
Why Not Try the Experiment and Stop Pointing the Finger? Modern University Research Unaffected by a Narrow Experimental Use Exception

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I. INTRODUCTION

Since the early nineteenth century U.S. patent law acknowledged the common law “Experimental Use Exception,”¹ which provides an exemption from infringement liability for unauthorized uses of patented inventions that is for research or experimental purposes and not for profit.² Traditionally invoked for *de minimis*

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¹ This comment does not address the “Experimental Use” doctrine, which provides that a public use for experimental rather than commercial purposes is an exception to the statutory bar to obtaining a patent grant under § 102(b) of the Patent Act. 35 U.S.C. § 102(b) (2000).

² There are two “Experimental Use Exceptions” to infringing uses. The first evolved from case law. *See e.g.*, *Pfizer v. Int’l Rectifier Corp.*, 217 U.S.P.Q. 157, 160 (C.D. Cal. 1982) (stating “nothing in the Patent Act of 1952 even mentions any experimental use exception and the experimental use exception is instead purely case law”). The second, known as the Hatch-Waxman Act, is a statutory experimental use exception that only applies to specific products, pharmaceutical drugs and medical devices. *See Drug Price Competition and Patent Term Restoration Act of 1984*, Pub. L. No. 98-417, 98 Stat. 1585 (codified

infringement, the experimental use defense first appeared in dictum in the 1813 case of *Whittemore v. Cutter*.³

In *Whittemore*, Justice Story opined that “it could never have been the intention of the legislature to punish a man, who constructed a [patented] machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”⁴ Thus, under this judicially created exception, modern courts have held that activities undertaken “merely for experimental purposes” without the “intent to derive profits or practical advantage” do not constitute infringement.⁵ Even though this defense has almost never succeeded in practice,⁶ courts have still consistently acknowledged the existence of a very limited and narrow experimental use defense.⁷

Despite this relatively meaningless defense, American academic and non-profit research institutions “have operated under the mistaken belief that basic science is protected by an experimental use exception....”⁸ Nevertheless, academic scientists feel adequately protected to undertake activities under the research rubric that would otherwise amount to patent infringement by continuing to rely upon this doctrine.⁹

While legitimate biotechnological academic research has never conventionally been a serious target for patent infringement, the increasing number of commercially valuable research tool patents¹⁰ in the biotechnology field has challenged traditional

as amended at 21 U.S.C. § 355 (West. Supp. 1994) and 35 U.S.C.A. § 271(d)-(h) [hereinafter Hatch-Waxman]. The Hatch-Waxman Act exempts a pharmaceutical manufacturer, seeking expedited FDA approval to market a generic equivalent of a patented drug, from infringement liability by modifying the patent laws to provide that “it shall not be an act of infringement to make, use, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.” 35 U.S.C. § 271(e)(1) (2000).

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

⁴ *Id.*

⁵ See e.g. *Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697, 713 (D. Colo. 1935), *rev'd on other grounds* by 87 F.2d 35, 42 (10th Cir. 1936) (holding the defendant, who sold parts for a patented machine to a School, was not liable for contributory infringement because the school used its machines in a laboratory for experimental purposes).

⁶ Because litigation costs often deter enforcement of unauthorized noncommercial uses of patented inventions, most judicial decisions considering the experimental use exemption have primarily included disputes involving commercial uses where the experimental use defense has been frequently raised but rarely sustained. See, e.g., *Spray Refrigeration Co. v. Sea Spray Fishing*, 322 F.2d 34, 36-37 (9th Cir. 1963) (finding the use of a patented apparatus and method for freezing fish constituted patent infringement because the use occurred in course of a commercial operation of kind which the patent was designed to serve); see also DONALD S. CHISUM, CHISUM ON PATENTS 16.03[1][B] (2005) (stating “relatively few decisions actually excused the making and use of patented products or processes on the basis of experimental or nonprofit purpose”).

⁷ See Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1086 (1989).

⁸ See Ed Ergenzinger & Murray Spruill, *Basic Science in U.S. Universities Can*

Infringe Patents, THE SCIENTIST, 43, 43 (Mar. 10, 2003); see also Philippe Ducor, *Research Tool Patents and the Experimental Use Exemption—a no-win situation?*, 17 NAT. BIOTECH. 1027 (1999).

⁹ E.g., S. Peter Ludwig & Jason C. Chumney, *No Room for Experiment: the Federal Circuit's Narrow Construction of the Experimental Use Defense*. 21 NAT. BIOTECH. 453 (2003) [hereinafter Ludwig & Chumney].

¹⁰ “Research tools” are generally are compositions or methods useful in conducting experiments used by scientists to conduct research and development of new drugs, therapies, diagnostic methods, and other therapeutic products. Research tools are further discussed in Part III. See *infra* notes 30-40 and accompanying text.

views on the experimental use exception.¹¹ Mostly, because court rulings broadly expanded patentable subject matter to include biotechnological inventions¹² and the Bayh-Dole Act¹³ granted universities ownership of patents on inventions created with federal research funding, the number of biotechnology patents obtained by universities has skyrocketed since 1980.¹⁴ Meanwhile, it is not unusual today for university research projects to receive millions of dollars in sponsored research funding from both public and private corporate companies.¹⁵ Thus, a sudden increase of biotechnological research and development in the United States in the past twenty years,¹⁶ coupled with a corresponding increase in patenting activity, has cooperatively changed the intellectual property relationships between universities and industry concerning patented research tools.¹⁷

The decision in *Madey v. Duke University*,¹⁸ however, reaffirmed the Court of Appeals for the Federal Circuit's ("CAFC") narrow construction of the experimental use defense and affords non-profit research institutions little, if any, protection under the experimental use defense.¹⁹ The CAFC held that a "very narrow and strictly limited experimental use defense" applies only if use of the patented invention is "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."²⁰ Furthermore, the defense does not apply if the use is "in furtherance of the alleged infringer's legitimate business" regardless of the "profit or non-profit" status of the user and "regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain."²¹ This decision, therefore, effectively narrows the research defense to exclude any unauthorized use of intellectual property in the course of university research, particularly when university research and

¹¹ See *Ducor*, *supra* note 8, at 1027.

¹² The Supreme Court construed the Patent Act's language to mean that "anything under the sun . . . made by man" was patentable subject matter so long it is a "product of human ingenuity" in the form of "a non[-]naturally occurring manufacture or composition of matter." *Diamond v. Chakrabarty*, 447 U.S. 303, 305, 308-09 (1980) (holding that a new, artificially engineered strain of bacteria was a patentable invention).

¹³ 35 U.S.C. §§ 200-12 (2000).

¹⁴ Academic institutions have seen a significant increase in technology transfer activity. For example, before 1980, fewer than 250 patents were issued to U.S. universities each year. Between fiscal year ("FY") 1991 and FY 2002, the number of new patents filed increased more than 310 percent. The Association of University Technology Managers, *available at* http://www.autm.net/aboutTT/aboutTT_faqs.cfm#4. See also J. Thursby & M. Thursby, *University Licensing and the Bay-Dole Act*, 301 *SCIENCE* 1052 (2003).

¹⁵ Universities, teaching hospitals, and research institutions generated nearly \$1.1 billion (U.S.) in royalties and fees from discoveries licensed to companies in FY 2001. Ted Agres, *The Fruits of University Research*, 17 *THE SCIENTIST*, July 14, 2003, at 55; see also Ludwig & Chumney, *supra* note 9, at 453.

¹⁶ Biotechnology Industry Organization, a trade group for the biotechnology industry, reports that the biotechnology industry has skyrocketed since 1992, with U.S. revenues increasing from \$8 billion in 1992 to \$39.2 billion in 2003. Biotechnology Industry Organization Guide to Biotechnology, *available at* <http://www.bio.org/speeches/pubs/er/> [hereinafter Biotechnology Guide].

¹⁷ Sasha Blaug et al., *Managing Innovation: University-Industry Partnerships and the Licensing of the Harvard Mouse*. 22 *NAT BIOTECH*, 761 (2004).

¹⁸ 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003).

¹⁹ *Id.*

²⁰ *Id.* at 1362.

²¹ *Id.*

development efforts are targeted at the commercialization of new biomedical research tools.²² Thus, universities are unlikely to continue to rely upon the common law experimental use exception as a defense in a patent infringement action for almost any research project, even non-profit projects, because almost all research would be furthering the university's legitimate business interests.²³

Consequently, the experimental use doctrine, as currently interpreted by the Federal Circuit, has renewed the scholarly debate about the access to patented research tools.²⁴ Most legal scholars believe that by increasing the risk of future litigation for the unauthorized use of patented research tools the current narrow construction of the experimental use exception will deter scientific discovery because it increases the transaction costs for the research tools necessary for a particular project. Basically, the cost or difficulty of acquiring these fragmented intellectual property rights may be so severe as to postpone, or even discontinue, the development of innovative products.²⁵

This comment, by addressing and disposing of the criticisms of the CAFC's current construction of the experimental use defense, proposes a minority view. Specifically, congressional or judicial reform of the experimental use defense is unnecessary because practical solutions that exist in a modern collaborative research setting encourage scientific discovery, even at universities. Part II provides a definition of biotechnological research tools and their importance to scientific discovery and unique research conducted by academic institutions. Part III outlines both past and present U.S. courts' interpretations of the experimental use doctrine. Part IV discusses and summarizes the criticisms of the current interpretation of the experimental use defense. Finally, Part V argues that these criticisms are merely conjectural and the CAFC's narrow experimental use defense has no substantive affect on academic research. Furthermore, this part presents the practical and realistic solutions that have emerged from the modern biotechnology research world that advance scientific discovery at universities in the face of the current narrow experimental use defense.

II. THE IMPORTANCE OF BIOTECHNOLOGY RESEARCH TOOLS

For the purpose of this comment, research tools are confined to the biotechnology field because access problems to patented research tools are most acute in biotechnology compared to any other scientific field.²⁶ This is mostly due to, the significant growth in the past three decades of transfer of biotechnology between universities and industry,²⁷ the research intensive nature of biotechnology,²⁸ and the

²² See Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 5-7 (2001).

²³ See Michelle Cai, *Madey v. Duke University: Shattering the Myth of Universities' Experimental Use Defense*, 19 BERKELEY TECHNOLOGY L. J. 175, 185 (2004); Tom Saunders, *Renting Space on the Shoulders of Giants: Madey and the Future of the Experimental Use Doctrine*, 113 YALE L. J. 261 (2003).

²⁴ These criticisms will be further addressed in Part VI *infra*.

²⁵ See Cai, *supra* note 23, at 185.

²⁶ See *id.* at 11.

²⁷ Blaug, *supra* note 17, at 761. See also Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L. J. 177, 179 n.6 (1987) (stating "The sudden juxtaposition of commercial incentives and scientific norms has been particularly striking in the

intellectual property protection that biotechnology research tools enjoy.²⁹

Research tools are generally accepted as inventions that, at least in part, provide the foundation for further invention and discovery, and therefore concern products or processes whose main use is in experimental research.³⁰ Since the discovery of the double helical structure of DNA,³¹ scientists have developed biotechnological research tools at a staggering pace, which has drastically transformed the modern biotechnology research industry.³² While some research tools represent fundamental research platforms that “open up new and uncharted areas of investigation,” others are narrower or even marketed as end products to ordinary consumers.³³ Some researchers view the resources they rely on in the laboratory as “tools,”³⁴ while the biotechnology industry, whose primary business is to manufacture and sell these resources, considers these same “research tools” as consumer “end products.”³⁵ Although “research tools” can have many meanings and serve different functions, they are primarily the experimental resources used for scientific discovery.

For instance, the National Institutes of Health (“NIH”) Working Group on Research Tools, formed in 1997 to investigate the problems of NIH grantees in obtaining access to patented research, broadly defined “research tools” as “the full range of resources that scientists use in the laboratory,” including “cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools, such as polymerase chain reaction (“PCR”),³⁶ methods, laboratory equipment and machines, databases and computer software.”³⁷ This definition broadly covers inventions upon which breakthrough research and end products can be built. In this context, accordingly, research tools are particularly important to the basic research³⁸ that

biomedical science . . . because of the strong public interest in health-related research and . . . the rapid onset and proliferation of university-industry research relationships in the biotechnology field”).

²⁸ The U.S. biotech industry spent \$17.9 billion on research and development in 2003. See *Biotechnology Guide*, *supra* note 16.

²⁹ Mueller, *supra* note 22, at 11. Overall, biotechnology significantly contributes to university technology strength. “In 2002, life sciences contributed 44% to the technological strength of the leading US universities, compared to a 35% contribution from information technology and a 21% contribution from all other technology categories.” Agres, *supra* note 15, at 55.

³⁰ A. Rai, *Genome Patents: A Case Study in Patenting Research Tools*, 77 *ACAD. MED.* 1368 (2002).

³¹ See J. D. Watson & F.H.C. Crick, *Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid*, 171 *NATURE* 737 (1953).

³² See *Biotechnology Guide*, *supra* note 16. The U.S. currently has 1,473 biotechnology companies, of which 314 are publicly held, with a total market capitalization of \$311 billion as of mid-March 2004 compared to only \$45 billion in 1994. *Id.*

³³ See Rai, *supra* note 30, at 1368.

³⁴ Some confine “research tools” to only methods and reagents or inventions that do not possess commercial potential beyond the realm of the research laboratory. Mueller, *supra* note 22, at 5-7.

³⁵ See NATIONAL INSTITUTES OF HEALTH (NIH), REPORT OF THE NATIONAL INSTITUTES OF HEALTH (NIH) WORKING GROUP ON RESEARCH TOOLS 3, at <http://www.nih.gov/news/researchtools> (June 4, 1998) [hereinafter NIH Report].

³⁶ The PCR process selectively and exponentially amplifies (or multiplies) a specific region of DNA, producing quantities of DNA sufficient for experimentation and analysis. See generally Kamrin T. MacKnight, *The Polymerase Chain Reaction (PCR): The Second Generation of DNA Analysis Methods Takes the Stand*, 20 *SANTA CLARA COMPUTER & HIGH TECH. L.J.* 95, 116-120 (2003) (explaining PCR for the non-scientist attorney).

³⁷ NIH Report, *supra* note 35.

³⁸ Basic research is “directed solely toward expanding human knowledge” and discovery, and not

yields landmark discoveries and is traditionally conducted at universities,³⁹ because future pioneering innovations depend upon the free availability of such technologies.⁴⁰

Specific groundbreaking examples of research tools include, among other things, recombinant DNA technology,⁴¹ monoclonal antibodies,⁴² the polymerase chain reaction and the enzymatic amplification of DNA,⁴³ DNA hybridization,⁴⁴ DNA sequencing,⁴⁵ chemical synthesis of DNA oligonucleotides,⁴⁶ and even particular genes.⁴⁷ These inventions subsequently ushered in significant modern biological research tools such as transgenic mice,⁴⁸ DNA micro-arrays,⁴⁹ the sequence of the

translational or applied research, which focuses on solving practical problems. Eisenberg, *supra* note 27, at 178 n.1.

³⁹ See Cai, *supra* note 23, at 179.

⁴⁰ See Ducor, *supra* note 8, at 1027.

⁴¹ Techniques that combine genetic material from different sources by cutting apart and splicing together different pieces of DNA. Stanley N. Cohen et al., *Construction of Biologically Functional Bacterial Plasmids In Vitro*, 70 PROC. NAT'L ACAD. SCI. USA 3240 (1973). Commonly known as the Cohen-Boyer patents. S.N. Cohen & H.W. Boyer, *Process for Producing Biologically Functional Molecular Chimeras*, U.S. Patent No. 4,237,224 (issued Dec. 2, 1980).

⁴² Monoclonal antibodies are antibodies of exceptional purity and specificity that are able to recognize and bind to a specific antigen. See generally G. Kohler & C. Milstein, *Continuous Cultures of Fused Cells Secreting Antibody of Predefined Specificity*, 256 NATURE 495 (1975). Monoclonal antibodies have numerous diagnostic roles, including grouping blood types and identifying infectious agents, as well as testing for pregnancy, blood clots, heart disease, and some cancers. Currently, eighteen monoclonal antibodies ("MAb") are approved for therapeutic use in the United States, and the global therapeutic MAb market is worth \$5.4 billion. Mark Greener, *MAbs Turn 30*, 19 THE SCIENTIST, Feb. 14, 2005, at 14.

⁴³ Kary B. Mullis & Fred A. Faloona, *Specific Synthesis of DNA in Vitro via a Polymerase-Catalyzed Chain Reaction*, 155 METHODS ENZYMOLOGY 335 (1987); Randall K. Saiki et al., *Primer-Directed Enzymatic Amplification of DNA with a Thermostable DNA Polymerase*, 239 SCIENCE 487 (1988); See MacKnight, *supra* note 36, at 116-20.

⁴⁴ This technique is useful for determining sequence similarity among DNAs of different origin and the amount of sequence repetition within one DNA sequence. E. M. Southern, *Detection of Specific Sequences Among DNA Fragments Separated by Gel Electrophoresis*, 98 J. MOLECULAR BIOLOGY 503 (1975).

⁴⁵ DNA sequencing is the process of determining the exact order of the chemical building blocks (called bases and abbreviated A, T, C, and G) that make up DNA. F. Sanger & A.R. Coulson, *A Rapid Method for Determining Sequences in DNA by Primed Synthesis with DNA Polymerase*, 25 J. MOLECULAR BIOLOGY 441 (1975).

⁴⁶ The making of short DNA molecules, often 10-40 bases. K. Itakura et al., *Synthesis and Use of Synthetic Oligonucleotides*, 53 ANN. REV. BIOCHEMISTRY 323 (1984).

⁴⁷ Human gene sequences play an important role in understanding, diagnosing, and even treating, the most common and serious of human diseases, including: infectious diseases, diabetes, cancer, multiple sclerosis, Alzheimer's disease, and even immune system disorders. For instance the BRCA1 gene patent covered any method of diagnosing a predisposition for breast or ovarian cancer that used the BRCA1 gene sequence. U.S. Patent No. 6,130,322 (issued Oct. 10, 2000)

⁴⁸ A transgenic animal is one that carries a foreign gene that has been deliberately inserted into its genome. The foreign gene is constructed using recombinant DNA methodology. For example, the Harvard "OncoMouse," invented by Leder-Stewart, assigned to Harvard University and subsequently exclusively licensed to E.I. du Pont de Nemours, is a mouse that grows tumors and is a useful model for cancer research. See T.A. Stewart et al., *Spontaneous Mammary Adenocarcinomas in Transgenic Mice that Carry and Express MTV/myc Fusion Genes*, 38 CELL 627 (1984).

⁴⁹ This technology allows the researcher to monitor the interactions among thousands of genes simultaneously. Thousands of DNA or protein molecules are arrayed on glass slides to create DNA chips and protein chips, respectively. Researchers currently use microarray technology mostly to study gene structure and function. Mark Schena et al., *Quantitative Monitoring of Gene Expression Patterns with a Complementary DNA Microarray*, 270 SCI. 467 (1995).

human genome,⁵⁰ and embryonic stem cells.⁵¹

Revolutionary laboratory methods have not only advanced basic research but also have changed the approach to applied commercial research.⁵² Modern drug development is yet another example of how research tools provide the necessary stepping stone to future inventions.⁵³ In the past, difficulties using recombinant DNA techniques were in identifying, cloning, sequencing, and expressing the genes that encoded particular proteins.⁵⁴ Technical advances in laboratory methods and automation have simplified this process by transforming previous painstaking laboratory tasks into routine techniques.⁵⁵ For instance, before recombinant DNA technology, applied pharmaceutical research typically involved time-consuming and expensive new drug searches that screened libraries of chemically synthesized derivatives.⁵⁶ But this process rarely yielded promising drug candidates and instead recombinant DNA technology quickly developed more complex plasmids⁵⁷ that have allowed proteins to be expressed *in vitro* as well as enabling new high-throughput screening⁵⁸ and combinatorial chemistry technologies that take advantage of recombinant DNA technology,⁵⁹ subsequently changing the strategic drug development paradigm.⁶⁰

The availability of patent protection for biotechnological research tools has undoubtedly promoted valuable investment in developing important “research platform technologies,” benefiting both private and public sector research.⁶¹ Even more notably, since the passage of the Bayh-Dole Act in 1980,⁶² universities have increasingly commercialized their research discoveries,⁶³ earning nearly \$1.24

⁵⁰ See The International Human Genome Sequencing Consortium, *Initial Sequencing and Analysis of the Human Genome*, 409 NATURE 860 (2001); J. Craig Venter et al. *The Sequence of the Human Genome*, 291 SCI. 1304 (2001).

⁵¹ See J.A. Thompson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCI. 1145 (1998).

⁵² See John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 107-08 (2001).

⁵³ See Anita Varma & David Abraham, *DNA Is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market*, 9 HARV. J.L. & TECH. 53, 65 (1996).

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ See Lawrence M. Gelbert & Richard E. Gregg, *Will Genetics Really Revolutionize the Drug Discovery Process?*, 8 CURRENT OPINION BIOTECHNOLOGY 669, 669 (1997) [hereinafter Gelbert].

⁵⁷ Plasmids are molecules of DNA that are found in bacteria separate from the bacterial chromosome, that allow foreign genes to be introduced into different bacterial strains. See *Biotechnology Guide*, *supra* note 16.

⁵⁸ High throughput screening involves monitoring a large number of samples at once, such as microarray technology. See generally Schena, *supra* note 49 and accompanying text.

⁵⁹ Gelbert, *supra* note 56, at 669.

⁶⁰ The Cohen-Boyer technology became the foundation of significant biotechnology-drug products, such as insulin for the treatment of diabetes, growth hormone for children with growth deficiencies and interferon for cancer patients. See *Biotechnology Guide*, *supra* note 16.

⁶¹ Rebecca S. Eisenberg, *Why the Gene Patenting Controversy Persists*, 77 ACAD. MED. 1381, 1384 (2002).

⁶² This legislation permitted universities and their contractors to take title, or legal right of possession, to inventions or discoveries that result from federally funded research, with the intent to place the burden on institutions to ensure that important discoveries were commercialized to benefit the public good. 35 U.S.C. §§ 200-212 (2000).

⁶³ See Shreefal Mehta, *The Emerging Role of Academia in Commercializing Innovation*, 22 NATURE

billion from their discoveries in 2000.⁶⁴ As a result, universities have increasingly pursued and protected their intellectual property rights, established new start-up companies, licensed their technologies, and even developed their own venture arms to finance and commercialize their technologies.⁶⁵ For instance, the Cohen-Boyer patents,⁶⁶ generated more than \$200 million for Stanford University and the University of California until they expired in 1997, and the loss of Cohen-Boyer revenue represented a drop of nearly \$12 million annually to each school.⁶⁷

But not only have universities generated revenue by procuring and licensing patented technologies, but universities have also aggressively pursued their commercial interests by suing commercial companies for patent infringement.⁶⁸ For example, in 1999, Genetech settled a patent infringement suit with the University of California for \$ 200 million and Glaxo-Wellcome settled its suit with the University of Minnesota for \$ 300 million. Subsequently, other universities have filed patent infringement lawsuits against corporations.⁶⁹ In fact, a simple survey of all patent infringement cases involving universities found that universities were plaintiffs in nineteen out of twenty cases that were decided by the Federal Circuit between 1983 and September of 2004.⁷⁰ Because obtaining and enforcing patents is an extremely expensive investment, this behavior is in the commercial self-interest of the universities.

Unquestionably, universities have become sophisticated in the intellectual property business and have without a doubt enjoyed the benefits of patenting their upstream research tool inventions. But these commercial benefits that universities have realized through patenting their research tools have further obscured the traditional differences between basic academic research and applied commercial research, where both commercial and academic research concurrently serve legitimate business interests.⁷¹

BIOTECHNOLOGY 21, 21 (2004) (noting “the university has been slowly changing from the ivory tower to economic engine”).

⁶⁴ This income represents 4.7% of their total research expenditures. See Thursby, *supra* note 14, at 1052.

⁶⁵ See Mehta, *supra* note 63, at 21. This is seen by the increase of Technology Transfer Offices (“TTO”) at Universities. TTOs determine whether discoveries can be patented, obtain and defend patents, and coordinate business relationships. Once rare, 25 in the United States prior to 1980, there are now about 3,300 TTOs in the US at major universities, research institutes, and hospitals. Karen Pallarito, *When Science Has a Potential Payoff*, 19 THE SCIENTIST, Jan. 17, 2005, at 34.

⁶⁶ See U.S. Patent No. 4,237,224 (issued Dec. 2, 1980).

⁶⁷ Ted Agres, *Life Science Patents Enrich Academe*, 16 THE SCIENTIST, Oct. 14 2002, at 63.

⁶⁸ Rebecca S. Eisenberg, *Patent Swords and Shields*, 299 SCI. 1018, 1018-19 (2003).

⁶⁹ *Id.* These include Baylor College of Medicine, Cornell University, Columbia University, University of Rochester, University of California and the Massachusetts Institute of Technology. *Id.*

⁷⁰ This survey provided empirical data of cases only decided by the Federal Circuit but did not include cases where universities were sued for patent infringement but never appealed to the Federal Circuit Tao Huang, *The Experimental Use Doctrine and Biomedical Research*, 11 MICH. TELECOMM. TECH. L. REV. 97 (2004).

⁷¹ See Rochelle Dreyfuss, SYMPOSIUM: BIOTECHNOLOGY PATENTS GET SPECIAL TREATMENT: Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived? 46 ARIZ. L. REV. 457, 464-65 (2004) (noting that “[t]o earn additional funding, universities have begun to reach further upstream for patents and to take a harder line on licensing, which makes them look even more commercial....”).

III. EXPERIMENTAL USE EXCEPTION

Patent infringement liability arises whenever an individual⁷² makes, uses, sells, offers for sale, or imports into the United States a patented invention without the patent owner's consent.⁷³ Even though the Patent Act does not authorize a statutory experimental use defense, courts have nevertheless recognized the common law "experimental use" defense, which exempts the unauthorized use of a patented invention from infringement liability if the use was experimental.⁷⁴ This defense is rooted in the early nineteenth century case of *Whittemore v. Cutter*, once thought to broadly shield research from patent infringement liability, where Justice Story found that "it could never have been the intention of the legislature to punish a man, who constructed a [patented] machine merely for philosophical experiments...."⁷⁵ Shortly after, in *Sawin v. Guild*,⁷⁶ Justice Story further explained that patent infringement must involve "an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification."⁷⁷

By the mid-nineteenth century, in *Poppenhusen v. Falke*,⁷⁸ it was "well settled" that experimentation "for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement" is not patent infringement.⁷⁹ The court in *Ruth v. Stearns-Roger Manufacturing Co.*⁸⁰ further suggested that educational research may be immune from infringement suits when use of the patented invention was "merely for experimental purposes, without any intent to derive profits."⁸¹ Thus, the experimental use defense was not applicable in instances where infringement was for commercial gain and it was instead limited to those rare instances where the accused infringer's use of a patented invention was for gratifying a philosophical taste, or curiosity, or for mere amusement.

The CAFC continued to narrow the experimental use exception, holding that if there is any commercial aspect whatsoever to the infringing activity, the experimental use defense is inapplicable.⁸² In *Roche Prod., Inc. v. Bolar Pharm. Co.*,⁸³ the court held that conducting unlicensed experiments with the purpose of adapting the patented invention to the infringer's legitimate business does not fall under experimental use, even though there was no economic injury to the plaintiff, and no direct economic gain to the infringer.⁸⁴

⁷² Liability may be imposed on corporations and other organizations for the acts of their agents and even on Governmental bodies under some circumstances. Donald S. Chisum, *Chisum on Patents* 16.06 (2005).

⁷³ 35 U.S.C. § 271(a) (2000). Liability for infringing research tool patents usually occurs under the "uses" and "makes" provisions of the statute. Mueller, *supra* note, at 22.

⁷⁴ See e.g., *Ruth*, 13 F. Supp. at 697.

⁷⁵ 29 F. Cas. 1120.

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

⁷⁷ *Id.* at 555.

⁷⁸ 19 F. Cas. 1048 (C.C.S.D.N.Y. 1861) (No. 11,279).

⁷⁹ *Id.* at 1049.

⁸⁰ 13 F. Supp. 697 (D. Colo. 1935), *rev'd on other grounds* by 87 F.2d 35, 42 (10th Cir. 1936).

⁸¹ *Id.* at 513.

⁸² See, e.g., *Madey*, 307 F.3d at 1363; *Embrex, Inc. v. Service Eng'g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000); *Roche Prod., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984).

⁸³ 733 F.2d 858.

⁸⁴ *Id.* at 863.

In *Roche*, the defendant had a strong economic incentive to conduct experiments on the generic version of a drug to satisfy as many of the FDA requirements as early as possible in order to avoid future administrative delays.⁸⁵ The plaintiff, Roche, learned of the defendant's activities and sued to enjoin the defendant's use of the drug alleging that the defendant's importation and subsequent use constituted infringement.⁸⁶

While acknowledging the existence of an experimental use exception, the court rejected the defendant generic drug manufacturer's argument that the experimental use defense applied to its use of a patented drug to conduct clinical tests during the patent term.⁸⁷ Characterizing the experimental use defense as "truly narrow," the court found that the defendant's use of the drug was "no dilettante affair such as Justice Story envisioned" because the purpose of the defendant's tests was to gather data necessary to obtain FDA approval to market a generic version of the drug as soon as the patent expired.⁸⁸ The court held that the defense does not permit unlicensed experiments conducted with the intent to adapt the patented invention to the experimenter's business, as opposed to experiments conducted "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."⁸⁹

In *Embrex*,⁹⁰ the Federal Circuit re-acknowledged the existence of the common law experimental use exception, but refused to apply it to the accused infringer's "commercial" activity.⁹¹ The case involved the alleged infringer's failure to design around⁹² Embrex's patents.⁹³ Acknowledging that "binding precedent" recognizes a narrow defense experimental use defense, the court held that the tests were motivated by a commercial purpose and therefore constituted infringement.⁹⁴ More notably, the *Embrex* court established that the post-Roche 1984 passage of the Hatch-Waxman Act⁹⁵ did not repeal the common law experimental use doctrine.⁹⁶

Most recently, the CAFC, in *Madey v. Duke*, reaffirmed its narrow position set forth in *Roche* and *Embrex*.⁹⁷ The plaintiff in *Madey*, was a former research professor at Duke University and owner of two patents covering laboratory equipment.⁹⁸ After a non-amicable parting, Duke University continued to use the

⁸⁵ *Id.*

⁸⁶ *Id.* at 860.

⁸⁷ *Id.* Congress enacted 35 U.S.C. § 271(e), in response to the *Roche* decision, which legislatively overruled part, but not all, of *Roche* by creating a "safe harbor" for generic drug manufacturers to test patented drugs for purposes of preparing FDA bioequivalency data. See 35 U.S.C. § 271(e), *supra* note 1.

⁸⁸ 733 F.2d at 863.

⁸⁹ *Id.*

⁹⁰ 216 F.3d 1343.

⁹¹ *Id.*

⁹² Making minor changes to the patented design to avoid infringement.

⁹³ See *Embrex*, 216 F.3d at 1349.

⁹⁴ *Id.*

⁹⁵ See Hatch-Waxman, *supra* text accompanying note 2.

⁹⁶ *Id.* (finding that Roche was "superseded on other grounds by 35 U.S.C. § 271(e) (1994)"). This characterization 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.

⁹⁷ See *Madey*, 307 F.3d at 1362.

⁹⁸ Duke University recruited Madey, from Stanford University, to establish a free electron laser laboratory ("FEL lab") and research program at Duke. While at Stanford, Madey obtained sole

patented research equipment in furtherance of a federal funded research project.⁹⁹ Madey subsequently brought suit against Duke for patent infringement based on Duke's continued unauthorized use of his patented research equipment.¹⁰⁰

Duke successfully defended at trial using, among other things, the experimental use exception.¹⁰¹ On appeal, however, the CAFC held that no "conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications" is immune from a patent infringement claim.¹⁰²

Adopting a very liberal view of "infringer's legitimate business," the court found that research projects at major research universities, like Duke University, may not have any "commercial application whatsoever" but may nevertheless further the institution's business objectives, such as "educating and enlightening students and faculty participating in these projects."¹⁰³ Therefore, according to the CAFC, when such research furthers "the institution's legitimate business objectives," infringement is possible regardless of the "profit or non-profit" status of the user and "regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain."¹⁰⁴

The consequences of the *Madey* court's decision do not make the unauthorized commercial uses of others' patented research tools in academic research illegal, as these uses were already likely considered infringement in light of pre-*Madey* interpretations of the experimental use defense. Instead, the *Madey* court has "merely shattered a long-held myth that universities are immune to patent infringement liability under the experimental use defense"¹⁰⁵ because nearly all university research serves legitimate business objectives by educating and enlightening students and faculty. Perhaps most importantly, universities derive significant commercial value from the ownership of patents arising from their research, in addition to the educational and academic value. Thus the *Madey* ruling is consistent with Justice Story's original view that commercial intent is the "hallmark of liability."¹⁰⁶

IV. ACADEMIC CRITICISMS OF A NARROW EXPERIMENTAL RESEARCH EXCEPTION

Even before the *Madey* court's holding, legal commentators advocated for a broader experimental use defense as a solution to the surmised problem that biotechnology research tool patents will ultimately impede innovation rather than promote it.¹⁰⁷ Unsurprisingly, the *Madey* court's restrictive construction of the

ownership of two patents, which included some of the equipment in his FEL lab, which he moved from Stanford to Duke. *Id.* at 1352-1353.

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.* at 1362.

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ Cai, *supra* note 23, at 175.

¹⁰⁶ Mueller, *supra* note 22, at 20.

¹⁰⁷ Mueller, *supra* note 22, at 38. (suggesting a broader experimental use defense that allows for the non-consensual "development use" of research tools); Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1201-02 (2000) (proposing a fair use doctrine that is similar to the one found in copyright law); Eisenberg, *supra* note 7, at 1017 (asserting that purpose and scope of

experimental use defense has only invigorated the scholarly debate over the proper scope of experimental use defense for research tools.¹⁰⁸

Critics of the CAFC's narrow construction of the experimental use defense argue that it will have "chilling effect on academic scientific research"¹⁰⁹ because it "threatens to delay or stymie research"¹¹⁰ conducted by universities, inevitably affecting scientific progress in general by introducing expensive transaction costs into research that are far removed from any commercial activity.¹¹¹ In short, the ever-increasing number of patentable research tools creates multiple patent rights owned by multiple actors¹¹² and the cost or difficulty of acquiring these intersecting patent rights that are necessary for a particular project can hinder further research and development.¹¹³ To overcome these problems, these critics urge a more expansive or even a statutorily sanctioned experimental use defense as an appropriate remedy.¹¹⁴

Much of this discourse echoes Professors Michael Heller's and Rebecca Eisenberg's prominent 1998 article in *Science* magazine that predicted a "tragedy of the anticommons" if patent protection for biomedical research tools continues.¹¹⁵

experimental use defense "are not well defined" and that "this vaguely defined doctrine is becoming less satisfactory" because academic research increasingly utilizes patented materials); *See also* Rai, *supra* note 30, at 1368. (suggesting broader interpretation of experimental use exception as one possible mechanism for reducing transaction and creativity costs associated with patenting basic scientific research).

¹⁰⁸ *See* Saunders, *supra* note 23, at 262. (finding that *Madey* should be replaced with "one that insulates the core academic functions of universities from lawsuits by protecting noncommercial experimentation on patented inventions"); Joseph Mohr, *Unshackle Academia and Allow it to Exemplify the Purpose of Patent Law: "To Promote the Progress of Science and the Useful Arts,"* 88 MARQ. L. REV. 671, 679 (2004) (offering a legislative wholesale exception to patent infringement under 35 U.S.C. § 271 for nonprofit university research that entitles the patentee to an interest in any subsequent innovations "directly attributable to a university's use of his patent"); Natalie M. Derzko, *In Search of a Compromised Solution to the Problem Arising from the Patenting of Biomedical Research Tools*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 347 (2004) (arguing for a broader experimental use defense that imposes legal limitations on the ability of patent owners to enforce their biomedical research tool patents); David C. Hoffman, *A Modest Proposal: Toward Improved Access to Biotechnology Research Tools by Implementing a Broad Experimental Use Exception*, 89 CORNELL L. REV. 993, 1000 (2004) (concluding that an "expansive experimental use exemption from patent infringement for noncommercial research offers the most promising antidote to problems associated with the proprietization of biotechnology"); Kevin Sandstrom, *How Much Do We Value Research and Development? Broadening the Experimental Use Exemption to Patent Infringement in light of Integra Lifesciences I v. Merck KgaA*, 30 WM. MITCHELL L. REV. 1059 (2004).

¹⁰⁹ *See* J. Miller, *Sealing the Coffin on the Experimental Use Exception*, 2003 DUKE L. & TECH. REV. 12 (2003). Specific types of obstacles to access include "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." *See also* NIH Report, *supra* note 35.

¹¹⁰ *Id.*

¹¹¹ *See generally* A. Caruso, *The Experimental Use Exception, An Experimentalist's View*, 14 ALB. L.J. SCI. & TECH. 215, 220 (2004); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698-99 (1998) [Hereinafter Heller & Eisenberg].

¹¹² Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J.L. REF. 141, 148 (2004) (referring to these multiple patent rights owned by multiple owners as a "patent thicket").

¹¹³ *Id.*

¹¹⁴ *See supra* note 108.

¹¹⁵ *See* Heller & Eisenberg, *supra* note 110, at 698-99. They describe anticommons property as the opposite of commons property. In a "tragedy of the commons," property is prone to overuse because too

Applying their theory to biomedical research, Professor's Heller and Eisenberg warn that an anticommons can arise either through "creating too many concurrent fragments of intellectual property rights in potential future products or by permitting too many upstream patent owners to stack licenses on top of the future discoveries of downstream users," ultimately stifling important innovations.¹¹⁶ Similarly, critics charge that the *Madey* court's decision will exacerbate an "anticommons" because biomedical researchers need access to a greater number of proprietary research tools to conduct their research as scientific research becomes progressively more cumulative.¹¹⁷ Besides increasing a university's risk of future litigation for the unauthorized use of patented research tools,¹¹⁸ these commentators believe that the current narrow experimental use exception will submit research institutions, like Duke, to the "mercy of patent holders."¹¹⁹ Mainly, academic researchers can no longer ignore the intellectual property rights of others¹²⁰ and instead must procure necessary license agreements for each patented research tool that is indispensable to a particular experiment.¹²¹

The numerous costs and difficulties associated with licensing patents¹²² will force academic research institutions to squander time and limited financial resources that might otherwise be devoted to discovery, as researchers and their organizations divert resources to "grapple with complex legal issues before carrying out even a simple experiment."¹²³ Meanwhile, research tool owners may demand exorbitant license fees and royalties that are beyond a researchers' limited budget or place significant limitations on licenses.¹²⁴ Even worse, research tool owners may simply refuse to grant the necessary license.¹²⁵

Opponents further maintain that these problems are particularly acute in biotechnological research because obtaining these multiple patent rights can be

many people have a privilege of its use, and thus no one has the right to exclude others. In contrast the "tragedy of the anticommons theory" posits that if too many people own property rights in a particular piece of property, then the rights may block one another, and therefore, no one owner can effectively use the property. *Id.*

¹¹⁶ *Id.*

¹¹⁷ See Derzko, *supra* note 108, at 349.

¹¹⁸ Cai, *supra* note, 23 at 183. (noting that "practically any project conducted by a research university, even one without any commercial implications, would be keeping with the university's legitimate business interests and hence would not qualify for the experimental use defense").

¹¹⁹ Miller, *supra* note 109, at 12.

¹²⁰ Because many research tools can be easily copied, university researchers "have a reputation for routinely ignoring IP rights" arising in the course of their work. John P. Walsh et al., Effects of Research Tool Patents and Licensing on Biomedical Innovation, in Patents in the Knowledge-Based Economy 285, 324 (Wesley M. Cohen & Stephen A. Merrill eds., 2003).

¹²¹ *Id.*

¹²² Examples of licensing costs and difficulties include; determining patent ownership, assessing which patents cover a particular research project, differing goals of licensors and licensees, difficulty in valuing research tool, time constraints, funding issues, uncertainty of research outcome, and the validity and scope of the patent claims. Mireles *supra* note 111, at 170.

¹²³ Caruso, *supra* note 110, at 220.

¹²⁴ Mueller, *supra* note 22, at 15. In the mid-1990s, E.I. du Pont de Nemours negotiated licenses for its Oncomouse with substantial monetary fees for commercial uses as well as restrictive academic licenses that required universities to report their use of the technology and seek DuPont's approval before sharing the results of research performed with the Oncomouse. See Blaug, *supra* note 17, at 762.

¹²⁵ Kate Murashige, Patents and Research-An Uneasy Alliance, 77 Academic Medicine 1329, 1331 (2002).

susceptible to negotiation breakdowns or the stacking of multiple license fees that ultimately outweigh a final product's value.¹²⁶ Rather than risk infringement liability or pay unaffordable license fees, some suggest that some academic researchers have even given up exploring certain research projects.¹²⁷

Legal scholars also claim that the Federal Circuit's strictly limited experimental use defense is incompatible with venerable scientific norms.¹²⁸ Particularly the scholars argue that a limited defense conflicts with the ubiquitous opinion among academic researchers who believe that non-commercial or pre-commercial infringement carried out in the interests of scientific research is always excused.¹²⁹ That is, academic researchers expect data, research tools, and other scholarly resources to be widely disseminated and shared by the scientific community because science mainly develops in a cooperative manner through the free and open disclosure of new discoveries.¹³⁰

This free access and open atmosphere "helps place the information in the possession of the people who can best use it" and consequently cultivates diverse viewpoints and originality.¹³¹ However, as research tool license agreements become more prevalent, the contractual obligations imposed by the patent holders may discourage open disclosure or influence how the research is conducted.¹³² But academic researchers balk at these research restrictions just to obtain a necessary license to conduct research.¹³³

Finally, some critics suggest that a narrow experimental use defense will inevitably deter scientific progress in general because these research tools are used mostly to conduct basic research at academic institutions.¹³⁴ Because basic research is directed toward understanding fundamental scientific phenomena, basic research sometimes provides the foundation for future breakthrough discoveries and applied commercial research, such as treatments for cancer, heart disease, AIDS, arthritis, or diabetes.¹³⁵ These academic institutions perform nearly half of this country's most basic research, approximately 54 percent of the national total, rather than applied commercial research.¹³⁶ Additionally, academic research is concentrated in this basic research, where an estimated 74 percent of academic research expenditures in 2002 went to basic research.¹³⁷ Opponents therefore warn that a strictly limited

¹²⁶ *Id.* For instance, to discover a drug targeting a cell receptor may involve patent claims to; the receptor itself, the DNA sequence encoding it, its means of production and the cell lines that produce it, screening methods using the receptor, antibodies to the receptor needed to purify it. *Id.*

¹²⁷ See Mueller, *supra* note 22, at 16.

¹²⁸ Hoffman, *supra* note 108, at 998.

¹²⁹ *Id.*

¹³⁰ Mireles, *supra* note 111, at 186.

¹³¹ *Id.* at 187.

¹³² See Mueller, *supra* note 22, at 16. For instance, a research tool owner may limit the tools use in order "to carve out a domain of exclusivity in subsequent research for themselves or collaborators." Eisenberg, *supra* note 7, at 1057.

¹³³ See, e.g., Mueller, *supra* note 22, at 15.

¹³⁴ See *supra* note 108.

¹³⁵ See Blaug, *supra* note 17, at 761.

¹³⁶ See National Science Foundation, *Science and Engineering Indicators 2004, Academic Research and Development, Highlights, Financial Resources for Academic R&D*, at www.nsf.gov/statistics/seind04/c5/c5h.htm [hereinafter Science and Engineering Indicators 2004].

¹³⁷ *Id.*

experimental use defense proffered by the *Madey* decision will jeopardize potential discoveries by endangering basic research experimentation.¹³⁸

V. RESEARCH WORLD REALTIES ALLOW FOR THE ADVANCEMENT OF SCIENCE
DESPITE A NARROW EXPERIMENTAL USE EXCEPTION

In theory, the academic community's devastating predictions of the *Madey* court's narrow and strictly limited experimental use defense may speciously deter scientific progress. Yet in practice, industry is not aggressively suing universities for patent infringement¹³⁹ despite both a university's greater than before vulnerability to patent infringement claims,¹⁴⁰ and academic scientists' pervasive and routine disregard for intellectual property rights.¹⁴¹ In fact, academic research using patented research tools has mostly remained unmarred¹⁴² and scientific advancement even seems to be accelerating.¹⁴³ Therefore the dire hypothetical consequences of a narrow experimental use defense are largely overstated and thus reforming the experimental use defense would be unjustified. Instead, science's innovative spirit and available practical solutions, operating against the backdrop of the academic

¹³⁸ Miller, *supra* note 109, at 21. "This nation has benefited enormously in the past from noncommercial academic scientific research, as more discoveries and greater understanding of the unknown have facilitated commercial research leading to new and socially beneficial products and applications." *Id.* (quoting the Brief of Amici Curiae Ass'n of Am. Med. Coll. at 16, *Madey v. Duke Univ.*, 397 F.3d 1351 (Fed. Cir. 2002)(No. 02-1007).

¹³⁹ See Huang, *supra* note 70, at 112. The author of this survey found that a university was not once sued by industry for patent infringement in the 20 patent infringement cases heard by the Federal Circuit in its first twenty-one years of existence. More notably, the only suits where industry did sue universities were when corporations sought declaratory judgments of non-infringement. *Id.* While this study provides only a limited estimation, a more comprehensive survey is currently being conducted to assess the impact of *Madey* court's ruling on the conduct of university research by the Association of American Universities (AAU), the Association of American Medical Colleges (AAMA), the Council on Governmental Relations (COGR), and the National Association of State Universities and Land-Grant Colleges (NASULGC). Available at <http://sippi.aaas.org/madey.shtml>. But clinical genetic tests represent a distinct exception. Clinical genetic tests are consumer end products often used in research. A survey of clinical laboratory directors that perform DNA-based genetic tests to examine potential effects interviewed one hundred thirty-two of 211 (63%) laboratory directors who performed genetic tests for clinical purposes. Mildred K. Cho *et al.* *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*. 5 J. MOLECULAR DIAGNOSTICS 3 (2003). Twenty-five percent of respondents reported that they had stopped performing a clinical genetic test because of a patent or license. *Id.* Fifty-three percent of respondents reported deciding not to develop a new clinical genetic test because of a patent or license. *Id.* These authors concluded that patents and licenses have had a significant effect on the ability of clinical laboratories to develop and provide genetic tests. *Id.*

¹⁴⁰ Eisenberg, *supra* note 68, at 1019.

¹⁴¹ This survey analyzed information collected from intellectual property attorneys, business managers, and scientists from biotechnology and pharmaceutical firms; university researchers and technology transfer officers; patent lawyers; government personnel; and trade personnel. Most respondents in this study acknowledged that infringement of research tool patents is common, where all nine university lab respondents admitted to using patented research tools without a license. Mostly because they are generally unaware of patent law, academics believe patents only govern commercial activities, regard the patents on certain common patented technologies as invalid, or recognize the difficulties in detecting infringement and therefore make the patented laboratory technology themselves. See Walsh, *supra* note 119, at 324.

¹⁴² See Huang, *supra* note 70, at 112. See also Cristina Weschler, *The Informal Experimental Use Exception: University Research after Madey v. Duke University* 79 N.Y.U. L. REV. 1536, 1538 (2004).

¹⁴³ See Peer M. Schatz *Life Sciences in the 21st Century* 19 THE SCIENTIST, Feb. 14, 2005 at 40 (stating "science has achieved such incredible successes in the last few years . . . the publication of the sequence of the human genome . . . stands for the spectacular speed at which science overall is advancing").

research world, determinedly advance scientific discovery.

The probability that an academic researcher will actually be threatened with legal action by research tool owners for unauthorized use is small.¹⁴⁴ This is partly attributable to the fading distinction between academic and commercial research as universities are increasingly eager to benefit from their intellectual property.¹⁴⁵ Consequently giving rise to progressively more collaborative relationships between universities and industry that are “characterized as much by cooperation and interdependence as by competition.”¹⁴⁶

Interwoven among these collaborations and partnerships are exchanges of knowledge, scientific expertise, working culture and money.¹⁴⁷ Industry now relies upon the “results of research conducted in universities rather than by their own in-house research staff” in order to shift their resources to more applied development as well as expanding its capabilities by having the research pursued by experts in a particular area.¹⁴⁸ Likewise, universities benefit from these collaborations because they concomitantly serve universities’ commercial and educational purposes, such as the subsequent licensing of developed technologies and providing opportunities for students to conduct research with cutting edge technologies, respectively.¹⁴⁹ Accordingly, these emerging partnerships, between universities and industry, encourage cooperation while simultaneously “temper[ing] the willingness of firms to pursue their intellectual property rights aggressively against their academic counterparts.”¹⁵⁰

Moreover the realities of patent litigation deter industry from launching a blitzkrieg of infringement actions against university researchers.¹⁵¹ First, litigation risks are mitigated simply because infringement of research tool patents by academic researchers is difficult to monitor and detect.¹⁵² Second, the financial and opportunity costs of litigating a patent infringement action are only justified when significant economic damages can be alleged.¹⁵³ The small prospective gains from a lawsuit rarely outweigh the potential risks and litigation costs, such as the legal fees

¹⁴⁴ See Walsh, *supra* note 119, at 324.

¹⁴⁵ Jurgen Drews, *Drug Discovery: A Historical Perspective*, 287 SCI. 1960, 1960 (2000) (noting the complexity of research “is enforcing changes” which are establishing the biotech industry as the discovery arm of the pharmaceutical industry “bridging the gap between academia and large pharmaceutical companies”). This is seen by industrial R&D support to academic institutions has grown more rapidly than support from all other sources during the past 3 decades, 6.8 percent in 2001, compared with 2.8 percent in 1972. See Science and Engineering Indicators 2004, *supra* note 135.

¹⁴⁶ See Weschler, *supra* note 141, at 1538 (identifying an “informal experimental use exception” that arises from the commercial relationships that exist between universities and industry that protects noncommercial academic research).

¹⁴⁷ See Blaug, *supra* note 17 at 761.

¹⁴⁸ See Mueller, *supra* note 22, at 33-34.

¹⁴⁹ See Weschler, *supra* note 141, at 1556 (finding sustained collaborations with universities provide a company with a competitive advantage as well as stronger subsequent growth).

¹⁵⁰ *Id.* at 1555.

¹⁵¹ See Huang, *supra* note 70, at 114.

¹⁵² See Walsh, *supra* note 119, at 324 (noting that if “research tool patents have created a minefield, they are mines with fairly insensitive triggers”).

¹⁵³ See Walsh, *supra* note 119, at 319 (finding some patent holders may send letters, offering terms, but they will not usually aggressively pursue infringers of research tools unless the university is generating revenue from the infringing use).

or the risk of the patent being narrowed or invalidated.¹⁵⁴ Even more, academic infringement may also be tolerated because it can possibly increase the patented technology's value, such as discovering new commercial applications that can arise from academic experimentation. Therefore only when a patent holder's commercial interests are seriously threatened by academic research, will a patent owner aggressively assert its intellectual property rights.¹⁵⁵

Third, the loss of goodwill and bad publicity that comes with suing large universities further curtails aggressive litigation.¹⁵⁶ Specifically, suing a university can enrage the academic community and make the company an "instant pariah" because the companies are suing the ultimate consumers of their patented technology with minor benefits.¹⁵⁷ Furthermore, research tool patent holders are reluctant to upset the norms of open access to materials and information in the scientific community.¹⁵⁸ For example, in an infringement action involving Polymerase Chain Reaction ("PCR"), Hoffman La Roche sued the commercial supplier, Promega, for infringing Roche's patented *Taq* polymerase.¹⁵⁹ Even though Roche charged that over 200 individual academic researchers and over forty universities infringed their patents on *Taq*,¹⁶⁰ it never actually pursued these alleged infringers.¹⁶¹ However, by only suing Promega, Roche was able to enforce its patents while maintaining goodwill without upsetting scientific norms.¹⁶² Indeed, it is advantageous for industry to foster free and open disclosure of new discoveries in order to develop trusting relationships with the academe.¹⁶³

Finally, universities are exceedingly capable of defending themselves, even if threatened with a patent litigation. Universities have metamorphosed from "ivory tower" to commercial enterprise, making them more adept at protecting and capitalizing on their intellectual property.¹⁶⁴ Once thought to be a "battle between David and Goliath," universities are equipped nowadays with the financial and legal resources necessary to litigate a patent infringement action, now creating "an even match between Goliaths."¹⁶⁵

As noted above, most of the disapproval regarding the *Madey* court's decision concern the numerous licenses that may be necessary for each patented research tool

¹⁵⁴ See Walsh, *supra* note 119, at 328. Study respondents found that patent litigation costs frequently outweigh their value, where one respondent claimed "the average suit costs millions of dollars. The target is worth \$100,000. Even with treble damages, it doesn't pay to sue." *Id.*

¹⁵⁵ *Id.* at 1021.

¹⁵⁶ *Id.* at 325.

¹⁵⁷ *Id.*

¹⁵⁸ *Id.* at 325-326.

¹⁵⁹ Hoffman-La Roche, Inc. v. Promega Corp., No. C-93-1748 VRW, 1999 U.S. Dist. LEXIS 19059, at 74 (N.D. Cal. Dec. 7, 1999) (holding La Roche's patent unenforceable because La Roche engaged in inequitable conduct in applying for the patent). *Taq* polymerase is the enzyme used in PCR, a research tool ubiquitously used in life science research. *Taq* automated PCR because it can withstand repeated heating cycles.

¹⁶⁰ Marcia Barinaga, *Scientists Named in PCR Suit*, 268 SCI. 1273, 1273 (1995).

¹⁶¹ See Cai, *supra* note 23, at 187-188.

¹⁶² *Id.*

¹⁶³ See Walsh, *supra* note 119, at 325-326.

¹⁶⁴ See *supra* notes 61-71 and accompanying text.

¹⁶⁵ See Huang, *supra* note 70, at 115.

underlying a worthwhile research project.¹⁶⁶ Critics warn that these numerous licenses will deter scientific progress by increasing both the cost and duration of research because royalty stacking can arise where multiple licensors may have a right to a royalty for every sale of a commercial application.¹⁶⁷ But, in reality, only a few patents actually require license agreements.¹⁶⁸ Generally, after identifying all relevant patents necessary for a commercially promising project, fewer than a dozen patents require serious consideration and the number of licenses actually required is much less because only the critical research tools are necessary for projects with commercial value.¹⁶⁹ Notably, researchers are mainly concerned about obtaining a license with reasonable terms and nearly all universities are sophisticated enough to evaluate its risks and decide whether to accept a license, negotiate more favorable license terms, or even ignore the patent and simply infringe and risk litigation.¹⁷⁰

Equally, the fear that high prices will restrict access to research tools is also unfounded, even when researchers cannot afford a license.¹⁷¹ In fact, many companies offer universities licenses at drastically discounted rates or even for free, especially to the extent that universities are pursuing “noncommercial” research.¹⁷² For instance, Dupont and the NIH entered into an agreement that allows scientists to use the Oncomouse related patents¹⁷³ for free as long as the use is not “for any commercial purpose or for the direct benefit of any profit institution.”¹⁷⁴ This agreement applies to all research conducted by public health service or organizations receiving NIH funds.¹⁷⁵ Likewise, Merck sponsors a publicly accessible EST¹⁷⁶ database that provides an important research tool freely available to all scientists.¹⁷⁷ By giving all research workers unrestricted access to the resources of the Merck Gene Index, Merck hoped to encourage progress in genomics research and its commercial applications.¹⁷⁸ Similarly, Celera¹⁷⁹ offers universities licenses to its human genome database for only \$7,500 to \$15,000 per year, while private firms pay \$5 million to \$15 million per year.¹⁸⁰

¹⁶⁶ See *supra* Part IV.

¹⁶⁷ Mireles, *supra* note 111, at 170.

¹⁶⁸ See Walsh, *supra* note 119, at 326.

¹⁶⁹ *Id.*

¹⁷⁰ A. Gogoris & P. Ancona *Research Tool Patents: Tips for Facing a “Pay Up Now or Litigate” Ultimatum*, 19 NAT. BIOTECH. 1075, 1077 (2001). See also Mireles *supra* note 111, at 188 (finding “[p]arties to a potentially productive coalition will see only the value of cooperating for a common benefit, and will ignore the possible costs of contracting”).

¹⁷¹ See NIH Report, *supra* note 35.

¹⁷² See Weschler, *supra* note 141, at 1553-1555.

¹⁷³ See Patent No. 6,130,322, *supra* note 47.

¹⁷⁴ Memorandum of Understanding between E.I. DuPont Nemours and Company and Public Health Service, available at <http://ott.od.nih.gov/pdfs/oncomouse.pdf>.

¹⁷⁵ See Blaug, *supra* note 17, at 762.

¹⁷⁶ Expressed Sequence Tags (“EST”) are short, single pass cDNA sequences generated from randomly selected library clones. The 415,000 human ESTs represent a valuable, low priced, and easily accessible biological reagent that are used for isolating full-length genes and locating genes on a genome map.

¹⁷⁷ The EST database is available at <http://www.ncbi.nlm.nih.gov/dbEST/>.

¹⁷⁸ See Merck Press Release, available at www.ncbi.nlm.nih.gov/Web/Whats_New/Announce/merck_feb10_95.html.

¹⁷⁹ Celera is the genomic firm that completed the private version of the human genome. See Venter *supra* note 50.

¹⁸⁰ R.F. Service, Can Data Banks Tally Profits? 291 SCI. 1203 (2001).

But providing these discounted licenses does not come without a price. Specifically, it can undermine the patentee's commercial interests.¹⁸¹ For instance, free research tools made available to academic researchers can undercut sales revenue because "would be" paying customers will instead "use the data generated by the academic researchers rather than buying the tool for use in their own internal research."¹⁸² Furthermore a patentee's research tool may be competitively used against him, such as to develop a blocking patent or advance a competitor's interests with a similar research agenda.¹⁸³

Yet solutions remain even for patented technologies that may be priced beyond a small lab's limited research budget. Unaffordable licenses force these small labs to collaborate and establish research alliances to obtain necessary technologies.¹⁸⁴ This collaboration can often lead to more fruitful discoveries, even if it means giving up intellectual property rights.¹⁸⁵ Furthermore, some researchers can opt to invent around the patent or for "do-it-yourself" solution, which involves making the patented laboratory technology without paying royalties.¹⁸⁶

Besides, researchers who cannot afford large up-front license payments can also contract for reach-through royalties. These are licenses whereby licensors seek royalties on future products developed through the use of the licensed tool.¹⁸⁷ Although critics argue that reach-through royalties conflict with research objectives,¹⁸⁸ reach-through royalties may facilitate research and development because they allow authorized access to a research tool at little or even no up-front cost or may be the only way for a patentee to benefit.¹⁸⁹

Reasonable reach-through royalties are to some extent speculative and difficult to calculate¹⁹⁰ because a patented research tool's prospects for successful application are often unknown.¹⁹¹ Thus licensors should carefully limit such royalty provisions, mainly because they may constitute patent misuse if the license royalty includes royalties on products outside the scope of the claimed invention.¹⁹² Specifically, licenses that base royalty payments on commercial products that are not claimed or adequately described in the patent will likely be invalid, as it would impermissibly broaden the patent grant.¹⁹³ Thus, a research tool patent holder may license the

¹⁸¹ See Mireles, *supra* note 111, at 178.

¹⁸² See NIH Report, *supra* note 35.

¹⁸³ *Id.*

¹⁸⁴ See Huang, *supra* note 70, at 116.

¹⁸⁵ E. Marshall *Property Claims: A Deluge of Patents Creates Legal Hassles for Research*, 288 SCI. 255 (2000).

¹⁸⁶ See also Walsh, *supra* note 119, at 324.

¹⁸⁷ See NIH Report, *supra* note 35.

¹⁸⁸ Eisenberg, *supra* note 61, at 1383

¹⁸⁹ Gerald Flattmann & Jonathan Kaplan, *Licensing Research Tool Patents*, 20 NAT BIOTECH 945, 946 (2002).

¹⁹⁰ *Id.* at 947.

¹⁹¹ *Id.* (stating "the serendipitous nature of research discoveries may make it difficult to place a value on the right to use a patented invention before the outcome of a research project is known).

¹⁹² Heather Hamme Ramirez, *Defending the Privatization of Research Tools: An Examination of the "Tragedy of the Anticommons"* in *Biotechnology Research and Development*, 53 EMORY L.J. 359, 386 (2004).

¹⁹³ Flattmann, *supra* note 188, at 946.

precise tool itself, but cannot claim commercial rights in the countless potential products that may be identified through use of the tool.¹⁹⁴ Interestingly, this will not likely be a significant obstacle to the academic researcher, whose focus is basic research rather than commercial applied research.

In addition, any resulting deterrence to innovation requiring the use of a research tool is not uniformly high for all types of tools.¹⁹⁵ 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.¹⁹⁶ Thus transaction costs and access barriers would not be at issue here.

Finally, both private and public sector responses have helped increase access to biotechnology research tools by taking steps to ensure open access to biotechnology research tools.¹⁹⁷ For instance, peer-reviewed scientific journals have urged authors to grant access to certain research tools, such as DNA sequences, by conditioning publication upon the deposit DNA sequences in publicly available databases.¹⁹⁸ To cite but one example, conditional to publishing its sequence of the human genome in *Science*, Celera had to make the entire sequence available free of charge on its web site so “[a]ll researchers, whether academic or commercial, may access the human genome data to verify, replicate or challenge” the published findings.¹⁹⁹

Similarly, the Wellcome Trust and eleven private pharmaceutical and technology firms cooperatively established the SNP Consortium, a non-profit foundation organized for the purpose of providing public genomic data.²⁰⁰ Its goal is “to develop and make 300,000 Single Nucleotide Polymorphisms (“SNPs”),”²⁰¹ as well as information related to these SNPs, freely available to the public without intellectual property restrictions.²⁰² The pharmaceutical companies anticipate that the database will enable tailor-made drugs to treat certain genetic based diseases that will be uncovered by this project.²⁰³

Likewise, the Federation of American Societies for Experimental Biology (“FASEB”)²⁰⁴ endorses the broadest distribution of research tools and resources to

¹⁹⁴ Ramirez, *supra* note 191, at 388.

¹⁹⁵ *Id.*

¹⁹⁶ The Jackson Laboratory has collection of over 2,800 strains of genetically defined and genetically modified mice that are commercially available. Available at <http://www.jax.org/>.

¹⁹⁷ See Ramirez, *supra* note 192, at 380-384.

¹⁹⁸ *Id.*

¹⁹⁹ *Celera and Science Spell out Data Access Provisions*, 291 *SCIENCE* 1191 (2001), available at <http://www.sciencemag.org/feature/data/announcement/gsp.shl>.

²⁰⁰ See the SNP Consortium, available at <http://snp.cshl.org> (last visited March 13, 2005). SNP Consortium members include Amersham Biosciences, AstraZeneca, Aventis, Bayer AG, Bristol-Myers Squibb, Hoffman-LaRoche, GlaxoSmithKline, IBM, Motorola, Novartis, Pfizer, Searle, and the Wellcome Trust.

²⁰¹ Single nucleotide polymorphisms (SNPs) are common single base pair variations in DNA among individuals and have great significance for biomedical research. The findings will be collected and made freely available in a database. *Id.*

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ FASEB is a coalition of 22 independent Member Societies with 65,000 members, making it the largest coalition of biomedical research associations in the United States. Available at http://www.faseb.org/about_faseb.htm.

best advance the interests of science and society.²⁰⁵ Specifically, FASEB encourages non-exclusive licensing of genomic inventions and that funding recipients reserve, in their license agreements, the right to use the licensed technologies for their own research and educational uses, as well as allow other non-profit institutions to do the same.²⁰⁶

Perhaps even more significant, the NIH promulgated guidelines to promote the free exchange of research tools between researchers in both, the public and private sectors.²⁰⁷ The purpose of these Principles and Guidelines is to ensure dissemination of research tools by providing NIH funding recipients with guidance concerning appropriate terms and conditions for acquiring unique research resources developed with federal funds and assisting recipients with complying with their obligations under the Bayh-Dole Act and NIH funding policy.²⁰⁸

Although the Principles and Guidelines are not regulations enforceable by law, they still represent an effort by the scientific community to provide an appropriate balance between ensuring broad dissemination of research tools and protecting legitimate proprietary interests and incentives for commercial development. Where grantees fail to demonstrate progress in implementing the Principles and Guidelines, NIH may, on a case-by-case basis, enforce its expectations in the form of specific grant restrictions.²⁰⁹ NIH expects licensees to reserve sufficient rights so that, even if the technology is licensed exclusively, they can still provide access to the technology to the non-profit research community.²¹⁰ Furthermore the NIH strongly encourages institutions to avoid accepting terms and conditions that will “limit traditional academic freedoms, such as long delays in publication or controls on collaboration.”²¹¹

VI. CONCLUSION

Since the enactment of Bayh-Dole, universities have undoubtedly acquired financial incentives for patent protection. Meanwhile, the academe’s aggressive pursuit of its intellectual property rights and enjoyment of significant financial benefits demonstrate that the university has transformed from the “ivory tower” to a

²⁰⁵ See Comment on Best Practices for the Licensing of Genomic Inventions, available at http://www.faseb.org/opa/news/docs/Genomic_lic_best_Prac.pdf.

²⁰⁶ *Id.*

²⁰⁷ Because the sharing of resources often serves as a catalyst for exciting discoveries in biomedical research, on December 23, 1999, NIH published in the *Federal Register* a summary of the public comments received and the agency response, along with the final policy entitled “Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice.” NIH sought comments on the guidelines not only from NIH grantees, but also from academic, not-for-profit, government, and private sector participants in biomedical R&D. 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).

²⁰⁸ *Id.* (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”)

²⁰⁹ *Id.*

²¹⁰ *Id.*

²¹¹ *Id.*

commercial intellectual property player.

Indeed, the Federal Circuit implicitly recognized that that pure academic research, devoid of commercial implications, is rapidly becoming extinct. Because the unauthorized use of others' patented research tools in commercial research was already likely illegal in prior interpretations of the experimental use defense, the *Madey* court's holding simply focused attention on the modern commercial practices accompanying academic research. By sensitizing academic researchers to the potential infringement liability for unauthorized uses of patented research tools, a narrow experimental use defense simply holds academic researchers to the same standard.

Moreover, academic researchers should not enjoy *carte blanche* access to others' prior discoveries even if future scientific advancement builds upon prior discoveries. In fact, the very risk and costly nature of biotechnological research requires a narrow experimental use defense that encourages the responsible use of patented technologies and continues to protect the reward afforded to inventors. Although the academic biomedical research community would welcome the ability to use research tools without any restrictions, they are still able to overcome the legal hurdles of using patented research tools.

Thus the post-*Madey* rhetoric overstates what is really occurring. Simply put, the dire consequences, predicted by legal commentators have remained greatly exaggerated. Mainly academic researchers find real-world solution to allow their research, as well as scientific discovery, to advance without any significant holdup.