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Unveiling the Distinction between the University and its Academic Researchers: Lessons for Patent Infringement and University Technology Transfer

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ABSTRACT

This Article explores the idea that a faculty member acting in the role of an academic researcher in the scientific disciplines should be viewed in the context of patent law as an autonomous entity within the university rather than as an agent of the university. The structure of the university laboratory within the university and the social norms associated with the activities that members of the research laboratory conduct supports such a view. Additionally, the data from the implementation of the Bayh-Dole Act reveal that universities and faculty scientists have different goals and motivations regarding the transfer of new technology to the private sector. Acknowledging a distinction between the university and its academic researchers would revive the application of the experimental use exception as a defense to patent infringement for the scientists who drive the innovation economy

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of our country. Also important, this distinction has implications for the way that entrepreneurship is defined in the context of academic researchers. A better understanding of academic entrepreneurship may lead universities to restructure incentives to encourage academic researchers to participate in transferring new inventions from the laboratory to the private sector.

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Dr. Anna Lucard,¹ a biomedical researcher at State University, holds the BigPharma® Endowed Chair in Molecular Biology. She spends much of her time on administrative duties such as her appointment as the chair of the Department. However, her driving force for entering academia was her research on genetic mutations that lead to breast cancer. Most of the funding for the research comes from government agencies such as the National Institutes of Health, but smaller amounts of money flow in from non-profit grants and industry collaborations. These multitudes of funding sources come with different benefits and drawbacks. Because of the availability of government funding, Dr. Lucard is able to explore avenues of research that do not seem to be immediately marketable. On the other hand, her industry collaborations help her feel as though she is making an immediate impact on the health of society, and has enabled her to buy a new multi-thousand dollar piece of equipment for general laboratory use. During that same period, Dr. Lucard has used government funding to isolate a genetic mutation and determined that it potentially could be used to screen for a particularly aggressive form of cancer. The university, which left her to plan, fund, and conduct her research on her own, is now pressuring her to patent the invention so that the university can license it to LittleBiotech™. Dr. Lucard understands that she is required by law² and by contract³ to disclose the new technology to the university, but she would prefer to publish the information to engage the scientific community and support her next grant rather than pursue a patent.⁴ She is unclear why the university is suddenly taking an interest in the technology developed during her research when its prior interest had been limited to the amount of overhead money she was bringing in to fund the building renovations. Some days, Dr. Lucard would just like to hide in her laboratory and forget that her university responsibilities exist.

1. Dr. Lucard and her story are fictional but representative of many faculty members at universities across the United States.

2. Bayh-Dole Act, Pub. L. No. 96-517, § 6(a), 94 Stat. 3015, 3019-28 (1980) (codified as amended at 35 U.S.C. §§ 200-212 (2006)).

3. Most universities have policies in place requiring faculty members to assign any inventions developed during employment by the university. See, e.g., DUKE UNIV., FACULTY HANDBOOK: POLICY ON INVENTIONS, PATENTS, AND TECHNOLOGY TRANSFER P-9 (2008), available at http://olv.duke.edu/Inventors/PoliciesAndProcedures/policy_on_inventions.pdf.

4. Dr. Lucard could both patent and publish the invention, but due to time restrictions and personal beliefs regarding ownership of publicly funded inventions, she may choose to focus on publication. For a fuller discussion of the choice between publications and patenting see *infra* Parts V.B and V.C.

Such is the life of many of today's academic researchers in the sciences. The university has become an increasingly commercial place with endowed chairs and licensing pressures.⁵ A researcher's one potential avenue of escape from that commercialization is her laboratory. In the laboratory, she alone determines what research will be conducted. She can choose to completely forgo commercial involvement by applying for federal grants rather than partnerships with industry—or not. The laboratory is her space to define.

This faculty autonomy while acting in the role of scientific researcher has not been explicitly recognized. Instead, many scholars lament the death of pure research, or the realm of philosophy, due to the increased commercialization of the university in today's society.⁶ In its most idealized form, the realm of philosophy is a place in which scientific research⁷ is conducted in an arena free from the pressures of commercialization,⁸ a stark contrast to the world of commerce.⁹ If, as has been argued, the university is at heart a money-making corporate endeavor,¹⁰ the realm of philosophy is certainly not to be found within its hallowed halls. Or is it? This Article seeks to unveil the distinction between the university and its academic researchers. It argues that the realm of philosophy continues to be found in the laboratories of the modern, more commercial university because each individual faculty scientist determines the degree of commercialization allowed into her laboratory.

In discussing this distinction, it must be remembered that the university is not a monolithic structure. The university itself does not conduct research; academic researchers within the university conduct scientific research independently of the university in laboratories that function as independent entities within the university.¹¹ The structure of the university research system demonstrates the

5. See *infra* Part III.

6. See, e.g., 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).

7. Philosophy refers to "natural philosophy," i.e., science. For a full discussion, see *infra* Part IV.D.1.

8. One of the goals of creating a federally funded research system was to free scientists from the pressures of pursuing only research with commercial implications. See, e.g., OFFICE OF TECH. ASSESSMENT, U.S. CONG., A HISTORY OF THE DEPARTMENT OF DEFENSE FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTERS 2 (1995), available at <http://www.fas.org/ota/reports/9501.pdf>.

9. *Brenner v. Manson*, 383 U.S. 519, 536 (1966).

10. JENNIFER WASHBURN, UNIVERSITY, INC.: THE CORPORATE CORRUPTION OF HIGHER EDUCATION (2005); see also Frank T. Rothaermel, Shanti D. Agung & Lin Jiang, *University Entrepreneurship: A Taxonomy of the Literature*, 16 INDUS. & CORP. CHANGE 691, 707-709 (2007).

11. See *infra* Part II.A.

independence of the academic researcher from the university.¹² Additionally, an analysis of the results of the Bayh-Dole Act,¹³ which Congress passed to incentivize the transfer of technology developed by federally funded research from the university to the private sector, further reveals the distinction between the university and its academic researchers. The different incentives and motivations that each group has for conducting research illustrate this distinction.¹⁴ Finally, courts interpreting patent law have recognized this implicit distinction in deciding some issues.¹⁵

Viewing the university and its academic laboratories and researchers as two distinct entities has a variety of implications for patent law as well as for university technology transfer.¹⁶ First, the experimental use exception¹⁷ to patent infringement, thought to be inapplicable to university research since *Madey v. Duke*,¹⁸ would once again be applicable to at least a subset of university research. Second, in light of this distinction, it may be time to redefine entrepreneurship in the context of academic researchers, recognizing that academic researchers are quite entrepreneurial but focus on goals and incentives quite different from the university at large. Based upon this new definition of entrepreneurship, universities may choose to modify the incentives to faculty for disclosing new inventions for transfer to private industry.

This Article argues that, in the context of patent law and innovation policy, courts, scholars, and university administrators should view academic researchers and their research laboratories as distinct entities from the universities in which they reside. Part I analyzes the structure of the university laboratory and the social norms surrounding academic researchers to support this distinction between academic researchers and the larger university. Part II describes the differences in goals and incentives between the academic researcher and the university as revealed by reactions to the Bayh-Dole Act. Part III details the implication of this distinction for the application of the experimental use exception to academic researchers

12. See *infra* Part II.A.

13. Bayh-Dole Act, Pub. L. No. 96-517, § 6(a), 94 Stat. 3015, 3019-28 (1980) (codified as amended at 35 U.S.C. §§ 200-212 (2006)).

14. See *infra* Part III.

15. See *infra* Part II.C.

16. University technology transfer as used in this article refers to the transfer of university-owned inventions to the private sector for further development and commercial litigation.

17. See *infra* Section IV.

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

in a university setting. Part IV describes the impact of the distinction on the discussion surrounding academic entrepreneurship and suggests ways to incentivize academic researchers to disclose new inventions to the university.

I. THE STRUCTURE AND HISTORY OF THE UNIVERSITY RESEARCH SYSTEM SUPPORT THE IDEA THAT THE UNIVERSITY OPERATES AS A DISTINCT ENTITY FROM ITS SCIENTIFIC RESEARCHERS

Faculties at universities play a number of different roles, including lecturer, researcher, and administrator. In many respects, a faculty member is a representative of the university. For instance, acting as an administrator, the faculty member is reasonably viewed as an agent of the university. Indeed, many scholars view the faculty as agents of the university in all aspects of university life.¹⁹ However, the structure and history of the academic research system illustrate the idea that when acting in the role of academic researcher, faculty and other laboratory staff are not acting as agents of the university.

A. University Research Laboratory Structure

The structure of a research laboratory varies depending in large part on the organization within which it is situated. Industrial laboratories are generally organized according to departments, and the organization directs all research conducted in the laboratory.²⁰ In contrast, university laboratories are generally organized around and run by a Principal Investigator who has a faculty appointment.²¹ The organization of a Principal Investigator-led laboratory varies based on the funding, space, and preferences of the Principal Investigator.

Although a Principal Investigator has departmental or school associations, it is the Principal Investigator, rather than the school or department, who determines the research strategy for the laboratory, hires staff, and acquires the major grants that fund the laboratory.²² In this manner, academic laboratories function as autonomous units

19. Richard A. Jensen, Jerry G. Thursby & Marie C. Thursby, *Disclosure and Licensing of University Invention: "The Best We Can Do with the S**t We Get to Work With,"* 21 INT'L J. INDUS. ORG. 1271, 1272 (2003), available at <http://www.nd.edu/~rjensen1/research/Disclosure.pdf>.

20. MICHAEL CROW & BARRY BOZEMAN, LIMITED BY DESIGN: R&D LABORATORIES IN THE U.S. NATIONAL INNOVATION SYSTEM 93 (1998).

21. *Id.* at 92.

22. *See, e.g.*, Dartmouth College Office of Sponsored Projects, Role of the Principal Investigator, <http://www.dartmouth.edu/~osp/resources/manual/post-award/pirole.html> (last visited Mar. 21, 2010).

within the university.²³ Principal Investigator-run academic laboratories have been analogized to independent firms,²⁴ and the Principal Investigator may be thought of as a Chief Executive Officer (CEO) who has ultimate control over the laboratory research.²⁵

While a Principal Investigator conducts research in her laboratory, her laboratory likely includes a number of other academic researchers, as well, including research assistants, postdoctoral fellows, graduate research assistants, and research technicians.²⁶ Research associates generally have a terminal degree and perhaps a faculty appointment.²⁷ Such researchers may work directly for the Principal Investigator, but often direct their own research projects within the laboratory.²⁸ Postdoctoral fellows also have terminal degrees, but work in the laboratories in a journeyman type of position.²⁹ Postdoctoral fellows have been trained to perform research and are continuing to hone those skills while developing skills in grant writing and other laboratory administrative functions in order to prepare to become Principal Investigators or research associates.³⁰ Graduate research assistants work within the lab on a small aspect of the Principal Investigator's larger project.³¹ These are usually students enrolled in a university graduate program who will use the data collected in these apprenticeships to demonstrate the ability to conduct scientific research.³² Finally, most laboratories have at least one research technician, who works directly for the Principal Investigator on research projects or general lab maintenance.³³ Thus,

23. See Henry Etzkowitz, *Research Groups as 'Quasi-Firms': The Invention of the Entrepreneurial University*, 32 RES. POL'Y 109 (2003).

24. *Id.*

25. For an in-depth analysis of the Principal Investigator's control of the research conducted, see discussion on academic freedom *infra* Part II.B.

26. See, e.g., Dartmouth College Office of Sponsored Projects: Role of the Principal Investigator, *supra* note 22.

27. See, e.g., Simon Fraser University, Policies & Procedures, University Research Associate, <http://www.sfu.ca/policies/research/r50-01.htm> (last visited Mar. 21, 2010).

28. *Id.*

29. See, e.g., American Cancer Society, Research Program & Funding: Postdoctoral Fellowships, http://www.cancer.org/docroot/RES/content/RES_5_2x_Postdoctoral_Fellowships.asp?sitearea=RES (last visited Mar. 21, 2010).

30. *Id.*

31. See, e.g., Montana State University, Division of Graduate Education, Graduate Assistantships, http://www.montana.edu/wwwdgc/cat_grad_assist.shtml (last visited Mar. 21, 2010).

32. *Id.*

33. See U.S. Department of Labor, Bureau of Labor Statistics, Occupational Outlook Handbook, 2010-11 Edition: Science Technicians, <http://www.bls.gov/oco/ocos115.htm> (last visited Mar. 21, 2010).

within any given laboratory, there is a mix of academic researchers who may be working for the Principal Investigator or quite independently.³⁴

Funding for the laboratory generally comes from outside sources such as government agencies and nonprofits, which further illustrates the dichotomy between the university and faculty. Although universities will often provide start-up funds for new hires, faculty members in the sciences who do not procure outside funding quickly find themselves unable to hire any type of researchers, purchase reagents, or even have a complete salary.³⁵ These grants are generally awarded in the name of the Principal Investigator's institution, but in practice are usually portable should the Principal Investigator move to a new institution.³⁶ Once a grant is received, the university essentially becomes its landlord. Up to fifty percent of the grant money is paid to the university in indirect costs. Funds for indirect costs are used to pay for utilities, common equipment, administrative support, waste disposal, and the like. The money left after such deductions is deposited into the Principal Investigator's faculty account, which is then used for payment of laboratory-related expenses, including the salaries of other researchers in the laboratory.³⁷

B. Scientific Norms and Academic Freedom

The independent nature of the structure of the university laboratory is the basis for the discussion of the social norms surrounding the research conducted within the university. Those social norms illustrate the idea that academic researchers define a societal group distinct from the university as an organization. Such a distinct structure stands in contrast to scientific researchers at commercial organizations who act on behalf of the commercial

34. Although some academic researchers operate independently within the Principal Investigator's laboratory so as to create a sort of mini-laboratory, this article confines its discussion to Principal Investigators; however, proper evaluation of any given piece of research would require an analysis of who controls the project under which it was conducted.

35. See, e.g., FACULTY OF ARTS AND SCIS. OFFICE OF FIN., HARVARD UNIV., SPENDING POLICY FOR FACULTY START-UP AND OTHER FAS FACULTY SUPPORT FUNDS 1-4 (2008), available at http://www.finance.fas.harvard.edu/files/policies/Faculty_Start-up_Funds.pdf.

36. University websites often have information regarding transfer of such grants. See, e.g., Oregon State University, Office of Sponsored Programs, Transferring a Grant or Change of Principal Investigator, <http://oregonstate.edu/research/osp/submission/transferringgrant.htm> (last visited Mar. 21, 2010).

37. See, e.g., OFFICE OF THE PROVOST, UNIV. OF MICH., POLICY STATEMENT ON THE USE OF FACULTY RESEARCH AND DISCRETIONARY ACCOUNTS (2005), available at http://www.provost.umich.edu/reports/discretionary/policy_statement.html.

organization's interest. Social norms that are particular to academic researchers have long been recognized to drive the actions of and relationships between these individuals.³⁸ Such norms include academic freedom and a lack of investment in the patent system in part growing out of the free sharing of research tools and materials as well as the publication of data in order to inform the public and other researchers of the results of current research.³⁹

One of the strongest social norms among university faculty is the norm of academic freedom. Academic freedom began as the idea that a faculty member does not leave her opinions and thoughts at the door when in the employ of the university.⁴⁰ While initially developed in reference to discussions in a classroom setting, academic freedom is equally applicable to a faculty member's role as an academic researcher.⁴¹ A Principal Investigator has the power to decide what research projects to pursue and the manner in which to tackle the projects.⁴²

The norm of academic freedom is particularly important when contrasting academic research with commercial research, where the general practice is to work on specific problems with short-range profitability as the organization directs. Principal Investigators exercise the freedom to direct research based on personal interests without bias from the university's drive to commercialize any particular technology. This is not to say that academic researchers are generally against the commercialization of scientific research. When asked about university commercialization efforts, faculty are generally supportive, but not to the extent that they would give up academic freedom.⁴³ In fact, academic researchers so value the academic freedom norm that researchers will often accept lower salaries in order to have jobs that allow significant personal freedom

38. *E.g.*, NORMAN W. STORER, *THE SOCIAL SYSTEM OF SCIENCE* 3 (1966); WARREN O. HAGSTROM, *THE SCIENTIFIC COMMUNITY* 9 (1965).

39. *See, e.g.*, Katherine J. Strandburg, *User Innovator Community Norms: At the Boundary Between Academic and Industry Research*, 77 *FORDHAM L. REV.* 2237 (2009); Nikolaus Franke & Sonali Shah, *How Communities Support Innovative Activities: An Exploration of Assistance and Sharing Among End-Users*, 32 *RES. POL'Y* 157 (2003).

40. *Tinker v. Des Moines Indep. Cmty. Sch. Dist.*, 393 U.S. 503, 506 (1969).

41. *See, e.g.*, *Dow Chem. Co. v. Allen*, 672 F.2d 1262, 1275 (7th Cir. 1982) (“[Academic freedom] extends as readily to the scholar in the laboratory as to the teacher in the classroom.”).

42. Philippe Aghion, Mathias Dewatripont & Jeremy C. Stein, *Academic Freedom, Private-Sector Focus, and the Process of Innovation*, 39 *RAND J. ECON.* 617, 621 (2008).

43. *See* Yong S. Lee, “*Technology Transfer*” and the Research University: A Search for the Boundaries of University—Industry Collaboration, 25 *RES. POL'Y* 843 (1996).

in the pursuit of a research agenda.⁴⁴ As a result, academic freedom is one of the key reasons that scientists choose to enter academia rather than industry.

An examination of the history of the governance of universities shows that faculties have fought for academic freedom when that freedom has been threatened.⁴⁵ Although U.S. universities are modeled in large part after European universities, the two differ in their methods of governance. Members of the faculty traditionally govern European universities, thus ensuring that the faculty retains control of all aspects of the university.⁴⁶ In contrast, boards of trustees composed of non-academics historically govern U.S. universities.⁴⁷ The early American institutions of Harvard University and the College of William and Mary began in the European tradition but rapidly adapted to the trustee model.⁴⁸ A faculty-governed university stands in stark contrast to a laymen-governed university, as the latter structure distances the faculty from identifying as closely with the university as an organization. Fearing that such distant governance would put the direction of academic research in the hands of university administrators, faculties fought to regain some internal control and have succeeded in the context of academic freedom.⁴⁹ As discussed above, U.S. faculties have managed to retain the academic freedoms of their European counterparts.⁵⁰

A second social norm that distinguishes the university from its academic researchers is based on the generally accepted practice of conducting academic research in the shadow of the patent system without directly engaging the patent system. Recently, universities have become heavily involved in the licensing⁵¹ and enforcement⁵² of

44. Aghion, Dewatripont & Stein, *supra* note 42, at 618 (discussing empirical work by Stern).

45. See WASHBURN, *supra* note 10, at 28-29; RICHARD HOFSTADTER & WALTER P. METZGER, *THE DEVELOPMENT OF ACADEMIC FREEDOM IN THE UNITED STATES* 120 (1955).

46. See WASHBURN, *supra* note 10, at 28; HOFSTADTER & METZGER, *supra* note 45, at 3-11.

47. See WASHBURN, *supra* note 10, at 28-29; HOFSTADTER & METZGER, *supra* note 45, at 120.

48. See WASHBURN *supra* note 10, at 28-29.

49. *Id.*

50. See discussion of academic freedom *supra* Part II.B.

51. For a detailed discussion of licensing under the Bayh-Dole Act, see *infra* Part III.A.

52. See generally Mark A. Lemley, *Are Universities Patent Trolls?*, 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 611 (2008). For an overview of initial data from a recent survey of patent litigation involving universities, see Chris Holman, Assoc. Professor of Law, Univ. of Mo.-Kansas City Sch. of Law, Presentation at Santa Clara University School of Law: University Patent Litigation (Jan. 30, 2009), available at <http://www.chtlj.org/sites/default/files/media/>

patent rights. At the same time, academic researchers have continued to operate with their traditional disregard of the patent system and the university's goals. For example, in spite of a government requirement to disclose government-funded inventions to the university for licensing and the university's considerable interest in licensing such inventions, academic researchers routinely publish their inventions in scientific journals without university disclosure rather than spending the extra time required to also disclose the inventions to the university.⁵³

Additionally, because of the strong emphasis on free sharing of materials and data,⁵⁴ academic researchers also adhere to a social norm of ignoring any patent rights related to a field of research.⁵⁵ One recent empirical study found that only 5 percent of academic researchers try to determine if their research projects might result in patent infringement.⁵⁶ This social norm may put the academic researcher at odds with a university that is trying to encourage the licensing of its own technology and is actively enforcing its own patent rights. In fact, universities and technology transfer offices advise academic researchers that ignoring patents covering one's research is patent infringement and could lead to liability,⁵⁷ usually to no avail.

The research conducted in the laboratory most vividly illustrates the dichotomy between the faculty researcher and the

symposiums/v025/slides/holman.ppt. For examples of specific patent lawsuits, see Bill Steele, *Cornell Wins \$184 Million Award from Hewlett-Packard for Patent Infringement*, CORNELL CHRON. ONLINE, June 6, 2008, <http://www.news.cornell.edu/stories/June08/HPpatent.ws.html> and Troy Yang, *University Loses Four-Year Patent Lawsuit*, STAN. DAILY, Oct. 8, 2009, available at <http://www.stanforddaily.com/2009/10/08/university-loses-four-year-patent-lawsuit>.

53. Daniel W. Efenbein, *Publications, Patents, and the Market for University Inventions*, 63 J. ECON. BEHAV. & ORG. 688, 689 (2007); Jensen, Thursby & Thursby, *supra* note 19, at 1272. The author notes that many researchers choose to both disclose to the university and publish; however, publication triggers a one year statutory bar window for filing a patent. 35 U.S.C. § 102(b) (2006).

54. Strandburg, *supra* note 39, at 2248; see also Franke & Shah, *supra* note 39.

55. Strandburg, *supra* note 39, at 2252; see also Mark A. Lemley, *Ignoring Patents*, 2008 MICH. ST. L. REV. 19 (2008); John P. Walsh, Wesley M. Cohen & Charlene Cho, *Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research*, 36 RES. POL'Y 1184, 1185-86 (2007).

56. Walsh, Cohen & Cho, *supra* note 55, at 1185-86, 1189-90.

57. See, e.g., Becky Mahurin, *No Research Exception in Patent Law*, MSU DISCOVERY NEWSL., Sept. 28, 2006, available at <http://tto.montana.edu/patentscorner/pcoct98.html>; Alan B. Bennett, Executive Dir., Univ. of Cal. Systemwide Office of Tech. Transfer & Research Admin., Presentation at the American Association for the Advancement of Science Annual Meeting: Intellectual Property and the Research Exemption: Its Impact on Science (Feb. 16, 2004), available at http://sippi.aaas.org/meetings/022004/presentations/bennett_exemption_files/v3_document.htm; Rodney L. Sparks, In-House Patent Counsel, Univ. of Va. Patent Found., Presentation at the Licensing Executive Society Winter Meeting (Feb. 2006), available at http://www.uvafp.org/live_data/documents/PatentIssuesFacingUniversities.ppt.

university. Faculty members follow social norms that set them apart from the university as a whole. Such social norms, including academic freedom and ignorance of patent issues, reflect the divergent goals and motivations that a faculty researcher and her host university hold.

C. Implicit Legal Recognition of the Distinction between the University and Its Academic Researchers

Although the discussion of an explicit view of the university and its academic researchers as distinct entities is a relatively novel one, at least two lines of legal reasoning dealing with patent law implicitly recognize that the university is inherently distinct from those conducting research within it. The application of patent law to determine ownership of inventions created by researchers working within the university and the availability of sovereign immunity as a defense against lawsuits for patent infringement both distinguish the university from the groups performing research.

1. Patent and Invention Ownership

Historically, patent law implicitly has recognized the independent structure of the university research laboratory and the social norms that further separate the academic researcher and the university. Generally, patent rights in a new technology accrue to the inventor.⁵⁸ However, some patent rights in an invention that an employee created will vest in the employer if the employee was hired specifically to invent the widget.⁵⁹ These rules apply whether the employer is a private entity or a government office.⁶⁰ Thus, if they are acting as distinct entities, academic researchers at both private and state universities should own any inventions created in a university laboratory.

Given that university faculties have a tradition of academic freedom, university faculty members are not hired to invent but rather to engage in general research as interests evolve. Thus, a faculty member retains patent rights to her widget under patent law.⁶¹ Indeed, the same is probably true of graduate students in the

58. See 35 U.S.C. §§ 111, 115 (2006).

59. See *United States v. Dubilier Condenser Corp.*, 289 U.S. 178 (1933) (noting that an employer retains a “shop right” to practice a patented invention if the invention is made during work hours with employer materials).

60. See *Solomons v. United States*, 137 U.S. 342, 346 (1890). Faculty at federal research campuses such as those of the National Institutes of Health and the Food and Drug Administration would be under the same rule.

61. See *Kaplan v. Corcoran*, 545 F.2d 1073 (7th Cir. 1976).

faculty member's lab who are co-inventors.⁶² Furthermore, in the early 1900s, universities fully recognized the research autonomy of its faculty and allowed faculty members to patent and license inventions through third parties.⁶³ The university generally did not want to be a part of the commercialization.⁶⁴

All of this changed in 1980 with the passage of the Bayh-Dole Act,⁶⁵ which requires that inventions developed by federally funded research be disclosed and assigned to the sponsoring university.⁶⁶ The Bayh-Dole Act, together with the concomitant increase in university emphasis on commercialization, has meant that universities generally require all academic researchers' inventions to be assigned to the university.⁶⁷ The history discussed above regarding invention within the university, however, indicates that the university and faculty traditionally viewed themselves as separate entities.⁶⁸

2. Sovereign Immunity

The application of sovereign immunity in university patent infringement cases also illustrates the distinction between the university and its researchers. In *Florida Prepaid Postsecondary Expense Board v. College Savings Bank*,⁶⁹ the Supreme Court established that a state and its universities are immune from lawsuits alleging patent infringement.⁷⁰ In spite of this safety net for public universities, the applicability of sovereign immunity to the academic researchers actually conducting the infringing research is in doubt.

62. See *Simmons v. Cal. Inst. of Tech.*, 209 P.2d 581 (Cal. 1949) (holding that a graduate student inventor retained rights to his invention in the absence of a contract to assign). For a general discussion of graduate student inventor rights, see G. Kenneth Smith, *Faculty and Graduate Student Generated Inventions: Is University Ownership a Legal Certainty?*, 1 VA. J.L. & TECH. 4 (1997).

63. WASHBURN, *supra* note 10, at 50-51.

64. *Id.*

65. Bayh-Dole Act, Pub. L. No. 96-517, § 6(a), 94 Stat. 3015, 3019-28 (1980) (codified as amended at 35 U.S.C. §§ 200-212 (2006)).

66. For discussion of the impact of the Bayh-Dole Act on university commercialization and faculty relations, see *infra* Part III.

67. See generally DUKE UNIV., *supra* note 3; HARVARD UNIV., STATEMENT OF POLICY IN REGARD TO INTELLECTUAL PROPERTY (Feb. 4, 2008), available at <http://www.otd.harvard.edu/resources/policies/IP/IPPolicy.pdf>; UNIV. OF CAL., PATENT POLICY (Oct. 1, 1997), available at http://www.ucop.edu/ott/genresources/pat-pol_97.html; UNIV. OF MICH., TECHNOLOGY TRANSFER POLICY (June 1, 2009), available at <http://www.techtransfer.umich.edu/resources/policies.php>.

68. WASHBURN, *supra* note 10.

69. Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627 (1999).

70. See *id.*

Without explicitly recognizing the distinction between the university and the academic researcher, some scholars have argued that the significant disconnect between the faculty researcher and the university may preclude the use of sovereign immunity as a viable defense for the infringing researcher.⁷¹ In *Kersavage v. University of Tennessee*, one district court used just such an interpretation.⁷² In that case, professors at the University of Tennessee, as well as the university itself, were sued for patent infringement.⁷³ The court dismissed the case with regard to the University of Tennessee on the grounds of sovereign immunity but refused to extend the defense to the professors.⁷⁴ The Tennessee professors might have been able to invoke a qualified immunity, but qualified immunity was a question of fact and could not be dealt with by summary judgment.⁷⁵ Therefore, the court made no decision regarding qualified immunity for the professors.⁷⁶

The case of *Riezler v. Allen* has the potential to clarify this issue.⁷⁷ In *Reizler*, two University of Colorado professors, Dr. Robert Allen and Dr. Sally Stabler, were sued in an inventorship dispute.⁷⁸ In response, the professors asserted sovereign immunity based on their actions disclosing the invention to Colorado University in their official capacity as professors at the university.⁷⁹ Like the *Kersavage* court, the *Riezler* court did not feel that professors could invoke sovereign immunity and rejected the motion to dismiss.⁸⁰ *Riezler* and *Kersavage* illustrate that some district courts have implicitly recognized the distinction between the university and its faculty,

71. Gary Pulsinelli, *Freedom to Explore: Using the Eleventh Amendment to Liberate Researchers at State Universities from Liability for Intellectual Property Infringements*, 82 WASH. L. REV. 275 (2007); Jennifer L. Owens, Note & Comment, "Not Quite Dead Yet": *The Near Fatal Wounding of the Experimental Use Exception and Its Impact on Public Universities*, 3 J. TELECOMM. & HIGH TECH. L. 453 (2005).

72. *Kersavage v. Univ. of Tenn.*, 731 F. Supp. 1327 (E.D. Tenn. 1989).

73. *Id.* at 1328.

74. *Id.* at 1330.

75. *Id.*

76. *Id.*

77. *Riezler v. Allen*, No. 108CV00332, 2008 WL 5530853 (D.Colo. Sept. 2, 2008) (Motion to Dismiss Amended Complaint).

78. *Id.* at *7.

79. *Id.* at *11-13.

80. *Reizler v. Allen*, No. 108CV00332, 2010 WL 1026981 (D. Colo. Jan. 26, 2010) (Trial Motion, Memorandum, and Affidavit). It is possible that the professors in *Riezler* have a better case for sovereign immunity than the professors in *Kersavage* because of the nature of the activities at issue. Unlike *Kersavage*, the actions of the professors at issue in *Riezler* were not alleged infringing activities in the course of scientific research, but rather compliance with the university's disclosure policy. *See id.*

leaving faculty members open to lawsuits when the university can invoke immunity.⁸¹

II. THE IMPLEMENTATION OF THE BAYH-DOLE ACT DEMONSTRATES THE DISTINCTION BETWEEN THE UNIVERSITY AND ITS SCIENTIFIC RESEARCHERS

Sponsorships such as the BMW Endowed Chair in Systems Integration,⁸² the Halliburton Endowed Chair in Engineering,⁸³ the Electronic Arts Interactive Entertainment Program,⁸⁴ the Mars, Inc. Endowed Chair in Developmental Nutrition,⁸⁵ and the Pfizer Distinguished Endowed Chair in Pharmaceutical Technology⁸⁶ leave little doubt as to the entanglement between today's universities and industry.⁸⁷ Add to such sponsorships the fact that, in 2007, universities received over 2 billion dollars in licensing revenue⁸⁸ from various inventions that academic researchers created, making it

81. *Riezler* is currently on appeal with the Federal Circuit. As this Article went to press, oral argument was scheduled for April 9, 2010. Calendar Announcement for the United States Court of Appeals for the Federal Circuit, <http://www.ca9.uscourts.gov/calendar.html> (last visited Apr. 12, 2010).

82. See Press Release, Clemson Univ., Clemson Hires Industry Leader as Fourth Endowed Chair for CU-ICAR Automotive Engineering Program (July 24, 2008), available at http://www.clemson.edu/newsroom/articles/2008/july/BMW_chair.php5.

83. See Halliburton Foundation Endows Million-Dollar Engineering Chair at Texas A&M (September 29, 2009), available at <http://engineering.tamu.edu/news/index.php/2009/09/29/halliburton-foundation-endows-million-dollar-engineering-chair-at-texas-am/> (last visited Apr. 12, 2010).

84. See Press Release, Sch. of Cinematic Arts, Univ. of S. Cal., Tracy Fullerton Named EA Endowed Chair (Dec. 5, 2008), <http://cinema.usc.edu/about/news/usc-school-of.htm> ("In 2004, Electronic Arts made a multi-million dollar donation to the USC School of Cinematic Arts to advance interactive entertainment and create a launch pad for the next generation of game design . . . The Electronic Arts Endowed Faculty Chair . . . is one of the key catalysts that enables the school to fulfill the intensifying demand for talented game developers who are solidly grounded in visual storytelling and innovative game play.").

85. University of California at Davis, College of Agricultural and Environmental Sciences, The Mars, Inc. Endowed Chair in Developmental Nutrition, <http://caes.ucdavis.edu/giving/ended-chairs#13> (last visited Mar. 22, 2010).

86. See Janice Palmer, *Pfizer Endows Distinguished Chair in Pharmacy*, UCONN ADVANCE, July 19, 2004, <http://advance.uconn.edu/2004/040719/04071901.htm>.

87. Industry sponsorships may include gifts to the university or general department as a whole as well as money for research projects to be carried out by specific faculty members. See, e.g., WASHBURN, *supra* note 10, at 3. Note that not all such sponsorships are named for the sponsoring company: Harvard University's Frank Baldino, Jr. Ph.D. Professor of Sleep Medicine endowed chair is named for the CEO of Cephalon, the company funding the endowment. See *Three HMS Endowed Chairs Named Simultaneously in Sleep Medicine*, HARV. GAZETTE, May 13, 2004, available at <http://www.news.harvard.edu/gazette/2004/05.13/11-sleep.html>.

88. See ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS, AUTM U.S. LICENSING ACTIVITY SURVEY: FY2007 138, 142 (Robert Tieckelmann et al. eds., 2008) [hereinafter AUTM REPORT].

tempting to view the modern university as just another corporate structure. In fact, there is growing concern over the increasing “corporatization” of the university,⁸⁹ and many have even argued that universities have always been entangled with industry.⁹⁰ However, this corporatization also illustrates the distinct motivations and goals of the university and its faculty scientists.

A. History and Impact of the Bayh-Dole Act

Many would argue that, since academia has essentially become a commercial enterprise, academic research should be treated as a commercial endeavor.⁹¹ Although some would argue that industry and academia were intertwined before 1980,⁹² many scholars point to the passage of the Bayh-Dole Act⁹³ as the beginning of the industrialization of academia.⁹⁴

The Bayh-Dole Act,⁹⁵ which President Carter signed into law in 1980,⁹⁶ was intended to promote the utilization of inventions arising from federally supported research or development.⁹⁷ To accomplish this goal, the Bayh-Dole Act provides a uniform system allowing non-profit organizations such as universities to take title of inventions created using federal funds.⁹⁸ In order to facilitate such a transfer of ownership, the Bayh-Dole Act requires that the inventor assign any

89. See WASHBURN, *supra* note 10.

90. DAVID C. MOWERY ET AL., *IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT IN THE UNITED STATES* (2004); CHRISTOPHER NEWFIELD, *IVY AND INDUSTRY: BUSINESS AND THE MAKING OF THE AMERICAN UNIVERSITY, 1880-1980* (2003).

91. See WASHBURN, *supra* note 10.

92. See, e.g., MOWERY ET AL., *supra* note 90; NEWFIELD, *supra* note 90; *cf. id.* (differentiating between universities that were industry focused and those dedicated to pure science).

93. Bayh-Dole Act, Pub. L. No. 96-517, § 6(a), 94 Stat. 3015, 3019-28 (1980) (codified as amended at 35 U.S.C. §§ 200-212 (2006)).

94. See MOWERY ET AL., *supra* note 90; Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457 (2004); Rothaermel, Agung & Jiang, *supra* note 10.

95. Bayh-Dole Act § 6(a).

96. Dove Greenbaum, *Academia to Industry Technology Transfer: An Alternative to the Bayh-Dole System for both Developed and Developing Nations*, 19 FORDHAM INTELL. PROP., MEDIA AND ENT. L. J. 311, 343 (2009). For a detailed summary of the events leading up to the signing of the Bayh-Dole Act, see Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663 (1996) [hereinafter Eisenberg, *Government-Sponsored Research*].

97. 35 U.S.C. § 200 (2006).

98. See *Bayh-Dole—The Next 25 Years: Hearing Before the Subcomm. on Technology and Innovation of the H. Comm. on Science and Technology*, 110th Cong. 4 (2007).

inventions made using federal funds to the organization with which the inventor is affiliated.⁹⁹ Further, a university could then grant exclusive or non-exclusive licenses for these inventions at its discretion.¹⁰⁰ In 1983, President Reagan's executive order expanded this allowance to include large businesses.¹⁰¹

Scholars have debated whether the Bayh-Dole Act has had the direct effects intended.¹⁰² While the debate continues, universities clearly have increased their efforts to transfer publicly funded research to the private sector in the years since the Act's passage.¹⁰³ Thus, whether or not the increased efforts are attributed to the Bayh-Dole Act, they have clearly occurred. Since the implementation of the Bayh-Dole Act, the number of patents issued to universities has increased ten-fold.¹⁰⁴ While there is some debate as to whether the quality of those patents has also increased during this time period, the rate of licensing indicates that universities have rights to technologies that are attractive to private industry.¹⁰⁵ In 2007, universities received 17,677 invention disclosures and filed 10,899 new patent applications.¹⁰⁶ Seven percent of these new inventions were licensed in the same year.¹⁰⁷ In total, universities executed 3,784 licenses in 2007.¹⁰⁸

To accomplish this increase in technology transfer, universities have become more entrepreneurial themselves—in part by setting up technology transfer offices to coordinate patent applications, promote technologies, and negotiate licenses.¹⁰⁹ These technology transfer

99. *Id.*

100. *Id.*

101. Eisenberg, *Government-Sponsored Research*, *supra* note 96, at 1695-96.

102. For an overview of the debate, see Charles R. McManis & Suchool Noh, *The Impact of the Bayh-Dole Act on Genetic Research and Development: Evaluating the Arguments and Empirical Evidence to Date* (unpublished manuscript), available at <http://law.wustl.edu/CLIEG/publications/mcmaniscommercializinginnovationpaper.pdf>.

103. See MOWERY ET AL., *supra* note 90; see also AUTM REPORT, *supra* note 88.

104. See WASHBURN, *supra* note 10, at 9.

105. See Tom Coupé, *Science Is Golden: Academic R&D and University Patents*, 28 J. TECH. TRANSFER 31 (2003) (arguing against increased patent quality); 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 RES. POL'Y 99 (2001) (arguing for increased patent quality).

106. AUTM REPORT, *supra* note 88, at 27, 30.

107. *Id.* at 29.

108. *Id.* at 38.

109. Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373, 1412 (2007) ("There were only twenty-five active technology-transfer offices in the United States at the time the Bayh-Dole Act was passed. By the twenty-fifth anniversary of the Act, there were 3300."). For an overview of the literature regarding university entrepreneurship, see Rothaermel, Agung & Jiang, *supra* note 10.

offices, which are involved in the more traditional patenting and licensing aspects of technology transfer,¹¹⁰ have become a source of revenue for many universities.¹¹¹ However, other university-sponsored organizations are also involved in the actual commercialization of technologies. For example, many universities help start up new companies by registering trademarks, filing incorporation documents, and providing referrals and incubator space.¹¹² A few even provide equity funding for new companies.¹¹³

This pressure to become entrepreneurial extends to the faculty as well. Many economics scholars encourage scientific faculty to be more entrepreneurial¹¹⁴ and have developed techniques to help them do so.¹¹⁵ Of particular interest are programs within the university that encourage researchers to consider commercial aspects of research during very early stage research. For example, participants in the Technological Innovation: Generating Economic Results (TI:GER) Program, a joint collaboration between the Georgia Tech College of Management and Emory Law School, form teams consisting of law school and business school students, along with a graduate student in the sciences, to determine the commercial possibilities of the graduate student's research.¹¹⁶ The University of Virginia Patent Foundation hosts graduate student interns to encourage students to learn about technology transfer and intellectual property rights.¹¹⁷ Other universities use their technology transfer offices to encourage faculty entrepreneurship. For example, the University of Virginia Patent Foundation recognizes several Inventors of the Year to encourage

110. See MOWERY ET AL., *supra* note 90; Rothaermel, Agung & Jiang et al., *supra* note 10.

111. Dreyfuss, *supra* note 94; cf. WASHBURN, *supra* note 10, at 169-71 (arguing that only fifty percent of technology transfer offices break even).

112. The University of Virginia has created the for-profit group SpinnerTech to provide assistance. See Spinner Technologies Inc., <http://www.spinnertechnologies.com/> (last visited Mar. 23, 2010). Washington University has joined resources with local universities and other nonprofit and for-profit entities to form a research district with laboratory space for the St. Louis area. See Cortex, <http://www.cortexstl.com/> (last visited Mar. 23, 2010).

113. See MOWERY ET AL., *supra* note 90; Rothaermel, Agung & Jiang, *supra* note 10.

114. See, e.g., Anthony A. del Campo et al., *The Transfer and Commercialization of University-Developed Medical Imaging Technology: Opportunities and Problems*, 46 IEEE TRANSACTIONS ON ENGINEERING MGMT. 289 (1999); Henry Etzkowitz et al., *The Future of the University and the University of the Future: Evolution of Ivory Tower to Entrepreneurial Paradigm*, 26 RES. POL'Y 313 (2000); Trevor Grigg, *Adopting an Entrepreneurial Approach in Universities*, 11 J. ENGINEERING & TECH. MGMT. 273 (1994).

115. Jensen, Thursby & Thursby, *supra* note 19, at 1272.

116. See Emory University School of Law, TI:GER, <http://www.law.emory.edu/academics/academic-programs/tiger.html> (last visited Mar. 23, 2010); Georgia Tech College of Management, TI:GER, <http://tiger.gatech.edu/> (last visited Mar. 23, 2010).

117. University of Virginia Patent Foundation, Graduate Student Internships, <http://www.uvapf.org/internships> (last visited Mar. 23, 2010).

disclosure of inventions.¹¹⁸ Additionally, technology transfer offices often hold open houses or conduct presentations for the faculty to familiarize the faculty with the offerings of the office.¹¹⁹

This increased emphasis on technology transfer has also led to a close university-industry relationship. The biggest benefit for universities in this relationship is funding.¹²⁰ As per capita state and federal funding for universities has decreased in recent years,¹²¹ universities have used industry dollars to update facilities and increase budgets.¹²² Additionally, industry has begun to sponsor specific endowed chairs within university departments.¹²³ Research funding from industry has also increased during this time period from 2.1 billion dollars in 1998 to 3.4 billion dollars in 2007 for much the same reason; however, industry funding has remained a relatively constant percentage of overall research funding during the same time period, varying only between seven and ten percent of overall research funding.¹²⁴ Many have argued that the increased commercialization and closer industrial relationships conflict with the public's interest in research that tax dollars also help to fund.¹²⁵

Some scholars have argued that this academic-industry relationship diverts universities from their traditional mission¹²⁶ because the resulting "multiversity" no longer has its focus on open public science.¹²⁷ Others debate whether there has ever been such a unity of mission. The history of "pure research" institutions born in

118. See Press Release, Univ. of Va. Patent Found., UVAPF Honors 2009 Inventors of the Year (Apr. 13, 2009), available at http://www.uvapf.org/live_data/live_site_page.php?page_id=23&article_id=29.

119. See, e.g., University of Michigan Tech Transfer, U-M Tech Transfer Open House, http://www.techtransfer.umich.edu/news_events/success_stories/story_52.php (last visited Mar. 23, 2010); Washington University in St. Louis, Office of the Vice Chancellor for Research, Technology Commercialization Seminar Series, <http://research.wustl.edu/events/Pages/EventDetails.aspx?EventID=294> (last visited Mar. 23, 2010).

120. Yong S. Lee, *The Sustainability of University-Industry Research Collaboration: An Empirical Assessment*, 25 J. TECH. TRANSFER 111, 121 (2000).

121. WASHBURN, *supra* note 10, at 8.

122. See *id.* at 5, 7 ("[B]uildings increasingly bore the names of corporate donors").

123. See *id.* ("[E]ven academic titles were changing, with Laura D'Andrea Tyson . . . known as the BankAmerica Dean of the Haas School of Business."); see, e.g., the Kmart chair of Marketing at Wayne State University and the examples discussed *supra* Part III.

124. See AUTM REPORT, *supra* note 88, at 23.

125. Walter W. Powell & Jason Owen-Smith, *Universities and the Market for Intellectual Property in the Life Sciences*, 17 J. POLY ANALYSIS & MGMT. 253, 255-56, 273 (1998) (noting that increased commercialization may lead to a corrosion of the mission of research universities, undercutting public trust in these institutions).

126. *Id.* at 257.

127. Richard R. Nelson, *Observations on the Post-Bayh-Dole Rise of Patenting at American Universities*, 26 J. TECH. TRANSFER 13, 17-18 (2001).

1800s Germany and giving rise to graduate education in the United States in 1876 at Johns Hopkins University can be juxtaposed against the numerous universities that have a long history of working with industry.¹²⁸ For example, the University of North Carolina and the University of Kentucky have long had ties to the tobacco industry, while the University of Minnesota historically developed iron ore processing methods for the mining industry.¹²⁹ Additionally, the Massachusetts Institute of Technology has long been a general friend to industry.¹³⁰ Others argue that, even with such alliances, universities were not merely suppliers of innovation to industry but also havens of “non-utilitarian knowledge and research driven by pure curiosity.”¹³¹

Regardless of the history of the university mission, current industry sponsorships raise concerns over who controls hiring and university spending.¹³² It is unclear to what extent sponsoring corporations influence how “gifts” are used. Industry research funding and partnerships are also fraught with dangers to the independence of scientific researchers. Confidentiality agreements¹³³ between researchers and industry sponsors and publication control by industry sponsors threaten the free flow of information that should be an academic norm.¹³⁴

In spite of the intellectual successes shown by the 2007 patent and licensing statistics,¹³⁵ some argue that the Bayh-Dole Act has not had the impact that many had hoped. These critics have argued that industry and academia have always been interconnected to a certain degree,¹³⁶ and that, because the relationship has always existed, the increased licensing and technology transfer could have happened without passage of the Bayh-Dole Act.¹³⁷ Therefore, these scholars argue that the impetus for the increased technology transfer is the natural progression of research to a stage where useful commercial results can be visualized.¹³⁸ Additionally, they argue, the increased spending by industry has actually remained a relatively constant 7

128. WASHBURN, *supra* note 10, at 33; *see also* MOWERY ET AL., *supra* note 90.

129. WASHBURN, *supra* note 10.

130. *Id.*

131. NEWFIELD, *supra* note 90, at 16-17.

132. *Id.* at 6-7.

133. *Id.* at 74.

134. *Id.* at 20-22, 108-18.

135. AUTM REPORT, *supra* note 88, at 32, 37.

136. *See* NEWFIELD, *supra* note 90; WASHBURN, *supra* note 10.

137. MOWERY ET AL., *supra* note 90, at 1.

138. *Id.* at 1-2.

percent of the total research funding¹³⁹ over a period of years that has seen the total number of researchers explode.¹⁴⁰ Others argue that the Bayh-Dole Act has had—at most—indirect effects. One study found that the true impetus for increased licensing is the establishment of a technology transfer office with a number of full time employees in the office.¹⁴¹ If these data are correct, the Bayh-Dole Act certainly would be a strong, albeit indirect, impetus for the technology transfer explosion because the Act is the cause of the massive creation of technology transfer offices.¹⁴²

Some studies go so far as to say that technology transfer offices on the whole are not successful, even in light of the statistics related to the large amount of university licensing.¹⁴³ Of the 141 universities granting licenses in 1999 and 2000, 80 percent of the income went to twenty-two universities, and 45 percent of the income went to only five universities.¹⁴⁴ In 2002, two-thirds of the revenue went to licenses from just thirteen universities.¹⁴⁵ By 2007, 49 percent of the gross license revenues went to just three universities.¹⁴⁶ In fact, one study estimated that 50 percent of technology transfer offices do not break even.¹⁴⁷

Additionally, one argument in favor of the Bayh-Dole Act is the need to give industry exclusive control over intellectual property rights in order to incentivize commercialization.¹⁴⁸ However, in 2007, only 43 percent of the outgoing licenses that universities executed were exclusive.¹⁴⁹ Finally, in spite of the focus on research and technology transfer, university patents are still a relatively small percentage of total patents. Between 1969 and 2005, universities were issued 48,612 patents¹⁵⁰ out of the 3.8 million utility patents and

139. See AUTM REPORT, *supra* note 88, at 23.

140. NAT'L INSTS. OF HEALTH, AGE DATA ON NIH PRINCIPAL INVESTIGATORS: 1970-2006, available at http://grants.nih.gov/grants/new_investigators/nih_age_data_principal_investigators_1970-2006.xls.

141. Coupé, *supra* note 105, at 42 (2003).

142. *Id.* at 43.

143. See AUTM REPORT, *supra* note 88, at 37.

144. *Bayh-Dole—The Next 25 Years*, *supra* note 98, at 4.

145. WASHBURN, *supra* note 10, at 169.

146. See AUTM REPORT, *supra* note 88, at 139-42.

147. WASHBURN, *supra* note 10, at 169-71.

148. Eisenberg, *Government-Sponsored Research*, *supra* note 96, at 1672.

149. See AUTM REPORT, *supra* note 88, at 38.

150. PATENT TECH. MONITORING TEAM, ELEC. INFO. PRODS. DIV., U.S. PATENT & TRADEMARK OFFICE, U.S. COLLEGES AND UNIVERSITIES-UTILITY PATENT GRANTS, CALENDAR YEARS 1969-2005 (2007), http://www.uspto.gov/go/taf/univ/org_fi/all_univ_af.htm. For an explanation of the data presented, see PATENT TECH. MONITORING TEAM, ELEC. INFO. PRODS.

290,000 non-utility patents that were issued during that time period,¹⁵¹ making up only 1.2 percent of the total patents issued.

B. Lessons from the Bayh-Dole Act

Whether or not one believes in the success of the Bayh-Dole Act, the statistics regarding university patents¹⁵² seem to paint a highly industrialized picture of universities and industry working together as one unit to commercialize innovations made by academic researchers. However, a closer investigation reveals that the effects of the Bayh-Dole Act highlight the breach between a university and its faculty and other academic researchers. Although the Bayh-Dole Act seems to directly or indirectly have had an effect on the transfer of technology disclosed to the university, its effect on the faculty is generally less pervasive.

If the Bayh-Dole Act impacted the faculty in the same way as the university, one would expect to see the commercialization of research become a major focus of academic researchers. This focus would likely result in a concomitant shift to applied research for easier commercialization. However, the increased licensing and industry funding seem to have had little effect on the overall type of research being performed.¹⁵³ One external study of a twenty-five million dollar funding deal between Novartis and the University of California Berkeley revealed that the influx of money from industry did not divert the focus of laboratories that were previously conducting basic research.¹⁵⁴ Additionally, faculties generally remain resistant to commercialization attempts. One study suggests that faculty disclosed less than 50 percent of inventions with commercial potential to the university.¹⁵⁵ Most academic researchers declining to disclose inventions did so because they did not want to take time away from their research¹⁵⁶ or pursue further commercial development.¹⁵⁷ Such

DIV., U.S. PATENT & TRADEMARK OFFICE, U.S. COLLEGES AND UNIVERSITIES-UTILITY PATENT GRANTS, CALENDAR YEARS 1969-2005: EXPLANATION OF DATA, http://www.uspto.gov/go/taf/univ/org_gr/explan.htm.

151. PATENT TECH. MONITORING TEAM, ELEC. INFO. PRODS. DIV., U.S. PATENT & TRADEMARK OFFICE, U.S. COLLEGES AND UNIVERSITIES-UTILITY PATENT GRANTS, CALENDAR YEARS 1969-2005: GENERAL DESCRIPTION OF THE REPORT, http://www.uspto.gov/go/stats/univ/doc/doc_info_2005.htm.

152. See AUTM REPORT, *supra* note 88, at 107-80.

153. Mowery et al., *supra* note 105, at 100.

154. WASHBURN, *supra* note 10, at 4.

155. Jensen, Thursby & Thursby, *supra* note 19, at 1272.

156. *Id.* Researchers must also fill out various disclosure forms for the university as well as assist the technology transfer offices during patent prosecution.

an attitude reveals that an academic researcher views her time and research to be such a personal, rather than institutional, investment that she will ignore federal and institutional mandates to disclose new inventions.

This seeming contradiction between the effects of the Bayh-Dole Act on the university and its faculty is better understood in light of the purpose of the Bayh-Dole Act—to promote transfer of technology by the university rather than to incentivize innovation by the faculty.¹⁵⁸ Although the Bayh-Dole Act requires universities to share proceeds from commercialization of the inventor's technology with the faculty inventor,¹⁵⁹ there is some reason to doubt that receiving this revenue is a true incentive for academic researchers to disclose the technology to the university.¹⁶⁰ The idea that monetary incentives promote university interest in technology transfer but not researcher interest illustrates the misalignment of interests and incentives between university administration and the faculty. When trying to commercialize a technology, technology transfer offices have to balance the interests of the university and the faculty¹⁶¹ because the two groups have very different perspectives on commercialization.¹⁶² While the university is highly incentivized by the money that it would receive in exchange for the transfer of technology, the average faculty member is more concerned with the research itself than with commercializing it. For example, Tom Doetschman, a scientist at the University of Arizona,¹⁶³ has created over 120 strains of transgenic mice, all of which are freely available to other researchers, indicating his priority for the free flow of research materials.¹⁶⁴ Additionally, as noted above, many faculty members choose not to pursue patenting because of the fear that it will take time away from research.¹⁶⁵

Often, faculty members, rather than the university, perceive a threat from industry to academic independence and public duty. In UNIVERSITY, INC., Jennifer Washburn, in proposing that the

157. *Id.* It is estimated that seventy-one percent of the technology licensed from a university requires further development before commercialization. *Id.*

158. Eisenberg, *Government-Sponsored Research*, *supra* note 96, at 1691-92.

159. 35 U.S.C. § 202(c)(7)(b) (2006).

160. See the discussion regarding the incentives of academic researchers *infra* Part V.

161. Jensen, Thursby & Thursby, *supra* note 19, at 1272-73.

162. *Id.* at 1273; see also Donald S. Siegel et al., *Commercial Knowledge Transfers from Universities to Firms: Improving the Effectiveness of University-Industry Collaboration*, 14 J. HIGH TECH. MGMT. RES. 111, 115-16 (2003).

163. See University of Arizona, Laboratory of Tom Doetschman, <http://www.mcrcp.med.arizona.edu/html/tomdoetschman/index.html> (last visited Mar. 23, 2010).

164. WASHBURN, *supra* note 10, at 154.

165. Jensen, Thursby & Thursby, *supra* note 19, at 1272.

university has become nothing more than a new corporate form due to its relationship with industry, inadvertently provides evidence of the distinction between the university and its academic researchers.¹⁶⁶ Although it is not her purpose, the book describes numerous examples that can be re-interpreted to support an argument for divergent views of the university and its faculty.¹⁶⁷ After the twenty-five million dollar deal between the University of California Berkeley and Novartis,¹⁶⁸ for example, only 41 percent of the faculty supported the alliance, while 50 percent were afraid that the industry funding would have a negative effect on research at Berkeley.¹⁶⁹ Additionally, because of faculty and student pressure on the university, internal and external groups monitored the impact of the deal on Berkeley research.¹⁷⁰ Yale University became a target of protests by faculty, postdoctoral fellows, students, and other researchers when it claimed to be unable to help African AIDS organizations due to exclusive licenses of its patented HIV drugs to Bristol Myers Squibb.¹⁷¹ Finally, the university's focus on proprietary licenses with opportunities to monetize the technology often brings it into conflict with academic researchers. For instance, faculty members in computer science departments often push for open source licenses for software rather than proprietary licenses,¹⁷² and a large percentage of knowledge and technology from academia is transferred through publication and other informal methods which may preclude any monetization of the technology.

Discussions of the impact of the Bayh-Dole Act clearly show that there is a distinction between the attitude and motivations of the university and those of its academic researchers. As a result, there is often a disconnect between the actions of the two parties, resulting in virulent and public disagreements between the university and its faculty, graduate students, post-doctoral fellows, and other researchers and staff.¹⁷³

166. See WASHBURN, *supra* note 10.

167. *See id.*

168. *Id.* at 3-4.

169. *Id.*

170. *Id.*

171. *Id.* at 164-67.

172. *Id.* at 159.

173. See the text accompanying footnotes 168-172 for descriptions of the results of universities and faculty disagreements.

III. THE DISTINCTION BETWEEN THE UNIVERSITY AND ITS ACADEMIC RESEARCHERS REVITALIZES THE EXPERIMENTAL USE EXCEPTION

The patent system was established to incentivize invention by granting exclusive rights to the patented invention during the life of the patent.¹⁷⁴ However, until recently, there generally was a recognition that patents and patent infringement deal with commercial applications rather than with research or uses for the public good.¹⁷⁵ This concept resulted in a number of exceptions to the general rules, including a research exception to the statutory bar,¹⁷⁶ march-in rights,¹⁷⁷ and the experimental use exception, a common law exception to patent infringement established in the early nineteenth-century.¹⁷⁸ In its original formulation, the experimental use exception provided a haven from patent infringement for people who used a patented invention for philosophical inquiry or for determining if the invention worked as disclosed.¹⁷⁹ Courts have reinterpreted the experimental use exception many times since its inception, but in the past it was generally thought to apply to educational institutions.¹⁸⁰

In the past decade, the Federal Circuit has substantially narrowed the experimental use exception. In *Madey v. Duke University*,¹⁸¹ a former Duke University professor brought a patent infringement claim against the university during an ownership contest regarding multiple pieces of laboratory equipment.¹⁸² Duke defended the patent claim using the experimental use exception, but the Federal Circuit held the doctrine inapplicable to Duke because Duke had a “legitimate business interest” in using the patent.¹⁸³ As a result, many scholars have declared that the experimental use exception is no longer available to academic scientists. However, recognizing that *Madey* applies to the university as an institution should still allow academic researchers to continue to use the exception under certain circumstances.

174. U.S. CONST. art. I, § 8, cl. 8.

175. See, e.g., *Brenner v. Manson*, 383 U.S. 519, 536 (1966) (quoting *In re Ruschig*, 343 F.2d 965, 970 (C.C.P.A. 1965)).

176. Controlled research necessary to develop an invention does not put the invention into public use. *Elizabeth v. Pavement Co.*, 97 U.S. 126, 134 (1878).

177. The government retains “march-in” rights to practice any patented inventions created with federal funding in certain circumstances. 35 U.S.C. § 203 (2006).

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

179. *Id.*

180. See *infra* Part II.A.

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

182. *Id.* at 1352.

183. *Id.* at 1362.

A. History of Experimental Use Exception

The concept of patent law was considered important enough to be authorized in the United States Constitution.¹⁸⁴ Patents confer to inventors the exclusive rights to exclude others from practicing their inventions for limited periods of time¹⁸⁵ in order to incentivize the production of new inventions.¹⁸⁶ Because of the exclusive nature of the rights, the patent holder can sue for infringement another person who uses the invention without a license before the patent expiration date.¹⁸⁷ However, the authors of the Constitution believed that patents were a trade-off to benefit society. Thomas Jefferson called them an “embarrassment” to be used only when necessary for the public good.¹⁸⁸ Therefore, it should not be surprising that, throughout much of U.S. history, patents have not been enforced against infringers when the infringement is deemed to be for the public good. For example, the government retains march-in rights to inventions created with government funds so that the public is never denied the use of a publicly funded invention due to patent infringement.¹⁸⁹ Similarly, the Hatch-Waxman Act allows generic drugs companies to use patented drugs under certain circumstances so as not to extend artificially the exclusive rights of a patent holder due to Food and Drug Administration approval issues.¹⁹⁰ Finally, patent rights initially were not believed to be so strong as to inhibit experimentation and tinkering.¹⁹¹

Since the early nineteenth-century, patent rights have been interpreted to include an exception to infringement when the

184. U.S. CONST. art. I, § 8, cl. 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”).

185. 35 U.S.C. § 101 (2006).

186. U.S. CONST. art. I, § 8, cl. 8.

187. 35 U.S.C. § 271(a) (2006).

188. See Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), in 13 THE WRITINGS OF THOMAS JEFFERSON 326, 334 (Andrew A. Lipscomb & Albert Ellery Bergh eds., 1905), available at http://press-pubs.uchicago.edu/founders/documents/a1_8_8s12.html. (“Considering the exclusive right to invention as given not of natural right, but for the benefit of society, I know well the difficulty of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not.”)

189. 35 U.S.C. § 203 (2006).

190. 35 U.S.C. § 271(e)(1) (2006). If generic companies were unable to use patented drugs for studies to submit to the FDA, the name brand drugs would enjoy a de facto patent extension while the generic companies completed studies required for FDA approval of sales after patent expiration.

191. See text accompanying footnotes 192-222.

invention is used for experimental purposes.¹⁹² This experimental use exception is a common law doctrine whose origins can be traced back to the 1813 case of *Whittemore v. Cutter*.¹⁹³ In *Whittemore*, Justice Story established experimental use as a defense to patent infringement¹⁹⁴ when the infringement occurred during the process of scientific research.¹⁹⁵ Recognizing that the Founding Fathers had not intended patents to preclude scientific research, Justice Story wrote that “it could never have been the intention of the legislature to punish a man who [used a patented invention] . . . merely for philosophical experiments, or for the purpose of ascertaining the sufficiency . . . to produce its desired effects.”¹⁹⁶ Justice Story went on to further define the experimental use exception as applying to uses of the invention in which the invention was not made for commercial gain.¹⁹⁷ This not-for-profit standard was developed in the case law and remained the test for over 150 years.¹⁹⁸ During this time, experimental use of a patented invention to improve the invention and procure an improvement patent was not considered to be a for-profit use.¹⁹⁹

The experimental use exception began evolving once again in the late 1970s as courts began to consider the commercial interests of the patent user. In *Pitcairn v. United States*,²⁰⁰ manufacturers used patented technologies to build and test helicopters for the government.²⁰¹ The *Pitcairn* court rejected the argument that use of the patented technology for testing or evaluation of the helicopters fell under the experimental use exception.²⁰² The *Pitcairn* court instead held that the infringing tests were required to prepare the helicopters

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

193. *Id.* at 1120.

194. Interestingly, Justice Story also set forth the fair use exception in copyright law. See *Folsom v. Marsh*, 9 F. Cas. 342 (C.C.D. Mass. 1841) (No. 4901).

195. *Whittemore*, 29 F. Cas. at 1121.

196. *Id.*

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

198. See, e.g., *Chesterfield v. United States*, 159 F. Supp. 371, 375 (Ct. Cl. 1958) (holding that a non-infringing technology “procured by the defendant was used only for testing and for experimental purposes”); *Dugan v. Lear Avia, Inc.*, 55 F. Supp. 223, 229 (S.D.N.Y. 1944) (holding that a defendant’s action did not constitute infringement where the “defendant built that device only experimentally and that it has neither manufactured it for sale nor sold any”); *Bonsach Mach. Co. v. Underwood*, 73 F. 206, 211 (C.C.E.D.N.C. 1896) (“[I]f an infringing machine is made or used as an experiment merely, it does not infringe former patents.”).

199. *Chesterfield*, 159 F. Supp. at 375.

200. *Pitcairn v. United States*, 547 F.2d 1106 (Ct. Cl. 1976).

201. *Id.* at 1125-26.

202. *Id.*

for sale, and as such, the experimental use exception was not available.²⁰³

Subsequent decisions from the Federal Circuit have further narrowed the application of the experimental use exception to the point of near extinction. In *Roche Products v. Bolar Pharmaceutical Co.*, a generic drug manufacturer used a patented drug to perform experiments for submission to the Food and Drug Administration once the patents had expired.²⁰⁴ The court held that the use of the patented drug was infringing, saying that infringing activity “in the guise of ‘scientific inquiry’ when that inquiry has definite cognizable, and not insubstantial commerce prospects” is not an experimental use.²⁰⁵ The majority later used the *Roche* standard in *Embrex, Inc. v. Service Engineering Corp.*²⁰⁶ to hold that testing for a commercial purpose is infringing, even if commercialization later proves unsuccessful.²⁰⁷ Judge Rader’s concurrence in *Embrex* went even further, saying that the Patent Act disallows the experimental use exception entirely.²⁰⁸

The *Embrex* concurrence significantly impacted the court, which further limited the experimental use exception in *Madey v. Duke University*.²⁰⁹ John Madey, a former Duke University professor, sued Duke over possession of a Free Electron Laser (FEL) and a Microwave Gun Test Stand (Test Gun).²¹⁰ Professor Madey had brought the FEL with him from Stanford University, and personally owned patents surrounding the FEL and Test Gun.²¹¹ Duke, however, had invested in a new facility to house the FEL²¹² and its associated laboratory space as well as aiding North Carolina Central University (NCCU) in building the Test Gun in Duke’s facility.²¹³ Unfortunately, ownership of the FEL and Test Gun was not addressed in the employment agreement between Professor Madey and Duke.²¹⁴ In the course of trying to get the equipment transferred to his new laboratory, Professor Madey alleged patent infringement by Duke

203. *Id.*

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

205. *Id.* at 863.

206. *Embrex, Inc. v. Serv. Eng’g Corp.*, 216 F.3d 1343 (Fed. Cir. 2000).

207. *Id.* at 1349.

208. *Id.* at 1352.

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

210. *Id.* at 1352.

211. *Id.*

212. *Id.*

213. *Madey v. Duke*, 266 F.Supp.2d 420, 421-422 (M.D.N.C., 2001)

214. *Id.* (indicating the elements contained in the agreement between Madey and Duke).

University.²¹⁵ Duke seemed to concede that both the Test Gun and FEL read on the claims of Madey's patents²¹⁶ because Duke based its defense for infringement of the FEL patent on the experimental use exception using Duke's non-profit status and its defense for infringement of the Test Gun on the fact that the Test Gun had been used solely by researchers from NCCU after Madey's departure.²¹⁷ Based upon the district court's determinations that no Duke researchers had used the Test Gun after Madey's departure, the NCCU researcher was not an agent of Duke, and Duke had no control over the Test Gun, the Federal Circuit upheld the district court's dismissal of Madey's patent infringement claim relating to Duke's "use" of the Test Gun Patent.²¹⁸ The Federal Circuit then addressed Duke's infringement of the patents relating to the FEL and the availability of the experimental use exception. Relying on *Roche*²¹⁹ and Judge Rader's concurrence in *Embrex*,²²⁰ the court held that the non-profit or commercial status of an accused infringer did not matter as long as the infringing activity furthered a legitimate business interest.²²¹ According to the *Madey* court, Duke University had a legitimate business interest in educating students and faculty.²²² The court also pointed out that Duke University funded research projects to increase the status of the university by luring grants, faculty, and students, thus furthering its business interest.²²³ Finally, in a footnote, the court noted that Duke pursued an aggressive licensing policy, receiving a "not insubstantial revenue stream."²²⁴ In so holding, the *Madey* court laid down a two-prong test for whether an act of infringement qualifies for the experimental use exception. The infringing act (1) must be solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, and (2) must not be performed in furtherance of the infringer's legitimate business interest.²²⁵

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

216. *Id.*

217. *Id.* at 1362.

218. *Id.* at 1363. The Federal Circuit seems to hint that Duke might be subject to vicarious or contributory infringement, but Madey failed to argue this cause of action. *Id.*

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

220. *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1353 (Fed. Cir. 2000) (Rader, J., concurring) (concluding that "the slightest commercial implication" disallows the experimental use exception).

221. *Madey*, 307 F.3d at 1362.

222. *Id.*

223. *Id.*

224. *Id.* at 1362 n.7.

225. *Id.* at 1362.

B. Current Interpretation of *Madey*

Reaction to *Madey* has been mixed. Many scholars initially proclaimed that *Madey* would be the death knell of academic research,²²⁶ but others have noted that companies are loath to sue universities for infringement, resulting in an informal experimental use exception.²²⁷ This informal experimental use exception has led many to theorize that no further discussion is warranted.²²⁸ Other scholars prefer not to rely on the restraint of companies for the continuation of the experimental use exception.²²⁹ On the other hand, many scholars argue that a formal experimental use exception is a bad idea, and point out the increased commercialization and industrialization of academia as the reasons why.²³⁰ Regardless of their views regarding the necessity of an experimental use exception, most scholars agree that the formal experimental use exception is dead for researchers at universities.²³¹

C. New Interpretation of *Madey*

Little scholarship exists defining how the *Madey* two-part test should be applied. Scholars seem uninterested in defining what the court meant by "legitimate business interests."²³² Indeed, most scholars have assumed that the experimental use exception is

226. See Dreyfuss, *supra* note 94; Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 BAYLOR L. REV. 917 (2004); Joseph Mohr, Comment, *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).

227. See, e.g., Richard J. Bauer, Comment, *Why Not Try the Experiment and Stop Pointing the Finger? Modern University Research Unaffected by a Narrow Experimental Use Exception*, 24 TEMP. J. SCI. TECH. & ENVTL. L. 121 (2005); Cristina Weschler, Note, *The Informal Experimental Use Exception: University Research After Madey v. Duke University*, 79 N.Y.U. L. REV. 1536 (2004).

228. See Elizabeth A. Rowe, *The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?*, 57 HASTINGS L.J. 921 (2006); Bauer, *supra* note 227; Weschler, *supra* note 227.

229. Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 HOUS. L. REV. 1059, 1097 (2008) [hereinafter Eisenberg, *Anticommons*].

230. See, e.g., Weschler, *supra* note 227.

231. Most scholars focus on calls for legislative reform or how the experimental use exception should be applied if it is reinstated. See, e.g., Katherine J. Strandburg, *What Does the Public Get?: Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81 (2004); Michelle Cai, Note, *Madey v. Duke University: Shattering the Myth of Universities' Experimental Use Defense*, 19 BERKELEY TECH. L.J. 175 (2004).

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

inapplicable to any research conducted within a university setting.²³³ What scholars have not recognized is that the Federal Circuit's holding in *Madey* only applies to infringement by a university *as an institution*. Based on the argument that the university and its academic researchers function as distinct entities²³⁴ and *Madey's* application to institutional infringement,²³⁵ this Article argues that academic researchers may invoke the experimental use exception under certain circumstances.

This Article posits that the *Madey* experimental use exception analysis was based on decisions and actions of Duke University that were made as a matter of institutional policy rather than the actions of any of its individual faculty members. Duke University withheld the FEL and Test Gun from Professor Madey during an ownership dispute.²³⁶ Professor Madey claimed that Duke University directly infringed his Test Gun patent by making the Test Gun available to researchers from North Carolina Central University (NCCU);²³⁷ however, neither the NCCU researchers nor NCCU were named as parties to the lawsuit.²³⁸ The Federal Circuit held that Duke did not directly infringe Madey's Test Gun patent because the direct infringer, NCCU, was not an agent of the university and Duke had no direct control over the Test Gun.²³⁹ Thus, although the Test Gun was located at Duke, Duke's lack of control over the researchers or the Test Gun resulted in a lack of infringement. Similarly, in the case of the FEL infringement, no Duke University researchers were named as parties to the lawsuit.²⁴⁰ However, since Duke effectively conceded

233. See, e.g., Eisenberg, *Anticommons*, *supra* note 229; Rowe, *supra* note 228; Tom Saunders, *Renting Space on the Shoulders of Giants: Madey and the Future of the Experimental Use Doctrine*, 113 YALE L.J. 261 (2003); Cai, *supra* note 231; Andrew J. Caruso, Comment, *The Experimental Use Exception: An Experimentalist's View*, 14 ALB. L.J. SCI. & TECH. 215 (2003); Kevin Sandstrom, Note, *How Much Do We Value Research and Development?: Broadening the Experimental Use Exemption to Patent Infringement in Light of Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), 30 WM. MITCHELL L. REV. 1059 (2004); Rebecca S. Eisenberg, *Patent Swords and Shields*, SCI., Feb. 14, 2003, at 1018-19.

234. See *supra* Part II.

235. See *supra* Part IV.A.

236. *Madey*, 307 F.3d at 1352.

237. *Id.* at 1353 (noting that the Test Gun Stand was owned by NCUU but housed by Duke University). The court specifically mentions that Professor Madey made no claim of vicarious or contributory infringement. *Id.* at 1363.

238. *Id.* at 1351. NCCU researchers were probably not included because this suit grew out of a dispute over possession of the FEL by Duke University.

239. *Id.* at 1357.

240. Several people were initially included in the lawsuit in their official capacities as administrators of the university. See *Madey v. Duke Univ.*, No. 1:97CV01170, 1998 WL 35259797 (M.D.N.C. Aug. 5, 1998) (First Amended and Supplemental Complaint) (naming as co-defendants: Charles E. Putman, Senior Vice President, Research Administration Policy of Duke

direct infringement of the FEL patent absent the experimental use exception,²⁴¹ the court had no reason to determine if research performed by Duke's faculty members would give rise to direct liability. Thus, the *Madey* decision reflects an analysis of the business interests of Duke as an institution.²⁴²

An analysis in light of infringement by a faculty researcher within a university should be different from that in *Madey*. As discussed in Parts I and II above, faculty researchers are largely autonomous from the university and have different motivations than the institution.²⁴³ Therefore, infringement by faculty researchers should be analyzed independently from infringement by the university as an institution. While *Madey* analyzed the test for use of the experimental use exception in the context of the university as an institution, the definition of a "legitimate business interest" in the context of a faculty researcher is still unclear.

D. Application of Madey to Academic Researchers

If, as suggested, the academic researcher and the university are operating as distinct entities and have different goals and incentives,²⁴⁴ then the *Madey* court's determination that universities have business interests at stake in patent infringement does not automatically mean that university faculty and researchers have the same business interests. Therefore, to invoke the experimental use exception, academic scientists' research must be analyzed to determine if it complies with the two-part test in *Madey*.²⁴⁵ The *Madey* court held that for a scientist using a patented invention to invoke the experimental use exception, the scientist must (1) be using the invention "for amusement, to satisfy idle curiosity, or for strictly

University; John Strohbehn, Provost of Duke University; William H. Chafe, Dean of the Faculty of Arts & Sciences of Duke University; Berndt Mueller, Chairman of the Department of Physics of Duke University; Bobby Guenther, Interim Director of the Duke FEL Laboratory, and Lawrence Evans, former Chairman of the Department of Physics).

241. By defending solely with the experimental use defense, Duke effectively conceded that, absent the defense, it had infringed *Madey's* patents. See *Madey v. Duke Univ.*, 307 F.3d 1351, 1353 (M.D.N.C. 2001) ("Duke seems to concede that the alleged infringing devices and methods read on the claims of the patents.").

242. It is unclear that a defense based on lack of control of the FEL and Duke researchers would have worked in this case because Duke seemed to have very tight control over the FEL laboratory.

243. See *supra* Parts II & III.

244. See *supra* Part II.

245. See *Madey*, 307 F.3d at 1362.

philosophical inquiry,”²⁴⁶ and (2) not further a “legitimate business interest” of the infringing party.²⁴⁷ Thus, academic researchers are left to determine if their research is philosophical inquiry and whether it furthers a legitimate business interest.

1. Scientific Research as a Form of Philosophical Inquiry

The first requirement that the actions be performed “for . . . strictly philosophical inquiry”²⁴⁸ is derived from the original wording of the common law exception.²⁴⁹ By stating that it “could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments,” Justice Story created the experimental use exception to protect scientific research.²⁵⁰ Such a perception of science as philosophy is consistent with the fact that authors have used various terms to refer to scientific research in our historical writings. The Constitution directs Congress to “promote science and the useful arts.”²⁵¹ Immediately, the change in nomenclature becomes apparent as Congress derives its copyright powers from the term “science” and its patent powers from the term “useful arts.”²⁵² Therefore, even the precise wording in the Constitution is different from our usage today. When Justice Story referred to philosophical experiments, he was using “philosophy” to mean pure science and possibly engineering.²⁵³ This is evident not only from the context of the case²⁵⁴ but also from the historical use of the term “philosophy.” Judge Newman, in her *Integra* dissent, describes the historical origins of science as natural philosophy.²⁵⁵ This connection between science and philosophy has been very strong and well recognized.²⁵⁶ Even in today’s world where science is thought

246. *Id.* at 1362 (quoting *Embrex, Inc. v. Serv. Eng’g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000)).

247. *Id.* at 1362.

248. *Embrex*, 216 F.2d at 1349.

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

250. *Id.*

251. U.S. CONST. art. I, § 8, cl. 8.

252. Karl B. Lutz, *Patents and Science: A Clarification of the Patent Clause of the U. S. Constitution*, 18 GEO. WASH. L. REV. 50, 50-51 (1949).

253. *Whittemore*, 29 F. Cas. at 1121.

254. *Id.* at 1120-22.

255. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 874-75 (Fed. Cir. 2003) (Newman, J., dissenting) (describing the historical origins of science as natural philosophy).

256. Will Durant stated the relationship elegantly: “The relation of science to philosophy needs no further clarification: the sciences are the windows through which philosophy sees the world, they are the senses of which it is the soul; without it their knowledge is as chaotically

of as objective, there is a realization that “fundamentals of a scientific understanding [are] not a static unchanging set of natural laws, rather these paradigms [are] human interpretations of phenomena as much dependant on the community in which they surfaced as on the nature of reality herself.”²⁵⁷

Courts have recognized that there are experimental uses that, while scientific, do go beyond philosophical inquiry. For example, the Federal Circuit referred to these uses in *Roche* when it spoke of experimental use that was in the “guise of scientific inquiry.”²⁵⁸ A review of patent cases reveals that scientific philosophy is often contrasted with commercial research. With respect to when a patent should be granted, the Supreme Court noted that the “patent system must be related to the world of commerce rather than to the realm of philosophy.”²⁵⁹ Similarly, the Federal Circuit in *Roche* held that the experimental use exception would not apply because Bolar’s use had “definite, cognizable, and not insubstantial commercial purposes.”²⁶⁰ It is these extensions of philosophical inquiry that give rise to the question of a legitimate business interest in *Madey*.

2. The Legitimate Business Interest of Academic Researchers

Once an alleged act of infringement is determined to be a form of philosophical inquiry, the question becomes whether the infringement furthers a legitimate business interest of the user. While the idea of philosophical inquiry is relatively straightforward, the definition of a “legitimate business interest” is unclear and depends on the identity of the entity infringing on the patent. Unfortunately, the *Madey* court muddied the waters by broadening the definition of a business interest to include interests related to non-commercial entities²⁶¹ without specifically defining what such a business interest could be. Instead, Judge Rader merely referred to “any reasonable interpretation of Duke’s legitimate business interest.”²⁶² It may be that Judge Rader used the “I know it when I

helpless as sensations that come to a disordered mind, making an idiot’s lore.” WILL DURANT, *THE PLEASURES OF PHILOSOPHY: A SURVEY OF HUMAN LIFE AND DESTINY* 7 (1953).

257. Philosophy of Science, by Roger Jones, <http://www.philosopher.org.uk/sci.htm> (last visited Mar. 25, 2010).

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

259. *Brenner v. Manson*, 383 U.S. 519, 536 (1966) (quoting *In re Ruschig*, 343 F.2d 965, 970 (C.C.P.A. 1965)).

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

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

262. *Id.*

see it”²⁶³ standard of defining a legitimate business interest. However, it seems reasonable that lower courts and scientists might need more guidance.

Therefore, the first step in determining whether an academic researcher can use the experimental use exception should be to determine exactly what the business interests of the academic researcher are. The Federal Circuit has been very clear that any commercial use is a legitimate business interest of the alleged infringer.²⁶⁴ Experiments that have “definite cognizable, and not insubstantial commercial purposes”²⁶⁵ or the “slightest commercial implications”²⁶⁶ are only in the “guise” of philosophical inquiry²⁶⁷ and are a legitimate business interest. Defining the business interest of a non-commercial entity is much less clear. In *Madey*, the Federal Circuit declared that Duke University had specific business objectives. Those objectives included educating students and faculty,²⁶⁸ obtaining research grants, and sanctioning research projects in order to increase its reputation.²⁶⁹ Additionally, the court pointed to the “aggressive patent licensing program” as a source of revenue and, presumably, a commercial interest.²⁷⁰

However, since the university and the academic researcher have been shown to be acting as distinct entities for purposes of scientific research and to have very different goals and incentives, the business objectives of the university are very different from the business objective of the academic researcher. Therefore, the question of how to define the business objective of the academic researcher remains.

This author posits that most academic researchers in the laboratory are focused solely on conducting scientific research. Put another way, the business of most academic researchers is philosophical inquiry.²⁷¹ This stands in contrast to that of the university, which does not, as an institution, conduct research.

263. *Jacobellis v. Ohio*, 378 U.S. 184, 197 (1964) (Stewart, J., concurring) (declining to define hard-core pornography).

264. *Madey*, 307 F.3d at 1362.

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

266. *Embrex, Inc. v. Serv. Eng’g Corp.*, 216 F.3d 1343, 1353 (Fed. Cir. 2000).

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

268. *Madey*, 307 F.3d at 1356.

269. *Id.* at 1362.

270. *Id.*

271. The author acknowledges that some academic research is conducted for reasons other than philosophical inquiry. However, the framework for determining whether the academic research at issue is conducted for philosophical inquiry (and thus whether it is eligible for the experimental use exception) is complex and beyond the scope of this article.

Instead, it receives money and prestige, and owes its existence as a research institution to the philosophical inquiry of others.²⁷² Activities conducted to further philosophical inquiry, when that inquiry is the sole business of the researcher, should not be considered to be “furthering a business objective” for the purposes of disallowing the experimental use exception. If such activities were considered to further a business objective, this interpretation would define the experimental use exception out of existence. In a time period where almost all philosophical inquiry requires massive inputs of equipment and reagents which are borne by the federal government and other granting agencies, almost all research is conducted in institutional contexts rather than basements or garages.

In whatever manner the “business objective” of a given academic researcher is defined, it is this definition that should guide the analysis of whether the experimental use exception defense is appropriate. The distinct nature of the role of the academic researcher within the university indicates that an academic researcher is acting on her own behalf when conducting infringing activities.

IV. THE DISTINCTION BETWEEN THE UNIVERSITY AND ITS ACADEMIC RESEARCHERS REVEALS THE ENTREPRENEURIAL NATURE OF FACULTY

Scholars have spent much time lamenting the lack of entrepreneurial drive of faculty members and devising the best way to get university faculty to accept and internalize the goal of transferring new technology to the private sector, hopefully with large financial returns.²⁷³ However, such an attitude represents a misunderstanding of the entrepreneurial nature of faculty researchers. Principal Investigators are indeed entrepreneurial. As noted above, Principal Investigators have been analogized to CEOs due to the leadership of the laboratory.²⁷⁴ In fact the nature of running a laboratory, including funding resources and publication, can also be analogized to a business cycle. Unfortunately for university technology transfer offices, the incentives of the research business cycle are often different from incentives that apply to corporations. An understanding of the entrepreneurial business cycle of research and the incentives at various points on the cycle may reveal better techniques for

272. See discussion of university laboratories acting as independent firms within a university *supra* Part II.A.

273. See Jensen, Thursby & Thursby, *supra* note 19; see also discussion *supra* Part II.B.

274. See *supra* Part II.A.

incentivizing faculty researchers to choose to take part in university technology transfer initiatives.

A. *The Academic Research Business Cycle*

The problem facing universities trying to encourage faculty members to embrace the goals of technology transfer is not a lack of entrepreneurial spirit among faculty. Rather, the problem is the lack of understanding of the nature of that entrepreneurial spirit. The university's technology transfer office acts much like the prototypical entrepreneur looking for the best and most profitable ways to transfer technology to the private sector.²⁷⁵ Policymakers and scholars viewing the universities' embrace of such technology transfer techniques²⁷⁶ do not understand the faculty member's reluctance to accept these same incentives.²⁷⁷ Even authors who acknowledge that academic entrepreneurship may be different from private industry entrepreneurship do not recognize the idea that academic entrepreneurship may not be commercial in nature at all.²⁷⁸ Understanding the distinction between the academic researcher and the university allows scholars to redefine the concept of entrepreneurship in the context of academic research, and to use that definition to properly incentivize academic researchers.

Faculty members can be viewed as small business owners in many respects. The Principal Investigator, above analogized to a CEO, runs the lab much like a small firm within the university.²⁷⁹ She alone determines the best course of research, develops a business plan (grant proposal), and procures funding by convincing investors (the National Institutes of Health or the Department of Energy, for example) to invest in her ideas (fund the grant). Once she has funding, the Principal Investigator hires and manages people to make her product (carry out her research) as efficiently as possible, both economically and time-wise. Once her research yields profit (research data or new technology), she determines the most effective way to

275. The statistics published each year by AUTM are an indication that universities value the license revenue from patents. See AUTM REPORT, *supra* note 88. Additionally, such revenue is a source of cachet to the university. See Dreyfuss, *supra* note 94 (discussing the trend for universities to view successful technology transfer offices as prestige-increasing).

276. See Dreyfuss, *supra* note 94, at 464-66.

277. Cf. Jensen, Thursby & Thursby, *supra* note 19, at 1272 (listing reasons why researchers might choose to ignore requirements to disclose inventions to tech transfer officer).

278. See Nicola Lacetera, *Academic Entrepreneurship*, 30 MANAGERIAL & DECISION ECON. 443, 443-44 (2009) (analyzing the difference between academic and private industry entrepreneurship in the context of a response to options to commercialize).

279. Etzkowitz, *supra* note 23.

reinvest her profits (typically publication, but perhaps technology disclosure and patenting) to begin the cycle again and achieve business stability (future funding and tenure). To say that such a process does not require entrepreneurial spirit is to completely misunderstand the motivations of the academic researcher.

Based on the way a Principal Investigator runs her laboratory, it is easy to see that faculty members have motivations that are similar to small business owners. Both desire to determine individualized paths that will benefit them in the long run. However, personal profits do not motivate academic researchers in the same way that they motivate a small business owner. In fact, most academic researchers could make significantly more money performing very similar research in private industry, but choose to take less pay to work on personally interesting problems. Both need to produce the best product possible and determine the best way to use past success to build new growth.

B. Usage of Monetary Incentives

The largest distinction between an entrepreneurial faculty member and a small business owner is the desire for money.²⁸⁰ Money is much less of a motivator for an academic researcher to perform research than it is for a business owner to go into business. Although funding is important to the academic researcher, after a relatively steady salary is paid to the researcher, excess funds generally go toward conducting more research.²⁸¹ Academic researchers do not write exceedingly large grant proposals in the hope that they will become correspondingly rich.

Unfortunately for the university, the university's largest incentive to encourage faculty to disclose new technology is the sharing of profits with the faculty inventor if the invention is commercialized. This profit-sharing incentive historically has not been sufficient to incentivize researchers. Practically speaking, less than 50 percent of inventions with commercial potential are disclosed to the university before publication.²⁸² Empirical studies that have shown the profit-sharing incentive to be of limited value to academic

280. Aghion, Dewatripont & Stein, *supra* note 42, at 621.

281. Many grants include a salary limitation. Thus, while some of the funds of any given grant may go toward a researcher's salary, that salary is capped. *See, e.g.*, Northwestern University, Office for Sponsored Research, NIH Salary Cap, http://www.research.northwestern.edu/osr/b_salary_limit.html (last visited Mar. 25, 2010).

282. Jensen, Thursby & Thursby, *supra* note 19, at 1272.

researchers explain the low participation in commercialization on the part of researchers.²⁸³

Such a result should be unsurprising. These monetary incentives of sharing profits upon commercialization are unlikely to be efficient motivators for academic researchers because such incentives do not influence a major decision of the business cycle of academic researchers. Once a researcher has a new technology, she must determine the best use of the technology and her time in order to continue to receive more funding and job stability such as tenure. While an invention disclosure may result in funding in the distant future, the academic researcher may decide that publication and further grant writing is a better use of her time than filing an invention disclosure, unless there are industrial contacts waiting to license the new technology. Such a decision is probably rational. In 2007, universities filed new patent applications on only 60 percent of invention disclosures that academic researchers filed with the university.²⁸⁴ It is unclear how many of those applications proceeded to the licensing stage, but with only 4,419 new licenses signed, including licenses for inventions from previous years, the possibility that a new invention will yield a large return is relatively slim.²⁸⁵ Additionally, once a potential licensee is found, the researcher has no input as to the terms of the license.²⁸⁶ Thus, even if profit sharing might incentivize a researcher, the fact that the researcher has no control over the amount of revenue that the technology will generate decreases such incentives.

Incentives, either monetary or otherwise, aimed at the decision of disclosure would be far more effective. For instance, credit toward tenure for patents (or even invention disclosures whether or not the university chose to pursue a patent) would be far more likely to incentivize academic researchers to disclose a new invention than the potential for future earnings. Monetary prizes directed at funding research to further develop the new technology might also be an incentive to disclosure, as such prizes would directly impact the ability of the academic researcher to continue research.

283. *Id.* at 1273.

284. *See* AUTM REPORT, *supra* note 88.

285. *Id.*

286. In fact, the prestige of the academic research has no effect on the license terms granted. Elfenbein, *supra* note 53, at 689.

C. Overcoming Social Norms against Commercialization

In addition to the current misapplication of monetary incentives, academic researchers are often bound by social norms that conflict with or are perceived to conflict with the university's interest in technology transfer.²⁸⁷ The publication norm is of immense concern to many academic researchers as it directly impacts the tenure prospects of a faculty member. Faculty members often do not understand that publication and university commercialization can and should co-exist. Educating faculty about intellectual property rights, explaining the potential bars to protection, and describing a best practice for incorporating both publication and commercialization could fairly easily resolve this problem.

More troubling to many faculty members is the potential violation of the norm of free sharing of information and technology. It is difficult to incentivize an academic researcher to disclose a new technology if she believes that such disclosure will limit the ability of others to use her invention due to restrictive licensing agreements with industry.²⁸⁸ Additionally, recent studies have shown that one of the largest impediments to technology sharing has become inter-university material transfer agreements, as each university becomes more protective of technology created within its halls.²⁸⁹ Such problems may leave academic researchers feeling as though intellectual property protection creates more problems than it solves.

There are several ways to address this problem. Education regarding the importance of intellectual property and the best way to transition academic inventions to the public is a key component of changing the way academic researchers think about intellectual property protection for new inventions.²⁹⁰ In fact, once a Principal Investigator buys into the concept of invention disclosure and commercialization, other members of the laboratory, especially graduate students, become far more accepting of the concept.²⁹¹

Listening to the academic researcher and working to cooperate with her to accomplish some free dissemination may also directly

287. See *supra* Part II.B.

288. See WASHBURN, *supra* note 10, at 159 (citing examples of researchers who prefer free dissemination over licensing); *supra* Part II.B (discussing the social norms of free dissemination of research).

289. Walsh, Cohen & Cho, *supra* note 55, 1185-86; John P. Walsh, Charlene Cho & Wesley M. Cohen, *View from the Bench: Patents and Material Transfers*, SCI., Sept. 23, 2005, at 2002-03.

290. Janet Bercovitz & Maryann Feldman, *Academic Entrepreneurs: Organization Change at the Individual Level*, 19 ORG. SCI. 69, 84-86 (2008).

291. *Id.*

address the norm perceived to be in conflict with technology transfer. An academic researcher who believes that her invention should be freely disseminated may be correct. Some inventions are easily disseminated without licenses or large investments. Computer software is a prototypical case. Many computer scientists would prefer to release software under an open source distribution.²⁹² Such open source software could be widely distributed and improved upon with little investment by users. In such cases, the university should listen to the input of the researcher and find a way to transfer the technology without tying the invention with intellectual property rights.

In more complicated cases, development of a technology may require high levels of investment, requiring exclusive rights to attract investors. Again, communication between academic researchers and the university will be essential. If the university can preserve some means of free distribution of the technology, such as by reserving a non-commercial research license for universities or executing narrow licenses limited to one element or field of use for the invention, academic researchers might be more likely to disclose inventions to the university.

V. CONCLUSION

Practical examination of the structure and function of academic laboratories illustrate how patent law should view the distinct nature of academic researchers within the university. The university structure stands in contrast to the relationship that scientists working within industry have with a corporate employer. Additionally, social norms within the academic research community further strengthen the distinction. Academic researchers value those social norms, which often underlie the idea of independence from the university. For instance, academic freedom highlights the idea that academic researchers conduct research programs without true university oversight. Also, norms related to free dissemination of data speak to the often divergent goals and incentives of the university and its faculty. Finally, patent law has implicitly recognized the distinction between the university and its academic researchers in the context of patent ownership and sovereign immunity.

This distinction between the university and its faculty researchers has implications for the application of the experimental use exception to patent infringement by academic researchers.

292. See WASHBURN, *supra* note 10.

Current case law abolishes the use of the experimental use exception for university infringement. This author posits that the case law should be read so as to limit such infringement liability to institutional infringement rather than abolishing the experimental use exception for individual academic researchers. Analysis of the application of the defense should focus on the business interests of the researcher rather than those of the university. A business interest of an academic researcher has not yet been defined.

Finally, the distinction between the university and its researchers sheds light on the entrepreneurial nature of the academic researcher. Academic researchers are highly entrepreneurial, albeit in an unorthodox manner that does not focus on personal monetary incentives. In fact, the pattern of research can be analogized to a business cycle with multiple decision points. Once the entrepreneurial nature of the academic researcher is better understood, new incentives and strategies can be implemented to increase technology transfer participation by academic researchers by focusing on the decision points important to researchers.