

**“NOT QUITE DEAD YET”:
THE NEAR FATAL WOUNDING OF THE
EXPERIMENTAL USE EXCEPTION AND ITS
IMPACT ON PUBLIC UNIVERSITIES**

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ABSTRACT

While federal legislators have given universities increased freedom to protect new inventions created at their institutions through the Bayh-Dole Act, the judicial branch has restricted universities' use of patented inventions to produce additional innovations. This paper discusses the problems resulting from the decision in *Madey v. Duke University*, which reduced the breadth and applicability of the experimental use exception defense to patent infringement claims. Limiting the accessibility of novel intellectual property to research universities jeopardizes scientific progress and weakens the educational experience. Possible solutions exist on many fronts: sovereign immunity may be an adequate defense to many infringement claims at public universities; other potential solutions may address the dilemma through the courts, supplementary legislation, or private settlement of infringement disputes.

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INTRODUCTION

Jason is a twenty-two year old student who just finished his first semester of graduate school in biomedical engineering at a top research university. Jason chose a dissertation project that involves the development of a novel synthetic bone replacement, a material that would biodegrade in the body at a rate similar to that of bone re-growth, provide a host to appropriate cell types to stimulate the regrowth, and allow the inclusion of therapeutic agents to promote bone regeneration. Although Jason's faculty advisor has outlined the project in the funding proposal, the actual synthesis path, composition, and properties of this new material remain undiscovered, presumably to be clarified by Jason, who will work on the project for the next four or five years.

Jason is unleashed in the lab with little previous laboratory experience and virtually no supervision by his advisor who manages a full-time teaching load, participates in a variety of departmental and campus-wide activities, frequently writes and reviews funding proposals, and manages a research lab with twenty-five undergraduate students, graduate students, and post-doctoral researchers. Jason does what most novice researchers do in the beginning: he reads a great deal of the existing literature and begins to learn the synthesis and characterization techniques that he will need for the development of the novel materials for his dissertation project. Jason finds a journal article by Professor Gikos, director of a well-known lab at another state university, whose research combines the fields of biomedical and bone tissue engineering. With no thought to existing patents, possible infringement, or potential liability, Jason follows the experimental section of the article to learn the details of the organic syntheses, produces many of the materials described

in the article, and experiments with the materials to learn of their suitability as bone replacements. He finds novel ways to alter the syntheses developed in, and patented by, the Gikos lab to produce more versatile materials that are better suited as bone replacements.

This microcosm represents the course of research in major universities worldwide, where experimentation with published research provides a learning tool for budding scientists and a base for “standing on the shoulders of giants.”¹ The scientific process requires that research be checked and duplicated and this process is commonly followed in research laboratories globally. Two hundred years of case law supports the common law doctrine of experimental use, which allows the experimental use of patented material so long as the use is not for commercial purposes. By allowing university researchers widespread access to fundamental research by exempting experimental uses from liability, a great deal of basic research has produced myriad important discoveries in university research laboratories. Additionally, universities produce tangential research, which stems from extending and innovating concepts in previously discovered and developed ideas. The experimental use doctrine, coupled with widespread federally funded research, has for many years stimulated innovation and promoted the transfer of knowledge.

However, these universal goals for research advancement are threatened by the recent solidification of *Madey v. Duke University*, a modern case that very narrowly limits the experimental use exception as a defense to patent infringement.² Furthermore, recent legislation has stimulated federally funded university research and facilitated commercialization, while at the same time, has paradoxically allowed widespread protection of intellectual property created by university laboratories, thereby hindering the transfer of knowledge of these new inventions outside the originating university.

This paper discusses the pitfalls of both the narrowing of the experimental use exception and the problems created by the increased freedom universities have to protect new inventions created in their institutions. Limiting widespread availability of novel intellectual property threatens scientific progress and limits the educational experience that students, the future creators of novel intellectual property, receive. Possible solutions exist on many fronts, the most viable contender being sovereign immunity as a possible defense to public

1. Isaac Newton in a 1676 letter to Robert Hooke *available at* <http://freespace.virgin.net/ric.martin/vectis/hookeweb/roberthooke.htm> (last visited Mar. 16, 2004).

2. *See Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003).

institution infringement problems. Other possible solutions may address the problem via the courts, additional legislation, or private parties settling infringement disputes.

Section I of the paper discusses the background of experimental use and Section II delves into an analysis of the decision in *Madey v. Duke University*. The effect of the Bayh-Dole Patent and Trademark Amendments Act (Bayh-Dole Act) on university research and the implications of the Bayh-Dole Act when coupled with a narrowed experimental use exception to patent infringement are explored in Section III. One potential remedy for public universities to the problem of the narrowed experimental use exception, as discussed in Section IV, lies in state sovereign immunity. Finally, Section V covers other possible solutions involving the judicial system, Congress, and private parties.

I. HISTORY OF THE EXPERIMENTAL USE EXCEPTION

The power to regulate the patent system was bestowed upon Congress by Article I of the United States Constitution: "The Congress shall have the power. . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."³ Congress defined patent infringement more specifically in the United States Code: "whoever without authority makes, uses, offers to sell, or sells any patented invention . . . infringes the patent."⁴ Numerous cases have interpreted this definition broadly, often allowing unfettered use where the use resulted in no profits or other commercial benefits. Judicially acceptable non-infringing experimental use first occurred in 1813 regarding the use of a machine that manufactured cotton and wool cards.⁵ The court opined "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."⁶ Thus, the experimental use exception was born.

Subsequent cases molded and shaped the experimental use exception established in *Whittemore v. Cutter*.⁷ In the same year that *Whittemore* was decided, the Massachusetts district court further expanded the doctrine instituted in *Whittemore* suggesting that an intent to infringe must exist and the infringer must "deprive the owner of

3. U.S. CONST., art. I, § 8, cl. 8.

4. 35 U.S.C. § 271 (2004).

5. *Whittemore v. Cutter*, 29 F. Cas. 1120 (D. Mass. 1813) (No. 17,600).

6. *Id.* at 1121.

7. *Id.* at 1120.

the lawful rewards of his discovery.”⁸ In *Poppenhusen v. Falke*, another court further broadened the experimental use exception, expanding it to include those uses employed “for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement” as non-infringing uses.⁹ Another case from the nineteenth century more explicitly allowed an experimental use of a patented invention, as long it was not utilized for “commercial purposes.”¹⁰

In more recent times, a defendant invoked the experimental use exception against a claim of possible university infringement, and the results echoed the sentiments of the established doctrine holding that use for educational purposes was not infringement.¹¹ The U.S. District Court for the District of Colorado in *Ruth v. Stearns-Roger Manufacturing Co.* found that the experimental use doctrine applied when the infringing user of the patented machinery was an educational institution, the Colorado School of Mines.¹² The court held that “the making or using of a patented invention merely for experimental purposes, without any intent to derive profits or practical advantage therefrom, is not infringement.”¹³

While some commentators suggest that the experimental use exception is justified in the realm of university research,¹⁴ others believe the exception is not appropriate in these circumstances precisely because a school has a legitimate commercial interest in its research, even if the experimental use is for educational purposes.¹⁵ The overarching concern is that university labs will exploit the experimental use exception by experimenting with patented inventions in the laboratory and will subsequently bring novel but tangential research to commercialization. Some would argue that this course of events follows exactly what the framers of the patent laws anticipated and intended in drafting the legislation that introduces published patents into the public domain.¹⁶ It remains unclear whether free universal access to new inventions or strict patent protection of these new discoveries will better promote scientific

8. *Sawin v. Guild*, 21 F. Cas. 554, 555 (D. Mass. 1813) (No. 12,391).

9. *Poppenhusen v. Falke*, 19 F. Cas. 1048, 1049 (S.D.N.Y. 1861) (No. 11,279).

10. *Bonsack Mach. Co. v. Underwood*, 73 F. 206, 211 (E.D.N.C. 1896).

11. *See Ruth v. Stearns-Roger Mfr.*, 13 F. Supp. 697, 713 (D. Colo. 1935), *rev'd on other grounds*, 87 F.2d 35, 42 (10th Cir. 1936).

12. *See id.*

13. *Id.*

14. *See* Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. & TRADEMARK OFF. SOC'Y 617, 633 (1985).

15. *See* Richard E. Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. PAT. & TRADEMARK OFF. SOC'Y 357, 371-72 (1957).

16. *See* Steven J. Grossman, *Experimental Use or Fair Use as a Defense to Patent Infringement*, 30 IDEA 243 (1990).

progress¹⁷ and universities seem to be walking a fine line between both paths.

Courts' interpretations of experimental use have not always been so generous. In a dispute over a patented mechanism for diverting jet engine combustion gases, the U.S. Court of Claims limited the experimental use exception by prohibiting the exception where the use was "in keeping with the legitimate business of the using agency."¹⁸ Even when the experimental use benefits the public, use of a patented invention infringes despite the invention serving "a valuable governmental purpose."¹⁹ In *Roche Products, Inc. v. Bolar Pharmaceuticals Co.*, the U.S. Court of Appeals for the Federal Circuit (CAFC) further narrowed the exception when it found infringement due to FDA testing of a generic drug prior to the patent expiration. The court held that the experimental use exception was not so broad as to include infringement under "the guise of 'scientific inquiry' when that inquiry has definite cognizable, and not insubstantial commercial purposes."²⁰ The U.S. Claims Court solidified the decision in *Roche*, stating in a subsequent infringement dispute: "At no time were the accused devices used for amusement, to satisfy idle curiosity, or for philosophical inquiry; to the contrary, each use was in keeping with the legitimate business of the using agency and served a valuable governmental and public purpose."²¹ In 2002, however, the well-established experimental use doctrine changed drastically with the decision in *Madey v. Duke University*.²²

II. THE DECISION AND IMPLICATIONS OF *MADEY V. DUKE UNIVERSITY*

The United States Supreme Court recently denied Duke University's Writ of Certiorari,²³ thereby confirming the CAFC's decision in *Madey v. Duke University*.²⁴ The result in *Madey* severely limits the experimental use exception that previously protected

17. See Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1046-60 (1989) (an excellent discussion of the conundrum).

18. *Douglas v. United States*, 181 U.S.P.Q. 170, 177 (Ct. Cl. 1974).

19. *Pitcairn v. United States*, 547 F.2d 1106, 1126 (Ct. Cl. 1977).

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

21. *Deuterium Corp. v. United States*, 19 Cl. Ct. 624, 631 (1990).

22. See *Madey v. Duke Univ.*, 307 F.3d 1351, 1351 (Fed. Cir. 2002), *cert denied*, 539 U.S. 958 (2003).

23. *Duke Univ. v. Madey*, 539 U.S. 958 (2003).

24. See *Madey*, 307 F.3d at 1351.

universities from patent infringement liability resulting from university research.²⁵

The dispute arose after Duke University removed Professor Madey from his position as director of the Free Electron Laser (FEL) Lab.²⁶ Madey, previously a professor at Stanford University, became the sole owner of several patents resulting from his FEL research at Stanford.²⁷ Madey brought his inventions to Duke after the university offered him directorship of a newly constructed lab that would house his research and he supervised the new FEL lab at Duke for ten years.²⁸ After his removal from the FEL lab, Professor Madey resigned from Duke and the university continued to manage the FEL lab, including Professor Madey's equipment.²⁹ Professor Madey sued Duke claiming patent infringement³⁰ and Duke asserted the experimental use defense.³¹

The CAFC held that only exploitations of patents "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry" satisfy the narrow experimental use exception.³² Furthermore, according to the case, whether or not the user maintains non-profit or for-profit status matters little and is not a determining factor in the experimental use analysis.³³ The court specifically relied on the educational and research motivations for "major research universities" like Duke, where even research that comes to no commercial fruition "further[s] the legitimate business objectives, including educating and enlightening students and faculty."³⁴ The decision suggests that university research, whether or not the research is commercially viable, furthers the university's "legitimate business objectives" of attracting students, faculty, and research grants, and is therefore not covered by the experimental use exception. As one commentator explains, "[s]cientific research in academia is no longer independent or idle enough to merit special dispensation from the law."³⁵

The impact of this decision on university research is considerable. The narrow interpretation of the experimental use exception means universities should obtain licenses to use any external intellectual

25. *See id.*

26. *Id.* at 1352.

27. *Id.*

28. *Id.*

29. *Id.* at 1353.

30. *Madey*, 307 F.3d at 1353.

31. *Id.* at 1355.

32. *Id.* at 1362.

33. *Id.*

34. *Id.*

35. Matt Fleisher-Black, *Schools Dazed*, THE AM. LAW., Oct. 3, 2003, at 61, available at <http://www.law.com/servlet/ContentServer?pagename=OpenMarket/Xcelerate/Preview&c=LawArticle&cid=1063212099232>.

property in conjunction with university research. The ensuing negotiations for license agreements will slow the progress of research and scientific exploration within university systems. Furthermore, this new requirement elevates the overall cost (*e.g.*, literature searches, licensing fees, transactional expenses, litigation costs, attorneys' fees) to perform research in a university setting, thereby inhibiting both the amount and the pace of progress made by universities. It proves very difficult for a university to comply with this licensing policy when budgets must include licensing fees for as yet unspecified technologies. Additionally, this decision may cause the exportation of research to educational and research institutions in other countries, and in so doing, potentially cripple the production of domestic inventions and limit the educational experiences of university students.³⁶

Some worry about the practical effect the decision in *Madey* will have on the day-to-day happenings in research laboratories where some researchers "may be forced to stop in the middle of a project upon the realization that a new patent has been implicated in the course of their experimentation."³⁷ Some courses of research may be abandoned altogether.³⁸ However, both of these arguments suggest some cognizance by the scientists regarding the perils of patent infringement and potential liability that is unlikely to be present. Under the current system, most universities do not typically have patent attorneys on-hand to help guide researchers through the quagmire of patent law, to make certain they do not infringe on others' patents, and to ensure the research developed fits the criteria for patentability.³⁹ Regardless of the current system, scientists would now be wise to consult with counsel to protect themselves from being the cause of university liability for patent infringement.⁴⁰

Whichever of these possible scenarios appropriately applies, the decision in *Madey* is significant for universities. Communications must now be opened between scientists, university attorneys, and technology transfer offices to make sure that universities obtain licenses and scientists design around patented work or refrain from using it at all. These new transaction costs make it increasingly difficult to appropriately fund and execute research proposals and projects occurring

36. Stephen B. Maebius & Harold C. Wegner, *Ruling on Research Exemption Roils Universities: Finding of No Academic Privilege from Infringement May Lead to New Legislation*, NAT'L L.J., Dec. 16, 2002, at C3.

37. Jennifer Miller, *Sealing the Coffin on the Experimental Use Exception*, 2003 DUKE L. & TECH. REV. 12, 19.

38. *Id.*

39. Maebius & Wegner, *supra* note 36, at C3.

40. Todd E. Garabedian, *Recent Developments in Intellectual Property Law: Avoiding Traps in the Pursuit of University Research*, RES. MGMT. REV., Winter/Spring 2002, at 7.

in universities. New scientists, like Jason, can no longer simply read a journal article or patent and perform the experiments described therein without thoughts of license agreements, possible infringement, and potential liability. However, other aspects of the law may influence *Madey's* impact on public universities.

III. THE BAYH-DOLE ACT: FRIEND OR FOE TO THE TRANSFER OF KNOWLEDGE?

The Bayh-Dole Act significantly affects *Madey's* impact on university research. Federal funding of research has increased in recent times, both in total expenditures and in research funds given to universities.⁴¹ Because of this large financial commitment by the government, the government desired a rapid transfer to the public domain of the intellectual property resulting from this funding. The motivation for this quick transfer of new technology to market occurred during World War II when it was necessary to rapidly develop and commercialize cutting-edge technology for wartime defense.⁴² The speedy production of new inventions created with federal research money required the federal government to develop a patent policy that would facilitate the distribution of inventions made from federal funding.⁴³ Early attempts at forming patent policy to deal with federally funded inventions created in universities involved Institutional Patent Agreements (IPAs) which would sometimes result in the government agency waiving its rights to any resulting inventions.⁴⁴ However, the government failed to apply IPAs ubiquitously to all institutions receiving monies, which created general ignorance as to the ownership of the resulting intellectual property.⁴⁵

Dealing with the federal government regarding federally funded research created impediments to developing, and offering to the public, commercially viable products due to confusion regarding ownership and

41. Between 1993 and 1999, federal expenditures for basic research increased from \$15 billion to \$17.4 billion, an increase of almost 17%. Overall research expenditures by the federal government increased by 12% over the same period. Between 1993 and 1999, federal funding of university research from the six largest funding agencies increased 20% from \$11 billion to \$13 billion; BOARD ON SCIENCE, TECHNOLOGY, AND ECONOMIC POLICY, TRENDS IN FEDERAL SUPPORT OF RESEARCH AND GRADUATE EDUCATION 13 (2001) [hereinafter TRENDS].

42. Howard W. Bremer, Presentation to National Association of State Universities and Land-Grant Colleges (Nov. 11, 2001) (transcript available at http://www.nasulgc.org/COTT/Bayh-Dohl/Bremer_speech.htm).

43. *Id.*

44. *Id.*

45. *Id.*

licensing of the resulting intellectual property.⁴⁶ In 1980, Congress enacted the Bayh-Dole Act to, among other things, stimulate the exploitation of inventions stemming from federally funded research.⁴⁷ To achieve this end, the Bayh-Dole Act bestowed a number of benefits on universities and small businesses that receive federal grant money, such as allowing universities to obtain patent rights for inventions stemming from federally funded research.⁴⁸ In return, the federal agencies require universities receiving funds to disclose the subject of the intellectual property to the appropriate funding agency,⁴⁹ patent the invention in a timely manner,⁵⁰ give a non-exclusive right to the funding agency,⁵¹ commercialize and bring into public use the novel technologies giving preference to small businesses,⁵² and share license revenues with university inventors.⁵³ It also requires the University to support its "research, development, and education."⁵⁴

The impact of the Bayh-Dole Act on universities has been observed in both the patenting and licensing arenas. In the period between 1969 and 1979, patenting in universities increased by 40%.⁵⁵ Post Bayh-Dole Act, in the period between 1984 and 1994, patenting in American universities increased 223%⁵⁶ compared to a 52% increase for all patenting in the United States for the same time period.⁵⁷ Furthermore, the percentage of U.S. patents obtained by universities increased from 1% to 2.5% in the period from 1975 to 1990.⁵⁸ Additionally, the number of university technology transfer offices increased by 700% between 1980 and 1990 and the ratio of patents to research and development spending approximately doubled over the period from 1975 to 1990.⁵⁹

Licensing revenue increased after the implementation of the Bayh-Dole Act as well. In the period between 1970 and 1980, the University

46. David C. Mowery et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RESEARCH POLY 99, 102 (2001).

47. Bayh-Dole University and Small Businesses Patent Procedure Act (Bayh-Dole Act), Pub. L. 96-517, 94 Stat 3019 (codified at 35 U.S.C. §§ 200 *et seq.*).

48. 35 U.S.C. § 202(a) (2004).

49. *Id.* § 202(c)(1).

50. *Id.* § 202(c)(3).

51. *Id.* § 202(c)(4).

52. *Id.* § 202(c)(7)(D).

53. *Id.* § 202 (c)(7)(B).

54. *Id.* § 202 (c)(7)(E)(i).

55. Calculated from Mowery, *supra* note 46, at 104.

56. *Id.*

57. Calculated from UNITED STATES PATENT AND TRADEMARK OFFICE, PATENT COUNTS BY COUNTRY/STATE AND YEAR: ALL PATENTS ALL TYPES 4 (Feb. 2002), at [www.uspto.gov/web/offices/ac/ido/oeip/taf/cst_all.pdf](http://www.uspto.gov/web/offices/ac/ido/oeip/taf/cst/all.pdf) (last visited Mar. 19, 2004).

58. *Id.*

59. *Id.*

of California at Berkeley and Stanford University increased their licensing income by 135%, while in the period between 1980 and 1990, licensing income increased by 775%, and increased further by 1995 to 2850% of the 1980 revenue.⁶⁰

However, experts are loathe to claim that the Bayh-Dole Act is responsible for the boom in the patenting and licensing of university intellectual property. Some experts argue that the trend of university patenting and licensing increased prior to the Bayh-Dole Act and attribute this growth to greater industrial funding of academic research.⁶¹ Others note that the sharp increase in biomedical related patents near the time of the Bayh-Dole Act could account for the increases in patenting and licensing after 1980.⁶² Additionally, significant portions of the increases in patenting and licensing might have resulted from participation by universities that had never before been active in protecting intellectual property resulting from their university research.⁶³ Regardless of the impetus, universities now increasingly patent inventions stemming from both basic and tangentially developed research.⁶⁴

Nevertheless, although a number of factors may have contributed to the increase in university patenting and licensing after 1980, it is clear that the Bayh-Dole Act facilitated universities' abilities to obtain ownership rights to their inventions resulting from federally funded research. Because universities perform substantial amounts of basic research,⁶⁵ the death of the experimental use doctrine may not be so detrimental. Universities should theoretically allow exploitation of their own patents within the inventing department as well as throughout their university system. Culturally, however, this does not happen because collaboration between university researchers rarely extends outside a given department. Sharing of information would benefit both universities and the public by allowing prior inventors to continue with tangential discoveries to perhaps invent additional useful and commercializable intellectual property. This does not happen either; researchers have niches and they tend to stay there, not integrating vertically into steps towards commercialization. However, many inter-institution licenses have minimal transaction costs and protect all intellectual property interests of universities and inventors. This could

60. *Id.*

61. See R. Henderson et al., *Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting, 1965-1988*, 80 REV. ECON. & STAT. 119 (1998).

62. See Mowery, *supra* note 46, at 117.

63. *Id.* at 104.

64. See Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1126 (2003).

65. See TRENDS, *supra* note 41.

potentially ease the transfer of information between university entities, which in turn might stimulate the production of additional novel intellectual property. Some commentators believe that the Bayh-Dole Act actually stimulates knowledge transfer because technology is best transferred through the patent system "since it offers protection to the intellectual property base while at the same time providing an incentive to the industrial partner because of the right it conveys to exclude other than the licensee from practicing the invention patented."⁶⁶

The passage of the Bayh-Dole Act also created a number of problems with respect to the transfer of knowledge that it was designed to promote⁶⁷ and is in conflict with the policies underlining the experimental use doctrine. First, The Bayh-Dole Act does not distinguish between basic research and more specific (and commercializable) research.⁶⁸ The inability to distinguish between basic and commercializable research proves especially difficult in biomedical fields, where small amounts of basic research (*i.e.*, delivery methods of therapeutics, novel DNA/RNA sequences, and methods of processing proteins) can often result in larger, more socially and commercially significant discoveries.⁶⁹ Prior to the Bayh-Dole Act, these fundamental but significant discoveries became part of the vast public domain, but now, these discoveries are recognized as valuable to tangential research and are quickly patented by universities.⁷⁰ Because the language of the Bayh-Dole Act neglects to distinguish between basic research and other types of research, nor does it recognize certain disciplines that may need special provisions, the Bayh-Dole Act may limit the transfer of knowledge that the drafters originally intended to encourage,⁷¹ especially in a world without the experimental use exception. This rapid intellectual property protection by universities coupled with the narrow application of experimental use seems now set to stymie the novel fundamental research that the combination of university research and federal funding was originally intended to promote.

Second, the government was not required to create patent rights for universities within the realm of publicly funded research. University research is a uniquely collegial environment where collaboration has historically flourished not only between laboratories within a given university, but also between extrinsic university institutions. Prior to the enactment of Bayh-Dole, the experimental use exception was

66. Bremer, *supra* note 42.

67. 35 U.S.C. § 200.

68. Arti K. Rai & Rebecca S. Eisenberg, *The Public Domain: Bayh-Dole Reform and the Progress of Biomedicine*, 290 LAW & CONTEMP. PROBS. 289, 290 (2003).

69. *Id.*

70. *Id.*

71. 35 U.S.C. § 200.

unnecessary because federally funded research results quickly traveled to the public domain via conference presentations and journal papers. The increased ability of the university to patent has changed this practice, and if the collegiality of university research is to be sustained and control over intellectual property preserved, maintaining the experimental use façade necessitates the use of inter-institution licenses. University technology transfer offices have often swapped Material Transfer Agreements with each other, even prior to the Bayh-Dole Act. However, with the post-Bayh-Dole Act desire to protect university intellectual property, and no safe experimental use of patented inventions, there will be an increased cost of creating unique license agreements to perpetuate the idyllic transfer of knowledge that universities desire to maintain and still protect university interests in any ideas or inventions that are shared with other entities.

Third, there is a distinct difference between commercialization-driven and academic research. The incentive to “patent it, or lose it” driven by the Bayh-Dole Act may result in a departure from producing the significant fundamental research created with the combination of federal funding and research freedom that the university atmosphere provides. No longer will university research labs be incentivized to produce speedy publication, thereby providing the research results to the public domain; instead, commercialization of a tangible product is often the emphasis, because the inventors share in any licensing revenue.⁷² In fact, it may be in a university’s interest to keep a new invention out of the public domain for as long as possible so that it may patent, license, and create a product before sharing the technology. Historically, universities have not had the same level of commitment to commercial research because universities have been uniquely able to pursue socially beneficial research that may lack commercial appeal. For example, medical technology and pharmaceutical companies have little interest in curing chronic diseases since they make their profits through treatment, whereas universities are in the position to explore these research issues without the financial pressures that researchers in companies face. The Bayh-Dole Act, by promoting patenting and licensing that otherwise would wind up in the public domain, “in effect redistributes some of the gains from innovation back upstream, charging the firms that develop commercial products and paying the universities and government agencies that made early discoveries related to the product. . . . [This method] would appear more likely to retard product development than to

72. See *id.* § 202 (c)(7)(B).

promote it.”⁷³ Driving university research to commercialization while the experimental use doctrine is simultaneously crippled may result in a void where socially useful fundamental research once flourished.

Finally, the Bayh-Dole Act tends to blur the line between academia and commercial endeavors, possibly refocusing academia’s general goal to that of patenting and commercialization instead of “the principle of sharing knowledge”⁷⁴ historically adopted in the universities. Universities have recently begun creating small start-up companies from their newly acquired intellectual property.⁷⁵ The companies benefit from not spending excessively on research because they may be able to purchase the possibly undervalued intellectual property from the universities.⁷⁶ This bargain of university intellectual property exists because inventions spawned in university labs are difficult to appraise appropriately.⁷⁷ Adoption of the Bayh-Dole Act has served as a subsidy to industry that may eventually move the ideals of education, primary research, and knowledge transfer into the background in favor of research geared solely towards commercialization and the ability to make a lucrative product.

The Bayh-Dole Act generally benefits universities by allowing them to patent inventions paid for by federal tax funds. However, it may also inhibit a university’s research progress by encouraging protectionism instead of the propagation of knowledge generally promoted by research universities. Technologies that were once freely disseminated through rapid publication will now be patented following a delay while protection is obtained. The resulting environment is a considerable departure from traditional collegiality toward that of business models requiring manufacture of a marketable product.

IV. PATENT INFRINGEMENT AND SOVEREIGN IMMUNITY

Although the experimental use doctrine suffered drastic curtailment with the *Madey* decision and universities increasingly protect their IP rights from one another under the Bayh-Dole Act, another affirmative defense to patent infringement exists in state sovereign immunity.

73. Rebecca S. Eisenberg, *Symposium on Regulating Medical Innovation: Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1712 (1996).

74. Clovia Hamilton, *University Technology Transfer and Economic Development: Proposed Cooperative Economic Development Agreements Under the Bayh-Dole Act*, 36 J. MARSHALL L. REV. 397, 407 (2003).

75. *Id.* at 409. The number of start-up companies resulting from university research has exceeded 1500 since 1980. *University Technology Transfer of Government-Funded Research Has Wide Public Benefits*, ASS’N AM. U. (June 2, 1998), at <http://www.aau.edu/research/TechTrans6.3.98.html>. Bremer puts the number of startups from university technology at 2922 in 2001. Bremer, *supra* note 42.

76. See Hamilton, *supra* note 74, at 406-07.

77. See *id.*

A patent gives its owner exclusive rights to the utilization of the invention for twenty years from the date the patent was filed.⁷⁸ Patent infringement claims are solely the jurisdiction of federal district courts,⁷⁹ which have the power to “grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent”⁸⁰ and may “award the claimant damages adequate to compensate for the infringement.”⁸¹

However, federal legislation limits the areas in which infringement can occur. For example, it is not infringement to exploit a patent for the purpose of obtaining and submitting information required under Federal law.⁸² This provision allows FDA clinical trials, drug manufacturing and testing, medical device experimentation and development⁸³ of patented inventions to occur without the users facing possible infringement liability. This narrowly tailored exception requires a “reasonable relationship” between the research performed and the collected information necessary to meet the legal requirements,⁸⁴ and does not always result in a finding of non-infringement even when the research in question might “at some point, however attenuated, . . . lead to an FDA approval process.”⁸⁵ The government also limits private party liability for patent infringement when the private party makes or uses goods for the United States government.⁸⁶ In all of these cases, the motivation for the infringement exception partially rests on the social benefit resulting from the facilitation of the suspect research and the desire to bring the research to rapid fruition. This policy suggests that university research could eventually be statutorily exempt from patent infringement if a vital use that merited exemption was shown.

The strongest argument that the *Madey* case will not terribly impinge on the progress made in university research is the issue of sovereign immunity. Under the Eleventh Amendment: “The Judicial Power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States. . . .”⁸⁷ The U.S. Supreme Court interpreted this to mean that (1)

78. 35 U.S.C. § 154(a)(2).

79. 28 U.S.C. § 1338 (2004).

80. 35 U.S.C. § 283.

81. *Id.*

82. *Id.* § 271 (e)(1).

83. See *Intermedics Inc. v. Ventritex Co.*, 775 F. Supp. 1269 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993); *Teletronics Pacing Sys., Inc. v. Ventritex, Inc.* 982 F.2d 1520 (Fed. Cir. 1992).

84. 35 U.S.C. § 271 (e)(1).

85. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 867 (Fed. Cir. 2003).

86. See 28 U.S.C. § 1498(a); *Crater Corp. v. Lucent Techns., Inc.*, 255 F.3d 1361, 1364 (Fed. Cir. 2001).

87. U.S. CONST. amend. XI.

States have sovereign immunity against suits and (2) States can waive sovereign immunity and consent to being sued.⁸⁸ Although sovereign immunity applies to solely public institutions, much of the fundamental research in the U.S. comes from public institutions;⁸⁹ therefore, this defense may be applicable in patent infringement suits against public universities.

In 1994, Congress enacted the Patent and Plant Variety Protection Remedy Clarification Act (Patent Remedy Act)⁹⁰ and modified the language of the patent laws which held previously that “whoever without authority makes, uses, offers to sell, or sells any patented invention, . . . infringes the patent.”⁹¹ The language contained in the Patent Remedy Act specifically abrogated state sovereign immunity, maintaining that

[a]ny State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity, shall not be immune, under the Eleventh Amendment of the Constitution of the United States or under any other doctrine of sovereign immunity, from suit in Federal court by any person.⁹²

Pursuant to this new legislation, College Savings Bank sued Florida Prepaid Postsecondary Education Expenses Board (Florida Prepaid) for infringement of College Savings’ patented financing system designed to help investors plan for the financial burden of college tuition.⁹³ Florida Prepaid, created by the State of Florida, sold a similar financing program to Florida citizens and College Savings claimed willful infringement, relying on the provisions in the Patent Remedy Act.⁹⁴

The Supreme Court analyzed the Patent Remedy Act provisions under the constitutional standard from *Seminole Tribe of Fla. v. Florida* to decide if “Congress has unequivocally expressed its intent to abrogate the immunity” and if Congress operated “pursuant to a valid exercise of its power.”⁹⁵ The Court determined that the language of the act “could not be any clearer” in showing Congress’s intent to abrogate the State’s sovereign immunity.⁹⁶ On the second issue of Congressional power to

88. See *Seminole Tribe of Fla. v. Florida*, 517 U.S. 44, 54 (1996).

89. See 15 U.S.C. § 3701(3) (2000).

90. Patent and Plant Variety Protection Remedy Clarification Act (Patent Remedy Act) of 1994, Pub. L. 102-560, 106 Stat 4230 (codified in title 7 and 35 U.S.C.).

91. 35 U.S.C. § 271(a).

92. *Id.* § 296(a).

93. *Fla. Prepaid Postsecondary Educ. Expenses Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 631 (1999) [hereinafter *Fla. Prepaid*].

94. *Id.* at 632-33.

95. *Seminole Tribe of Fla.*, 517 U.S. at 55 (quoting *Green v. Mansour*, 474 U.S. 64, 68 (1985)).

96. *Fla. Prepaid*, 527 U.S. at 635.

effect this abrogation, the Court examined three possible sources for this power: the Patent Clause,⁹⁷ the Commerce Clause,⁹⁸ and the Fourteenth Amendment.⁹⁹ Under *Seminole Tribe of Fla.*, Congress is prohibited from abrogating state sovereignty under its Article I powers.¹⁰⁰ Furthermore, the Fourteenth Amendment prevents States from denying “any person of life, liberty, or property, without due process of law” and gives Congress the power to implement this provision with legislation.¹⁰¹ The Court interpreted this provision to require Congress to recognize and identify the conduct that affronts the constitutional provisions and to narrowly tailor the remedy or prevention measures employed to assuage the offending conduct.¹⁰² In examining whether the Patent Remedy Act was a sufficient remedial or preventative measure, the Court relied heavily on the fact that in the 110 years prior to 1990, states were sued for patent infringement only eight times.¹⁰³ The Court found that the dearth of cases of patent infringement against the States suggested “little support for the proposition that Congress sought to remedy a Fourteenth Amendment violation in enacting the Patent Remedy Act” and, therefore, the legislation was too broad and sweeping to solve such a minimal problem.¹⁰⁴ Additionally, states’ generally innocent infringement did not elevate the patent infringement problem to a level of “widespread and persisting deprivation of constitutional rights.”¹⁰⁵

A Fourteenth Amendment violation occurs only if deprivation of a constitutionally protected interest occurs without due process.¹⁰⁶ In *Fla. Prepaid*, the Court held that wronged patent owners have redress under other causes of action such as tort, unfair competition, and conversion¹⁰⁷ and that less convenient remedies than a patent infringement suit litigated in federal court did not equate to a violation of due process under the Fourteenth Amendment.¹⁰⁸

The decision in *Fla. Prepaid* is far reaching. Sovereign immunity abrogation by Congress was struck down in both the trademark¹⁰⁹ and

97. U.S. CONST., art. I, § 8, cl. 8.

98. U.S. CONST., art. I, § 8, cl. 3.

99. U.S. CONST., amend. XIV, § 5.

100. *Fla. Prepaid*, 527 U.S. at 636; see also *Seminole Tribe of Fla.*, 517 U.S. at 72-73.

101. U.S. CONST., amend. XIV, § 5.

102. *Fla. Prepaid*, 527 U.S. at 639.

103. See *Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expenses Bd.*, 148 F.3d 1343, 1353-54 (Fed. Cir. 1998); *Fla. Prepaid*, 527 U.S. at 640.

104. *Fla. Prepaid*, 527 U.S. at 642.

105. *Id.* at 645 (quoting *City of Boerne v. Flores*, 521 U.S. 507, 526 (1997)).

106. *Id.* at 643.

107. *Id.*

108. *Id.* at 644.

109. Trademark Remedy Clarification Act, 15 U.S.C. §§ 1122, 1125(a) (2000); *Fla. Prepaid*, 527 U.S. at 666.

copyright¹¹⁰ areas under reasoning similar to that in *Fla. Prepaid* (i.e., lack of evidence of a pattern, no deprivation of a protected property right, remedy overly broad).¹¹¹ These results allow intellectual property infringement to occur “with impunity until it rises to a level deserving of ‘remedial’ action by Congress.”¹¹² This line of cases directly conflicts with *Madey*, which finds that any non-experimental use by public university researchers, even if innocent infringement, creates liability.¹¹³ However, under *Fla. Prepaid*, patent owners suing a public university for infringement are forced to find remedies in state court on grounds not ordinarily applied to intellectual property disputes.¹¹⁴ This is a particularly unusual form of redress since patent law was designed so that the federal government, through the CAFC, has sole appellate jurisdiction.¹¹⁵

Given these decisions, what effect does sovereign immunity have on university liability for patent infringement and how will it impact Jason and other university researchers? Courts may find that employees acting within the scope of their employment duties as scientists and researchers can cause university liability for patent infringement,¹¹⁶ although some courts may be reluctant to identify a lowly first-year graduate student as a state actor. However, some university employees have been held accountable for their actions as state actors resulting in abrogation of sovereign immunity for the university.¹¹⁷ Other universities, because of their minimal ties to the state, are held to be autonomous, and fail to qualify for the protection of sovereign immunity,¹¹⁸ although university

110. Copyright Remedy Clarification Act, 17 U.S.C. §§ 501, 511 (2000); *Chavez v. Arte Publico Press*, 204 F.3d 601 (5th Cir. 2000) [hereinafter *Chavez II*].

111. *Chavez II*, 204 F.3d at 601; *Fla. Prepaid*, 527 U.S. at 666.

112. John C. O’Quinn, *Protecting Private Intellectual Property from Government Intrusion: Revisiting SmithKline and the Case of Just Compensation*, 29 PEPP. L. REV. 435, 476 (2002).

113. *Madey v. Duke Univ.*, 307 F.3d 1351, 1351 (Fed. Cir. 2002), *cert denied*, 539 U.S. 958 (2003).

114. Peter S. Menell, *Symposium on New Directions in Federalism: Economic Implications of State Sovereign Immunity From Infringement of Federal Intellectual Property Rights*, 33 Loy. L.A. L. REV. 1399, 1452 (2000).

115. 28 U.S.C. § 1498 (2000).

116. Robert C. Wilmoth, *Toward a Congruent and Proportional Patent Law: Redressing State Patent Infringement After Florida Prepaid v. College Savings Bank*, 55 SMU L. REV. 519, 554 (2002).

117. See *Chavez v. Arte Publico Press*, 59 F.3d 539, 546 (5th Cir. 1995), *vacated by Univ. of Houston v. Chavez*, 517 U.S. 1184 (1996), *superseded by* 157 F.3d 282 (5th Cir. 1998), *vacated by* 178 F.3d 281 (5th Cir. 1998), *remanded to* 204 F.3d 601 (5th Cir. 2000) [hereinafter *Chavez I*] (Congress compels states to waive sovereign immunity where university employee violates the Copyright and Lanham Acts); *Kashani v. Purdue Univ.*, 813 F.2d 843, 848 (7th Cir. 1987) (allowing suits against university employees, despite a finding of sovereign immunity for the university, in their official capacities for prospective injunctive relief).

118. *Kovats v. Rutgers*, 822 F.2d 1303, 1307-12 (3d Cir. 1987) (finding Rutgers University is not entitled to Eleventh Amendment sovereign immunity).

autonomy is not mutually exclusive from a university operating as an “arm of the state.”¹¹⁹ A significant disconnect exists between what occurs in the laboratory and what activities university officials are reasonably aware of. This disconnect creates not only an enforcement problem, but also a lack of coordination between infringement offenses and the appropriate university officials, which may preclude the use of sovereign immunity as a viable defense. Perhaps the problem of preventing infringing experimental use is best left to the universities, because the possible lack of immunity may implore university officials to better communicate with researchers and counsel to prevent liability.

And what of the effect on the policy that motivates the Bayh-Dole Act and other legislation that encourages university patenting and licensing? Some commentators suggest state university sovereign immunity could be devastating for the ideals of stimulating federally funded inventions though the likes of the Bayh-Dole Act. Sovereign immunity protection may discourage corporations from licensing technology from a university “if it knows in advance that there is no easy way to hold the university accountable for patent infringement disputes that might ensue”¹²⁰ because of companies’ reluctance to face potential litigation.

The sovereign immunity issue, as it pertains to enforcing now infringing experimental uses of patented material, is a complex one. No clear answers exist as to whether the problem will become widespread enough to merit courts’ renewed attention. Furthermore, it is unclear what level of university researchers’ illegal experimentation using patented inventions is necessary for the research to be considered a sufficient exercise of state power as to invoke the protection of sovereign immunity. However, the decision in *Madey* has put university officials on notice regarding the illegality of the previously acceptable experimental use of patented material.

V. PROPOSAL

Jason’s predicament is perplexing, however, remedies for this dichotomous problem exist on many levels. Courts may realize the difficult situation facing universities after the narrowing of the experimental use exception and move towards a broadening of the exception based on policy reasons to solve the problem. Congress can assuage the problem through further legislation in the patent code,

119. Kelly Knivila, Note, *Public Universities and the Eleventh Amendment*, 78 GEO. L.J. 1723, 1742 (1990).

120. Jennifer Polse, *Holding the Sovereign’s Universities Accountable for Patent Infringement After Florida Prepaid and College Savings Bank*, 89 CAL. L. REV. 507, 529 (2001).

amendments to the Bayh-Dole Act, or via new legislation. Finally, universities themselves can take steps to minimize the problem by instituting better communication between their researchers and legal counsel and by finding more efficient ways to implement licensing agreements.

A. Courts

What is the purpose of distributing intellectual property to the public domain through the publishing of patents if the discoveries cannot even be used in university research, which at least before the Bayh-Dole Act was fairly innocuous with respect to threat of commercialization? What began in the courts several hundred years ago as a gift to curious researchers, the experimental use doctrine evolved into a specific common law rule: commercial use of patented technologies was prohibited, while non-commercial use, including use by universities, was acceptable. However, due to increasing commercialization of universities and their research, "what might have once been a bright-line rule has become difficult to implement without inquiring into the details of the research at issue."¹²¹ Following suit, courts have shifted their position as well, as evidenced by the *Madey* decision, to forbid the commercialized university institution to experimentally employ patented technology because it is not free from industrial entanglements.

However, other policy considerations may influence courts to again broaden the experimental use exception. Strong public policy for the advancement of science and new technology exists. With recent patent legislation shifting university research in the direction of commercialization, courts may find that university experimental use is necessary and justified to stimulate the production of basic and fundamental discoveries in university research. Important cost considerations persist regarding developing new research infrastructure instead of exploiting university resources. If most university research becomes economically driven, the government may be forced to establish additional resources to produce basic fundamental research instead of relying, as in the past, on expensive university facilities. Courts may also realize that the absence of experimental use of patented ideas hinders the rapid pace of technological advancement. Technological advancement may be hindered because minimal amounts of research funds are available due to both (a) the commercialization of university research (including the goals of protectionism and bringing products to market, instead of publication to the public domain), and (b) the absence of basic fundamental research generally, because such research may not coincide

121. Rai, *supra* note 64, at 1109.

with corporate goals. Finally, the courts may examine the impact on new faculty, who may be most disadvantaged by the narrowing of the experimental use doctrine. As a condition for receiving money under the Bayh-Dole Act, the statute requires universities to reinvest portions of invention royalties in university research.¹²² New faculty are likely most in need of the experimental use exception to have a chance at developing the viable research program necessary to survive in academia. By emphasizing commercialization instead of promoting fundamental research, universities threaten to drive intelligent and ambitious students like Jason to other endeavors.

Perhaps courts will neglect to follow the decision in *Madey*, and instead follow the opinion in *Ruth*,¹²³ which refused to recognize university experimental use of a patented invention as infringement. The collective impact of the now-narrowed experimental use exception, although unknown, has the potential to change the course of research in ways that may result in hindering the advancement of American technology.

B. Congress

One way around the problems with the now-limited experimental use doctrine is to amend the Bayh-Dole Act to account for experimental use within the university system. The federal government supplies funds for much of the research undertaken in the university system and through the Bayh-Dole Act, it gives most of the intellectual property rights to the institutions receiving money. The government could institute an experimental use clause that would allow non-commercial use of inventions patented under the Bayh-Dole Act by the numerous universities and small businesses that receive federal funding. This would only be a partial fix since most patents are not a result of federal funding.

Amending the patent code to explicitly include experimental use by universities without opening the door to widespread use of patented intellectual property is an equally viable solution. Currently, the patent code allows an experimental use of patented "biological products" in anticipation of expiration of the patents. This experimental use is permitted so that FDA approval can be submitted on biologic inventions, such as a generic drug, enabling generic drug availability as soon as the patent on the primary drug expires.¹²⁴ This policy driven

122. 35 U.S.C. § 200.

123. See *supra* notes 11-13 and accompanying text (discussing the application of the experimental use exception to eliminate a university's infringement liability).

124. 35 U.S.C. § 271 (e)(1). This overrules *Roche Products, Inc. v. Bolar Pharms. Co.* See *supra* note 20 and accompanying text.

exception to patent infringement allows generic drugs to reach the marketplace earlier than would be expected under traditional infringement rules. Our nation's legislature may deem the transfer of knowledge and stimulation of innovation an equally worthy goal and allow a narrow exception for experimental use of patents in university research.

Additionally, exceptions have been proposed for research that pertains to mapping genomes. The Genomic Research and Diagnostic Accessibility Act of 2002 endeavors to exempt "for the purposes of research" the use of patent protected genomic sequences.¹²⁵ This legislation would allow university researchers to effectively "experimentally use" patented genome sequences for creating, among other things, diagnostic tests, furthering disease research, and advancing genetic engineering.¹²⁶ This potential legislation's exemption contrasts sharply with the principles outlined in *Madey* and suggests a shift by federal legislators toward reviving the experimental use exception, especially where it directly benefits the public.

However, instead of protecting state universities' experimental use of intellectual property, some members of Congress have recently endeavored to do the opposite by introducing the Intellectual Property Protection Restoration Act (IPPRA)¹²⁷ that would accompany the patent code with respect to remedies for infringement.¹²⁸ In the IPPRA, Congress attempts to equate intellectual property rights with real property rights, which would cause infringement liability to be considered a taking by the state (the offending public university being an agent of the state).¹²⁹ The IPPRA would force universities to choose between losing the right to protect their intellectual property or waiving their sovereign immunity protection against being sued for violations of copyright, trademark, and patent laws.¹³⁰ Universities would generally be loathe to open themselves up to the costs of litigation and damages that the waiver of sovereign immunity may incur, but under this provision, they could be forced instead to give up protection of their own

125. Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. (2002).

126. *Id.*

127. Intellectual Property Protection Restoration Act of 2003, H.R. 2344, 108th Cong. (2003).

128. 35 U.S.C. § 284.

129. Himanshu Vyas, *Federal Intellectual Property Law v. State Sovereignty: Can Congress Win?*, 2 J. MARSHALL L. REV. 159, 168 (2002).

130. Intellectual Property Protection Restoration Act of 2003, H.R. 2344, 108th Cong. (2003).

intellectual property,¹³¹ causing the universities to forfeit what would otherwise be a large source of revenue for higher education.

This legislation appears to “attempt to level a perceived uneven playing field”¹³² between universities and industry. But Congress confuses the issue, because much enacted and proposed patent legislation stimulates universities’ participation with industry, while other legislation condemns it. Legislators should decide how best to define the role the university should take in research in terms of commerciality and enact legislation consistent with the goals and ideals of that role, striking a balance between being completely commercial and being completely non-commercial, instead of trying to push the university to either extreme with conflicting legislation.

C. *Individual Parties*

It seems unlikely that any policy implemented by a public university could minimize the impact of the ruling in *Madey*. In *Madey*, Duke argued that its patent policy stated that its primary objective was that of knowledge transfer, but the CAFC recognized that this was not Duke’s only objective and noted that “Duke, however, like other major research institutions of higher learning, is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream.”¹³³ This ruling suggests that any university that maintains a patenting and licensing program from which it derives “not insubstantial” revenue will be prevented from having its use of unlicensed intellectual property fall within the narrow experimental use exception.

However, it is unclear how much delay or litigation would result from a university using unlicensed intellectual property in its research. The Bayh-Dole Act, which allows universities to patent inventions stemming from federally funded research, may assuage some of the hurdles created by *Madey* because the Act enables a university to possess much of the intellectual property created during externally funded research. If university research does utilize unlicensed intellectual property, it is unlikely that any litigation will result unless significant revenue is produced from the research. Some organizations may actually encourage the use of intellectual property (by not litigating infringement

131. *Colleges Oppose New Intellectual Property Act*, HIGHER EDUC. & NAT’L AFF., Vol. 52, No. 12, June 30, 2003.

132. *H.R. 2344, the “Intellectual Property Protection Restoration Act of 2003”*: Hearings on H.R. 2344 Before the Subcomm. on Courts, the Internet and Intellectual Property of the House Comm. on the Judiciary, 108th Cong. (2003) (testimony of Leslie J. Winner, Vice-President and Gen. Counsel, Univ. of N. Carolina).

133. *Madey v. Duke Univ.*, 307 F.3d 1351, 1363 (Fed. Cir. 2002), *cert denied*, 539 U.S. 958 (2003).

claims or providing cost-free licensing) by a university as the resulting research may produce new inventions or applications that would require the purchase or licensing of the intellectual property in question.

Can a university rely on lack of infringement enforcement as a sufficient reason to ignore *Madey*? The dearth of sovereign immunity cases (eight in 110 years) suggest that either public university infringement is not a problem, or that it is difficult to police. Having spent a great deal of time in the university laboratories, the author believes the latter to be more plausible. Given the threat of treble damages, "it may be foolhardy for nonprofit researchers to rely on the forbearance of patent holders."¹³⁴ Others argue that patents do not severely financially affect university researchers because patent owners favor working with nonprofit researchers.¹³⁵ Companies implement this strategy by not bringing infringement suits against these non-profit researchers for what is essentially experimental use.¹³⁶

CONCLUSIONS

Let us revisit Jason and examine his fate under the new, narrowed experimental use exception. Under historical common law, Jason would have been protected in his attempts to use patented work in his university laboratory to help sharpen his experimental skills and stimulate new ideas. With the decision in *Madey*, Jason faces a dilemma of choosing willful infringement or suffering educationally from the lack of exposure to practical laboratory experience. Jason may find safety in his state university's sovereign immunity claim or in lack of enforcement, but he still takes a great risk in exposing either himself or his employer to infringement liability.

The best avenue for a permanent solution is likely in the hands of the legislature, which could make a profound difference if it could decide the extent to which prodding universities to commercialization is a productive endeavor. Although the courts seem fixed in their course of narrowing exceptions to infringement liability, public policy may eventually dictate that experimental use of patented inventions is necessary for the development of new technology and the production of basic fundamental research. One thing is clear: university administrators must begin to clearly communicate with researchers regarding the practicalities and perils that this shift in patent policy signifies.

134. Rai & Eisenberg, *supra* note 68, at 296.

135. See generally J.P. Walsh et al., *Patenting and Licensing of Research Tools and Biomedical Innovation*, in INNOVATION IN A KNOWLEDGE-BASED ECONOMY (S. Merrill et al., eds., forthcoming 2004), available at <http://tiger.uic.edu/~jwalsh/BioIPNAS.pdf>.

136. *Id.*