LEAVING ROOM FOR RESEARCH: THE HISTORICAL TREATMENT OF THE COMMON LAW RESEARCH EXEMPTION IN CONGRESS AND THE COURTS, AND ITS RELATIONSHIP TO BIOTECH LAW AND POLICY

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ABSTRACT

The recent suit over the validity of gene patents between the American Civil Liberties Union and Myriad Genetics has highlighted the troubling ways in which patents may be interfering with the willingness of scientists and companies to engage in basic biotechnology research on matters of vital importance to human health and disease. Many scholars have argued for a legislative research exemption to protect this sort of research. Theoretically, the common law already contains an exemption to protect certain uses of a patented product from being deemed patent infringement. This Article evaluates the history of the common law research exemption alongside the history of biotechnology policymaking since the 1970s, identifying how confusion over the scope of the judicial research exemption may have led to legislative stagnation on the issue of protecting research. Even during the infancy of biotechnology, members of Congress believed in the existence of a robust research exemption when making policy decisions about whether to create a legislative exemption. Now that the scope of the research exemption has been narrowed significantly by recent Federal Circuit decisions, at a time when the intellectual property regime permits patents on human building blocks as basic as genes, this Article highlights the need for a clear exemption. It also overviews and comments on existing policy solutions scholars have offered to counteract the chilling effect that the lack of a clear exemption might be having on basic research, including research in the biotechnology sector.

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INTRODUCTION

In March, 2010, the American Civil Liberties Union made news when its lawsuit against a prominent genetics company—Myriad Genetics—won its case on summary judgment in a New York district court,[1] after surviving an earlier summary judgment battle over its standing to bring the suit in November, 2009.[2] Myriad holds a patent on the BRCA1 and BRCA2 genes, the presence of which indicate a woman's predisposition to certain types of cancer.[3] With its patent, Myriad has a monopoly over the gene, including all diagnostic testing related to it. Women cannot seek a second opinion and there is no cheaper alternative test; scientists cannot look at the gene, let alone perform research on it without Myriad's permission.[4] The heart of the ACLU complaint alleges that Myriad's monopoly over the BRCA genes interferes with women's health and doctors' practices. But the complaint also alleges that Myriad's patent prohibits independent, non-commercial research on the genes from taking place in university and nonprofit labs.[5] Indeed, the other plaintiffs in the ACLU suit are researchers who received cease and desist letters from Myriad after engaging in unsanctioned work, work which could have provided valuable information about the gene itself and technologies directed to it.[6] In preparation for trial, the ACLU argued that:

> [G]ene patents interfere with the ability of physicians and researchers to investigate complex diseases. For example, BRCA1/2 may be associated with cancers other than breast and ovarian cancer, but so long as the patents on these genes remain, no one will be able to include these genes in tests for other disease predispositions.[7]

Although the district court ruled for the ACLU summarily on other grounds relating to the invalidity of Myriad's patents, the

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[1] Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, No. 09 Civ. 4515, 2010 U.S. Dist. LEXIS 30629, at *108 (S.D.N.Y. Mar. 29, 2010).

[2] Press Release, American Civil Liberties Union, Court Upholds Right of Scientists and Patients To Challenge Gene Patents (Nov. 2, 2009), http://www.aclu.org/free-speech_womens-rights/court-upholds-right-scientists-and-patients-challenge-gene-patents.

[3] Complaint at 18, *Ass'n for Molecular Pathology*, No. 09 Civ. 4515, *available at* http://www.aclu.org/files/images/asset_upload_file939_39568.pdf.

[4] *Id.* at 18-19.

[5] *Id.* at 6, 28.

[6] *Id.* at 6.

[7] *Ass'n for Molecular Pathology*, 2010 U.S. Dist. LEXIS 30629, at *76-77.

court did not rule out the possibility that were a full trial to occur, it could be proven that Myriad's patents were indeed functioning to prevent basic, beneficial research from continuing.[8]

The clause of the Constitution dealing with patents—Article I, Section 8, Clause 8—optimistically describes the patent monopoly as meant to "promote the Progress of Science and useful Arts" by promoting disclosure of novel and useful methods and inventions.[9] Although patents do encourage the disclosure of beneficial ideas, patent holders use their patents for a number of other reasons in modern society: to encourage investor confidence in a new product or market; to gain bargaining chips for cross-licenses, sales, mergers, and acquisitions; or defensively, to secure freedom to work on a new technology or product without fear of infringement.[10] More detrimentally, a patent holder may engage in behavior like Myriad's—rarely licensing the patented technology, but instead enforcing the patent strategically to stifle basic research, the development of competitive alternatives, and other non-sanctioned uses. This type of guarded behavior preserves the patentee's dominance, but may ultimately harm the public by impeding beneficial research on or with the patented technology.

Long before the advent of biotechnology, the fundamental importance of experimentation was recognized by the judiciary, and some research activities were granted qualified immunity from patent infringement suits. This immunity is known as the "research exemption" or "experimental use exemption."[11] Although the scope of the exemption is and always has been murky,[12] since the nineteenth century, judges around the country have recognized that common sense seems to dictate that certain not-for-profit experimentation should not constitute patent infringement under the patent statutes.[13] In recent years, however, the Federal Circuit—the federal court with exclusive appellate jurisdiction over patent suits—has narrowed the common law exemption substantially, leaving it difficult to discern whether there is any room for non-commercial research using patented technologies in

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[8] *Id.* at *81 ("[T]here exists a sharp dispute concerning the impact of patents directed to isolated DNA on genetic research and consequently the health of society. . . . [T]he resolution of these disputes of fact and policy are not possible within the context of these motions.").

[9] U.S. CONST. art. I, § 8, cl. 8.

[10] Benjamin K. Sovacool, *Placing a Glove on the Invisible Hand: How Intellectual Property Rights May Impede Innovation in Energy Research and Development (R&D)*, 18 ALB. L.J. SCI. & TECH. 381, 437 (2008).

[11] The exemption is also called the "research exception" in other literature. I use it to mean the judicially-created immunity for users of patented technology who engage in non-commercial research. *See infra* Part I.

[12] *See infra* notes 28-31 and accompanying text.

[13] *See infra* notes 28-31 and accompanying text.

universities and nonprofits after the court's recent holdings. Although the specter of a possible research exemption may have at least discouraged patent holders from suing non-commercial experimenters, the Federal Circuit's erosion of the exemption makes it likely that any non-commercial experimenter, whether individual or institutional, could risk being sued if her work involves patented technology.

This Article examines how, historically, the research exemption has been discussed and relied upon in patent policymaking, and how the demise of the common law research exemption relates to practices in the biotechnology industry. Did the common law research exemption ever really exist? Were fundamental policy choices made in reliance on it? What results from the evisceration of the common law exemption, given the state of current policy toward biotechnology? What should legislators do about it?

Biotechnology is a particularly vulnerable technology because of its deep relationship to our understanding of health and disease. Continued research is vital to confirm the accuracy of genetic tests, to discover potential flaws and fixes, and to allow researchers to find suitable alternatives or substitutes if possible. In an industry so intertwined with life and death, the threat of an anticommons is particularly worthy of concern.[14] Without the space and freedom to research, patients, doctors, and society at large are at the patentee's mercy. A person's health may depend on the patentee granting licenses, choosing a reasonable price for products incorporating the monopolized technology, and doing further research that may improve or cheapen the technology. As Myriad's behavior has demonstrated, a bad actor has little incentive to do any of these things. The pro-competitive goal of patent law is undermined by the anti-competitive effect of patents on genetic material: with a gene, there is no way to invent around the patented technology, so the patentee need not fear competition for the term of the patent. In a competitive environment, the patentee would be incentivized to do more research, to charge reasonable prices, and potentially to cross-license the technology. In an environment free of competition, profit-maximizing behavior and progress-maximizing behavior may be at odds.[15] A research

[14] *See generally* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 6918 (1998) (discussing the seriousness of the patent thicket impeding continued research in the biomedical field).

[15] *See id.* There is some specific evidence that biotechnology patents are being used to slow progress or impede competition. Lori Andrews has identified a case in which GlaxoSmithKline pursued a patent on a test which would examine the effectiveness of one of their drugs, not because they intended to develop the test, but rather so that no one could do further work on it. Lori B. Andrews, *Genes*

exemption might help alleviate at least some of these problems, and legislators and policymakers should consider ways in which the research exemption might be reinstated and clarified now that the common law exemption has been eviscerated.

Part I of this Article tells the story of the common law research exemption as it evolved prior to the advent of biotechnology. Part II discusses the beginnings of biotechnology and the passage of the Bayh-Dole Act, which essentially gave researchers (including academic and nonprofit researchers) a duty to commercialize and license their work, a subtle yet dangerous threat to the underpinnings of the research exemption. Part III examines the ways in which biotechnology policymakers, aware of the threats to public health posed by biotechnology patents, discussed and relied upon the research exemption in their decisions during the 1980s and 1990s. Part IV overviews the recent narrowing of the common law exemption and its ramifications, specifically for the most recent advancement in the modern biotechnology industry—genetic analysis and testing. Part V sets forth the solutions that have been advanced by academics and policymakers to address the current system's chilling effect on basic, beneficial research, and concludes with some recommendations for future action.

I. THE HISTORY OF THE COMMON LAW RESEARCH EXEMPTION

Although many authors have discussed the origins of the research exemption,[16] their interpretations of the exemption vary as widely as the interpretations advanced by various courts over the years. This section attempts to briefly overview the history of the experimental use or research exemption prior to the advent of biotechnology, highlighting its inconsistent application and meaning. While perhaps offering no clear answers to questions about the traditional meaning or scope of the exemption, the

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and Patent Policy: Rethinking Intellectual Property Rights, 3 NATURE REVIEWS GENETICS 803, 804 (2002). Progress and profit may not always be in competition, though; a company that obtains a patent might work to cheapen the production of the patented biotechnology, or to develop technologies that enhance the value of the patented product, in cases where the ability to charge monopoly prices would allow the patent holder to reap additional profits. I thank Bret Hembd, Executive Editor of the *Yale Journal of Law and Technology*, for these suggestions.

[16] *See* Richard Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. PAT. OFF. SOC'Y 357 (1957); Donald S. Chisum, *The Patentability of Algorithms*, 47 U. PITT. L. REV. 959 (1986); Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987); *supra* note 11.

history does demonstrate that there would be at least some basis to believe that certain applications of patented technology—particularly uses for the purposes of testing the accuracy of an invention or testing its proper enablement by the specification—are protected from infringement because of the absence of harm to the patentee.

A. Origins of the Exemption

The common law research exemption originated in an 1813 case from Massachusetts, *Whittemore v. Cutter*.[17] The defendant, who was charged with infringement for constructing the plaintiff's patented machine, challenged a jury instruction which stated that making a machine with "a design to use it for profit" constituted infringement.[18] Justice Story, sitting in his appellate capacity on the Massachusetts federal circuit court, affirmed the instruction, noting that making a patented technology for profit was within the purview of the Patent Act of 1793; it was not-for-profit use of the patented technology that might not be covered. Justice Story stated 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."[19] Justice Story thus believed that Congress intended to punish persons deriving profit from their use of the invention, but not those who used the patent for certain other purposes.

Justice Story again discussed the issue of profit as a component of infringement just five months later in *Sawin v. Guild*, another Massachusetts circuit court case.[20] The defendant, a deputy sheriff, seized and sold the plaintiff's patented nail cutting machine as part of an execution of the plaintiff's debts. In holding that this was not infringement, Justice Story referenced *Whittemore* in dicta while remarking that the Act of 1793 had already been construed. He stated that

> [For] the making of a patented machine to be an offence within the purview of [the statute], [it] must

[17] 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600). The history of the research exemption has been given full treatment by many scholars. Particularly detailed histories can be found in Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 BAYLOR L. REV. 917 (2004); and Jordan P. Karp, Note, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169 (1991).

[18] *Whittemore*, 29 F. Cas. at 1121.

[19] *Id.*

[20] 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391).

> be the making with 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. 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."[21]

One commentator has interpreted these two 1813 cases to mean that Justice Story believed that the experimental use exemption consisted of two separate requirements: "(1) the activity must not be performed with the intent to gain profit and (2) the activity must be either (a) for philosophical experiments or (b) for ascertaining the verity and exactness of the specification."[22]

While it may be easy enough to look at the question of intent, and it is a matter of fact whether the use was for ascertaining "verity" or "exactness," the problem lies in interpreting what Justice Story meant by "philosophical experiments." One interpretation would be that Justice Story contemplated only a man "tinkering around" in his basement with another's invention; however, it seems unlikely that Justice Story would have limited philosophical experiments to such an invisible, individual use.[23] Another view states that "philosophical experiments" would include use of the invention in the course of developing new technologies, although this would seem to extend directly to future for-profit uses that Justice Story would likely consider infringement.[24]

Rebecca Eisenberg has advocated an interpretation somewhere in the middle of these two extremes: "[t]he first prong of Justice Story's experimental use privilege, permitting 'philosophical experiments' . . . seems to permit subsequent researchers to use the patented invention at least in traditional basic research with no commercial implications."[25] Eisenberg defines

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[21] *Id.* at 555 (internal citation omitted).

[22] Karp, *supra* note 17, at 2171.

[23] Bee, *supra* note 16, at 367.

[24] Chisum, *supra* note 16, at 1019 n.203. This view is probably the weakest. The nineteenth century case *Poppenhusen v. Falke* held that use of patents to develop future technology is not protected, and similar fact patterns were also held not to be experimental uses by other courts. 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279) ("[The defendants] are rivals of the complainant in the very business to which his patents relate . . . . The answer alleges that all the defendants have thus far done since the organization of said company, has been done by way of experiment, for the purpose of hereafter working under certain patents, grants, and licenses of their own . . . it can hardly be necessary for the respondents to experiment with the complainant's inventions in order to perfect their own . . . .").

[25] Eisenberg, *supra* note 16, at 224.

"basic research" as "'pure' research directed solely toward expanding human knowledge, as opposed to 'applied' research directed toward solving practical problems."[26] Eisenberg's definition encompasses the basement inventor, but leaves out researchers who use the invention for eventually for-profit purposes. More importantly for this inquiry, Eisenberg's interpretation exempts researchers who aim to test an invention or use it to add to human knowledge and understanding, a more liberal construction of "philosophical experiments" than one which would protect only the casual, curious experimenter in his basement. Eisenberg's definition is also consistent with the more recent research done by Janice Mueller, who evaluated other nineteenth century uses of the word "philosophical" and suggested that "philosophy referred to natural philosophy, which in turn meant science generally."[27] Under this definition, "philosophical experiments" might thus cover scientific research on a patented invention to ascertain its workings and to either evaluate them or attempt to design around them.

In any case, by the close of the nineteenth century, it was almost unanimously agreed that a narrow exemption for experimental use existed at common law.[28] One nineteenth century treatise on patents stated that "where [the invention] is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized."[29] The experimental use exemption was narrow from the outset—even prior to 1900, courts typically found that various uses of patented inventions by commercial infringers were not experimental—but even in the cases where the courts found no experimental use, the courts acknowledged that some exemption did exist for not-for-profit uses.[30] As early as

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[26] *Id.* at 178 n.1.

[27] Mueller, *supra* note 17, at 929.

[28] *But see* Clerk v. Tannage Patent Co., 84 F. 643 (3d Cir. 1898) (holding that contracts were required even to conduct experimental testing); Albright v. Celluloid Harness-Trimming Co., 1 F. Cas. 320 (C.C.N.J. 1877) (No. 147); Palmer v. United States, 20 Ct. Cl. 432 (1885), *aff'd on other grounds*, 128 U.S. 262 (1888). These latter two cases held that clearly experimental uses—one, testing the performance of patented molds in the process of manufacturing trimming, and the other, testing a knapsack for its wartime practicality—were indeed infringements. However, the majority of cases both before and after followed Story's logic rather than these aberrant holdings.

[29] 3 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 898 (1890).

[30] *See* U.S. Mitis Co. v. Carnegie Steel Co., 89 F. 343, 351 (C.C.W.D. Penn.) (holding that "use in the course of business and for profit" is not experimental), *aff'd without opinion*, 90 F. 829 (3d Cir. 1898); Cimiotti Unhairing Co. v. Derboklow, 87 F. 997, 999 (C.C.E.D.N.Y. 1898) (acknowledging a "legitimate use for experimental purposes only"); Bonsack Mach. Co. v. Underwood, 73 F.

1861, one court even called it "well settled" that an experimental use exemption existed at common law,[31] but the conflicting interpretations later given in courts around the country demonstrate that the scope of that exemption and the nature of the activities that would fall under it were hardly clear.

B. Subsequent Interpretations of the Exemption Prior to Biotech

As is evident from the limited history thus far, the scope of the exemption was murky from its outset. Although most courts recognized that, according to common sense, some experimental use could not have been intended to be infringement by the legislature, they frequently conflicted in their interpretations of what exactly permissible experimentation was or would be. This pattern of inconsistent interpretation continued for the majority of the early twentieth century,[32] and overwhelmingly, plaintiffs prevailed against a defendant's claim of experimental use.[33] However, one interesting pattern during this period is of note: although strictly commercial enterprises were almost never exempted on the grounds of experimental use, in those cases in which experimental use was found, the defendant was the U.S. government, a frequent government contractor, or a nonprofit educational institution.

The educational institution absolved from infringement was the Colorado School of Mines. The school and its faculty and students were released from liability in a 1935 decision, *Ruth v. Stearns-Roger Manufacturing Co.*[34] The disputed technology was a certain type of patented flotation machine. Although the named defendant, a commercial enterprise, was found guilty of

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206, 211 (C.C.E.D.N.C. 1896) ("It is true that, if an infringing machine is made or used as an experiment merely, it does not infringe former patents.");.

[31] Poppenhusen v. Falke, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279) ("It has been held, and no doubt is now well settled, that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee.").

[32] *See* 5 DONALD S. CHISUM, CHISUM ON PATENTS § 16.03(1)(b) (2010); *see also* Steven P. Caltrider & Paula Davis, *The Experimental Use Defense: Post-*Madey v. Duke *and* Integra LifeSciences I, Ltd. v. Merck KGaA, 86 J. PAT. & TRADEMARK OFF. SOC'Y 1011 (2004) (providing an overview of the parameters of the exemption in individual cases throughout this period). In his 1957 article, Richard Bee also has a very detailed (although overwhelmingly critical) case-by-case description of these continuously inconsistent interpretations of experimental use. Bee, *supra* note 16, at 370-75.

[33] *See* Bee, *supra* note 16, at 377; Eisenberg, *supra* note 16, at 222.

[34] 13 F. Supp. 697 (D. Colo. 1935), *rev'd on other grounds*, 87 F.2d 35 (10th Cir. 1936).

infringement, the school (which bought parts from the company) was immune from liability because the school used the technology in "laboratory machines used for experimental purposes, and consequently did not contribute to an infringing use."[35] Although it is not completely clear what the type of experimentation was, the court seems to have overlooked the fact that even educational institutions are in a sense commercial, in that they are in the business of attracting students and endowment investors. The court seems only to have considered that the use of the technology was in the lab and was for the purpose of satisfying scientific inquiry, an educational and experimental activity which it held to be exempt.

In addition to covering educational use of patented technology, the exemption seems also to have covered some work for government research.[36] Although not explicitly for government use, one wartime case, *Dugan v. Lear Avia*, involved a type of technology for a direction-finding and position-indicating system in airplanes, and since Lear was an essential government contractor during World War II, one might imagine that the suit had implications for national defense.[37] Although the case was decided on other grounds—the invalidation of the plaintiff's patents—the court stated that "defendant built [one of the allegedly infringing] device[s] only experimentally and that it has neither manufactured it for sale nor sold any."[38] The device was only constructed to understand how it worked—a form of reverse engineering and industrial research that the court stated would be free from liability under the experimental use exemption. The exemption covered more obvious, explicit government research in a later case which found the United States not guilty of infringement: *Chesterfield v. United States*.[39] In dicta, the court referenced the experimental use exception, stating that the government's use of an alloy as part of government experiments was not infringement; unfortunately, it is completely unclear how or for what purpose the technology was used.[40] The court stated only that "a portion of the 422-19 alloy procured by the defendant was used only for testing and for

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[35] *Id.* at 703.

[36] I contrast this to work for government *use*—for example, use of the technology in warfare or as part of national defense. This type of use is clearly not experimental or research-based, and the "experimental use" defense has failed for the government in these situations. *See* Pitcairn v. United States, 547 F.2d 1106 (Ct. Cl. 1977); Palmer v. United States, 20 Ct. Cl. 432 (1885).

[37] 55 F. Supp. 223 (S.D.N.Y. 1944).

[38] *Id.* at 229.

[39] 159 F. Supp. 371 (Ct. Cl. 1958).

[40] *Id.* The patent was invalidated in this case, so the experimental use discussion is therefore dicta—the court need not have reached the question of experimental use.

experimental purposes, and there is no evidence that the remainder was used other than experimentally. Experimental use does not infringe."[41] The issue in both *Dugan* and *Chesterfield* seems to be whether the invention was being used by the government or a contractor in a strictly non-commercial sense: testing the sufficiency of an item for its own sake, or reverse engineering an item to see how it works without the intention of producing a copy.

Although these decisions indicate that courts were perhaps more likely to find a nonprofit or governmental entity engaged in basic research to be protected by the experimental use exemption, the application and construction of the exemption remained far from clear prior to the 1970s. There appears to have been some recognition that functionally non-commercial enterprises—university research, and perhaps certain research by the government—should not give rise to liability for the use of patented technology in non-commercial ways. However, in ways unforeseen, the lines between commercial and non-commercial were about to be blurred. With an action as small in scale as the introduction of DNA into a host bacterium, the business of biotechnology was on its way.

II. 1970S AND 1980S: BIOTECHNOLOGY AND THE BAYH-DOLE ACT

Biotechnology is generally defined as "any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses."[42] Beginning in the mid-1970s, with advances in genetic technology, the contemporary biotechnology industry was born. Molecular biologists researching recombinant DNA—a method of splicing, cloning, and isolating genetic material—quickly realized its implications and possibilities for the future of scientific research, given that they now possessed the ability to single out DNA segments and analyze their structure and function.[43] However, as recombinant DNA technology became widespread, many others, including patent attorneys for universities, speculative venture capitalists, and even enterprising scientists themselves, recognized the commercial possibilities of recombinant DNA technology.[44] The rise of biotechnology and the

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[41] *Id.* at 845-46.

[42] Frank E. Young, *Harvesting the Fruits of Biotechnology*, FDA CONSUMER, Sept. 1, 1987, at 2.

[43] Sally Smith Hughes, *Making Dollars Out of DNA: The First Major Patent in Biotechnology and the Commercialization of Biotechnology, 1974-1980*, 92 ISIS 541, 541-42 (2001).

[44] *See id.*

battles the fledgling industry faced have been extensively chronicled and analyzed.[45] Although biotechnology faced a number of detractors who feared its capabilities and hazards, many viewed biotechnology as an industry with the ability to stimulate much-needed domestic economic growth.[46] In 1980, when news broke that one of the earliest biotechnology companies, Genentech (a combination of the first syllables of "genetic engineering technology"), had produced synthetic insulin with recombinant DNA technology, its stock price more than doubled on the day it went public.[47] Start-up companies sold promises of medical miracles to their investors, and established pharmaceutical and chemical companies began investing millions in biotechnology research and development.[48] The fruits of the biotechnology industry include the creation of many synthetic hormones with profound implications for human health, and in the following decades, genetic testing used to indicate biological predisposition for certain diseases.

The term "industry" brings to mind the private sector and private development, but from its very beginnings, the public and nonprofit sectors were at the heart of the biotech industry. It was an academic lab at Stanford University that spawned recombinant DNA technology, not a private-sector team of inventors.[49] Academic molecular biologists were increasingly courted by biotechnology corporations with promises of funding and profits.[50] In addition, and perhaps most troubling, academic scientific research was largely being funded by the government. The National Institutes of Health, Department of Defense, Department of Agriculture, Department of Energy, National Science Foundation, and other federal groups spent billions of dollars on university research and development over the course of the 1970s and 1980s.[51] Alerted to the conflicts of interest inherent in public money funding private enterprise, members of the media began to cover biotechnology with no shortage of skepticism and cynicism.[52] The concerns largely fell into two categories: first,

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[45] *See* SHELDON KRIMSKY, BIOTECHNICS AND SOCIETY: THE RISE OF INDUSTRIAL GENETICS (1991); Hughes, *supra* note 43; Daniel J. Kevles, *The Battle over Biotechnology*, *in* DAYS OF DESTINY 453 (Alan Brinkley & James M. McPherson eds., 2001).

[46] KRIMSKY, *supra* note 45, at 25.

[47] Daniel J. Kevles, *Principles, Property Rights, and Profits: Historical Reflections on University/Industry Tensions*, 8 ACCOUNTABILITY IN RES. 293, 298 (2001).

[48] KRIMSKY, *supra* note 45, at 30-37.

[49] Hughes, *supra* note 43, at 541-42.

[50] KRIMSKY, *supra* note 45, at 60.

[51] *Id.* at 66-68.

[52] *Id.* at 70-71.

concerns over the "commingling of funds" and whether scientists were using publicly funded labs and materials for commercial work, and second, the concern that private companies were appropriating the profits and the fruits of publicly funded academic research, making the public "pay twice for its investment."[53]

Congress took notice of the controversies and the excitement surrounding biotechnology. Initially, Congress's focus was on regulation and driven by safety concerns;[54] however, as private firms found success with commercial applications of recombinant DNA technology, Congress recognized that biotech could provide a serious boost to the American economy, and thus began to focus on ways the government could support the industry and ensure American dominance.[55] Long before the 1970s, both universities[56] and the government[57] had encouraged the patenting of publicly funded research results. However, in the 1970s, two factors were different: first, the amount of federal money in R&D had increased dramatically,[58] and second, the profits to be gleaned from the exploitation of biotechnology research were absolutely enormous compared to the paltry amount universities received from controlling and licensing their pre-biotechnology patents.[59] As the biotechnology frenzy swept the U.S. economy, the government was not equipped to quickly commercialize the results of the research it funded; besides, the commercial infrastructure was set up already by private biotech companies and start-ups. The nexus between government and the private sector was nonprofit and university research, but with the amount of funding and profits at stake, clear guidelines for ownership and transfer of technology from the universities to the private sector were needed.

Hence, Congress took action, first, to enable universities to retain ownership in the results of their federally funded research, and second, to facilitate (and all but mandate) the transfer of that technology to the commercial private sector.[60] In 1980, Congress passed two pieces of legislation—the Stevenson-Wydler

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[53] *Id.* at 71.
[54] Hughes, *supra* note 43, at 566-68.
[55] H.R. REP. NO. 96-1307, at 1 (1980), *reprinted in* 1980 U.S.C.C.A.N. 6460, 6460.
[56] *See* Kevles, *supra* note 47.
[57] *See* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1677-84 (1996) (discussing initiatives from the 1960s and earlier to encourage the patenting of inventions created with government funding).
[58] Kevles, *supra* note 47, at 298.
[59] *Id.* at 298-99.
[60] Eisenberg, *supra* note 57, at 1663-64.

Technology Innovation Act[61] and the Bayh-Dole Act[62]—in order to encourage the commercial development of university and government discoveries, promote the creation of new jobs, and thereby stimulate the U.S. economy.[63] The Bayh-Dole Act, also known as the University and Small Business Patent Procedures Act, has had a lasting effect on the university's role in the patent system; it grants universities—as opposed to government agencies—title in inventions made with government funding, provided that these universities satisfy a number of requirements, including obtaining patents in the technology and actively pursuing "practical application," or the commercial development of the invention, through licensing if necessary. The Bayh-Dole Act was Congress's response to what U.S. universities perceived as a lack of clarity about their rights in federally funded technology,[64] and moreover, to a fear that beneficial research would languish in university labs that lacked the tools to commercialize it.[65] In addition to giving universities clearer rights and duties, the Act also provided the government with "march-in rights" to grant licenses to other contractors regardless of the patentee university's willingness to license, if deemed necessary to hasten commercialization, "meet requirements for public use," or "alleviate health and safety needs."[66] By requiring universities to find commercial outlets for their patented research (or else face government intrusion), the provisions of the Bayh-Dole Act have been interpreted by universities as creating an "implied duty to commercialize" any inventions or technologies created with public money.[67]

Although the congressional hearings contained discussions about whether patent rights would be allocated to the government or the universities, Congress does not seem to have discussed the dedication of the developed technologies to the public domain. From the outset, patent protection was viewed as the best means for facilitating technology transfer, as opposed to open sharing of

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[61] Pub. L. No. 96-480, 94 Stat. 2311 (1980) (codified as amended at 15 U.S.C. §§ 3701-3714 (2006)).

[62] Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200-212).

[63] Eisenberg, *supra* note 57, at 1663-65.

[64] H.R. REP. NO. 96-1307, at 1-2 (1980), *reprinted in* 1980 U.S.C.C.A.N. 6460, 6461-62.

[65] Eisenberg, *supra* note 57, at 1663-64.

[66] 35 U.S.C. § 203. The march-in rights may be exercised against the university and against licensees, despite the provisions of any existing contracts.

[67] For an extended discussion of the implied duty to commercialize, see Jennifer A. Henderson & John J. Smith, Academia, Industry, and the Bayh-Dole Act: An Implied Duty To Commercialize (Oct. 2002), https://www.cimit.org/news/regulatory/coi_part3.pdf.

university- or nonprofit-developed inventions and methods. There is only a hint that some senators may have been considering public dedication in the remarks of Representative Jack Brooks (D-TX), contained in the house report on the Bayh-Dole bill:

> My concern is simply the role of the government and the rights of the people in the patent process. When a private company risks its own money to develop new products and procedures it deserves and receives the profits that may result. There should not be a different standard applied when it is the government that risks the taxpayers' money. *The rewards of successful research and development conducted at government expense should go to all the people*.[68]

The final form of the bill ensured the opposite: universities were to hold patents that would be licensed to private firms and developers. By the early 1980s, many universities had already established deep ties to the commercial sector.[69] In 1980, the Supreme Court decision *Diamond v. Chakrabarty* encouraged further ties and investment in university biotech research, by clarifying that living material was not per se unpatentable subject matter.[70] *Chakrabarty* paved the way for universities to work toward patents on DNA material, microorganisms, and farther down the road, even higher life forms.[71]

With the advantage of hindsight, it is now apparent that the creation of a "duty to commercialize" stands in direct conflict not only with certain academic norms,[72] but also with the university's function as a center of basic research.[73] Before the 1970s and 1980s, the experimental use exception may have protected universities from being liable for their research work using patented technologies—at the very least, the exception was murky enough that patent holders might not have been willing to gamble time and money to sue universities and nonprofits. But the passage

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[68] H.R. REP. NO. 96-1307, at 29 (1980), *reprinted in* 1980 U.S.C.C.A.N. 6460, 6488 (emphasis added).
[69] Kevles, *supra* note 47, at 303.
[70] 447 U.S. 303 (1980).
[71] For a history of the patenting of animals, see Daniel J. Kevles, *The Advent of Animal Patents: Innovation and Controversy in the Engineering and Ownership of Life*, *in* INTELLECTUAL PROPERTY RIGHTS IN ANIMAL BREEDING AND GENETICS 17, 17-30 (Max Rothschild & Scott Newman eds., 2002).
[72] For example, norms encouraging the sharing of research, or the independence and integrity of chosen research projects. *See* Eisenberg, *supra* note 16; Kevles, *supra* note 47.
[73] Eisenberg, *supra* note 16, at 224.

of the Bayh-Dole Act blurred the line between basic research and applied research in this setting, leaving it difficult to determine whether certain types of research on patented technologies in university or nonprofit labs would constitute infringing uses. In biotechnology, the stakes were financially high, but additionally, in fields touching public health and disease, the progress of certain kinds of research are critical: verifying and testing health-related technologies and methods, or encouraging and developing new ideas to design around preexisting inventions. After Bayh-Dole, with universities becoming heavily invested in commercialization, the ability of the experimental use defense to cover basic nonprofit and university research was jeopardized. But policymakers believed that an exemption existed, and that it would protect valued types of research. Indeed, in considering regulation and guidance for the development of the biotechnology industry in the 1980s and 1990s, legislators seem to have relied on the existence of the common law research exemption to ensure that critical and beneficial basic research would continue.

III. 1980S AND 1990S: CONGRESSIONAL UNDERSTANDING OF THE RESEARCH EXEMPTION

In the legislative history of the Bayh-Dole Act, there is a notable absence of concern about the protection of university and nonprofit research activities. However, Congress was confronted again with biotechnology policy questions (including questions about the "experimental use" protection for basic research) in the subsequent decade, most notably during the debates on the patenting of transgenic animals and attempts to pass policies which would clarify U.S. patent law and bring it into line with global practices. This Part will examine the legislative history surrounding two bills in particular—the Transgenic Animal Patent Reform Act of 1988[74] and the Patent Competitiveness and Technological Innovation Act of 1990[75]—neither of which was ever enacted. Although they never became law, the legislative history of the bills preserves the ways in which members of Congress discussed the value of university and nonprofit research, perceived the research exemption, and made choices about the codification of the common law exemption in proposed legislation.

A. The Transgenic Animal Patent Reform Act of 1988

It was not too long before the advancement of biotechnology rendered scientists able to genetically modify higher

[74] H.R. 4970, 100th Cong. (1988).
[75] H.R. 5598, 101st Cong. (1990).

life forms which satisfied the criteria of patentability—cancer-susceptible mice, for example, or genetically modified pigs capable of producing more meat.[76] The technology involved in *Diamond v. Chakrabarty* was a kind of bacteria,[77] perhaps more easily viewed as a patentable man-made composition of matter than as a living, breathing animal. Moral and environmental opposition to the patenting of these higher life forms again drew the attention of Congress to the biotech industry. Congress thus began to consider whether a moratorium on the granting of animal patents would be appropriate, and moreover, whether and what guidelines were necessary to govern patentability and infringement questions with regard to animal patents specifically.[78] Representative Robert Kastenmeier (D-WI), Chairman of the House Judiciary Subcommittee that handled patents, held hearings on the issue and began formulating a bill to cover the patenting of transgenic animals, called the Transgenic Animal Patent Reform Act.[79]

Prior to the drafting of the bill, in the hearings held by the Committee on the Judiciary, a statutory "research exemption" came up in the testimony of three individuals: Robert Merges, a professor of law at Columbia, Reid Adler, a patent attorney at Finnegan Henderson in Washington, D.C., and Leo Walsh, dean of the College of Agriculture at the University of Wisconsin.[80] Ostensibly, the research exemption was suggested because such an exemption would mirror the exemption Congress inserted in the Plant Variety Protection Act of 1970[81] (PVPA).

Unfortunately, there is very little legislative history clarifying why the research exemption appeared in the PVPA.[82] It seems likely that legislators included the research exemption because it was mandatory if the United States wished to become a member of the International Union for the Protection of New

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[76] Kevles, *supra* note 71, at 19-21.
[77] 447 U.S. 303 (1980).
[78] Kevles, *supra* note 71, at 23-26.
[79] *Id.* at 24, 28.
[80] H.R. REP. NO. 100-888, at 12-14 (1988), *reprinted in* 1988 U.S.C.C.A.N. 1, 12-14.
[81] *Id.* at 12 ("Both [a farmer's exemption and a research exemption] are paralleled in legislation Congress passed under the Plant Variety Protection Act.").
[82] *See* H.R. REP. NO. 91-1605 (1970), *reprinted in* 1970 U.S.C.C.A.N. 5082. Section 114 of the bill—covering the "research exemption"—is explained in the report only by the statement that "[u]se and production for research is not to constitute infringement." *Id.* at 5093. Section 111 of the bill—covering the "infringement of plant variety protection" clarifies that "[u]se of the protected variety as one source of germ plasm to breed a novel variety is permissible" under the research exemption, *id.*, seeming to indicate that Congress wished to protect the ability of experimenters to design around the patented variety to produce diverse, novel varieties.

Varieties of Plants[83] (UPOV). UPOV is an intergovernmental organization which encourages intellectual property protection for plant breeders' creations internationally.[84] The organization sets forth uniform legal standards that member nations must comply with—one of which is a robust research exemption.[85] The reason for the exemption may be as simple as this: in order for the United States to join UPOV, and gain the attendant benefits of membership, Congress passed the PVPA with the required research exemption. But post-hoc rationalization of the inclusion of the research exemption is also instructive for interpreting how later legislators understood the importance of the exemption. After the passage of the PVPA, legislators have stated that the exemption exists because (1) there was concern about granting private entities exclusive control over federally funded technology, and a research exemption alleviated this concern,[86] and (2) they were trying to protect valuable germplasm from being locked up in patents, preventing experimenters from using patented germplasm as a source to develop novel and diverse varieties of plants.[87]

The latter reason is strikingly evocative of the fair use doctrine in trademark law, which prevents the holder of a trademark from removing particular language from public discourse (or controlling use of the language) on First Amendment grounds.[88] Similarly, experimental use in the PVPA seems to try to prevent a patent holder from removing important germplasm from the collection of germplasm available to plant breeders.

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[83] *See* Anne E. Crocker, *Will Plants Finally Grow into Full Patent Protection on an International Level? A Look at the History of U.S. and International Patent Law Regarding Patent Protection for Plants and the Likely Changes After the U.S. Supreme Court's Decision in* J.E.M. Ag Supply v. Pioneer Hi-Bred, 8 DRAKE J. AGRIC. L. 251, 256-80 (2003).

[84] Int'l Union for the Protection of New Varieties of Plants, What It Is, What It Does (Oct. 22, 2009), http://www.upov.int/export/sites/upov/en/about/pdf/pub437.pdf.

[85] Crocker, *supra* note 83, at 81-83.

[86] H.R. REP. NO. 101-960, at 32 (1990) ("This amendment [creating a research exemption in the PVPA] was made, in part, because of the involvement of publicly funded research on plants.").

[87] This is supported by congressional debate surrounding the Plant Variety Protection Act Amendments of 1993: "The research exemption [in the 1970 bill] was included to promote the free flow of germplasm—essential to the maintenance of genetic diversity." 139 CONG. REC. S10841-02, S10868 (daily ed. Aug. 7, 1993) (statement of Sen. Kerrey). It is also supported by the "design around" provisions. *See supra* note 82.

[88] *See* Mattel, Inc. v. MCA Records, Inc., 296 F.3d 894, 900 (9th Cir. 2002) (discussing the fair use doctrine in relationship to the First Amendment). For a more thorough discussion of the relationship between trademark fair use and the research exemption in PVPA, see Mark D. Janis & Stephen Smith, *Technological Change and the Design of Plant Variety Protection Regimes*, 82 CHI.-KENT L. REV. 1557, 1563-65 (2007).

Germplasm and genetically modified animals share basic similarities, in that they are composed of identifiable genetic material and thus tied to life and the environment; it seems deleterious to permit patents to remove basic building blocks of life from the research scientist's tool kit, whether those building blocks are germplasm or genetic sequences. While this theory is completely speculative, perhaps this connection between plants and animals motivated Merges, Adler, and Walsh to suggest that a research exemption comparable to the one in PVPA be included in any legislation covering transgenic animal patenting.

Adler and Walsh went into deeper detail than Merges on the scope of the proposed statutory research exemption. Walsh expressed fears that animal patents would concentrate valuable resources in the hands of a few patentees and licensees, and thus recommended the legislation include "a university research exemption, compulsory licensing of the patent, public research focusing efforts on helping the smaller firms stay competitive in the market place, [and] public institutions cooperating in establishing and maintaining a gene bank," among other suggestions which would protect university and nonprofit research.[89] Adler seems to have argued that although a common law exemption existed, a statutory exemption was necessary because "the boundary between permissible research uses and impermissible infringement [was] not totally clear" from the case law.[90] He further expressed concerns that because of the ambiguous precedents, courts might not recognize basic research on transgenic animals as exempt, even when "no direct commercial benefit" was at stake for the research scientists.[91] The record thus demonstrates that Congress was warned by a few prominent advocates that a research exemption would be necessary in order to keep valuable genetic information in the public domain for basic research purposes.

Yet prior to the bill's passage by the House of Representatives, the House Committee on the Judiciary *deleted* a proposed statutory research exemption. The reason: "*a statutory exception was unnecessary in light of the existing judicially fashioned doctrine.*"[92] It was not oversight or lack of consideration that kept the Act from including a research exemption: it was reliance on the existence of a common law "experimental use" exemption that would protect basic research activities from constituting infringement.

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[89] H.R. REP. NO. 100-888, at 14 (1988), *reprinted in* 1988 U.S.C.C.A.N. 1, 14.
[90] *Id.* at 13
[91] *Id.*
[92] *Id.* at 3 (emphasis added).

The Transgenic Animal Patent Reform Act died in the Senate after being passed in the House.[93] However, the debate about the Act is instructive for viewing how contemporary legislators viewed the function and strength of the experimental use doctrine. Two years later, in the debates surrounding another bill advanced by Kastenmeier, it would become even clearer that legislators believed that a robust common law research exemption existed.

B. Patent Competitiveness and Technological Innovation Act of 1990

The Patent Competitiveness and Technological Innovation Act of 1990 was broadly intended to "improv[e the] country's patent law."[94] Like the Transgenic Animal Patent Reform Act, the bill was introduced by Kastenmeier, and it contains sections regulating everything from inventions made in space to genetically engineered animals.[95] For our purposes, the critical component of the bill is Title IV, which would have created a statutory research exemption for basic scientific research activities. Title IV of the Patent Competitiveness Act would have amended 35 U.S.C. § 271, a section of the patent law, by adding a subsection which would state that "[i]t shall not be an act of infringement to make or use a patented invention solely for research or experimentation purposes."[96]

To contextualize the drafting of Title IV, it is essential to realize that the legislators viewed the bill as "an attempt to codify and clarify current case law in the United States which currently excludes experimental use or research as an act of infringement," and stated that it was a "central tenet of American patent law that there is a right to use scientific information to create new and better inventions in competition with the patented invention."[97] Legislators thus did *not* see the bill codifying the research exemption as a *departure* from current case law, but rather as the *legislation* of an already existing common law exemption.

The report by the House Committee of the Judiciary on the bill contains some clarification of which activities would constitute protected research and which would not.

> [T]he making or using of a patented invention solely for research or experimentation shall not be

[93] Kevles, *supra* note 71, at 28.
[94] H.R. REP. NO. 101-960, at 1 (1990).
[95] H.R. 5598, 101st Cong. (1990).
[96] H.R. 5598, 101st Cong. § 402 (1990).
[97] H.R. REP. NO. 101-960, at 32.

> an act of patent infringement unless the patented invention has a primary purpose of research or experimentation. If the patented invention has a primary purpose of research or experimentation (such as a transgenic mouse used for cancer research or a laboratory implement such as a microscope), it shall not be an act of infringement to manufacture or use one of these inventions to study, evaluate, or characterize it or to create a product outside the scope of the patent covering the particular invention.[98]

The House Report identified six additional examples of "experimental use":

> (1) testing an invention to determine its sufficiency or to compare it to prior art;
> (2) tests to determine how the patented invention works;
> (3) experimentation on a patented invention for the purpose of improving on it or developing a further patentable invention;
> (4) experimentation for the purpose of "designing around" a patented invention;
> (5) testing to determine whether the invention meets the tester's purposes in anticipation of requesting a license; and
> (6) academic instructional experimentation with the invention.[99]

These permissible uses fall broadly into two groups: (1) *research on* the technology, or in other words, evaluations and studies of the technology itself; and (2) use of the patented technology in an effort to *design around* the technology. Both seem to fit within at least some interpretations of Justice Story's original formulation,[100] and moreover, both are important parts of biotechnology research.

Indeed, the clarification of biotechnology policy was expressly mentioned as reason to support the statutory exemption.[101] Citing the progress of university-industry partnerships following the Bayh-Dole Act, the House Report stated that allowing scientists and researchers to remain confused over

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[98] *Id.*
[99] *Id.* at 35-36.
[100] *See supra* notes 25-27 and accompanying text.
[101] H.R. REP. NO. 101-960 at 34-35 ("The field of biotechnology would particularly [sic] benefit from a statutory research exception.").

which research activities were permissible and exempt would be "contrary to sound public policy."[102] In addition to alleviating confusion, legislators cited two other main reasons to support a statutory research exemption for biotechnology: first, the prevalence of public funding in the biotechnology industry, and second, the fear that basic testing activities would be sent to countries with robust research exemptions, such as Japan and the countries in Western Europe.[103] To indicate the widespread support for a statutory research exemption in biotechnology, the House Report quotes professors, economists, and scientists, all in support of the proposition that without a clear exemption, "[u]nnecessary litigation occurs, excessive threats are levelled, transaction costs are raised, and experimentation and research are chilled."[104]

Though legislators emphasized that legislating an exemption would merely be codification of the case law, the House Report also identified a strong tradition within Congress of supporting statutory research exemptions, evidenced by the PVPA and the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly called the Hatch-Waxman Act). The House Report states that the PVPA research exemption "was made, in part, because of the involvement of publicly funded research on plants," and suggests that Title IV was thus appropriate because, as of 1990, "more than 50 per cent of all scientific research and experimentation is Federally funded."[105] The argument in the House Report about the statutory exemption in the Hatch-Waxman Act is particularly interesting because in that legislation, Congress was responding to a Federal Circuit case from 1984 which confronted the experimental use exception: *Roche Products v. Bolar Pharmaceutical*.[106] In *Roche*, the Federal Circuit rejected Bolar's argument that its use of patented drugs in order to ensure FDA approval of generic drugs (meant to hit market immediately after the patent expired) was experimental use, because of its commercial purpose.[107] Congress overturned this decision by including a narrow statutory research exemption in the Hatch-Waxman Act, which established that "the use of a patented invention in preparation for the submission of data to the Food and Drug Administration in connection with approval for marketing a drug was not an act of patent infringement," thus shielding some

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[102] *Id.* ("It only stands to reason in this public-private partnership that government and university scientists should not be confused about the permissible parameters of their research and experimentation. Clarity about research will promote competitiveness and creativity.").
[103] *Id.*
[104] *Id.* at 35.
[105] *Id.* at 33.
[106] 733 F.2d 858 (Fed. Cir. 1984).
[107] *Id.*

biomedical and pharmaceutical research from being considered infringement.[108] Using the PVPA and Hatch-Waxman Act as examples, the House Report argued that both common law and congressional tradition supported a strong research exemption to protect basic research.

The report accompanying the Patent Competitiveness Act therefore provides clear guidance as to how legislators perceived the common law research exemption: the parameters of the exemption were murky, yes, but legislators considered the exemption itself to be well-established and completely necessary. Because the bill contains a research exemption fashioned after the common law exemption, the provisions contained in the bill provide some indication as to what legislators believed the parameters of the common law exemption were and should be. They certainly believed an exemption existed, and that it should cover experiments to "research on" and "design around" patented technology.

Indeed, even the main critic of the bill, Representative Carlos Moorhead (R-CA), recognized the existence of the common law exemption in his dissenting remarks (in fact, as a reason *not* to legislate an exemption):

> I am aware that since 1813, the doctrine of "experimental purpose" has been recognized as an exemption to patent infringement. Throughout the years, U.S. courts have recognized that making or using a patented invention for the purpose of studying or analyzing how the invention works has not given rise to patent infringement liability, so long as this is done in a way which does not directly interfere with the commercial interests of the patentee. This long standing legal principle is sound and is a recognized feature of the patent system. *I am not aware of any reason to believe that there is a need for Congress to codify this doctrine.*[109]

To Moorhead, Title IV was unnecessary not only because of the existing common law exemption, but also because it sought to protect university research which he could not perceive as endangered:

> The stated purpose of this title is to protect university research activity. I fail to understand what universities are being protected from. There

[108] H.R. REP. NO. 101-960, at 34.
[109] *Id.* at 56 (emphasis added).

> has never been a case, to my knowledge, where a university has been sued for patent infringement for carrying on research on a patented invention. If the existing patent law is harming universities or interfering with their research, I believe they should come forward and explain the nature of the problem.[110]

At the time, it may have seemed unthinkable that a university would be sued for its basic research activities involving patented technology. And in any case, the bill evidently was not at the forefront of Congress's agenda: the Patent Competitiveness Act, like its predecessor the Transgenic Animal Patent Reform Act, languished in Congress for several years without being passed,[111] probably due in part to the defeat of its main proponent, Kastenmeier, in the 1990 primary election.[112] In the coming years, as the biotechnology sector failed to live up to both positive and negative expectations, biotechnology policy fell off of the public agenda, and a statutory research exemption fell away with it.[113] However, there were hints—particularly in *Roche v. Bolar*—that if confronted with an experimental use defense, the Federal Circuit would construe the research exemption strictly and narrowly. These hints foreshadowed future judicial decisions that would dramatically alter researchers' understanding of the common law exception, spurred on by something that may have been unimaginable to Moorhead and his contemporaries: a university was sued for its research work.

IV. 2000S: JUDICIAL EVISCERATION OF THE COMMON LAW EXEMPTION

While the controversies surrounding biotechnology played out in the 1980s, changes in the federal court system were taking place—specifically, the Court of Appeals for the Federal Circuit was created in 1982.[114] The Federal Circuit has subject matter jurisdiction over patent appeals from U.S. district courts. Its decisions in patent cases are crucial, because they are binding

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[110] *Id.* at 57.

[111] *See* H.R. REP. NO. 102-18, at 334 (1991) ("In the Second Session of the 101st Congress, the Subcommittee developed and the full Committee reported legislation (Title IV of H.R. 5598) to provide a research exemption to the patent laws of the United States. The bill was not considered in the House, and activity may resume on this matter in this Session.").

[112] Kevles, *supra* note 71, at 28.

[113] *Id.* at 28-29.

[114] Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, § 165, 96 Stat. 25, 50 (codified as amended in scattered sections of 28 U.S.C. (2006)).

precedent in district courts throughout the United States. Indeed, shortly after coming into existence, the Federal Circuit had the opportunity to create binding precedent on the scope of the research exemption in *Roche v. Bolar*,[115] although its decision to interpret the common law research exemption extremely narrowly was overturned quickly by Congress. In the early 2000s, the Federal Circuit had new opportunities to rule on the scope of the common law research exemption—and the court has clarified just how narrow it perceives the exemption to be.

After *Roche v. Bolar*, the next experimental use case to come up in the Federal Circuit was *Embrex, Inc. v. Service Engineering Corp.*[116] Embrex had a patent on a method of inoculating chicks against diseases before they hatched; Service Engineering evaluated the patented method in an effort to design around it.[117] Because Service Engineering planned to compete with Embrex, the Federal Circuit held that its use of the patented technology was impermissible commercial use that could not be protected by the research exemption.[118]

This case could have come out either way: on the one hand, because Service Engineering intended to eventually profit from designing around Embrex's technology, its experiments with the technology may not have been experimental use under Justice Story's original formulation.[119] But on the other hand, the patent bargain requires patentees to disclose their inventions so that others might invent new and better methods around the technology, not so that patentees can stifle attempts to design around it. The facts of *Embrex* might actually be a "paradigm case of exempted experimental use": the researchers at Service Engineering were using the technology only to understand how to avoid infringement, and the intent to profit was only remotely related to the use.[120] In any case, *Embrex* reaffirmed that the Federal Circuit would not permit an experimental use defense if the alleged infringer would receive commercial gain and eventual profit from experimenting with patented technology. But what about functionally non-commercial research by nonprofit entities? The Federal Circuit illustrated just how remote the commercial connection that barred the experimental use defense could be in

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[115] *See supra* note 106 and accompanying text.

[116] 216 F.3d 1343 (Fed. Cir. 2000). It is not completely clear why the exemption is brought up so infrequently as a defense, but speculation suggests that the exemption's track record of failure in federal courts may explain why defendants do not raise it as an affirmative defense as frequently as, say, patent invalidity.

[117] *Id.* at 1346-47.

[118] *Id.* at 1349.

[119] *See supra* note 22 and accompanying text.

[120] Mueller, *supra* note 17, at 935.

two subsequent cases: *Madey v. Duke University*[121] and *Integra LifeSciences v. Merck*.[122]

A. Madey v. Duke

The facts and posture of *Madey* are worth discussing in some detail. John Madey had formerly worked for (and directed) Duke University's Free Electron Laser lab, and invented and owned certain equipment used in the lab.[123] Prior to the lawsuit, Madey and Duke had a particularly vicious falling out, Madey left the lab, and Duke University scientists continued using his patented equipment in non-commercial research.[124] In addition to suing Duke on employment-related claims, Madey sued Duke for patent infringement stemming from the continued use of his equipment. The North Carolina district court dismissed the patent infringement claim on summary judgment, based in part on the experimental use defense presented by Duke and its lawyers: Duke's use of the technology was exempt because it was in the course of non-commercial, not-for-profit research.[125]

The Federal Circuit reviewed this judgment. Madey argued for an extremely narrow interpretation of experimental use, which would make any beneficial use of the patent infringing;[126] Duke countered that the experimental use defense protected the university's basic, non-commercial scientific research.[127] Both Duke[128] and the district court[129] cited *Ruth v. Stearns-Roger Manufacturing Co.*—a 1935 case in which the research exemption protected the Colorado School of Mines regarding its experiments with patented technology—as evidence that basic university research was protected by longstanding precedent.[130]

The Federal Circuit ultimately rejected Duke's arguments, overturning *Ruth* in the process. Not only did the court reaffirm

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[121] 307 F.3d 1351, 1352 (Fed. Cir. 2002).

[122] 331 F.3d 860 (Fed. Cir. 2003). This Article will only generally cover the holdings of *Madey* and *Integra*, in order to demonstrate how they conflict with legislators' understanding of the common law exemption. There is already a wealth of scholarship on the ramifications of these cases for the common law exemption. *See, e.g.*, Caltrider & Davis, *supra* note 32; Chester G. Moore, Comment, *Killing the Bayh-Dole Act's Golden Goose*, 8 TUL. J. TECH. & INTELL. PROP. 151, 163-68 (2006); Mueller, *supra* note 17, at 936-61.

[123] *See* Madey v. Duke Univ., No. 1:97CV1170, 1999 U.S. Dist. LEXIS 21379, at *2-3 (M.D.N.C. Dec. 1, 1999).

[124] *Id.* at *6.

[125] *Madey*, 307 F.3d at 1352.

[126] Appellant's Reply Brief at 7-13, *Madey*, 307 F.3d 1351 (No. 01-1567).

[127] Brief of Defendant-Appellee at 15-22, *Madey*, 307 F.3d 1351 (No. 01-1567).

[128] *Id.* at 22.

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

[130] *See supra* notes 34-35 and accompanying text.

prior holdings that no commercial use is protected by the exemption, it also established that even an extremely remote relationship between the use and the profit might prevent utilization of the experimental use defense:

> Our precedent clearly does not immunize use that is in any way commercial in nature. Similarly, our precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications. For example, major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.
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> In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or nonprofit status of the user is not determinative.
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> In the present case, the district court attached too great a weight to the nonprofit, educational status of Duke, effectively suppressing the fact that Duke's acts appear to be in accordance with any reasonable interpretation of Duke's legitimate business objectives. On remand, the district court will have to significantly narrow and limit its conception of the experimental use defense. The correct focus should not be on the nonprofit status of Duke but on the legitimate business Duke is involved in and whether or not the use was solely for amusement, to

> satisfy idle curiosity, or for strictly philosophical inquiry.[131]

The Federal Circuit thus held that experimentation or research in the university setting with "no commercial application whatsoever" may not be protected by the research exemption because of the university's business of attracting students, faculty, and grants. At least when researchers could rely on the distinction between commercial and non-commercial work, there was some guidance as to which activities would be protected. After *Madey*, only the old, vague guidelines protecting experiments for "philosophical inquiry" and "idle curiosity" remained, creating more confusion for nonprofit researchers than there may have been before the holding. As one commentator has put it, under the strict test in *Madey*, "it appears that any use of patented tools by researchers and faculty engaged in the constant pursuit of funding, whether in the form of research grants or licensing arrangements for inventions developed at the institution, is unlikely to be experimental use."[132]

Duke immediately petitioned the Supreme Court for certiorari, identifying a number of concerns: first, that all nonprofit research institutions, because they are in the business of seeking grants and attracting researchers, would no longer be eligible for the research exemption. Second, Duke argued that the unavailability of the defense would create high licensing demands and transactions costs for nonprofits facing a thicket of corporate patents in the way of their research.[133] The Supreme Court took some interest in these arguments, and invited the Solicitor General to submit a brief on the issue of whether certiorari should be granted.[134]

The Solicitor General's brief recommended that the petition for certiorari be denied, which it ultimately was.[135] The brief reasoned that the Federal Circuit ruling was not directly antagonistic to prior experimental use precedent, nor was it an inaccurate ruling given the facts of Madey's case.[136] The arguments in the brief are also direct evidence that the model of

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[131] *Madey*, 307 F.3d at 1362-63.

[132] Melissa J. Alcorn, Note, *Biotechnology Law: A Tale of Peptides and Lasers: Is* Integra Lifesciences I, Ltd. v. Merck KGaA *the End of the Experimental Use Defense for Biomedical Innovation, or Does § 271(e)(1) of the Patent Act Save the Day?*, 57 OKLA. L. REV. 381, 387 (2004).

[133] *See* Brief for the United States as Amicus Curiae at 10, Duke Univ. v. Madey, 538 U.S. 959 (2003) (No. 02-1007), *available at* http://www.justice.gov/osg/briefs/2002/2pet/6invit/2002-1007.pet.ami.inv.pdf.

[134] Duke Univ. v. Madey, 538 U.S. 959 (2003).

[135] Duke Univ. v. Madey, 539 U.S. 958 (2003).

[136] Brief for the United States as Amicus Curiae, *supra* note 133, at 6-13.

university patenting promoted by the Bayh-Dole Act rendered the research exemption untenable, at least in the view of the Department of Justice. The brief states that after Bayh-Dole, the university's role as a center of non-commercial research was no longer "clear-cut" given the rise of deep university-industry partnerships, and that universities and other research institutions deserved no blanket exemption as a result.[137] Not-for-profit research institutions were no longer primarily considered centers for advancement of human knowledge, but rather became institutions with deep corporate ties and conflicts of interest. The advent of biotechnology, the Bayh-Dole duty to commercialize, and the lack of clearly defined exempt uses combined to create a perfect storm, jeopardizing the continuation of basic research in even the most independent settings.

Nevertheless, the Solicitor General stated that the experimental use defense might be ripe for legislative (as opposed to judicial) consideration. The brief identified the "weighty concerns" raised by Duke about the scope of permissible research and the feasibility of licensing, and identified Congress as the authority most capable of evaluating those concerns and creating a solution.[138] The brief identified the Hatch-Waxman Act (Congress's response to *Roche v. Bolar*), the Transgenic Animal Patent Reform Act, and the Patent Competitiveness Act as evidence of Congress's willingness and ability to address the experimental use exception if necessary.[139] After certiorari was denied, universities were left questioning whether their activities were protected research, and unfortunately, the legislature took no immediate action to clarify.

B. Integra LifeSciences v. Merck

Integra is less instructive for this study because the research exemption was ultimately determined to be a collateral issue by the majority of the Federal Circuit panel.[140] Moreover, the Supreme Court ultimately overturned the Federal Circuit decision in favor of the defendants, but on grounds not involving the

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[137] *Id.* at 12-13.

[138] *Id.* at 15-16. The Solicitor General discussed the judiciary's ability to address these concerns: "Indeed, it seems improbable that a 190-year-old, judge-made defense with little rooting in any statutory text could anticipate the challenges of the modern academic and research environment and adequately accommodate the competing policy concerns raised by the parties in this case."

[139] *Id.* at 16-17 (citing the Hatch-Waxman Act, 35 U.S.C. § 271(e)(1); the Transgenic Animal Patent Reform Act, H.R. 4970, § 2, 100th Cong. (1988); and the Patent Competitiveness Act, H.R. 5598, § 402, 101st Cong. (1990)).

[140] Integra LifeSciences I, Ltd. v. Merck KGaA, 331 F.3d 860 (Fed. Cir. 2003).

experimental use debate.[141] Nevertheless, in the Federal Circuit case, the dissenting judge, Judge Newman, offered an interesting view of the experimental use exemption that merits discussion, particularly in view of some recent developments in biotechnology and some of the recently proposed solutions for the research exemption problem.

The facts of *Integra* are somewhat complex, but essentially involve the experiments of a scientist, David Cheresh, at the (nonprofit) Scripps Research Institute. Integra had a patent directed toward recombinantly-produced peptides (RGD peptides) and certain uses for them,[142] chiefly for healing wounds and adhering prosthetics, although Integra was never successful in commercializing its patents.[143] Cheresh discovered a new use for certain forms of the RGD peptides: inhibiting blood vessel growth, which could have profound implications for inhibiting cancerous tumor growth.[144] Recognizing the possibilities of this technology, Merck, a German pharmaceutical company, entered into an agreement with Scripps to develop it.[145]

The majority did not discuss experimental use,[146] but in her dissent, Judge Newman expressed the opinion that the experimental use exception would have properly protected some of Cheresh's early work.[147] Judge Newman expressed her concern that the "right to [use patented technology to] conduct research to achieve [basic] knowledge need not, and should not, await expiration of the patent," and her frustration at the majority's decision to further "disapprove[] and essentially eliminate[] the common law research exemption."[148] Judge Newman distinguished "research" from "development," and stated that the exemption should protect the former:

> [T]here is a generally recognized distinction between "research" and "development," as a matter of scale, creativity, resource allocation, and often the level of scientific/engineering skill needed for

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[141] Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005).
[142] *Integra*, 331 F.3d at 862-63.
[143] Mueller, *supra* note 17, at 949-50.
[144] *Id.*
[145] *Id.*
[146] *Integra*, 331 F.3d at 864 n.2 (stating that the experimental use exemption was not before them in the case, but suggesting that even if it had been briefed or argued, "the Patent Act does not include the word 'experimental,' let alone an experimental use exemption from infringement").
[147] *Id.* at 874. (Newman, J., dissenting) (stating that "either the common law research exemption or the development associated with § 271(e)(1) immunity embraces all of [the allegedly infringing] activities").
[148] *Id.* at 873.

> the project; this distinction may serve as a useful divider, applicable in most situations. Like "fair use" in copyright law, the great variety of possible facts may occasionally raise dispute as to particular cases. However, also like fair use, in most cases it will be clear whether the exemption applies.[149]

Despite leaving the parameters of the exemption open, Judge Newman did give some guidance as to the types of research activity that should be protected:

> The subject matter of patents may be studied in order to understand it, or to improve upon it, or to find a new use for it, or to modify or "design around" it. Were such research subject to prohibition by the patentee the advancement of technology would stop, for the first patentee in the field could bar not only patent-protected competition, but all research that might lead to such competition, as well as barring improvement or challenge or avoidance of patented technology. Today's accelerated technological advance is based in large part on knowledge of the details of patented inventions and how they are made and used. Prohibition of research into such knowledge cannot be squared with the framework of the patent law.[150]

Judge Newman's language is evocative of the "research on"/"research with" dichotomy that has been advanced by many scholars, including Rebecca S. Eisenberg and the National Research Council,[151] and is also evocative of the protected uses outlined in the statutory exemption contained in the Patent Competitiveness Act.[152] Under Judge Newman's formulation, pre-commercial research on the technology as an end in itself—intended to help researchers understand the invention or avoid infringement—would be exempted, while research *using* the technology as a tool or a means to another end would be infringement.

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[149] *Id.* at 876 (footnote omitted).
[150] *Id.* at 875.
[151] *See* Mueller, *supra* note 17, at 957-59; Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1074-75 (1989); Report of the National Institutes of Health Working Group on Research Tools Appendix D (June 4, 1998), http://www.nih.gov/news/researchtools/appendd.htm.
[152] *See supra* notes 98-99 and accompanying text.

The majority opinion in *Integra* was ultimately vacated and remanded by the Supreme Court on other grounds, and in any case, Judge Newman's dissent would have had no precedential force.[153] However, the dissent reflects the desperate need for guidance in delineating the bounds of the research exemption: even a basic, vague line between "research" and "development" might aid researchers and courts in their application and assessment of permissible research activities. As the Federal Circuit was narrowing the experimental use exception in the legal sphere, new challenges for experimental use were arising in the scientific world. The patenting of genes and genetic sequences was in full swing. And as the 2000s continued, the tension between gene patents and the progress of basic research would further illustrate the need for clear guidelines to govern not-for-profit research on patented technology.

V. THE FUTURE OF THE RESEARCH EXEMPTION IN BIOTECHNOLOGY

The need for clarification of the research exemption has been heightened by the rise of gene patenting, as new questions arise about how researchers can use basic DNA strands to do beneficial research on health and disease. The history of gene patenting has been written elsewhere;[154] suffice it to say that since around the year 2000, the Patent Office has granted patents on small strands of complementary DNA—not on methods of using them, but on the fragments themselves—allegedly because a human's actions in isolating and purifying the fragments renders them patentable.[155] Gene patenting has held great promise for the biotechnology industry, but has also generated objections from groups with moral and ethical concerns about patenting sequences found naturally in human and animal bodies.

Deep controversies have arisen surrounding gene patenting.[156] Some of the most troubling questions implicate the

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[153] For more in-depth discussion of the *Integra* case and the research exemption, see Alcorn, *supra* note 132; Rebecca Lynn, Note, Merck KGaA v. Integra Lifesciences I, Ltd.: *Judicial Expansion of 271(e)(1) Signals a Need for a Broad Statutory Experimental Use Exemption in Patent Law*, 21 BERKELEY TECH. L.J. 79 (2006).

[154] *See* KEVIN DAVIES, CRACKING THE GENOME: INSIDE THE RACE TO UNLOCK HUMAN DNA (2001); Daniel J. Kevles & Ari Berkowitz, *The Gene Patenting Controversy: A Convergence of Law, Economic Interests, and Ethics*, 67 BROOK. L. REV. 233 (2001).

[155] *See* Andrews, *supra* note 15, at 803.

[156] *See supra* note 154. For another thorough and recent overview of the gene patenting controversies, see Lisa Larrimore Ouellette, Note, *Access to Bio-Knowledge: From Gene Patents to Biomedical Materials*, 2010 STAN. TECH. L. REV. N1, http://stlr.stanford.edu/pdf/ouellette-access-to-bio-knowledge.pdf.

fate of basic research on these genes and sequences, many of which are correlated with predisposition to certain health problems or diseases. Most obviously, there is no way to "invent around" a particular genetic sequence. Researchers who wish to work on genetic therapy or diagnostic testing related to a patented gene fragment often cannot do so without infringing the patent.[157] A patent on a gene sequence can hinder research on the technology *and* attempts at the development of tests and therapy around it; any progress that occurs must happen in the labs and by the employees of the patentee and its licensees.

As with every new advancement in biotechnology, members of Congress attempted to legislate a research exemption, this time one that would allow non-commercial research on patented genes. The Genomic Research and Diagnostic Accessibility Act of 2002[158] would have protected the use of patented genetic information in the course of "systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge," as well as use of the patented sequence in the creation of "any test, designed to detect disease, to predict the potential for a medical disorder, or to predict the effectiveness of therapeutics."[159] But like nearly every other attempt to legislate a statutory research exemption, the bill was never acted on after being referred to committee, and it expired at the end of that session of Congress.[160] Another bill, the Genomic Research and Accessibility Act of 2007,[161] sought to remedy the research problems by prohibiting gene patenting altogether,[162] but it, too, died after being referred to committee.[163]

Confusion about the scope of permissible research may deter researchers from doing work on patented genes: after a patent was granted on a gene pertaining to hemochromatosis, thirty percent of the U.S. laboratories surveyed ceased their work on it.[164] Many other researchers also report stopping their work after learning that a patent has been granted, or after being contacted by the patent holder with threats of suit or offers of exorbitant

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[157] Andrews, *supra* note 15, at 804.
[158] H.R. 3967, 107th Cong. (2002).
[159] *Id.* §§ 2(E), 3(F).
[160] Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong., *available at* http://www.govtrack.us/congress/bill.xpd?bill=h107-3967.
[161] H.R. 977, 110th Cong. (2007).
[162] 153 CONG. REC. E315-05 (daily ed. Feb. 9, 2007) (statement of Rep. Becerra).
[163] Genomic Research and Accessibility Act, H.R. 977, 110th Cong., *available at* http://www.govtrack.us/congress/bill.xpd?bill=h110-977.
[164] Andrews, *supra* note 15, at 805.

licensing fees.[165] In any event, the effects of confusion deter beneficial competition and development, perhaps not for the most brazen researchers, but for enough researchers that it is a serious problem.[166] Restrictions on basic research threaten to stunt advances in technology that could have profound effects both for public health and for economic growth. The confusion about the permissibility of basic research on DNA fragments remains.

Gene patents are only one subset of biotechnology patents which seem to be affected by the murky research exemption. Although recent scholarship has indicated that patents and patent infringement suits may not be the most serious obstacle that scientific researchers face in their efforts to access and use patented technology,[167] the extant confusion created by the unclear exemption is terrible policy for a host of reasons. Researchers and universities are somewhat less likely to engage in activity which might be infringing; excessive licensing breeds high prices and transactions costs that may be transferred to the government and the public funding the research;[168] there is also the possibility that basic research that would otherwise take place in U.S. labs is being taken on by countries with robust and clear research exemptions.[169] Even if many researchers are not afraid of being sued for their work with patented technology, the norms which might be keeping researchers from being sued could one day be violated (envision another Myriad, or worse, universities suing one another over their patent portfolios).

Up to this point, this Article has attempted to point out the tensions between congressional understanding of experimental use and judicial understanding of experimental use. The two branches seem to be talking past one another: in the past half-century, judges have stated that a broader exemption could only be created by the legislature, while various legislators have relied on the existence of a common law exemption in deciding whether to support or amend a statutory exemption. Adding to the mess, important advances in biotechnology—most recently, the technology involved in gene patents—have resulted in broad patents that may be having a chilling effect on the continuation of basic research, particularly

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[165] *Id.*

[166] Although Ouellette's research demonstrates that the patent problem may be overstated, she also notes that some studies indicate that "DNA patents are limiting both the availability of testing and the development of new genetic tests." Ouellette, *supra* note 156, ¶ 56.

[167] *See id.*

[168] *See* Maurice Cassier, *Private Property, Collective Property, and Public Property in the Age of Genomics*, 54 INT'L SOC. SCI. J. 83, 90-91 (2002).

[169] *See* John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 BERKELEY TECH. L.J. 685, 717-19 (2002) (discussing the possibility of outsourcing as a result of the lack of a research exemption in the United States).

since *Madey* and *Integra*, which rendered the parameters of exempted non-commercial research even more unclear. This Part will provide a brief overview of a few of the solutions and alternatives that scholars and policymakers have advanced for the research exemption problem, suggestions which would protect the continuation of basic research without damaging the value and the incentives that the patent system provides. Although I discuss the arguments made for different types of solutions generally—in other words, the solutions recommended below could cover research using all patented technologies—many of these solutions could in theory be narrowed to specifically address the biotechnology sector.

A. Liability Rules

One of the solutions that has been proposed by scholars such as Rebecca S. Eisenberg and Janice M. Mueller would be to change the rule protecting the patentee's intellectual property from a property rule to a liability rule;[170] a property rule protects an owner's rights against any non-consensual use of the property, while a liability rule permits non-consensual use with the payment of damages after-the-fact.[171] The liability rule would not permit a broad research exemption, but it would allow courts to examine uses of patented technology case-by-case, balancing the harm to the patent owner against the scope, nature, and necessity of use by the infringer, and adjusting damages accordingly. This approach has been advocated by Judge Rader of the Federal Circuit.[172]

In its recent decision in *eBay Inc. v. MercExchange, L.L.C.*, the Supreme Court held that injunctions are not an automatic remedy for patent infringement, and the Court suggested that a balance-of-harms approach and adjusted damages may be more appropriate in particular cases.[173] The public interest in the progress of basic research and improvements in public health thus might make a liability rule a good substitute for the experimental use exception, by permitting non-commercial university and nonprofit researchers to use technology in de minimis, non-commercial ways that would likely not cause great damages. However, there are two obvious problems: first, while assessing

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[170] Eisenberg, *supra* note 151, at 1078; Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 54-57 (2001).

[171] *See generally* Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089 (1972).

[172] *See* Mueller, *supra* note 17, at 934-36 (discussing Judge Rader's arguments for a similar rule in *Embrex* and *Integra*).

[173] 547 U.S. 388, 391, 394 (2006).

damages on past research may be possible, valuing the damages caused by prospective or ongoing experimentation may be very difficult;[174] and second, the patent holder's uncertain ability to wield exclusive control over use and licensing of the patent will make the patent far less valuable and will also damage the overall value of the incentives provided by the patent system.[175]

B. A "Fair Use" Exemption

While Justice Story is famous for creating the experimental use exception that is the topic of this Article, he is also responsible for creating another intellectual property doctrine: copyright fair use.[176] Copyright fair use allows certain users to reproduce copyrighted material without permission, under limited circumstances. Though the doctrine originated at common law, it was somewhat murky (as experimental use is today); hence, in the Copyright Act of 1976, Congress enacted a fair use exemption meant to codify the existing common law standard.[177] The Copyright Act provides that a court considering whether a defendant's use is "fair use" and thus not copyright infringement should consider four factors:

> (1) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;
> (2) the nature of the copyrighted work;
> (3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and
> (4) the effect of the use upon the potential market for or value of the copyrighted work.[178]

Many scholars have suggested that patent law might benefit from a "fair use" type exemption, in which courts could use a multi-factor test to determine whether a defendant's use of patented technology should be protected or not.[179] An exemption

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[174] *See* Mueller, *supra* note 17, at 979.
[175] *See* F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697, 703 (2001).
[176] Folsom v. Marsh, 9 F. Cas. 342, 344 (C.C.D. Mass. 1841) (No. 4901). Copyright fair use is distinct from trademark fair use, discussed briefly in my discussion of the PVPA above. *See supra* note 88 and accompanying text.
[177] 4 MELVILLE B. NIMMER & DAVID NIMMER, NIMMER ON COPYRIGHT § 13.05[1] (2009).
[178] Copyright Act of 1976, 17 U.S.C. § 107 (2006).
[179] *See, e.g.*, Donna M. Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1687 (2001); Mueller, *supra* note 170, at 42; Maureen A. O'Rourke, *Toward a*

could look very similar to the "four factors" test of copyright law: for example, courts could consider the purpose of the use of the patented technology, the amount of the use, and so on in determining whether a defendant's activities would be permissible research or impermissible infringement.[180] The test could be created through either legislative guidance or common law decisions. An unambiguous, "fair use" style research exemption in patent law would help ensure that creation and sharing would still be incentivized, and would also protect the valid interests of the patentee in the fruits of his or her hard work.

However, the suggestion to create a "fair use" affirmative defense is not without its problems. It is a broad solution requiring significant legislative or judicial action that risks unintended consequences and might result only in added complexity and confusion.[181] It may also be expensive. Although some have alleged that creating a clear exemption would reduce litigation and the costs of case-by-case adjudication and modification of an unclear research exemption,[182] one could envision another scenario in which defendants would be more encouraged to present the defense or bring declaratory judgment actions, and hence, litigation might increase as courts build a body of "experimental use" precedent. There are also problems with the complexity of the evidence to be considered. Although factors like the "amount of use" are comparatively easy to judge in copyrightable works, in the patent scenario, courts might be confronted with particularly detailed, scientific, and subjective documents and testimony on the amount and purpose of use, further increasing the cost of litigation.[183] Courts would also have to face "difficult pricing decisions" to decide the scope, amount, and intent of the use, in order to perform the balancing test.[184] Furthermore, the current process, which provides courts with flexibility in computing damages for infringement, may already provide a sort of multi-

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Doctrine of Fair Use in Patent Law, 100 COLUM. L. REV. 1177, 1205 (2000) ("The preceding analysis identified five factors relevant to a fair use finding: (i) the nature of the advance represented by the infringement; (ii) the purpose of the infringing use; (iii) the nature and strength of the market failure that prevents a license from being concluded; (iv) the impact of the use on the patentee's incentives and overall social welfare; and (v) the nature of the patented work. While this test resembles that of copyright fair use, it diverges to reflect the different incentive scheme of patent."); *see also* Eisenberg, *supra* note 151, at 1018 n.6. ("The U.S. copyright laws also exempt some research uses of copyrighted works from infringement liability under the 'fair use' doctrine.").

[180] *See* O'Rourke, *supra* note 179, at 1230-31.

[181] *See id.* at 1242.

[182] *Id.*

[183] *Id.* at 1246-47.

[184] Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457, 470 (2004).

factor test which protects de minimis, nonprofit researchers from having to pay large damages to patent holders,[185] rendering a "fair use"-type defense redundant given the significant trouble creating a new fair use doctrine might entail.

C. Compulsory Licensing, Non-exclusive Licensing, and Patent Pools

Patent pools and compulsory licenses are traditional tools of patent law that could be harnessed to ensure the continuation of valued research, and this approach has been advocated by Lori Andrews as well as the National Research Council Committee on Science, Technology, and Law.[186] Similar consortia and collective licensing programs have been utilized with great success in Europe.[187] Patent pools are agreements in which two or more patent holders agree to license their technology to one another (or to third parties for a set fee). These agreements prevent parties seeking to use the technologies from having to seek licenses from each individual patentee. Because of the existing norms of sharing and scholarship in academia, universities and nonprofits who invent technology might be predisposed to make commitments to join these voluntary associations.

As a similar alternative, the norms in the scientific community could be utilized to promote non-exclusive licensing of university- or nonprofit-developed technology. This approach might require universities and nonprofits to sacrifice the high payments that come with exclusive licenses, but non-exclusive licensing could promote more widespread research and development on and around patented work. Although it would be more difficult, some scholars have advocated that the non-exclusivity reforms go even further: using public domain projects such as the Human Genome Project and some components of pharmaceutical research as examples, they have suggested that basic research in universities and nonprofits that is funded by the public go directly into the public domain.[188] This would require revision of the Bayh-Dole Act, but one could imagine a revision

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[185] *See* Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1352 (Fed. Cir. 2000) (Rader, J., concurring).

[186] Andrews, *supra* note 15, at 807; *cf.* NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 14-15 (2006) (recommending that "NIH . . . undertake a study of potential university, government, and industry arrangements for the pooling and cross-licensing of genomic and proteomic patents, as well as research tools").

[187] *See* Cassier, *supra* note 168, at 94-95.

[188] Rebecca S. Eisenberg & Richard R. Nelson, *Public v. Proprietary Science: A Fruitful Tension?*, 131 DAEDALUS 89, 100 (2002).

permitting and requiring universities to pursue patent protection for *applications* of basic research, but not for the results of basic research and new knowledge itself.[189]

Compulsory licensing, in contrast, requires no volunteerism on the part of the patent holder; instead, the government can grant a license on a patent to serve the public interest.[190] The march-in rights in the Bayh-Dole Act would clearly seem to give the government this ability, but to date, these rights have not been utilized.[191] The obvious problem with this and all of the licensing/pooling approaches is that they require volunteer, collective, or administrative actions, all of which are susceptible to high transactions costs and inertia.

D. Legislation

With the common law research exemption in its current state, the best choice would be congressional action to legislate a research exemption. In the past, Congress has legislated exemptions for certain types of possibly infringing activity involving patented technology when matters of life and health are at stake: Congress has protected research use of germplasm in the PVPA, drug experimentation in the Hatch-Waxman Act, and most recently, it has exempted doctors using patented surgical procedures from being sued for infringement.[192] A legislative research exemption has been advocated by nearly every single scholar who has considered the problems inherent in the current system.[193] The exception could be narrowly drawn—for example, protecting only genetic testing or certain types of research on certain biotechnologies—or it could guide all basic research in the field of public health.

As this paper has shown, for the past century, nearly every scholar, legislator, and judge to consider what kinds of experimentation and research *should* be protected has agreed upon two broad categories: (1) *research on* the patented technology and (2) research to *design around* the technology. The National

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[189] *See id.*

[190] Andrews, *supra* note 15, at 807.

[191] *See supra* note 66 and accompanying text; *see also* NAT'L RESEARCH COUNCIL, *supra* note 186, at 96.

[192] Omnibus Consolidated Appropriations Act, Pub. L. No. 104-208, § 616, 110 Stat. 3009, 3009-67 to -68 (1996) (codified at 35 U.S.C. § 287(c) (2006)).

[193] *See, e.g.*, NAT'L RESEARCH COUNCIL, *supra* note 186, at 14; Andrews, *supra* note 15, at 806-07; Sherizaan Minwalla, *A Modest Proposal To Amend the Patent Code 35 U.S.C. § 287(c) To Allow Health Care Providers To Examine Their Patients' DNA*, 26 S. ILL. U. L.J. 471, 473 (2002); Mueller, *supra* note 17, at 980.

Research Council Committee has drafted four useful guidelines that outline the work which it believes should be exempted:

> [M]aking or using a patented invention should not be considered infringement if done to discern or to discover:
>
> a) the validity of the patent and scope of afforded protection;
> b) the features, properties, or inherent characteristics or advantages of the invention;
> c) novel methods of making or using the patented invention; or
> d) novel alternatives, improvements, or substitutes.[194]

Such an exemption would seem to protect both the patentee's interests and the user's. Research with the patented technology for commercial development would be infringing, but research incidental to commercial business—for example, in the course of developing an alternative, or ascertaining the veracity of the patent's specifications—would not.[195]

While any proposed legislation would require extensive hearings and the input of judges, scholars, researchers, and private firms,[196] the suggestions already contained in past judicial opinions and legislative history are a good start. A clear exemption would ultimately benefit not only public health and non-commercial biotechnology research, but would also help private, commercial industry. Such an exemption would offer patent holders better guidance as to when they should pursue costly and time-consuming enforcement of their patents, and when enforcement would be unsuccessful or inappropriate. Moreover, clearly defined exempt uses would allow patent holders to cut through the thicket of both commercial and non-commercial researchers that may be using their technology, allowing them to focus on strategically licensing their patents to those engaging in non-exempt work.

CONCLUSION

There is a complex web of law and policy surrounding biotechnology and the university's role in basic biotech research: at best, this Article has strived to identify some of the incongruities

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[194] NAT'L RESEARCH COUNCIL, *supra* note 186, at 14.
[195] *Id.*
[196] The difficulties in outlining the scope of such an exemption are briefly discussed in Eisenberg & Nelson, *supra* note 188.

between Congress's historical understanding of the common law research exemption and the narrow judicial reality, and how these misunderstandings have ultimately resulted in confusion that is affecting researchers and universities alike. Legislation to protect basic biotechnology research is necessary.

The ACLU's victory in its suit against Myriad at the district court level leaves the future of gene patents uncertain. Although the court decided the case on limited grounds at summary judgment, namely, the unpatentability of products of nature,[197] it did not rule out the possibility that gene patents may be impeding beneficial, basic research, and that further findings of fact might reveal that to be the case.[198] If the ACLU suit survives an appeal from Myriad, litigation might be enough to effect changes in gene patenting, but as history has demonstrated, with each new advance in biotechnology there have been new problems and challenges implicating the research exemption, and clear legislative policy going forward would help alleviate the problem. At the very least, even if the ACLU suit is ultimately unsuccessful, it is possible that it will draw public attention to the problems inherent in the obstacles to basic research and will force some legislative action.

While the confusion may not yet have led to a crisis implicating public health, it would be better to have Congress act prematurely than to act too late. Since *Madey* and *Integra*, given the importance of continued basic research in biotechnology fields such as human genetics, a clear, legislated exemption to guide researchers and the universities and nonprofits that employ them is badly needed. A clear exemption would free Progress, that lofty aim of the patent law, from the patents that currently may be stifling it.

[197] Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, No. 09 Civ. 4515, 2010 U.S. Dist. LEXIS 30629, at *108 (S.D.N.Y. Mar. 29, 2010).
[198] *Id.* at *77.