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No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools

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NO "DILETTANTE AFFAIR": RETHINKING THE EXPERIMENTAL USE EXCEPTION TO PATENT INFRINGEMENT FOR BIOMEDICAL RESEARCH TOOLS

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Abstract: Scientists who require multiple "research tools" (i.e., laboratory resources such as transgenic animals and biological receptors) to develop new drugs and medical diagnostic products are frequently finding that these tools are patented or subject to other proprietary constraints. Stacking royalty obligations and heightened transaction costs resulting from the proliferation of patents on research tools threaten to slow or stop the development of new drugs and devices critical to public health. Because U.S. courts have very narrowly interpreted the common law "experimental use" defense of patent law as limited to "dilettante" uses of inventions for mere "amusement" or "philosophical" inquiry, scientists face the daunting choice of either negotiating numerous licenses or risking the possibility that their research and development will be enjoined. In response to this dilemma of mounting transaction costs and increasingly restricted access to patented research tools, this Article argues for a broadened rule of "development use" that would permit scientists to use certain patented research tools without prior authorization, but require that the research tool patent owner be paid an ex post royalty based on the ultimate commercial success of the new drugs or other products developed through use of the tool. This "reach-through" royalty approach maintains incentives for the development and patenting of new research tools, but alleviates the access restrictions and up-front costs currently associated with their acquisition and use.

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I. INTRODUCTION

The thermostable enzyme *Thermus aquaticus* YT1 DNA polymerase (Taq)[1] is a basic and widely used biotechnology tool. Purified and isolated from a bacterium discovered in the hot springs of Yellowstone National Park,[2] a small amount of Taq is added to the test tube every time a forensic scientist analyzes blood from a crime scene or a laboratory technician tests an AIDS patient's HIV levels.[3] Taq is also widely used in DNA sequencing.[4] In both its native and recombinant forms, Taq is patented.[5] In

1. The identification, purification, and introduction of Taq are described in PAUL RABINOW, MAKING PCR: A STORY OF BIOTECHNOLOGY 128–32 (1996).

2. Bruce Rubenstein, *Complicated IP Suit Raises Fears Among Researchers: Litigation Progresses Over Important Biotech Tool*, CORP. LEGAL TIMES, Aug. 1998, at 28.

3. Tom Abate, *Drug Companies Battle Over Patent for Enzyme Used in DNA Testing*, S.F. CHRON., Jan. 31, 2000, at B1.

4. *All Things Considered: Court Calls Biotechnology Patent Into Question* (National Public Radio broadcast, Aug. 14, 1996), *at* 1996 WL 12726284 (statement of ProMega official Randy Diamond that over half of world's life science research laboratories use Taq "in either the PCR process or in DNA sequencing").

1991, the Swiss pharmaceutical giant Hoffman-La Roche (Roche) obtained from the now-defunct Cetus Corporation the patent rights in Taq as well as polymerase chain reaction or "PCR," the revolutionary DNA amplification process that utilizes Taq.[6]

By means of an unprecedented federal court filing in May 1995, Roche accused more than forty U.S. universities and research institutes (including Harvard, Stanford, Massachusetts Institute of Technology, the Salk Institute, the Scripps Research Institute, and the National Cancer Institute) and more than 200 individual scientists of infringing these patents.[7] The scientists' alleged wrongdoing was purchasing Taq for use in the PCR process from a bioscience supply company that, according to Roche, did not have a proper license to sell Taq for use in PCR.[8] Roche officials professed no concern about the use of Taq for "pure research" purposes, but stated that they felt compelled to take action against those scientists engaged in what Roche termed "highly practical" research with profit-making potential.[9] Although Roche officials denied any intent to formally join the scientists as parties to Roche's ongoing patent litigation against the Taq supplier, Promega Corporation of Wisconsin, a Roche spokesperson obliquely warned that she "wouldn't want to predict what action Roche would take relative to any patent . . . in the future."[10] At a San Francisco press conference hastily called by Promega in the days following Roche's filing, Nobel laureate Dr. Arthur Kornberg of Stanford University decried Roche's attempts to restrict the use of Taq and PCR technology as "violat[ing] practices and principles basic to the advancement of knowledge for the public welfare."[11]

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6. Service, *supra* note 5, at 2251. The discovery of Taq, which can withstand repeated heating cycles, made it possible to fully automate the PCR process. MAXIM D. FRANK-KAMENETSKII, UNRAVELING DNA 133–34 (1997). PCR selectively and exponentially amplifies (or multiplies) a specific region of DNA, producing quantities of DNA sufficient for experimentation and analysis. KARL DRLICA, UNDERSTANDING DNA AND GENE CLONING: A GUIDE FOR THE CURIOUS 153–57, 314 (3d ed. 1997). The invention of PCR is detailed in RABINOW, *supra* note 1.

7. *See generally LaRoche*, *supra* note 5; *see also* Mario C. Aguilera, *Local Institutes Named in Lawsuit*, SAN DIEGO DAILY TRANSCRIPT, May 25, 1995, at 1; Marcia Barinaga, *Scientists Named in PCR Suit*, 268 SCIENCE 1273, 1273 (1995).

8. Bruce Rubenstein, *La Roche and Promega in Tug of War Over Enzyme; DNA-Testing Tool Patent at Issue*, CORP. LEGAL TIMES, Jan. 1996, at 15.

9. Rubenstein, *supra* note 2, at 28.

10. Barinaga, *supra* note 7, at 1274.

11. *Hoffman-La Roche Challenges Freedom of Researchers; List of "Infringers" Includes Hundreds of Researchers and Dozens of Government-Supported Laboratories*, BUS. WIRE, May 24, 1995.

Roche's naming of hundreds of prominent scientists as potential patent infringers dramatically underscores the current debate over proprietary rights in biomedical "research tools," the many varied resources used by scientists to conduct research and development of new drugs, therapies, diagnostic methods, and other therapeutic products.[12] At bottom, the dispute stems from the broad rights conferred by the patents covering these tools. A U.S. patent grants its owner the right, inter alia, to prevent others from *using* the patented invention, without qualification as to the nature or purpose of the use.[13] Non-consensual uses of patented inventions that lead to the development of other products may result in patent infringement liability, even though sales of these products do not involve selling the patented invention. For example, a researcher may infringe if he or she uses without a license[14] a patented research tool, such as Taq, a biological receptor,[15] or a transgenic animal model[16] in the research and development

12. "Research tools" are further defined in Part II *infra*.

13. 35 U.S.C. § 154(a)(1) (1994) ("Every patent shall contain . . . a grant to the patentee . . . of the right to exclude others from making, *using*, offering for sale, or selling the invention throughout the United States or importing the invention into the United States . . . .") (emphasis added); *id.* § 271(a) ("Except as otherwise provided in this title, whoever without authority makes, *uses*, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent.") (emphasis added).

14. The "use" contemplated by § 271(a) as an act of infringement is limited by the statute to use "without authority." *Id.* By contrast, "use" of a patented device legally purchased is not infringement. A purchaser is deemed to have obtained an implied license to use the purchased patented device. Aro Mfg. Co. v. Convertible Top Replacement Co., 377 U.S. 476, 484 (1964) ("[I]t is fundamental that sale of a patented article by the patentee or under his authority carries with it an 'implied license to use.'") (citing Adams v. Burke, 84 U.S. (17 Wall.) 453, 456 (1873)). The limits of authorized "use" are informed by the "permissible repair" versus "infringing reconstruction" debate. *See* Hewlett-Packard Co. v. Repeat-O-Type Stencil Mfg. Corp., 123 F.3d 1445, 1451–52 (Fed. Cir. 1997).

15. *See* John H. Barton, *Patents and Antitrust: A Rethinking In Light of Patent Breadth and Sequential Innovation*, 65 ANTITRUST L.J. 449, 451 (1997) (suggesting scenario in which firm obtaining patent protection on biological receptor useful in schizophrenia research could preempt others from further research in schizophrenia, without itself having any truly "marketable product"); *see also* Eliot Marshall, *Patent on HIV Receptor Provokes an Outcry*, 287 SCIENCE 1375, 1375–77 (2000) (describing academic researchers' criticism of patent issued to Human Genome Sciences, Inc. (HGS) on CCR5 cell-surface receptor that HIV uses as cell entry point, and reporting HGS's position that it will enforce patent against "anyone [who] wants to use the receptor to create a drug"). A "receptor" is a portion of a cell's surface that binds with specific molecules "like a lock accepting a key." *Human Pheromone Link May Have Been Found*, N.Y. TIMES, Sept. 28, 2000, at A22.

16. For example, U.S. Patent No. 5,675,060 (issued Oct. 7, 1997) ("Transgenic arthritic mice expressing a T-cell receptor transgene") discloses and claims transgenic arthritic mice that are useful as animal models for the evaluation of human arthritogenic and therapeutic anti-arthritic compositions. Genetically altered mice are preferred models for many human diseases because the mouse genome is similar to the human genome. David Malakoff, *The Rise of the Mouse, Biomedicine's Model Mammal*, SCIENCE, Apr. 14, 2000, at 248.

of new drugs, therapies, or diagnostic products to be sold commercially. "Use" liability arises under the patent laws even though the researcher has not physically incorporated the patented tool into the new product that is ultimately marketed.[17]

Many industrialized countries recognize an exception to patent infringement liability for non-consensual uses of patented inventions for experimental or research purposes.[18] An experimental use exception has met with little success in the United States, however.[19] The U.S. Court of Appeals for the Federal Circuit has grudgingly recognized the existence of a common law experimental use defense, but characterizes it as "truly narrow" and applicable only to trifling "dilettante affairs."[20] Banished from the experimental use defense is any activity viewed as "commercialization" or otherwise grounded on profit motive.[21] The current narrow interpretation of the doctrine virtually assures that it cannot be relied on by the rapidly growing number of university and industry collaborations whose research and development efforts are ultimately targeted at the commercialization of new biomedical products.[22]

The shortcomings of the experimental use doctrine as currently interpreted in the United States are receiving increasing attention in a climate of heightened concern over access to patented research tools. The explosion of biotechnological and biomedical research and development in the United States in the past twenty years,[23] with a corresponding increase

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17. Because the patented research tool is not incorporated into the commercial product, the researcher has not violated the "sells" prohibition of 35 U.S.C. § 271(a). *See supra* note 13.

18. Part V *infra* examines the implementation of the experimental use doctrine in foreign patent laws.

19. Part III *infra* details the judicial treatment of the experimental use doctrine in U.S. courts.

20. Roche Prods. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984).

21. *E.g.*, *Roche*, 733 F.2d at 863 (refusing to adopt broader view of experimental use doctrine that would "allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes"); Pitcairn v. United States, 547 F.2d 1106, 1125–26 (Ct. Cl. 1976) (rejecting government's experimental use defense because government's unauthorized use of infringing helicopters for testing, demonstrations, and experiments was "in keeping with the legitimate business of the using agency"); Deuterium Corp. v. United States, 19 Cl. Ct. 624, 633 (1990) (Rader, J.) (rejecting experimental use defense because government agency's participation in demonstration project with for-profit partner corporation "was not strictly intellectual experimentation, but development of technology and processes for commercial applications").

22. *See* Part IV *infra*.

23. The U.S. Supreme Court's 1980 decision in *Diamond v. Chakrabarty*, 447 U.S. 303, which upheld the patentability of a living, genetically engineered bacterium, *see id.* at 318, is generally viewed as having given the green light to the U.S. biotechnology industry. The initial public offering of Genentech, Inc. in October, 1980, is also considered a watershed event in biotechnology commercialization. Lynne G. Zucker et al., *Geographically Localized Knowledge: Spillovers or*

in patenting activity,[24] particularly in the area of genomics,[25] has concomitantly heightened difficulties of access to and dissemination of patented research tools.[26] Burgeoning research and development will

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Markets?, 36 ECON. INQUIRY 65 (1998). By 1998, there were reportedly 1,283 biotechnology companies operating in the United States and market capitalization for the U.S. biotechnology industry had reached $97 billion. Biotechnology Industry Organization: Editors' & Reporters' Guide to Biotechnology (Feb. 2000), *available at* http://www.bio.org/ aboutbio/guide2000/facts.html [hereinafter Guide to Biotechnology]. The total amount of external financing raised annually by new U.S. biotechnology firms (including financing from venture capital, initial public offerings, follow-on offerings, private placements, debt and convertible security issues, and issuance of shares in research and development financing organizations) increased from $248 million in 1980 to approximately $3.1 billion in 1995 (amounts computed in 1995 dollars); the high year was 1990, when approximately $5.4 billion was raised. Josh Lerner & Robert P. Merges, *The Control of Technology Alliances: An Empirical Analysis of the Biotechnology Industry*, 46 J. INDUS. ECON. 125, 128 (1998). The National Venture Capital Association reports that U.S. biotechnology firms received $1.18 billion in venture capital funding in 1999. Martin Van Der Werf, *Universities Could Benefit from Venture Capitalists' Renewed Interest in Biotechnology*, CHRON. HIGHER EDUC., (Feb. 28, 2000), *at* http://chronicle.com/daily/2000/02/2000022802n.htm. This figure represents an increase from the 1998 funding level of $1.03 billion. *Id.*

24. Guide to Biotechnology, *supra* note 23(providing graphical representation of total numbers of U.S. biotechnology patents granted per year , shows that biotechnology patenting has escalated from less than 2000 patents issuing in 1985 to more than 9000 patents issuing in 1998); Report of the National Institutes of Health (NIH) Working Group on Research Tools 3, *at* http://www.nih.gov/news/researchtools/ index.htm (June 4, 1998) [hereinafter NIH Research Tools Report] (reporting "increasing use of the patent system to obtain proprietary rights in research tools and increasing use of license agreements and material transfer agreements (MTAs) delineating the terms and conditions under which research tools can be used").

25. *See generally* Karen Hall, *Genomic Warfare*, AM. LAW., June 2000, at 68. "Genomics" refers to that subset of the biotechnology industry which is engaged in finding, sequencing, and frequently patenting purified and isolated sequences of genes. Many of the genomics firms have piggybacked on the work of the Human Genome Project, a federal government effort to identify all genes in the human body. As of September 1999, reportedly 1800 U.S. patents had issued on animal, plant, and human genes, and 7000 other genes were the subject of pending U.S. patent applications. *Should Congress Liberate Gene Data?*, CHI. TRIB., Sept. 16, 1999, at A26 [hereinafter *Gene Data*]. In January 2000, more than seventy genomics companies were poised to issue public stock offerings. *Another Boom in Biotechnology Stocks: Genetic Research Lures Internet Cash*, N.Y. TIMES, Jan. 23, 2000, at B9.

26. *See, e.g.*, Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72,090, 72,090 (Dec. 23, 1999) [hereinafter NIH Principles and Guidelines] (reporting formation of advisory committee to Director of NIH, Dr. Harold Varmus, to "look into problems encountered in the dissemination and use of proprietary research tools, the competing interests of intellectual property owners and research users underlying these problems, and possible NIH responses"); Irving N. Feit, *Biotechnology Research and the Experimental Use Exception to Patent Infringement*, 71 J. PAT. & TRADEMARK OFF. SOC'Y 819, 821 (1989) (predicting that "[a]s commercial products [of biotechnology] become available, the infringement of patents covering the basic research methods that led to the product will become an increasingly difficult problem"); Lita Nelsen, *The Rise of Intellectual Property Protection in the American University*, 279 SCIENCE 1460, 1460–61 (1998) (listing "[r]estricted availability or delays in exchange of 'research tools' (such as vectors or transgenic mice) in biological research" as one of several unresolved problems currently facing university technology-

require ever-greater numbers of proprietary tools,[27] giving rise to transaction costs associated with acquiring the right to use each such tool. In some cases, the patentee may refuse to license the research tool altogether. The sum total of the transaction costs involved with acquisition of all necessary research tools may be so severe as to impede, postpone, or stop the development of important new products.

Within the highly patent-centric environment of biotechnological and biomedical research and development, Michael Heller and Rebecca Eisenberg have argued that the scientific community is approaching a "tragedy of the anti-commons."[28] The anti-commons theory predicts that the proliferation of patents on "upstream" basic tools of biotechnological and biomedical research will stymie the development of sufficient numbers of downstream application products. Innovation is impeded by the "royalty stacking" problem imposed by the numerous upstream patents that must be practiced in order to make the new downstream product.[29] The problem of too many restrictions on upstream research tools resulting in an impoverishment of downstream products is the reverse of the famous "tragedy of the commons" theorized by Garrett Hardin in 1968.[30] In Hardin's metaphor, the absence of restrictions on access to public lands resulted in a tragedy of over-grazing; here the result is under-development of potentially important commercial drugs and therapeutic products.

The anti-commons theory is far from a merely academic construct. The National Institutes of Health (NIH) Working Group on Research Tools found in 1998 that "all segments" of the biotechnology research and development community surveyed agreed that "the stacking of intellectual property obligations as successive tools are used in the course of an extended research project has the potential to impede or even preclude the development of new and better diagnostic and therapeutic products."[31] The

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transfer management); *Gene Data*, *supra* note 25 ("Holders of genetic patents have been charging steep licensing fees for use of their information and sending 'cease and desist' notices to competing companies, academic medical centers and clinical laboratories that use it without permission.").

27. Kyla Dunn, *A Look at . . . Patents & Biotech*, WASH. POST, Oct 1, 2000, at B3 (reporting that "[t]he cost of doing [biotechnology] research now includes the cost of accessing these [research tool] patents—at whatever price the market will bear").

28. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998).

29. *Id.* at 699.

30. Garrett Hardin, *The Tragedy of the Commons*, SCIENCE, Dec. 13, 1968, at 1243–48.

31. NIH Research Tools Report, *supra* note 24, at 22; *see also* Rebecca S. Eisenberg, *Technology Transfer and the Genome Project: Problems With Patenting Research Tools*, 5 RISK 163, 168 (1994) (asserting that patents on research tools "can create obstacles to subsequent [reasearch and

patenting of numerous "knockout" (gene-deleted) laboratory mice in recent years has incensed scientists concerned about the high prices and burdensome licensing conditions associated with these research tools.[32] University licensing directors list "[r]estricted availability or delays in exchange of 'research tools' (such as vectors or transgenic mice) in biological research" as a key, unresolved challenge.[33] Scientists using "DNA chip" technology to screen patients for genetic variations envision a nightmare scenario in which a license is required for each of the thousands of DNA sequences attached to a thumbnail-sized chip.[34] In the plant biotechnology sector, technology-transfer officials report stifled development because of the veto power wielded by the owners of patents on research tools such as promoters and transformation systems that are necessary for the commercial development of transgenic plants.[35] In an attempt to overturn what they view as overly restrictive licensing terms and excessive licensing fees, the families of children afflicted with Canavan disease, a rare genetic disorder of the brain, are suing the research scientists who isolated and patented the gene responsible for the illness.[36]

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development] and add to a thicket of rights that firms must negotiate their way past before they can get their products on the market"); *Gene Data*, *supra* note 25, at A26 (reporting that "[r]ather than risk a lawsuit or pay fees they consider exorbitant, some researchers have stopped exploring diseases whose genetic profiles already have been licensed").

Specific types of obstacles to access that the NIH Working Group investigated included "refusals to license, onerous royalty obligations, restrictions on the dissemination of materials and information, restrictions on the ability to collaborate with commercial firms, and advance commitments regarding intellectual property rights in future discoveries." NIH Research Tools Report, *supra* note 24, at 4.

32. Eliot Marshall, *A Deluge of Patents Creates Legal Hassles for Research*, 288 SCIENCE 255, 255–57 (2000). Marshall reports that "[t]his tension between the creators and the controllers of knockout mice is indicative of a tension throughout the research world." *Id.* at 255.

33. Nelsen, *supra* note 26, at 1460–61 (Ms. Nelsen is director of the Technology Licensing Office of the Massachusetts Institute of Technology); *see also* Richard Florida, *The Role of the University: Leveraging Talent, Not Technology*, ISSUES SCI. & TECH., Summer 1999, at 69–70 (noting concerns of smaller industrial firms that partner with universities over "protracted negotiations by university technology-transfer offices or attorneys over intellectual property rights," which impede goal of getting new innovations to market as quickly as possible).

34. Robert F. Service, *Will Patent Fights Hold DNA Chips Hostage?*, 282 SCIENCE 396, 397 (1998).

35. Colm Lawler & Fred Erbisch, *From Mice to Maize*, 283 SCIENCE 33, 33 (1999).

36. Peter Gorner, *Parents Suing Over Patenting of Genetic Test*, CHI. TRIB., Nov. 19, 2000, at 1. On October 30, 2000, the parents of children suffering from Canavan disease, along with the New York-based Canavan Foundation and other foundations, sued Dr. Reuben Matalon and his institution, Miami Children's Hospital, in federal district court in Chicago seeking to block the hospital's commercial use of the Canavan gene and recover money damages based on royalties that the hospital has collected from licensing a patented test that screens for the Canavan gene. *Id.* at 9. The Canavan Foundation alleges that it was forced to stop offering free genetic screening after learning that it would have to pay royalties and comply with licensing terms it considered onerous. *Id.*

This dilemma of gaining access to patented research tools needed in biotechnological and biomedical development suggests the importance of re-conceptualizing the experimental use doctrine as a partial, if not complete, solution.[37] This Article argues that where significant transaction costs are associated with accessing the patented research tools necessary to develop downstream application products such as new drugs, therapies, and diagnostics, the non-consensual use of those tools, even though for ultimately commercial purposes, should no longer be automatically disqualified from the benefits of the experimental use doctrine. This Article further proposes a "liability rule"[38] model that, while prohibiting the patent owner from enjoining the non-consensual use of the research tool, would appropriately compensate the patent owner in the form of an ex post

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The lawsuit does not attack the validity of the Canavan gene patent, but instead seeks damages and equitable and injunctive relief to redress the defendants' alleged breach of informed consent, breach of fiduciary duty, unjust enrichment, fraudulent concealment, conversion, and misappropriation of trade secrets. Complaint at 1, Daniel Greenberg v. Miami Children's Hosp. Research Inst., Inc., (N.D. Ill. Oct. 30, 2000) (No. 00C 6779) (copy on file with author). The plaintiffs allege that, as owner of the Canavan gene patent, Miami Children's Hospital "substantially restricted the number of laboratories authorized to conduct Canavan disease testing through exclusive licensing agreements" and "restricted public accessibility to testing through 'volume caps' that limited the number of tests to be performed by licensed laboratories and by requiring all such laboratories to pay royalty and licensing fees." *Id.* at 10. Among other remedies, the plaintiffs seek a permanent injunction restraining the hospital "from restricting access to prenatal and carrier testing for Canavan disease through exclusive licensing and/or collection of royalties, and from impeding research on finding a cure or therapies for Canavan disease through enforcement of Patent No. 5,679,635 or related international patents, or pursuit of pending international patents." *Id.* at 13.

37. *See* NIH Research Tools Report, *supra* note 24, at 23 n.5 (proposing "clarification of the research exemption" as one of several issues for further consideration).

A number of academic commentators have suggested a larger role for the experimental use exemption, or at least the importance of a clearer understanding of the doctrine's scope. *See* Barton, *supra* note 15, at 457 (proposing revision of experimental use exemption "so as clearly to permit use of patented technology for technology improvement purposes without needing to obtain an explicit license"); Jon Cohen, *Chiron Stakes out Its Territory*, 285 SCIENCE, 28 (1999) (quoting Robert Merges's description of experimental use exemption's reach as "one of the great unsolved mysteries of contemporary patent metaphysics"); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1020 (1989) (asserting that purpose and scope of experimental use defense "are not well defined" and that "this vaguely defined doctrine is becoming less satisfactory" as level of research utilizing patented materials continues to accelerate); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 866 n.118 (1990) (characterizing "precise contours" of experimental use defense as "unclear"); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 139 (1999) (suggesting broader interpretation of experimental use exception as one possible mechanism for reducing transaction and creativity costs associated with patenting basic scientific research).

38. "Liability rules" and "property rules" are defined *infra* note 278.

royalty based on the marketplace value of any new products developed through use of the tool; in other words, a "reach-through" royalty approach.

Part II provides a further definition of the nature of research tools and the increasingly problematic restrictions on access to the tools. Part III addresses the traditional narrow interpretation of the experimental use doctrine by the U.S. courts. Part IV discusses the implications of that interpretation for university-industry research and development collaborations. Part V examines the more liberal treatment of the experimental use doctrine in Europe and Japan. Part VI responds to arguments commonly cited against the experimental use exemption and suggests additional justifications for its broadening in the context of research tools. In Part VII, this Article proposes an expanded model of the experimental use doctrine that would permit the non-consensual "development use" of research tools, coupled with an ex post royalty payment based on the marketplace-determined value of the new products that result from that use. It concludes that the present "truly narrow" formulation of the experimental use doctrine in the United States is inapplicable to most research tool users, and the doctrine should be expanded in a manner that will maximize the development of important new therapeutic products while maintaining appropriate investment incentives for the ongoing creation of new research tools.

II. DEFINING AND ACCESSING "RESEARCH TOOLS"

The debate over patenting research tools begins with defining what research tools truly are. This Part surveys candidate meanings and provides examples of prominent research tools that have been subject to proprietary constraints. It contends that restrictions on access to such research tools are currently most problematic in the field of biotechnological research and development, and describes the types of escalating transaction costs faced by these enterprises.

"Research tools" is a phrase of many meanings depending on perspective. While researchers view the resources they rely on in the laboratory as "tools," firms whose primary business is to manufacture and sell these resources may consider the same "tools" as "end products."[39] A clear definition of "research tools" is an essential prerequisite to any

39. NIH Research Tools Report, *supra* note 24, at 3.

proposal for modification of the patent owners' right to prohibit non-consensual uses of the tools.[40]

The NIH Working Group on Research Tools (Working Group) was formed in 1997[41] to investigate the problems of NIH grantees in obtaining access to patented research resources.[42] The Working Group report defines "research tool" in its broadest sense as "embrac[ing] the full range of resources that scientists use in the laboratory,"[43] including "cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools (such as PCR [polymerase chain reaction]), methods, laboratory equipment and machines, databases and computer software."[44]

The problem of access to patented research tools is currently more acute and better documented in biotechnology than in any other scientific field.[45] Biotechnology is research-intensive.[46] A high percentage of the basic research tools and laboratory techniques of biotechnology are subject to proprietary restraints such as patents[47] or material transfer agreements.[48]

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40. Evelyn H. McConathy & Clifford K. Weber, *Committee Report: University and Government IP Issues*, AM. INTELL. PROP. L. ASS'N BULL., Mid-Winter 2000, at 178 (identifying "gray areas" in definition of research tools that impact determination of how their use "can, or should be, protected").

41. Eliot Marshall, *Making Research Tools More Accessible*, 280 SCIENCE 1687 (1998).

42. NIH Research Tools Report, *supra* note 24, at 4.

43. *Id.* at 3.

44. *Id.*; *see also* James G. Cullem, *Panning for Biotechnology Gold: Reach-Through Royalty Damage Awards for Infringing Uses of Patented Molecular Sieves*, 39 IDEA 553, 553 (1999) (describing "molecular sieves" as next-generation research tools used to "screen for, and identify, novel, specific compounds for known molecular targets").

45. In contrast with the field of biotechnology, restrictions on proprietary research tools have not yet been reported as problematic in the development of Internet- and computer-implemented business methods and products. As patenting activity in these technologies continues to increase at an explosive pace, however, access to developmental tools may become an issue. For example, the developer of a new software program might need access to various patented algorithms in order to test the performance of a new program. Of course, developers who use "tools" that would qualify as "methods" under the new Prior Inventor Defense provisions of the American Inventors Protection Act of 1999 (codified at 35 U.S.C.A. § 273 (West Supp. 1999)) may be able to assert that defense without needing to rely on an experimental use doctrine as proposed in this Article.

46. The Biotechnology Industry Organization, a trade group for the biotechnology industry, reports that the U.S. biotechnology industry's expenditure for research and development was $9.9 billion in 1998. Guide to Biotechnology, *supra* note 23.

47. *See* Feit, *supra* note 26, at 819 (contending that experimental use exception "is likely to have a particularly important impact on biotechnology, where basic laboratory methods and materials constitute the subject matter of patent claims").

48. A material transfer agreement (MTA) is a negotiated contract between the owner of a tangible material, either patented or unpatented, and a party who seeks the material for research use. *See* NIH Research Tools Report, *supra* note 24, at App. B. MTA's tend to be less formal and shorter than patent

proprietary restraints such as patents[47] or material transfer agreements.[48] Proponents of patent protection contend that the high cost of developing these tools can be recouped only through temporary, sole-source pricing control.[49] Moreover, because of the scientific complexity of their work, biotechnology researchers generally need access to a relatively greater number of proprietary research tools in order to conduct their research than do workers in other technologies.[50]

Some of the most important research tools in biotechnology, all subject to proprietary restraints, include:

- The *cre-loxP* mouse. E.I. du Pont de Nemours owns the patented technology[51] used to create "conditional mutants," mice in whom a targeted gene is deleted when the *cre* gene encounters two *loxP* DNA segments bracketing the targeted gene.[52]

- The Cohen-Boyer patents covering the basic method and plasmids for gene cloning, assigned to the University of

47. *See* Feit, *supra* note 26, at 819 (contending that experimental use exception "is likely to have a particularly important impact on biotechnology, where basic laboratory methods and materials constitute the subject matter of patent claims").

48. A material transfer agreement (MTA) is a negotiated contract between the owner of a tangible material, either patented or unpatented, and a party who seeks the material for research use. *See* NIH Research Tools Report, *supra* note 24, at App. B. MTA's tend to be less formal and shorter than patent license agreements, and generally do not require financial payments at the time of the material transfer. *Id.* The NIH and academic community have developed a standardized MTA for transfers of biological materials known as the "Uniform Biological Material Transfer Agreement" (UBMTA). *Id.*

49. Scott A. Chambers, *Comments on the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 53, 54 (1995); Maurice A. Flores, *Taking the Profits out of Biomedical Research Tools*, 17 NATURE BIOTECHNOLOGY 819, 820 (1999).

50. For example, DNA-chip technology involves layering chains of nucleotides onto silicon. *See* Sandeep Junnarkar, *'GeneChip' Encodes DNA on Silicon*, N.Y. TIMES (Mar. 15, 1997), *at* http://search1.nytimes.com/search/daily/bin/fastweb?getdoc+site+site+126360+2+wAAA+genechip. These thumbnail-size chips offer a myriad of potential applications in diagnosing genetic mutations and studying genes believed to be responsible for various types of cancer. *Id.* More than 40,000 gene sequences may be attached to a single 2.5-centimeter chip. Service, *supra* note 34, at 397. If each of those sequences is covered by a patent, a nightmarish licensing scenario may ensue. *Id.*

51. U.S. Patent No. 4,959,317 (issued Sept. 25, 1990) ("Site-Specific Recombination of DNA in Eukaryotic Cells").

52. Eliot Marshall, *The Mouse that Prompted a Roar*, 277 SCIENCE 24 (1997). Research institutions including the NIH protested when DuPont required academic researchers to sign no-cost "research licenses." *Id.* at 25. Some commercial institutions have taken licenses for more than $100,000. *See id.* The science press has characterized the restrictions on cre-loxP as "a lightning rod for scientists chafing at restrictions on the free flow of research materials," *id.* at 24, and the National Academy of Sciences has cited the restrictions as a "commercial barrier[] to basic research," *id.* at 25.

widely licensed[54] and are often cited as a positive example of the benefits of patenting research tools.[55]

- PCR (polymerase chain reaction) technology.[56] Cetus Corporation originally owned the patents on PCR, a basic method of amplifying DNA sequences and the key reagent used in PCR, the enzyme Taq DNA polymerase.[57]

- The Harvard "oncomouse" patent of Leder-Stewart, assigned to Harvard University and exclusively licensed to E.I. du Pont de Nemours.[58] The tumor-prone "oncomouse" is useful as a model in cancer research.[59]

- The expressed sequence tags (ESTs)[60] that have been identified in the decoding of the human genome. Many of these small

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54. The Cohen-Boyer patents have been "licensed to all comers." Merges & Nelson, *supra* note 37, at 906. There are reportedly more than seventy licensees of the Cohen-Boyer patents. *See* Feit, *supra* note 26, at 820 (reporting that Cohen-Boyer patent license "provides for a minimum royalty of $10,000 per year and royalties based on net sales of final products at a rate of 0.5% to 10% based on the type of final product and country of sale").

55. *E.g.*, Molly A. Holman & Stephen R. Munzer, *Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequences*, 85 IOWA L. REV. 735, 803 (2000); Rochelle K. Seide & Janet M. McLeod, *Response to Policy Commentary*, SCIENCE (contending that Cohen-Boyer patents did not stymie technology because broadly licensed at reasonable rates), *available at* http://www.sciencemag.org/feature/data/980465/seide.shl (last visited Oct. 23, 2000).

56. The PCR process selectively and exponentially amplifies (or multiplies) a specific region of DNA, producing quantities of DNA sufficient for experimentation and analysis. DRLICA, *supra* note 6, at 153–57, 314. The invention of PCR is detailed in RABINOW, *supra* note 1.

57. Eliot Marshall, *Battling Over Basics*, 277 SCIENCE 25 (1997). Cetus's efforts to impose licenses on academic researchers using PCR were widely criticized. *E.g.*, Barinaga, *supra* note 7, at 1273. Roche acquired the patent rights from Cetus in 1991 for $300 million. Service, *supra* note 5, at 2251. Since that time, it has imposed a multi-tiered licensing system. Marshall, *supra* note 57, at 25. Roche's patent on the "native" form of the Taq enzyme (i.e., purified from the bacterium *Thermus aquaticus*) was recently held unenforceable by a federal district court as having been procured through inequitable conduct. Hoffman-La Roche, Inc. v. Promega Corp., No. C-93-1748 VRW, 1999 WL 1797330 (N.D. Cal. Dec. 7, 1999) (holding all claims of U.S. Patent No. 4,889,818 unenforceable); Service, *supra* note 5, at 2251. The ruling, now on appeal, was limited to n-Taq and did not directly effect Roche's other patents on a recombinant form of Taq and on the PCR process. *Id.* at 2253.

58. U.S. Patent No. 4,736,866 (issued Apr. 12, 1988) ("Transgenic Non-Human Mammals").

59. In 1988, DuPont was selling the genetically modified mice to cancer researchers for approximately $50 each. *See* Eisenberg, *supra* note 37, at 1084.

60. An EST is a short fragment of complimentary DNA (cDNA), typically 150–400 base pairs in length, that is potentially useful as a probe to find the corresponding full-length gene. Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter As To the Patentability of Certain Inventions Associated With the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 1, 2, 13–14 (1995). Complimentary DNA is DNA synthesized in test tubes from ribonucleic acid (RNA). DRLICA, *supra* note 6, at 305.

segments of complimentary DNA have no presently known utility, although they are believed to be useful as probes in searching for corresponding full-length genes.[61]

- Human embryonic stem cells, from which any type of human tissue can be grown.[62] Stem cell research may someday permit doctors to grow transplant organs that identically match a patient's tissue.[63] The Wisconsin Alumni Research Foundation (WARF) owns a broad patent on these cells[64] and has granted an exclusive license to Geron Corporation for commercial use.[65]

This Article limits the analysis of "research tools" to those patented tools used in development of new biotechnological or pharmaceutical products that do not themselves physically incorporate the tool. Thus defined, the sale of such products would not trigger the "sells" or "offers to sell"

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61. Eisenberg & Merges, *supra* note 60, at 13–14. Whether ESTs are properly characterized as "research tools" requires that a distinction be made between ESTs themselves and patents on ESTs. An EST itself, i.e., the short segment of complimentary DNA, is a research tool in the sense that it is used as a tool to find a corresponding full-length gene. Public comments received by the U.S. Patent and Trademark Office (USPTO) in response to its first round of Interim Written Description Guidelines, published in June 1998, reflect this view. Commentators asserted that "ESTs are genomic research tools that should be available for unencumbered research to advance the public good." Department of Commerce, Patent and Trademark Office, *Revised Utility Examination Guidelines*, 64 Fed. Reg. 71,440, 71,441 (Dec. 21, 1999) [hereinafter *Examination Guidelines*].

"Research tool" may not be a proper characterization for the many patents and pending patent applications directed to ESTs. Many in the biotechnology industry are concerned about EST patent claims of "open" scope (i.e., those reciting a purified and isolated "DNA comprising the sequence [EST nucleotide sequence data]"). Janice M. Mueller, *Patent Law Examination Guidelines*, NAT. L.J., Jan. 24, 2000, at B7; Rai, *supra* note 37, at 104 (stating that many pending EST patent applications claim "not only the EST but also the full gene of which it is a part and future uses of the gene"). Such claims appear to read on the full-length gene (as yet unknown), which could include within it the recited EST sequence plus a multitude of other sequences or regulatory elements. Thus, the EST sequence recited in the "comprising" claim would not be merely a tool, but actually a physical subset of the full-length gene once located. This is a very different paradigm from the use of the *cre-loxP* mouse to develop a new drug, where the mouse "tool" is used to make a new product but is not part of or incorporated into that product. *See* Robert Blackburn, Chief Patent Counsel, Chiron Corporation, remarks at the National Academies Board on Science, Technology, and Economic Policy's Conference on "Intellectual Property Rights: How Far Should They Be Extended?" (Washington, D.C., Feb. 3, 2000) (contending that ESTs are not true "research tools" because they have no clear utility other than as part of final product).

62. Dunn, *supra* note 27, at B3.

63. *Id.*

64. U.S. Patent No. 5,843,780 (issued Dec. 1, 1998) ("Primate Embryonic Stem Cells").

65. Dunn, *supra* note 27, at B3 (reporting that although WARF is permitting scientists to access patented stem cells for "purely academic research," researchers and patent experts are concerned that Geron's right to exclude others from commercial use of cells "may determine whether or not new lifesaving therapies reach the public").

liability provisions of the Patent Act.[66] Rather, the liability for infringement of patents on these research tools, absent a license or exemption, would occur only under the "uses" (and in some cases, the "makes"[67]) provisions of the statute.

Another important qualifier on the meaning of "research tools" as used herein is that the analysis is limited to those patented tools for which access is problematic. The patenting of a particular research tool does not necessarily create dissemination problems for that tool. Likewise, any resulting impediment to innovation of products requiring use of the tool is not uniformly high for all types of tools. Economically rational researchers would not risk infringement liability when they can simply buy widely available tools such as patented chemical reagents or genetically modified laboratory mice via supplier catalog or other anonymous market transactions.[68] Transaction costs and access barriers would not be at issue here, and a broadened research exemption would not be necessary in such cases.[69]

In contrast, the possibility that research will be delayed or foregone, or that it will be conducted without authorization to use the patented research tool and lead to subsequent litigation, is much greater where the research tool must be acquired through direct license negotiations.[70] Researchers may balk at the prospect of having to disclose the nature of their research in the course of obtaining the licenses they need.[71] Alternatively, the suppliers of patented research tools may simply refuse to license them,[72] or place

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66. 35 U.S.C. § 271(a) (Supp. IV 1998) ("Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent."); *see also supra* notes 13–14.

67. The "making" liability under 35 U.S.C. § 271(a) would involve the construction or synthesis of the research tool as a precursor to its use in developing a new product that does not incorporate the tool. For example, a *cre-loxP* mouse might be made (rather than purchased from an external source) by the research worker before it was used, but the ultimate sale of a new therapeutic product developed by using the patented mouse would not involve a sale of the mouse itself.

68. Eisenberg, *supra* note 31, at 171.

69. *Cf.* Barton, *supra* note 15, at 457 (advocating broadened experimental use exemption for follow-on innovators, "unless, of course, the technology is readily available, as through a research kit").

70. *Id.*; *see generally* Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1053–55 (1997) (describing various transaction costs involved in licensing intellectual property and concluding that these costs are "significant").

71. Barton, *supra* note 15, at 457.

72. Refusal to license a patent, even where the patent owner has market power in the antitrust law sense, has not been held to violate the antitrust laws. *See* Intergraph Corp. v. Intel Corp., 195 F.3d 1346, 1362 (Fed. Cir. 1999); *see also* 35 U.S.C. § 271(d)(4) (1994). Section 271(d)(4) provides:

significant limitations on licenses, such as refusing to grant non-exclusive licenses to multiple researchers.[73]

Even where research tool patent owners are amenable to licensing, the price demanded can represent a barrier to entry. When there is not yet any commercial product in existence, the research-tool patent owner and the tool user may have very different views about the proper economic valuation of the tool.[74] With increasing frequency, research tool patentees are demanding the payment of "reach-through royalties."[75] Such royalties are computed as a share of the ultimate market value of some future commercial product to be developed with the tool, rather than the current market value of the research tool itself.[76] Although reach-through royalties are often attractive to biotech start-up firms because they minimize or eliminate up-front licensing costs, other potential licensees may object to them.[77] The NIH have recently issued a strongly-worded criticism of reach-through royalties, at least for tools licensed by or to NIH grantees.[78]

No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: . . . (4) refused to license or use any rights to the patent.

Id.

73. Nelsen, *supra* note 26, at 1460–61 (criticizing exclusive licensing of receptor "targets" for high-throughput drug screening in situations where non-exclusive licensing "might better foster development").

74. Flores, *supra* note 49, at 819 (contending that often "the promise of generating commercial value is remote and the up-front use fee that scientists are willing to pay without extended negotiation is correspondingly low"); *cf.* Josh Lerner & Robert P. Merges, *The Control of Technology Alliances: An Empirical Analysis of the Biotechnology Industry*, 46 J. INDUS. ECON. 125, 126 (1998) (describing early-stage biotechnology research and development efforts as "highly complex and uncertain" and characterized by great difficulty in "specify[ing] the features of the product to be developed").

75. John H. Barton, *Economics of Patent Enforcement*, 532 PLI/PAT. 343, 350 (1998).

76. For example, assume that Firm X is the supplier of a transgenic mouse useful in pharmaceutical research. Firm Y wants to use the mouse in laboratory testing in order to develop a new drug. By demanding a reach-through royalty, Firm X seeks to obtain from Firm Y some portion of future revenues from marketplace sales of the end product, the new drug. *See* Jorge A. Goldstein, *Research Tools and Reach Throughs*, *in* PROCEEDINGS OF THE 17TH ANNUAL AMERICAN TYPE CULTURE COLLECTION BIOTECH PATENT & LICENSING FORUM (Sept. 23–26, 1999); *see also* Barton, *supra* note 75 (noting patenting of research tools by biotechnology entities and universities and efforts of these firms to obtain reach-through royalty provisions in licenses); Cohen, *supra* note 37, at 28 (reporting attempts of Chiron Corporation, owner of patents on hepatitis C viral protease enzyme, to obtain reach-through royalties based on future sales of protease inhibitors developed by firms that use Chiron's enzyme to screen for these inhibitors).

77. Basing royalties on sales of a possible future end-product rather than the patented research tool itself creates the potential for greatly enhanced royalty income to the patentee, particularly if the licensee develops a product that is successful in the marketplace. Some scholars contend that this reach-through mechanism works to reduce the licensee's incentives to innovate and develop

These difficulties in defining and accessing research tools suggest the need for an experimental use doctrine that would, if not completely exempt research and development uses of patented tools from infringement liability, at least permit the use of patented research tools without prior consent, so long as appropriate compensation were subsequently paid to the research tool patent owner.[79] As illustrated in the next Part, however, the current formulation of the experimental use doctrine in the United States is far too narrow to permit such activity and must therefore be expanded.

III. LIMITED RECOGNITION OF A "TRULY NARROW" EXPERIMENTAL USE DOCTRINE IN THE UNITED STATES

For almost 200 years U.S. patent jurisprudence has paid homage to the concept of an exception (or exemption[80]) from infringement liability for unlicensed or otherwise unauthorized uses of patented inventions carried out for a research or experimental[81] purpose.[82] In practice, however, the experimental use doctrine has rarely been applied in favor of an accused

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commercially successful products. *E.g.*, Barton, *supra* note 15, at 461 (asserting that reach-through royalties "directly reduce the follow-on inventor's incentive to develop new technologies"). On the other hand, reach-through royalties may facilitate increased research and development activity because they allow authorized access to a research tool at little or no up-front cost.

78. NIH Principles and Guidelines, *supra* note 26, at 72,091 (finding that reach-through royalties "contribute not only to specific restriction of access to subsequent tools arising out of the NIH-funded work, but also to the general proliferation of multiple ties and competing interests that is the source of the current access problems"); Barton, *supra* note 75, at 350 (noting opposition of pharmaceutical firms to reach-through royalties). Patent bar groups have also identified concerns with demands for reach-through royalties in consensual licensing transactions of research tools. McConathy & Weber, *supra* note 40, at 178 (noting that reach-through license "increases the royalty burden, requires full disclosure of the licensee's intended use of the technology, and may so enlarge the stacking provisions that the entire project is killed"). *But see* Flores, *supra* note 49, at 819–20 (criticizing NIH Proposed Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources; Request for Comments, 64 Fed. Reg. 28,205 (May 25, 1999), as overly broad in attempting to prohibit reach-through royalties in licenses to commercial entities as well as to academics). The propriety of reach-through royalties is further addressed *infra* notes 286–305 and accompanying text.

79. Part VII *infra* details this proposed liability rule.

80. Although the U.S. case law has generally referred to an experimental use "exception," the term "exemption" is more precise and will be used herein.

81. The terms "research use" and "experimental use" appear interchangeably in U.S. case law and literature that recognizes an exemption from infringement liability.

82. *See generally* 5 DONALD S. CHISUM, CHISUM ON PATENTS § 16.03 [1] (2000).

infringer.[83] Although Congress enacted legislation in 1984 that created a safe harbor for generic drug manufacturers to test patented drugs for purposes of preparing FDA bioequivalency data,[84] that narrow and specific statutory safe harbor is not the subject of this Article. Rather this Part focuses on what remains of the common law doctrine of experimental use[85] and suggests that the burgeoning nonprofit and for-profit collaborative environment of biotechnology research and development calls for a fundamental rethinking of this doctrine's very limited contours.

In the great majority of cases, U.S. courts have recognized the experimental use exemption as doctrinally legitimate but found it inapplicable to the facts of the particular cases before them. The accused infringer's use of a patented invention, even for a socially-beneficial purpose such as scientific research, typically has been labeled a commercial or profit-making endeavor and, therefore, ineligible for the doctrine's protections.[86] The courts have considered even a minimal flavor of commerciality sufficient to take the accused activity outside the realm of protected experimental or research use.[87]

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83. *E.g.*, Douglas v. United States, 181 U.S.P.Q. 170, 176 (Ct. Cl. Tr. Div. 1974) (characterizing experimental use defense as "only sparingly applied" in U.S. patent case law), *aff'd on other grounds*, 184 U.S.P.Q. 613 (Ct. Cl. 1975).

84. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (Hatch-Waxman Act) (codified in pertinent part at 35 U.S.C. § 271(e) (1994)).

85. Although the U.S. Patent Act includes among the enumerated defenses to patent infringement the "absence of liability for infringement," 35 U.S.C. § 282(1), no court has pointed to that statutory provision as encompassing the experimental use doctrine. *E.g.*, Pfizer, Inc. v. Int'l Rectifier Corp., 217 U.S.P.Q. 157, 160 (C.D. Cal. 1982) ("There is nothing in the Patent Act of 1952 which even mentions any experimental use exception. The experimental use exception is . . . purely case law."). The commentary by a co-author of the 1952 codification of the Act does not mention the experimental use doctrine. P.J. Federico, *Commentary on the New Patent Act*, 35 U.S.C.A. 1 (1954 ed.) *reprinted in* 75 J. PAT. & TRADEMARK OFF. SOC'Y 161, 215 (1993) (stating that item one of § 282 "would include the defenses such as that the patented invention has not been made, used or sold by the defendant; license; and equitable defenses such as laches, estoppel and unclean hands"). Thus, the general experimental use doctrine, as opposed to the explicit regulatory data-gathering safe harbor of 35 U.S.C. § 271(e), is one of common law rather than statute.

86. CHISUM, *supra* note 82, § 16.03[1] (characterizing defense as limited to those acts conducted "solely for an experimental or other nonprofit purpose").

87. *See, e.g.*, *Pfizer*, 217 U.S.P.Q. at 161 ("The underlying rule of permissible experimental use demands there must be no intended commercial use of the patented article, none whatsoever, if the exception is to be recognized at all.").

That almost all of the reported cases invoking the experimental use defense involved some degree of commercialization is not surprising because litigation costs will most likely deter enforcement where a defendant's use is merely for amusement or philosophical inquiry, not involving some significant sales diversion or other profit-taking from the patentee. The U.S. Supreme Court's decision in *Beedle v. Bennett*, 122 U.S. 71 (1887), is a rare exception to this general rule. The plaintiff in *Beedle* held a patent on a driven well for drawing water from the ground. *Id.* at 72. The defendant, without

A. *United States Common Law Evolution of a "Truly Narrow" Experimental Use Exemption*

1. *Early Development: Commercial Intent Prohibited*

The experimental use exemption from patent infringement liability originated in the opinions of Justice Joseph Story, one of the country's early leading intellectual property jurists.[88] Justice Story's first and most commonly cited case on the subject is *Whittemore v. Cutter*,[89] involving an alleged infringement of a patent directed to a machine for making cards. In discussing the trial court's instruction on infringement to the jury, Justice Story opined that:

> It could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.[90]

In *Sawin v. Guild*,[91] Justice Story cited his earlier decision in *Whittemore* as establishing that patent infringement must concern:

> the making [of the invention] with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the

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authorization, constructed the patented well on his farm for his personal use and that of his family members, but never sold the infringing well to others. *Id.* at 73. The plaintiff's total damages from the defendant's use over the lifetime of the well were calculated at ten dollars. *Id.* at 75. The U.S. Supreme Court found in favor of the plaintiff without mention of any exception to liability for mere personal amusement or for merely de minimus use. *See id.* at 78. *Beedle* makes clear that no sale need occur for patent infringement liability; mere use is enough.

88. Indeed, Justice Story was an early interdisciplinarian in his thinking about intellectual property law. Some years after he recognized an experimental use exemption from patent infringement in *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600), Justice Story authored the seminal U.S. decision recognizing the fair use defense in copyright law, *Folsom v. Marsh*, 9 F. Cas. 342 (C.C.D. Mass. 1841) (No. 4901). Codified in the 1976 Copyright Act, the fair use doctrine provides that certain socially beneficial uses of copyrighted works such as scholarly criticism, classroom use, news reporting, and the like are not copyright infringement. 17 U.S.C. § 107 (1994). The U.S. courts' reticence to embrace a meaningful experimental-research use exemption in the patent law context stands in sharp contrast to the well-developed fair use jurisprudence in copyright law. Part VI *infra* discusses the applicability of the fair use "transformative use" notion to the patent law experimental use doctrine.

89. 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

90. *Id.* at 1121. In reality, this frequently quoted language was Justice Story's explanation of the rationale for the jury charge given by the trial court. While Justice Story appears to approve the rationale, his explanation is dicta because the patentee was granted a new trial for several unrelated errors by the trial court.

91. 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391).

> verity and exactness of the specification . . . . In other words, that the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.[92]

In *Sawin*, Justice Story thus makes the accused infringer's commercial intent the hallmark of liability, and the absence of such motive as the prerequisite for exemption under the experimental use doctrine.[93] Justice Story's dichotomy was adopted in subsequent decisions,[94] and it remains the rule today.[95]

Several explanations have been posited for Justice Story's profit-dispositive view. Suits for patent infringement were brought in Justice Story's era as actions for trespass on the case, a tort theory requiring a showing of wrongful intent or negligence.[96] Justice Story simply may have recognized the absence of such intent. Alternatively, Justice Story may have relied on the doctrine of *de minimis non curat lex* ("the law takes no account of trifles").[97] One commentator suggests that Justice Story was merely invoking the common law principle of *injuria absque damno* (wrong without damage),[98] which applies when a party's rights have been violated but the party has not suffered any legally recognizable damage. This explanation seems unlikely, however, in view of Justice Story's statement in *Whittemore* that "where the law gives an action for a particular act, the doing of that act imports of itself a damage to the party. Every violation of a right imports some damage, and if none other be proved, the law allows a nominal damage."[99]

Professor William Robinson in his famous 1890 treatise seconded Justice Story's "intent to deprive the patentee of his rewards" theory, titling

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92. *Id.* at 555.

93. It is unclear whether Justice Story would view an infringement that is unknowing or "innocent" (i.e., where the accused infringer was not aware of the plaintiff's patent) as equally disqualified from any experimental use exemption as a willful infringement, so long as in either case the accused infringer intended to make a profit.

94. *E.g.*, Byam v. Ballard, 4 F. Cas. 934, 934 (C.C.D. Mass. 1852) (No. 2,262).

95. Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000); Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 862 (Fed. Cir. 1984).

96. Richard E. Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. PAT. OFF. SOC'Y 357, 364–65 (1957).

97. Radio Corp. of Am. v. Andrea, 15 F. Supp. 685, 687 (D.C.N.Y. 1936) (characterizing as understandable view that "the law, not concerning itself with trifles, would ignore a mere casual appropriation [of a patented invention] for amusement or even scientific purpose"), *modified on other grounds*, 90 F.2d 612 (2d Cir. 1937).

98. Bee, *supra* note 96, at 365.

99. 29 F. Cas. 1120, 1121 (C.C.D. Mass 1813) (No. 17,600).

section 898 of the treatise with the phrase that "no act [is] an infringement unless it affects the pecuniary interests of the owner of the patented invention."[100] In Robinson's view, these interests, or "emoluments," are not affected when the accused infringer's use of the patented invention "produce[s] no pecuniary result."[101] Robinson would have exempted an invention "made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement."[102] In these cases, Robinson contended, "the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promotion of the employer's knowledge or the relaxation afforded to his mind."[103]

In the years following Justice Story's decision in *Whittemore*, a number of federal trial and appellate courts recognized the existence of an experimental use exemption from infringement liability, but following the Story-Robinson rule generally refused to apply the exemption because the cases involved commercial activity or some degree of profit motive.[104] The defense of experimental use was limited to those rare instances where the accused infringer's use of a patented invention was for "the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement."[105]

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100. 3 W. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 898 (1890).

101. *Id.*

102. *Id.*

103. *Id.*

104. CHISUM, *supra* note 82, § 16.03[1]. Although the opinion in *Deuterium Corp. v. United States*, 19 Cl. Ct. 624 (1990) (Rader, J.), seemed to recognize the reality of profit motive when it described the experimental use exemption as "protect[ing] an individual making unauthorized use of a patent (a potential infringer) during tests seeking advancement *or commercialization* of the patented teaching," *id.* at 632 (emphasis added), the court declined to apply the exemption in that case because the accused steam cleaning, pilot plant-scale demonstration project represented "not strictly intellectual experimentation, but development of technology and processes for commercial applications," *id.* at 633.

105. Poppenhusen v. Falke, 19 F. Cas. 1048, 1049 (C.C.N.Y. 1861) (No. 11,279). One of the few cases in which the experimental use doctrine was applied in favor of an accused infringer is *Ruth v. Stearns-Roger Manufacturing. Co.*, 13 F. Supp. 697, 703, 713 (D. Colo. 1935) (exempting from infringement flotation machines and their parts used by Colorado School of Mines, which were "all used in the laboratory and . . . cut up and changed from day to day"), *rev'd on other grounds*, 87 F.2d 35 (10th Cir. 1936). *See also* Chesterfield v. United States, 159 F. Supp. 371, 375–76 (Ct. Cl. 1958) (stating in dicta that if patent in suit was not invalid, then defendant's use of patented metallic alloy was for testing and experimentation and thus not infringing).

2. *Federal Circuit Development: Toward a Restrictive Application of Experimental Use Exemption*

The key case addressing the experimental use exemption in the modern era is *Roche Products v. Bolar Pharmaceutical Company*,[106] which has attracted significant scholarly commentary.[107] The *Roche* decision led Congress to enact 35 U.S.C. § 271(e), which legislatively overruled part, but not all, of *Roche* by creating a safe harbor for using patented inventions for regulatory data gathering.[108] The "residue" of *Roche*, in terms of what remains of the common law exemption from patent infringement for experimental uses, is a focal point of this Article.

Roche sued Bolar for infringing Roche's U.S. patents on the active ingredients of Dalmane, Roche's commercially successful prescription sleeping aid.[109] Roche's patent was due to expire in early 1984.[110] Bolar, planning to market a generic version of Dalmane as soon as the drug went off-patent, chose to begin testing and gathering the data that would be required for submission of a generic equivalent drug application to the FDA before Roche's patent expired.[111] Bolar obtained the drug from foreign sources and began using it in tests in 1983.[112] The New York federal district court held that Bolar's use of the patented compound for federally mandated testing was experimental and de minimis and thus not infringement.[113]

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106. 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

107. *See, e.g.*, Eisenberg, *supra* note 37; Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987); Steven J. Grossman, *Experimental Use or Fair Use as a Defense to Patent Infringement*, 30 IDEA 243 (1990); Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. OFF. SOC'Y 617 (1985); Ned A. Israelsen, *Making, Using, and Selling Without Infringing: An Examination of 35 U.S.C. Section 271(e) and the Experimental Use Exception to Patent Infringement*, 16 AIPLA Q.J. 457 (1989); Jordan P. Karp, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169 (1991); Suzanne T. Michel, *The Experimental Use Exception to Infringement Applied to Federally Funded Inventions*, 7 HIGH TECH. L.J. 369 (1992).

108. *See infra* Part IV.B.

109. *Roche*, 733 F.2d at 860. Roche was assignee of U.S. Patent No. 3,299,053. One of the chemical compounds claimed in the '053 patent is flurazepam hydrochloride, the active ingredient in Roche's "Dalmane" brand sleeping pill. *Id.*

110. *Id.*

111. *Id.*

112. *Id.* Specifically, Bolar formed the drug into "dosage form capsules" with which it commenced testing to obtain stability data, dissolution rates, bioequivalency studies, and blood serum studies needed for an FDA New Drug Application. *See id.*

113. *Id.* at 860–61; Roche Prods., Inc. v. Bolar Pharm. Co., 572 F. Supp. 255, 258 (E.D.N.Y. 1983).

The Federal Circuit reversed, holding that Bolar was liable for infringement.[114] The Federal Circuit explained that on its face, § 271(a) of the Patent Act prohibits any "making, using *or* selling."[115] A mere "use" that does not result in a sale is still actionable.[116] Thus, "the patentee does not need to have *any* evidence of damage or lost sales to bring an infringement action."[117]

Although the Federal Circuit held Bolar's use to be infringing, it stopped short of adopting a definition of § 271(a) "use" in its "utmost possible

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114. *Roche*, 733 F.2d at 867.

115. *Id.* at 861 (emphasis added).

116. *Id.*

117. *Id.* The *Roche* court's stance would thus seem to have evolved away from the Story-Robinson view that actionable harm to the patentee's pocketbook is required for patent infringement.

The historical origin of the inclusion of "use" of a patented invention as one of the U.S. patent owner's exclusionary rights is uncertain. In post-Elizabethan England, patents were recognized as an explicit exception to the general rule against monopolies, but the right granted by the Crown was positively defined as the patent owner's affirmative right to "work" or "make" the invention:

> Provided also and be it declared and enacted, that any declaration [against monopolies] before mentioned shall not extend to any letters patent and grants of privilege for the term of fourteen years or under, hereafter to be made *of the sole working or making of any manner of new manufactures within this Realm*, to the true and first inventor and inventors of such manufactures, which others at the time of making such letters patent and grants shall not use, so as also they be not contrary to the law or mischievous to the State, by raising prices of commodities at home, or hurt of trade, or generally inconvenient . . . .

English Statute of Monopolies, 1623, § 6 (emphasis added), *reprinted in* EDITH TILTON PENROSE, THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM 7 (1951). "Use" is of course an explicit part of the qualification that the patented invention be one "which others at the time of making such letters patents and grants shall not *use*," *see id.* (emphasis added), but "use" in this manner merely denoted a novelty requirement and did not form part of the exclusive right granted by the patent. The recited exclusive right to "work" the patented invention may have been intended as synonymous with an exclusive right to "use," but that interpretation is inconsistent with the separate presence of the terms "work" and "use" in the same statutory provision.

The early U.S. patent system was strongly influenced by that of England. *In re* Bergy, 596 F.2d 952, 958 n.2 (C.C.P.A. 1979) (Rich, J.). But in contrast with Section 6 of the Statute of Monopolies, the first federal patent statute in the United States explicitly included "use" within the definition of infringement. Act of 1790, § 1 (defining patent grant as "sole and exclusive right and liberty of making, constructing, *using* and vending to others to be used" the patented invention) (emphasis added), *reprinted in* 9 LIPSCOMB'S WALKER ON PATENTS app. 2, at 9 (3d ed. 1990). The broader definition of the patent right through the addition of a "use" right may represent the first foreshadowing of the broader treatment of patents generally in the United States, as compared to foreign systems.

Alternatively, the presence of "use" in the list of a patentee's exclusive rights may have been intended to specifically refer to patents on processes or methods (then termed "arts"), which are used rather than made or sold. If this assumption is correct, it does not explain the extension of the "use" right to the other statutory categories of patentable subject matter, such as machines, manufactures, and compositions of matter.

scope."[118] The court cited Justice Story's opinion in *Whittemore* as the origin of the common law experimental use doctrine[119] and recognized that one of the Federal Circuit's predecessor courts, the Court of Claims, had considered the doctrine in several decisions.[120]

The Federal Circuit in *Roche* ultimately interpreted this earlier authority as having established a very restricted experimental use defense, but refused to apply the defense to Bolar's clearly commercial activity:

> [W]e hold the experimental use exception to be truly narrow, and we will not expand it under the present circumstances. Bolar's argument that the experimental use rule deserves a broad construction is not justified. . . . Bolar's intended "experimental" use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. . . .
>
> [Bolar's] unlicensed experiments conducted with a view to the adaptation of the patented invention to the experimentor's business is a violation of the rights of the patentee to exclude others from using his patented invention. It is obvious here that it is a misnomer to call the intended use de minimis. It is no trifle in its economic effect on the parties even if the quantity used is small. It 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 that inquiry has definite, cognizable, and not insubstantial commercial purposes.[121]

Thus, after *Roche*, scientists engaged in research and development having more than negligible commercial purpose could no longer rely on the experimental use doctrine to exempt their experiments from patent infringement liability.

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118. *Roche*, 733 F.2d at 861.

119. *Id.* at 862.

120. The Federal Circuit in *Roche* characterized *Pitcairn v. United States*, 547 F.2d 1106 (Ct. Cl. 1976) as "the most persuasive" of the Court of Claims cases concerning the experimental use defense. *Roche*, 733 F.2d at 863; *see also Pitcairn*, 547 F.2d at 1124–26 (recognizing that experimental use may be defense to infringement and that government's "tests, demonstrations, and experiments" were not eligible for defense because they were "in keeping with the legitimate business of the using agency").

121. *Roche*, 733 F.2d at 863.

B. *The Hatch-Waxman Act: A Limited Exemption for Regulatory Data Gathering*

The generic-drug industry quickly and successfully moved to devise an escape route from *Roche*.[122] The industry argued to Congress that if a generic-drug manufacturer had to wait to begin testing of an equivalent drug until after the relevant patent had expired, the patentee of the branded drug would receive a de facto extension of the patent term.[123] Such an extension was contrary to the public's interest in obtaining lower-cost drugs as soon as possible and, of course, contrary to the profit-maximizing goals of the generics.[124]

The generic-drug companies' lobbying efforts succeeded. Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984,[125] popularly known as the "Hatch-Waxman Act." The legislation added, inter alia, § 271(e) to the Patent Act, which provides in pertinent part that the use of a patented invention solely for purposes reasonably related to gathering data to support an FDA application for generic versions of previously approved drugs (i.e., an Abbreviated New Drug Application)[126] is not patent infringement.[127]

The U.S. Supreme Court subsequently interpreted § 271(e) as broad enough to encompass not only regulatory data gathering on pharmaceuticals, but also the comparable testing of medical devices.[128] The Court in *Eli Lilly & Co. v. Medtronic, Inc.* limited its review of the Federal Circuit's decision in *Roche* to the Circuit's refusal to exempt Bolar's particular testing for generic-drug equivalency, however.[129] The Federal Circuit's recognition in *Roche* of the less-specific common law exemption for experimental uses of patented inventions was not addressed in *Eli Lilly*, nor any subsequent U.S. Supreme Court decision.

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122. *See* Eli Lilly & Co. v. Medtronic, Inc., 872 F.2d 402, 404 (Fed. Cir. 1989).

123. *Id.* at 405.

124. *Id.* at 404–05.

125. Pub. L. No. 98-417, 98 Stat. 1585 (1984).

126. A generic-drug manufacturer submits an Abbreviated New Drug Application to the FDA in order to seek expedited approval of the generic version of a "listed drug" (one previously approved by the FDA). Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1244 (Fed. Cir. 2000). The generic drug must be the bioequivalent of the listed drug if an Abbreviated New Drug Application is used. *Id.*

127. 35 U.S.C. § 271(e)(1) (1994).

128. Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 679 (1990) (affirming Federal Circuit's interpretation).

129. *Id.* at 665.

There are valid reasons to conclude that the common law exemption for experimental use survived Congress's enactment of 35 U.S.C. § 271(e)'s safe harbor, albeit in narrow form. In responding to the generic manufacturers' concerns, it is reasonable to believe that Congress intended to overrule the *Roche* holding only insofar as it impacted the generic manufacturers—limited to unlicensed use of an invention for purposes of gathering data for the FDA—but not to wipe away *Roche*'s broader recognition of the common law experimental use exemption. The legislative history of the Hatch-Waxman Act makes no mention of the common law doctrine discussed in *Roche*.[130] It addresses no "use" of patented inventions other than for the purpose of regulatory data gathering. Nor does the legislative history indicate that by enacting § 271(e), Congress intended to fill the field on this issue and preempt any and all common law doctrines related to experimental use.[131]

Enactment of the Hatch-Waxman Act supports, rather than detracts from, a broadened interpretation of the common law experimental use exemption that does not turn solely on the commerciality of the accused infringer's use. Bolar's testing for purposes of gathering data needed to expedite the FDA approval of its generic equivalent of Dalmane was clearly profit-driven activity. Congress's exemption from liability of this particular form of non-consensual, commercial use of a patented invention should be viewed as supportive of, rather than in opposition to, the broader proposition that certain unlicensed uses of patented inventions should be exempted from liability. The legislative history does not indicate that by enacting § 271(e) Congress meant to exempt one particular variety of research use from infringement liability while forever excluding all others. That Congress's intent was not so limited is also evidenced by subsequent

130. The legislative history notes only that "the net effect of the legislation is to reverse the holding of the Federal Circuit in *Roche*." H.R. REP. NO. 98-857, pt. 2, at 27 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2711 ("The provisions of § 202 of the bill [amending 35 U.S.C. § 271 to add new subsection (e)] have the net effect of reversing the holding of the court in *Roche Prod., Inc. v. Bolar Pharms. Co.*").

The legislation was narrowly tailored to uses of patented products that are necessary for data-gathering for regulatory approval. H.R. REP. NO. 98-857, pt. 1, at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48 (stating that purposes of this legislation are "to make available more low cost generic drugs and to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket approval").

131. *But see id.* at 30, *reprinted in* 1984 U.S.C.C.A.N. at 2714 (quoting legislative-history conclusion that "[j]ust as we have recognized the doctrine of fair use in copyright, it is appropriate to create a similar mechanism in the patent law. That is all this bill does."). While a positive justification for passage of the legislation, this statement does not purport to define or broaden its scope beyond the particular context of the exemption for regulatory data gathering purposes.

legislative proposals to statutorily implement a second type of experimental use provision in the Patent Act.[132] Section 271(e)'s narrow purview merely reflects the successful lobbying of one particular industry: the generic-drug manufacturers. Absent lobbying pressure from other sectors of the patenting community, Congress would have had no reason or motivation to enact a broader safe harbor at the time of passage of the Hatch-Waxman Act. The fact that § 271(e) is limited to unlicensed use of patented inventions for purposes of gathering FDA data does not refute a broadened interpretation of the common law experimental use doctrine.

C. *Whither the Residue of* Roche?

Following its 1984 decision in *Roche*, the Federal Circuit did not revisit the common law experimental use doctrine for more than fifteen years.[133] In *Embrex, Inc. v. Service Engineering Corp.*,[134] decided in June 2000, the Federal Circuit re-confirmed the existence of the common law doctrine, but refused to apply it to the accused infringer's "commercial" activity. Embrex's patent in suit was directed to a method of inoculating chicks against diseases while still *in ovo*, i.e., before hatching.[135] The claimed

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132. Four years after the enactment of the Hatch-Waxman Act, Representative Kastenmeier introduced a bill titled "Transgenic Animal Patent Reform Act." H.R. 4970, 100th Cong. (1988). In the form in which the measure passed the House on September 13, 1988, the bill would have amended Title 35 of the U.S. Code to declare that "[i]t shall not be an act of infringement for a person whose occupation is farming to: reproduce a patented transgenic farm animal through breeding; use it in the farming operation; or sell it or its offspring." *See* 134 CONG. REC. 23,564 (1988) After passage in the House, the measure was referred to a Senate committee and no further action was taken. *Id.*

133. Although several intervening decisions cited *Roche* in determining whether the regulatory data-gathering safe harbor of 35 U.S.C. § 271(e) should apply, the accused infringers in those cases did not rely on the common law experimental use doctrine. *E.g.*, Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1568 (Fed. Cir. 1997); Telectronics Pacing Sys., Inc. v. Ventritex, Inc., 982 F.2d 1520, 1524–25 (Fed. Cir. 1992); Eli Lilly & Co. v. Medtronic, Inc., 872 F.2d 402, 404–06 (Fed. Cir. 1989), *aff'd*, 496 U.S. 661 (1990).

Two recent Federal Circuit decisions in the Glaxo "Zantac" litigation have recognized, almost in passing, the possibility of a related "de minimus" exception to infringement, but both times the court has refrained from deciding the issue. *See* Glaxo, Inc. v. TorPharm, Inc., 153 F.3d 1366, 1374 n.3 (Fed. Cir. 1998) (citing Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1566 n.1 (Fed. Cir. 1997)). The Glaxo patents were directed to ranitidine hydrochloride, which can occur in at least two crystalline forms. *Glaxo*, 153 F.3d at 1368. The issue raised, but not decided, was whether Glaxo's Patent No. 4,521,431, which was limited to Form 2, was infringed by the accused infringer's making of the Form 1 compound that was 99.5% pure, but included 0.5% Form 2. *Id.* at 1374 n.3. The Federal Circuit recognized earlier case law that speaks of a de minimus exception, but chose not to reach the issue because other issues in the case were dispositive. *Id.*

134. 216 F.3d 1343 (Fed. Cir. 2000).

135. *Id.* at 1346.

method required administration of a vaccine within the "region defined by either the amnion or the yolk sac."[136] Accused infringer Service Engineering retained scientific consultants to help it design around the Embrex patents, but was unsuccessful in avoiding infringement; Service Engineering's scientists were unable to prevent injection into the claimed amnion or yolk region.[137] A jury found that Service Engineering had willfully infringed, and the district court denied Service Engineering's motion for judgment as a matter of law.[138]

On appeal, the Federal Circuit rejected Service Engineering's argument that the accused tests were merely experimental and thus exempt from infringement liability under the common law experimental use doctrine.[139] Citing *Roche*, the Federal Circuit reiterated that it construes the experimental use exception "very narrowly."[140] The court also acknowledged that "[b]inding precedent" recognizes a "narrow defense to infringement performed 'for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.'"[141] Service Engineering's tests did not qualify for the defense, the Federal Circuit concluded, in view of the district court's findings that the tests were performed "expressly for commercial purposes,"[142] and were chiefly conducted by Service Engineering in order to sell its own *in ovo* injection machines to potential customers.[143]

The Federal Circuit's recognition of the common law experimental use doctrine in *Embrex* clarifies that Congress did not overrule that portion of *Roche* in which the Federal Circuit first recognized the common law doctrine.[144] Even for unlicensed uses of patented inventions that do not fall

136. *Id.*

137. *Id.* at 1346–47.

138. *Id.* at 1347.

139. *Id.* at 1349.

140. *Id.* (citing Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984)).

141. *Id.* at 1349 (citing Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984); Pitcairn v. United States, 547 F.2d 1106 (Ct. Cl. 1978)).

142. *Id.*

143. *Id.*

144. Notably, the *Embrex* court cites *Roche* as having been "superseded *on other grounds* by 35 U.S.C. § 271(e) (1994)." *Embrex*, 216 F.3d at 1349 (emphasis added). This characterization of *Roche* indicates that the Federal Circuit does not view Congress's 1984 enactment of 35 U.S.C. § 271(e)'s safe harbor for regulatory data gathering use as having overruled *Roche* in its entirety; i.e., as having overruled those statements in *Roche* respecting the common law experimental use doctrine. In other words, *Embrex* establishes that the post-*Roche* 1984 passage of the Hatch-Waxman Act did not repeal sub silentio the common law experimental use doctrine.

within § 271(e)'s safe harbor for regulatory data-gathering, the common law experimental use defense remains available, at least theoretically. As illustrated by Service Engineering's failure to prevail under the experimental use defense in *Embrex*, however, the Federal Circuit's extremely narrow interpretation of the doctrine virtually precludes successful reliance by any commercial enterprise. Few users of patented methodologies will be able to mount a more compelling case for exemption from infringement liability than Service Engineering did; rather than proceeding to use Embrex's patented method without permission, Service Engineering retained outside scientists for the commendable purpose of attempting to design around Embrex's patent by developing an alternative method sufficiently different to avoid Embrex's claims. This kind of activity should be facilitated, rather than penalized, by patent law.[145]

Federal Circuit Judge Rader concurred in *Embrex*, but wrote a separate opinion contending that the experimental use defense is no longer viable following the U.S. Supreme Court's 1997 statement in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*[146] that "'[a]pplication of the doctrine of equivalents . . . is akin to determining literal infringement, and neither requires proof of intent.'"[147] In Judge Rader's view, "[t]he Supreme Court's recent reiteration that infringement does not depend on the intent underlying the allegedly infringing conduct . . . precludes any further experimental use defense, even in the extraordinarily narrow form recognized in *Roche*."[148] According to Judge Rader, when "wholly non-commercial" infringement is proven, "the damage computation process provides full flexibility for courts to preclude large (or perhaps any) awards for minimal infringement."[149]

Contrary to Judge Rader's concurrence, the U.S. Supreme Court in *Warner-Jenkinson* did not create new law nor change the law with respect to the common law experimental use doctrine. The accused infringer in *Warner-Jenkinson* did not rely on the experimental use doctrine, nor did the case involve the use of research tools; both parties were commercial

145. Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1078 (1989) (contending that patent holder should not be able to enjoin researcher who uses patented invention in course of attempting to develop alternative means of achieving same purpose).

146. 520 U.S. 17 (1997).

147. Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1353 (Fed. Cir. 2000) (Rader, J., concurring) (quoting *Warner-Jenkinson*, 520 U.S. at 34).

148. *Id.* (Rader, J., concurring).

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

manufacturers of purified dyes.[150] Rather, liability turned on whether the accused infringer's dye purification method, operating at a pH of 5, infringed the patent owner's claimed method for purifying dyes at a pH "from approximately 6.0 to 9.0."[151] The accused infringer asserted that it independently developed its own process with no knowledge of the plaintiff's patent.[152] On this basis, the accused infringer contended that the patent owner should be required to establish, as an equitable threshold factor, an "intent to copy" on the part of the accused infringer, before the patent owner could assert infringement under a doctrine of equivalents theory.[153] The U.S. Supreme Court rejected this argument, explaining that because the "essential predicate" of the doctrine of equivalents is the identity between the claimed invention and its equivalent, there is no basis for treating an infringing equivalent any differently from a device that literally infringes.[154] The Court concluded that "intent plays no role in the application of the doctrine of equivalents."[155] Thus, *Warner-Jenkinson* merely establishes that an accused infringer need not be aware of the plaintiff's patent in order to be liable for infringing it. In no way does *Warner-Jenkinson* hold or suggest that an accused infringer's experimental or research purpose is irrelevant to the question of infringement liability or remedy. Moreover, an accused infringer's purpose or intent *has* been held relevant in other aspects of the infringement determination.[156]

Judge Rader's suggestion that accused infringers who assert the experimental use defense are adequately protected by the courts' flexibility in adjusting the damages award for "minimal or non-commercial

150. Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997).

151. *Id.* at 22–23.

152. *Id.* at 23 (noting that Warner-Jenkinson did not learn of Hilton Davis's patent until "after [Warner-Jenkinson] had begun commercial use of its ultrafiltration process").

153. *Id.* at 34–36.

154. *Id.* at 35.

155. *Id.* at 36.

156. For example, in determining whether an infringement was willful, which may lead to an award of enhanced damages under 35 U.S.C. § 284 (1994), the Federal Circuit looks to whether the accused infringer was aware of the plaintiff's patent, and once aware, whether the accused infringer proceeded to act with due care and in good faith (e.g., obtained a competent non-infringement or invalidity opinion of counsel before proceeding with manufacture). *E.g.*, Read Corp. v. Portec, Inc., 970 F.2d 816, 826–31 (Fed. Cir. 1992). More recently, the U.S. Supreme Court suggested that the nature and purpose of a state government's patent infringement (i.e., whether it was merely "negligent" rather than "intentional or reckless") governs whether the state's infringement violated the Due Process Clause of the Fourteenth Amendment. Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 645 (1999).

infringement"[157] is also problematic. Although compensatory damages might be reduced to a nominal level under Judge Rader's proposed framework, a research tool user would nevertheless remain subject to an injunction against any further use of the patented tool. Moreover, compelling the research tool user to litigate the question of liability and damages in the hopes that damages might be reduced to a nominal level ignores the tremendous costs of patent litigation.[158]

D. District Court Decisions: Continued Vitality of the Common Law Exemption

Several lower courts have had occasion to address the exemption following *Roche*. The emergent consensus is that *Roche*'s recognition of a general common law exemption continues to have vitality after the enactment of the Hatch-Waxman Act.

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157. Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1352 (Fed. Cir. 2000).

158. The different judicial viewpoints expressed in *Embrex* with respect to the viability of the common law experimental use doctrine will likely be fleshed out in future Federal Circuit decisions as pending litigation over unlicensed use of research tools wends its way toward appeal. *E.g.*, Cohen, *supra* note 37, at 28 (describing lawsuit filed in July 1998 by Chiron Corporation, owner of patents directed to hepatitis C viral protease enzyme, against Vertex, corporation involved in research and development efforts to find drugs that block enzyme, in which Vertex has invoked experimental use exemption as defense).

The experimental use defense is also at issue in *Integra v. Merck*, a patent infringement lawsuit currently pending in the Southern District of California. *See* Integra LifeSciences I Ltd. v. Merck KgaA, 50 U.S.P.Q.2d 1846 (S.D. Cal. 1999) (granting summary judgment on single claim of one of five patents in suit). Merck, a German corporation, is a co-defendant in the action with the Scripps Research Institute, a nonprofit, public benefit corporation, and Dr. David A. Cheresh, a tenured professor in Scipps's Immunology Department. *Id.* at 1847. Scripps and Merck entered into a research support agreement in 1988 to fund Dr. Cheresh's study of "integrins," proteins that serve as receptors on the surface of certain living cells. *Id.* As part of the agreement, Scripps granted Merck an option to license any inventions arising from Dr. Cheresh's work. *Id.* When Dr. Cheresh reported his findings that the growth of new blood vessels can be inhibited by binding various molecules to receptors on the surface of certain cells, Integra sued Cheresh, Scripps, and Merck in order to enjoin Cheresh's further work on his discovery and to "collect damages for the underlying research." *Id.* The defendants asserted that the experimental use doctrine shields them from infringement liability, but Integra contended that the defense was unavailable to them because Merck is a for-profit entity. E-mail Interview with William C. Rooklidge, counsel for defendants (May 25, 2000). The trial court granted judgement as a matter of law that the defendant's pre-1995 activities were exempt under the experimental use doctrine. *Id.* The trial court refused to instruct the jury on the experimental use defense with respect to the defendants' post-1994 activities; however, a jury found that those activities infringed Integra's patents. *Id.* As of January 2001, the case was still pending before the trial court on post-trial motions. *Id.*

The clearest judicial support for a viable exemption is the Claims Court decision in *Deuterium Corp. v. United States.*[159] Then-Claims Court Judge Rader, now a member of the Federal Circuit, cited the Robinson treatise as support for the doctrine and explained that "[a]lthough [the Hatch-Waxman Act] changed that narrow application of the doctrine affecting reporting requirements for federal drug laws, Congress did not disturb the Federal Circuit's enunciation [in *Roche*] of the parameters of the experimental use exception."[160]

The view that the experimental use exemption remains valid was seconded by the federal district court in *Giese v. Pierce Chemical, Co.*[161] The end users of Giese's patented methods of detecting cancer cells were largely academic researchers.[162] Giese sued two chemical companies as contributory and inducing infringers based on their acts of supplying the academic research institutions with kits of chemical reagents for use in Giese's patented method.[163] Although the trial court denied the defendant chemical companies' motion for summary judgment of non-infringement because of unresolved factual disputes,[164] it gave strong support to the notion that the experimental use doctrine survives. The *Roche* decision "establish[es] a restrictive definition of the traditional common law doctrine, but in no way eliminat[es] it in those cases which involve experimentation for 'idle curiosity or for strictly philosophical inquiry.'"[165]

159. 19 Cl. Ct. 624 (1990).

160. *Id.* at 632 n.14.

161. 29 F. Supp. 2d 33 (D. Mass. 1998) (Young, J.).

162. *Id.* at 35.

163. *Id.* at 34–35.

164. *Id.* at 37.

165. *Id.* at 36 (quoting Roche Prods., Inc. v. Bolar Pharm. Co., Inc. 733 F.2d 858, 863 (Fed. Cir. 1984)). The court in *Giese* further suggested, albeit in dicta, that if end users of a patented method are exempt from infringement liability because they are beneficiaries of the experimental use exemption, then their suppliers by definition cannot be liable as contributory infringers. *Id.* at 36. Non-liability would hold even where the suppliers, as in *Giese*, were decidedly for-profit enterprises. *Id.* This result certainly follows from application of the black-letter patent rule that there can be no contributory infringement without direct infringement. *See* Aro Mfg. Co. v. Convertible Top Replacement Co., 377 U.S. 476, 483 (1964); *see also* Ruth v. Stearns-Roger Mfg. Co., 13 F. Supp. 697, 703 (D. Colo. 1935) (holding that sale of parts for use in accused flotation machine did not constitute contributory infringement where machine was used in laboratory of Colorado School of Mines for experimental purposes), *rev'd on other grounds*, 87 F.2d 35 (10th Cir. 1936). Moreover, the pro-innovation policies underlying the recognition of a viable research use exemption would be stymied if the research user could not obtain necessary supplies from for-profit sources for fear that these sources would be subject to indirect liability under § 271(b) or (c) or both of the Patent Act.

The *Giese* court's decision allowing suppliers of the direct infringer to share in the benefits of the experimental use exemption, a judge-made doctrine of equitable roots, thus seems to assume without

IV. IMPLICATIONS FOR ACADEMIC-INDUSTRIAL COLLABORATIVE RESEARCH AND DEVELOPMENT

Much of the burgeoning biotechnology research and development activity in the U.S. involves public-private partnerships, collaborations, joint ventures, sponsored research, and the like between nonprofit universities or research institutions and for-profit corporations.[166] Many

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deciding that the experimental use exemption is not a personal defense, limited to the individuals actually conducting the experimentation. This treatment contrasts the newly enacted "prior inventor defense," which is personal to the defendant prior user and can only be licensed or transferred as part of a good faith transfer of the prior user's entire line of business. *See* American Inventors Protection Act of 1999, Pub. L. No. 106-113, 113 Stat. 1536 (amending Title 35, U.S.C., by adding new § 273 titled "Defense to Infringement Based on Earlier Inventor"). The potential for exploiting the exemption, thus interpreted, to absolve large commercial, profit-making suppliers of liability, whenever their customers are deemed to be conducting research or experimentation, looms large.

The contributory liability of a research-tool supplier is also at issue in the long-running patent litigation battle between Hoffman-La Roche, the Swiss corporate holder of patents on polymerase chain reaction (PCR) and Taq polymerase, the key reagent used in PCR, and Promega Corporation, a Wisconsin supplier of Taq to researchers across the United States. *See supra* notes 1–11 and accompanying text. Roche sued Promega in October 1992 for selling Taq in violation of the terms of Promega's license granted by the now-defunct Cetus Corporation, the original owner of the patents. *See* Barinaga, *supra* note 7, at 1273. Roche reads that license as limiting Promega to sales of Taq for non-PCR purposes; Promega disputes this interpretation. Abate, *supra* note 3, at B1; Barinaga, *supra* note 7, at 1273; Rubenstein, *supra* note 2, at 28. Among other contentions, Hoffman-La Roche asserts that Promega is liable for contributory or inducing infringement of the PCR method patent based on Promega's sales of Taq to more than 200 researchers whom Roche identified as direct infringers (though not named as parties to the lawsuit). *See* Rubenstein, *supra* note 2, at 28. One of the several patents involved in the dispute was held unenforceable in December 1999 for inequitable conduct. Hoffman-La Roche, Inc. v. Promega Corp., No. C-93-1748 VRW, 1999 WL 1797330 (N.D. Cal. Dec. 7, 1999) (holding all claims of U.S. Patent No. 4,889,818 unenforceable).

166. NIH Research Tools Report, *supra* note 24 (explaining that since mid-1970s "[b]iomedical researchers increasingly chose to collaborate with entrepreneurial companies that understood and valued basic science, or to leave academia and join these firms as founders or employees. Many biotechnology companies emerged with strong ties to the academic world."); *see also* Florida, *supra* note 33, at 69 (reporting dramatic growth of joint university-industry research centers as evidenced by 1990 Carnegie Mellon University study of 1,056 such U.S. centers that received total funding of more than $4.12 billion); David E. Korn, *Patent and Trade Secret Protection in University-Industry Research Relationships in Biotechnology*, 24 HARV. J. LEGIS. 191, 191 (1987) (noting "rapid and substantial growth in biotechnology research conducted jointly by industry and academia" in recent years); *id.* at 222 (characterizing industry-sponsored research as "big business" for many U.S. research universities); Rai, *supra* note 37, at 110 (contending that legal developments in 1980s and 1990s, including passage of Bayh-Dole Act and pro-patent decisions by the Federal Circuit, have generated "large variety of academic-industrial relationships," some of which resemble commercial joint ventures, and citing examples); Jeff Gerth & Sheryl Gay Stolberg, *Drug Makers Reap Profits on Tax-Backed Research*, N.Y. TIMES, Apr. 23, 2000, at 20 (reporting that since enactment of Bayh-Dole Act, universities and their scientists have become "more commercially oriented; many are spinning off their own biotech companies to develop their ideas.").

A widely publicized biotechnology nonprofit and industry collaboration was formed in May 1998 when The Institute for Genomic Research (TIGR), a private, nonprofit research enterprise headed by

private corporations are shifting their research and development resources toward "external innovation,"[167] building on the results of research conducted in universities rather than by their own in-house research staff.[168] Private industry is estimated to have funded approximately twelve percent of university research and development activity in the life sciences in 1994,[169] and that percentage has likely increased in subsequent years.[170] Seventy percent of the funding for clinical trials of new drugs comes from private industry rather than the federal government.[171]

The 1980 enactment of the Bayh-Dole Act[172] fundamentally enhanced the incentives for such collaborations; an explicit objective of the Act was

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Doctor J. Craig Venter, joined forces with the Perkin-Elmer Corporation, a leading manufacturer of DNA sequencing devices. The collaboration announced plans to compete against the federal government's Human Genome Project in attempting to sequence the entire human genome. *Genetic Warfare*, ECONOMIST, May 16, 1998, at 87.

167. Gerth & Stolberg, *supra* note 166, at 1, 20 (describing Bayh-Dole Act as having allowed private corporations engaged in drug development to "shift resources away from in-house research and development and towards outside collaborations, a strategy known as 'external innovation'").

168. Korn, *supra* note 166, at 196 (contending that firms in biotechnology industry are much more dependent on university research than are firms in other technologies); Philip H. Abelson, *Editorial: Global Technology Competition*, 277 SCIENCE 1587 (1997) (stating that only about six percent of U.S. industry research and development expenditures are "devoted to longer range directed basic research"); Richard C. Atkinson, *Universities: At the Center of U.S. Research*, 276 SCIENCE 1479 (1997) (describing changing pattern of U.S. corporate research and development in last decade, evolving from conduct of "significant basic research" in-house to current model in which corporations "build[] on the results of long-term university research" to solve "specific short-term problems").

169. David Blumenthal et al., *Relationships Between Academic Institutions and Industry in the Life Sciences—An Industry Study*, 334 NEW ENG. J. MED. 368, 369 (1996). More than ninety percent of U.S. firms in the life sciences reported some relationship with academia in 1994; almost sixty percent of such firms supported research conducted by academic institutions. *Id.*

170. *Cf.* Abelson, *supra* note 168, at 1587 (reporting that total corporate support for U.S. research and development has increased by about twenty-seven percent since 1994); Nelsen, *supra* note 26, at 1460–61 (noting that following corporate downsizing of late 1980s and early 1990s, industry has displayed increased interest in establishing research partnerships with universities); Timothy Caulfield, *The Commercialization of Human Genetics: Profits and Problems*, MOLECULAR MED. TODAY, Apr. 1998, at 148 (reporting "substantial growth in the number of academic industry collaborations"); Charles F. Larson, *The Boom in Industry Research*, ISSUES SCI. & TECH., Summer 2000, at 27 (stating that industry support of all university research has grown from $1.45 billion in 1994 to $2.16 billion in 1999).

171. Thomas Bodenheimer, *Health Policy Report: Uneasy Alliance–Clinical Investigators and the Pharmaceutical Industry*, 342 NEW ENG. J. MED. 1539, 1539 (2000). "Clinical" research involves the design, conduct, and interpretation of drug testing on human subjects, and thus represents a later stage of the research process than "basic" research. *See* Marcia Angell, *Is Academic Medicine for Sale?*, 342 NEW ENG. J. MED. 1516, 1517 (2000) (arguing that in clinical research most technology development has already been completed and is simply being tested).

172. Pub. L. No. 96-517, § 6(a), 94 Stat. 3019, 3019–28 (1980) (codified at 35 U.S.C. §§ 200–212 (1994)).

"to promote collaboration between commercial concerns and nonprofit organizations, including universities."[173] As a result of the Bayh-Dole Act, the interest level in university-industry partnerships is significantly greater than before the legislation's enactment.[174] The Bayh-Dole Act encourages universities to patent "subject inventions" made with federal government funds,[175] and contemplates the grant of exclusive licenses under those patents to the universities' private-sector partners.[176] Predictably, university patenting activity[177] and university revenues from patent licensing fees have increased dramatically since the enactment of the Bayh-Dole Act.[178] So too have problems of access to patented research tools.[179]

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173. 35 U.S.C. § 200 (1994) ("Policy and Objective"). The enactment of the Bayh-Dole Act has been viewed as part of a broader push by the Reagan administration in the early 1980s to maintain the United States's stance as an international leader in technological development in the face of increasing imports of high-quality electronic goods from Japan. Gerth & Stolberg, *supra* note 166, at 1, 20.

174. *See* Angell, *supra* note 171, at 1517 (describing Bayh-Dole Act as "frequently invoked to justify the ubiquitous ties between academia and industry"); Nelsen, *supra* note 26, at 1460–61 (describing increasing interest in research partnerships between industry and universities, on the part of both groups, as having developed in parallel with formation of Bayh-Dole Act university licensing framework); *see also* Blumenthal et al., *supra* note 169, at 368 (describing greater acceptance in 1990s among life-sciences academics of relationships with industry than in 1980s).

175. 35 U.S.C. § 202 ("Disposition of Rights").

176. Nelsen, *supra* note 26, at 1460–61 (stating university position that right to grant exclusive licenses is "key aspect" of Bayh-Dole Act because substantial risk taken by licensees to develop "early-stage technologies" justifies exclusivity); Rai, *supra* note 37, at 97 n.113; *Editorial: The Patent Craze and Academia*, 342 LANCET 1435, 1435 (1993) [hereinafter *Editorial*] (characterizing Bayh-Dole Act as having made it easier for universities and nonprofit research institutions to obtain and exclusively license patents); *see also* 35 U.S.C. § 203 (referring to "exclusive licensee" as entity that is subject to march-in rights). The federal government always retains a nonexclusive, paid-up license to practice a subject invention. 35 U.S.C. § 202(c)(4).

177. The number of patents annually assigned to U.S. academic institutions, including colleges, universities, and associations thereof, has increased dramatically from 1984, when 551 utility patents were issued to these institutions, to 1997, when the number of patents issued to U.S. academic institutions had increased to 2436. Technology Assessment and Forecast Report, U.S. Colleges and Universities–Utility Patent Grants 1969–1997 5 (Sept. 1998), *at* http://www.uspto.gov/web/offices/ac/ido/oeip/taf/ univ_97.pdf. Most of this patenting activity was in the life sciences. *See id.* at 6 (listing five biotechnological and chemical patent classes (Classes 800, 435, 530, 536, and 424) in six classes of highest university patenting activity). The 158 universities surveyed by the Association of University Technology Managers (AUTM) reported patent application filings of more than 6000 in the year 1997 alone. *See* Florida, *supra* note 33, at 68.

178. *See* Florida, *supra* note 33, at 68 (describing universities' increasing focus on technology licensing to generate income and reporting that approximately 3000 licenses granted by U.S. universities to industry in 1998 generated approximately $500 million in royalties); *see also* Gerth & Stolberg, *supra* note 166, at 1, 20 (reporting that Bayh-Dole Act represents "a windfall" for universities).

179. *See* Flores, *supra* note 49, at 819 (reporting "[r]ising frustration among scientists about difficulties in accessing critical research tools"); Nelsen, *supra* note 26, at 1460–61 (listing "[r]estricted

Under the traditional "narrow" view of the experimental use exemption in the United States as set forth in *Roche*, this type of collaborative research and development generally does not qualify for exemption. It is difficult to posit a collaboration involving a for-profit firm as having anything other than "definite, cognizable, and not insubstantial commercial purposes."[180] Indeed, the Bayh-Dole Act expressly promotes the commercialization of inventions made by universities.[181]

This Article contends that the *Roche* treatment of "pure" experimentation for "philosophical" purposes versus "commercialization" as two polar extremes is no longer supportable. A better way to view such use is as overlapping regions on a continuum of experimental use. The sharp distinctions drawn by the *Roche* court have blurred dramatically in the last twenty years.[182] The fundamental changes to the U.S. research and technology sector, brought about by the Bayh-Dole Act and other legal, technical and marketplace factors,[183] are breaking down traditional barriers between academic research and for-profit commercialization. Research tools are at the heart of the research and commercialization overlap.[184] The experimental use doctrine requires appropriate flexibility to reflect this changing research and development landscape.

The public policies promoted by choosing to exempt "philosophical" research from liability while denying the benefits of the exemption to innovation having the slightest "commercial" flavor are suspect. Society benefits from new therapeutic and diagnostic products, whether or not they

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availability or delays in exchange of 'research tools' (such as vectors or transgenic mice) in biological research" as unresolved problem facing university technology-transfer management).

180. Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984). This would appear to hold even when industry funds "basic" rather than "applied" research. *Cf.* Eisenberg, *supra* note 37, at 1023 n.26 (contending that "[a]cademic researchers whose work is funded by industry are likely to be motivated by 'philosophical' and 'commercial' interests at the same time").

181. 35 U.S.C. § 200 (1994).

182. Dunn, *supra* note 27, at B3 ("Defining when research becomes commercial is tricky, given that an experiment done in a university lab today may be the founding idea for a biotech company tomorrow.").

183. *See* Nelsen, *supra* note 26, at 1460–61 (describing drive to balance federal budget and decline of communism (resulting in fewer military research expenditures) as two key events leading to reduced federal government funding of research and development, and contending that this reduction in government funding has led U.S. universities to seek increased research and development funding from private industry).

184. *See* McConathy & Weber, *supra* note 40, at 177–78 (describing research tools as existing at overlap "where universities seek patents and royalties, where industry finances and supports academic research, and where collaborations between the two occur").

arose from a profit motive.[185] Arguably, society may benefit *more* when profit motive drives innovation. This is because industry funding of university research tends to focus on short-term projects leading to marketable products rather than longer-term basic research.[186] Thus, the "anti-commercialism" element of the experimental use doctrine as currently interpreted actually works against the prompt introduction of new drugs and therapies into the market place.

Profit motive should no longer be held antithetical to the experimental use doctrine. A re-conceptualization of the experimental use doctrine must consider the commercial realities of the twenty-first century research and development process. The involvement of a for-profit firm in the use of patented research tools to develop new products should not be treated as per se outside the scope of the experimental use doctrine. Foreign patent systems have adopted legal rules that come much closer to reflecting these notions than has the United States, as demonstrated in the next Part.

V. INTERNATIONAL ACCEPTANCE OF AN EXPERIMENTAL USE EXEMPTION

National patent systems other than that of the United States have generally accepted the concept of an exemption from patent infringement for experimental or research use of a patented invention.[187] This acceptance is consistent with the international patent community's greater tolerance of

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185. *See* Barton, *supra* note 15, at 457 ("Under current law the exemption most likely applies only for noncommercial purposes . . . yet, the benefit to society of the follow-on research does not depend on whether the research is done for commercial or noncommercial purposes.") (citation omitted).

186. *Editorial*, *supra* note 176, at 1436 (1993) ("Private industry is unlikely to provide funding for basic research in areas in which societal benefit is not immediately apparent but could ultimately be realized with lengthy and continued nurturing.").

187. For example, French law provides that "[a]cts accomplished for personal or domestic purposes or for the purpose of testing the object of the patented invention shall not be considered as affecting the patentee's rights." French Patent Law Including Modifications of 1978, Art. 29, *reprinted in* 2D JOHN P. SINNOTT ET AL., WORLD PATENT LAW AND PRACTICE (1999), at FRANCE-9. Germany provides that the "effects of the patent shall not extend to . . . acts done for experimental purposes relating to the subject matter of the patented invention." German Patent Act of 16 December 1980, § 11.2, *reprinted in* 2D SINNOTT ET AL., *supra*, at WEST GERMANY-78.22. Great Britain exempts from infringement liability those acts "done privately and for purposes which are not commercial" as well as those acts "done for experimental purposes relating to the subject-matter of the invention." Patent Act 1977, § 60(5), *reprinted in* 2D SINNOTT ET AL., *supra*, at GREAT BRITAIN-269. The Japanese patent laws provide that "[t]he effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research." Japanese Patent Law of 1959, as amended through May 6, 1998, effective June 1, 1998, § 69(1), *reprinted in* 2F SINNOTT ET AL., *supra*, at JAPAN-194.

incursions on patent exclusivity such as working requirements and compulsory licensing.

For example, Germany's patent laws provide that "'[t]he effects of the patent shall not extend to acts performed for experimental purposes relating to the subject-matter of the patented invention.'"[188] The Federal Supreme Court of Germany recently interpreted this provision to absolve from liability certain clinical trials of a patented pharmaceutical, although the trials were conducted for the purpose of finding new applications for the pharmaceutical.[189] The court indicated that the exemption would be available even if the unlicensed use resulted in the accused infringer filing a patent application on the results of its research.[190]

An experimental use exemption is included in the European Commission's proposed Council Regulation on the Community Patent.[191] Article 9 of the proposed regulation excludes from the effects of a Community patent those acts "done privately and for non-commercial purposes,"[192] and those "acts done for experimental purposes relating to the subject-matter of the patented invention."[193] The term "relating to" is not

188. Wolfgang von Meibom & Johann Pitz, *Experimental Use and Compulsory License Under German Patent Law*, PATENT WORLD, June/July 1997, at 27 (quoting Section 11, No. 2 of German Patent Act of 1981).

189. Von Meibom & Pitz, *supra* note 188, at 29 (describing German Supreme Court, GRUR 1996, 109-clinical trials (November 7, 1995)). According to these commentators, application of the exemption from liability does not turn on "whether, over and above the character of pure research, commercial interests are also in the background." *Id.*; *see also* Christian Hertz-Eichenrode, *Germany*, *in* 1 WORLD INTELLECTUAL PROPERTY RIGHTS AND REMEDIES (1999), at GER-14 (characterizing German Supreme Court decisions as giving "wide interpretation" to Germany's experimental use provision, German Patent Act of 16 December 1980, § 11.2).

190. Von Meibom & Pitz, *supra* note 188, at 29.

191. Commission of the European Communities, *Proposal for a Council Regulation on the Community Patent*, 69 (Aug. 1, 2000), *available at* http://europa.eu.int/comm/internal_market/en/intprop/indprop/412en.pdf [hereinafter *Community Patent*]. The proposed regulation provides for the grant of a unitary "Community patent" of equal effect throughout the European Community. *Id.* § 2.4.1, at 9 ("Explanatory Memorandum"). A newly-created, centralized "Community Intellectual Property Court" with Community-wide jurisdiction will determine enforcement and validity questions. *Id.* § 2.4.5.1, at 13. The proposed regulation on the Community Patent is independent from the European Patent Convention (EPC), which was signed in 1973. *Id.* § 1.1, at 4. The EPC provides a single procedure for the examination of patent applications in the European Patent Office. *Id.* Once a European patent has been granted, however, it becomes a national patent in each member country designated by the applicant, and is subject to the patent laws of each such designated country. *Id.* The EPC does not provide any Community-wide enforcement forum; rather, any infringement of a European patent "shall be dealt with by national law." European Patent Convention, Art. 64(3), *available at* http://www.european-patent-office.org/legal/epc/e/ar64.html (last modified Nov. 8, 2000).

192. *Community Patent*, *supra* note 191, at Art. 9(a).

193. *Id.* Art. 9(b).

defined, but suggests a scope broad enough to envision the use of patented research tools. The proposed regulation follows a thirty-year effort to create a unitary Community patent.[194] The European Council has recommended that the Community patent be implemented by the end of 2001.[195]

Japanese patent laws provide that "[t]he effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research."[196] Japan has implemented an experimental use exemption in reverse fashion from the United States; Japan provides a broad exemption for experimental use, but generic-drug manufacturers have had to rely on the judiciary for an interpretation placing them within the exemption. The Supreme Court of Japan recently held that the statutory exemption does apply to the testing of patented drugs for purposes of obtaining the data required for application to manufacture a generic equivalent under Japan's Drugs, Cosmetics and Medical Instruments Act.[197]

The NIH Working Group contends that these foreign patent systems properly distinguish between "experimenting *on* a patented invention—i.e., using a patented invention to study the underlying technology or perhaps to invent around the patent," and "experimenting *with* a patented invention to study something else."[198] The Working Group suggests that treating the former as eligible for the research exemption and the latter as ineligible is a "sensible distinction,"[199] because:

> It is difficult to imagine how a broader research exemption could be formulated without effectively eviscerating the value of patents on research tools. Researchers are ordinary consumers of patented research tools, and if these consumers were exempt from infringement liability, the patent holder would have nowhere else to turn to collect patent royalties. An excessively broad research exemption could eliminate incentives for private firms to develop and

194. *Id.* § 1.1, at 4 ("Explanatory Memorandum").

195. *Id.* § 4, at 69 ("Impact Assessment Form").

196. Japanese Patent Law of 1959, as amended through May 6, 1998, effective June 1, 1998, § 69(1), *reprinted in* 2F SINNOTT ET AL., *supra* note 187, at JAPAN-194.

197. Yusuke Hiraki, *Japan: Patents–Infringement–Experimental Use Exempted for Clinical Trials*, 21 EUROPEAN INTELL. PROP. REV. N-140 (1999) (reporting decision of Japanese Supreme Court in Ono Pharm. Co. Ltd. v. Kyoto Pharm. Ltd., Case 1998 (Ju) No. 153 (Apr. 16, 1999).

198. NIH Research Tools Report, *supra* note 24, at App. D-8.

199. *Id.*

disseminate new research tools, which could on balance do more harm than good to the research enterprise.[200]

The Working Group's position that a broadened experimental use rule should not be available to those "working *with*" a patented invention (e.g., those using the patented invention as a research tool) is reasonable only *if* such workers are truly "ordinary consumers" of the tool. In other words, these research workers can freely acquire the tools they need in the marketplace at reasonable cost via anonymous purchasing without the need for licensing transactions. The growing incidence of high transaction costs associated with accessing multiple patented research tools[201] contravenes the ordinary consumer assumption, however. When research tool transaction costs are severe enough to impede or stop the development of new biomedical products, line-drawing between "experimenting on" and "experimenting with" is no longer justified. In such cases, access to the experimental use doctrine should not turn on the relatively fine distinction between experimenting on or experimenting with the patented invention.[202]

The Working Group's concern that a broadened experimental use doctrine would leave holders of research tool patents uncompensated and without sufficient incentives to develop new research tools is a valid one if all non-consensual tool users were given a complete exemption from liability. A more viable alternative, however, is the adoption of a liability rule under which the patent holder cannot enjoin the researcher's use, but will obtain an ex post royalty based on the marketplace valuation of products developed through use of the tool. The research user's access problem is alleviated because a license need not be negotiated prior to the use and an appropriate level of royalty to the patent holder will ensure that incentives to innovate are not significantly decreased.[203]

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200. *Id.*

201. *See supra* notes 31–36.

202. The general notion of discerning whether a patented invention has been "experimented on" rather than "experimented with" may be an exercise in semantics. Consider, for example, the case of a widget manufacturer who seeks to avoid infringement liability by designing around the widget patent of a competitor. The manufacturer's goal is to develop an acceptable but non-infringing alternative. Has the manufacturer experimented *on* the competitor's widget in designing around it, or experimented *with* it?

203. Part VII *infra* discusses this proposal.

VI. RESPONDING TO TRADITIONAL ARGUMENTS AGAINST A BROADENED EXPERIMENTAL USE DOCTRINE

This Article proposes to broaden the "truly narrow" experimental use defense as it is currently interpreted in the United States. Where transaction costs of accessing patented research tools are severe enough to impede or halt the development of new products important to public health, the non-consensual "development use" of such tools should be permitted without injunction, in exchange for an ex post royalty payment based on the marketplace value of the newly created products.[204] This Part responds to a number of the traditional arguments against expanding the experimental use doctrine and provides additional justifications for re-thinking the doctrine to address the research tools access dilemma.

A. Incentive Function of Exclusivity

The most commonly stated objection to broadening the experimental use doctrine is the possibility that it would significantly reduce the incentives for invention of new research tools.[205] Any reduction in the value of patents as drivers for new innovation might result in either a decreased level of innovation or a shift away from disclosure; i.e., protecting inventions as trade secrets rather than by patenting. If a reduction in innovation were to result from a broadened experimental use doctrine, then modifying the experimental use doctrine merely trades one problem for another.

The extent of any potential reduction in innovation, and the optimal balance between a desired level of innovation in research tools versus innovation in new commercial products developed through the unrestricted use of those tools, are probably impossible to determine.[206] Although an expanded experimental use doctrine might feasibly result in some reduction in the development of new research tools, it is just as likely that lessening the probability of the royalty stacking problem will promote increased development of new products that require the use of multiple tools. The

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204. *Id.*

205. Karp, *supra* note 107, at 2181 (contending that "[a]n expansive experimental use exception, which threatens the patentee's potential for economic returns, would reduce inventive activity, particularly in those industries that rely heavily on patent protection").

206. Eisenberg, *supra* note 37, at 1030–31 (stating that level of reduction in incentives to invent that would result from reducing strength of patents via research exemption is difficult to determine, as is determining whether recognition of research exemption would have different impact from other reductions of patent strength such as reducing patent term). Ultimately the question reduces to an empirical one. *Id.* at 1074.

diminution of incentive occasioned by divesting a patent owner's injunctive remedy may be compensated for by creating the opportunity for a sufficiently generous after-the-fact monetary award. The adoption of a reach-through royalty approach that correlates the level of ex post royalty payments to the tool patent owner with the commercial value of the new products developed by use of the patented tool would work to minimize the disincentive effect.[207]

B. Transformative Versus Commercial Purpose

An expanded experimental use doctrine is in keeping with the need for "safety valves" in all areas of intellectual property law, and especially so in view of the current climate of increasing "propertization" of intellectual property.[208] Existing safety valves that safeguard against intellectual property rights of excessive scope include the reverse doctrine of equivalents in patent law[209]and the fair use doctrines of the copyright[210]and trademark[211] laws.

The policies underlying the fair use doctrine of copyright law can readily support an expanded experimental use doctrine in patent law. Statutorily

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207. The proposed adoption of reach-through royalties as the means for compensating the research tool patentee is detailed *infra* notes 286–305 and accompanying text.

208. Lawrence Lessig, *The Problem With Patents*, INDUS. STANDARD (Apr. 23, 1999), *available at* http://www.thestandard.com/article/display/0,1151,4296,00.html (decrying "feeding frenzy" in intellectual property law and asserting that Clinton administration was "obsessed" with intellectual property rights).

209. The reverse doctrine of equivalents absolves an accused infringer from infringement liability where the accused device, although literally falling within the scope of the asserted patent claim, is so far changed in function, way, or result that a finding of liability cannot be justified as a policy matter. Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608–09 (1950); Westinghouse v. Boyden Power Brake Co., 170 U.S. 537, 568 (1898). Although the topic of favorable academic attention, *see* Merges & Nelson, *supra* note 37, at 862–68 (advocating reverse doctrine of equivalents as mechanism to limit patent scope in face of significant technological improvement by accused infringer), the reverse doctrine of equivalents has rarely been applied by the courts to excuse liability. Lemley, *supra* note 70, at 1011.

210. 17 U.S.C. § 107 (1994) (providing that fair use of copyrighted work is not infringement of copyright). Unlike copyright law, patent law has not contemplated any fair use provision. The traditional, narrow experimental use doctrine of patent law has been characterized as the closest patent doctrine to copyright's fair use. Lemley, *supra* note 70, at 1038 n.236.

211. *See* 15 U.S.C. § 1115(b)(4) (Supp. IV 1998) (codifying "fair use" defense to trademark infringement where defendant uses term "which is descriptive of and used fairly and in good faith only to describe" the defendant's goods or services or their geographic origin); J. THOMAS MCCARTHY, 2 MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 11.17 (4th ed. 1996) (explaining that under trademark fair use doctrine, junior user of descriptive term always remains free to use such term in its "primary, descriptive sense," rather than in its source-indicating sense).

enacted in the 1976 Copyright Act, the fair use doctrine provides that certain socially beneficial uses of copyrighted works, such as for research, criticism, and news reporting, are not copyright infringement.[212] Recognition of the copyright fair use doctrine has been seen as necessary to fully promote the constitutional goal of stimulating the production of new copyrightable works.[213] As a means of lessening or alleviating the restrictions on research and development that have been occasioned by the patenting of research tools, an expanded experimental use doctrine would likewise promote the constitutional goal of progress in the useful (technological) arts.

The commercial nature or profit motive of the accused infringer's use is not fatal to enjoyment of the fair use defense in copyright law. In contrast with the traditional narrow understanding of patent law's experimental use doctrine, recent judicial interpretations have expanded the copyright fair use doctrine to encompass unlicensed uses that are decidedly commercial in nature. The U.S. Supreme Court's 1994 decision in *Campbell v. Acuff-Rose Music, Inc.*[214] made clear that commercial uses are not per se unfair and thus infringing.[215]

Rather than focusing on whether an accused infringer's unauthorized use is commercial in its purpose, fair use in copyright law turns primarily on the degree to which that use is "transformative" in nature.[216] In contrast with a use that would merely supercede or supplant the original work, a transformative use is one that generally furthers the goals of copyright

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212. 17 U.S.C. § 107.

213. Campbell v. Acuff-Rose Music, Inc., 510 U.S. 569, 575 (1994) (stating that opportunity for some fair use of copyrighted materials seen as necessary to "fulfill copyright's very purpose, '[t]o promote the Progress of Science and useful Arts.'") (quoting U.S. CONST., Art. I, § 8, cl. 8) (footnote omitted). It should be noted that the Framers' use of the word "Science" in the quoted constitutional clause referred to copyrightable subject matter, while "useful Arts" meant patentable subject matter. *In re* Bergy, 596 F.2d 952, 958 (C.C.P.A. 1979) (Rich, J.).

214. 510 U.S. 569 (1994).

215. *Id.* at 572 (reversing court of appeals holding that defense of fair use for rap parody of copyrighted song was barred by parody's commercial character and excessive borrowing from original). *Compare* Sony Corp. of Am. v. Universal City Studios, Inc., 464 U.S. 417, 451 (1984) (stating that "every commercial use of copyrighted material is presumptively . . . unfair"), *with Campbell*, 510 U.S. at 584–85 (rejecting narrow interpretation of *Sony* as creating presumption of unfair use arising from commerciality and recognizing that such presumption would "swallow nearly all of the illustrative uses listed in the preamble paragraph of [17 U.S.C.] § 107, including news reporting, comment, criticism, teaching, scholarship, and research, since these activities 'are generally conducted for profit in this country'") (quoting Harper & Row Pubs., Inc. v. Nation Enters., 471 U.S. 539, 592 (1985) (Brennan, J., dissenting)).

216. *Campbell*, 510 U.S. at 583–85, 590–91.

law.[217] When the unauthorized use of another's copyrighted work results in something that copyright law seeks to promote[218]—i.e., "adds something new, with a further purpose or different character, altering the [copyright owner's work] with new expression, meaning, or message"[219]—the use is more likely to be held a fair one and therefore outside the realm of copyright infringement.

Judicial elevation of transformative character over commerciality in the copyright regime can serve as a model for a similar treatment in patent law, and particularly so with respect to the patent experimental use doctrine, given its proximity to copyright fair use principles.[220] Another patent law doctrine, the doctrine of equivalents, has already been the subject of a transformative-use type of analysis, although not given that label. Compelling arguments have been made that patent infringement determinations under the doctrine of equivalents should take into consideration the extent to which an accused infringement represents a technological improvement over the patented invention.[221] In other words, the technological contribution made by the accused infringer should be part of the calculus of patent infringement liability.[222]

Analysis of the accused infringer's contribution is particularly applicable when it is not operating within the literal boundaries of the patentee's claims, but rather is liable, if at all, under the more imprecise rubric of the doctrine of equivalents.[223] In such cases, the greater the extent of the accused infringer's technological advance over the patented invention, the

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217. *Id.* at 579.

218. *Id.* ("[T]he goal of copyright, to promote science and the arts, is generally furthered by the creation of transformative works.").

219. *Id.*

220. The common law experimental use doctrine of patent law has been characterized as the closest patent doctrine to copyright's fair use. *See* Lemley, *supra* note 70, at 1038 n.236.

221. Merges & Nelson, *supra* note 37, at 857–59 (citing with approval court's analysis in *Texas Instruments, Inc. v. United States International Trade Commission*, 805 F.2d 1558 (Fed. Cir. 1986), that focused on "the merits of the accused device"); *id.* at 909–11 (advocating that after courts have determined significance of patented invention they should also consider "importance of the advance represented in the *accused* device").

222. The infringer's contribution could be relevant in determinations of equivalency under the doctrine of equivalents, as well as in assessing whether the reverse doctrine of equivalents should be applied to excuse a literal infringement that is so far changed in principle from the patented invention that it is unfair to find liability. *See* Merges & Nelson, *supra* note 37, at 862–68 (advocating reverse doctrine of equivalents as mechanism to limit patent scope in face of significant technological improvement by accused infringer); *id.* at 867 & n.120 (noting that same rationale applies to doctrine of equivalents analysis and is perhaps even more useful there).

223. *Id.* at 867 n.120.

less likely that the differences between the claimed and accused devices are merely "insubstantial"[224] and therefore invoking application of the doctrine of equivalents.[225] Indeed, the Federal Circuit has recognized that where an accused infringer's product is itself patented, this fact may evidence that the differences between the claimed and accused devices are beyond those permissible for application of the doctrine of equivalents.[226]

Professor Mark Lemley has proposed a patent law model in which the class of "truly radical improvements" would be exempted from liability for infringement,[227] even if the improvement falls within the literal scope of the patent claim at issue.[228] Such an exemption would create an incentive for the creation of improvements and avoid the licensing transaction costs that might otherwise prevent those improvements from reaching the marketplace.[229] The same analysis can be extended to uses of research tools that produce a commercial product not physically incorporating the patented tool itself. Such products can be viewed as representing the ultimate category of improvement within Professor Lemley's hierarchy, as well as the epitome of transformative use in the copyright fair use sense.

C. Research Tool Patentability and Claim Scope

Broadened acceptance of the non-consensual use of patented research tools might also be criticized as a makeshift solution to the more fundamental problem of the issuance of biotechnological patent claims of

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224. Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1423 (Fed. Cir. 1997) (stating that doctrine of equivalents applies at claim-limitation level if only "insubstantial differences" distinguish claimed limitation from corresponding component of accused device); Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1516–18 (Fed. Cir. 1995) (expressing test for application of doctrine of equivalents in terms of whether differences between claimed and accused devices are "insubstantial").

225. Merges & Nelson, *supra* note 37, at 867.

226. Zygo Corp. v. Wyko Corp., 79 F.3d 1563, 1570 (Fed. Cir. 1996) (explaining in context of doctrine of equivalents infringement analysis that "[t]he nonobviousness of the accused device, evidenced by the grant of a United States patent, is relevant to the issue of whether the change therein is substantial"); Nat'l Presto Indus., Inc. v. W. Bend Co., 76 F.3d 1185, 1192 (Fed. Cir. 1996) (characterizing fact of patentability of accused device as "relevant" and "entitled to due weight" in infringement analysis, though not determinative); Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1580 n.3 (Fed. Cir. 1984) (suggesting that patentability of accused device based on "unexpected results" over patentee's device might evidence non-equivalency based on substantially different "result").

227. Lemley, *supra* note 70, at 1010–13, 1070.

228. When the "radical improvement" does fall within the literal boundaries of the claim, this invokes the reverse doctrine of equivalents. *Id.* at 1010–11.

229. *Id.* at 1070.

unjustified scope.[230] But administrative and judicial actors are beginning to respond to the scope problem. The U.S. Patent and Trademark Office (USPTO) recently issued guidelines requiring a more rigorous showing of utility as a prerequisite to patentability,[231] and the Federal Circuit seems more than willing to wield the enablement and written description requirements of the first paragraph of 35 U.S.C. § 112 as claim scope-shrinking implements.[232]

Others contend outright that research tools should be completely excluded from patenting.[233] They argue that, rather than exempting

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230. *Cf.* Barton, *supra* note 15, at 449 (criticizing broad patents as potentially "usable to prevent entry by others . . ." or to "affect the incentives for further research by others"); Merges & Nelson, *supra* note 37, at 916 (concluding that "[w]hen a broad patent is granted or expanded via the doctrine of equivalents, its scope diminishes incentives for others to stay in the invention game, compared again with a patent whose claims are trimmed more closely to the inventor's actual results"); Rai, *supra* note 37, at 120–29 (criticizing "development-oriented perspective" of Edmund Kitch and others as advocating broad patents on basic inventions as "prospects" to encourage further development of that technology, coordinated by single rights holder).

231. *See Examination Guidelines*, *supra* note 61, at 71,441; *see also* Q. Todd Dickinson, *Reconciling Research and the Patent System*, ISSUES SCI. & TECH., Summer 2000, at 69 (asserting that USPTO is cognizant of concerns that patents on gene fragments "might retard basic research and that these claims will form an intricate licensing web that will impede their use in developing cures for diseases," and that USPTO "continue[s] to take steps to ensure that patent applications in these areas are meticulously scrutinized for an adequate written description, sufficiency of the disclosure, and enabled utilities").

232. 35 U.S.C. § 112 (1994). Other recent examples of the Federal Circuit's application of the first paragraph of § 112 in a restrictive fashion include *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1377 (Fed. Cir. 1999) (affirming judgment of invalidity based on failure of patent directed to "highly unpredictable" antisense technology to satisfy enablement requirement of § 112's first paragraph, where claims at issue were "quite broad" and extent of experimentation required to practice invention as claimed in all prokaryotic or eukaryotic cells would be undue in light of examples disclosing successful performance of invention with only single prokaryotic cell, *e. coli*), and *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997) (reversing preliminary injunction and holding invalid for non-enablement patent directed to method of producing human growth hormone through cleavable fusion expression that, in Federal Circuit's view, provided only "a direction for further research"). *E.g.*, Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615 (1998) (characterizing Federal Circuit's decision in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), as having effectively elevated written description requirement of § 112's first paragraph to "super enablement" standard, and having improperly applied written description requirement to originally filed claims).

233. Public comments received by the USPTO in response to its first round of Interim Written Description Guidelines, published in June 1998, asserted that "ESTs [Expressed Sequence Tags] are genomic research tools that should be available for unencumbered research to advance the public good." *Examination Guidelines*, *supra* note 61, at 71,441; *see also* McConathy & Weber, *supra* note 40, at 177 (expressing alarm of many in biotechnological community that exclusive rights in research tools will preclude opportunities for development of products in long term, and arguing that research tool inventions should not be patentable); *cf.* Rebecca S. Eisenberg & Robert P. Merges, *Opinion*

unauthorized research uses of patented research tools from infringement liability, research tools would be better dealt with by excluding them from patentability in the first instance.

But prohibiting the patenting of any particular technology or type of invention is a draconian step that has generally been avoided in the United States.[234] To take away any possibility of any remedy, injunctive or monetary, for unauthorized uses of all research tools could deleteriously constrict incentives for the creation of new research tools.[235] A complete exclusion would also run afoul of the developmental history of U.S. patent jurisprudence, which traditionally has taken an expansive stance toward patentable subject matter.[236] Exclusion of particular technologies from patentability also contravenes U.S. treaty obligations under the non-discrimination provisions of the General Agreement on Tariffs and Trade (GATT) Uruguay Round Agreements, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[237]

Letter As To the Patentability of Certain Inventions Associated With the Identification of Partial cDNA Sequences, 23 AIPLA Q.J. 1, 19 (1995) (contending that "[t]here are reasons to be wary of patents on research tools, including concerns that they might be licensed on an exclusive basis to the detriment of subsequent research").

234. Even though the U.S. Supreme Court's decision in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), affirmed the patentability of living, genetically engineered subject matter, life patenting continues to be the subject of robust public debate and vocal criticism twenty years later. *E.g.*, Council for Responsible Genetics, *No Patents on Life!*, *available at* http://www.gene-watch.org/petition.html (last visited May 30, 2000). Congress in the intervening time period has not amended the patent laws to exclude living subject matter or genetically engineered subject matter from patenting.

The only technology-specific subject matter exclusions from patenting currently recognized in U.S. law involve inventions directed to national security and nuclear technology. 35 U.S.C. § 181 (Supp. IV 1998) (authorizing withholding of patent grants on inventions "detrimental to the national security"); 42 U.S.C. § 2181(a) (Supp. IV 1998) ("No patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon.").

235. Eisenberg & Merges, *supra* note 233, at 19 (recognizing that to withhold patent protection from research tools would undermine their creation and distribution, particularly with respect to tools developed by private-sector firms).

236. *E.g.*, *Chakrabarty*, 447 U.S. at 309–10 (holding that live, genetically engineered bacterium is patentable subject matter under 35 U.S.C. § 101); State St. Bank v. Signature Fin. Group, Inc., 149 F.3d 1368, 1370 (Fed. Cir. 1999) (holding that data-processing system for administering mutual fund of "hub and spoke" configuration is patentable subject matter under 35 U.S.C. § 101).

237. General Agreement on Tariffs and Trade Uruguay Round Agreements, Agreement on Trade-Related Aspects of Intellectual Property Rights, Art. 27(1) (1994) (providing that, subject to limited exceptions, "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application").

Reliance interests of patent owners and innovators who rely on the possibility of patent protection would also be threatened by excluding research tools from patentability. Numerous patents have already been granted on research tools.[238] In view of the current industry practice of patenting to the greatest extent possible, any proposal for the outright prohibition of patents on research tools appears destined for failure.

Lastly, the issuance of patents on research tools results in social benefits as well as costs. Publication of enabling descriptions of how to make and use new research tools increases the store of public knowledge, despite the "royalty stacking" problem that may arise when development of commercial products demands multiple authorizations to practice several different research tool patents. As the USPTO's Director has contended, "the need for a possible research tool exemption . . . should not drive a narrowing of subject matter in order to create . . . a de facto patenting exception."[239] The patenting of research tools should not be barred.

D. Constitutional Implications

A broadened experimental use exemption arguably might run counter to a textualist interpretation of the Intellectual Property Clause of the U.S. Constitution.[240] The core of U.S. patent law, absent in many foreign regimes,[241] is Congress's constitutional power to promote the progress of the useful arts in a manner that the Framers in 1787 spelled out with an unusual degree of particularity[242] by securing to inventors, for limited

238. See *supra* notes 51–61 and accompanying text for examples. An on-line search of the LEXIS U.S. Utility Patents database (which includes patents issued from 1971 through the present) conducted on June 6, 2000 for patents having the phrase "research tool" in the "Summary of the Invention" section retrieved 666 hits.

239. Dickinson, *supra* note 230, at 70.

240. *See* U.S. CONST., art. I, § 8, cl. 8 ("Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."). The quoted constitutional text serves a dual purpose by establishing the basis of both copyright and patent law in the United States. The Framers' use of the word "Science" is believed to refer to copyrightable subject matter, while "useful Arts" is thought to mean "technological arts" or patentable subject matter. *In re* Bergy, 596 F.2d 952, 958–59 (C.C.P.A. 1979) (Rich, J.).

241. In many foreign countries, the existence of a patent system is viewed as a limited exception to a general prohibition against monopolies. *E.g.*, PENROSE, *supra* note 117, at 7 (describing Statute of Monopolies of 1623 as basis of present British patent law); Edwin S. Flores Troy, *The Development of Modern Frameworks for Patent Protection: Mexico, a Model for Reform*, 6 TEX. INTELL. PROP. L.J. 133, 137 (1998) (describing Article 28 of the Mexican Constitution of 1917 as prohibiting all monopolies except those that "serve the nation," including privileges granted to inventors and authors).

242. No other enumerated power is spelled out in such detail. *See* U.S. CONST., art. I.

times, the "*exclusive* right" to their discoveries.[243] As expressed in the Patent Act, the "exclusive right" is now understood as the patentee's "right to exclude" all others from making, using, or selling (and more recently, offering to sell and importing) the patented invention.[244]

The Framers' use of the modifier "exclusive" to describe the right that Congress was authorized to secure to inventors probably does *not* create a Constitutional barrier to modification of that right, however. To conclude otherwise would require ignoring the instances in which Congress or the courts have already recognized exceptions to patent exclusivity.[245] Moreover, a strict textualist interpretation of the Intellectual Property Clause is of minimal use given the Clause's expansive terms and lack of "built-in limits."[246] The Intellectual Property Clause is probably best understood as giving Congress the *power* to grant exclusive rights, but not *requiring* that it do so.[247] Thus, Congress has the power to grant less-than-exclusive patent rights. A broadened experimental use defense would not run afoul of the Constitution.

E. Conventional U.S. Norms of Patent Exclusivity

Re-conceptualizing the experimental use exemption will require a decided change in the culture of the American patent system. The tradition of sharing scientific information is the hallmark of the communalistic

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243. U.S. CONST., art. I, § 8, cl. 8 (emphasis added).

244. 35 U.S.C. § 154 (a)(1) (1994) ("Every patent shall contain . . . a grant to the patentee . . . of the *right to exclude others* from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States . . . .") (emphasis added); Bloomer v. McQuewan, 55 U.S. (14 How.) 539, 548–49 (1852) ("The franchise which the patent grants, consists altogether in the right to exclude every one from making, using, or vending the thing patented, without the permission of the patentee.").

245. *See infra* notes 253, 256–67 and accompanying text.

246. Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 584 (1999) (finding "little hope" for "originalist interpretation" of Intellectual Property Clause as meaningful indicator of any limits on patentable subject matter).

247. *Cf.* NIMMER ON COPYRIGHT § 1.07 (1999). Professor Nimmer asserts that with respect to U.S. copyright law:

> Inasmuch as Congress manifestly has the power either to grant complete exclusivity or no protection at all, it would seem that it may properly invoke protection somewhere between these two polar positions. Nonexclusivity under a compulsory license appears to constitute such a reasonable middle ground. It may then be concluded that the phrase 'the exclusive right' imports words of authority, but not of limitation.

Id.

nature of science.[248] This tradition would be greatly facilitated with less restricted access to patented research tools. On the other hand, expanding the doctrine clearly contravenes historical norms of expansive patent rights and traditionally fierce antipathy by the U.S. patent-holding community toward incursions on exclusivity.

The experimental use exemption is a decidedly unappealing notion to advocates of the view that the exclusionary power of a U.S. patent bestows its owner with broad-ranging control over future technology. This view is grounded in the well-established rule that the owner of a U.S. patent on a "basic" or "pioneer" invention may enjoin a follow-on developer from using the improvement invention, even if the improvement invention is independently patentable over the basic invention.[249] The basic patent "dominates" the improvement patent, so long as the claims of the basic patent are interpreted broadly enough to read on the improvement. The existence of "dominant" and "subservient" patents flows from the fact that a U.S. patent grants its owner a *negative* exclusionary right to prohibit others from using the patented invention, rather than bestowing on the patentee an *affirmative* right to use the invention.[250]

The doctrine of equivalents also fosters the U.S. norm of patents as broad property rights relatively immune from incursions. New technology developed after the issuance of a particular patent, in an effort to improve on or even design around the patented invention, may still infringe that patent under the doctrine of equivalents, even if it does not fall within the literal boundaries of the patentee's exclusionary right as defined by the patent's claims.[251] The doctrine of equivalents in essence creates a penumbra of exclusionary power around the explicit boundaries specified in the patent instrument, and its extent is determinable only through litigation to enforce the patent. Notably, the fact that the infringed patent

248. *Cf.* Rai, *supra* note 37, at 89–90 (defining "communalism norm" of U.S. scientific community as one that views scientific information as "shared resource" and promotes "public domain of freely available scientific information").

249. *See* Fiskars, Inc. v. Hunt Mfg. Co., 221 F.3d 1318, 1324 (Fed. Cir. 2000); Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1240 (Fed. Cir. 1989); Atlas Powder Co. v. E.I. DuPont de Nemours & Co., 750 F.2d 1569, 1580 (Fed. Cir. 1984).

250. *See* 35 U.S.C. § 154(a)(1) (1994) (defining patent grant as "the right to exclude others"). Thus, the holder of the improvement patent does not obtain from the patent any affirmative right to practice the improvement invention, even though it is patented.

251. *See* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 37 (1997) (rejecting argument that doctrine of equivalents should not extend to "after-arising equivalents").

did not (and could not) disclose nor *factually* enable others to make and use the after-arising accused equivalent is not fatal to the patentee's claim.[252]

When viewed from this doctrinal and historical perspective, the U.S. patent community's reticence to embrace a meaningful experimental use doctrine is entirely understandable. At least until recently, the far-reaching exclusionary power of the patent property right was sacrosanct. Absent very limited exceptions,[253] the patentee's right to exclude was not burdened by governmental intrusion. Courts reacted negatively to any limitations on enforcement rights.[254] At the behest of patent owners and patent bar groups, U.S. legislators have traditionally rejected derogations of the patentee's

252. The basic patent need only comply with the enablement requirement in the first paragraph of 35 U.S.C. § 112 insofar as the claimed invention was understood as of its patent application filing date; it need not enable the later-developed infringing device. United States Steel Corp. v. Phillips Petroleum Corp., 865 F.2d 1247, 1250–52 (Fed. Cir. 1989); *In re* Hogan, 559 F.2d 595, 605–07 (C.C.P.A. 1977).

253. Historically, only a small number of exceptions were recognized to the general rule against derogations of a patent's exclusivity. For example, the federal government retains the power to use any patented invention but must pay just compensation for the taking if infringement is proved. 28 U.S.C. § 1498 (1994).

Since the enactment of the Bayh-Dole Act in 1980, the federal government has retained a "march-in" right to require that the patentee grant licenses under the patent to third party applicants where the small business firm or nonprofit entity having title in the patent has failed to achieve sufficient practical application of the subject invention. 35 U.S.C. § 203 (1994). Although the federal government's "march-in" right has been on the books since 1980, it has never been exercised. *See* Gerth & Stolberg, *supra* note 166, at 1, 20; *see also* Eliot Marshall, *NIH Nixes Appeal To Bypass Patent Law*, 277 SCIENCE 759, 759–60 (1997) (reporting NIH Director Harold Varmus's decision not to exercise "march-in" rights under Bayh-Dole Act in dispute between patentee Johns Hopkins University and accused infringer CellPro, Inc., rejecting CellPro's contention that Hopkins' exclusive licensee Baxter Healthcare Corporation had delayed in commercializing patented technology directed to use of CD34 antibodies to separate stem cells from human blood or bone marrow).

Compulsory licensing is permitted under the Atomic Energy Act, 42 U.S.C. § 2183 (Supp. IV 1998) (authorizing governmental grant to applicants of non-exclusive licenses under patents declared to be "affected with the public interest" because of "primary importance in the production or utilization of special nuclear material or atomic energy"), and the Clean Air Act, 42 U.S.C. § 7608 (Supp. IV 1998) (authorizing federal district courts to order licensing of air pollution prevention and control patents "on such reasonable terms and conditions as the court, after hearing, may determine," where unavailability of such licenses might result in "substantial lessening of competition" or "tendency to create a monopoly").

Compulsory licensing has also been ordered as a remedy for antitrust or patent misuse violations in several cases. *See generally* JAY DRATLER, JR., LICENSING OF INTELLECTUAL PROPERTY § 3.03[2][d] (2000).

254. *E.g.*, Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1578 (Fed. Cir. 1983) ("Without the right to obtain an injunction, the right to exclude granted to the patentee would have only a fraction of the value it was intended to have, and would no longer be as great an incentive to engage in the toils of scientific and technological research.").

right to exclude that are widely recognized in foreign systems, such as compulsory licensing, working requirements, and prior-user rights.[255]

More recently, however, fundamental changes in U.S. patent law have begun to foster an increasingly hospitable environment for acceptance of a broader experimental use doctrine. Congressional, executive, and judicial actors are implementing a number of significant incursions into patent exclusivity. As described previously, Congress passed the Hatch-Waxman Act in 1984, adding to the Patent Act § 271(e)'s safe harbor for testing of patented drugs and medical devices for purposes reasonably related to regulatory data gathering.[256] In 1996, Congress enacted the remedies limitation found in § 287(c) of the Patent Act, which precludes the owner of a patent directed to a "medical procedure" from enjoining or obtaining damages from an infringer of that patent.[257] By passage of the American Inventors Protection Act of 1999,[258] the United States has for the first time a limited form of prior-user rights,[259] which have long been recognized in Europe and Japan.[260] Over the protests of American pharmaceutical manufacturers, President Clinton in May 2000 issued an Executive Order

255. *E.g.*, Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980) (describing compulsory licensing as "rarity" in U.S. patent system); *see also* PENROSE, *supra* note 117, at 172 (explaining that compulsory licensing has been "violently opposed" in United States because it "can be such a serious derogation of the monopoly 'rights' of the patentee"); F.M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 456 (1970) ("[E]very attempt to alter the U.S. law in this direction [of introducing general compulsory licensing provisions] has been beaten down as a result of determined opposition from industrial groups and the patent bar."); Feit, *supra* note 26, at 840 n.102 (characterizing U.S. policy as "not favoring compulsory licenses."); McConathy & Weber, *supra* note 40, at 178 (describing compulsory licensing as "abhorrent to both academia and industry"); Merges & Nelson, *supra* note 37, at 911 (describing compulsory licensing as "anathema" to U.S. patent law).

Congress considered but ultimately dropped the idea of compulsory licensing as part of the 1952 Patent Act. *Dawson*, 448 U.S. at 215 n.21.

256. *See supra* notes 125–27 and accompanying text.

257. 35 U.S.C. § 287(c) (Supp. IV 1998).

258. American Inventors Protection Act of 1999, Pub. L. No. 106-113, 113 Stat. 1536, 1536 (1999) (codified as amended in 35 U.S.C. § 273 under the title "Defense to Infringement Based on Earlier Inventor").

259. In general terms, a prior-user right permits one who, prior to the filing of the patent in suit, had independently invented the same subject matter, to continue making, using, or selling it at pre-suit levels. A prior-user right is in essence a license to continue practicing the invention subsequently patented by another.

260. Boesch v. Graff, 133 U.S. 697, 701–04 (1890) (enjoining importation of product covered by U.S. patent and acquired abroad from authorized German source with prior-user rights); *see also* Lisa M. Brownlee, *Trade Secret Use of Patentable Inventions, Prior User Rights and Patent Law Harmonization: An Analysis and Proposal*, 72 J. PAT. & TRADEMARK OFF. SOC'Y 523, 535–40 (1990) (collecting prior-user right provisions of patent laws of Japan, England, Germany, and France).

providing that the U.S. government will not challenge those sub-Saharan African governments that grant compulsory licenses under pharmaceutical patents on HIV/AIDS drugs or permit parallel imports of these drugs from other countries where they are available at lower prices.[261] And in November 2000, the Federal Circuit sitting en banc announced in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*[262] stringent new rules of prosecution history estoppel that significantly contract the ability of patent owners to rely on the doctrine of equivalents.[263]

Perhaps the most significant recent incursion into patent exclusivity occurred in 1999 when the U.S. Supreme Court held in *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*[264] that Congress's 1992 abrogation of Eleventh Amendment immunity from patent infringement liability for states, instrumentalities of states, and state employees acting in their official capacity was unconstitutional.[265] As a result of *College Savings Bank*, state universities are immune from patent infringement liability under the federal patent laws.

The potential ramifications of the *College Savings Bank* decision are quite troubling in at least two respects. First, the state courts may begin to

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261. Exec. Order No. 13155, Access to HIV/AIDS Pharmaceuticals and Medical Technologies, 65 Fed. Reg. 30,521 (May 10, 2000); Neil A. Lewis, *Clinton TriesTo Expedite AIDS Drugs into Africa*, N.Y. TIMES, May 11, 2000, at A7; Donald G. McNeil, Jr., *Companies To Cut Cost of AIDS Drugs for Poor Nations*, N.Y. TIMES, May 12, 2000, at A12.

262. 234 F.3d 558 (Fed. Cir. 2000) (en banc).

263. *Id.* at 569 (holding that when amendment of claim creates prosecution history, no range of equivalents is available for amended claim limitation).

264. 527 U.S. 627 (1999).

265. As a general rule, state governments are immune from lawsuits under the Eleventh Amendment of the U.S. Constitution, which provides that the "Judicial Power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or subjects of any foreign state." U.S. CONST. amend. XI. In 1992, Congress stripped the states of their immunity for patent infringement by enacting the Patent Remedy Act. Patent and Plant Variety Protection Remedy Clarification Act, Pub.L. No. 102-560, 106 Stat. 4230 (1992) (codified at 35 U.S.C. §§ 271(h), 296(a) (1994)).

In *Seminole Tribe v. Florida*, 517 U.S. 44 (1996), the U.S. Supreme Court held that Congress cannot abrogate the states' Eleventh Amendment sovereign immunity under Congress's Article I powers. *Seminole Tribe* thus foreclosed reliance on congressional authority under either the Commerce Clause or the Intellectual Property Clause to sustain the Patent Remedy Act. In *College Savings Bank*, the argument for constitutionality of the Patent Remedy Act was accordingly premised on the Due Process Clause of the Fourteenth Amendment. 527 U.S. at 636. The petitioner contended that patents are private property and to allow states to use them without authorization and without remedy was a deprivation of private property without due process. *Id.* The U.S. Supreme Court rejected the Due Process theory on the grounds that there had not been a sufficient showing that state governments routinely infringe, that such infringement is willful rather than merely negligent or "innocent," or that such infringement results in a property deprivation without due process. *Id.* at 639–46. In support of its ruling, the Court pointed to the possibility of alternative remedies in state court such as unfair competition causes of action. *Id.* at 643–44 & nn.8–9.

hear patent infringement cases brought under the guise of state unfair competition actions. State court activity in this arena is contrary to federal preemption principles of patent law and the federal nature of patent rights as recognized in U.S. law since 1790. Placing quasi-patent jurisdiction in the state courts is also antithetical to the "national uniformity" rationale underlying the Federal Circuit's formation.[266]

Second, *College Savings Bank* may have an unforeseen impact on the formation, arrangement, and management of research and development collaborations between state universities and private industry. Private-sector partners will presumably seek to maximize their opportunities to be shielded from liability under the state universities' umbrella of immunity. However, the minimum level of state funding or control or both that would render a state university-industry collaboration eligible for the immunity as an instrumentality of the state is yet unknown. Moreover, state universities may balk at the potential negative impact on their academic independence with good reason. Research agendas ought not to be controlled by funding manipulations for the purpose of helping industry collaborators gain the protections of Eleventh Amendment immunity.

The *College Savings Bank* holding is especially significant to the debate over access to patented research tools insofar as state universities and their industry collaborators may be frequent users of these tools. Because *College Savings Bank* gives states immunity from patent infringement liability under Title 35, state university research would appear to have no immediate need for a broadened experimental use doctrine as proposed here.[267] Yet as frequent users of patented research tools, the state university is a critical participant in the debate over a broadened exemption.

VII. A PROPOSED "DEVELOPMENT USE" MODEL

This Part reviews a previous proposal for expanding the experimental use doctrine and concludes that further modifications are needed for the case of patented research tools. It proposes a "liability rule" model that would permit the non-consensual "development use" of patented research tools that are not readily available for licensing or purchase, while providing an ex post royalty payment to the owner of the patented research

266. *See* Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (creating U.S. Court of Appeals for the Federal Circuit); 28 U.S.C. § 1295 (Supp. IV 1998) (providing that Federal Circuit has exclusive nationwide jurisdiction over patent appeals).

267. Exceptions would include state and industry collaborations that are not sufficiently "instrumentalities of the state" to qualify for Eleventh Amendment immunity and state officials acting in the scope of their official capacity who may still be subject to prospective injunctive relief under *Ex Parte Young*, 209 U.S. 123, 167–68 (1908).

tool of sufficient amount to maintain adequate incentives for innovation in new tools. The proposed "reach-through" royalty approach, as it is referred to in consensual biotech licensing transactions, would compute the royalty payment to the tool patent owner based on the marketplace value of the new products or diagnostics developed through use of the patented research tool.

In her seminal 1989 article, Professor Rebecca Eisenberg proposed a three-pronged model for an expanded experimental use doctrine.[268] First, Professor Eisenberg contended that use of a patented invention to verify that the patent's written description and drawings adequately enabled the claimed invention should be altogether exempt from infringement liability.[269] This aspect of Professor Eisenberg's proposal is probably closest to Justice Story's view that the construction of a patented machine "for the purpose of ascertaining the sufficiency of the machine to produce its described effects"[270] is not infringement. Such use is also most likely to fall within the current post-*Roche* "truly narrow" view of the experimental use defense as limited to "non-commercial" uses.[271]

Second, Professor Eisenberg argued that use of an invention having a "primary or significant market" among research users who are "ordinary consumers" of the invention should not be exempt from liability; in Professor Eisenberg's view, these "consumers" must obtain a license prior to their use.[272] For example, in a scenario where users of patented transgenic mice as tools for conducting cancer research represent the target market of the mouse patent holder, it is reasonable to assume that the patentee will want to make the mouse widely available at reasonable licensing terms. These "ordinary consumers," as Professor Eisenberg's use of that term suggests, do not face access problems if they can readily license or buy the research tool on the open market.[273]

Third, Professor Eisenberg proposed that those who use a patented invention in a manner that leads to improvements in the technological field of that patent, or for the purpose of "designing around" the patent's claims to avoid infringement, should not have to negotiate for a license prior to

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268. Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1074–78 (1989).

269. *Id.* at 1078 ("Research use of a patented invention to check the adequacy of the specification and the validity of the patent holder's claims about the invention should be exempt from infringement liability.").

270. Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600).

271. *See supra* note 121 and accompanying text.

272. Eisenberg, *supra* note 268, at 1078.

273. *Id.* at 1085 (suggesting that patentee "will want to sell to these users—they fall squarely within the market for the patented invention").

their use.[274] Such users would still be considered infringers in Professor Eisenberg's model but would enjoy a remedies limitation. The patent owner would not be able to enjoin their uses, but "in some cases" would receive an after-the-fact "reasonable royalty" in recognition of the patent owner's initial investment in developing the patented invention.[275] Professor Eisenberg did not identify criteria for choosing among those patent owners for whom the royalty remedy should be available, nor a method for quantifying its amount.

The third "improver" prong of Professor Eisenberg's proposed framework can be viewed as a variation on compulsory licensing,[276] without the necessity of first petitioning the patentee or the government for a license.[277] The limitation of the patentee's remedy to a royalty rather than

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274. *Id.* (citing example of researchers attempting to design improved transgenic mouse or non-infringing transgenic mouse).

275. *Id.* at 1078.

276. *See* Rai, *supra* note 37, at 139 (noting that system under which users pay reasonable royalties to patent owner after unlicensed use is "not very different from a compulsory license scheme"). Professor Scherer has defined "compulsory licensing," which he also refers to as "mandatory licensing," as the act of "waiving a patent holder's normally exclusive right to his invention under specified conditions such as nonutilization of the invention, monopolistic abuses, or other circumstances engendering a public interest in wider availability." F.M. Scherer, *The Economic Effects of Compulsory Patent Licensing* 5 *in* NEW YORK UNIVERSITY'S MONOGRAPH SERIES IN FINANCE AND ECONOMICS (1977).

277. Edith Tilton Penrose has described the most extreme form of such a system as "unconditional compulsory licensing," under which a license would be available as of right to any requestor without the need for petitioning a governmental agency or establishing the patentee's failure to supply the domestic market with the patented invention or license on reasonable terms. *See* PENROSE, *supra* note 117, at 184 (contending that if unconditional compulsory licensing were adopted "the worst of the social costs of the patent system would be abolished at one stroke," but also noting traditional fears that such system would abolish social gains from patenting because royalty remedy alone might be insufficient to motivate desired level of innovation).

Yet another variation on unconditional compulsory licensing, available in the United Kingdom and Germany, is a scheme under which a patentee may voluntarily request that the government make licenses available to all comers upon payment of a reasonable royalty. In exchange for the patentee's agreement to license without restriction, it obtains reduced maintenance fees over the life of the patent. *See id.* at 177–78 & 177 n.29; German Patent Act of 16 December 1980, § 23(1) (reducing maintenance fees by one half prescribed amounts after patentee files written declaration of willingness to allow anyone to practice patented invention in return for reasonable compensation), *reprinted in* 2D SINNOTT ET AL., *supra* note 187, at WEST GERMANY-78.24.

A system of compulsory licensing without satisfaction of *any* threshold conditions would likely not comply with current international patent agreements. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Goods, Dec. 15, 1993, art. 31, 33 I.L.M. 81, 95 (GATT Uruguay Round Agreements) (permitting use without authorization of rights holder only if "prior to such use, the proposed user has made efforts to obtain authorization from the rights holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time"); Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, art. 5.A.4, 828 U.N.T.S. 107, 123 (Stockholm 1967 rev.) (permitting compulsory licenses to be applied for in cases of patentee's "failure to work" or "insufficient working" of patent, after later of four years

an injunction also illustrates the choice of a "liability rule" over a "property rule."[278]

The royalty stacking problem in biotechnology, occasioned by increasing need for patented tools that are not freely available for purchase by ordinary consumers in the marketplace, has escalated in severity since the 1989 publication of Professor Eisenberg's article.[279] In the current environment, the assumption inherent in Professor Eisenberg's second prong that research tools are readily available to "ordinary users" with minimal transactions costs is increasingly less certain. Moreover, innovation in one technology increasingly involves the use of patented research tools from other technologies. For example, a genetically modified mouse may be used to develop and screen new pharmaceuticals for the treatment of cancer in humans, or a DNA chip (formed by layering chains of nucleotides onto silicon) may be used to determine the link between specific single nucleotide polymorphisms (genetic variations) and particular diseases,[280] leading to new screening techniques for these diseases. To the extent that they 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 third, "improver" prong of Professor Eisenberg's model.[281] Yet such uses of research tools result in valuable new products that are just

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from filing or three years from grant, but mandating refusal of request for compulsory license if "patentee justifies his inaction by legitimate reasons").

278. Ian Ayres & Eric Talley, *Solomonic Bargaining: Dividing a Legal Entitlement To Facilitate Coasean Trade*, 104 YALE L.J. 1027, 1036–37 (1995) (contrasting "property rules" that protect legal entitlements against all non-consensual takings with "liability rules" that permit non-consensual takings but compensate entitlement holders). A framework for the setting and protection of entitlements under "property rules" and "liability rules" was first proposed in Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089 (1972). In the patent context the right to an injunction against infringement represents a property rule, while compulsory licensing of patented inventions represents a liability rule. Ayres & Talley, *supra*, at 1036–37. In the context of a patented improvement invention that is blocked by a dominant patent, Ayres and Talley contend that liability rules are preferable to property rules. *Id.* Liability rules would facilitate revelation of information which, when it is otherwise not disclosed in cross-licensing negotiations, would lead to significant delay if not complete breakdown of those negotiations. *Id.* at 1092–93. Ayres and Talley's implementation of a liability rule in the patent setting accordingly contemplates a compulsory licensing scheme that would "giv[e] the improver an option to infringe the pioneer's patent in exchange for a fee determined by a licensing tribunal." *Id.* at 1093.

279. *See supra* notes 28–35 and accompanying text; *see also* Marshall, *supra* note 57, at 25 (describing debate over restrictions on research use of *cre-loxP* mouse as "just the latest skirmish in a decade-long battle over commercial controls on basic tools in biomedical research").

280. Nicholas Wade, *Where Computers and Biology Meet: Making a DNA Chip*, N.Y. TIMES, Apr. 8, 1997, at C1.

281. *See* Eisenberg, *supra* note 268, at 1078 (limiting proposed reasonable royalty limitation to "use of a patented invention in subsequent research in the field of the invention").

as important, if not more so, from a societal benefit standpoint.[282]

This Article proposes to extend and adapt Professor Eisenberg's model to the current research tool milieu so as to permit non-consensual use of research tools not readily available for licensing on reasonable terms or via anonymous marketplace purchase.[283] This "development use" rule[284] would not discriminate against research tool users who seek to develop commercial products. It would be limited to "uses" of research tools as tools, however, and would not encompass the sale of products by the tool user that physically incorporate the patented invention. This latter scenario involves liability for "selling" the patented invention under 35 U.S.C. § 271(a),[285] which should not be exempted from injunctive or damages remedies.

This Article further proposes the adoption of a reach-through royalty structure that would link the royalty payment with the ultimate commercial value of the products developed from use of the patented research tool. The new products would serve as the royalty base.[286] 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. Such an approach would also work to minimize the disincentive effect on innovation in research tools. The research tool patent owner would acquire the right to a potentially commercially significant future royalty stream, while the tool user would avoid the burdens of pre-use license negotiations, up-front payments, and blocked access to the proprietary research tools.

To ensure adequate notice to the research tool patentee in the proposed model, the putative user would be required to notify the patentee in writing of the user's intent to use the patented research tool, prior to the use. In contrast with typical consensual licensing negotiations for use of research

282. *See* Barton, *supra* note 15, at 457.

283. The limitation of the proposed development use rule to situations where the research tool is not readily accessible through licensing or purchase in the marketplace is in keeping with the "failure of private bargaining" restriction on compulsory licensing under GATT TRIPS. Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Goods, Dec. 15, 1993, art. 31, 33 I.L.M. 81, 95 (providing that compulsory licensing shall be available only after "the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time").

284. The phrase "development use" is employed in this Article to explicitly encompass those uses of research tools that lead to commercialization of products, and to make clear that the experimental use doctrine should no longer be limited to the purely "philosophical" (in the *Roche* sense) research component of "research and development."

285. "Except as otherwise p.ovided in this title, whoever without authority makes, uses, offers to sell, or *sells* any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent." 35 U.S.C. § 271(a) (Supp. IV 1998) (emphasis added).

286. Reach-through royalties are discussed in *supra* note 76 and accompanying text.

tools,[287] however, no disclosure of the nature or details of the use would be required. This minimal declaration of an "intent to use" will place the patentee sufficiently on notice so that it can police any subsequent introduction of new products into the marketplace by the tool user. The patentee's detection ability can be supplemented by requiring that the tool user additionally provide written notice of the new products at or shortly before sales are commenced.[288] Tool users who choose to opt out and not give proper notices could be made subject to treble damages if infringement is ultimately established.

Whether the utilization of a reach-through royalty approach triggers patent misuse or antitrust concerns has been the subject of some debate in the consensual (i.e., non-compulsory) licensing of biotechnological research tools.[289] Advocates of reach-through royalties contend that patent misuse does not occur if the reach-through royalty results from a bargained, arms-length licensing transaction.[290] The reach-through approach is seen as an expedient method of measuring the value of the use of the research tool rather than an unlawful leverage of the patent right.[291] This treatment of reach-through royalties is consistent with the Federal Circuit's approval of a license agreement in which the royalty base encompassed not just the

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287. *See* McConathy & Weber, *supra* note 40, at 178 (characterizing conventional reach-through licenses for research tools as requiring "full disclosure" of licensee's intended use).

288. Germany's patent code provides a somewhat analogous notice framework, but requires disclosure of the nature of the licensee's use. Owners of German patents have the option of filing a written declaration with the German Patent Office stating their willingness to allow anyone to practice the patented invention in return for reasonable compensation; the patent owner's maintenance fees are thereafter reduced by half. German Patent Act of 16 December 1980, § 23(1), *reprinted in* 2D SINNOTT ET AL., *supra* note 187, at WEST GERMANY-78.24. Following the recording of the patentee's declaration, any individual wishing to exploit the invention may do so by notifying the patentee of his or her intent. *Id.* at § 23(3). The notification must include a statement "of how the invention is to be exploited." *Id.* The notifying party is then entitled to practice the invention in the manner stated. *Id.* The notifying party must also provide the patentee with quarterly reports of the "particulars of the use" and pay compensation for the use, which is assessed by the Patent Division. *Id.*

289. NIH Principles and Guidelines, *supra* note 26, at 72,091 (criticizing reach-through royalties); David S. Block & Daniel J. Curran, *Patenting Genomic Technologies*, 282 SCIENCE 1419 (1998) (denying, in letter responding to Heller & Eisenberg, *supra* note 28, at 698, that DuPont's reach-through royalty agreement on patented *cre-loxP* mice allows DuPont to "leverage its proprietary position in upstream research tools into a broad veto right over downstream research and development products").

290. Barton, *supra* note 15, at 461 (asserting that "if [reach-through royalties] are reasonable, they should be permitted and . . . insistence on such terms should not be read as an antitrust violation"); Goldstein, *supra* note 76; Robert Blackburn, Chief Patent Counsel, Chiron Corporation, remarks at the National Academies Board on Science, Technology, and Economic Policy's Conference on "Intellectual Property Rights: How Far Should They Be Extended?" (Internet broadcast, Feb. 3, 2000).

291. DRATLER, *supra* note 253, § 4.03 (asserting that "a royalty base that extends beyond the scope of patent protection is lawful if accepted by both parties for their mutual convenience, for example, in calculating royalties and avoiding disputes").

patented device but also unpatented components used in practice of the patented invention.[292] The court characterized the inclusion of unpatented subject matter in the royalty base as merely a "convenient means for measuring the value of the license."[293]

Recent liberalization of the Federal Circuit's damages jurisprudence provides additional support for the legitimacy of a reach-through royalty approach. The court has expanded traditional notions of recoverable damages in patent infringement cases to encompass virtually any type of economic harm that was "reasonably foreseeable" from the infringement.[294] For example, damages may now be based on sales of infringing devices that do not directly compete in the marketplace with the patentee's patented product,[295] and lost profits may be awarded even when the patentee does not manufacture the patented device at all.[296] Where the patented device is part of a larger system that also includes unpatented components, the "entire market value" rule recognizes that the damages award can be properly based on the value of the overall system.[297] The Federal Circuit has specifically rejected arguments that its expansion of recoverable

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292. Engel Indus., Inc. v. Lockformer Co., 96 F.3d 1398, 1408 (Fed. Cir. 1996) (approving license agreement in which royalty base included both claimed system for connecting ends of sheet metal duct sections and corner connectors not covered by patent) (citing Automatic Radio Mfg. Co. v. Hazeltine Research, Inc., 339 U.S. 827 (1950), *overruled on other grounds by* Lear v. Adkins, 395 U.S. 653, 671 (1969); and Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 138 (1969)). The Federal Circuit stressed the "voluntariness" of the license provision, and the fact that the licensee was not required to (and in fact did not) purchase the unpatented connectors from the patentee. *See id.* at 1408–09.

293. *Id.* at 1408 (agreeing with magistrate judge that "royalties may be based on unpatented components if that provides a convenient means for measuring the value of the license"); *see also* Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1350 (Fed. Cir. 2000) (explaining that although compensatory damages based on "reasonable royalty" under 35 U.S.C. § 284 (1994) are "ordinarily computed based upon the sales of a patented product or process . . . parties may choose other methods to compute the amount that a licensee may pay for the right to use a patented product or process, such as flat fees or milestone payments in the case of pre-commercialization licenses").

294. King Instruments Corp. v. Perego, 72 F.3d 855, 857 (Fed. Cir. 1995) (Nies, J., dissenting from denial of panel rehearing) (unpublished disposition) (characterizing 1995 Federal Circuit majority decision in *Rite-Hite* as having "expanded legal injury for patent infringement" and worked "fundamental change in patent rights"); *see also* Rite-Hite Corp. v. Kelly Co., 56 F.3d 1538, 1546 (Fed. Cir. 1995) (en banc) (holding that "[i]f a particular injury was or should have been reasonably foreseeable by an infringing competitor in a relevant market, broadly defined, that injury is generally compensable absent a persuasive reason to the contrary").

295. *Rite-Hite*, 56 F.3d at 1549 (affirming award of lost profits damages based on lost sales of patentee's ADL-100 vehicle-restraint device, which was not covered by patent in suit but directly competed with defendant's infringing "Truk Stop" device).

296. King Instruments Corp. v. Perego, 65 F.3d 941, 947 (Fed Cir. 1995).

297. *Id.* at 950–51 n.4 (characterizing entire market value rule as recognizing that "the economic value of a patent may be greater than the value of the sales of the patented part alone," and therefore permitting recovery based on value of unpatented as well as patented components of patentee's product).

infringement damages facilitates patent owners' restriction of competition in unpatented products; rather, the court's stated objective is that "the patentee be made whole."[298]

The propriety of reach-through royalties is most problematic from a patent-misuse standpoint when the royalty payments extend beyond the enforceable life of the patent on the underlying research tool.[299] This will likely occur with relative frequency in biotechnology, where long-term research and development projects (and regulatory approval of their results) often result in the marketplace introduction of a new product lagging several years behind the actual use of the patented research tools that led to the product's development.

Rather than improper leveraging of the patent right, a better way to approach the use of reach-through royalties is simply as a time-shifting mechanism. Reach-through royalty payments continuing beyond the expiration date of an underlying research tool patent more accurately recognize the value of the patented research tool, which cannot be definitively established during the enforceable life of the patent.[300] The premise underlying reach-through royalties is that the true value of the patented research tool will be determined by the ultimate marketplace

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298. *Rite-Hite*, 56 F.3d at 1547 (explaining that court's decision "simply asks, once infringement of a valid patent is found, what compensable injuries result from that infringement, i.e., how may the patentee be made whole").

299. *See* Brulotte v. Thys Co., 379 U.S. 29, 31–32 (1964) (holding that license agreement requiring farmers to make royalty payments after expiration date of patent on hop-picking machine was unlawful per se where payments were for farmers' use of machine during post-expiration period, not "deferred payments for use during the pre-expiration period").

300. *Cf.* Harold See & Frank M. Caprio, *The Trouble with* Brulotte*: The Patent Royalty Term and Patent Monopoly Extension*, 1990 UTAH L. REV. 813 (1990). See and Caprio contend that *Brulotte* was incorrectly decided. *Id.* at 814. Licensees can be assumed to understand that a patentee's right to exclude ends at the date of patent expiration. *Id.* Therefore, when licensees agree to make royalty payments beyond that date, "the parties base those payments on the licensees' assessment of the value of the license during the patent period. These payments, therefore, do not represent an extension in time of the patent monopoly." *Id.*; *see also* Mark A. Lemley, *The Economic Irrationality of the Patent Misuse Doctrine*, 78 CAL. L. REV. 1599, 1630 (1990) (disagreeing with proposition that licensing practices which extend royalty payments beyond enforceable life of patent are per se patent misuse, and asserting that "[a] licensee will pay a fixed amount for a license, and the courts should not care whether the licensee pays that amount up front, in ten years, or in a hundred years").

See and Caprio also dispute the *Brulotte* Court's negative view of post-expiration royalty payments to the extent that such payments are perceived as unfairly imposing on the licensee a financial burden not shared by the licensor. See & Caprio, *supra* at 848 (noting concern that "[a]rguably, upon expiration of the patent, the royalty obligation impairs the licensee's ability to compete with the licensor because only the licensee must pay a royalty"). The fallacy of this concern, See and Caprio point out, is that it assumes the licensor and licensee are competitors. *Id.* at 848. This was not the case in *Brulotte*, where the licensees were farmers using patented hop-picking machines, *Brulotte*, 379 U.S. at 31–32, nor would it generally be the case when researchers are using another's research tool to produce a new drug or therapeutic product.

success of the new product developed through use of the tool. A reach-through license agreement merely time-shifts the royalty payments to the period when they are most accurately indicating the research tool's true value to the user. That sales of the new product may extend beyond the life of the underlying tool patent will be neither surprising nor unknown to the patent owner and the tool user. Basing royalty payments on those sales should not be construed as patent misuse or as an antitrust violation.

Reach-through royalty payments are prima facie reasonable so long as the total time period over which they are paid is no longer than the term of the underlying tool patent, i.e., a period of twenty years less the patent application's pendency.[301] This limitation assures the patentee of obtaining full value for the researcher's use and satisfies the constitutional requirement that exclusive rights in intellectual property are to be granted only "for limited times."[302]

The reach-through royalty approach is less straightforward when the non-consensual use of the patented research tool does not ultimately result in a commercial product; in these cases there is no end result to be "reached" as the royalty base. Nevertheless, the research tool user has obtained a benefit. Unproductive dead-ends have been identified and can be avoided in future research. The informational value of this understanding should not be underestimated; indeed, it may represent the largest cost component of other products that are ultimately developed and successfully marketed.[303] To the extent that a specific research tool can be identified as instrumental in the development of a particular product, the royalty should be based on that product. In situations where this is not possible, however, a standardized schedule of royalty fees could be legislatively enacted. The mechanical license for musical works protected by copyright law suggests a possible model.[304] Alternatively, a specialized administrative body similar

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301. For example, if a research tool patent is applied for in the United States in 2000 and issues in 2002, it will expire in 2020 (absent other extensions or term adjustments) and have an enforceable life of eighteen years. 35 U.S.C. § 154(a) (Supp. IV 1998). This Article proposes that reach-through royalties be paid beginning with the date of the first sale of the product developed through use of the patented tool, whenever that sale occurs, and ending eighteen years thereafter. The recovery period of eighteen years has been time-shifted to correspond with the period of sales of the new product.

302. U.S. CONST., art. I, § 8, cl. 8.

303. Gerth & Stolberg, *supra* note 166, at 1, 20 (stating that "only a small percentage" of $500 million average cost of developing new drug is attributable to actual development costs and that balance represents "cost . . . attributed to lost opportunities: years spent going down scientific 'dry holes' and research money that could have generated interest had it been invested instead").

304. 17 U.S.C. § 115 (Supp. IV 1998) ("Scope of exclusive rights in nondramatic musical works: Compulsory license for making and distributing phonorecords"). Once the owner of a copyright in a non-dramatic musical work has sold the work to the public, any other person has a compulsory license to record and sell phonorecords of the same work. *See generally* MARSHALL LEAFFER, UNDERSTANDING COPYRIGHT LAW § 8.7 (2d ed. 1995) (explaining how copyright mechanical license

to the Copyright Arbitration Royalty Panels could be created to adjudicate royalty disputes.[305]

Adopting the notion of a royalty that will reach-through to use the downstream product as the royalty *base*, as proposed here, still leaves undetermined the royalty *rate* to be applied to that base.[306] The difficulty of royalty quantification has been a leading argument against adoption of compulsory licensing in the United States.[307] The determination of appropriate rates can be a very complex and expensive process.[308] Absent

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operates). A monthly statutory royalty must be paid to the copyright owner for each record distributed under the license. *Id.* Many licensees negotiate rates below the statutory rate, which acts as a ceiling price. *Id.*

305. 17 U.S.C. §§ 801–803 (Supp. IV 1998) (providing establishment and operation of Copyright Arbitration Royalty Panels under Copyright Act). These panels, convened from time to time on recommendation of the Register of Copyrights to determine royalty rates under copyright compulsory licenses, replaced the now-defunct Copyright Royalty Tribunal in 1993. LEAFFER, *supra* note 304, §§ 8.2–8.3.

Germany's patent laws provide for the determination of royalty payment by the German Patent Office in cases where the patentee has declared willingness to grant licenses to all interested persons in return for "reasonable compensation." *See* German Patent Act of 16 December 1980, § 23(4), *reprinted in* 2D SINNOTT ET AL., *supra* note 187, at WEST GERMANY-78.24; *id.* § 27(1) *reprinted in* 2D SINNOTT ET AL., *supra* note 187, at WEST GERMANY-78.25 (providing for establishment in German Patent Office of "Patent Division" for assessment of compensation under section 23).

306. DRATLER, *supra* note 253, § 4.03 (defining "running royalties" of intellectual property as being determined by two quantities: either royalty rate, which is typically percentage amount; or royalty base, which is subject matter to which royalty rate is applied to calculate total amount of royalty).

307. PENROSE, *supra* note 117, at 172 (listing lack of way to determine what royalties are reasonable as one of six primary arguments against compulsory licensing); *see also* Rai, *supra* note 37, at 141–42 (arguing that expanded experimental use exemption is problematic because courts are not well-equipped to determine reasonable royalties for use of patented aspects of basic scientific research).

308. Patent infringement litigation against the federal government under 28 U.S.C. § 1498 provides a vivid example of the considerable transaction costs involved in a reasonable royalty determination. *See* 28 U.S.C. § 1498 (Supp. IV 1998). The federal government cannot be enjoined from infringing another's patent, and it is deemed to have condemned a license in the eminent domain sense when it infringes. Decca Ltd. v. United States, 640 F.2d 1156, 1166 (Ct. Cl. 1980). If the federal government is found to have infringed, it must pay "just compensation" for the taking in accordance with the Fifth Amendment. *Id.* at 1167 n.17. The typical remedy for infringement by the government is a reasonable royalty. Leesona Corp. v. United States, 599 F.2d 958, 968 (Ct. Cl. 1979). The court in Leesona explained that:

> The nature of the property taken by the government in a patent infringement suit has traditionally been a compulsory compensable license in the patent, and just compensation has in most cases been defined by a calculation of a "reasonable royalty" for that license, or, when a reasonable royalty cannot be ascertained, another method of estimating the value of the lost patent.

Id.

Because of the complexity of this determination, which frequently involves the testimony of competing expert witnesses, litigation to determine reasonable royalties can consume a number of years. An extreme example is the long-running *Hughes Aircraft* litigation against the federal government, in which suit under 28 U.S.C. § 1498 was filed in 1973 and liability found on appeal in 1983. *See* Hughes Aircraft Co. v. United States, 717 F.2d 1351 (Fed. Cir. 1983). The royalty rate was determined by the trial court in 1994, *Hughes Aircraft Co. v. United States*, 31 Fed. Cl. 481 (1994), and

evidence of an established royalty rate,[309] the traditional method of determining reasonable royalty in the patent litigation context involves application of the multi-factor "hypothetical license negotiation" framework of *Georgia-Pacific Corp. v. United States Plywood*.[310] The Patent Act provides that a "reasonable royalty" represents the minimum amount of "compensation adequate to compensate for the infringement,"[311] and invites the use of competing expert witnesses to assist the court in making this determination.[312] Any such system, requiring elaborate individual litigations and competing expert testimony, would involve transaction costs far too high to be a solution of the research tools accessibility dilemma.

Recent scholarship suggests alternative methods of royalty rate determination that could short-circuit or at least simplify the elaborate multi-factor hypothetical negotiation method. These alternative methods could be adapted to a reach-through royalty approach where the royalty base is the commercial product rather than the research tool itself.[313] One such method is a heuristic approach that involves payment of a royalty computed as twenty-five percent of the licensee's pre-tax profit rate on its

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the government's final certiorari petition denied in 1999, *Hughes Aircraft Co. v. United States*, 525 U.S. 1177 (1999).

309. It is unlikely that any established royalty rates would exist for patented research tools that have not been widely licensed or sold in the marketplace.

310. 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970). Former Federal Circuit Chief Judge Howard Markey has termed the challenge of applying the *Georgia-Pacific* factors to hypothesize a license negotiation between willing parties an exercise in "fantasy and flexibility":

> The methodology encompasses . . . fantasy because it requires a court to imagine what warring parties would have agreed to as willing negotiators; flexibility because it speaks of negotiations as of the time infringement began, yet permits and often requires a court to look to events and facts that occurred thereafter and that could not have been known to or predicted by the hypothesized negotiators.

Fromson v. Western Litho Plate & Supply Co., 853 F.2d 1568, 1575 (Fed. Cir. 1988) (Markey, C.J.).

311. 35 U.S.C. § 284 (1994); *see also* Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1544 (Fed. Cir. 1995) (en banc) (explaining that purpose of reasonable-royalty provision of § 284 is to "set a floor below which damage awards may not fall").

312. 35 U.S.C. § 284 (providing that "[a] court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances").

313. *Cf.* James G. Cullem, *Panning for Biotechnology Gold: Reach-Through Royalty Damage Awards for Infringing Uses of Patented Molecular Sieves*, 39 IDEA 553, 562 (1999) (suggesting, in context of determining damages for infringement of patented drug discovery tools, that licensor demand for reach-through royalties is appropriately factored into hypothetical license negotiation analysis of *Georgia-Pacific*); Richard S. Toikka, *Patent Licensing Under Competitive and Non-Competitive Conditions*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 279, 283 (2000) (stating that only slight modifications are needed to adapt economic model of patent having claims that directly read on patentee's product to case where patent covers technology or method used to make product).

sales.[314] This twenty-five percent baseline figure may be "fine-tuned" as necessary to the circumstances of each individual case[315] and apportioned between patent owners in the case of products developed through use of multiple patented research tools.

Another method is known as the "analytical approach," which calculates the reasonable royalty to be paid to the patentee as the difference between the sales prices of the accused product and the sum of: (1) the infringer's "direct or variable costs in the producing" the product; (2) the infringer's "fixed costs, including allocated overhead to produce the article"; and (3) "normal profits to the infringer on similar products."[316] Thus, the analytical approach represents the "residual between the infringer's anticipated net profit from practicing the infringed invention and the infringer's normal net profit."[317] Reasonable royalty rates have also been estimated as a percentage of the infringer's "net margin," i.e., its operating income before taxes.[318]

Despite the difficulties of assessing an appropriate royalty rate, the challenge of royalty quantification may be more of a problem in theory than practice. As foreign countries with compulsory licensing systems have recognized, the mere enactment of laws that contemplate judicial or administrative determination of licensing fees acts as an incentive to

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314. The "twenty-five percent rule" was proposed by Robert Goldscheider based on his empirical observations of several successful commercial license negotiations in the 1950s. Robert Goldscheider, *Measuring Damages in U.S. Patent Litigation*, 5 J. PROPRIETARY RTS. 2, 6–7 (May 1993) (explaining that each licensee "earned about 20 percent pre-tax profit on sales and each paid a 5 percent royalty on sales—or 25 percent of the pre-tax profitability rate"). *But see* Toikka, *supra* note 313, at 292–93 (criticizing rule as overly simplistic for applying twenty-five percent split to total gross profit without distinguishing between monopoly profit and normal profit).

315. Goldscheider, *supra* note 314, at 7.

316. *Id.* The "analytical approach" was recognized and applied in *TWM Mfg. Co. v. Dura Corp.*, 231 U.S.P.Q. 525, 528 (E.D. Mich. 1985), *aff'd*, 789 F.2d 895, 898–99 (Fed. Cir. 1986) (approving special master's award of thirty percent royalty determined by analytical approach rather than entirety of *Georgia-Pacific* factors).

Goldsheider warns that because it computes the royalty based on the value of the entire product sold by the infringer, the analytical method is only appropriately used in circumstances where the "entire market value" rule can be applied; i.e., where the patented component is part of a larger product and it is the patented component that creates purchaser demand of the product. Goldscheider, *supra* note 314, at 8–9. Thus, the "analytical approach" would require modification if it were to be applied to compute a reasonable royalty for use of a patented research tool not incorporated into the defendant's product.

317. Toikka, *supra* note 313, at 280 n.5.

318. John A. McMullen & David A. Halprin, *A New Technique for Quantifying Reasonable Royalty from Appropriate Case Law*, 75 J. PAT. & TRADEMARK OFF. SOC'Y 843, 844 (1993) (asserting that this method "gives a relative, but quantitative, measure of the importance of the infringing activity to the infringer's financial performance").

voluntary licensing at more reasonable terms.[319] This phenomenon may explain why few applications for compulsory licenses have actually been made in Europe.[320] By analogy, the mere fact of legislative or judicial recognition in the United States of a broadened experimental use doctrine as proposed herein may encourage consensual agreements to reasonable licensing terms between research tool patent holders and research tool users.[321]

VIII. CONCLUSION

The current narrow formulation of the experimental use doctrine in U.S. patent jurisprudence, which limits exemption from infringement liability to purely non-commercial, "philosophical" uses of patented inventions, means that the defense is not available to the vast majority of users of patented research tools. Many of these users are involved in collaborative efforts between universities and industry that require proprietary research tools to develop new therapeutic and diagnostic products, activity that by definition will involve some degree of commercialization or profit expectation. The proliferation of patents on research tools in the biotechnological and biomedical sector has resulted in stacking royalty obligations and heightened transaction costs that threaten to slow or stop the development of new drugs and devices critical to public health.

A potential solution is a "liability rule" model that permits the non-consensual "development use" of research tools not readily available for licensing or purchase, while providing an ex post royalty payment to the patent owner that would be correlated to the commercial value of the new product developed from the non-consensual use. This "reach-through" royalty approach provides the best approximation of the true worth of the research tool to its user. It ensures a royalty award of sufficient amount to maintain incentives for the development and patenting of new research tools, yet alleviates the access restrictions and up-front costs currently associated with acquisition and use of many proprietary research tools.

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319. DRATLER, *supra* note 253, § 3.03[1][a] (contending that mere threat of royalty rate determination by judicial or administrative officials "may have the effect of spurring private voluntary transactions"); PENROSE, *supra* note 117, at 174–75 (explaining modest number of official adjudications of reasonable royalty in compulsory licensing context).

320. PENROSE, *supra* note 117, at 175 n.25 (recognizing that compulsory licensing schemes in Europe and Canada provide "every inducement for the patentee and the foreign concern desiring to use the invention to get together and settle their differences").

321. Ayres & Talley, *supra* note 278, at 1094 (suggesting, in context of patented improvement inventions, that if liability rule such as compulsory licensing were applied, traditional perceptions of extensive litigation and courts' inability to tailor royalty amount would actually facilitate parties' bargaining "on their own terms, not those dictated by the underlying liability rule").