Killing the Bayh-Dole Act's Golden Goose

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I. INTRODUCTION

The economic outlook in the United States during the late 1970s was bleak. Inflation was high, the stock market was low, and lines for gasoline were long. Out of this general malaise came an inspired piece of legislation, known commonly as the Bayh-Dole Act, which vested ownership of patent rights stemming from government-funded research "in any contractor who is a non-profit research institution or a small business."[1] This relaxation of governmental ownership "unlocked all the inventions and discoveries that had been made in laboratories throughout

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1. H.R. REP. NO. 96-1307, pt. 1, at 5 (1980), *as reprinted in* 1980 U.S.C.C.A.N. 6460, 6464.

the United States with the help of taxpayers' money."[2] More than two decades after its enactment, Bayh-Dole is credited with rescuing the United States from economic irrelevancy and with making today's biomedical and information-based industries possible. However, a recent series of decisions by the United States Court of Appeals for the Federal Circuit threaten the continued viability of Bayh-Dole. The Federal Circuit, by questioning and possibly eliminating the common law experimental use exception, has forced academic researchers to question whether they may still carry out basic scientific research without fear of being sued for patent infringement.[3]

This Comment first discusses the Bayh-Dole Act, giving particular consideration to the political and economic circumstances that led to its enactment, to the concerns voiced by its critics and its supporters, and to the ensuing consequences. Second, the Comment examines the history of the common law experimental use exception to patent infringement and its importance to universities and small businesses under Bayh-Dole. Third, the Comment explores whether the experimental use exception remains viable in light of modern judicial interpretations, especially those of the Federal Circuit. Lastly, the Comment considers questions left unanswered by the Federal Circuit's decisions and seeks to chart a course toward safe practices.

II. THE BAYH-DOLE ACT[4]

The Bayh-Dole Act of 1980 has been called "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century."[5] Like all legislation, Bayh-Dole is a product of its time. America in the late 1970s faced an "energy crisis" due in part to oil price increases, a declining stock market, escalating inflation, a recession, and a President seemingly unable to cope with the turmoil.[6] From this crucible emerged the Bayh-Dole Act. Although it was crafted in response to the economic realities of the time, it is today even more

2. *Innovation's Golden Goose*, 365 ECONOMIST 3, 3 (2002).

3. The "experimental use exception" has also been termed an "exemption." Here, "exception" is used to denote immunity to infringement derived from the common law; "exemption" is used to denote immunity granted by statute.

4. Bayh-Dole University and Small Business Patent Procedures Act of 1980, Pub. L. No. 96-517, § 6(a), 94 Stat. 3019 (1980) (codified as amended at 35 U.S.C.A. §§ 200-212 (West 2005)).

5. *Innovation's Golden Goose*, *supra* note 2, at 3.

6. *See* Jerry Flint, *Why Shoot the Piano Player?*, FORBES, July 9, 1979, at 137 (observing widespread dissatisfaction with President Carter); *see also* James E. Carter, *Address to the Nation (July 15, 1979)*, WASH. POST, July 16, 1979, at A14 ("The erosion of our confidence in the future is threatening to destroy the social and the political fabric of America.").

important to America's continued economic well-being than it was when it was enacted.

A. The Origins of Bayh-Dole

In May of 1978, President Carter addressed the ongoing crisis in American productivity and called for a panel of experts to conduct a "review of industrial innovation as the key to increased productivity in the United States."[7] When the White House advisory panel issued its report a year later, it emphasized "the role of the patent system and the patent policy regarding government funded research in promoting industrial innovation."[8] This was the genesis of the Bayh-Dole University and Small Business Patent Procedures Act of 1980. Sponsored by Senators Birch Bayh and Robert Dole, the Act aimed "to establish a uniform federal system for the commercialization and allocation of rights in inventions resulting from federally sponsored research and development."[9]

Prior to Bayh-Dole, twenty-six different federal agencies disposed of patent rights to government-funded research in twenty-six different ways.[10] The result was confusion, frustration, and stagnation.[11] Reform was also motivated by the knowledge that the U.S. government owned "between 25,000 and 30,000 patents" derived from federally funded research, almost none of which were being pursued for commercial

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7. H.R. REP. NO. 96-1307, pt. 1, at 2 (1980), *as reprinted in* 1980 U.S.C.C.A.N. 6460, 6461; *see also* Bradley Graham, *Patent Bill Seeks Shift To Bolster Innovation; Patent Ownership Question Heats Up Again*, WASH. POST, Apr. 8, 1979, at M1 (citing "heightened national concern over the waning of American innovation").

8. H.R. REP. NO. 96-1307, pt. 1, at 2, *as reprinted in* 1980 U.S.C.C.A.N. 6460, 6461.

9. *Id.* at 11, *as reprinted in* 1980 U.S.C.C.A.N. 6460, 6470; *see also* 35 U.S.C.A. § 200 (West 2005) ("It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.").

10. *See* H.R. REP. NO. 96-1307, pt. 1, at 3, *as reprinted in* 1980 U.S.C.C.A.N. 6460, 6462; *see also* Graham, *supra* note 7 (noting twenty-two different funding agencies).

11. *See* Graham, *supra* note 7 (noting government contractors' "confusion and discouragement").

purposes.[12] As will be discussed below, Bayh-Dole has exerted tremendous influence over the transfer and commercial development of federally funded technology in the twenty-five years since its enactment.

B. The Supposed Costs of Bayh-Dole

Testifying against enactment, Admiral Hyman Rickover and Representative Jack Brooks both regarded the idea of transferring patent rights derived from federally funded research to the private sector as a giveaway of public property.[13] Other observers questioned whether "companies [would] really stop taking government work if there [were] no change in patent policy?"[14]

Years after its passage, concern was also raised over whether Bayh-Dole exacerbates an effect known as the "tragedy of the anticommons."[15] This theory as applied to biomedical research was explained in a seminal article by law professors Michael Heller and Rebecca Eisenberg, writing that "[t]he tragedy of the anticommons refers to the more complex obstacles that arise when a user needs access to multiple patented inputs to create a single useful product."[16] In other words, patents protecting basic technology (upstream patents) "create obstacles to subsequent [(downstream) research and development] and add a thicket of rights that

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12. *See id.* (noting that "less than 4 percent of the government's whole portfolio" of patents had "been developed for commercial use"); *see also* Birch Bayh, *Celebrating 30 Years of AUTM and the Bayh-Dole Act, Address Before the Association of University Technology Managers Annual Meeting (2004)*, *in* RECOLLECTIONS: CELEBRATING THE HISTORY OF AUTM AND THE LEGACY OF BAYH-DOLE 7 (Ann Hammersla et al. eds., 2004) ("[T]he government's policy of taking patents away from universities killed the incentives necessary for innovative companies to develop new ideas.").

13. H.R. REP. NO. 96-1307, pt. 2, at 22, *as reprinted in* 1980 U.S.C.C.A.N. 6492, 6511-12 (testimony of Adm. Hyman G. Rickover, "father of the nuclear navy" ("I believe the [Bayh-Dole Act] would achieve exactly the opposite of what it purports. It would impede, not enhance, the development and dissemination of technology. It would hurt small business. It would inhibit competition. It would promote greater concentration of economic power in the hands of large corporations. It would be costly to the taxpayer.")); *see also id.* (testimony of Rep. Jack Brooks ("[W]hat the government acquires through the expenditure of its citizens' taxes, the government owns. Assigning automatic patent rights and exclusive licenses to companies . . . for inventions developed at government expense is a pure giveaway of rights that properly belong to the people.")).

14. Graham, *supra* note 7.

15. *See* Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621, 639 (1998) (defining anticommons property as "a property regime in which multiple owners hold effective rights of exclusion in a scarce resource"); *cf.* Garrett J. Hardin, *The Tragedy of the Commons*, 162 SCI. MAG. 1243 (1968).

16. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. MAG. 698, 699 (1998) (describing the anticommons dilemma in scientific research).

firms must [navigate] before [placing] their products on the market."[17] As an example, Heller and Eisenberg pointed to the wide assortment of patent applications covering fragments of gene sequences filed before the complete sequence of the corresponding genes were isolated.[18] Although the information divulged in such patents is scientifically valuable, "[f]oreseeable commercial products, such as therapeutic proteins or genetic diagnostic tests, are more likely to require the use of multiple fragments."[19] Therefore, a proliferation of patents protecting the tools of basic science will lead inevitably to higher transaction costs, borne ultimately by the American consumer.[20]

The anticommons theory, as applied to biomedical research, remains controversial. Indeed, Heller and Eisenberg mention only two examples where the downstream use of patented upstream research tools may have been hampered, but both involved large corporations, not universities or small businesses.[21] Because the Bayh-Dole Act facilitates ownership of patent rights by universities and small businesses, the Act's contribution to the tragedy of the anticommons is tenuous, at best.

C. The Demonstrated Benefits of Bayh-Dole

Ample evidence exists to suggest that Bayh-Dole has yielded measurable and substantial benefits at many levels.[22] Since enactment of Bayh-Dole in 1980, university technology transfer has shown extraordinary growth. In fiscal year 2003 alone, at least 3933 U.S. patents were issued to universities.[23] "Three hundred seventy-four new companies based on an academic discovery were formed in fiscal year 2003 [and] 4,081 new companies have been formed based on a license from an academic institution" since 1980.[24] Approximately 2547 new commercial products derived from university licensing activities were

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17. Rebecca S. Eisenberg, *Technology Transfer and the Genome Project: Problems with Patenting Research Tools*, 5 RISK 163 (1994) (examining the drawbacks to patenting the basic tools of science).

18. *See* Heller & Eisenberg, *supra* note 16, at 699.

19. *Id.*

20. *See id.*

21. *See id.* at 699-700 (discussing reach-through license agreements, whereby patentees reserve rights in downstream discoveries made using patented invention).

22. *See* ASS'N OF UNIV. TECH. MANAGERS, FISCAL YEAR 2003 AUTM LICENSING SURVEY SUMMARY 20-22 (2003); *see also* Alfred R. Berkeley III, *The Economic Impact of University Technologies*, 16 J. ASS'N U. TECH. MANAGERS 1, 7 (2004) ("The Bayh-Dole Act is an important centerpiece to university technology transfer success and should be defended at all costs.").

23. Berkeley, *supra* note 22, at 16 (reporting patent filings and issuances by university respondents to survey).

24. *Id.* at 4 (reporting startup commercial activity attributable to university technology transfer).

launched between fiscal years 1998 and 2003.[25] Finally, "the licensing of inventions from universities, teaching hospitals, research institutes and patent-management firms added approximately $40 billion to the domestic economy and was responsible for creating 260,000 new jobs."[26] Accordingly, it is not surprising that Alfred Berkeley, the former president and vice chairman of the Nasdaq Stock Market Inc., views university technology transfer as a critical component of America's past, present, and future growth.[27]

The benefits of Bayh-Dole have received worldwide attention. Bayh-Dole was identified by *The Economist* magazine as "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century."[28] "Together with amendments in 1984 and augmentation in 1986, [Bayh-Dole] unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance."[29] In Japan, a "Law on Special Measures for Industrial Revitalization" was enacted to provide incentives to small and middle-sized corporations by supporting their use of patents, and is sometimes referred to as the Japanese equivalent of Bayh-Dole.[30] In Europe, Canada, and Australia, government-industry partnerships using Bayh-Dole as a template have been implemented as well.[31]

Finally, in a broad analysis of America's manufacturing capacity and its relationship to research and development, the President's Council of Advisors on Science and Technology stressed that "maintaining a strong base of university [research and development]" is crucial to America's

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25. *See id.* (reporting technologies derived from licensing activities).

26. Bayh, *supra* note 12, at 9.

27. *See* Berkeley, *supra* note 22, at 1, 7 (discussing the manifold benefits of university technology transfer).

28. *Innovation's Golden Goose*, *supra* note 2, at 3.

29. *Id.*

30. *See* J. Steven Rutt & Stephen B. Maebius, *Technology Transfer Under Japan's Bayh-Dole: Boom or Bust Nanotechnology Opportunities?*, 1 NANOTECH. L. & BUS. 1, ¶ 1 (2004), *available at* http://www.nanolabweb.com (follow "Browse by Issue" dropdown menu to "Volume 1, Issue 3"; then follow "View Abstract" hyperlink under article name) (recognizing similarity of Japanese legislation to Bayh-Dole Act); *see also* Kishimoto Shuhei, *Shoring Up Japan's Content Industry*, 31 JAPAN ECHO 19 (2004) (discussing intellectual property barriers in Japan).

31. *See* Warren H. Hunt Jr., *The Government Is Here To Help: A Small Business Perspective*, 56 JOM 14 (2004), *available at* 2004 WLNR 14444391 (noting worldwide implementation of legislation similar to Bayh-Dole); *see also* Gate2Growth, ProTon Europe, http://www.gate2growth.com/proton.asp (last visited Mar. 15, 2005) (describing a network of technology offices contributing to European economic development).

future economic viability.[32] The same council, in an earlier "Report on Technology Transfer of Federally Funded R&D," recommended that "[e]xisting technology-transfer legislation [is successful] and should not be altered."[33]

III. THE COMMON LAW RESEARCH EXCEPTION TO PATENT INFRINGEMENT

A. Patent Rights and Patent Infringement

The basis for patent rights in the United States is found in the Constitution: "The Congress shall have Power To promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."[34] A U.S. patent is the grant of "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States."[35] Thus, making, using, offering for sale, or selling a patented invention without permission of the patentee and during the patent term constitutes infringement.[36]

B. The Common Law Research Exception

Before the Federal Circuit's decision in *Madey v. Duke University*, basic scientific research that used patented inventions was considered immune from suit for patent infringement due to the experimental use exception (also called the research exception).[37] Research performed for the purpose of studying or understanding a patented invention was considered noninfringing activity.[38] Universities and academic scientists

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32. PRESIDENT'S COUNCIL OF ADVISORS ON SCI. & TECH., SUSTAINING THE NATION'S INNOVATION ECOSYSTEMS, INFORMATION TECHNOLOGY MANUFACTURING AND COMPETITIVENESS 19, 21 (2004) (underscoring the importance of university research and development, and noting attempts by foreign nations to replicate the success of the Bayh-Dole Act).

33. *Id.* at 8-9 (noting the Bayh-Dole role in facilitating or stimulating commercialization of technology).

34. U.S. CONST. art. I, § 8, cl. 8.

35. 35 U.S.C.A. § 154(a)(1) (West 2005) (defining the contents of U.S. patents).

36. *See id.* § 271(a) ("[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.").

37. *See, e.g.*, Poppenhusen v. Falke, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11279) (observing that "it is now well settled" that experimental use is not infringing use); *cf.* Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958, *appeal denied*, 78 Fed. App'x 105 (Fed. Cir. 2003) (per curiam), *partial summary judgment denied*, 336 F. Supp. 2d 583 (M.D.N.C. 2004) (casting doubt on viability of experimental use exception).

38. The term "experimental use exception" as used here denotes an exception to patent infringement and should not be confused with the exception recognized under 35 U.S.C. § 102(b).

understood that most laboratory activity—research for its own sake, and lacking commercial intent—was not infringing activity. The concept of an experimental use exception originated in U.S. case law with Justice Joseph Story's 1813 opinion in *Whittemore v. Cutter*, where he noted (albeit in dicta) that "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[39]

The archaic term "philosophical experiments" denotes what we label "basic science" today. Benjamin Franklin used the term in 1743 to describe the activities he proposed for the first scientific society of the colonies, the American Philosophical Society.[40] Justice Story elaborated further on his conception of the exception for philosophical experiments in *Sawin v. Guild*, where he opined that to find infringement, "the making of a patented machine . . . must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification."[41] Taken together, *Whittemore* and *Sawin* demonstrate that the exception applies to basic research so long as there is no commercial intent. By 1861, the experimental use exception was accepted generally: "It has been held, and no doubt is now well settled, that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee."[42]

In *Ruth v. Stearns-Roger Mfg. Co.*, the only case before *Madey* to involve the experimental use exception as applied to a university, Stearns-Roger was accused of contributory infringement for selling parts of patented machines to the Colorado School of Mines.[43] The court observed that the parts "were all used in the [school's] laboratory and were cut up and changed from day to day."[44] After quoting *Poppenhusen*, the court noted that the "making or using . . . without any intent to derive

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The statutory exception is concerned with public, experimental use by an inventor prior to patenting of his invention.

39. 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17600) (Story, J.) (noting the limits of liability for patent infringement).

40. *See* FRANKLIN: THE AUTOBIOGRAPHY AND OTHER WRITINGS ON POLITICS, ECONOMICS, AND VIRTUE 174-76 (Alan Houston ed., 2004).

41. 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12391) (Story, J.) (citing *Whittemore*, 29 F. Cas. 1120).

42. *Poppenhusen*, 19 F. Cas. at 1049.

43. *See* 13 F. Supp. 697, 699-700 (D. Colo. 1935), *rev'd*, 87 F.2d 35 (C.C.A. 10 (Colo.) 1936).

44. *Id.* at 703.

profits or practical advantage . . . is not infringement."[45] The court concluded "that sales of parts for machines used for experimental purposes did not constitute contributory infringement."[46] Finally, in *Chesterfield v. United States*, use by a company of a patented alloy was found to be experimental and thus noninfringing when the alloy was used to establish the possibility of interchanging certain metals in the patented alloy.[47] The use was for "testing and for experimental purposes . . . . Experimental use does not infringe."[48]

After almost 150 years of case law, it appeared safe to pronounce that the experimental use exception to infringement applied so long as there was actual experimental use, and the use was not directed toward generating profits.

IV. THE COMMON LAW RESEARCH EXCEPTION UNDER ATTACK

Despite widespread and long-term acceptance of the experimental use exception, a string of modern decisions—mostly by the Federal Circuit—have restricted the exception to such a degree that its continued viability is doubtful.[49] In fact, a review of relevant cases reveals that the Federal Circuit has tended toward an ever more restrictive interpretation of patent infringement almost since the court was created.[50]

A. Modern Judicial Perspective

The current drive to eliminate the common law research exception originated in *Pitcairn v. United States*, a case predating the Federal Circuit.[51] The patents in *Pitcairn* related to "rotary-wing aircraft" (helicopters), and the infringing activity was performed by government

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45. *Id.* at 713 (citing *Poppenhusen*, 19 F. Cas. 1048).

46. *Id.*

47. 159 F. Supp. 371 (Ct. Cl. 1958) (holding that use of alloy was experimental and that experimental use does not infringe a patent).

48. *Id.* at 375.

49. *See, e.g.*, Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002) ("[T]he act does not qualify for the very narrow and strictly limited experimental use defense."), *cert. denied*, 539 U.S. 958, *appeal denied*, 78 Fed. App'x 105 (Fed. Cir. 2003) (per curiam), *partial summary judgment denied*, 336 F. Supp. 2d 583 (M.D.N.C. 2004); Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 864 n.2 (Fed. Cir. 2003) ("[T]he Patent Act does not include . . . an experimental use exemption from infringement."), *vacated*, 125 S. Ct. 2372 (2005).

50. *See, e.g.*, NAT'L RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY 166-82 (2004) (examining the influence of patents and patent law on scientific research); *see also* Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958, *appeal denied*, 78 Fed. App'x 105 (Fed. Cir. 2003) (per curiam), *partial summary judgment denied*, 336 F. Supp. 2d 583 (M.D.N.C. 2004).

51. 547 F.2d 1106 (Ct. Cl. 1976).

contractors.[52] The contractors were hired by the U.S. government to produce different helicopter models, which were found to infringe one or more patent claims.[53] The government asserted that its manufacture of the helicopters was "for testing and experimental purposes."[54] Rejecting the experimental use defense, the court noted that "every new helicopter must be tested for lifting ability . . . and numerous other factors. Tests, demonstrations, and experiments of such nature are intended uses of the infringing aircraft . . . and are in keeping with the legitimate business of the using agency."[55] In other words, testing for the purpose of establishing the desirability of using a particular patented invention in one's "legitimate business" constitutes infringement.

In *Roche Products, Inc. v. Bolar Pharmaceutical. Co.*, generic drug manufacturer Bolar obtained one of Roche's patented pharmaceutical compounds from a foreign manufacturer.[56] Bolar intended to use the compound (a tranquilizer related to Valium) to make "dosage form capsules, to obtain stability data, dissolution rates, bioequivalency studies, and blood serum studies" in preparation for submitting a New Drug Application to the U.S. Food and Drug Administration (FDA).[57] To gain FDA approval of its generic version of the Roche tranquilizer, Bolar was required to present data showing its drug was equivalent to the already approved Roche drug.[58] Not surprisingly, Roche sued to prevent Bolar from using the drug in any way for the entire term of the patent.[59] Bolar countered that its use was protected by the common law experimental use exception and that "public policy favors generic drugs and thus mandates the creation of a new exception in order to allow FDA required drug testing."[60] The Federal Circuit, though, relied on the finding in *Pitcairn* that "'[t]ests, demonstrations, and experiments . . . [which] are in keeping with the legitimate business of the . . . [alleged infringer]' are infringements for which '[e]xperimental use is not a defense.'"[61] The court distinguished the *Chesterfield* decision that

52. *See id.* at 1110.

53. *See id.* at 1110-11 (finding "59 patent claims in 11 patents" valid, with specific claims "infringed by [at least] seven different models of helicopters").

54. *Id.* at 1124.

55. *Id.* at 1125-26.

56. 733 F.2d 858, 860 (Fed. Cir. 1984).

57. *Id.*

58. *See* 21 U.S.C.A. § 355(i) (West 2005) (providing that preclinical tests are a precondition to FDA approval for clinical trials).

59. *See Roche*, 733 F.2d at 860.

60. *Id.* at 862.

61. *Id.* at 863 (citing Pitcairn v. United States, 547 F.2d 1106, 1125-26 (Ct. Cl. 1976)).

"experimental use does not infringe" as "pure obiter dictum."[62] In finding Bolar liable for infringement, the court stated, "[I]t is no dilettante affair such as Justice Story envisioned. We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes."[63] More ominously, for universities and academic researchers, the court said, "Bolar may intend to perform 'experiments,' but unlicensed experiments conducted with a view to the adaptation of the patented invention to the experimentor's business is a violation of the rights of the patentee to exclude others from using his patented invention."[64] Although *Roche* was, in part, statutorily overruled by 35 U.S.C. § 271(e)(1),[65] the Federal Circuit seemed to misunderstand Justice Story's use of the term "philosophical experiments" when it referred to the exception as a "dilettante affair."[66] The court also seemed to suggest that not all "experiments" are really experiments and placed significant emphasis on the link to business interests.[67]

B. Purpose of the Hatch-Waxman Act

The Hatch-Waxman Act, known formally as the Drug Price Competition and Patent Term Restoration Act of 1984, was Congress's response to *Roche*. It was enacted to facilitate entry of lower-priced generic drugs to the market while providing manufacturers of brand-name pharmaceuticals with incentives to research and develop new drugs.[68] To this end, the Hatch-Waxman Act amended section 355 of the Federal Food, Drug and Cosmetic Act to "authorize an abbreviated new drug application [ANDA] for generic new drugs equivalent to approved drugs," thus creating a route for generic drug manufacturers to circumvent the difficult, costly, and time-consuming FDA approval process.[69]

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62. *Id.* (citing *Pitcairn*, 547 F.2d at 1125 (observing that where patent claims at issue are found invalid, it may not be necessary to consider infringement)).

63. *Id.*

64. *Id.*

65. *See* H.R. REP. NO. 98-857, pt. 1, at 45-45 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2679.

66. *See Roche*, 733 F.2d at 863.

67. *See id.*

68. *See* Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1568 (Fed. Cir. 1997) (noting that goal of Hatch-Waxman Act was "to benefit makers of generic drugs, research-based pharmaceutical companies, and . . . the public").

69. *See* H.R. REP. NO. 98-857, pt. 1, at 1, *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2647; *see also* 21 U.S.C.A. § 355(j) (West 2005).

C. The Hatch-Waxman Statutory Exception to Infringement

The Hatch-Waxman Act, addressing the *Roche* decision directly, provided that "it is not an act of patent infringement for a generic drug maker to import or test a patented drug in preparation for seeking FDA approval if marketing of the drug would occur after expiration of the patent."[70] The statutory exemption to patent infringement was codified at 35 U.S.C. § 271(e)(1).[71]

D. The Federal Circuit Forges Ahead

Subsequently, the Federal Circuit addressed the breadth of the statutory exemption in *Eli Lilly & Co. v. Medtronic, Inc.*, finding that § 271(e)(1) extended also to medical devices.[72] Medtronic allegedly infringed Lilly's patents by developing and marketing implantable cardiac defibrillators and related catheter electrodes.[73] While the lower court found that § 271(e)(1) was inapplicable to medical devices, the Federal Circuit parsed the statutory language to reach a different result.[74] Lilly argued that the § 271(e)(1) exception for "patented inventions" should be limited to patented drugs "by reading the last clause of [§] 271(e)(1) as a restriction on that otherwise broad statutory language."[75] Medtronic countered, and the court agreed, that "the exception extends to all types of 'patented inventions' provided the use being made is for testing to obtain approval from FDA for sale of a product after the relevant patent has expired."[76] Consequently, the holding in *Roche* survives for circumstances not related to drug or medical device development. Where research is not related to submission of information to the FDA, *Roche* severely restricts the experimental use exception and denies it altogether where such activity is "with a view" toward business.

In 2000, the Federal Circuit had another opportunity to address the common law experimental use exception in *Embrex, Inc. v. Service*

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70. H.R. REP. NO. 98-857, pt.1, at 15, *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2648.

71. 35 U.S.C.A. § 271(e)(1) (West 2004) ("It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . .").

72. 872 F.2d 402, 404-06 (Fed. Cir. 1989).

73. *See id.* at 403.

74. *See id.* at 405-06 (reversing lower court's ruling that § 271(e)(1) is restricted to drugs).

75. *Id.* at 405.

76. *Id.*

Engineering Corp.[77] Service Engineering Corporation (SEC) developed and tested certain methods directed at immunizing chicken embryos *in ovo*, in an effort to design around Embrex's patent.[78] After stressing the court's narrow interpretation of the experimental use exception in *Roche*, the court found that "SEC's chief commercial purpose was to demonstrate to its potential customers the usefulness of the methods performed by its [own] *in ovo* injection machines. Just because SEC was unsuccessful in selling its machines does not confer . . . immunity . . . for its infringing acts."[79] Thus, because SEC's ultimate goal was to commercialize a noninfringing process, the tests did not fall under the experimental use exception. Judge Rader, in a concurring opinion, wrote that "the Patent Act leaves no room for any *de minimis* or experimental use excuses for infringement."[80] He explained that the United States Supreme Court decision in *Warner-Jenkinson* foreclosed all consideration of exceptions to patent infringement.[81] The *Warner-Jenkinson* decision, though, was about the doctrine of equivalents; that case simply did not raise the issue of experimental use. To Judge Rader, *Warner-Jenkinson* precluded the exception "even in the extraordinarily narrow form recognized in *Roche*," and that "the slightest commercial implication will render the 'philosophical inquiry/experimental use' doctrine inapplicable."[82] According to this model, infringement is a simple objective determination: infringement either exists or it does not; there is no middle ground. Furthermore, the only exceptions are statutorily granted exemptions. Viewed from this perspective, the decision in *Madey* was all but foretold.[83]

E. The Exception in Danger of Extinction

Dr. John Madey, a professor, was employed by Duke University for almost a decade as director of Duke's "Free Electron Laser" laboratory.[84] Before coming to Duke, Dr. Madey invented and later patented certain

77. 216 F.3d 1343 (Fed. Cir. 2000) (per curiam).
78. *See id.* at 1343.
79. *Id.* at 1349.
80. *Id.* at 1352 (Rader, J., concurring).
81. *See id.* at 1353 (Rader, J., concurring) (quoting Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 34 (1997) ("Application of the doctrine of equivalents, therefore, is akin to determining literal infringement, and neither requires proof of intent.")).
82. *Id.*
83. *See generally* Madey v. Duke Univ., 307 F.3d 1351, 1352 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958, *appeal denied*, 78 Fed. App'x 105 (Fed. Cir. 2003) (per curiam), *partial summary judgment denied*, 336 F. Supp. 2d 583 (M.D.N.C. 2004).
84. *See Madey*, 307 F.3d at 1352 (describing relationship between Duke University and Dr. Madey).

technology relating to free-electron lasers (a component of the Strategic Defense Initiative's space-based weapons systems proposal, promoted by then President Ronald Reagan).[85] The laboratory used equipment developed under Dr. Madey's patents and, after he was removed as director due to a dispute with Duke, the University continued to use the patented technology to perform scientific research.[86] Dr. Madey then sued Duke for infringing his two patents.[87] While the lower court dismissed Dr. Madey's claim, finding the common law experimental use doctrine applied, the Federal Circuit reversed and remanded, stating that the lower court's "application of the common law experimental use defense" was in error.[88]

In its analysis of the experimental use exception, the Federal Circuit noted Judge Rader's concurring opinion in *Embrex*, which asserted that the experimental use defense had been eliminated, but "conclude[d that] the experimental use defense persists albeit in the very narrow form articulated by [the majority] in *Embrex*."[89] The court proceeded to discuss the experimental use exception in light of *Pitcairn*, *Roche*, and *Embrex*, and concluded that "[o]ur precedent does not immunize use that is in any way commercial in nature . . . [or] any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications."[90] It is clear from this explanation that commercial intent precludes application of the research exception, just as it did under Justice Story's formulation. However, by stressing the "legitimate business" link of *Pitcairn*, the Federal Circuit proceeded to remove all doubt that the experimental use exception was truly no more than a dilettante affair.[91] The court summed up *Pitcairn*, *Roche*, and *Embrex*, saying:

> [S]o long as the [allegedly infringing] act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.[92]

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85. *See* U.S. Patent No. 4,641,103 (issued Feb. 3, 1987) ("Microwave electron gun"); U.S. Patent No. 5,130,994 (issued July 14, 1992) ("Free-electron laser oscillator for simultaneous narrow spectral resolution and fast time resolution spectroscopy.").

86. *See Madey*, 307 F.3d at 1352-53.

87. *See id.* at 1353.

88. *Id.* at 1364.

89. *Id.* at 1360-61.

90. *Id.* at 1362.

91. *Id.*

92. *Id.*

The court further held that "Duke's acts appear to be in accordance with any reasonable interpretation of Duke's legitimate business objectives."[93] In a telling footnote, the court conceded that "Duke's patent and licensing policy may support its primary function as an educational institution," but then observed that Duke, "like other major research institutions of higher learning, is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream."[94] As though technology transfer activity were not enough to find "business objectives," the court also noted that

> major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.[95]

Accordingly, it appears that because Duke and other educational research institutions exercise certain rights and obligations under federal law—pursuing a "patent licensing program" under the Bayh-Dole Act—they are precluded from claiming a research exemption. Worse, business objectives may be found where an entity engages in "educating and enlightening," status-building, and attracting "grants, students and faculty."[96] Under the Federal Circuit's test, it is difficult (and perhaps impossible) to conceive of any entity consisting of more than one person that could qualify for the exception.

F. Is the Exception Dead?

Any hopes that the experimental use exception might not be so restricted after *Madey* were dashed by the Federal Circuit's latest case to touch on the issue.[97] In *Integra v. Merck*, Merck, the Scripps Research Institute, and Dr. David Cheresh were sued for infringing Integra's patents covering recombinantly produced RGD peptides.[98] Dr. Cheresh, a scientist at Scripps, discovered that certain receptor proteins expressed

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93. *Id.*
94. *Id.* at 1362-63 n.7.
95. *Id.* at 1362.
96. *Id.*
97. *See* Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860 (Fed. Cir. 2003), *vacated*, 125 S. Ct. 2372 (2005).
98. *See id.* at 862-63. "RGD" denotes a three-amino acid sequence (in single-letter notation) consisting of arginine (R), followed by glycine (G), followed by aspartate (D). *See id.* at 862.

on the surfaces of cells interacted preferentially with substrates containing an RGD peptide sequence.[99] These proteins, called integrins, are one of the principal mediators of cell-cell and cell-substrate adhesion. Consequently, Dr. Cheresh's discovery had significant implications for human diseases in which cellular adhesion and migration is a component, particularly cancer.[100] Merck agreed with Scripps to fund Dr. Cheresh's subsequent work, which included further study of the RGD-integrin interaction, using RGD-containing peptides supplied by Merck.[101] Their goal was to identify a peptide that would block interaction, then develop the experimental data (from "preclinical trials," which includes testing in laboratory animals) that the FDA requires before it will approve the commencement of human clinical trials.[102] Integra learned of Dr. Cheresh's work and offered Merck licenses to the relevant patents, but Merck ultimately declined.[103] This suit followed.

The question before the Federal Circuit in *Integra* was whether Dr. Cheresh's research pursuant to the Merck-Scripps agreement was exempt from liability under § 271(e)(1).[104] Interestingly, the experimental use exception was not before the court in this case.[105] Nevertheless, in dicta Judge Rader restated his view that there is no exception to infringement for "experiments."[106] Indeed, Judge Rader noted pointedly that Merck did not argue "that the common law research exemption should apply to any of the infringing activities evaluated."[107] Judge Newman, in her dissent, explained Merck's reticence: "[The common law research exemption] was before the district court, and counsel explained at oral argument that they were not pressing this argument 'in part because of a very recent case.'"[108] There is little doubt that the "recent case" was *Madey*.

Judge Rader, writing for the majority in *Integra*, explained that neither the experimental use exception nor the exemption of § 271(e)(1) applied to the Merck-Scripps activities.[109] It is interesting to note that in

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99. *See id.* at 862-63.
100. *See id.* at 863.
101. *See id.*
102. *See id.*
103. *See id.*
104. *See id.* at 865.
105. *See id.* at 863 n.2 ("[T]he common law experimental use exception is not before the court in the instant case.").
106. *See id* at 864 n.2 ("[T]he Patent Act does not include the word "experimental," let alone an experimental use exemption from infringement.").
107. *Id.*
108. *Id.* at 878.
109. *See id.* at 872 ("Merck's infringing activities were not 'solely for uses reasonably related' to provision of information to the FDA.").

Integra the Federal Circuit required a direct relationship between the research and the intent to submit an FDA application before § 271(e)(1) would apply; in *Madey*, the court found that even a tangential relationship between allegedly infringing research and commercial interest is sufficient to find liability.[110] In Judge Rader's view, either infringement exists or it does not. After disposing of that issue, all that remains is to determine whether § 271(e)(1) provides an exemption.

Judge Newman, in a particularly cogent dissent, expressed that the Merck-Scripps research was "either exempt exploratory research, or was immunized by § 271(e)(1). It would be strange to create an intervening kind of limbo."[111] Judge Newman's view of the relationship between the common law experimental use exception and the statutory exemption of § 271(e)(1) is notable. She explained that

> an ultimate goal or hope of profit from successful research should not eliminate the exemption. The better rule is to recognize the [experimental use exception] for research conducted in order to understand or improve upon or modify the patented subject matter, whatever the ultimate goal. That is how the patent system has always worked: the patent is infringed by and bars activity associated with development and commercialization of infringing subject matter, but the research itself is not prohibited, nor is comparison of the patented subject matter with improved technology or with designs whose purpose is to avoid the patent.[112]

Indeed, while a "threshold invention may . . . exact tribute from or enjoin commercial and pre-commercial activity, the patent does not bar all research that precedes such activity."[113] Judge Newman explained her idea as the difference between *using* a patented invention as one would use a tool, which would constitute infringement, and *studying* a patented invention, which would not.[114] While this distinction is somewhat clear for mechanical inventions, it is less clear for biomedical inventions because biomedical science is an inherently additive process: Yesterday's inventions are the building blocks of today's experiments.[115] However, it is instructive to view the difference as one between "experimenting with" (using as a tool, e.g., employing patented DNA polymerase enzymes in

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

111. *Integra*, 331 F.3d at 877.

112. *Id.* at 876.

113. *Id.*

114. *See id.* at 878 ("Use of an existing tool in one's research is quite different from study of the tool itself.").

115. *See id.* at 877-88 ("There is a fundamental distinction between research into the science and technology disclosed in patents, and the use in research of patented products or methods, the so-called 'research tools.'").

PCR reactions) and "experimenting on" (studying the same enzymes as the very object of an experiment). While Judge Newman declined to "define the boundaries of the research exemption for all purposes and all activities," she noted that "the statutory immunity of § 271(e)(1) takes effect wherever the research [exception] ends"—a continuum of protection.[116]

Along the research spectrum—from tinkering in one's basement, to basic science, then preclinical research, followed by clinical trials, and culminating in FDA approval—where do the boundaries of exceptions and exemptions lie? The majority in *Integra* held that only clinical trials leading to FDA approval received § 271(e)(1) immunity, and refused to consider the possibility of an experimental use exception. Applying Judge Rader's view of the experimental use exception, it is difficult to conceive of any qualifying entity whatsoever, especially because the *Madey* decision emphasized that even an unrelated business interest voided the exception.[117] Judge Newman's model is most similar to the original exception, carved over time from Justice Story's dicta, but whether overlap or some "intervening limbo" exists between exception and exemption remains uncertain.

Subsequently, the Supreme Court unanimously vacated the *Integra* decision and remanded.[118] Justice Scalia's holding was crafted very narrowly, finding that § 271(e)(1) provides exemption from liability for (1) use of patented pharmaceutical or biological compounds, that are (2) the subject of experimentation, when (3) an FDA submission is contemplated.[119] The Court did not address the scope of the common law research exception or the effects of a "legitimate business interest" on the exception. The Court also did not define when, along a sequence of research experiments, an FDA submission must be contemplated for the statutory safe harbor to apply.

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116. *Id.* at 876.

117. *See* Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958, *appeal denied*, 78 Fed. App'x 105 (Fed. Cir. 2003) (per curiam), *partial summary judgment denied*, 336 F. Supp. 2d 583 (M.D.N.C. 2004).

118. Merck KGaA v. Integra Lifesciences I, Ltd., 125 S. Ct. 2372, 2383-84 (2005) ("[T]he use of patented compounds in preclinical studies is protected under § 271(e)(1) as long as there is a reasonable basis for believing that the experiments will produce 'the types of information that are relevant to an IND or an NDA.'" (quoting Brief of United States as Amicus Curiae at 23, Merck KGaA v. Integra Lifesciences I, Ltd., No. 03-1237 (Dec. 10, 2004))).

119. *See id.*

V. CONCLUSION

It is still unclear whether the § 271(e)(1) exemption extends to using patented pharmaceutical or biological compounds as research tools (rather than as the objects of study, as with Dr. Cheresh's experiments), when the use will produce data relevant to a submission to the FDA.[120] If use of patented research tools "as tools" is exempt from infringement under § 271(e)(1), the interests of pharmaceutical and biotechnology companies would be harmed greatly; if such use is not exempt, academic research could be somewhat curtailed. It is also uncertain whether an initial lack of intent to submit an application to the FDA will prevent a later claim of exemption under § 271(e)(1) (Judge Newman's "intervening limbo" between basic research and clinical trials), or whether some overlap between exception and exemption (when experimenting on, not with, a compound) exists. If a lack of intent to submit an FDA application does not preclude the possibility of later claiming exemption under § 271(e)(1), might the "legitimate business interest" link of *Madey* render the question of overlap moot?

After *Madey*, it is clear that America's universities are dramatically more vulnerable to litigation. Whether a viable experimental use exception remains at all is an open question.[121] Indeed, anecdotal evidence indicates that "a number of [educational] institutions [have received] more notification letters with respect to patent infringement in the aftermath of the [*Madey*] decision."[122] Outcomes such as these cause scientists and university administrators to wonder: "is it safe to do basic research anymore?"

It appears that the "legitimate business interest" link of *Madey* is dispositive when no submission to the FDA is contemplated. Consequently, the experimental use exception doctrine is truly narrow; certain safety lies only in statutory exemption. However, because what is meant by "use" remains undefined, even the simple language of § 271(e)(1) provides only rigidly defined areas of doubt and uncertainty.

Understanding whether the common law exception continues to exist or not is tremendously important to modern science. Virtually no significant research today is performed by any entity devoid of

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120. *See* 35 U.S.C.A. § 271(e)(1) (West 2005) (providing that "[i]t shall not be an act of infringement to . . . use . . . a patented invention").

121. *See, e.g.*, *Scholars for Dollars—Patents*, 373 ECONOMIST 59, 59 (2004) (discussing how Bayh-Dole Act caused universities to behave like businesses); Bernard Wysocki Jr., *Cutting Edge: A Laser Case Sears Universities' Right To Ignore Patents*, WALL STREET J., Oct. 11, 2004, at A1 (describing university concern over *Madey*).

122. NAT'L RESEARCH COUNCIL, *supra* note 50, at 117-18.

"legitimate business interests" as defined by *Madey*. Applying the logic of *Madey*, only individuals or groups totally lacking any business interest would qualify. Moreover, as soon as any such researchers seek outside funding, student assistants, or "prestige," the exception evaporates. Presumably, merely receiving federal funding is also "commercial" activity because a principal goal of the Bayh-Dole Act is "to promote the commercialization and public availability of inventions made in the United States."[123]

As Oliver Wendell Holmes, Jr., stated, "[T]he life of the law has not been logic; it has been experience."[124] Logically, strong enforcement of patent rights—in return for enabling disclosures of patented inventions—helps drive modern commerce. Experience, though, tells us that certain limited exceptions to infringement are fundamentally necessary. If, in a tragedy of the anticommons, basic research could be prohibited by patent, "the advancement of technology would stop, for the first patentee in the field could bar not only patent-protected competition, but all research that might lead to such competition, as well as barring improvement or challenge or avoidance of patented technology."[125]

Given the *Madey* and *Integra* decisions, it is unclear whether precautionary measures taken to avoid infringement will prevent universities from conducting research as they have done for decades. It is also ironic that the Bayh-Dole Act, which revolutionized academic research and helped create the biotechnology sector of our modern economy, has also indirectly endangered the experimental use exception. Although a tragedy of the anticommons is not likely, any working solution involving licensing arrangements and their attendant transaction costs will add to the already enormous expense of basic research.

As it did in response to the decision in *Roche v. Bolar*, Congress could decide to provide its own working solution. A simple answer would be to amend the Bayh-Dole Act to provide an "academic research exemption." For example, patents derived from federally funded research could be subject to a compulsory license, such that anyone performing federally funded research could "use" the patented invention (use as a tool, or use as an object of experimentation). In other words, the pool of patents derived from government-funded inventions would be freely available to government-sponsored researchers. Owners of such patents

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123. 35 U.S.C.A. § 200 (West 2005).

124. OLIVER WENDELL HOLMES, JR., THE COMMON LAW 5 (Mark DeWolfe Howe ed., Little Brown & Co. 1963) (1881).

125. Integra Lifesciences I, Ltd. V. Merck KGaA, 331 F.3d 860, 875 (Fed. Cir. 2003) (Newman, J., dissenting).

(universities, mostly) could be expected to object to this as a government "taking," but they would remain free to license their inventions to third parties outside the stream of federal funding for further commercial development. This approach would devalue patents with mostly academic utility, rendering them unattractive to prospective licensees, yet patents with broad commercial viability would remain highly desirable despite the exemption to infringement.

Another solution, similar to the one above, would be to link university technology transfer offices under a "blanket rights" model, like that employed by the American Society of Composers, Authors and Publishers (ASCAP). Each member of ASCAP grants ASCAP the nonexclusive right to grant licenses over his works, as well as the right to bring suit on his behalf. Each member also agrees to abide by ASCAP's royalty-distribution system. A similar organization driven by university and small-business interests, the beneficiaries of Bayh-Dole, could provide a viable and powerful extrajudicial solution.

The Bayh-Dole Act has served America well for twenty-five years—its means and ends are at least as important today as they were at its inception. However, while appreciating the utility of the Act we should also consider whether it ought to be amended to resolve the uncertainty felt by those it was designed to assist.

While greatly increased litigation in light of *Madey* is unlikely, there is little doubt that universities and academic researchers must bear the costs of educating and defending themselves with regard to the intellectual property rights of others. Between clear liability for infringement and the safe harbors of exception and exemption lies uncharted territory. Prudent universities and scientists will avoid this uncharted territory, but it would help science, industry, and the American public greatly if the uncertainty were resolved.