BAYH-DOLE UNDER SIEGE: THE CHALLENGE TO FEDERAL PATENT POLICY AS A RESULT OF *MADEY V. DUKE UNIVERSITY*

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INTRODUCTION

Few would disagree with the proposition that the Bayh-Dole University and Small Business Patent Act[1] ("Bayh-Dole" or "the Act") has transformed the landscape of technology transfer in the United States. While the Act has had substantial effects upon the entire U.S. economy, the sector most dramatically affected has been that of the nation's colleges and universities. Patent filings by these institutions have skyrocketed, as has licensing income flowing back to these schools as a result of the commercialization of technology developed through federally-sponsored research support. All evidence reveals that research and development activities at colleges and universities have substantially grown in the past twenty-five years as a direct result of the Act. Moreover, evidence even suggests that the technology boom experienced during the 1990s, fueled by start-up companies and other high-tech industry clustered around major universities, may have been due in large part to the surge in technology transfer facilitated by Bayh-Dole.

Nevertheless, many commentators point to the costs of such a policy. They assert that the rapid expansion of patent activity occasioned by Bayh-Dole has created an emerging "anticommons" effect, a phenomenon where resources of an economy may become underutilized as a result of a plethora of competing legal interests in those resources, with a consequent inability of the legal stakeholders of such resources to resolve their diverse interests in an efficient way.[2] The commentators warn that, as a result of this anticommons effect, critically necessary technology tools are at risk of becoming "locked up" by research university stakeholders via the patent process and, as a result, research and technology

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1. Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C.A. §§ 200–212 (2001 & West Supp. 2003)).

2. *See infra* Part II.

transfer activities will be hindered.[3]

A new event has now rocked the technology transfer sector. A Federal Circuit case, *Madey v. Duke University*,[4] has been widely read to have substantially scaled back the experimental use defense in patent infringement cases, with the result that it is now unclear whether a nonprofit research institution may use, for purposes of pure research or scientific experimentation, or even for educational purposes, third-party patent rights without first obtaining permission from the owner to do so, and to pay a fee for the privilege if required.[5]

This article will address the effect of this new decision on the federal patent policy regimen established by the Bayh-Dole Act, and in particular, whether this holding will serve to impair the positive effects that the Act was enacted to achieve. It will also address whether this decision may serve to exacerbate the alleged anticommons effect of complex, multi-party structures of patent ownership regarding patented technologies.

Part I will discuss the statutory framework of the Bayh-Dole Act and will describe how it is designed to work in practice. Part II will analyze the effects, both positive and negative, of Bayh-Dole. Part II will also examine the substantial economic effects of the Act on educational institutions within the United States and on the economy as a whole, as well as the exponential growth of the "start-up" company sector of the U.S. economy, which is fueled by the many "incubators" established by universities and local government—growth that has been directly linked by many commentators to Bayh-Dole. Part II will also review the arguments advanced regarding the negative effects of the statute as a result of the anticommons effect. Part III will review the actual holding of *Madey* and analyze whether the case was decided consistent with precedent concerning the experimental use defense and, importantly, whether *Madey* may serve to complicate the alleged anticommons effect of Bayh-Dole. Part IV will provide observations about possible remedies to alleviate the anticommons effect, at least as it may pertain to research and development activities now complicated by *Madey*, including the creation of a collective rights organization arrangement for research-only licensing along the lines of the proposals advanced by Professor Merges and others to ameliorate the anticommons effect of Bayh-Dole generally.

I. THE EMERGENCE OF BAYH-DOLE

The enactment of the Bayh-Dole Act[6] in 1980 established a settled federal patent policy with the following goals: (1) the establishment of a uniform federal policy for the disposition of patent rights created as a result of government-sponsored research; (2) the disposition of those patent rights to the private sector, particularly nonprofit institutions, with the aim of providing financial support to, and encouraging research activities at, those institutions; and (3) the licensing of those patent rights to commercial partners of those nonprofit institutions,

3. *Id.*
4. 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 535 U.S. ___, 123 S. Ct. 2639 (2003).
5. *See infra* notes 91–112 and accompanying text.
6. 35 U.S.C.A. §§ 200–212 (2001 & West Supp. 2003).

particularly emerging small business, so that the United States as a whole could benefit from the developed technology.[7]

Review of the law itself demonstrates that it was carefully crafted to effectuate these goals. The centerpiece of Bayh-Dole was the provision that a nonprofit organization or a small business firm which developed a "subject invention" with the support of federal funding now had the right to elect to retain title to that invention if it complied with certain conditions.[8] A "subject invention" was defined as any invention of the contractor which was conceived or first actually reduced practice in the performance of work under a "funding agreement."[9] The term "funding agreement," in turn, was defined as any contract entered into between the contractor and any federal agency for the performance of experimental, developmental, or research work funded in whole or in part by the federal government.[10]

This grant came with certain conditions. First, the contractor was required, within a reasonable period of time, to disclose the subject invention to the federal agency that provided funding; failure to do so would result in the federal government receiving title to any such invention.[11] In addition, the contractor, within two years after disclosure, was required to make a written election indicating whether or not it would retain title or whether it wished to cede title to the federal government.[12] A contractor that elected to retain right would then be required to file a patent application prior to any statutory bar date,[13] as well as file any corresponding foreign applications,[14] within a reasonable time. In addition, the federal funding agency retained a non-exclusive, non-transferable, paid-up license to practice the invention throughout the world for governmental purposes.[15] The federal agency could also require periodic reporting on the efforts made to obtain utilization of a subject invention,[16] and that any U.S. patent application filed by the contractor concerning a subject invention include in its specification a statement specifying that the invention was made with the support of the government and that the government retained certain rights in the invention.[17]

7. *See id*. § 200.

8. *Id*. § 202. While the penumbra of Bayh-Dole initially extended only to nonprofit organizations or small business concerns, in 1983, President Ronald Reagan quietly extended the reach of Bayh-Dole by providing a Presidential Memorandum to federal agencies which required agencies to include *all* businesses which performed research for the government, regardless of size. *See* Rebecca S. Eisenberg, *Public Research and Private Development: Patent and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1665–66 n.8 (1996). That Presidential Memorandum was subsequently adopted shortly thereafter by Congress in a non-publicized housekeeping amendment to the statute. *Id*. at 1694–95.

9. 35 U.S.C.A. § 201(e) (2001).

10. *Id*. § 201(b).

11. *Id*. § 202(c)(1).

12. *Id*. § 202(c)(2).

13. *Id.* § 202(c)(3).

14. 37 C.F.R. § 401.14(c)(3) (2003).

15. 35 U.S.C.A. § 202(c)(4) (2001 & West Supp. 2003).

16. *Id*. § 202(c)(5).

17. *Id*. § 202(c)(6).

In the case of a contractor which was also a nonprofit organization, the following restrictions also applied: (1) rights to a subject invention could not be assigned to a third-party by the contractor without approval of the federal agency that provided funding, unless the transfer was to an organization that has as one of its primary functions the management of inventions; (2) the contractor was required to share royalties with the actual inventors and employees who had participated in the discovery; (3) royalties that were not paid to the inventors were to be put into scientific research or education; (4) whenever possible, the contractor was to favor entering into licenses with small businesses; and (5) certain additional requirements were to be followed concerning the spending of royalties and the administration of licenses for government-owned contractor-operated facilities.[18]

In addition, a participating small business firm or nonprofit organization could not, absent government approval, grant an exclusive license to use or sell the invention unless the licensor agreed that any product embodying the subject invention would be manufactured substantially within the United States.[19]

Finally, the statute reserved to the federal government the ability to require the contractor to grant a non-exclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that were reasonable, based upon a showing of the following conditions: (1) that the contractor had not taken or was not expected to take steps within a reasonable time to achieve practical application of the invention; (2) there was a special need for reason of health or safety, or in order to meet requirements for public use, to license the technology; or (3) there had not been an implementation of the preference for using the technology within the United States.[20] The terms of this provision were known as the federal agency's "march in rights."

Thus, following the enactment of Bayh-Dole and its companion and amending legislation throughout the 1980s,[21] federal patent policy had become clear. Except in rare instances, patent rights to inventions developed through the use of federal funds could be retained by those contractors who develop that technology subject only to: (1) a non-exclusive right to use that technology granted to the federal government; and (2) the rarely used "march in" right of the government to take the

18. *Id*. § 202(c)(7).

19. 35 U.S.C.A. § 204 (2001).

20. 35 U.S.C.A. § 203 (2001 & West Supp. 2003).

21. The Stevenson-Wydler Technology Innovation Act, Pub. L. No. 96-480, 94 Stat. 2311 (1980) (codified as amended at 15 U.S.C.A. §§ 3701–3714 (1998 & West Supp. 2003)), extends Bayh-Dole's policy to government-owned, contractor-operated laboratories, requiring them to establish an Office of Research and Technology Application to facilitate transfer of technology developed entirely by government employees to the private sector. 15 U.S.C.A. § 3710 (1998 & West Supp. 2003). The Federal Technology Transfer Act, Pub. L. No. 99-502, 100 Stat. 1785 (1986) (codified as amended at 15 U.S.C.A. § 3710 (1998 & West Supp. 2003)), amended the Stevenson-Wydler Act to authorize *all* governmental laboratories to enter into Cooperative Research And Development Agreements ("CRADAs") to facilitate, subject to the reservation of a royalty-free license, the assignment of patents to inventions made by federal employees to the collaborating companies and to waive any federal claims made to such inventions. *Id*. § 3710(a)–(c).

technology away from the contractor and give it to another, in the event that the contractor did not develop the technology. As will be shown in Part II, this statute has had enormous repercussions on technology transfer in the United States, both positive and, in the eyes of some, negative.

II. THE EFFECT OF BAYH-DOLE: BENEFITS AND DRAWBACKS

The effect of Bayh-Dole has been profound. By every measure, the last twenty-five years of university technology transfer involving inventions created as a result of federally-sponsored research has shown extraordinary growth. According to statistics published by the Association of University Technology Managers ("AUTM"), a professional organization comprised of technology transfer professionals affiliated with colleges and universities, the number of patents granted annually to universities has exploded, from 619 in 1986[22] to 3,673 in 2002.[23] In fact, statistics reveal that the college and university sector now receives approximately three percent of *all* U.S. patents issued.[24] Moreover, as revealed in a recent survey conducted by AUTM, patenting and licensing activity is decidedly on the upswing. For example, at the end of fiscal year 2002, the university sector reported 26,086 active licenses or options.[25] Invention disclosures for universities have been increasing each year and in 2002 reached 15,573, with 7,741 new patent applications filed by AUTM member organizations.[26]

As a result of this surge in patenting and licensing activities, universities, and teaching hospitals affiliated with universities, have experienced adjusted gross license income that is estimated to be nearly $1.267 billion as of 2002, with running royalties on product sales of $1.005 billion.[27] Supporters of Bayh-Dole note that this success has been achieved without any cost to taxpayers in that no separate appropriation of government funds has been needed to either establish or manage this effort.[28] Supporters also cite estimates that the economic benefit flowing from university licensing activities adds about $41 billion annually to the U.S. economy.[29]

Equally impressive is the emergence of the "start-up" company sector of the U.S. economy which finds its basis in the technology generated during the course of sponsored research at universities. Since 1980 at least 2,922 new companies

22. *See* Howard Bremer, *The First Two Decades of The Bayh-Dole Act as Public Policy*, Presentation to National Association of State Universities and Land Grant Colleges (Nov. 11, 2001) *available at* http://www.nasulgc.org/cott/bayh-dohl/bremer_speech.htm [hereinafter Bremer Presentation].

23. *See* AUTM, Licensing Survey: FY 2002 A Survey Summary of Technology Licensing and Related Performance of U.S. and Canadian Academic and Nonprofit Institutions, and Patent Management and Investment Firms, *available at* http://www.autm.net/surveys/02/2002spublic.pdf [hereinafter 2002 AUTM Licensing Survey].

24. Bremer Presentation, *supra* note *22*.

25. 2002 AUTM Licensing Survey, *supra* note 23, at 1.

26. *Id*.

27. *Id*.

28. Bremer Presentation, *supra* note 22.

29. *Id*.

have been formed which have as their major asset a license on technology developed at an academic institution, including 344 such companies created in 1999 alone.[30] This "start-up" company phenomenon is closely tied to the emerging use of "incubators," or small business centers created to develop small high-tech businesses throughout the United States. This model, which was first used to commercialize technology developed in government-sponsored labs, was extended by both universities and local government as a way to follow the mandate of Bayh-Dole—to foster entrepreneurship in technology transfer at research institutions.[31] It is estimated that in 2001 alone, "North American incubators assisted more than 35,000 start-up companies that provided full-time employment for nearly 82,000 workers and generated annual earnings of more than $7 billion."[32] The National Business Incubator Association has estimated that the "graduates" of North American incubators have created approximately 500,000 jobs since 1980.[33]

Other commentators point to the possible adverse effects of Bayh-Dole. One issue identified by commentators as an emerging problem causally related to Bayh-Dole is a doctrine memorably labeled the "tragedy of the anticommons." In a pioneering article published in Science Magazine in May 1998, law professors Michael Heller and Rebecca Eisenberg explained the concept as follows: "The 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."[34] According to this theory, each "upstream" patent (i.e., a patent on fundamental or basic technology) allows its owners to set up a "toll booth" on the road to product development, adding to the cost and slowing the pace of "downstream" innovation (i.e., a commercial product).[35] Heller and Eisenberg theorized that this phenomenon has been inadvertently aggravated by the surge in federal government-sponsored research and the consequent increase in patent activity on the part of the research universities.[36] Professor Eisenberg, in another law review article authored in 2003 with Professor Rai of the University of Pennsylvania Law School, noted a further anticommons aggravation: many university-owned patents do not cover commercial-ready technologies, but rather cover fundamental research discoveries and research tools,[37] and thus the anticommons effect has a directly deleterious effect on basic research and development efforts.[38]

30. *Id*.

31. *See* DC Venture Partners, *An Incubator Primer*, *at* http://www.dotcomventuresatl.com/incubators.htm (last visited Feb. 11, 2004).

32. National Business Incubation Association, Business Incubation Facts, *available at* http://www.nbia.org/resource_center/bus_inc_facts/index.php (last visited Feb. 11, 2004).

33. *Id*.

34. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998) (identifying anticommons problems in biomedical research).

35. *Id*. at 699.

36. *Id.* at 698.

37. Arti K. Rai & Rebecca S. Eisenberg, *A Public Domain: Bayh-Dole Reform and Progress of Bio-Medicine*, 66 LAW & CONTEMP. PROBS. 289, 292 (2003).

38. *Id.*

As an example of the problems created by this anticommons effect, Heller and Eisenberg discussed, in Science Magazine, the multiplicity of patent filings for newly identified DNA sequences including gene fragments.[39] Heller and Eisenberg pointed out that although a database of gene fragments is a useful resource for discovering and defining property rights around isolated gene fragments, patenting that database serves to compound the problem of developing a commercial product such as therapeutic proteins or genetic diagnostic tools because these commercial products are more likely to require the use of multiple rather than single fragments.[40] Therefore, a proliferation of patents on individual fragments held by different owners will inevitably require costly future legal transactions to bundle licenses together before a company seeking to commercialize this technology can have an effective right to develop these products.[41]

The anticommons theory is by no means universally accepted. Some commentators argue that there is no empirical evidence whatsoever to support the theory, and that all arguments rest on merely colloquial evidence.[42] In that regard, it does appear that no hard evidence of actual factual situations which demonstrate the failure of the ability to commercialize a technology as a result of the anticommons effect has ever been proffered by Heller, Eisenberg, Rai, or any other commentator articulating an anticommons concern.

Whether academic or real, Heller and Eisenberg's theory does raise an undeniably important concern. As the statistics set forth by AUTM and others so vividly reveal, the level of patenting in the United States as a result of government-sponsored research institution activity has dramatically increased. If, as Heller and Eisenberg have theorized, these patents typically relate more to items of basic research tools rather than to "downstream" commercial products, it appears likely that a company which attempts to commercialize these technologies would at least face some difficulty navigating around numerous "blocking" patent rights in order to develop clear title so as to be able to successfully commercialize the technology.

Thus, the Bayh-Dole Act, while having undeniably salutary goals and a profound economic impact, may also have hidden deleterious effects that may actually serve to hinder these salutary goals. Moreover, as will be shown in Part III, the anticommons effect of the statute may well be aggravated as a result of new limitations upon the experimental use defense.

III. THE CHALLENGE TO BAYH-DOLE AS A RESULT OF *MADEY*

A recent Federal Circuit decision that appears to have sharply rolled back the experimental use defense in patent infringement cases may well have aggravated the problems that naturally arise as a result of the Bayh-Dole Act.[43]

39. Heller & Eisenberg, *supra* note 34, at 698–701.

40. *Id*. at 698–700.

41. *Id*. at 700.

42. Interview with Howard Bremer, Patent Counsel to Wisconsin Alumni Research Foundation and a leading commentator to the Bayh-Dole Act (Dec. 2, 2003).

43. *See* Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 535 U.S. ___,

Courts have historically recognized that some uncompensated or unlicensed use of patented technology should be allowed. In 1883, in the landmark case of *Whittemore v. Cutter*,[44] the plaintiff brought an action against the defendant for an infringement of plaintiff's patent for a machine that produced playing cards.[45] In his decision, Justice Story for the first time carved out a new defense to an infringement action based on mere experimental use of the patented technology by the alleged infringer, issuing the memorable phrase that it could never have been the intention of the legislature to punish the use of patent rights "merely for philosophical experiments or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[46] The exception was further refined in *Sawin v. Guild*[47] where Justice Story stressed that the pertinent inquiry was whether the use was 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."[48] Read together, these seminal cases established the view that the key issue for determination by the court was whether the challenged use of the patented technology was either for commercial purposes or for experimental purposes.

Generally, the early cases which followed *Whittemore* and *Sawin* reiterated this view: if the challenged activity was merely to assess the usefulness of a technology or to generally further research, the use was upheld. For example, in *Akro Agate Co. v. Master Marble Co.*,[49] the defendants used the plaintiff's patented marble-making machine merely to determine whether or not the machine would be useful in their business.[50] The court held that defendant's use of the machine was therefore not infringement because it was merely to assess the usefulness of plaintiff's machine and not for actual manufacture of marbles for commercial sale.[51] In *Chesterfield v. United States*,[52] where the plaintiff claimed that defendant infringed a patent which protected an invention used to produce improved cutting tools,[53] the district court held that, even though the patents themselves were invalid, defendant's use would not have been infringing even if the patents were valid because the defendants did not market, manufacture, or sell any of the patented articles. [54] The district court held the challenged use non-infringing because, at most, the use of the alloy in question was only for experimental use and testing.[55]

123 S. Ct. 2639 (2003).

44. 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).
45. *Id*. at 1121.
46. *Id*.
47. 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391).
48. *Id*. at 555 (internal citation omitted).
49. 18 F. Supp. 305 (D. Va. 1937).
50. *Id*. at 315.
51. *Id*. at 333.
52. 159 F. Supp. 371 (Ct. Cl. 1958).
53. *Id*. at 372.
54. *Id*. at 376.
55. *Id*.

On the other hand, in these early cases, courts would not hesitate to refuse to extend the doctrine where commercial use was in fact demonstrated. For example, in *Cimiotti Unhairing Co. v. Derboklow*,[56] defendant claimed that his use of the patented machines was merely for the purpose of experiment;[57] the circuit court held, however, that the actual commercial sale of products utilized through the use of such machines made such use non-experimental.[58] In *Baxter Diagnostics Inc. v. AVL Scientific Corp.,*[59] the district court held that research and development use of third-party technology by a commercial concern which was engaged in the manufacture and sale of the very type of devices and activities which were being examined could not be considered "merely gratifying its curiosity or scientific tastes."[60]

Only one case during this time period appears to address the situation where the alleged infringer, seeking to avail itself of the defense, was an educational institution. In the 1935 case of *Ruth v. Stearns-Roger Manufacturing Co*.,[61] the district court, without elaborate discussion, held that the Colorado School of Mines was not guilty of infringement as a result of the defense because the use in question was for educational or research purposes.[62] The district court did not detail, however, what that specific educational purpose was. Close reading of the case only reveals that the infringing devices were "cut up" and "used for experimental purposes."[63] Unfortunately the case offers no other details of the actual use.

In more modern times, however, a more restrictive approach to the experimental use defense seemed to emerge from the Federal Circuit. In 1984, the Federal Circuit decided *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*[64] In *Roche Products*, Bolar, the allegedly infringing party, obtained from a foreign manufacturer the active ingredient to Dalmane, a sleeping pill manufactured by Roche, for purpose of testing to determine stability data, dissolution rates, bio-equivalency studies, and blood serum studies necessary for a new drug application to the United States Food and Drug Administration ("FDA");[65] as a result, Bolar infringed the patent rights held by plaintiff Roche.[66] The use was occasioned by Bolar's desire to make a generic equivalent to Dalmane as soon as the patent term for Dalmane expired.[67] The district court held that Bolar's use came within the experimental use, because it was experimental and also de minimis.[68]

56. 87 F. 997 (C.C. N.Y. 1898).
57. *Id*. at 997–98.
58. *Id*. at 999.
59. 798 F. Supp. 612 (C.D. Cal. 1992).
60. *Id.* at 620.
61. 13 F. Supp. 697 (D. Colo. 1935).
62. *Id*. at 713.
63. *Id*. at 703.
64. 733 F.2d 858 (Fed. Cir. 1984).
65. *Id*. at 860.
66. *Id*.
67. *Id*.
68. Roche Prods., Inc. v. Bolar Pharm. Co., 572 F. Supp. 255, 258 (E.D. N.Y. 1983).

The Federal Circuit reversed, specifically noting that the experimental use exception was "truly narrow," and that it should not be construed so 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."[69] The Federal Circuit held: "Bolar may intend to perform 'experiments,' but unlicensed experiments conducted with a view to the adaptation of the patented invention to the experimenter's business is a violation of the rights of the patentee to exclude others from using his patented invention."[70]

Roche was, in part, statutorily overruled by 35 U.S.C. § 271(e)(1), which now provides immunity from infringement liability for a person or entity to use patented technology solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture of generic drugs, and acts to provide a safe-harbor immunity to generic drug manufacturers when those manufacturers use third-party-owned technology in its final years of patent protection during the course of FDA-required clinical trials and other regulated research steps.[71] Nevertheless, the *Roche* holding survives for situations not involving generic drug testing, and consequently has been widely read as limiting the experimental use defense in research and development activities when those research and development activities were "with a view" toward adaptation for commercial use.

A federal claims court case, *Deuterium Corp. v. United States*,[72] (decided in 1990 by Judge Randall Rader, a prominent figure in later Federal Circuit decisions involving the experimental use defense) also lends support to the emerging view that the experimental use defense would only be narrowly applied for "strictly intellectual experimentation,"[73] and would not apply where such uses were "designed to adapt the invention to pecuniary and business uses."[74] In *Deuterium*, the claims court determined that the demonstration project under challenge was not for strictly intellectual experimentation, but was instead development of technology and processes for commercial application, thus depriving defendant of the use of the defense.[75] Judge Rader observed that the analysis of whether a use was experimental or commercial in the situation at hand was "complex" because part of the "legitimate business" of the alleged infringer was in fact the conducting of experiments and demonstration projects,[76] thus signaling a concern regarding the proper treatment to be afforded a defendant whose regular business was in research rather than in the development of commercial products, a concern that foreshadowed the actual fact pattern faced by the Federal Circuit in *Madey*.[77]

In 2000, the Federal Circuit next had an opportunity to review the defense. In

69. *Roche*, 733 F.2d at 863.
70. *Id*.
71. 35 U.S.C.A. § 271(e)(1) (2001).
72. 19 Cl. Ct. 624 (1990).
73. *Id*. at 633.
74. *Id.*
75. *Id.*
76. *Id*. at 632.
77. *See infra* notes 91–112.

Embrex v. Service Engineers Corp.,[78] the Federal Circuit, while still confirming the existence of the defense, refused to apply the experimental use defense where the court determined that certain tests conducted by defendant, using plaintiff's patented process of inoculating the yolk sac of chickens, did not immunize defendant from liability[79] because the tests were conducted for the ultimate purpose of attempting to design around plaintiff's patented processes and to commercialize an alternative injection process.[80] Judge Rader, then on the Federal Circuit, wrote a concurring opinion flatly declaring that the experimental use defense no longer existed at all,[81] seizing on a comment in the Supreme Court decision of *Warner-Jenkinson Co. v. Hilton Davis Chemical Co*.[82] that "application of the doctrine of equivalents . . . is akin to declaring literal infringement, and neither requires proof of intent."[83] Judge Rader argued that *Warner-Jenkinson's* new "reiteration" that a finding of infringement did not depend upon the underlying intent of the infringer (which he construed to be a defense based upon intent not to use for commercial purposes) therefore served to abrogate the experimental use defense.[84]

The observation is revealing, to say the least. Judge Rader, by now unmistakably demonstrating outright hostility to the experimental use defense, neglected to explain in his concurring opinion specifically how it was that intent ever had anything to do with the defense in the first place. His broad statement that before *Warner-Jenkinson* the Federal Circuit in *Roche* was able to address "arguments based on the character or intent of infringement,"[85] and now, following *Warner-Jenkinson*, it could not,[86] was made without the benefit of reference to any specific statement in *Roche* so stating. Indeed, a fair reading of *Roche* would suggest that the intent of the alleged infringer was completely irrelevant to the wholly objective determination of the court regarding whether the use was experimental or commercial.[87] In addition, review of the prior case law on the experimental use defense reveals no case that had centered on a finding of intent. Finally, despite the logical implication of Judge Rader that some "new" pronouncement had emanated in *Warner-Jenkinson* regarding the issue of intent to infringe, thus calling for a review of related doctrines, including the experimental use defense, it had certainly never been the law before *Warner-Jenkinson* that only

78. 216 F.3d 1343 (Fed. Cir. 2000).

79. *Id.* at 1348–49.

80. *Id*. at 1349.

81. *Id.* at 1352–53.

82. 520 U.S. 17 (1997).

83. *Embrex*, 216 F.3d at 1353 (Rader, J., concurring) (quoting *Warner-Jenkinson Co.*, 520 U.S. at 34).

84. *Id.*

85. *Id.*

86. *Id*.

87. Judge Rader evidently seized on the language of the *Roche* panel which occasionally referred to the defendant's "intended" experimental use, but the Federal Circuit, consistent with prior precedent, objectively determined whether the use was commercially oriented or not regardless of the intent of the defendant. Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 862 (Fed. Cir. 1984).

intentional infringement is actionable—clearly, it is hornbook law that infringement occurs regardless of intent.[88] Judge Rader's view is thus perplexing.

Therefore, prior to 2002, while courts seemed settled in the view that the experimental use exception was to be construed narrowly,[89] there was nevertheless a well-recognized ability to examine and use third-party technology for non-commercial purposes. While restrictions on the use of the defense in research activities did occur, it only occurred where a defendant was found to have been involved in activities "with a view" toward adaptation for commercial use, although as hinted in *Deuterium,* a "complex" situation could arise when the primary business of the alleged infringer was in the field of pure research and development.[90]

It therefore came as quite an unpleasant surprise to the technology transfer community when *Madey v. Duke University*[91] was decided. In *Madey*, a professor, while employed at another university, had developed and then patented certain intellectual property rights concerning laser research.[92] He left that first university for employment at Duke, where he integrated some of his patented laser technology in equipment developed in a Duke research lab.[93] He then left Duke in an employment dispute.[94] Duke continued to use devices which had integrated Madey's patented technology in its laboratories.[95] Madey then sued Duke for patent infringement, and Duke asserted a defense based on experimental use, claiming that its activities were non-infringing because Duke was a nonprofit entity and was only using the patented technology for non-commercial research activities.[96]

The Federal Circuit's decision stunned the university technology community. First, Justice Gajarsa, speaking for the unanimous panel (a panel that did not include Judge Rader) held that Madey's arguments that the experimental use defense had been abrogated entirely by *Warner-Jenkinson* (an argument inspired by Judge Rader's concurrence in *Embrex*) was unavailing and that the experimental use defense in fact survives, "albeit in the very narrow form" as already articulated in *Embrex* and *Roche.*[97] The Federal Circuit then determined that the district court had erred when it shifted the burden to the plaintiff to demonstrate whether the use came within the defense; defendant, held the Federal Circuit, bore such a burden.[98] The Federal Circuit, holding the district court to task for what it termed an "overly broad conception" of experimental use,[99] indicated

88. CHISUM ON PATENTS § 16.02 (2003).
89. *Roche*, 733 F.2d at 863.
90. *See generally* Deuterium Corp. v. United States, 19 Cl. Ct. 624, 632 (1990).
91. 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 535 U.S. ___, 123 S. Ct. 2639 (2003).
92. *Id.* at 1352.
93. *Id.*
94. *Id.* at 1353.
95. *Id.*
96. *Id.* at 1362.
97. *Id.* at 1360–61.
98. *Id*. at 1361.
99. *Id.*

that the defense would be inapplicable to uses that had the "slightest commercial implication"[100] or "in keeping with the legitimate business of the alleged infringer."[101] The Federal Circuit then flatly held that irrespective of Duke's nonprofit status, Duke's research-only activities could nevertheless be considered "commercial" use and thus outside the experimental use defense:

> [R]egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is furtherance of the alleged infringer's legitimate businesses 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.[102]

The Federal Circuit stated that the district court had placed too great a weight on the nonprofit educational status of Duke, and had effectively suppressed the fact that Duke's acts "appear to be in accordance with any reasonable interpretation of Duke's legitimate business objectives."[103] The Federal Circuit therefore remanded the case with instruction to the district court to focus its inquiry not on the nonprofit status of Duke but on the legitimate business Duke was involved with, and whether or not the challenged use was "solely for amusement, to satisfy idle curiosity or for strictly philosophical inquiry."[104]

The Federal Circuit had particularly interesting things to say about the only reported prior case involving application of the defense to an educational institution, *Ruth v. Stearns-Roger Manufacturing Co.*[105] Stating that the "case represents the conceptual dilemma that may have led the district court astray,"[106] the Federal Circuit first underscored the fact that the reason why the *Ruth* court held that the experimental use defense applied was because of the combination of the nonprofit educational status of the defendant with the lack of evidence of commerciality of the use.[107] Even there, the Federal Circuit criticized the *Ruth* holding as not providing a detailed analysis of the character, nature, and effect of the use, an analysis the Federal Circuit stated would be required under its current precedent.[108] The Federal Circuit cautioned that *Ruth* could not be read in any way to immunize any conduct that was "in keeping with the alleged infringer's legitimate business, regardless of commercial implications."[109] The Federal

100. *Id.* at 1362 (quoting Embrex v. Service Engineers Corp., 216 F.3d 1343, 1353 (2000) (Rader, J., concurring)).

101. *Id.* (quoting Pitcairn v. United States, 547 F.2d 1106, 1125–26 (Ct. Cl. 1976)).

102. *Id.*

103. *Id*. In a footnote, the Federal Circuit then observed that Duke, like other major research institutions of higher learning, was "not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream." *Id*. at 1367 n. 3.

104. *Id*. at 1363.

105. 13 F. Supp. 697 (D. Colo. 1935), *rev'd*, Stearns-Roger Mfg. Co. v. Ruth, 87 F.2d 35 (10th Cir. 1936).

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

107. *Id.*

108. *Id.*

109. *Id.*

Circuit then sent waves of terror though major research universities when it stated that research projects with arguably no commercial application nevertheless "unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects,"[110] and by clear implication, would therefore not be clothed with the privilege.[111]

Despite such sweeping statements, however, the actual *Madey* holding is somewhat enigmatic. Clearly, the Federal Circuit has held that the experimental use defense will never apply even in a nonprofit educational setting when the challenged use is for the purpose for which a patented device is made, which was the precise question before it; the actual challenged use was the use of Madey's laser technology by Duke in an improved product that it had created, not testing or otherwise experimenting with the technology. The larger, and unanswered, question is whether the decision, with its sweeping dicta, can be read to flatly prohibit use of third-party technology for any nonprofit research or educational purposes whatsoever, and specifically in those instances where an educational institution uses patented technology of another for either pure educational purposes (i.e., educating students) or for research activities directed toward understanding or improving the design or operation of a patented product or process.[112]

If the direction of the Federal Circuit was not clear after *Madey,* it has certainly not been clarified by the next (and as of this writing latest) major decision on experimental use, issued by the Federal Circuit subsequent to *Madey,* entitled *Integra Lifesciences I, Ltd. v. Merck.*[113] In *Integra*, pursuant to a research agreement with Merck, Scripts Research Institute began an investigation into potential drug candidates that might inhibit angiogenesis, the process for generating new blood vessels, for possible use in inhibiting rapid tumor growth or for treatment of other disease.[114] Integra was the holder of certain patents which it claimed precluded Merck's use of certain RGD peptides, which were allegedly used by Scripts during the course of its research.[115] Integra sued Merck for patent infringement.[116] The Federal Circuit found as a factual matter that Merck, through Scripts, was in fact using such peptides in its research activities.[117] Merck sought to defend on the safe harbor defense offered by 35 U.S.C § 271(e)(1),[118] which as discussed previously, provided immunity from infringement liability for a person to use patented technology solely for uses reasonably related to obtaining FDA and other approvals of general equivalents.[119] The Federal Circuit, however, held that the Merck investigation was not confined to efforts to obtain federal regulatory

110. *Id*.

111. *Id*.

112. *See, e.g.*, Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 878 n.10 (Fed. Cir. 2003) (Newman, J., dissenting in part, concurring in part).

113. 331 F.3d 860 (Fed. Cir. 2003).

114. *Id.* at 863.

115. *Id.*

116. *Id*.

117. *See id.* at 862–64.

118. *See id.* at 863.

119. *See supra* note 71 and accompanying text.

approval but was instead general bio-medical research to identify new pharmaceutical compounds (which the dissent labeled "discovery-based" research)[120] and therefore not entitled to the exemption.[121] The Federal Circuit therefore held in favor of Integra.[122]

The truly interesting aspect of *Integra* related to the dicta traded between Judge Rader's majority decision and Judge Newman's dissent. The first volley appeared in a footnote appearing early on in the majority decision, where Judge Rader took elaborate pains to address arguments contained in Judge Newman's dissent that the majority had deliberately ignored the common law experimental use defense.[123] Judge Rader insisted that the decision only addressed the statutory experimental use defense of § 271(e)(1) and its safe harbor for clinical trials and other necessary steps for generic drug approval, and that the defendant had not pled or attempted to prove the common law experimental use defense and even had specifically advised the Federal Circuit at oral argument of the appeal that it was not relevant.[124] This presumed lack of relevance, however, did not dissuade Judge Rader from then launching into a broadside against the defense, albeit in a footnote, in which he stated that even if the defense was raised, the Federal Circuit would not find such an experimental use to be allowable in this instance, if even again.[125] Judge Rader went on to observe that the experimental use defense should not even be a defense at all, but, if anything, a doctrine of de minimis infringement allowing, at best, a mitigation of damages.[126]

Judge Newman had a very different view. In the opening sentence of her opinion, she flatly contradicted the majority's observations that the case merely concerned § 271(e)(1) immunity and stated that the case very much had to do with the common law experimental use defense,[127] even later noting the apparent disingenuousness of the majority's arguments to the contrary by referring to a statement from oral argument, where counsel for Merck stated that it decided not to press the experimental use argument on appeal "in part because of a very recent case," [128] obviously referring to *Madey*. She claimed that the majority opinion, by refusing to even consider the common law experimental use defense, in effect held that any discovery-based research will no longer be clothed with the defense, even though, as aforesaid, Judge Rader's majority opinion took great pains to state that the common law defense was not before the Federal Circuit.[129] She eloquently stated that the essential question to be addressed by the Federal Circuit to clarify the true reach of the defense was, "whether and to what extent, the patentee's

120. *Integra*, 331 F.3d at 872.
121. *Id.* at 866.
122. *Id*. at 872.
123. *Id.* at 863–64 n.2.
124. *See id*. at 872–78 (Newman, J., dissenting).
125. *Id.* at 863–64 n.2.
126. *Id.*
127. *Id.* at 872.
128. *Id.* at 878.
129. *Id*. at 863.

permission is required in order to study that which is patented."[130]

The rest of Judge Newman's opinion set forth how she would answer that question. She would emphatically retain the defense, for it "facilitates further knowledge and understanding of what was done by the patentee, and may lead to further technologic advance,"[131] and that "[t]he right to conduct such research to achieve such knowledge need not, and should not, await expiration of the patent."[132] She revisited the original decisions which articulated the defense in the first instance, *Whittemore* and *Sawin,* and in a footnote, opined that the use of the phrase "philosophical experiments" by Justice Story was typical nineteenth-century parlance for "natural philosophy, the term then used for what we today call 'science,'"[133] suggesting that Justice Story actually intended to encompass scientific research activities when he first articulated the defense nearly two hundred years before. She also inserted a footnote to underscore her view that *Madey* should be restricted to its facts, and that its holding only related to the use of a patent device for the purpose for which it was made, rather than a use which related to research efforts into understanding or improving the design or operation of the machine,[134] thus attempting to reserve arguments over the true reach of *Madey* for another day. She stated that she did not undertake in her decision to define the boundaries of the research exception for all purposes and activities, other than to observe that there is a "generally recognized distinction between 'research' and 'development' as a matter of scale, creativity, resource allocation, and often the level of scientific/engineering skill needed for the project."[135] These considerations, in her view, could "serve as a useful divider, applicable to most situations."[136] Turning to apply these considerations to the facts in *Integra*, Judge Newman posited that the actual activity under challenge was merely laboratory experimentation, or at most the development of data for ultimate presentation to the FDA, which she considered either exempt exploratory research, or immunized by § 271(e)(1).[137]

In the end, *Integra* serves at best as a debate of dicta between two very articulate jurists, neither of which, at least at this juncture, actually carry the force of law. Judge Rader's pronouncements that the experimental use defense should henceforth be relegated to an issue merely going to mitigation of damages only, buried in a footnote, and irrelevant to the court's carefully limited holding regarding the reach of § 271(e)(1), is clearly dicta, and Judge Newman's arguments in her dissent in part are clearly her own alone.

The question of the precise status and scope of the experimental use defense thus remains to be decided by the Federal Circuit. For now, Judge Newman's

130. *Id*. at 873.
131. *Id*.
132. *Id*.
133. *Id*. at 874–75 n.8.
134. *Id.* at 878 n.10.
135. *Id.* at 876.
136. *Id.*
137. *Id*. at 877.

observation in *Integra* that *Madey* should be restricted to its facts and only prohibits use for the purpose of which a patented technology was made, appears to represent the most reasonable view amongst the many commentators who have attempted to decipher *Madey*. But clearly, even so restricted, that holding itself represents a significant contraction of the reach of the experimental use defense in the eyes (and usual practice) of the nonprofit research institution sector, who, until *Madey,* had always believed that all research and development activities, unless clearly made in furtherance of the development of a tangible commercial product, were protected by this defense. Moreover, it is certainly possible that cases which follow *Madey* will elaborate on the dicta in *Madey* which seemingly implied that even the use of third-party patented technology by an educational institution in pursuit of its "business objectives" of "educating and enlightening students"[138] might not be clothed with the privilege, a result which would create a contraction of the experimental use defense to an almost non-existent state. Thus, under any practical measure, *Madey* has vastly diminished the availability of the experimental use defense by a research institution when it conducts virtually all of its sponsored research.

This limitation will most likely have a number of effects. First, it will substantially increase the cost of doing business for the research institution. If research at an educational institution involves the use or even review of third-party-technology, permission from the owner of that technology would probably be needed. Unless universities can arrive at some kind of courtesy exchange of intellectual property rights (and that could be complicated if the relevant patented technologies are in the hands of a competitor, whether commercial or nonprofit, who may not wish to help the university develop competing technology), it is quite likely that the cost of research will increase, perhaps substantially. If one proceeds on the assumption that the Bayh-Dole Act was intended to encourage and facilitate research activities at nonprofit educational institutions, the imposition of this cost factor on what could even be basic research in a nonprofit, non-commercial setting would certainly seem to impair this goal.

More significantly, it is clear that the imposition of this experimental use limitation will serve to exacerbate whatever anticommons phenomenon that has been set in motion by Bayh-Dole. It is bad enough, as Heller and Eisenberg have argued, that Bayh-Dole, with its widespread patent activity by research universities, may have begun to tie up the basic research tools that are necessary to conduct downstream product commercialization.[139] Add to this mix the inability to even *experiment* with third-party technology in pure research and development activities without being able to easily secure the often myriad approvals necessary to unblock patent rights, and these hurdles will greatly complicate the work of the research institution. Instead of the tragedy of the anticommons affecting the *commercialization* of a product, it will now affect *research and development* of that technology.

138. Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002), *cert. denied*, 535 U.S. ___, 123 S. Ct. 2639 (2003).

139. Heller & Eisenberg, *supra* note 34, at 699.

Thus, *Madey* may have the potential to greatly exacerbate whatever problems result from the anticommons effect. As will be more fully discussed in Part IV, unless this problem is addressed, the anticommons effect may infiltrate even further upstream, and serve to impair pure research and development activities.

IV. THE ROAD AHEAD

Given the undeniable risk of an anticommons effect now traveling upstream to impair research activities as a result of *Madey*, what, if anything, can be done to ameliorate this situation? The following solutions appear to be possibilities: (1) statutorily overturn *Madey* and expressly codify an experimental use defense along the lines of that proposed by Judge Newman in *Integra;*[140] (2) statutorily modify U.S. patent law to limit the penumbra of patentable subject matter, so that basic tools of research could not be patented; (3) statutorily modify Bayh-Dole to require that some or all of the technology developed under federal sponsorship must be either retained by the government and thereafter non-exclusively licensed out to all interested parties, or abandoned to the public domain by the inventors; or (4) create, either permissively or by government fiat, a collective licensing clearinghouse, limited to the transfer of a research-only license for the use of patented technology, with pre-set fees, subject to a registration process so as to ensure that such use is identified to avoid future infringement.

Option one is certainly feasible. While the prior common law iteration of "experimental use" to allow nonprofit use of third-party technology may have had its problems (the line between "research-only" and "commercial" use can often be thin) it did allow for the free flow of ideas in the educational and research setting, and thus assisted in supporting the Bayh-Dole goal of promoting technological development. Option one, however, will not affect the anticommons problems already noted in regard to the over-arching effects of Bayh-Dole—it would just return the situation to exactly where it was before the Federal Circuit decided *Madey*. There are practical problems as well. Neither Congress nor the Executive Branch seem likely, at this juncture, to rush to support legislation that would appear to promote the "free" use of property rights held by another, much less on the basis of what could be viewed as an expansion of the Bayh-Dole doctrine. The doctrine itself appears to have fallen from grace in recent years although it is probably not yet in danger of outright repeal.[141] Therefore, while there might be legal reasons to amend the Bayh-Dole Act, such a proposal would unlikely gain

140. *See Integra*, 331 F.3d at 876 (Newman, J., concurring in part, dissenting in part).

141. *See* Mark R. Wisner, *Proposed Changes to the Laws Governing Ownership of Inventions Made With Federal Funding*, 2 TEX. INTELL. PROP. L.J. 193 (1994) (discussing emerging legislative schemes which contain mechanisms that contradict Bayh-Dole, such as the Advanced Technology Program ("ATP"), administered by the National Institute of Standards and Technology ("NIST"), and created by the Emerging Technologies and Advanced Technology Program Amendments Act, Pub. L. No. 102-245, 106 Stat. 15 (1991), which enacted a patent policy, codified as amended at 15 U.S.C. § 278n(d)(11) (2000), that mandated ownership of patentable inventions made during activities funded by the ATP Program by the private sector participant in the Program, in place of the nonprofit collaborator, an exact reversal of the Bayh-Dole model).

widespread political support.

Option two is probably an even more unsatisfactory solution. Most commentators observe that the significant increase in patentable subject matter is probably here to stay as a result of recent case law.[142] Moreover, changing the rules of the game may now have devastating economic consequences, particularly to specialized industries such as the biotechnology sector, which has seen heavy investment on the broad assumption that this kind of technology can be patented and its exclusive development held in private hands. Finally, as with option one, such a proposal is unlikely to gain broad political support.

Option three, which if adopted at its extreme level, would have Congress abrogate Bayh-Dole entirely and return to the pre-1980 model of government ownership of inventions with non-exclusive licensing to private parties who desire to commercialize the technology. To many, such a course might seem a step backwards, depriving the inventor of his exclusive right to "prospect" his technology,[143] with a consequent resumption of the same problems that had bedeviled that policy before—the inefficient development of valuable technology and the resulting loss to society of its benefits. There is support, however, for occasional, targeted efforts by government to deliberately place absolutely essential research tools (many of which are traditionally funded by government largess in the area of basic research, with the consequent ability of the government to be in the driver's seat on how and by whom this technology will be developed) into the public domain. The example of the Human Genome Project, where the National Institute of Health deliberately devolved to the public the fruits of its research,[144] comes to mind, as does the decision by Welcome Trust to disclose all raw sequencing data from the human genome to the public domain.[145] Certainly, however, wide-scale use of this doctrine would be neither politically palatable nor consistent with the over-arching policy considerations of Bayh-Dole.

Option four offers intriguing possibilities. In a thoughtful article published in 1996, Professor Robert P. Merges of the Boalt Hall School of Law at the University of California, Berkeley, offered a unique suggestion to resolve the anticommons effect regarding the general proliferation of patent rights occasioned by Bayh-Dole.[146] He proposed a voluntary licensing scheme for patent rights through the creation of a collective clearinghouse for this effort, with pre-determined royalty rates and administrative provisions to systemize record

142. The Supreme Court recently provided a generous interpretation of the Patent Act in *Diamond v. Chakrabaty*, 447 U.S. 303 (1980).

143. *See* Edmund Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 267–71 (1977) (stating the case for the social benefit of providing exclusive monopoly rights to technology as an incentive to the inventor, who will then act with the enthusiasm and vigor of a "prospector" of that technology).

144. *See* Artikaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science* 94 NW. U. L. REV. 77, 90–99 (1999).

145. *See* Alexander K. Haas, *The Welcome Trust's Disclosure of Gene Sequencing Data into the Public Domain and the Potential for Proprietary Rights in the Human Genome* 16 BERKELEY TECH. L.J. 145, 151–52 (2001).

144. Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights* Organizations, 84 CAL. L. REV. 1293 (1996).

keeping, payment collection and royalty distribution.[147] His scheme would be modeled after collective organizations already existing in the copyright area, such as the American Society of Composers, Authors, and Professors ("ASCAP").[148]

Perhaps this proposal could be modified to provide for a patent pool of the sort contemplated by Professor Merges, but only for the transaction of non-exclusive, research-only licenses. Such a pool could be administered by a government tribunal, or more preferably by either an existing technology association (i.e., AUTM) or a newly created collective association. The pool would serve several purposes. It would act as a disincentive to patent holders of valuable technology to charge exorbitant rates. If a patent holder wants to use the patent rights of others, it would have to share its own patent rights based on pre-determined rates. This arrangement would also greatly reduce transaction costs. Even if the pre-set fees ultimately negotiated upon were significant (and that is doubtful because all negotiators would be both buyers and sellers in the scheme, thus having the motivation to be reasonable), legal and licensing fees that would otherwise be needed to handle separate transactions for each patent interest would be eliminated. Moreover, if the system required registration of the research-only use of a technology, a patent owner would be aware of all users of her technology and be on the lookout for later infringement of that technology by those identified entities.

While the details of such a system would certainly have to be carefully considered, it could offer a solution to whatever anticommons effects may emerge as a result of both the expansive view of patentable subject matter which has evolved in the last twenty years and the surge in privately held patent rights occasioned by the effects of Bayh-Dole. Unless such a system is implemented, or unless *Madey* is substantially modified or overruled, it is clear that the anticommons effect will infiltrate pure research and development activities, and even educational activities, and seriously undermine the salutary goals of Bayh-Dole.

CONCLUSION

As this article shows, the goals of the Bayh-Dole Act are the following: (1) the establishment of a uniform federal policy for the disposition of patent rights created as a result of government-sponsored research; (2) the disposition of those patent rights to the private sector, particularly nonprofit institutions, with the aim of providing financial support to, and encouraging research activities at, those institutions; and (3) the licensing of those patent rights to commercial partners of nonprofit institutions, particularly emerging small business, so that the United States as a whole can benefit from the developed technology.

In addition to its salutary effects of spurring both technology development in education and research centers, as well as economic development, particularly in the start-up sector, Bayh-Dole may have a hidden, emerging problem—the anticommons effect caused by a proliferation of patent rights in the area of

147. *Id.* at 1299.

148. *See id.* at 1329 for an explanation of ASCAP's organization.

upstream technology tools. With this comes a consequent impairment of the ability of a single entity to commercialize downstream product development without extensive and complicated negotiations with various patent holders, where each holds a vital piece of the technology necessary to create that commercial product. To the extent that this anticommons effect exists, or will increase over time, it is certainly logical to assume that *Madey* may serve to aggravate this problem in the area of pure research and development activities, and perhaps even into the area of education itself.

Thus, *Madey,* unless overturned, may have a directly deleterious effect upon the very goals that Bayh-Dole intended to promote. Instead of acting to encourage nonprofit research and the transfer of its resulting technology, *Madey* may have actually added an entirely new road block that, heretofore, had only been present when a technology was ready for commercial development—the inability to review and use, in pure research-only applications, third-party rights without seeking permission, and paying what could be an exorbitant fee to a recalcitrant patent holder for the privilege. It is also conceivable that a patent holder who does not want any rivals in her field of use might outright refuse to agree to provide even a limited research-only license to their technology at any price, thus locking out competition on an even more significant scale than has been seen before.

Unless some carefully crafted solution to this anticommons effect of *Madey* is deployed, perhaps through the use of a collective rights mechanism for the licensing of research-only rights to third-party patented technology, the risk of legal gridlock stymieing the development of socially valuable technology appears to be very real. This gridlock would cause substantial damage to the salutary goals that Bayh-Dole was enacted to promote.