

Unshackle Academia and Allow It to Exemplify the Purpose of Patent Law: "To Promote the Progress of Science and the Useful Arts"

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Joseph Mohr, *Unshackle Academia and Allow It to Exemplify the Purpose of Patent Law: "To Promote the Progress of Science and the Useful Arts"*, 88 Marq. L. Rev. 671 (2004).

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UNSHACKLE ACADEMIA AND ALLOW IT TO EXEMPLIFY THE PURPOSE OF PATENT LAW: “TO PROMOTE THE PROGRESS OF SCIENCE AND THE USEFUL ARTS”¹

I. INTRODUCTION

A patentee’s right to exclude nonprofit academic use of his invention,² without exception for experimental use,³ is inconsistent with the patent law purpose of promoting science and innovation⁴ because royalty deterrents arise that hinder scientific progress in nonprofit academic institutions. This tension in patent policy is most evident with nonprofit research universities that constantly tread in the realm of patented technology to explore the forefront of scientific knowledge.⁵ Historically, the experimental use defense, a common law affirmative defense to patent infringement when the alleged infringing use involves mere experimentation,⁶ provided universities using patented technology for research purposes some level of protection.⁷ Modern decisions, however, have sharply curtailed the applicability of the experimental use defense for universities today.⁸

1. U.S. CONST. art. I, § 8.

2. 35 U.S.C. § 271 (2003) (detailing patent infringement).

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

4. U.S. CONST. art. I, § 8. “The Congress shall have Power To . . . promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries. . . .” *Id.*

5. *See* *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 875 (Fed. Cir. 2003) (Newman, J., concurring in part, dissenting in part).

6. *See* DONALD CHISUM ET AL., *PRINCIPLES OF PATENT LAW: CASES AND MATERIALS* 1204 (2d ed. 2001) (discussing recent applications of the experimental use defense).

7. *See* Jennifer Miller, *Sealing the Coffin on the Experimental Use Exception*, 2003 DUKE L. & TECH. REV. 12 (2003).

8. *See* *Madey*, 307 F.3d at 1362 (alleged experimental “use is disqualified from the defense if it has the ‘slightest commercial implication’”); *Soitec v. Silicon Genesis Corp.*, 81 Fed. Appx. 734, 737 (Fed. Cir. 2003) (unpublished opinion) (refusing to distinguish between use of patented technology at the “research and development stage” versus the “manufacturing stage”); *Embrex, Inc. v. Serv. Eng’g. Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000) (“constru[ing] both the experimental use and de minimus exceptions very narrowly”); *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (finding experimental use defense ineffective when the alleged scientific “inquiry has definite, cognizable, and not insubstantial commercial purposes”). With regard to the experimental use defense, the Federal Circuit *Madey* court held that:

[R]egardless 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

This Comment explores three issues pertaining to scientific progress in nonprofit research universities: Part II discusses how the government, universities, and private industry often partner to conduct collaborative research that benefits each partnership member and concurrently promotes scientific progress; Part III explores the effect that the Federal Circuit's narrow interpretation of the experimental use defense⁹ has on scientific progress; and Part IV suggests reforms that will allow universities to advance science, while at the same time fairly compensating patent owners for the use of their patented technology.

II. THE INTERRELATIONSHIP BETWEEN ACADEMIC, PRIVATE, AND PUBLICLY FUNDED RESEARCH

While at one time universities, private industry, and the government mostly conducted research independently, today they commonly engage in collaborative research efforts.¹⁰ Indeed, "[t]he chasm separating universities from industry and basic research from applied research now is bridged routinely."¹¹ The trend towards partnerships appears likely to continue as evidenced by a recent 20% increase in industry-sponsored research conducted by universities from 1991 to 1997.¹² The impetus for this trend was the government's initial collaboration with research universities to develop advantageous wartime technology.¹³

A. Government and Academic Collaborative Research Efforts

The government significantly increased public funding for research at universities in the 1940s due to World War II pressures for improved medicines, materials, and weaponry.¹⁴ The success of the collaboration prompted a continued policy of publicly funding academic research with formal oversight by such government agencies as the Office of Naval Research, the National Institutes of Health, and the National Science Foundation.¹⁵ While this scheme was effective at producing innovations,¹⁶ the

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.

Madey, 307 F.3d at 1362.

9. *See id.*

10. *See* Kenneth Dueker, *Biobusiness On Campus: Commercialization Of University-Developed Biomedical Technologies*, 52 FOOD DRUG L.J. 453 (1997).

11. *Id.*

12. PORT ET AL., LICENSING INTELLECTUAL PROPERTY 177 (1999).

13. Dueker, *supra* note 10, at 459-60.

14. *Id.*

15. *Id.* at 460.

fact that the government held ownership rights over the resulting patents led to inefficient use of the innovations: the government's role was not to commercially exploit innovations, and private industry was hesitant to license patents held by the government.¹⁷ As a result, many useful innovations that were developed at universities with public funding failed to achieve their full potential to benefit the public.¹⁸

In 1980, congressional discontent with innovations developed at the public's expense going unutilized, coupled with a perceived decline in the United States' output of new innovations, prompted Congress to pass the University and Small Business Patent Procedure Act,¹⁹ commonly referred to as the Bayh-Dole Act.²⁰ The Bayh-Dole Act allows a nonprofit institution, university, or small business to retain title to patents associated with publicly funded inventions that result from its research in collaboration with a federal agency.²¹ Although a university's right to retain title to patents that arise from its publicly funded research is subject to certain limits,²² the Act confers substantial incentives to commercialize any resulting inventions.²³ The incentives to commercialize new inventions arise because universities, which now hold patent ownership rights, may license the inventions to private industry at mutually beneficial financial terms.²⁴

Today, the government and university collaborative research effort remains strong.²⁵ The National Science Foundation ("NSF") partners with over 2000 universities, nonprofit institutions, and small business to conduct research in mostly physical science and engineering fields of inquiry.²⁶ To fund the research at these institutions, the NSF spends approximately \$150 million per year, which represents approximately 3.8% of the United States'

16. See generally National Institute of Health, *Selected Research Advances of NIH*, at <http://history.nih.gov/history/advances.htm> (historical sampling of National Institute of Health advances and innovations) (last visited Sept. 2004).

17. Dueker, *supra* note 10, at 460.

18. *Id.* at 460–61.

19. *Id.*

20. Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980), amended by Pub. L. No. 98-620 (codified as amended at 35 U.S.C. § 200 et seq.).

21. PORT ET AL., *supra* note 12, at 183.

22. Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980), amended by Pub. L. No. 98-620 (codified as amended at 35 U.S.C. § 200 et seq.).

23. PORT ET AL., *supra* note 12, at 181

24. *Id.*

25. National Science Foundation, *NSF By the Numbers* (reporting data that pertains to National Science Foundation annual funding and its general allocation of funds), at <http://www.nsf.gov/od/lpa/nsf50/nsfnumbers.htm> (last visited Sept. 2004).

26. *Id.*

annual budget.²⁷ Indeed, major research universities depend on federal public funding for approximately 87% of their research budgets.²⁸

Collaborative efforts between the government and universities represent just one facet of modern collaborative research.²⁹ Research partnerships between private industry and nonprofit research universities are also prevalent today.³⁰ Furthermore, partnerships between private industry and research universities sometimes function to link private industry and the government into collaborative research initiatives.³¹

B. Private Industry and Academic Collaborative Research Efforts

For most of this nation's history, technology transfer between academia and private industry was mainly accomplished by indirect and informal means.³² While a few private industry pioneers explored formal collaboration with university research departments prior to World War II,³³ the impetus for increased private involvement in academic research was the government's attempt to garner scientific progress through its cooperation with research universities.³⁴ Specifically, the inherent inefficiencies, discussed in Part II.A, which plagued the government's efforts to realize commercial applications for the innovations developed under its direction led to reforms that brought private industry and academia closer together.³⁵

1. Legal Development of Research Partnerships Between Private Industry and Academia

A researcher's prestige among the scientific community was the main driving force behind technology transfer prior to the mid-twentieth century.³⁶ Publication of scientific advancements in journals and presentation of

27. *Id.*

28. Dueker, *supra* note 10, at 457 (citing the Association of University Technology Managers, AUTM Licensing Survey, FY 1991–FY 1995: A Five-Year Survey Summary of Technology Licensing (And Related) Performance For U.S. And Canadian Academic And Nonprofit Institutions, And Patent Management Firms 28 (1997)).

29. See PORT ET AL., *supra* note 12, at 180

30. *Id.*

31. *Id.*

32. See Clovia Hamilton, *University Technology Transfer And Economic Development: Proposed Cooperative Economic Development Agreements Under The Bayh-Dole Act*, 36 J. MARSHALL L. REV. 397, 398–405 (2003).

33. Dueker, *supra* note 10, at 456–57 (discussing the University of Wisconsin's creation of the Wisconsin Alumni Research Foundation to financially exploit scientific advances created by its professors); see also Hamilton, *supra* note 32, at 400.

34. See generally Hamilton, *supra* note 32.

35. Dueker, *supra* note 10, at 460.

36. See Hamilton, *supra* note 32, at 402.

advances at scientific conferences were the researcher's main means of demonstrating his or her accomplishments and advancing his or her career.³⁷ These publications and presentations also provided private industry with a source of new knowledge that it could then develop into commercially viable innovations.³⁸ This system, therefore, was mutually beneficial for both the academic researcher and the private commercial entity; however, it did not directly confer benefits between the parties in a formal manner as the intellectual property system does today.

Formal licensing and cooperative research investments dictate technology transfer today.³⁹ To rectify the inefficient utilization of innovations created through public funding,⁴⁰ Congress passed the Bayh-Dole Act⁴¹ and the Stevenson-Wydler Act.⁴² The combined effect of these Acts was to vest patent ownership in universities for patents arising from their federally funded research, which the universities could license to private industry.⁴³ Furthermore, the Acts "enable[] cooperative research and development agreements (so-called CRADAs) between government owned laboratories, industry, and academia."⁴⁴ Notable examples of post Bayh-Dole collaboration structures between universities, private industry, and the government include licensing agreements, industry sponsored university research, spin-off companies, and idea labs.⁴⁵

Undoubtedly, research partnerships between the government, universities, and private industry have become ubiquitous in modern research.⁴⁶ The extensiveness of such partnerships today did not result because the government thrust this system upon universities and private industry, but rather the partnership system developed because it was mutually beneficial to all partnership members.⁴⁷

37. *Id.*

38. *Id.* at 403.

39. PORT ET AL., *supra* note 12, at 178–184.

40. *See id.*

41. Pub. L. No. 96-517, 94 Stat. 3015 (1980), *amended* by Pub. L. No. 98-620 (codified as amended at 35 U.S.C. § 200 et seq.).

42. *Id.*

43. PORT ET AL., *supra* note 12, at 182–85.

44. *Id.* at 182.

45. Joshua A. Newburg & Richard L. Dunn, *Keeping Secrets in the Campus Lab: Law, Values and Rules of Engagement for Industry-University R&D Partnerships*, 39 AM. BUS. L.J. 187, 200–06 (2002) (defining and discussing the following collaboration structures: licensing, industry sponsored university research, spin-off companies, and idea labs).

46. *See generally id.* at 188.

47. *Id.* at 197–98.

2. Benefits and Advantages

The industry-university research partnership yields many advantages for the partnership as well as for society.⁴⁸ When private industry sponsors research at a university, it benefits from the scientific horsepower that universities provide. Universities provide dedicated research facilities, filled with some of the brightest minds in a given field, to direct toward a particular research effort. In addition, graduate students, to satisfy academic requirements, contribute considerable hours of skilled research at a fraction of the cost that privately paid researchers would demand. Partnering with a university allows a private company to reduce its overhead expenditures for lab equipment and personnel, while at the same time having its research directives pursued by highly educated pioneers in the field.

Likewise, universities benefit from industry sponsored research initiatives because the research often serves concurrent educational and commercial purposes.⁴⁹ The universities' ability to retain ownership of patents arising from their research and their subsequent licensing of that technology have generated more than twenty billion dollars in revenue for universities since the passage of the Bayh-Dole Act.⁵⁰ Undoubtedly, industry sponsored research aims to produce commercial innovations, but most often the research also has educational and academic value for the universities. For example, a drug company may fund research at a university to develop a new cancer drug. The research provides students with an opportunity to learn aspects of pharmaceutical research and provides professors with an opportunity to report the new drug's effect on cancer cells in academic journals. Thus, industry sponsored research can yield new innovations for private industry while concurrently allowing universities to pursue their academic mission.

Additionally, universities benefit from research partnerships by raising revenue from licensing the innovations that they discover.⁵¹ Depending on specific research agreements, universities may maintain the right to patent the products of their research, whether the research was backed by public, private, or their own funds.⁵² Universities can use this revenue to purchase lab facilities and equipment that would normally require higher tuitions or other means to pay for them. Revenue derived from innovation licensing, therefore,

48. *Id.* at 197–98.

49. *Id.* at 197 (describing the different benefits universities receive by partnering with industry: “(1) access to industry resources including financial support and advanced technology; (2) superior training and placement opportunities for students; (3) the stimulation of exposure to current industry problems; and (4) income from commercially valuable inventions”).

50. Dueker, *supra* note 10, at 453.

51. *See id.*

can potentially support continued university research initiatives.⁵³

While universities may receive royalties from collaboration with private industry, such royalties are generally of limited significance.⁵⁴ “[W]ith one or two exceptions, even the most successful university licensing offices receive licensing revenue equal to 1 or 2% of their universities’ total research budgets.”⁵⁵ Even the universities lucky enough to receive a percent or two of their research budget through collaboration with private industry “rely on single “blockbuster” patents for the majority of their revenue.”⁵⁶ Thus, while universities may hope to receive funding sufficient to cover certain research expenses that further both commercial and educational goals, they are highly unlikely to substantially profit from industry-university collaborations.

Finally, society benefits from research partnerships because of the partnerships’ role as an economic stimulant.⁵⁷ “Economic research over the past sixty years has amply demonstrated the causal link between intellectual property and the growth of our national economy.”⁵⁸ Indeed, as the United States manufacturing industry continues to decline due to cheaper overseas labor, its economy must rely more on intellectual property rights associated with new innovations that it develops.⁵⁹ “Intellectual property is an increasingly critical component of the United States capital and foreign trade and economic research has demonstrated that changes in intellectual property laws can be used deliberately to promote innovation and national economic development.”⁶⁰ Congress itself found that “[t]echnology and industrial innovation are central to the economic, environmental, and social well-being of citizens of the United States.”⁶¹ Therefore, the industry-university collaboration structure’s ability to foster innovation is instrumental to continued vitality of the United States economy.⁶²

The many benefits that derive from industry-university collaborations, however, need to be viewed in conjunction with some of the potential disadvantages that may result from such partnerships.

55. *See id.*

56. *Id.* at 466

57. *Id.* (quoting Lita Nelsen, *The Lifeblood of Biotechnology: University-Industry Technology Transfer*, in *THE BUSINESS OF BIOTECHNOLOGY: FROM THE BENCH TO THE STREET* 39, 44 (R. Dana Ono ed., 1991)).

58. Dueker, *supra* note 10, at 466.

59. *See* CHISUM ET AL., *supra* note 6, at 59.

60. *Id.*

61. *See generally id.*

62. *Id.*

63. 15 U.S.C. § 3701 (2003).

64. *See* CHISUM ET AL., *supra* note 6, at 59.

3. Disadvantages and Challenges

Heavy funding of research at universities can potentially bias the research results in favor of the industry providing the funding.⁶³ A study by the Yale University School of Medicine called into question the impartiality of biomedical research conducted at a number of universities that was funded by the pharmaceutical industry.⁶⁴ The study indicated “that research backed by [the pharmaceutical] industry was three times more likely to arrive at pro[-] industry conclusions than studies without such backing.”⁶⁵ The disproportionate “pro[-]industry” research results, if actually caused by bias, may derive from unethical manipulation of data, or may derive slightly more innocuously from an initial “pro[-]industry” design of research studies.⁶⁶ At a minimum, academic research heavily funded by industry runs the risk that the public will perceive it as biased in favor of industry.⁶⁷

In addition, differing goals and mindsets pose continuing challenges for industry and university research partnerships. “Universities are bastions of academic freedom and open discourse”;⁶⁸ conversely, industry seeks focused and secretive technological advances to procure a competitive advantage in the marketplace.⁶⁹ While private industry is interested in research that is likely to lead to profitable commercial applications, “[u]niversities seek the advancement of knowledge for knowledge’s sake.”⁷⁰ These differing goals can lead to disagreements as to the direction that research should proceed, as well as disagreements concerning how much of the researchers’ time and resources should be applied to the collaborative aspects of the research.⁷¹

A further challenge results from industry-university research partnerships when researchers are pressured by universities they work for to pursue industry sponsored research, rather than research directed towards their particular academic interests.⁷² Researcher discontentment is particularly relevant because many researchers choose lower-paying academic positions instead of positions in industry to maintain their freedom to pursue their

63. Charles Hirshberg, *Ties With Drug Companies Bias Biomedical Research*, DISCOVER, Jan. 2004, at 71.

64. *Id.*

65. *Id.*

66. *Id.* A “pro-industry” design to a research study is a design that sets up the industrial product to perform well. *Id.* An example would be “comparing a medication against a placebo . . . instead of comparing it with its most effective competitors.” *Id.*

67. Hirshberg, *supra* note 63, at 71.

68. PORT ET AL., *supra* note 12, at 177.

69. *Id.*

70. *Id.*

71. Newburg & Dunn, *supra* note 45, at 198–99.

72. Hamilton, *supra* note 32, at 399.

intellectual interests.⁷³ Thus, universities must strive to balance their researchers' intellectual drive and job satisfaction with the need to allocate human research resources towards industry-sponsored programs that provide financial support for the universities.

While the many benefits of industry-university research partnerships may be tempered somewhat by certain disadvantages,⁷⁴ these disadvantages pale in comparison to the detrimental effect that the modern experimental use jurisprudence has on scientific progress.⁷⁵

III. THE MODERN INTERPRETATION OF THE EXPERIMENTAL USE DEFENSE AND ITS EFFECT ON SCIENTIFIC PROGRESS

Courts construe the experimental use defense narrowly to the benefit of patent holders and to the detriment of research institutions and the public in general.⁷⁶ At one time, "there [was] a line of authority suggesting that use of a patented product for non-commercial, experimental purposes [was] not . . . an act of infringement."⁷⁷ Under modern decisions, however, free use of patented technology for research is prohibited unless the use is solely "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."⁷⁸

A recent decision regarding the experimental use defense by the Court of Appeals for the Federal Circuit, *Madey v. Duke University*,⁷⁹ weighs heavily against effective use of patented technology by research universities.⁸⁰ One commentator aptly describes *Madey* as "[s]ealing the [c]offin on the [e]xperimental [u]se [e]xception."⁸¹ The *Madey* decision reiterates and

73. See Karen Kreeger, *Research in the Business World* (Oct. 16, 2000) (discussing the "perceived lack of freedom that people mention time after time when comparing scientific research in a university lab versus a company lab" and comparing the "supposed freedom in academia" with the larger amounts of resources found in private business labs), available at http://www.the-scientist.com/yr2000/oct/prof_001016.html ("labs") (last visited Sept. 2004); Nathan Dykes, *Statement on a new Faculty Title: Clinical Professorship* (discussing the benefits of an academic position versus private practice despite "the perception, and perhaps reality, that private veterinary practice is more lucrative, less demanding, more organized, [and] less stressful, compared with a University position"), at <http://web.cornell.edu/UniversityFaculty/forums/Dykes> statment.pdf (last visited Sept. 2004).

74. Hirschberg, *supra* note 63, at 71.

75. See generally Miller, *supra* note 7.

76. See *Madey v. Duke Univ.*, 307 F.3d 1351, 1361–63 (Fed. Cir. 2002) (interpreting the experimental use defense to be narrow and limited); *Soitec v. Silicon Genesis Corp.*, 81 Fed. Appx. 734, 737 (Fed. Cir. 2003) (unpublished opinion) (refusing to distinguish between use of patented technology at the "research and development stage" versus the "manufacturing stage").

77. CHISUM ET AL., *supra* note 5, at 1204.

78. *Madey*, 307 F.3d at 1362; *Soitec*, 81 Fed. Appx. at 737 (unpublished opinion).

79. 307 F.3d 1351.

80. See *id.* at 1351–64.

81. Miller, *supra* note 7, at 12.

expands the Federal Circuit's staunch position against an experimental use exception for universities from a patent holder's general right to exclude.⁸²

A. *Madey v. Duke University*

In *Madey*, the Federal Circuit Court of Appeals held that the experimental use defense did not apply to Duke University's potentially infringing use of patented technology.⁸³ Duke employed *Madey* to run a free electron laser lab that included laser equipment patented by *Madey*.⁸⁴ Years later, disagreements between Duke and *Madey* resulted in Duke removing *Madey* as lab director; however, Duke continued to use the laser equipment over which *Madey* held patents.⁸⁵ When *Madey* sued for patent infringement, the lower court determined that *Madey* failed to establish that Duke was using the equipment for purposes other than mere nonprofit experimentation; thus, it granted Duke's motion for summary judgment of non-infringement.⁸⁶ The Federal Circuit Court of Appeals, however, closed the door to the lower court's reasonable approach to the experimental use exception.⁸⁷ It declared that *Madey* did not have to establish that Duke used the patented technology for profit oriented purposes and reversed that portion of the lower court's dismissal of *Madey*'s patent infringement claims against Duke.⁸⁸

The *Madey* court found that distinctions between commercial research and theoretical, non-commercial research are immaterial with regard to the experimental use defense.⁸⁹ "[R]egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain,"⁹⁰ the experimental use defense does not apply if the institution's endeavor furthers its legitimate business, such as theoretical research.⁹¹ Apparently, the experimental use defense applies only to trivial uses, such as for amusement, satisfaction of idle curiosity, or strict philosophical inquiry, which are inconsistent with research universities' role in pursuing higher learning.⁹² Thus, the Federal Circuit's narrow interpretation of the experimental use defense significantly impacts research universities and affects their ability to further scientific progress.⁹³

82. *Id.*

83. *Madey*, 307 F.3d at 1362-63.

84. *Id.* at 1352.

85. *Id.* at 1352-53.

86. *Id.* at 1356.

87. *Id.* at 1361-63.

88. *Id.* at 1362-63.

89. *Id.* at 1362.

90. *Id.*

91. *Id.*

92. *Id.*

93. Tom Saunders, Case Comment: *Renting Space on the Shoulders of Giants: Madey and the*

B. Application of the Madey Decision

Scientific progress occurs when new ideas are presented and accepted by the scientific community. First, the new idea is evaluated, probed, and scrutinized by the scientific community; then, if the scientific community generally accepts the idea, it is considered legitimate.⁹⁴ Only after that process is fully undertaken can a new idea be considered sufficiently solid to serve as a rung in the ladder of scientific progress that allows others to climb higher.

1. The Federal Circuit's Differing Treatment of Research Universities and Individuals

The *Madey* decision circumscribes a vital group from the scientific progress equation with regard to patents, namely research universities.⁹⁵ A substantial portion of the scientific community pursue academic careers at research universities, yet “[t]he practical effect of the *Madey* decision is to draw an artificial line between experiments conducted by individuals and experiments conducted by university researchers.”⁹⁶ Indeed, *Madey* precludes researchers at universities from freely experimenting with patented technology while it allows individuals to do so in certain instances.⁹⁷

Placing individuals under the ambit of the experimental use exception and excluding research universities, which are in a prime position to extend existing scientific boundaries, is antithetical to the purpose of patent law. Granted, individuals not affiliated with a research institution who tinker in fields of interest to them comprise some small fraction of the scientific community, but they generally lack the resources necessary to make significant contributions to scientific progress. With these resource limitations in mind, society expects research universities to contribute the lion's share of time and effort to achieve scientific progress. But *Madey*

Future of the Experimental Use Doctrine, 113 YALE L.J. 261, 265 (2003).

94. See Lambert Dolphin, *Steps in the Scientific Method* (May 2, 1992), at <http://www.ldolphin.org/SciMeth2.html> (last visited Sept. 2004).

95. See *Madey*, 307 F.3d at 1362–63.

96. Saunders, *supra* note 93, at 265.

97. See *Madey*, 307 F.3d at 1362–63. For example, I suggest an individual testing a patented invention to determine how it worked could more easily allege that his experimentation was to satisfy such personal interests as idle curiosity, amusement, or philosophical inquiry than could an employee in a research institution because employees generally are not paid to satisfy personal interests. Even if the individual's and employee's goal was the same—to advance science—and the research project had “no commercial application whatsoever,” the Federal Circuit would still preclude the research university from using the experimental use defense based on its conclusion that research projects “unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects” and that they further “increase the status of the institution and lure lucrative research grants, students and faculty.” *Id.* at 1362.

precludes research universities from freely using an important research tool, patented technology, to achieve the scientific progress expected of them.⁹⁸

Patents are laden with useful scientific information and discoveries, which makes them essential to expanding scientific thresholds. “The information contained in patents is a major source of scientific as well as technologic knowledge. Indeed, in many areas of technology, technical information is not published outside of patent documents.”⁹⁹ Therefore, decisions such as *Madey*, which affect patent law, also affect general scientific knowledge part and parcel.

2. The *Madey* Decision’s Effect on Scientific Progress

The overall effect of the *Madey* decision is to reduce the patent law system’s potential to promote scientific progress. In multiple different ways, *Madey* precludes academia from utilizing, for the public benefit, the science contained within patents.¹⁰⁰

First, *Madey* undercuts the value of the specification requirement¹⁰¹ necessary to obtain a patent.¹⁰² The specification requirement is intimately related to the patent law purpose of promoting the useful arts: inventions granted patents must be described in sufficient detail to ensure that the public benefits scientifically from the new knowledge underlying the patented invention.¹⁰³ The persons, other than the inventor himself, most able to understand new inventions, as described in a patent specification, are often academic researchers.¹⁰⁴ Denying academic researchers the opportunity to freely experiment with patented inventions hinders their ability to fully understand new inventions and to subsequently pass on that new knowledge

98. *See id.*

99. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 875 (Fed. Cir. 2003) (Newman, J., concurring in part, dissenting in part).

100. *See generally* Saunders, *supra* note 93.

101. 35 U.S.C. § 112 (2003) (describing the written description, enablement, best mode, and definiteness disclosure requirements to obtain a patent). The specification requirement reads as follows:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor carrying out his invention.

Id.

102. Saunders, *supra* note 93, at 265–66.

103. 35 U.S.C. § 112 (2003).

104. Saunders, *supra* note 93, at 265–66.

to their students.¹⁰⁵ Therefore, *Madey* interferes with the patent law purpose of passing on the knowledge contained in patents to persons skilled in the relevant art.¹⁰⁶

Second, *Madey* removes a substantial source of patent peer review that is useful for confirming the validity and accuracy of a patent's claims.¹⁰⁷ The Patent and Trademark Office is inundated with new patent applications every year and this significant burden prevents it from thoroughly testing all aspects of patent claims.¹⁰⁸ Research universities are better suited to fully explore the limits of a patent and could review a patent's claims in conjunction with their own research initiatives. Ensuring that patent claims are valid allows business and academia to more fully rely on patents for their respective financial and scientific pursuits.

Finally, additional beneficial uses of the patented technology unknown to the patent holder, but known to others, are trapped by the patent under *Madey*.¹¹² When a researcher knows that patented technology is useful in an area not considered by the patent holder, such technology may fail to be utilized because *Madey* prevents the researcher from experimenting with the patented technology.¹¹⁰ This result can potentially trap lifesaving advances, such as when Immunex patented a protein it only knew was useful for enhancing general immune system function.¹¹¹ Had a research group from England not further researched Immunex's patented protein, its drug resistant cancer fighting properties may not have been discovered.¹¹²

In short, *Madey* hinders scientific progress in the United States by interfering with research universities' ability to use patented technology for nonprofit research purposes. At least one other country, with acute interests in fostering innovation, has rejected the *Madey* court's line of reasoning in favor of systems with broader experimental use allowances.¹¹³

105. *Id.*

106. *Id.*

107. *Id.*

108. See 2002 USPTO Performance & Accountability Rep. for Fiscal Year 2002, at 17, available at <http://www.uspto.gov/web/offices/com/annual/2002/lowres/1-58.pdf> (last visited Mar. 10, 2004). The USPTO received 333,688 patent applications in 2002 and it employed 3538 patent examiners to process all of the patent applications. *Id.*

109. Saunders, *supra* note 93 at 265-66.

110. *Id.*

111. *Id.* at 266 n.26.

112. *Id.*

113. Jennifer Johnson, Comment, *The Experimental Use Exception In Japan: A Model For U.S. Patent Law?*, 12 PAC. RIM. L. & POL'Y J. 499, 510-511 (2003) (discussing Japan's patent law system).

C. The Experimental Use Exception in Japan as an Alternative

In contrast to the United States, researchers in Japan may use patented technology for noncommercial research purposes.¹¹⁴ Japan designed its patent law system to encourage innovation and scientific progress because, at the time it designed the system, it lagged scientifically behind the world.¹¹⁵ Interestingly, Japan and the United States share the same goal of fostering scientific progress, yet they take diametrically opposed positions to the experimental use defense.¹¹⁶ One need only look at an electronics store or a car dealership to determine that Japan's patent law system and its application of the experimental use defense continues to yield considerable innovation. Indeed, "[i]n Japan, where a general statutory experimental use exception has been in place for over one hundred years, inventive activity is growing at an exceptional rate."¹¹⁷

The Japanese patent system includes a statutory exception to patent infringement for experimental use that provides significantly more protection to Japanese researchers experimenting with patented technology than exists in the United States.¹¹⁸ Specifically, the Japanese Patent Law states "the effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research."¹¹⁹ The fact that the Japanese experimental use exception derives from a statute, whereas the United States' general experimental use defense derives from the common law,¹²⁰ indicates that the experimental use exception is more binding in Japanese courts than it is in American courts. In Japan, courts seem to interpret the experimental use exception to require only that the research result in a technological advance, but even that limited element has not been consistently required by Japanese

114. *Id.*

115. *Id.*

116. Compare Johnson, *supra* note 113, at 519 (discussing Japan's expansive experimental use exception), with *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002) (holding that the experimental use defense in the United States is extremely narrow and strictly limited).

117. Johnson, *supra* note 113, at 532.

118. *Id.* at 519–520 (noting that the Japanese experimental use exception applies to all forms of research and experimentation, whereas the United States' common law experimental use defense is construed extremely narrowly and its ancillary statutory experimental use exception, 35 U.S.C. § 271(e)(1), applies only to generic pharmaceutical manufacturers for testing in preparation for FDA regulatory requirements).

119. *Id.* at 510 (quoting Tokkyoho [Patent L.], Law No. 121 of Apr. 13, 1959 (Japan), amended by Law No. 24 of Apr. 17, 2002 (Japan), art. 67(2), translated in JAPANESE LAWS RELATING TO INDUSTRIAL PROPERTY (Japanese Patent Office trans., 1996)).

120. *Id.* Of course, the generic drug approval experimental use provision of 35 U.S.C. § 271(e)(1) is a statutory experimental use provision, but since it is limited only to the pharmaceutical industry, it does not approach the inclusiveness of Japan's statutory experimental use exception. See *id.*

courts.¹²¹

Japan's patent system demonstrates that proper tailoring of an experimental use exception for nonprofit research universities can be an effective means of promoting scientific progress and innovation.¹²² Like Japan, the United States would benefit from increased scientific progress and innovation if Congress improved the patent laws by including a statutory experimental use defense to patent infringement for nonprofit research universities.

IV. PROPOSED IMPROVEMENTS

To promote scientific progress, the experimental use exception should be revised and expanded. Congress should incorporate a wholesale exception to patent infringement under 35 U.S.C. § 271 for nonprofit university research. The exception should give nonprofit universities wide latitude to use patented technology to conduct their research; however, to protect the patentee's property interest in his patent, the exception should entitle the patentee to an interest in any subsequent innovations or patents directly attributable to a university's use of his patent.¹²³

The patentee's interest in innovations developed by a university's use of his patented technology under the modified experimental use exception should be proportional to his patent's contribution to the innovation. This scheme may be characterized as a "reach-through" royalty scheme whereby "the true value of the patented [technology] will be determined by the ultimate marketplace success of the new product developed through use of the [patented technology]."¹²⁴ The patentee's interest would be a function of the fraction of his invention utilized by the university in relation to the fraction of other patented inventions also utilized.¹²⁵ Additionally, the patentee's interest would be a function of how much the university research was responsible for the subsequent innovation.¹²⁶ This scheme would shift the university's financial burden to pay royalties to the back end of the research process, as compared to the current front end scheme of paying royalties initially to use

121. *Id.* at 517–18 (discussing the Japanese court's inconsistent application of the technological advance requirement with experimental use in the pharmaceutical industry and other inventions).

122. *See id.* at 519, 532.

123. *See generally* Janice M. Mueller, *No "Dilettante Affair": Rethinking The Experimental Use Exception To Patent Infringement For Biomedical Research Tools*, 76 WASH. L. REV. 1, 62 (2001).

124. *Id.* at 61–62.

125. *See id.* at 62.

126. This Comment does not propose to define exactly how the courts would determine the patentee's interest, but rather it suggests that the concept would be feasible and would better balance the interests of promoting science and protecting a patent owner's interest.

patented technology.¹²⁷ Furthermore, the scheme would also require universities to pay royalties only for the use of patented technology that resulted in economically useful innovations.¹²⁸

These proposed changes would provide researchers with the freedom to advance science while compensating the patent owners whose patents fulfilled the purpose of patent law. The science advanced would be both theoretical and innovative: (1) without front end royalty costs, researchers would be more free to advance theoretical fields of science because they would have less obligation to pursue commercially useful inventions to recoup licensing expenses paid when using patented technology and (2) royalty costs shifted to the back end and limited to the patented technology that the university actually advanced into new commercial innovations would decrease deterrents to innovative research.¹²⁹ The public would benefit from these changes because they would allow universities to efficiently devote their time and resources towards *advancing* science beyond existing thresholds of knowledge defined by then existing patented technology. In sum, a system that fosters research to advance science and innovation has marked advantages over the current system, which too often impedes science and innovation.

A. *Benefits to Theoretical Research*

Theoretical science would benefit from these proposed changes because universities currently have little financial incentive to pursue science that will not lead to immediately useful innovations. With the inherent high cost, delay, and inconvenience a university incurs when it uses patented technology for research,¹³⁰ researchers may be pressured into pursuing research that will result in commercially viable inventions. This pressure diverts research efforts away from pure, theoretical fields that are unlikely to have immediate economic applications, but yet may yield future quantum leaps in scientific advancement.

Theoretical research is essential to science and mankind's well-being. Even when such research does not appear to offer the marketplace practical applications, it can open the door to innovations beyond current comprehension. How can society begin to measure the effects Newton's Laws of Mechanics have had on all subsequent scientific progress? More

127. See Mueller, *supra* note 123, at 62.

128. *Id.*

129. *Id.*

130. See Eyal H. Barash, Comment, *Experimental Uses, Patents, and Scientific Progress*, 91 Nw. U. L. REV. 667, 698-700 (1997).

recently, the world community's effort to combat the SARS virus provides an example extolling theoretical research:

Coronaviruses had never been associated with lethal diseases in humans before. Nevertheless, work on those viruses had been supported by the National Institutes of Health and other places, so we knew quite a bit about this family of viruses before the outbreak, which meant we were in a better position to make vaccines that could prevent another outbreak. If basic research hadn't been done, SARS would have been a much more serious threat.¹³¹

By allowing nonprofit universities uninhibited use of patented technology to push the boundaries of current scientific theories, which may or may not yield immediate economically useful inventions, the patent system would promote, rather than hinder, scientific progress.

B. Benefits to Innovative Research

Granting nonprofit universities the freedom to use patented technology will promote innovation by eliminating deterrents to research that arise when universities must pay royalties to explore paths that later turn out to be dead-ends.¹³² When a university must pay a license fee to use ten different patented technologies, but only succeeds in advancing the technology of one of them, it likely incurs a financial loss. The loss occurs even though the university may receive a reasonable royalty for the invention it creates because it has paid at least a reasonable royalty rate¹³³ for each of the ten patented technologies it used to achieve that one invention. Because scientific research, by its very nature, abounds with unsuccessful pursuits, the imposition of royalty fees for use of patented technologies that never result in useful inventions creates a deterrent to pursuing the research in the first place.¹³⁴ If a university, however, were free to use all ten patented technologies for research, paying a royalty only for its use of the one patent that it successfully advanced into a useful, new innovation, the university would have promoted science it may have otherwise been deterred from pursuing, and the deserving patentee would be justly compensated.¹³⁵

131. Barry Yeomen, *SARS Storm Spurs Surprising Strategies*, DISCOVER, Jan. 2004, at 50 (quoting Robert Garry, a virologist from Tulane University School of Medicine).

132. See Mueller, *supra* note 123, at 61–63.

133. 35 U.S.C. § 284 (2003) (defining patent infringement damages); see Donald Ware, *Research Tool Patents: Judicial Remedies*, 30 AIPLA Q. J. 267, 280 (2002).

134. See Mueller, *supra* note 123, at 61–63.

135. *Id.*

Under this system, universities could strive to advance science without reinventing the wheel. To acquire patent protection, the patentee must disclose his invention.¹³⁶ The disclosure requirement aims to allow the public to derive the benefit of the patentee's scientific contribution.¹³⁷

The patent statute requires full disclosure of the invention Such details would be idle and purposeless if this information cannot be used for 17–20 years. Indeed, there would be little value in the requirement . . . if the information is then placed on ice and protected from further study and research investigation. To the contrary, the patent system both contemplates and facilitates research into patented subject matter, whether the purpose is scientific understanding or evaluation or comparison or improvement. Such activities are integral to the advance of technology.¹³⁸

Allowing a university to make full use of this knowledge through experimentation, without the front end hassles of royalty negotiations,¹³⁹ would encourage researchers to take patented technology forward towards new and improved innovations.¹⁴⁰

However, under *Madey*, a university researcher is dissuaded from experimenting with patented technology because he does not qualify for the experimental use exception.¹⁴¹ Thus, financial pressures encourage a university researcher to inefficiently work around patented technology in an attempt to understand the principles they contain in a non-infringing manner, rather than more efficiently using inventions as they are disclosed.¹⁴² In her dissent in *Integra Lifesciences*, Judge Newman lamented the public loss of valuable knowledge caused by narrow interpretation of the experimental use defense:

The requirement of disclosure of the details of patented inventions facilitates further knowledge and understanding of what was done by the patentee, and may lead to further technologic advance. The right to

136. 35 U.S.C. § 112 (2003) (describing the written description, enablement, best mode, and definiteness disclosure requirements to obtain a patent).

137. *Id.*

138. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 875 (Fed. Cir. 2003) (Newman, J., concurring in part, dissenting in part).

139. See Barash, *supra* note 130, at 698–700.

140. See Mueller, *supra* note 123, at 61–63.

141. *Madey v. Duke Univ.*, 307 F.3d 1351, 1362–63 (Fed. Cir. 2002).

142. *Integra Lifesciences*, 331 F.3d at 872 (Fed. Cir. 2003) (Newman, J., concurring in part, dissenting in part) (“Indeed, in many areas of technology, technical information is not published outside of patent documents.”).

conduct research [without royalty payment] to achieve such knowledge need not, and should not, await expiration of the patent.¹⁴³

The public would be better served if this effort expended working around patented technology was directed toward actual scientific progress and innovation, thus exemplifying the purpose of the patent system.¹⁴⁴

The reformed patent system described in this section would undoubtedly benefit the public due to increased innovation and scientific knowledge. In addition, the reformed system would also affect individual patentees in a manner they might at first perceive to be negative; however, a full evaluation of the reformed system demonstrates that their rights would be respected and protected.

C. Melding a Patentee's Compensation with Patent Law's Purpose

The benefits to science of the reformed system need to be weighed against the potential negative effects this system may have on a patentee's rights and interests. Following these proposals, congressional reform of the patent infringement statute¹⁴⁵ would undoubtedly weaken patent rights to some degree; however, this does not necessarily mean that Congress should not take this path. Rather, it begs the question of whether a patentee's interest in an infallible right to exclude the nonprofit academic use of his patented technology is worth the public cost incurred by hindering scientific progress. The answer becomes apparent when the contours of a patentee's interest in a right to exclude are explored.

First, a patentee does not have a valid interest in hindering public scientific progress; rather, such an interest is antithetical to the purpose of patent law.¹⁴⁶ A patentee's right to exclude must be limited to commercial uses that will allow the user to profit in some manner; that right must not serve as a tool to hinder science. Notwithstanding lost royalties, patentees suffer no financial loss if universities use patented technology to advance pure, theoretical science because improved scientific theories generally have no immediate commercial application in and of themselves.¹⁴⁷ Furthermore, since abstract theoretical concepts are not patentable subject matter,

143. *Id.* at 873.

144. *Id.* "The purpose of a patent system is not only to provide a financial incentive to create new knowledge and bring it to public benefit through new products; it also serves to add to the body of published scientific/technologic knowledge." *Id.*

145. 35 U.S.C. § 271 (2003) (defining patent infringement).

146. *See* U.S. CONST. art. I, § 8.

147. 35 U.S.C. § 101 (2003) (establishing patentable subject matter which does not include abstract theoretical ideas).

theoretical advances would not result in patents that render the patentee's patent obsolete.¹⁴⁸ Allowing universities to freely conduct nonprofit theoretical research using patented technology comports with the patent system's goals of promoting science and compensating patentees for commercial use of their patent¹⁴⁹ because science would be advanced without commercial use requiring compensation.

Second, the patentee has no legitimate interest in profiting from a nonprofit university's use of his invention if the university never succeeds in producing any economically useful inventions. While the university's purpose for using patented technology may be to discover related new innovations, until an economically useful invention results from the university's efforts, the use is not actually commercial, but rather is a philosophical inquiry. University research is based on a researcher's hypothesis, that is, a researcher's philosophical notion that he can improve an invention or make a new discovery. If the researcher uses patented technology to pursue his hypothesis and his efforts result in a commercially viable innovation, then his use of the patented technology was commercial *because* it resulted in a commercial product. But if the researcher's hypothesis fails, then the whole process was nothing more than a philosophical inquiry because the end product was nothing more than an intangible answer to his inquiry: that his hypothesis was incorrect.

Finally, a patentee does indeed have a valid interest in profiting from a university's subsequent improvement of his invention that it achieved by using his patented technology. When a university's use of patented technology results in an improved, new, commercially useful product, a large part of its success is based on the patentee's prior efforts. Patentees generally must expend considerable time, money, and effort to develop new inventions and also to prosecute patents protecting the inventions.¹⁵⁰ Therefore, a patentee deserves some form of compensation for commercial innovations that result from a university's use of his patented technology; however, the compensation need not be front-end royalties as are now required, but rather the patentee could fairly be compensated under the modified system using "reach through" type royalties.

148. ROBERT P. MERGES ET AL., *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 131 (3rd ed. 2003) (citing *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. (20 Wall.) 498, 507 (1874)).

149. U.S. CONST. art. I, § 8.

150. See generally Commission on Industrial Intellectual Property, *Policy Statement: The Reduction of Patent Costs* (Jan. 30, 1997) (discussing the high costs associated with both worldwide and United States patents), available at http://www.iccwbo.org/home/statements_rules/statements/1997/patent_costs.asp (last visited Sept. 2004).

Fully evaluating the patentee's interest in an exclusionary right demonstrates that the patent law should not sacrifice the benefit to society that the modified system and an effective experimental use exception would provide. Certainly a patentee deserves compensation when the use of his patent leads another to further commercial gain. However, the costs to society that result from not allowing free nonprofit experimental use are not justified. The modified system balances the public's need for the patent laws to promote science by providing for an effective experimental use exception for nonprofit research while fairly compensating patentees with "reach-through" type royalties. The modified system, accordingly, makes a patentee's compensation for use of his invention consistent with the patent law purpose of promoting science and innovation.¹⁵¹

V. CONCLUSION

Research partnerships among academia, private industry, and government have evolved into effective methods of fostering innovation; however, recent Federal Circuit decisions, most notably *Madey*, interpreting the experimental use defense have imparted inefficiency and deterrents into the system. Furthermore, theoretical research in particular receives short shrift by a narrow interpretation of the experimental use defense because universities may have less incentive to pursue abstract science that does not readily yield immediate, commercially viable innovations.

The modified patent system presented in this Comment addresses these issues and seeks to ground the patent laws within the purpose of patent law elicited in the Constitution. It promotes both theoretical and innovative research by expanding the scope of the experimental use defense to include nonprofit research universities. While fostering science it also protects deserving patentees by providing for "reach-through" type royalties only to patentees whose patented technology directly contributed to advancing the useful arts. The modified patent system starkly contrasts with the current system where universities must pay royalties to all patentees, regardless of whether their patents helped advance science. In sum, the current system's lack of an effective experimental use defense undercuts the constitutional purpose of patent law, whereas the modified patent system would allow nonprofit academic research institutions to promote science, thereby fulfilling the constitutional purpose of patent law.

JOSEPH MOHR

151. U.S. CONST. art. I, § 8.

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