if the patented invention is used in research for commercial purposes.¹⁷³

¹⁶⁷ *Id.* at 530-34. Walters suggests that a patentee might be particularly disposed to grant a license to an experimenter when the purpose of the experimenter is to develop an improvement that incorporates the original patented invention. *Id.* at 532. Walters’ suggestion assumes that patentees welcome licensee improvements to their inventions and trust that licensees will not engineer around their patent. Both assumptions are problematic.

¹⁶⁸ Karp, *supra* note 158 at 2180.

¹⁶⁹ *Id.* at 2180.

[A] broad experimental use exception, by discouraging inventors from relying on the patent system, would decrease the level of public disclosure of new inventions as well as reduce innovative activity in those industries that rely on patent protection. A broad exception, rather than fostering innovation, would have exactly the opposite effect.

Id.

¹⁷⁰ *Id.* at 2179-80.

¹⁷¹ *Id.* at 2188.

¹⁷² *Id.*

¹⁷³ *Id.*

An experimenter would only have to compensate the patentee when the experimental activity actually resulted in a benefit to the experimenter (thus, allowing ‘pure’ scientific research to continue unhindered).

David Parker has proposed another limited experimental use exemption.¹⁷⁴ Parker believes that a broad experimental use exemption would be particularly harmful to universities and to the advancement of basic research.¹⁷⁵ According to Parker, a significant number of university patents cover basic research subject matter that serve as building blocks for the eventual development of commercial products or processes. If these basic research patents can be used without a license to develop commercial products and processes, which in many cases would not infringe the basic research patent, Parker believes the return on investment in current basic research needed to support future basic research would be lost.¹⁷⁶ Parker's proposal is similar to Karp's, but more detailed. Parker would exempt commercial and non-commercial research use of patented inventions performed by for-profit and non-profit organizations.¹⁷⁷ However, the exempted research use would retroactively become an act of infringement upon the sale or offer to sell any product or process developed under the research exemption.¹⁷⁸ Parker would not allow the patentee to enjoin the sale or offer to sell products or processes developed under the research exemption, thus creating in essence a compulsory license to use patented inventions in research.¹⁷⁹ Finally, Parker would require a separate license if the product or process developed under the research exemption would infringe the patented invention used in the research.¹⁸⁰

Because experimental use will only dissuade an inventor from utilizing patent protection to the extent that an experimenting party is able to develop a competing product, a properly administered reasonably royalty regime should strike an optimal balance between the inventor's desire to appropriate the returns on her investment in R&D and the public's desire for a steady flow on innovations.

Id.

¹⁷⁴ Parker, *supra* note 33.

¹⁷⁵ *Id.* at 644-45.

¹⁷⁶ *Id.* at 659.

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

Id. (internal citations omitted).

¹⁷⁷ *Id.* at 659-60.

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

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

Id.

B. Qualified Exemptions

Probably the most thoughtful and comprehensive article on the experimental use exemption was published in 1989 by Professor Rebecca Eisenberg.¹⁸¹ Eisenberg's article is worth considering in some detail because of her analysis of the experimental use exemption in the context of the economic theories that have been advanced to explain the operation of the patent system. Eisenberg discusses four economic theories of patent law - the incentive to invent theory, the incentive to disclose theory, the incentive to innovate theory and the incentive to invest in subsequent research theory.

The *incentive to invent* theory posits that patent protection is necessary to reward investment in research which in turn promotes the public good.¹⁸² Eisenberg does not believe that the incentive to invent theory provides clear guidance on the experimental use exemption because analyses of the theory have focused on commercial technology rather than on basic science research.¹⁸³ The *incentive to disclose* theory suggests that patent protection is necessary to encourage inventors to reveal information about their inventions rather than keeping this information secret and unavailable to the public.¹⁸⁴ Although Eisenberg questions whether secrecy is a practical strategy to protect inventions in many instances, and whether patent disclosures in fact convey enough information to be useful to the public, she appears to acknowledge that an experimental use exemption might diminish the incentive to disclose information about inventions.¹⁸⁵ The more fundamental problem that Eisenberg notes with both the incentive to invent and incentive to disclose theories as guides to an appropriate experimental use exemption is that there is no empirical evidence on how much incentive is necessary for optimal levels of invention and disclosure, nor on whether the current level of incentive is too high or too low.¹⁸⁶

¹⁸¹ Eisenberg, *supra* note 10.

¹⁸² *Id.* at 1024-27. Eisenberg notes three criticisms of the incentive to invent theory. First, patent protection might restrict the use of new inventions and thereby reduce their social benefits. Second, patent protection might distort economic activity if firms race to obtain patents by means of inefficient research efforts. Third, patent protection might hinder progress by providing a disincentive to other persons to make improvements to patented inventions or to waste time and effort finding duplicative solutions to problems in order to avoid patent infringement. *Id.* at 1026-28.

¹⁸³ *Id.* at 1030.

¹⁸⁴ *Id.* at 1028.

¹⁸⁵ *Id.* at 1028-30.

¹⁸⁶ *Id.* at 1030.

One might assume that, other things being equal, reducing the strength of patents would reduce incentives to make and disclose new inventions and that, conversely, increasing the strength of patents would increase incentives to make new inventions and to patent them in lieu of protecting them as trade secrets. But the

Eisenberg finds a similar problem with the *incentive to innovate* theory. The incentive to innovate theory suggests that the patent monopoly is necessary to promote investment in the post-invention commercial development of new technologies.¹⁸⁷ Eisenberg acknowledges that the incentive to innovate theory does provide a rationale for post-invention rewards and that the loss of these rewards under an experimental use exemption could shorten the effective life of the patentee's technology and deprive the patentee of royalties that would otherwise be collected for research use of the patentee's technology, and that if this happened it would reduce to some degree the incentive to innovate.¹⁸⁸ However, in the absence of empirical measurement of the magnitude of these effects, Eisenberg concludes that the incentive to innovate theory leads to the same "analytical dead end" as the incentive to invent and incentive to disclose theories; "its policy implications turn on empirical questions without clear answers."¹⁸⁹

Finally, Eisenberg considers the *incentive to invest in subsequent research* theory, commonly referred to as the "prospect theory."¹⁹⁰ The prospect theory holds that patent rights promote efficiency in follow-on research by allowing the patent owner to monitor and coordinate subsequent research activity and thereby avoid duplicative and wasteful resource expenditures.¹⁹¹ Eisenberg notes a number of limitations to the prospect theory including its criticism by economists and the incentive for follow-on researchers to obtain a license in the event the research might result in an improvement to the patented technology.¹⁹² In the end, however,

magnitude of these effects is uncertain. Moreover, it is difficult to say whether the current level of incentives is too high or too low.

Id.

¹⁸⁷ *Id.* at 1037. Eisenberg contrasts the incentive to invent theory and incentive to innovate theory; the incentive to invent theory does not warrant strong patent protection after the point of invention while the incentive to innovate theory warrants strong patent protection throughout the patent term. *Id.* at 1037-38.

¹⁸⁸ *Id.* at 1036-38. Eisenberg discusses the Schumpeterian Theory that posits monopolies are conducive to innovation:

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

Id. at 1038-39.

¹⁸⁹ *Id.* at 1040.

¹⁹⁰ The "prospect theory" proposed by Edmund Kitch analogizes the function of patent monopolies to mineral rights in government lands. *Id.* at 1040. ("Kitch contends that patents promote efficiency in the use of resources to develop patented inventions in part by putting patent owners in a position to coordinate subsequent research and development efforts."). *Id.* at 1041.

¹⁹¹ *Id.* at 1040-43.

¹⁹² *Id.* at 1044.

Eisenberg does acknowledge that the experimental use exemption could arguably interfere with the efficient pursuit of follow-on research.¹⁹³ She did not note, but could have noted, the lack of empirical evidence to support the prospect theory as well.

Based on her analysis of the economic theories underlying the patent system and their implications for an appropriate experimental use exemption, Eisenberg distinguishes three experimental use situations: the researcher is using a patented research tool for its intended purpose; the researcher is using patented subject matter to test the validity of the patent claims; and the researcher is using the patented subject matter to make further advances in the technology in competition with the patent owner.¹⁹⁴ Eisenberg believes that an experimental use exemption is not needed in the first situation because patentees of research tools will make these tools available to researchers in the ordinary course of business.¹⁹⁵ On the other side, Eisenberg believes the case for an experimental use exemption is strongest in the second situation because patent law is intended to promote the advancement of knowledge and to allow challenges to a patent's validity.¹⁹⁶

Eisenberg sees the conflict between the interests of the patent holder and the interests of subsequent researchers most intractable when they are competitors each seeking to develop superior technology.¹⁹⁷ The compromise solution that Eisenberg proposes in this situation is to

Thus, while the right to prevent ultimate commercial exploitation of an invention might sometimes be enough to put patent holders in a position to coordinate subsequent research efforts to improve their inventions, it seems likely that in some cases unauthorized (and uncoordinated) research will proceed unless patent holders have the right to enjoin the use of their inventions in research. In such cases an experimental use exemption arguably undermines the prospect function, thus interfering with efficient development of a patent prospect.

Id.

¹⁹³ *Id.* at 1044.

¹⁹⁴ *Id.* at 1074-75.

¹⁹⁵ *Id.* at 1074. Eisenberg assumes that owners of patented research tools will want to extend licenses to researchers "in order to extract the full value of the patent monopoly." *Id.* at 1074. Other writers have suggested that the primary financial return to a research tool patentee might come from exclusive control of the results yielded by the research tool rather than from the widespread use of the tool itself. *See e.g.*, Strandburg, *supra* note 11 at 123.

¹⁹⁶ *Id.* at 1074-75.

Free access to patented inventions for the limited purpose of permitting scrutiny of new research claims serves the policies underlying the patent law as well as the interests of research science. Indeed, patent law promotes scrutiny of the research claims embodied in patented inventions through its requirement that patent holders make enabling disclosures of their inventions freely available to the public.

Id.

¹⁹⁷ *Id.* at 1075-76. Eisenberg notes that an experimental use exemption in the context of competitors reduces the value of the patent monopoly in two ways; first, it deprives the patentee of the royalties that might otherwise be collected from researchers; second, it shortens the expected duration of the patent monopoly by lowering the cost to invent around the patent. *Id.* at 1075-1076. The loss of royalties from researchers assumes that the patentee has the right to prohibit the use of the patented invention by researchers in the first instance. The loss of value of patent

deny the subsequent researcher an experimental use exemption, but also to deny the patent owner the right to enjoin the research activity.¹⁹⁸ The result of this compromise solution is that the patent owner's only remedy would be reasonable royalty damages; or viewed in another way, the subsequent researcher would be entitled to a compulsory license to use the patented technology for research purposes upon payment of reasonable royalty damages to the patent owner.¹⁹⁹

A final noteworthy proposal for a qualified experimental use exemption has been advanced by Suzanne Michel.²⁰⁰ The focus of Michel's concern, similar to Parker, is the disadvantage to universities, research centers and small firms that could result from a broad experimental use exemption.²⁰¹ Michel suggests that these organizations are the source of major research advances, but that they lack the resources necessary to convert these research advances into commercial technologies.²⁰² If larger firms with much greater resources were able to use this advanced research without a license, Michel believes that universities and research centers would lose the licensing revenue needed to support new research projects and that small firms would lose the investment capital needed for commercial development of early-stage research.²⁰³

There are two parts to Michel's experimental use proposal; the first part is similar to other proposals discussed above while the second part is novel. The first part of Michel's experimental use proposal would grant universities and other non-profit research centers a broad experimental use exemption; however if a for-profit firm sought to commercialize the research undertaken by a non-profit organizations under the benefit of the experimental use exemption,

monopolies assumes that patentees will not also benefit from an experimental use exemption that allows them to perform research on their competitors' inventions just as their competitors can perform research on their inventions.¹⁹⁸ *Id.* at 1076-78.

¹⁹⁹ *Id.* at 1078. Eisenberg suggests that damages would not have to be paid to the patentee for the unauthorized research use of the patented technology if the technology developed by the researcher is an improvement upon the patented technology that requires a license to commercialize. *Id.* at 1077. However, if the researcher used the patented technology to invent around the patent, then the researcher would have to pay damages for the unauthorized research use of the patented technology. *Id.* at 1077-78.

²⁰⁰ Suzanne T. Michel, Comment, *The Experimental Use Exception to Infringement Applied to Federally Funded Inventions*, 7 HIGH TECH. L.J. 369 (1992).

²⁰¹ *Id.* at 396-97.

²⁰² *Id.* at 396.

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

Id.

²⁰³ *Id.* at 397.

the firm would have to negotiate a license with the patentee as if the firm itself had performed the research initially.²⁰⁴ The second part of Michel's experimental use exemption would allow both non-profit and for-profit organizations to use patented technology for research purposes if the technology has been developed with federally funded research.²⁰⁵ Michel believes that this exemption is warranted because the goal of the federal government in funding research is to encourage additional research and this goal would be undermined if federally funded research could not be freely used.²⁰⁶ Unlike Michel's experimental use exemption for universities and research centers, however, the commercialization of federally funded research by firms would only require a license if the resulting commercial product or process was covered by the patentee's patent claims.²⁰⁷

C. Broad Exemptions

There are three reasons most often given in support of a broad experimental use exemption; the need to understand how patented technology works in practice in order to advance knowledge in fields of science; the need to improve upon, and invent around, patented technology in order to promote development of new technologies; and the need to limit the ability of owners of research tools to control downstream inventions in order to promote competition in technology product and process markets.²⁰⁸

²⁰⁴ *Id.* at 397-99. Michel claims that a broad experimental use exemption harms the incentive to invent by allowing subsequent inventors to free ride on the original inventor's work if the subsequent inventor can use the original invention to improve on, or design around, the original invention. *Id.* at 394. There are two responses to Michel's concerns. First, if the subsequent inventor *improves* upon the original invention, the subsequent inventor will require a license from the original inventor prior to commercializing the improved invention and this will provide a return to the original inventor on her investment in the original invention. Second, if the subsequent inventor is viewed as a potential free rider on the original inventor's work, the original inventor must also be viewed as a potential free rider on the subsequent inventor's work. A commercial experimental use exemption is a two-way street that increases the competition, as well as the risks and benefits, for all firms in a market.

²⁰⁵ *Id.* at 400. This proposal would be tantamount to a repeal of the Bayh-Dole Act. 35 U.S.C. §§ 200-212. The great majority of university patents derive from federally funded research and if these patents can be freely used by industry for research their value to universities will be significantly reduced. There is some inconsistency between Michel's concern to protect universities from unauthorized industry research under a broad experimental use exemption and her allowance of unauthorized industry research in the case of patents derived from federally funded research, which patents constitute the great majority of universities' patent portfolios.

²⁰⁶ *Id.* at 402.

²⁰⁷ *Id.* at 407-08.

²⁰⁸ See, e.g., Eyal H. Barash, Comment, *Experimental Uses, Patents and Scientific Progress*, 91 NW. U. L. REV. 667, 699-700 (1997); Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. OFF. SOC'Y 617, 640 (1985); Mueller, *supra* note 78 at 11-12.

In a 1985 article, Ronald Hantman undertook the same historical review of the experimental use exemption as Bee and reached the exact opposite conclusion - that the case law supports a broad interpretation of the experimental use exemption.²⁰⁹ Under Hantman's analysis, commercially motivated research and development to find new uses and improvements for patented technology should be included within the experimental use exemption to encourage the innovation of new technology.²¹⁰ Hantman responds directly to the argument that a broad experimental use exemption would allow persons to use a patented technology to develop new and improved technologies that could replace the patented technology in the marketplace. In Hantman's opinion, "that's exactly what the [patent] system is supposed to do. In exchange for the patent monopoly given to an inventor, the inventor discloses his invention to the public and runs the risk that his invention may be made obsolete."²¹¹

The only experimental use law reform proposal that has been put forth in the form of legislation is the Research, Experimentation and Competitiveness Act of 1990 (RECA), passed by the House Judiciary Committee but withdrawn before consideration by the full House of Representatives.²¹² The RECA provided:

It shall not be an act of infringement to make or use a patented invention solely for research or experimentation purposes unless the patented invention has a primary purpose of research and experimentation. If the patented invention has a primary purpose of research or experimentation, it shall not be an act of infringement to

²⁰⁹ Hantman, *supra* note 209 at 618.

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

Id.

²¹⁰ *Id.* at 639-40. Hantman distinguishes between experimental use *on* patented inventions and using patented inventions *for* experimental purposes. Experimental use *on* patented inventions would be allowed under Hantman's proposal because it would result in improvements to patented inventions and new scientific knowledge. Using patented inventions for experimental purposes would not be allowed under Hantman's proposal because it would not result in improvements to patented inventions and would allow the experimenter to profit at the expense of the patent owner. *Id.*

²¹¹ *Id.* at 643. Hantman defines research and development as activities "carried out to discover something new, sometimes for pure knowledge and other times for commercial application." *Id.* at 640. He defines innovation as "the entire process of recognizing a problem, identifying a new solution (through research), and developing and marketing an economically attractive process or product." *Id.* Hantman believes research and development "ought to be included within the experimental use exception in order to encourage and support the innovation of new technology." *Id.*

²¹² H.R. 5598 101st Cong. §§ 401-03 (1990).

manufacture or use such invention to study, evaluate, or characterize such invention.²¹³

The proposed RECA did not distinguish between for-profit and non-profit research organizations, nor between commercial and non-commercial research purposes; in each of these instances, a third party would be allowed to make or use patented technology to perform scientific research, to improve upon patented technology and to engineer around patented technology.²¹⁴ The only distinction drawn in the RECA for the experimental use exemption was based on the intended use of the patented subject matter; if the patented subject matter was primarily intended for use in performing research (a research tool), then it could not be made or used for its intended purpose without a license, although it could be made or used to perform scientific research outside of the research tool's intended use, either to improve upon the research tool or to engineer around the research tool.²¹⁵ One of the proposals for a broad experimental use exemption would support the adoption of a limited version of the RECA, while other proposals would support an expanded version of the RECA.

Eyal Barash has argued for a limited adoption of the RECA exemption only for universities and non-profit research centers.²¹⁶ The focus of Barash's concern is the risk of infringement law suits against universities and non-profit research centers based on their use of patented technologies for research and experimentation purposes.²¹⁷ In Barash's view, the scope of this risk is increasing, especially for universities, due to two sets of factors. The first set of

²¹³ *Id.* § 402.

²¹⁴ H.R. REP. NO. 101-960, pt. 1 at 9-10 (1990). The House Report quoted noted patent authority, Harold C. Wegner.

It is ludicrous to expect every researcher to obtain a license in advance of conducting a simple experiment, each time he sees a newly issued patent and attempts to duplicate the efforts in his laboratory. It is equally ludicrous and burdensome if every Ph.D. research (sic) in a New Jersey pharmaceutical organization would need to have a patent attorney sitting at his side, to first opine whether his research for the day was within the scope of a third party's patent, and then to obtain a license because he should tap his test tubes and precipitate out the 'infringing' product! (While, the fellow Ph.D. working in a sister facility in Basel, Paris or the Rhine would be totally immune from this onerous requirement. *Id.* 8.

²¹⁵ *Id.* at 9. ("The easiest method of limiting and describing the 'experimental use of research exception' is to differentiate between experimentation on a patented invention and experimentation using a patented invention in order to accomplish another purpose, the former type of experimentation constituting the scope of the exception."). *Id.*

²¹⁶ Barash, *supra* note 209.

²¹⁷ *Id.* at 697-699. ("Universities, in cooperation with industry, may find themselves embroiled in costly intellectual property litigation....The effect of extensive patent litigation against universities may chill many research activities, not just those in which an invention may be patented, by requiring researchers to investigate whether their proposed laboratory research infringes any known patent."). *Id.* at 698.

factors involves changes in the patent laws and the general way in which university researchers pursue research projects.²¹⁸ Congress amended the patent laws in 1984 to allow universities to license patents resulting from federally funded research²¹⁹ and Barash notes that this amendment has lead to greatly increased research and patenting activity by universities.²²⁰ At the same time, however, university researchers continue to pursue research projects as they have in the past taking little account of patent rights and rarely performing patent searches prior to undertaking research projects.²²¹ The combination of the increased research and patenting activity coupled with the traditional neglect of patent rights, Barash believes increases the risk of infringement law suits against universities.²²²

The second set of factors Barash sees increasing the risk of infringement suits against universities involve industry's responses to the changing university research environment. As university research becomes more valuable, Barash predicts that corporations will have an increasing commercial interest in university research, sometimes having interests aligned with the university and sometimes having interests antagonistic to the university.²²³ In either case, Barash believes industry's growing commercial interest in university research increases the risk of infringement litigation and threatens the advancement of research activities.²²⁴

Three other writers, Professors Rochelle Dreyfuss, Janice Mueller and Katherine Strandburg have advocated experimental use exemptions broader than the RECA. Dreyfuss, Mueller and Strandburg are primarily concerned with the use of patented research tools to control downstream inventions and each has proposed some form of compulsory license to address this problem.²²⁵ Although these authors do not explicitly recommend the adoption of the RECA, one would assume that if they support compulsory licenses for the use of research tools

²¹⁸ *Id.* at 697-698. (“In 1980 and again in 1984, the patent laws of the United States were changed so that universities could keep the titles to patents issued based on federally-funded research projects....Patents issued to universities are often licensed to industry in the hope of developing commercially useful products and processes.”). *Id.* at 697.

²¹⁹ Bayh-Dole Act, 35 U.S.C. §§ 200-212 (1980).

²²⁰ Barash, *supra* note 280 at 697.

²²¹ *Id.* at 697-98. (“At the heart of the problem lies the manner in which research occurs at universities. University researchers rarely check the patent literature to determine whether their proposed research will infringe on any patents.”). *Id.*

²²² *Id.* at 698.

²²³ *Id.*

²²⁴ *Id.* at 698-99. (“As the value of university licenses continues to increase and as federal funds become harder to get, university researchers may face increasing opposition from corporations who may vehemently attempt to prevent their intellectual property from being used or sold.”). *Id.* at 698.

for their intended purpose they would also support the RECA exemptions for the use of research tools and non-research tools for the purposes of scientific research, technology improvement and development of new, non-infringing technology.

Dreyfuss proposes an experimental use exemption similar to Barash's proposal that would apply only to non-profit research institutions.²²⁶ However, Dreyfuss articulates a far broader set of concerns than Barash and her proposal is considerably more detailed than that of Barash. Dreyfuss suggests that the progress of scientific research and technology innovation, especially in the field of biotechnology, are being thwarted by a combination of three factors; a change in the characteristic of science, a transformation in the organization of science and a shift in public policies governing information production and sharing.²²⁷

The change Dreyfuss perceives in the characteristic of science is the growing merger of fundamental research and commercial products.²²⁸ She notes, for example, that in the fields of genomics and proteomics basic science discoveries often have immediate commercial applications as medical diagnostic devices or disease treatments and therefore qualify for patent protection; however, these same basic science discoveries are also critical to innovation in a host of other technologies.²²⁹ Dreyfuss attributes the change in the organization of science primarily to the rapidly changing role of universities in the research enterprise.²³⁰ Dreyfuss describes past university research as freely available to both academic and commercial scientists under an ethos of a free and open exchange of scholarship; however, Dreyfuss suggests that today universities are "deep in the intellectual property business" and their technology transfer offices are often seen as a source of revenue to reduce tuition costs, decrease the burden on alumni and, for state-supported universities, lower the taxes on state residents.²³¹ Finally, Dreyfuss believes that the

²²⁵ Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457 (2004); Mueller, *supra* note 72 at 65; Strandburg, *supra* note 11 at 143-44.

²²⁶ Dreyfuss, *supra* note 297 at 471.

²²⁷ *Id.* at 462-66.

²²⁸ *Id.* at 463.

²²⁹ *Id.* Dreyfuss describes past science as a "linear progression from basic science, to applied science, to commercializable technology, to consumer end-products....That conception was essentially hardwired into the law. The developments at the end of that progression were patentable, the developments along the rest of the trail were not."

²³⁰ *Id.* at 463-65.

²³¹ *Id.* Dreyfuss is quite critical of university technology transfer offices.

Universities have also begun to regard their technology transfer offices as the academic equivalent of their football teams: even if the offices aren't winning, there is cachet in fielding them. And the technology transfer offices want to win, just like football teams do. They are judged by the number of patents granted and the value of the licenses negotiated. And so they have tremendous

public policies governing information production and sharing have shifted from a preference for a strong public domain in which information was freely available to all to a preference for protecting all creative works as intellectual property.²³² Within this milieu, Dreyfuss finds it not surprising that faculty and universities seek intellectual property protection for their creative efforts.²³³

The solution Dreyfuss proposes to resolve the conflict between intellectual property rights and the progress of scientific research and technology innovation is to replenish the public domain by allowing universities to use patented research tools for their intended purpose, but to place conditions on how universities can use the results of such research. Dreyfuss would allow the unlicensed use of research tools if the research tools were not available on reasonable terms, the researcher agreed to publish the results of the research, and the researcher agreed to refrain from patenting the results of the research.²³⁴ Richard Nelson has suggested a modification of Dreyfuss' proposal that would allow non-profit research institutions to patent research results obtained through the unlicensed use of research tools if the institution agreed to license the results on a non-exclusive basis and upon reasonable terms and conditions.²³⁵

Mueller also believes that there is a serious problem today with the availability of research tools. Mueller argues that Eisenberg's position on the use of patented research tools is increasingly untenable in the current research environment.²³⁶ Recall that Eisenberg proposed that

incentives to obtain every patent that they can get and to argue for more protection for the work that universities do, which is to say, for developments that are far more upstream.

Id. at 464.

²³² *Id.* at 465. ("As Professor Jerry Reichman has so graphically put it, the classical patent and copyright systems were once islands of protection in a sea of competition. Now what we have is a sea of protection in which intrepid entrepreneurs encounter remote islands of free competition."). *Id.*

²³³ *Id.* at 466.

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

Id. at 466-77.

²³⁴ *Id.* at 471. Dreyfuss notes some alternative approaches to the problems she describes that do not depend upon an experimental use exemption including redefining patentable subject matter to exclude fundamental principals of science, making patents more difficult to obtain by heightening the standards for utility and non-obviousness, changing the test for infringement by narrowing or eliminating the doctrine of equivalence and amending the Bayh-Dole Act to make it easier for the federal government to control the use of patents derived through federal funding.

²³⁵ *Id.* Dreyfuss takes Nelson's suggestion as a "friendly amendment."

²³⁶ Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exemption to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 57 (2001).

the use of research tools for their intended purpose should not be covered by an experimental use exemption because research tools were readily available to ordinary users with minimal transaction costs.²³⁷ Mueller asserts that research tools today are often not freely available for purchase by ordinary consumers and that when they are available the frequent need for multiple research tools creates a problem of royalty stacking which greatly increases the transaction costs involved in licensing research tools.²³⁸

Mueller also does not believe that Eisenberg's proposed experimental use exemption for the use of research tools in order to improve upon them or to engineer around them is sufficient to address the problem of control over downstream inventions.²³⁹ Mueller agrees with Dreyfuss that today technology advances in one field often spill over into other fields; Mueller gives as examples a genetically modified mouse that might be used to screen drugs for treatment of cancers or a DNA chip that might be used to identify genetic variations associated with diseases.²⁴⁰ Mueller does not think that the use of patented technologies in these ways would fall within Eisenberg's proposed experimental use exemption, however in Mueller's view these activities could result in new products that are much more valuable to society than new or improved research tools.²⁴¹

Under Mueller's proposal, patented research tools that are not readily available for licensing on reasonable terms could be used by third parties for their intended research purpose without a license to develop commercial products.²⁴² In exchange for the unlicensed uses of patented research tools, patentees would be entitled to reach-through royalties on the products developed with the use of their research tools.²⁴³ Mueller believes that this arrangement would be fair to both third party product developers and to research tool patentees because the royalty payments would be linked to the commercial success of the resulting products and therefore approximate the value of the research tools to the tool users-product developers.²⁴⁴ To

²³⁷ See *supra* note 196 and accompanying text.

²³⁸ Mueller, *supra* note 237 at 57.

²³⁹ *Id.*

²⁴⁰ *Id.* at 57-58.

²⁴¹ *Id.* ("To the extent that [the users] are not improving the technology of the research tool patent itself (i.e., resulting in improved research tools of the same type), these trans-technologic uses of research tools would appear to fall outside the ...'improver' prong of Professor Eisenberg's model."). *Id.* at 57.

²⁴² *Id.* at 58. Mueller does not define "readily available for licensing" or "reasonable terms."

²⁴³ *Id.* at 58-59.

²⁴⁴ *Id.* at 58. ("The new products [developed from the use of the research tool] would serve as the royalty base. In this manner the royalty payment to the research tool patentee would approximate the true value of the research tool to the tool user and product developer."). *Id.* (internal citation omitted).

implement this model, Mueller would require the third party user to notify the research tool patentee in advance of the tool's use.²⁴⁵ Finally, Mueller suggests alternative methods by which reach-through royalties could be determined.²⁴⁶

Strandburg supports Mueller's proposal, but with an important modification. Strandburg suggests a two-term system of compulsory licensing for research tool patents; during the first term, approximately three to five years, the research tool would be under the exclusive control of the research tool patentee; during the second term, the remainder of the patent's life, the research tool would be subject to compulsory licensing by third parties upon payment of a reasonable royalty to the research tool patentee.²⁴⁷ Strandburg sees a number of benefits in this modification to Mueller's proposal; the initial exclusivity period would allow patentees the opportunity to control downstream inventions developed using their research tools either by directly performing the research themselves or by collaborating with other researchers; the initial exclusivity period would allow patentees the opportunity to recoup their investment in research tools through private market transactions before the tools become subject to compulsory license; and the initial exclusivity period would provide a frame of reference for the determination of reasonable royalty rates when the compulsory license term begins.²⁴⁸

IV. Conclusion

The experimental use exemptions to patent infringement have important practical and policy implications for all researchers. For researchers working in the fields of pharmaceuticals and medical devices, the Hatch-Waxman Act provides a safe-harbor exemption from infringement for the use of patented subject matter in the course of research projects. Under the Supreme Court's recent ruling in *Merck v. Integra*, the Hatch-Waxman Act safe-harbor exemption to patent infringement covers the use of patented subject matter in research intended to develop a pharmaceutical compound or medical device, even if the research does not

²⁴⁵ *Id.* at 58-59. Mueller would not require the third party user to disclose the nature or details of the intended use of the research tool. *Id.* at 59.

²⁴⁶ *Id.* at 63-66. These methods include the "twenty-five percent rule" where the licensor receives twenty-five percent of the licensee's pre-tax profits on its sales and the "analytical approach" which calculates the royalty as the "residual between the infringer's anticipated net profit from practicing the infringed invention and the infringer's normal net profit." *Id.* at 64-65.

²⁴⁷ Strandburg, *supra* note 11 at 143.

²⁴⁸ *Id.* at 143-45.

ultimately yield a compound or device that is submitted to the FDA for pre-market approval.²⁴⁹ Likewise, the Hatch-Waxman Act safe-harbor exemption covers the use of patented subject matter in research intended to obtain data for submission to the FDA, even if the data is never submitted to the FDA.²⁵⁰ So long as a researcher has a reasonable basis for believing that her research might yield a drug product, medical device or research data that might be submitted to the FDA for review, the researcher is free to use patented subject in the course of the research project.²⁵¹

On the other hand, researchers working in fields other than pharmaceuticals and medical devices are at great risk of patent infringement in the event they use patented subject matter in the course of their research work. Under the CAFC decision in *Madey v. Duke*, any use of patented subject matter in research outside the fields of pharmaceuticals and medical devices, whether by a non-profit or a for-profit entity, that is in any way related to the business objective of that entity, constitutes patent infringement.²⁵² For universities, the business objective would include educating students, supporting faculty research, obtaining research grants and enhancing the status of the university.²⁵³

Some have suggested that universities have a lesser risk of being sued for patent infringement because an infringement suit brought by a corporation would generate adverse publicity for the corporation and an infringement suit brought by another university would breach an informal compact among universities to share research results openly. The extent to which these factors lower universities' infringement risk, however, is increasingly doubtful. As companies rely more and more on universities to provide research breakthroughs for their new products and services, universities will inevitably be drawn into the competition between companies and be subject to heightened risk of infringement suits.²⁵⁴ A company threatened with loss of market share due to university research sponsored by a competing firm would be as likely to sue the university for infringement as it would be to sue the competitor, in the event the research made use of the company's patented technology. Likewise, a company that licensed patented technology from a university might well demand that the university bring an

²⁴⁹ See *supra* note 147 and accompanying text.

²⁵⁰ *Id.*

²⁵¹ See *supra* note 152 and accompanying text.

²⁵² See *supra* notes 94-95 and accompanying text.

²⁵³ See *supra* note 97 and accompanying text.

²⁵⁴ See *supra* notes 224-25 and accompanying text.

infringement suit against another university using the licensed patented technology in research that potentially could yield a superior, competing technology.

There is one type of patented technology, however, that cannot be used by researchers in any field of research without infringing the rights of the patent owner--patented research tools. The use of patented research tools for their intended purpose, whether the tools are mechanical, electrical, biological, or photonic, constitutes patent infringement unless the user has obtained a license from the patent owner. The Hatch-Waxman Act provides no safe harbor exemption for the use of research tools for their intended purpose and, of course, no such infringement exemption exists under the common law experimental use exemption.

Recently, an association of university-affiliated organizations, including the Association of American Universities, the American Council on Education, the Association of American Medical Colleges and the Council on Government Relations, urged Congress to enact an experimental use research exemption as part of the proposed Patent Act of 2005.²⁵⁵ The association suggested that an experimental use exemption should cover the use of patented subject matter to determine whether it functions as claimed, to better understand its operation under different conditions, to discover something unknown about it, and to improve upon it.²⁵⁶ In the association's view, such an experimental use exemption would advance the "fundamental goal of the patent system to promote innovation through a combination of disclosure and proprietary protection" while not harming the market for the patented invention.²⁵⁷ At present, however, the proposed Patent Act of 2005 does not contain an experimental use exemption.

Until Congress and/or the courts allow an experimental use exemption for the use of patented subject matter outside the fields of pharmaceuticals and medical devices, researchers in other fields will continue to be subject to a high risk of potential patent infringement suits.

²⁵⁵ See AAU/ACE/AAMC/CORG Comments on H.R. 2795 submitted to Lamar Smith, Chairman, H. Judiciary Subcomm. on Courts, the Internet and Intellectual Property, June 23, 2005, *available at* <http://www.acenet.edu/AM/Template.cfm?Section=Search> (last visited Sept. 6, 2005). Patent Act of 2005, H.R. 2795, 109th Congress, (2005).

²⁵⁶ H.R. 2795 §6.

²⁵⁷ *Id.*