

Share and Share Alike: Increasing Access to Government-Funded Inventions Under the Bayh- Dole Act

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Introduction	394
I. Background.....	397
A. The Bayh-Dole Act	397
1. History.....	397
2. Enactment and Implementation	402
a. Policy and Affected Parties	402
b. Terminology and Implementation	404
3. The Stevenson-Wydler Act	409
4. Reaction and Criticism	410
B. Patent Law Concerns.....	412
1. The Patent Right and Blocking Patents	413
2. Anticommons.....	415
3. Experimental Use	418
4. Patent Pools	428
II. Bayh-Dole: Prior Criticism and Proposed Solution	430
A. The Critics: Rai and Eisenberg.....	430
B. Their Proposed Solution	432
C. Critique of the Solution.....	435
III. An Alternative Proposal.....	442
A. The Proposal.....	442
B. Potential Impact.....	446
1. Potential Impact on Patent Incentives	446
2. Experimental Use	458
3. Patent Pools	459
C. Practical Considerations.....	461
1. Implementation.....	461

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2. Terms of the License.....	468
a. Limitation on Rights Licensed.....	468
b. Sublicensing.....	470
c. Notice to the Patentee	470
d. Giving Away the Technology	471
3. Participation	473
D. Related Proposals	474
IV. Conclusion.....	481

INTRODUCTION

In 1980, scientific research funded by the federal government was at a crossroads. Up until that time, very little of this research ever generated products that benefited the public that had paid for the research. Congress studied the problem and concluded that the culprit was, at least in part, a governmental policy of not patenting the inventions that arose from such research, or, when patents were obtained, a policy of refusing to license the patents on an exclusive basis.¹ Without the protection of a patent or exclusive license, private companies were reluctant to proceed with the next phase—development of saleable products—because they feared that once they had done the hard (and expensive) part, other companies would step in and free-ride on their efforts.² In response, Congress passed the Bayh-Dole Act³ as a means to utilize the incentives of the patent system to persuade companies to develop inventions into products. Under the Bayh-Dole Act, recipients of government funding may (subject to certain rights retained by the government) obtain patents on their inventions and then sell or license those patents as they see fit, including granting exclusive licenses.⁴

The Act has dramatically changed the way universities

1. See Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1685-87 (1996) (discussing the findings of the Commission on Government Procurement). See generally *id.* at 1671-91 (discussing the history of technology transfer prior to 1980).

2. See *id.* at 1672-75, 1681-82.

3. Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015-28 (codified as amended at 35 U.S.C. §§ 200-212 (2000 & Supp. II 2002)).

4. 35 U.S.C. §§ 202-203.

operate and how they interact with private industry.⁵ Universities and other recipients of government research funding have vastly expanded their patenting and licensing activities in an attempt to bring in revenue from patents on inventions developed in university laboratories.⁶ Most universities now routinely obtain and license patents, and some have made enormous amounts of money off their patent portfolios.⁷ Much of this revenue has come from companies, which now routinely monitor university research in search of technology that can be licensed and developed into marketable products.⁸ Thus, in many instances, the Bayh-Dole Act has had exactly the desired effect of generating products for the benefit of the public.

However, from its inception, the Act has had its critics. Recently, Professors Arti Rai and Rebecca Eisenberg have expressed dissatisfaction with the current implementation of the Bayh-Dole Act.⁹ They assert that while some inventions that would otherwise have languished are now exploited because of the Act, other inventions that would have been developed anyway are now being developed under the auspices of the Act.¹⁰ As a consequence, these latter inventions now carry a “tax” in the form of a royalty that subsequent researchers must pay to the patent holder, and this royalty is then passed on to the ultimate consumer, the public. Since these inventions would have been developed and used without the patent incentives provided by the Act, they argue, the Act requires that the public pay extra for something it otherwise would have obtained more cheaply.¹¹ Thus, from a societal standpoint, patenting such inventions is undesirable.

To solve this problem, the authors propose requiring the National Institutes of Health (NIH) to evaluate each grant it

5. See generally, e.g., Thomas A. Massaro, *Innovation, Technology Transfer, and Patent Policy: The University Contribution*, 82 VA. L. REV. 1729, 1731-32 (1996) (discussing the impact of Bayh-Dole on university research and technology transfer).

6. See Eisenberg, *supra* note 1, at 1708-09; Massaro, *supra* note 5, at 1731-32.

7. See Eisenberg, *supra* note 1, at 1710-11 (giving examples of patents bringing large revenues to universities).

8. See *id.* at 1709.

9. Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289 (2003).

10. See *id.* at 295.

11. See *id.* at 300-01.

makes and decide whether any invention (or inventions) that might result from the research conducted pursuant to that grant would or would not be further developed without a patent. If the NIH concludes that any such potential inventions would be developed without a patent, the grant should prohibit the researcher from patenting them; otherwise, the grant should permit the researcher to patent them.¹² While this solution is perhaps appealing in the abstract, it is unworkable in practice. It suffers from difficulties both practical—the NIH lacks the institutional competence and personnel to perform such an analysis effectively—and fundamental—for the vast majority of inventions, *nobody* could make such a decision *ex ante*.

This Article proposes an alternative reform. Any researcher whose work is funded by federal funds should have a limited, royalty-free license to make or use, for research purposes on the funded project, any patent for which the underlying invention was developed with federal funds. The license would be strictly limited to research activities, and would not extend to the right to sell or otherwise commercialize the patented invention; the patentee would retain all rights to commercialize the invention.

Focusing on the user and whether he or she receives federal funds, rather than on the Rai and Eisenberg test aimed at assessing the desirability of patenting the invention, greatly simplifies the job of the NIH while addressing many of the complaints voiced by critics of the Bayh-Dole Act. The terms of this license would, of course, require careful drafting to prevent the licensee's overreaching into the commercial arena. The license would have the further benefit of implementing a limited form of experimental use, and it might also serve as the foundation for a "patent pool" in the biotechnology industry, resulting in increased availability of the tools and techniques of the trade, whether developed with or without government funding.

The following discussion focuses primarily on the NIH and biotechnology patents, because that is the area Rai and Eisenberg address in their article and is also the area with which I have the most familiarity. In addition, biotechnology patents are currently an area of great contention, and many

12. *See id.* at 310-11.

commentators advocate substantial changes with U.S. patent law and policy in the realm of biotechnology. Due to its universal nature, however, the licensing reform that I propose could also be expanded to apply to other agencies and fields. Indeed, implementation of the proposed reform at the NIH might serve as a model for later adoption by other agencies.

Part I of this Article covers the history and structure of the Bayh-Dole Act, as well as some basic patent law doctrines and concerns. Part II examines in detail the reform proposed by Professors Rai and Eisenberg, highlights some of the problems, and concludes that it is unworkable. Part III then explores the proposed new license for recipients of government funding, including possible ways to implement it. It also discusses the potential benefits of the proposal and addresses some of its weaknesses.

I. BACKGROUND

A. THE BAYH-DOLE ACT

1. History

The federal government has long been a major source of funding for scientific research, and as a consequence it has become the owner of many patents that resulted from this research. Prior to 1980, however, almost no one ever developed or used most of these patented inventions.¹³ Statistics indicated that only about four percent of the patents issued under NASA, Department of Defense (DoD), and NIH grants were ever used.¹⁴ Thus, while the government was spending taxpayer money on research, the taxpayers were not getting

13. See Eisenberg, *supra* note 1, at 1664, 1702. The following discussion is derived in considerable part from Professor Eisenberg's work.

14. *Id.* at 1702. The four percent figure comes from the sources cited in note 159 therein. See *The University and Small Business Patent Procedures Act: Hearings on S. 414 Before the S. Comm. on the Judiciary*, 96th Cong. 2 (1979) [hereinafter *Senate Bayh-Dole Hearings*] (statement of Sen. Birch Bayh); *id.* at 28 (statement of Sen. Robert Dole); *id.* at 32 (statement of Sen. Orrin G. Hatch); *id.* at 46 (testimony of Elmer B. Staats, Comptroller General of the United States) (citing FEDERAL COUNCIL ON SCIENCE & TECH., REPORT ON GOVERNMENT PATENT POLICY, 1973-76 (1978)). Professor Eisenberg notes that these statistics are open to challenge. See Eisenberg, *supra* note 1, at 1702-03. However, the basic premise—that many government-funded inventions were not getting out of the lab—is generally accepted.

useful products in return.¹⁵ Desiring to increase the return on federal investments in research, Congress began looking for ways to get these taxpayer-funded inventions developed into commercial products.¹⁶

The first step in designing such a reform was to figure out *why* the development rate was so low. The problem traced its roots, at least in part, to a split within and among the various agencies (and commentators observing the agencies) between two competing views and practices on the proper policy for the patenting of federal research: the license policy or the title policy.¹⁷

For agencies practicing the license policy, the government kept only a license to use technology developed with federal funds, for its own use; title resided with the funding recipient who actually performed the research.¹⁸ Advocates of this policy argued that it gave funding recipients the necessary incentive to bid on government contracts and then to proceed to develop the inventions made under them. Licensing policy advocates believed that if title in these inventions rested with the government and it granted only nonexclusive licenses, firms would be unwilling to take such licenses.¹⁹ These firms would worry that their competitors would wait for them to develop the markets and work out kinks in the technology, and then steal their markets by getting similar licenses from the government. Since these later competitors would avoid the startup costs, they would then undercut the original firm, destroying profitability.²⁰

For agencies practicing the title policy, the government retained full title to inventions developed with government funding and thus owned all resulting patents.²¹ Advocates of this policy believed that the public had an equitable claim to the research for which it paid, and therefore the government should protect the public by retaining title in the technology,

15. Another impetus behind the Bayh-Dole Act was concern that innovating American firms frequently lost out to foreign competitors. See Eisenberg, *supra* note 1, at 1665.

16. See, e.g., *Senate Bayh-Dole Hearings*, *supra* note 14, at 3 (statement of Sen. Birch Bayh).

17. See Eisenberg, *supra* note 1, at 1674-75.

18. See *id.* at 1674.

19. See *id.* at 1674-75.

20. See *id.* at 1673.

21. See *id.* at 1674.

either dedicating it to the public domain or granting nonexclusive licenses.²² Otherwise, the government would be inappropriately involved in selecting licensees, policing licensees, and policing infringement.²³ If nonexclusive licenses turned out to be insufficient to get the product developed by the private sector, then the government should step in and finance the necessary further development itself, on behalf of the public.²⁴

Historically, Congress did not set forth uniform policy on this issue, and so for many years different agencies took different approaches to handling patents arising out of funded research, generally following one or the other of the two described policies.²⁵ Indeed, one of the stated purposes for the adoption of the Bayh-Dole Act was to create a uniform policy to replace the twenty-six separate variations of the licensing and title policies then in effect for the various funding agencies.²⁶

Earlier, in 1963, President Kennedy had issued a presidential memorandum that attempted to set a more general policy somewhere in between the title and licensing policies, recognizing the advantages and disadvantages of each.²⁷ The memorandum provided guidelines for determining when the government should retain title, but it ultimately left agencies with considerable discretion.²⁸

One important outcome of the memorandum was that it led, indirectly, to a detailed study of the issue by Harbridge House.²⁹ The Harbridge House study found low usage rates of inventions made with government funding, particularly when

22. *See id.* at 1673-74.

23. *See id.* at 1673.

24. *See id.* at 1673-74. Professor Eisenberg points out the interesting fact that almost no one considered a policy of not getting patents at all and simply publishing to prevent others from subsequently obtaining patents. She gives some practical reasons why patenting might be more effective, but it is still interesting that this option was not even discussed. *See id.* at 1675-76.

25. *See generally id.* at 1671-95.

26. *See Senate Bayh-Dole Hearings, supra* note 14, at 2 (statement of Sen. Birch Bayh); *id.* at 30 (statement of Sen. Robert Dole) (citing Bradley Graham, *Patent Bill Seeks Shift to Bolster Innovation*, WASH. POST, Apr. 8, 1979); *id.* at 33 (statement of Sen. Orrin G. Hatch).

27. *See Eisenberg, supra* note 1, at 1677-79 (citing Memorandum and Statement of Government Patent Policy, 28 Fed. Reg. 10,943 (Oct. 10, 1963)).

28. *See id.*

29. *See id.* at 1679-82 (citing 1 HARBRIDGE HOUSE, GOVERNMENT PATENT POLICY STUDY, FINAL REPORT FOR THE FCST COMMITTEE ON GOVERNMENT PATENT POLICY, at ii (1968)).

the government held title.³⁰ The report ultimately concluded, however, that its data could not resolve the debate, and that the preferable policy depended on the invention in question—that is, some inventions would only be developed into useful products if the government held title, while other inventions would be unlikely to be developed if the government held title.³¹

In 1971, President Nixon issued a subsequent presidential memorandum stating that agencies could grant more than minimal, nonexclusive rights where such rights were necessary to get the inventions developed into commercial products, thus endorsing the licensing policy in at least some contexts.³² However, this memorandum raised questions regarding whether the agencies had the power to take such actions absent congressional authorization, as they arguably transferred property belonging to the United States, a power the Constitution reserves to Congress.³³

Meanwhile, in 1969, Congress established the Commission on Government Procurement to research licensing issues.³⁴ The Commission eventually issued its report in 1972. The Commission's final report deferred to the intervening 1971 presidential memorandum so that empirical data resulting from the memorandum's implementation could inform future policy decisions.³⁵ However, the Commission also suggested an alternative approach: Congress should replace all existing relevant statutes with a uniform government policy that would generally leave title in the hands of funding recipients, subject to strengthened government "march-in" rights.³⁶ This policy would also have two exceptions: The government should retain title to inventions that it planned to develop to completion, and

30. *See id.* at 1680.

31. *See id.* at 1681-82.

32. *See id.* at 1684-89 (citing Memorandum and Statement of Government Patent Policy, 36 Fed. Reg. 16,887 (Aug. 26, 1971)).

33. *See id.* at 1687-88.

34. *See id.* at 1685-87.

35. *See id.* at 1685-86.

36. *See id.* at 1686-87. March-in refers to the right of an agency to "march in" and force the patentee to grant third parties a license to a patent arising from work performed with funds provided by the agency. *See* 35 U.S.C. § 203 (2000 & Supp. II 2002). An agency may march in only under very specific circumstances, such as when the patentee is not developing the invention or cannot meet the demand for a patented technology that is important for health or safety. *Id.* § 203(a)(1), (2). March-in is discussed in more detail *infra* notes 93-95 and accompanying text.

educational and nonprofit institutions generally would not receive title.³⁷

Finally, in 1979, President Carter, in the context of his Domestic Policy Review on Industrial Innovation, investigated the situation and indicated support for a policy of getting title out of the hands of the government and into the hands of funding recipients.³⁸

By and large, the title policy prevailed before 1980. The general aim of the agencies was to achieve widespread dissemination of the results obtained in laboratories operating with federal money and to encourage wide development and usage through dedication to the public domain and nonexclusive licenses.

Universities, however, became increasingly frustrated over changes in the ways in which the Department of Health, Education and Welfare (HEW), now the Department of Health and Human Services, and the DoD handled patent rights.³⁹ Beginning in the 1960s, the HEW rule was to let universities retain patent rights as long as they had an approved technology transfer system in place, and to allow them to grant exclusive rights to industry under Institutional Patent Agreements (IPAs).⁴⁰ These generalized requirements obviated the need for case-by-case waivers for each invention, which pleased the universities.⁴¹ Then in 1978, HEW's general counsel recommended rethinking IPAs, as they limited the agency's control over the availability and cost of HEW-sponsored inventions. At the same time, HEW began taking longer to review individual requests for patent rights. This change in policy created concern that HEW was reverting to older policies and led to pressure for legislation to make the existing arrangements permanent and non-discretionary.⁴²

Meanwhile, DoD generally allowed funding recipients to retain title as long as they had "an established commercial position in the field."⁴³ This worked well for industry funding recipients, but it created a problem for universities, which had no such positions and therefore had to seek approval for each

37. See Eisenberg, *supra* note 1, at 1687.

38. See *id.* at 1689-91.

39. See *id.* at 1691-93.

40. See *id.* at 1692-93.

41. See *id.* at 1692.

42. See *id.* at 1692.

43. See *id.* at 1692.

invention. Many universities worked around this problem by taking advantage of a general “special situations” exception that allowed them to retain title without the need for individualized approval.⁴⁴ However, in 1975, DoD revised its regulations to eliminate this exception. Under the revised regulations, universities needed to show an established technology transfer program in the field of the invention, not merely an approved patent policy as previously required. The change led to an eighty percent increase in deferred, case-by-case determinations of whether the university was permitted to take title or whether title should remain with the agency.⁴⁵ Although these determinations were generally resolved in the universities’ favor, they were time-consuming, and the universities found the bureaucratic burden frustrating.⁴⁶

2. Enactment and Implementation

Congress pulled all these varying threads together in 1980, enacting two pieces of legislation aimed at increasing development of federal research into private sector products: the Bayh-Dole Act and the Stevenson-Wydler Technology Innovation Act.⁴⁷

a. Policy and Affected Parties

The Bayh-Dole Act focuses on small businesses and nonprofit entities receiving federal funding, such as universities and research foundations.⁴⁸ The Act as passed was silent as to large funding recipients,⁴⁹ who would continue

44. *See id.* at 1692-93.

45. *See id.* at 1693.

46. *See id.*

47. The Stevenson-Wydler Technology Innovation Act is discussed *infra* Part I.A.3.

48. Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015-28 (codified as amended at 35 U.S.C. §§ 200-212 (2000 & Supp. II 2002)).

49. “Large” in this context refers to the residual category of funding recipients that fit neither the definition of “small business firm,” 35 U.S.C. § 201(h), nor the definition of “nonprofit organization,” *id.* § 201(i). The definition of “small business firm” refers to 15 U.S.C. § 632, which states: “For the purposes of this chapter [that is, 15 U.S.C. ch. 14A—Aid to Small Business, which, *inter alia*, establishes the Small Business Administration], a small-business concern . . . shall be deemed to be one which is independently owned and operated and which is not dominant in its field of operation.” 15 U.S.C.A. § 632(a)(1) (1997 & Supp. 2005), *referenced in* 35 U.S.C. § 201(h). The Bayh-Dole definition further incorporates the “implementing regulations

under the existing regime of agency-by-agency determination.⁵⁰ The Act encourages small businesses and nonprofit funding recipients to patent the results of government-sponsored research by allowing them to retain title to the inventions if they diligently file patent applications and promote commercial development of the inventions.⁵¹ The Act also clarifies the authority of federal agencies to hold patents and license them on an exclusive or nonexclusive basis.⁵²

Not surprisingly, universities and small businesses supported the Act and its clarification of their right to retain title.⁵³ Large businesses would have preferred to have been included; indeed, the Carter Administration had wanted to make the Act more comprehensive, but failed to do so.⁵⁴ However, large businesses were no worse off as they were still able to obtain title via individualized agency determinations, and therefore they did little more than grumble over their exclusion from the Act.⁵⁵ This differential treatment was ultimately eliminated in 1983, when President Reagan issued a memorandum extending Bayh-Dole to large businesses.⁵⁶ This extension was later quietly endorsed by Congress as part of a housekeeping provision in 1984.⁵⁷

Since its passage, the scope of the Bayh-Dole Act has gradually expanded. As the Act now stands, almost any party involved in creating an invention that wants to obtain a patent on it can prevail over any party that does not want the invention to be patented.⁵⁸ The funding recipient gets priority in electing to retain title in the subject invention.⁵⁹ If the recipient declines, the sponsoring agency may receive title to the invention.⁶⁰ If neither of these parties seeks to patent the

of the Administrator of the Small Business Administration.” 35 U.S.C. § 201(h).

50. See Eisenberg, *supra* note 1, at 1691.

51. See 35 U.S.C. § 202.

52. See *id.* §§ 207-209.

53. See Eisenberg, *supra* note 1, at 1693.

54. See *id.* at 1693-94.

55. See *id.*

56. See *id.* at 1694-95 (citing Memorandum to the Heads of Executive Departments and Agencies: Government Patent Policy, 1 PUB. PAPERS 248 (Feb. 18, 1983)).

57. See *id.* at 1694-95, 1704 n.168 (citing Trademark Clarification Act of 1984, § 501(13), 35 U.S.C. § 210(c) (1994)).

58. See *id.* at 1666.

59. See *id.* at 1666 (citing 35 U.S.C. § 202(c)(2) (1994)).

60. See *id.*

invention, the opportunity falls to the individual inventor.⁶¹

In essence, the Bayh-Dole Act expresses a strong preference for allowing funding recipients (or, if the recipients are not interested, individual inventors) to retain rights in inventions created with federal funding.⁶² The policy and objectives of the Act are to maximize the return on federal research dollars by getting inventions made with government funding into the hands of those who will develop them—preferably small businesses located in the United States—for the benefit of the public in general.⁶³ However, the government should retain sufficient rights to serve its own needs and protect the investment of the public in the inventions.⁶⁴ The rights are therefore subject to certain limited exceptions: denial of such rights in very limited “exceptional circumstances,”⁶⁵ the government’s retention of a license to use (or have used on its behalf) any government-funded invention,⁶⁶ and a very limited agency march-in right.⁶⁷

b. Terminology and Implementation

The Bayh-Dole Act and its implementing regulations use the broad term “funding agreement” to mean “any *contract, grant, or cooperative agreement entered into between any Federal agency . . . and any contractor for the performance of experimental, developmental, or research work funded in whole*

61. *See id.* (citing 35 U.S.C. § 202(d)). Actually, the statutes are slightly ambiguous on the order of precedence when the funding recipient declines to patent. Section 202(c)(2) states “the Federal Government may receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect rights within [the statutory] times.” 35 U.S.C. § 202(c)(2) (2000 & Supp. II 2002). Section 202(d) states “[i]f a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder.” *Id.* § 202(d). Thus, the statutes seem to give *both* parties the opportunity to patent. However, given that the statute gives the Federal agency the authority to approve the inventor’s request, it could presumably deny the request on the grounds that the agency elected to patent the invention itself.

62. *See* 35 U.S.C. § 202(a), (d).

63. *See id.* § 200.

64. *See id.*

65. *See id.* § 202(a)(ii).

66. *See id.* § 202(c)(4).

67. *See id.* § 203.

or in part by the Federal government.”⁶⁸ In the federal system, “contracts” and “grants” have specific technical meanings.⁶⁹

Contracts are used when the government needs a solution to a particular scientific or technical problem, for its own purposes and under its own control.⁷⁰ For example, when the NIH wanted to create a Molecular Libraries Small Molecule Repository (that is, a facility that could maintain and supply a collection of small molecules that might be of interest to researchers throughout the NIH), it issued a contract

68. *Id.* § 201(b); 37 C.F.R. § 401.2(a) (2005) (emphasis added).

69. The basics of the federal procurement system are set forth in 31 U.S.C. Chapter 63. Section 6301 states that the general purpose of this chapter is to clarify under what circumstances agencies should use which type of funding arrangement. *See* 31 U.S.C. § 6301 (2000). Section 6303 specifies:

An executive agency shall use a procurement contract as the legal instrument reflecting a relationship between the United States Government and a State, a local government, or other recipient when—

(1) the principal purpose of the instrument is to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the United States Government; or

(2) the agency decides in a specific instance that the use of a procurement contract is appropriate.

Id. § 6303. Section 6304 specifies:

An executive agency shall use a grant agreement as the legal instrument reflecting a relationship between the United States Government and a State, a local government, or other recipient when—

(1) the principal purpose of the relationship is to transfer a thing of value to the State or local government or other recipient to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring (by purchase, lease, or barter) property or services for the direct benefit or use of the United States Government; and

(2) substantial involvement is not expected between the executive agency and the State, local government, or other recipient when carrying out the activity contemplated in the agreement.

Id. § 6304. Part 35 of the Federal Acquisition Regulations (F.A.R.), which addresses “Research and Development Contracting,” evokes this distinction:

Contracts shall be used only when the principal purpose is the acquisition of supplies or services for the direct benefit or use of the Federal Government. Grants or cooperative agreements should be used when the principal purpose of the transaction is to stimulate or support research and development for another public purpose.

48 C.F.R. § 35.003(a) (2005). As one commentator has observed, “Few things are as befuddling as the parlance involved in the doling out of the federal largesse.” Jerome S. Gabig, Jr., *Federal Research Grants: Who Owns the Intellectual Property?*, 9 HARV. J.L. & PUB. POL’Y 639, 640 (1986).

70. *See* 31 U.S.C. §§ 6301, 6303; *see also* Diane M. Sidebottom, *Updating the Bayh-Dole Act: Keeping the Federal Government on the Cutting Edge*, 30 PUB. CONT. L.J. 225, 230-31 (2001).

solicitation (through the auspices of the National Institute of Mental Health (NIMH)).⁷¹ Similarly, the NIH (through the National Institute of Allergy and Infectious Diseases (NIAID)) issued a contract solicitation when it wanted assistance developing products that could operate as countermeasures against radiological threats.⁷²

Grants, on the other hand, are used when the government wishes to fund the scientific enterprise more broadly, rather than to solve a specific problem.⁷³ Grantees are typically much freer to explore as they see fit, relatively free of government control.⁷⁴ Thus, almost all extramural, investigator-initiated research sponsored by NIH is funded through grants. For example, the NIH has used grants to fund research into novel ways of using retroviral vectors to make a vaccine against HIV⁷⁵ and mechanisms for regulating gene transcription using novel “protein nucleic acid” molecules.⁷⁶ Thus, even though

71. See National Inst. of Mental Health, U.S. Dep’t of Health & Human Servs., RFP No. RM-04-0001, Molecular Libraries Small Molecule Repository (Dec. 29, 2003), available at <http://www.nimh.nih.gov/contracts/ROADMAP-04-0001.pdf>.

72. See National Inst. of Allergy & Infectious Disease, U.S. Dep’t of Health & Human Services, Solicitation No. RFP-NIH-NIAID-DAIT-05-37, Medical Countermeasures Against Radiological Threats: Product Development Support Services (April 27, 2005), available at <http://www.niaid.nih.gov/contract/archive/RFP0537.pdf>. A list of open Requests for Proposals at the NIH is available at <http://ocm.od.nih.gov/ContractOpportunity/rfps/mainpage.htm> (last visited Feb. 5, 2006). A similar list for the entire federal government is available at “FedBizOpps,” <http://www.fbo.gov/> (last visited Feb. 5, 2006).

73. See 31 U.S.C. §§ 6301, 6304; see also Sidebottom, *supra* note 70, at 231.

74. See *Forsham v. Califano*, 587 F.2d 1128, 1138 (D.C. Cir. 1978) (“In a grant program the federal government gets the advantage of services rendered by someone who is doing his own thing, his own autonomous thing.”).

75. See Grant No. 1R03AI044677-01, HIV/SIV Structural Gene Vectors as a Live HIV Vaccine (May 1, 1999), available at [http://crisp.cit.nih.gov/crisp/CRISP_LIB.getdoc?textkey=2799594&p_grant_num=1R03AI044677-01&p_query=&ticket=15293961&p_audit_session_id=71335355&p_keywords=\(providing the abstract for the grant\)](http://crisp.cit.nih.gov/crisp/CRISP_LIB.getdoc?textkey=2799594&p_grant_num=1R03AI044677-01&p_query=&ticket=15293961&p_audit_session_id=71335355&p_keywords=(providing the abstract for the grant)).

76. See Grant No. 5R01GM060642-06, Controlling Gene Expression With Peptide Nucleic Acids (July 1 2000), available at [http://crisp.cit.nih.gov/crisp/CRISP_LIB.getdoc?textkey=6915683&p_grant_num=5R01GM060642-06&p_query=&ticket=15293933&p_audit_session_id=71335355&p_keywords=\(providing the abstract of the grant\)](http://crisp.cit.nih.gov/crisp/CRISP_LIB.getdoc?textkey=6915683&p_grant_num=5R01GM060642-06&p_query=&ticket=15293933&p_audit_session_id=71335355&p_keywords=(providing the abstract of the grant)). The NIH issues grants to fund almost any imaginable type of research relating to the life sciences. Individual grants

grants are ultimately embodied in contracts in the legal sense, they are not considered “contracts” in the technical way that term is used in the Bayh-Dole Act. Therefore, to avoid confusion, I will follow the Act’s convention of using the broader terms “funding agreement” and “federally funded research[er]” (or obvious variants thereof) to refer to both types of arrangements collectively.

The Act defines a “subject invention” as “any invention of the [funding recipient] conceived or first actually reduced to practice in the performance of work under a funding agreement.”⁷⁷ The Act broadly implements a policy that favors placing ownership of these inventions created with government funds in the hands of the funding recipient: “Each nonprofit organization or small business firm may . . . elect to retain title to any subject invention.”⁷⁸ To obtain these rights, the funding recipient must make a specific election to retain rights within a specified timeframe⁷⁹ and file patent applications prior to any patent bar dates.⁸⁰ Should the recipient decline to exercise its right to patent, the agency can then either elect to patent the invention itself⁸¹ or grant the individual inventor’s request to retain rights in the invention.⁸² Congress placed authority to implement the Act in the Department of Commerce.⁸³

The Act also contains certain exceptions that limit the scope of the patent owner’s rights. These limitations mostly relate to foreign contractors⁸⁴ or to inventions related to security⁸⁵ or weapons.⁸⁶ In addition, a funding agreement may refuse to allow the retention of title “in exceptional circumstances when it is determined by the agency that

may be found in the CRISP database. See Computer Retrieval of Information on Scientific Projects, <http://crisp.cit.nih.gov/> (last visited April 14, 2006).

77. 35 U.S.C. § 201(e) (2000 & Supp. II 2002).

78. *Id.* § 202(a). The funding recipient must comply with various disclosure and reporting requirements to retain rights to the invention, including reporting the existence of the invention to the agency, *id.* § 202(c)(1), and keeping the agency apprised of progress toward patenting, and utilizing the invention, *id.* § 202(c)(5).

79. See *id.* § 202(c)(2).

80. See *id.* § 202(c)(3).

81. See *id.* § 202(c)(2).

82. See *id.* § 202(d). See *supra* note 61 for a discussion of the interaction between § 202(c) and § 202(d).

83. See 35 U.S.C. §§ 202(b)(1), 206, 207(b), 208.

84. See *id.* § 202(a)(i).

85. See *id.* § 202(a)(iii).

86. See *id.* § 202(a)(iv).

restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter.”⁸⁷ That is, the funding agency may, in “exceptional circumstances,” decide that a particular invention should not be patented or that the agency should retain title. However, the Act makes clear that any such exercise is to be strictly limited, with specific substantive and procedural requirements for any such determination,⁸⁸ administrative oversight,⁸⁹ and specific appeal rights for the funding recipient.⁹⁰

Under §202, the government also reserves certain rights in subject inventions:

With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable [sic], irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: *Provided*, That the funding agreement may provide for [certain] additional rights.⁹¹

Thus, the government may itself practice any invention it funded, and it may also authorize others to practice the invention on its behalf. The funding recipient must also place notice in any patent applications on retained inventions, informing the public of the government’s rights in the inventions.⁹²

Under certain circumstances and subject to certain procedural safeguards, the funding agency may require the rights holder to assign rights to another party.⁹³ If the rights holder refuses, the agency may “march in” and itself grant such rights.⁹⁴ Section 203(a)(1)-(4) permits the agency to march in if it determines that: the owner of the patent has not taken sufficient steps to put the invention into practice, the owner cannot meet the demand for an invention important to health or safety, the owner cannot meet the need for the invention as required by a Federal regulation, or the owner has in some way violated the provisions requiring a preference for United States

87. *Id.* § 202(a)(ii).

88. *See id.* § 202(b)(1).

89. *See id.* § 202(b)(2), (3).

90. *See id.* § 202(b)(4).

91. *Id.* § 202(c)(4).

92. *See id.* § 202(c)(6).

93. *See id.* § 203(a), (b).

94. *See id.*

industry.⁹⁵

3. The Stevenson-Wydler Act

Around the same time as it passed the Bayh-Dole Act, Congress also passed the Stevenson-Wydler Technology Innovation Act,⁹⁶ which was a counterpart to the Bayh-Dole Act. The Stevenson-Wydler Act applied to research conducted by the government or government actors (for example, by scientists at the NIH), where no outside funding recipient existed to take the rights and develop the inventions under the Bayh-Dole Act. Thus, the government was given the role of acting as its own licensor. Stevenson-Wydler directed the research agencies to get more involved in technology transfer when there was no external funding recipient, and to grant exclusive licenses more frequently.⁹⁷

The Stevenson-Wydler Act made technology transfer an explicit part of the federal research enterprise. Under the Act, “[t]echnology transfer, consistent with mission responsibilities, is a responsibility of each laboratory science and engineering professional,”⁹⁸ and federal agencies should “strive where appropriate to transfer federally owned or originated technology to State and local governments and to the private sector”⁹⁹ and set aside funds to support technology transfer.¹⁰⁰ The Federal Technology Transfer Act of 1986¹⁰¹ took these ideas a step further, allowing government-operated laboratories to enter into cooperative research and development agreements (CRADAs) with industry, in which the laboratories agree in advance to assign patent rights to industry.¹⁰²

The combined result of Bayh-Dole and Stevenson-Wydler is this: On the extramural side, Congress encourages agencies to forego patent rights, in favor of funding recipients who will either develop the technology themselves or license it to others

95. *See id.*

96. Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311 (codified as amended at 15 U.S.C.A. §§ 3701–3717 (1998 & Supp. 2005)).

97. *See Eisenberg, supra* note 1, at 1705-06.

98. 15 U.S.C. § 3710(a)(2).

99. *Id.* § 3710(a)(1).

100. *See id.* § 3710(b)(2).

101. Federal Technology Transfer Act of 1986, Pub. L. No. 99-502, 100 Stat. 1785 (1986).

102. *See Eisenberg, supra* note 1, at 1706. Subsequent amendments have pushed further in this direction. *See id.* at 1706-08.

to develop. Meanwhile, on the intramural side, it encourages agencies to seek patents more actively so that they can license these patents to industry for development.¹⁰³ Thus, the Acts employ a dual-pronged strategy to clear away government obstacles to patenting by funding recipients and to encourage individuals and institutions lacking their own development capacities to own and share patent rights.¹⁰⁴

4. Reaction and Criticism

Many view the Bayh-Dole Act as a rousing success.¹⁰⁵ Patent activity by research universities and other funding recipients has expanded dramatically, and some of the resulting patents have generated enormous income for their institutions.¹⁰⁶ Awareness of patents and their uses has also expanded, leading to both increased industry-university collaboration and the rise of a large number of start-up companies to commercialize patents licensed from universities.¹⁰⁷ Thus, in many ways, the Bayh-Dole Act has achieved many of its goals.

Not everyone, however, has hailed the Bayh-Dole Act as a success. Many commentators still stress one of the “fundamental” arguments against Bayh-Dole Act—the concern over “double paying.”¹⁰⁸ The Bayh-Dole Act allows for private ownership of patents on inventions created with public funds,

103. *See id.* at 1708.

104. *See id.* at 1709.

105. *See id.* at 1708 (“Since its passage in 1980 the Bayh-Dole Act has been consistently hailed as an unqualified success in stimulating the commercial development of discoveries emerging from government-sponsored research in universities.”); Heather Hamme Ramirez, Comment, *Defending the Privatization of Research Tools: An Examination of the “Tragedy of the Anticommons” in Biotechnology Research and Development*, 53 EMORY L.J. 359, 372-74 (2004) (discussing the role of Bayh-Dole in getting many biotechnology inventions commercialized). *See generally, e.g.*, Massaro, *supra* note 5 (discussing the changes and benefits Bayh-Dole has brought to university research).

106. *See Eisenberg, supra* note 1, at 1708-10; Massaro, *supra* note 5, at 1731-32; Rai & Eisenberg, *supra* note 9, at 292, 300-01.

107. *See Eisenberg, supra* note 1, at 1708-09; Ramirez, *supra* note 105, at 376.

108. *See Eisenberg, supra* note 1, at 1666. Representative Jack Brooks was a major proponent of this argument in the debates surrounding the passage of the Bayh-Dole Act. *See H.R. REP. NO. 96-1307*, pt. 1 at 29-32, (1980), *reprinted in* 1980 U.S.C.C.A.N. 6487, 6487-91 (dissenting views of Honorable Jack Brooks).

and these patents allow the patent holders to charge users increased prices for the protected inventions. Because the public paid for the research that led to the invention in the first place, the argument goes, why should the public have to pay a second time in the form of monopoly prices on the fruits of the research? The argument is a good one, with strong intuitive appeal.¹⁰⁹ However, the premise underlying Bayh-Dole is that, prior to the Act, the public was paying for the research and deriving no benefit from it (at least not in the form of commercial products), thus wasting public funds. Accepting this premise, then,¹¹⁰ the actual choice is between the pre-Act result of paying once and getting nothing, or the Act's result of paying twice and getting something, in the form of commercial products.¹¹¹ Bayh-Dole operates on the assumption that the latter situation is preferable.

Other commentators have questioned the need for Bayh-Dole at all. According to these commentators, the purpose of the patent system is to give inventors the incentive to perform research leading to inventions. The Bayh-Dole Act, however, applies only to research conducted with federal funding, which funding should itself provide the necessary incentive to perform the inventive research. Thus, the argument goes, since the government funding allows the public to get the results without the need for the patent incentive, why should the public now allow the inventor to get a patent on the results?¹¹²

However, the Bayh-Dole Act was concerned not with the initial incentive to perform the inventive research, but rather with the subsequent incentive to *develop* the resulting inventions into useful products.¹¹³ Even after an invention is

109. See Eisenberg, *supra* note 1, at 1666 (noting that Bayh-Dole implements “a counterintuitive policy in a number of respects” and citing *inter alia* the double-paying argument).

110. And not everyone does. See, e.g., *id.* at 1703-04 (discussing the argument that the patent-licensing statistics are misleading, and that government-funded inventions were, in fact, widely used).

111. There is, of course, always the choice of eliminating public funding of research, and thus paying only the monopoly rents on inventions from the private sector. The discussion of this option is well beyond the scope of this Article.

112. See Eisenberg, *supra* note 1, at 1666-67 (presenting this as another reason the Bayh-Dole policy is “counterintuitive”); *id.* at 1668-69 (discussing this “standard instrumental argument for patents”).

113. See *id.* at 1669-70. Indeed, some argue that the incentive to develop is the more important incentive generated by the patent system. See generally, e.g., F. Scott Kieff, *Property Rights and Property Rules for Commercializing*

made, extensive further development may be required to convert the basic idea into a final product; indeed, development costs typically greatly exceed research costs.¹¹⁴ While the government may perform and fund basic research, it typically does not perform or fund this subsequent development research, preferring to leave this task to private industry. Absent a patent or exclusive license to a patent, or some other mechanism that allows recovery of these development costs, however, firms will be unwilling to incur such costs. If the rights in government inventions are freely available to all, then any firm that pays to develop such an invention runs the risk that later competitors will jump in and undercut it, as the competitors would be able to charge lower prices because they did not incur the development costs. The Bayh-Dole Act effectively gets the invention into the hands of industry, the more appropriate place for such product development.¹¹⁵

B. PATENT LAW CONCERNS

The Bayh-Dole Act brought an increased role for patents in government-funded research, but it also highlighted the tension between the patent system and the government-funded research system. Both systems have the ultimate goal of advancing scientific progress and thereby benefiting society as a whole, but in the short run patents may sometimes interfere with scientific progress. Patents conferring exclusive rights to basic discoveries or tools (that is, tools that are not themselves intended to be developed into consumer products, but that are nevertheless important in facilitating future research that may lead to such products) may obstruct further research into important areas, as may multiple patents covering different pieces of a larger research enterprise. Various solutions have arisen to address some of these obstructions, including infringement exemptions for basic research and the sharing of patents in patent pools. This Section explores some of these obstructions and solutions (or proposed solutions) for relieving these obstructions. The proposed Bayh-Dole licensing scheme presented in this Article utilizes some aspects of these solutions to help resolve the tension created by allowing patents on

Inventions, 85 MINN. L. REV. 697 (2001); Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977).

114. See Eisenberg, *supra* note 1, at 1669.

115. *Id.*

research funded by the public.

1. The Patent Right and Blocking Patents

A patent is a personal property right in an invention.¹¹⁶ Importantly, the fundamental patent right is a *negative* right rather than a positive right.¹¹⁷ As U.S. statutory patent law makes clear, the only right conferred by a patent is the right to *exclude* another from “mak[ing], us[ing], offer[ing] to sell, or sell[ing] any patented invention, within the United States or import[ing] into the United States any patented invention”;¹¹⁸ a patent gives the patentee no positive right to do anything. For example, a patent on a potential pharmaceutical does not give the patentee the right to sell a pharmaceutical product to the public; the Food & Drug Administration (FDA), not the Patent & Trademark Office, is the entity charged with approving drugs for sale, and the existence of a patent is largely irrelevant to the approval process.¹¹⁹ The patent on the pharmaceutical simply gives the patentee the right to prevent anyone else from selling that pharmaceutical.¹²⁰

Because they are personal property rights, patent rights may be licensed or assigned (sold) to others.¹²¹ As the patent right is a negative right, a patent license is in reality the patentee’s promise not to sue the licensee for infringement.¹²² Furthermore, patent rights are divisible: “A patentee may limit the grant of rights awarded under a license. A licensee could, for example, obtain the right to use a patented invention but not to sell it.”¹²³ In addition, there are two broad categories of patent licenses. An exclusive license grants all of the patent rights to a single licensee and requires that the patentee grant no further licenses, while a nonexclusive license allows the patentee to grant licenses to many parties.¹²⁴ These attributes may also be combined, as in, for example, an exclusive license to make the patented invention or an exclusive license to all of

116. See 35 U.S.C. § 261 (2000) (“Patents shall have the attributes of personal property.”).

117. See ROGER E. SCHECHTER & JOHN R. THOMAS, PRINCIPLES OF PATENT LAW 4 (2004).

118. 35 U.S.C.A. § 271(a) (2001 & Supp. 2005).

119. See SCHECHTER & THOMAS, *supra* note 117, at 4.

120. See *id.*

121. See *id.* at 362.

122. See *id.* at 364.

123. *Id.* at 364.

124. See *id.* at 365.

the rights to the invention in a particular geographic region or commercial market.¹²⁵

The positive right/negative right distinction comes into play with blocking patents.¹²⁶ Two patents are said to “block” each other when a later invention infringes an existing patent, but is nonetheless patentable itself.¹²⁷ In such a case, neither patentee can practice the new invention without a license from the other. For example, if *A* has a patent on a new drug and *B* then obtains a patent on an improved method of making that new drug, neither patentee can make the drug using the new process without infringing the other’s patent: *A*’s patent allows *A* to exclude *B* from making the patented drug by any method, but *B*’s patent allows *B* to exclude *A* from making the patented drug by the improved method.¹²⁸ For anyone to make the drug by the improved method, the parties will have to work out some sort of licensing arrangement.¹²⁹ Alternatively, different parties might own patents on components that need to be combined to make a saleable product. Neither party can build the complete product without a license from the other. For example, if one party owns the patent on the television tuner and another party owns the patent on the television tube, neither party will be able to build a complete television without a license from the other. The parties generally resolve this fairly common situation by agreeing to license each other, often called cross-licensing.

The negative right granted by a patent is a major strength of the patent system, but in some circumstances it can lead to problems. The presence of multiple overlapping rights over a piece of technology can operate to block development of that technology, as no one can get sufficient rights to advance the technology.¹³⁰ Problems also may arise when a patent on a core

125. See, e.g., *Waterman v. Mackenzie*, 138 U.S. 252, 255-56 (1891) (discussing various possible license terms).

126. See SCHECHTER & THOMAS, *supra* note 117, at 4-5 (citing Robert P. Merges, *Intellectual Property Rights and Bargaining Breakdowns: The Case of Blocking Patents*, 62 TENN. L. REV. 75 (1994)). See generally ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW & POLICY: CASES & MATERIALS* 88-89, 392-93 (3d ed. 2002) (discussing blocking patents).

127. See SCHECHTER & THOMAS, *supra* note 117, at 4-5 & n.3.

128. Cf. *id.* at 4-5 (using the example of a patented mousetrap and an improved version of the mousetrap).

129. See *id.* at 5.

130. This problem arose in the early days of the airplane and automobile

technology is used to block development of future research.¹³¹ Various solutions have been used or proposed to address these issues, including an explicit legal exemption for experimental use and the sharing of patent rights among the members of an industry, both of which will be discussed below.

2. Anticommons

One possible ramification of the negative patent right is that it may create an “anticommons” that leads to underuse of a particular technology. The anticommons concept has its roots in an influential article in *Science* in 1968, in which Garrett Hardin proposed the “tragedy of the commons.”¹³² According to this theory, “people often overuse resources they own in common because they have no incentive to conserve.”¹³³ Over time, Hardin’s paper became “a powerful justification for privatizing commons property.”¹³⁴ In 1998, again in *Science*, Professors Michael Heller and Rebecca Eisenberg propounded an inverse “tragedy of the anticommons.”¹³⁵ According to this theory, the reverse situation may also arise: If too many people have rights to exclude others from a piece of property, then that piece of property may be underused.¹³⁶ In particular, Professors Heller and Eisenberg propose that too many patent rights are being awarded in the biotechnology field, and these patents are interfering with the progress of research in this area.¹³⁷

Professors Heller and Eisenberg present their theory this way:

[A] resource is prone to underuse in a “tragedy of the anticommons” when multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use. In theory, in a world of costless transactions, people could always avoid commons or anticommons tragedies by trading their rights. In

industries. See Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293, 1342-47 (1996).

131. See MERGES & DUFFY, *supra* note 126, at 393.

132. See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998) (citing Garrett Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243 (1968)).

133. *Id.*

134. *Id.*

135. *Id.*

136. See *id.*

137. See *id.*

practice, however, avoiding tragedy requires overcoming transaction costs, strategic behaviors, and cognitive biases of participants, with success more likely within close-knit communities than among hostile strangers. Once an anticommons emerges, collecting rights into usable private property is often brutal and slow.¹³⁸

The authors worry that exactly this situation is emerging in the biotechnology field, particularly with “upstream” basic research that is needed to feed “downstream” applied research.¹³⁹ They note that changes in U.S. policy, exemplified by legislation such as Bayh-Dole, have led to increased patenting of discoveries that in the past would have been left to the public domain.¹⁴⁰ Accompanying this increased patenting in the public sector is an increase in both the number of biotechnology companies and their awareness of the value of intellectual property rights.¹⁴¹ Taken together, these trends have led to more pieces of the biotechnology landscape being covered by proprietary rights, typically patent rights.¹⁴² Because the patent right is the right to exclude, researchers in the biotechnology field are at risk of being excluded from advancing their research.

Professors Heller and Eisenberg point to two mechanisms currently in place that may lead to an anticommons in biotechnology. The first mechanism involves the tendency to give concurrent rights in potential future products.¹⁴³ For example, the authors note that many researchers may wind up with patents on individual segments of a particular gene sequence, each patent hindering the others from doing further basic research on the gene as a whole.¹⁴⁴ Similarly, a wide division of ownership of the various genes needed for a test to screen for useful pharmaceuticals might prevent any one researcher from collecting all the pieces needed to perform the screen.¹⁴⁵

The second mechanism involves the increased “stacking” of licenses.¹⁴⁶ An increasingly common type of license to use

138. *Id.* (endnotes omitted).

139. *See id.*

140. *See id.*

141. *See id.*

142. *See id.*

143. *See id.* at 699.

144. *See id.*

145. *See id.*

146. *See id.*

biotechnology research tools is the “reach-through” license, which requires the licensee to pay the patentee a royalty on any product developed using the patented technology, whether the patented technology appears in the final product or not.¹⁴⁷ When a large number of these upstream patented technologies are needed to create a particular saleable product, the aggregation of license fees may make the project economically untenable.¹⁴⁸

After concluding that these mechanisms may contribute to the rise of a biotechnology anticommons, the authors explore whether such an anticommons is likely to persist if it does arise.¹⁴⁹ They cite three reasons why it might. First, the transaction costs of bargaining are high, and biotechnology firms might not be able to bear these high costs.¹⁵⁰ Bearing high costs is particularly difficult for the nonprofit entities such as universities that—through Bayh-Dole—hold a large number of the important patents.¹⁵¹ Furthermore, the rights involve such a wide variety of techniques that valuing them is difficult, and this uncertainty increases disputes over license terms.¹⁵² Finally, other considerations, particularly antitrust laws, may stand in the way of effective bargaining.¹⁵³

Second, the diverse range of interested parties in the biotechnology industry will impede resolution of anticommons problems.¹⁵⁴ For example, public entities (such as the NIH) view themselves as playing an important role in facilitating public health, and thus desire to spread discoveries and inventions widely. Meanwhile, private entities generally will prefer to keep their inventions closer to home, benefiting from the monopoly on the resource.¹⁵⁵ Another conflict is between those entities performing “upstream” basic research and those performing “downstream” applied research. The latter would clearly prefer that the tools they need be widely available, while the former might prefer to maximize their return by

147. *See id.*

148. *See id.* at 699-700.

149. *See id.* at 700-01.

150. *See id.* at 700.

151. *See id.*

152. *See id.*

153. *See id.*

154. *See id.*

155. *See id.*

granting limited or even exclusive licenses to the tools.¹⁵⁶ Differences in culture may also lead to differing perspectives on the propriety of enforcing and/or infringing patents.¹⁵⁷

Third, cognitive biases may impede bargaining.¹⁵⁸ In particular, owners of upstream research tools are all likely to view their particular tool as the most vital to the success of the whole project, even though their tool is only one of many needed in the project, and therefore are likely to overvalue their own contribution. As a consequence, they will all tend to demand more compensation than their contribution is worth to the developer. No rational developer will be willing to pay the price to obtain access to all of the necessary tools.¹⁵⁹ Researchers may also be loathe to bargain with a scientific rival, even when the transaction might be economically advantageous for both parties.¹⁶⁰

In the end, Professors Heller and Eisenberg conclude that “[a]n anticommmons in biomedical research may be more likely to endure than in other areas of intellectual property because of the high transaction costs of bargaining, heterogeneous interests among owners, and cognitive biases of researchers.”¹⁶¹ They then finish with a few policy suggestions, recommending more careful use of privatization of research results, clearer patent limits on upstream patents, and decreased use of restrictive terms in licenses to upstream patents.¹⁶² “Otherwise, more upstream rights may lead paradoxically to fewer useful products for improving human health.”¹⁶³

3. Experimental Use

The common law experimental use exemption¹⁶⁴ is an

156. *See id.*

157. *See id.* at 700-01.

158. *See id.* at 701.

159. *See id.*

160. *See id.*

161. *Id.*

162. *See id.*

163. *Id.*

164. This Article uses the term “experimental use exemption” rather than “research exemption,” as that is the term more commonly used in the literature. This usage is not to be confused with the doctrine of “experimental use” as applied to negating a prior public use or sale. *See, e.g., City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126 (1877) (applying the experimental use doctrine); *see also* Gregory N. Pate, *Analysis of the*

important but narrow patent law doctrine that exempts certain uses of patented inventions from claims of infringement. The doctrine traces its roots to Justice Story's 1813 opinion in *Whittemore v. Cutter*.¹⁶⁵ According to Justice Story, "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."¹⁶⁶ Justice Story subsequently distinguished this type of use from "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."¹⁶⁷ As Judge Newman of the Federal Circuit recently noted, in 1813 when these cases were decided, "philosophical experiments" referred to "natural philosophy"—what we now call simply "science."¹⁶⁸ Justice Story's creation rapidly evolved into an accepted defense to infringement, as evidenced by its inclusion in treatises from the late nineteenth century.¹⁶⁹

The experimental use exemption is premised on the idea that patent law is eminently a utilitarian doctrine. As a consequence, pure research not directed towards profits should not be deemed an infringement, as it does not interfere with the pecuniary interests of the patentee.¹⁷⁰ Similarly, one of the major purposes of the patent system is to provide an incentive for inventors to disclose their invention and thereby get

Experimental Use Exception, 3 N.C. J.L. & TECH. 253, 256 (2002) (noting that "[t]he 'experimental use exception' actually describes two entirely separate [patent law] doctrines").

165. 29 F. Cas. 1120 (C.C.D. Mass. May 1813).

166. *Id.* at 1121.

167. *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. Oct. 1813).

168. See *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 874-75 n.8 (Fed. Cir. 2003) (Newman, J., dissenting), *vacated*, 125 S. Ct. 2372 (2005); see also Brief for *Amicus Curiae* Bar Association of the District of Columbia — Patent, Trademark & Copyright Section in Support of Neither Party at 6-8, *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005) (No. 03-1237) ("Later cases show that the term 'philosophical,' as used in *Whittemore I*, is synonymous with the term 'scientific.'").

169. See *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 862 (Fed. Cir. 1984) (discussing the history of the experimental use exemption and citing W. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* § 898 (1890)).

170. And as a corollary of this view of the doctrine, research done in a corporate context is virtually never deemed to be eligible for the exemption. See Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. & TRADEMARK OFF. SOC'Y 617, 626-30 (1985) (collecting cases).

technical information into the hands of those who can make use of it.¹⁷¹ Thus, the common law experimental use exemption, as traditionally understood, allows for non-commercial research on the patented invention.¹⁷²

Commentary on the common law experimental use exemption has been mixed. Some commentators believe that any but the most minimal exemption is entirely inappropriate and undermines the strength of the patent system.¹⁷³ Others counter that the doctrine plays a crucial role in the law, particularly in accommodating patent law to the norms of science (principally the scientific norm of the free sharing of ideas and techniques as part of a unified endeavor), especially in the realm of “basic” research, and in resolving otherwise intractable sharing problems (such as anticommons).¹⁷⁴

The commentators often divide experimental use into three basic categories.¹⁷⁵ The first category traces its roots back to

171. See SCHECHTER & THOMAS, *supra* note 117, at 12.

172. For a summary and discussion of some of the varying proposed implementations of an experimental use system, including its widespread use in foreign patent systems, see NATIONAL RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY 108-17 (Stephen A. Merrill, Richard C. Levin & Mark B. Myers eds., 2004) (chapter entitled “Seven Recommendations for a 21st-Century Patent System: Shield Some Research Uses of Patent Inventions from Infringement Liability”).

173. See generally, e.g., Richard E. Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. PAT. OFF. SOC'Y 357 (1957); Jordan P. Karp, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169 (1991); Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J.L. REFORM 141, 201-05, 211-16 (2004); Ramirez, *supra* note 105, at 384-88.

174. See generally, e.g., Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989); Hantman, *supra* note 170; Janice M. Mueller, *No “Dilettante Affair”: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001); Rochelle C. Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457 (2004); Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 81 WIS. L. REV. 81 (2004). Cf. Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000) (proposing a “fair use” right for patent law based on the copyright fair use doctrine; the impact of this right would be similar to experimental use).

175. See FEDERAL TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 4, at 34-37 (2003) [hereinafter FTC INNOVATION REPORT], available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf> (discussing the three

Justice Story's formulation—"for the purpose of ascertaining the sufficiency of the machine to produce its described effects"¹⁷⁶ and "to ascertain the verity and exactness of the specification."¹⁷⁷ In other words, later researchers are allowed to experiment with the patented invention to make sure that it works as claimed and that its description in the patent specification complies with the patent laws.¹⁷⁸ Without such a right, competitors would have no way of determining the validity of the patent, and the patent would be effectively invincible to this type of challenge.¹⁷⁹ This aspect of experimental use is relatively uncontroversial and is generally accepted, even by those who reject a broader experimental use right.¹⁸⁰

The second category of experimental use involves research on the patented invention for the purpose of designing around it or improving upon it.¹⁸¹ This category is more controversial. For those commentators who accept experimental use in general, this category is their prime motivation.¹⁸² If

categories).

176. *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. May 1813).

177. *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. Oct. 1813).

178. The patent laws require that:

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

35 U.S.C. § 112 (2000). Failure to comply with these enablement and written description requirements results in the patent being invalid. *See id.* § 282 (2000) (listing as a defense to infringement "[i]nvalidity of the patent or any claim in suit for failure to comply with any requirement of section[] 112 . . . of this title").

179. *See Eisenberg, supra* note 174, at 1074-75. Professor Eisenberg also notes that such scrutiny of the results of others is important to the integrity of the scientific enterprise itself. *See id.* at 1053-55.

180. *See, e.g.,* FTC INNOVATION REPORT, *supra* note 175, at ch. 4, at 36 ("Both scholarly analysis and Hearing participants favor an experimental use defense in the first setting. Research to determine if or how a patented invention works essentially makes effective the required enablement disclosure." (footnote omitted)); Karp, *supra* note 173, at 2176-77. Indeed, it seems so accepted as to have never been challenged in court.

181. *See* FTC INNOVATION REPORT, *supra* note 175, at ch. 4, at 36.

182. *See, e.g.,* Eisenberg, *supra* note 174, at 1078 ("A patent holder should not be entitled to enjoin the use of a patented invention in subsequent research in the field of the invention, which could potentially lead to improvements in the patented technology or to the development of alternative means of achieving the same purpose."); Hantman, *supra* note 170, at 639-40 ("[A]ctivity directed to improvements and new uses for patented technology

subsequent researchers cannot experiment on the claimed invention for these purposes, the reasoning goes, what is the point of the detailed disclosure provisions of the Patent Act?¹⁸³ As Judge Newman recognized in her dissent in *Integra Lifesciences I, Ltd. v. Merck KGaA*:

The patent statute requires full disclosure of the invention, including details of enabling experiments and technical drawings and best modes and preferred embodiments, even commercial sources of special components. Such details would be idle and purposeless if this information cannot be used for 17-20 years [that is, the length of the patent term]. . . . To the contrary, the patent system both contemplates and facilitates research into patented subject matter, whether the purpose is scientific understanding or evaluation or comparison or improvement. Such activities are integral to the advance of technology.¹⁸⁴

Patentees understandably oppose such a right, because exempting these types of uses runs directly counter to their economic interests—the exemption is aimed at providing alternatives to the patented invention.¹⁸⁵ Supporters of the exemption respond that such uses are an important part of experimental use—indeed, as Judge Newman noted, such uses are fundamental to the patent system itself. A major goal of the patent system is to get patented inventions into the hands of researchers so that they can be exploited in these ways.¹⁸⁶ Successful research, if the resulting product no longer infringes the patent, could be handled with a royalty on any commercial products.¹⁸⁷

The third and most controversial category is research tools, that is, tools that facilitate research into *other* areas.¹⁸⁸ The

should fall within the experimental use exception.”).

183. Indeed, one commentator argues:

[E]xperimental use aimed at understanding, designing around, or improving a patented invention is merely an extension of disclosure [as required in § 112]. . . . “Experimenting on” a patented invention can, and should, be broadly permitted, regardless of commercial intent, as a means of ensuring that the public receives the benefit of its patent bargain with respect to follow-on innovation.

Strandburg, *supra* note 174, at 146.

184. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 875 (Fed. Cir. 2003) (Newman, J., dissenting), *vacated*, 125 S. Ct. 2372 (2005).

185. See Eisenberg, *supra* note 174, at 1075-76

186. See Hantman, *supra* note 170, at 643.

187. See Eisenberg, *supra* note 174, at 1078-79 (suggesting such a remedy).

188. See *id.* at 1074; *Integra Lifesciences*, 331 F.3d at 878 (Newman, J., dissenting).

sole purpose of research tools is to facilitate subsequent research, and thus the only market for research tools is researchers.¹⁸⁹ If researchers are exempt from infringement of such tools, then the patentee has no one left to exclude, and so cannot recoup its development costs. Allowing experimental use of such tools effectively destroys any market for them, and therefore any incentive to develop them.¹⁹⁰ Even the commentators who favor the experimental use exemption often exclude research tools, limiting the exemption to further research into the thing patented for purposes of improving on or designing around the patent.¹⁹¹ However, some recent commentators—particularly those concerned with anticommons and related problems in the biotechnology area—advocate expanding the exemption to cover even research tools, at least when these tools are being unreasonably withheld and are not available through the anonymous market.¹⁹²

Research tools are a particularly hot topic in biotechnology. The NIH appointed a working group, the NIH Working Group on Research Tools, to study the issue. The Working Group

189. See Eisenberg, *supra* note 174, at 1072-74.

190. *Id.* (“An experimental use exemption seems most likely to undermine critical patent incentives when the researcher is an ordinary consumer of an invention with a primary or at least significant market among research users.”).

191. *Id.* (“Nor does it seem likely that a research exemption is necessary to ensure that scientists will have access to such an invention: the patent holder will see research users as potential customers rather than hostile rivals and will want to extend licenses to them in order to extract the full value of the patent monopoly.”); Hantman, *supra* note 170, at 639; FTC INNOVATION REPORT, *supra* note 175, at ch. 4, at 36 (“Inventors of tools used by researchers need an income stream from those who use their inventions. The Hearing record provides no basis for exempting such tools from patent protection, and leading scholarly commentary agrees.”); *Integra Lifesciences*, 331 F.3d at 878 (Newman, J., dissenting) (“A research tool . . . is as subject to the patent right as is any other device or method, whether it is used to conduct research or for any other purpose.”).

192. See Mueller, *supra* note 174, at 58 (proposing researchers be able to use research tools in this situation, subject to a government-determined royalty); Strandburg, *supra* note 174, at 142-46 (proposing the same, but only after an initial five-year period of exclusivity). On the other hand, arriving at the royalty would be difficult, particularly where multiple patents are infringed (as when, for example, the researcher screens a library that contains multiple patented DNA or protein products). See Mueller, *supra* note 174, at 63-66 (discussing the difficulties of determining the proper royalty rate, and stating, “The determination of appropriate [royalty] rates can be a very complex and expensive process”); Eisenberg, *supra* note 174, at 1077 (discussing the same difficulties, for a different aspect of experimental use, and stating, “Determination of reasonable royalties is never an easy task”).

issued a report that subsequently led to a set of guidelines for use of such tools at the NIH.¹⁹³ The report provided the following definition:

We use the term “research tool” in its broadest sense to embrace the full range of resources that scientists use in the laboratory, while recognizing that from other perspectives the same resources may be viewed as “end products.” For our purposes, the term may thus include cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools (such as PCR), methods, laboratory equipment and machines, databases and computer software.¹⁹⁴

Similarly, Judge Newman, in her dissent in *Integra Lifesciences*, stated: “A research tool is a product or method whose purpose is use in the conduct of research, whether the tool is an analytical balance, an assay kit, a laser device (as in *Madey v. Duke University*), or a biochemical method such as the PCR (polymerase chain reaction).”¹⁹⁵ Concern over the use of these research tools in biotechnology has been the subject of extensive recent commentary and analysis.¹⁹⁶

However, the distinction between experimenting on the patented invention and using the patented invention as a tool for other research is not without its problems—in many cases, drawing the line between the two types of uses is difficult.¹⁹⁷ For example, a researcher may be performing research into a

193. See NATIONAL INSTS. OF HEALTH, REPORT OF THE NATIONAL INSTITUTES OF HEALTH WORKING GROUP ON RESEARCH TOOLS (1998) [hereinafter NIH RESEARCH TOOLS REPORT], available at <http://www.nih.gov/news/researchtools/>; see also Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72090 (Dec. 23, 1999) [hereinafter NIH Research Tools Guidelines], available at <http://ott.od.nih.gov/pdfs/64FR72090.pdf>.

194. NIH RESEARCH TOOLS REPORT, *supra* note 193 (Background section).

195. *Integra Lifesciences*, 331 F.3d at 878 (Newman, J., dissenting) (footnote omitted).

196. See generally, e.g., NIH RESEARCH TOOLS REPORT, *supra* note 193; NIH Research Tools Guidelines, *supra* note 193; Mireles, *supra* note 173; Mueller, *supra* note 174; Ramirez, *supra* note 105.

197. See NATIONAL RESEARCH COUNCIL, *supra* note 172, at 114-15 (“[A]lthough it may seem relatively simple to distinguish use of a patented invention to ‘see how it works’ or for the purpose of ‘improvement’ from use of a patented research tool, it may be very difficult in practice.”); Eisenberg, *supra* note 174, at 1084-86 (indirectly exploring the difficulty in making the distinction regarding transgenic mice); cf. *Integra Lifesciences*, 331 F.3d at 878 (Newman, J., dissenting) (chiding the majority for misunderstanding the distinction and therefore mischaracterizing the invention of the patents in suit).

particular pharmaceutical product. If the researcher needs large quantities of the pharmaceutical, he or she may be simultaneously refining a method for producing the pharmaceutical product more efficiently and using the resulting product in other experiments. If a step in the production method is patented, is the researcher legitimately experimenting “on” this step (as part of the refinement research), or is he or she illegitimately using the step as a “tool” for other research (because the step is used to produce a product that is itself used for further research)? In this type of situation, which is not uncommon, both arguments are equally plausible. Thus, the necessary distinction between the two types of uses is not always easy to make.

Cases involving the common law experimental use exemption for researchers at academic institutions have not actually arisen with much frequency. The exemption has traditionally operated more informally, in that historically academic scientists have patented their inventions only rarely, and commercial patentees have sued academic researchers only rarely.¹⁹⁸ The modern emphasis on extracting the full value from patents, coupled with the increase of profit-motivated research in universities in response to Bayh-Dole, is causing a shift in this behavior, and so experimental use has taken on more importance recently.¹⁹⁹

The Federal Circuit has generally viewed the common law experimental use exemption with grave suspicion, reading the exemption narrowly. In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,²⁰⁰ a generic drug company argued that its research and testing on a patented drug prior to the expiration of the patent, with the goal of releasing a generic equivalent of the drug immediately upon expiration of the patent, qualified for the experimental use exemption.²⁰¹ The court disagreed, holding that this research and testing was for commercial purposes and was therefore an infringement of Roche’s patent.²⁰² Although Congress later overruled the specific

198. See FTC INNOVATION REPORT, *supra* note 175, at ch. 4, at 35 (“The strength and contours of the defense have not been fully tested; as several panelists testified, corporations typically have not sued universities.”).

199. See Dreyfuss, *supra* note 174, at 457-61 (exploring the reasons for this shift).

200. 733 F.2d 858 (Fed. Cir. 1984).

201. See *id.* at 860, 862.

202. See *id.* at 863 (“[W]e hold the experimental use exception to be truly narrow, and we will not expand it under the present circumstances. . . . Bolar’s

holding in *Roche* by creating a special statutory exemption for infringements that are “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” (that is, research related to the FDA drug approval process),²⁰³ it did not address the common law experimental use exemption as a general proposition. Later, in his concurrence in *Embrex, Inc. v. Service Engineering Corp.*,²⁰⁴ Judge Rader stated flatly that the common law experimental use exemption no longer existed: “[N]either the statute nor any past Supreme Court precedent gives any reason to excuse infringement because it was committed with a particular purpose or intent, such as for scientific experimentation or idle curiosity.”²⁰⁵

More recently, the Federal Circuit considered the common law research exemption in *Madey v. Duke University*.²⁰⁶ John Madey was a researcher at Duke who had a patent (granted before he was hired by Duke) on a laser that was useful for certain research applications.²⁰⁷ Madey subsequently left Duke after a series of disputes over his position,²⁰⁸ yet even after his departure, Duke continued to use his laser, without a license, to complete work under various government grants.²⁰⁹ In response, Madey sued Duke for patent infringement.²¹⁰ As a defense, Duke asserted that its use was entirely experimental, and therefore its infringement should be excused.²¹¹ The Federal Circuit declined to allow the exemption.²¹² More importantly, it expressed its holding in very broad language that severely narrowed (if not destroyed) the exemption, taking “philosophical” in its narrow modern sense of esoteric inquiry

intended ‘experimental’ use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry . . . [and] is thus an infringement of the ‘053 patent.”).

203. 35 U.S.C. § 271(e) (2000). The Federal Circuit has also interpreted this exemption narrowly. See *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 865-68 (Fed. Cir. 2003), *vacated*, 125 S. Ct. 2372 (2005).

204. 216 F.3d 1343 (Fed. Cir. 2000).

205. *Id.* at 1353 (Rader, J., concurring).

206. 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003).

207. *See id.* at 1352.

208. *See id.* at 1352-53.

209. *See id.* at 1353-54.

210. *See id.* at 1353.

211. *See id.* at 1360-63.

212. *See id.* at 1362-63.

rather than its historic sense of science generally:²¹³

[R]egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate 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.²¹⁴

Shortly after *Madey*, the common law exemption arose again in *Integra Lifesciences I, Ltd. v. Merck KGaA*.²¹⁵ On its face, *Merck* involved interpretation of the statutory exemption for research relating to the FDA drug approval process contained in 35 U.S.C. §271(e), and how far back into the research process the exemption extended.²¹⁶ Indeed, the majority opinion of the Federal Circuit specifically stated that the common law experimental use exemption was not at issue.²¹⁷ However, Judge Newman dissented, contending that the §271(e) exemption extended back to the point at which the common law experimental use exemption ended, and thus all of *Integra's* conduct was covered under one or the other exemption.²¹⁸ She also used the opportunity to attack the broad language of *Madey* regarding the common law exemption, characterizing the breadth of the *Madey* holding as unnecessary dicta.²¹⁹ In her view, *Madey* involved using a research tool for its intended purpose (that is, facilitating research into *other* areas), which should be an infringement not implicating the common law experimental use exemption.²²⁰ The common law exemption should apply only to further research into the thing patented, for purposes of improving on or designing around the patent.²²¹ Thus, *Madey's* language attacking the foundation of the common law experimental use exemption was unnecessary. The Supreme Court subsequently reversed the Federal Circuit's narrow reading of the statutory exemption, expanding its coverage to a broader range of

213. See *supra* note 168 and accompanying text.

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

215. 331 F.3d 860 (Fed. Cir. 2003), *vacated*, 125 S. Ct. 2372 (2005).

216. See *id.* at 864-68 (concluding that the answer was "not very far").

217. See *id.* at 863 n.2.

218. See *id.* at 872-78 (Newman, J., dissenting).

219. See *id.* at 878 n.10.

220. See *id.*

221. See *id.*

research relating to FDA drug approval.²²² However, the Supreme Court's opinion did not address the scope of the common law research exemption.²²³

Despite the Federal Circuit's current reluctance to apply it, the experimental use exemption plays an important role in facilitating research, and so it should be implemented in at least a limited way.

4. Patent Pools

Another way to accommodate the conflicting exclusionary rights in a complex technology is with a patent pool. In a patent pool, individual patentees assign their patents to a single collective entity in exchange for license to use the other

222. Merck KGaA v. Integra Lifesciences I, Ltd., 125 S. Ct. 2372, 2383-84 (2005).

223. Several commentators who favor a broad experimental use exemption filed amicus briefs urging the Court *not* to address the issue in this case. See *Amicus Curiae* Brief of the American Intellectual Property Law Association in Support of Neither Party at 22-24, Merck KGaA v. Integra Lifesciences I, Ltd., 125 S. Ct. 2372 (2005) (No. 03-1237) ("The question presented by the petitioner does not implicate the scope of the common-law exception, and in any event the facts of this case do not raise the issue. AIPLA therefore urges this Court not to consider the scope and nuances of the common-law doctrine as part of its review."); Brief of Intellectual Property Professors as *Amici Curiae* in Support of Neither Party at 15-21, Merck KGaA v. Integra Lifesciences I, Ltd., 125 S. Ct. 2372 (2005) (No. 03-1237) ("Th[is] case therefore does not provide a good opportunity for the Court to determine the reach of the traditional experimental use exemption. There are, however, important reasons for the Court to state explicitly that any decision in this case does not foreclose the assertion of the traditional experimental use exemption."). However, other parties favoring the exemption requested that the Court consider the issue. See Brief of *Amici Curiae* Consumer Project on Technology, Electronic Frontier Foundation & Public Knowledge in Support of Petitioner at 24-30, Merck KGaA v. Integra Lifesciences I, Ltd., 125 S. Ct. 2372 (2005) (No. 03-1237) [hereinafter EFF Amicus Brief] ("It is critically important that the Court take this opportunity to correct the Federal Circuit's improperly narrow interpretations of the experimental use exception in *Roche*, *Embrex*, *Madey*, and this case."); Brief for *Amicus Curiae* Bar Association of the District of Columbia — Patent, Trademark & Copyright Section in Support of Neither Party at *passim*, Merck KGaA v. Integra Lifesciences I, Ltd., 125 S. Ct. 2372 (2005) (No. 03-1237) ("An experimental use exemption is recognized either by statute or by common law in developed countries and is fundamentally necessary to foster innovation. Failure to recognize this important exemption to infringement will deter research in the United States and encourage companies to conduct their research and development off-shore."). The various briefs from the case are available on Dennis Crouch's Patently-O Blog, at http://patentlaw.typepad.com/patent/2005/02/merck_kgaa_stat.html (last visited Aug. 12, 2005).

patents in the pool.²²⁴ Patent pools typically charge royalties and then redistribute the royalties to their members according to an agreed formula.²²⁵ Although these royalty payments can be very important, in many instances the main function of a patent pool is to provide access to the patents in the pool, not to make money directly.²²⁶

Historically, patent pools have arisen in such industries as the early airplane and automobile industries, where a few competing manufacturers held overlapping patents that blocked each other and thus prevented any of the manufacturers from making any products.²²⁷ These blocking problems were often resolved with patent pools.²²⁸ More recently, patent pools have been used to resolve blocking situations that were preventing deployment of the MPEG-2 video compression format and DVD-video/DVD-ROM formats.²²⁹ Indeed, a patent pool has been repeatedly proposed as a solution to the similar blocking problems that are arising in the biotechnology area.²³⁰ Many of the historical patent

224. See Merges, *supra* note 130, at 1340-42.

225. See *id.* at 1341-42.

226. See, e.g., *id.* at 1344 (“[In the airplane patent pool,] most licensing was conducted on a royalty-free basis, with mutual forbearance from infringement suits as the real payment for the exchange.”); *id.* at 1346 (“As with the [airplane pool], most members of the automobile pool seemed content to rely on the blanket, royalty-free cross licensing that was also available under the pool.”).

227. See *id.* at 1340-47; see also Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 888-91 (1990) (discussing the impact of patents on the development of the automobile and airplane industries).

228. See Merges, *supra* note 130, at 1340-47.

229. See JEANNE CLARK ET AL., U.S. PATENT & TRADEMARK OFFICE, PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS? 4-5 (2000), available at <http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf>.

230. See, e.g., *id.* at 8-11; David B. Resnik, *A Biotechnology Patent Pool: An Idea Whose Time Has Come?*, J. PHIL., SCI. & L. (Jan. 23, 2003), <http://www.miami.edu/ethics/jpsl/archives/papers/biotechPatent.html>; Lawrence M. Sung & Don. J. Peltó, *Greater Predictability May Result in Patent Pools: As the Federal Circuit Refines Scope of Biotech Claims, Use of Collective Rights Becomes Likely*, NAT’L L.J., June 22, 1998, at C2. This proposal dates back at least as far as 1983. See *Stanford, California Push Patent-Pool—With Caution*, BIOTECHNOLOGY NEWSWATCH, Mar. 21, 1983, at 5 (discussing a proposed patent pool for basic biotechnology research tools). Not everyone supports this proposal, however. See Bradley J. Levang, Comment, *Evaluating the Use of Patent Pools for Biotechnology: A Refutation to the USPTO White Paper Concerning Biotechnology Patent Pools*, 19 SANTA CLARA COMPUTER & HIGH TECH. L.J. 229 (2002).

pools, however, ultimately required government intervention to get the pool started.²³¹ To date, no comprehensive patent pools have arisen in the biotechnology field.

II. BAYH-DOLE: PRIOR CRITICISM AND PROPOSED SOLUTION

The Bayh-Dole Act has been, in the estimation of many, very successful in getting more government-funded inventions into private hands so they can be developed for the use of the public. The Bayh-Dole Act has also been the subject of substantial criticism. And as with any criticized statute, suggestions for its reform abound. This Section focuses on one particular criticism and proposed reform.

A. THE CRITICS: RAI AND EISENBERG

In their article *Bayh-Dole Reform and the Progress of Biomedicine*,²³² Professors Rai and Eisenberg express dissatisfaction with the current implementation of the Bayh-Dole Act and propose a solution that, while perhaps appealing in the abstract, is unworkable in practice. Professors Rai and Eisenberg appear to accept the basic premise behind the Bayh-Dole Act—that is, some inventions created with federal funds will not be developed into products without a patent.²³³ However, they also point out that many other federally funded inventions will still be developed, or in fact do not need further development, even in the absence of a patent.²³⁴ In the latter cases, the patent is unnecessary and only imposes a tax on future research, or in some cases even blocks such future research.²³⁵ Their primary concern is that the current Act creates a heavy bias in favor of patenting *all* inventions, whether such patenting advances development of the invention, or merely imposes a tax or erects a block.²³⁶

231. See Merges, *supra* note 130, at 1356-57 & n.226 (discussing formation of the aircraft and synthetic rubber research patent pools at the behest of the government, triggered by entry in to World War I and II, respectively).

232. Rai & Eisenberg, *supra* note 9.

233. See *id.* at 302-03. They cite as an example the machines that have been developed for rapid DNA sequencing. See *id.* But see Eisenberg, *supra* note 1 (expressing deep skepticism about Bayh-Dole and its rationale).

234. See Rai & Eisenberg, *supra* note 9, at 300.

235. See *id.*

236. See *id.* at 291, 303.

As an example, they cite the Cohen-Boyer patent on basic recombinant DNA techniques.²³⁷ The research leading to this patent, which covered technology fundamental to the biotechnology industry, was conducted with government funding, and once created, the invention required no further development.²³⁸ The employers of the researchers, Stanford University and the University of California, patented the invention anyway, and then widely licensed the patent nonexclusively at a low royalty rate to anyone who requested a license.²³⁹ Thus, the patent on the techniques offered no incentive effects at all—the spread of the invention would have been the same if it had been dedicated to the public domain. The patent served only to bring in revenue to the universities, at the cost of imposing a tax on essentially all biotechnology research.²⁴⁰

Such a tax on research is, however, only part of the problem. The Cohen-Boyer patent was at least licensed widely and with relatively few restrictions.²⁴¹ Professors Rai and Eisenberg express concern over fundamental patents similar to Cohen-Boyer that are *not* licensed to all comers, but are instead kept exclusive.²⁴² Such patents have the potential to block large areas of research, severely limiting their further development. As an example, the authors discuss the current state of research into human embryonic stem cells.²⁴³ And even when the patentee is amenable to licensing, the licensing may not take place, for a variety of reasons.²⁴⁴ Even when licensing does eventually take place, the costs and delays in reaching the agreement will have an adverse impact on the research

237. *See id.* at 300-01.

238. *Id.* at 300.

239. *See* NATIONAL RESEARCH COUNCIL, INTELLECTUAL PROPERTY RIGHTS AND THE DISSEMINATION OF RESEARCH TOOLS IN MOLECULAR BIOLOGY 41 (1997); Rai & Eisenberg, *supra* note 9, at 300.

240. *See* Rai & Eisenberg, *supra* note 9, at 300. *But see* Ramirez, *supra* note 105, at 376 (“The Cohen-Boyer patent is a positive example of the benefits of patenting research tools.”).

241. *See* Rai & Eisenberg, *supra* note 9, at 300.

242. *See id.* at 301.

243. *See id.* at 301. Indeed, their concern that research into these embryonic stem cells will be (or already has been) blocked seems to be the driving force behind their proposal. *See id.* at 292-93, 296, 301-02, 309-10, 313.

244. *See id.* at 297-98. Some of the reasons for bargaining breakdown and how this breakdown may lead to an “anticommons” are discussed in more detail *supra* Part I.B.2.

enterprise.²⁴⁵

These disadvantages may occur with either category of invention, those that would have been developed without a patent and those that would not have been developed. If the invention would not have been developed without the patent, then these disadvantages may simply be acceptable costs of the system.²⁴⁶ When the invention would have been developed anyway, however, then these disadvantages simply become drags on the research system, with no concomitant benefit.²⁴⁷ The primary concern of Professors Rai and Eisenberg is that the current Act strongly favors patents, making no distinction between the two categories. Thus, many important inventions are being unnecessarily locked up by patents, creating needless costs and blocks to the research enterprise.²⁴⁸

B. THEIR PROPOSED SOLUTION

To address this problem, Professors Rai and Eisenberg propose giving the NIH the duty of analyzing each funding agreement it makes to determine into which category any resulting invention will fit, and then basing the decision to award or deny the funding recipient the right to seek patents on this determination.²⁴⁹ If an invention needs further development, then the inventor should be permitted to seek a patent for it (and this should be the presumptive route). If, however, the invention is fundamental and needs no further development, or such development would proceed even without a patent, then the inventor should not be permitted to seek a patent for it.²⁵⁰

Professors Rai and Eisenberg then explore the mechanisms in the current Bayh-Dole Act by which the NIH might exercise such power.²⁵¹ They first look to 35 U.S.C. §202(a)(ii), which provides that the agency may, “in exceptional circumstances . .

245. See Rai & Eisenberg, *supra* note 9, at 297.

246. See *id.* at 302-03 (discussing situations where patenting is justified).

247. See *id.* at 300-02 (discussing situations where patenting is not justified).

248. See *id.* at 300-03.

249. See *id.* at 303-310 (discussing why NIH is the appropriate body for making this determination); *id.* at 310-13 (discussing how to give NIH this authority).

250. See *id.* at 310-11.

251. *Id.* at 310-13.

. determin[e] . . . that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter.”²⁵² Thus, if the agency determines that the inventions likely arising from research under a proposed funding agreement would be better developed if they were not patented, the agency can draft the funding agreement to prevent the researcher from patenting any resulting inventions. While this provision would seem ideally suited to their purposes, the authors note that in fact it is an unwieldy tool.²⁵³ First, the term “exceptional circumstances” suggests that this section should be applied only on rare occasions; it should not be a routine part of the funding decision.²⁵⁴ Second, use of the provision carries with it the requirement that the agency follow specific procedures designed to protect the rights of the funding recipient. These procedures include “an elaborate administrative procedure for challenging such determinations, with a right of appeal to the United States Claims Court.”²⁵⁵ Any time an agency makes such a determination, it must also notify the Commerce Department and provide a detailed analysis justifying the decision.²⁵⁶ These limitations make this provision unsuitable for routine use, including the purpose envisioned by the authors.²⁵⁷

Professors Rai and Eisenberg next consider using the funding agency’s “march-in” powers to compel licensing of university patents.²⁵⁸ However, they conclude that, although these powers are not limited by the “exceptional circumstances” requirement, they are similarly unsuitable for the authors’ purposes because they are subject to similar procedural hurdles:²⁵⁹ The rights may be exercised only for the very narrow reasons set forth in the statute, and the procedure is extremely slow because the actual transfer of rights to other parties is deferred until the completion of elaborate

252. 35 U.S.C. § 202(a)(ii) (2000 & Supp. II 2002).

253. See Rai & Eisenberg, *supra* note 9, at 310.

254. See *id.* at 293, 310.

255. *Id.* at 293.

256. See *id.* at 293 (citing 35 U.S.C. § 202(b)(1)).

257. See *id.* at 310; see also *id.* at 294 n.28 (noting that NIH has only declared exceptional circumstances in one case of which the authors are aware).

258. See *id.* at 294, 311 (citing 35 U.S.C. § 203). March-in under Bayh-Dole is discussed *supra* notes 94-95 and accompanying text.

259. See Rai & Eisenberg, *supra* note 9, at 294.

administrative proceedings and subsequent court appeals.²⁶⁰ The authors further note that the NIH has never used the march-in right.²⁶¹ Thus, they conclude that the existing provisions of the Bayh-Dole Act are unsuitable for their purposes.

To address these problems with the existing Bayh-Dole regime, Professors Rai and Eisenberg propose two “modest reforms.”²⁶² First, they propose that “the circumstances in which an agency may depart from the statutory presumption that the [funding recipient] may retain title to an invention in the terms of particular grants should be liberalized” by deleting the “exceptional circumstances” language.²⁶³ According to the authors:

Once the “exceptional circumstances” language is deleted, the substantive standard set forth in the current statutory language, which permits departure from the usual rule “when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter,” could be more freely applied to achieve the legislative goal of promoting widespread dissemination and use of research results.²⁶⁴

They also propose streamlining the existing administrative review process and allowing infringing research to proceed while the agency and courts conduct their respective reviews.²⁶⁵

Second, the authors propose to modify the march-in right, removing the requirement that the government hold the authority in abeyance until the parties exhaust all court appeals. They argue that this requirement, with its inherent delays, is in conflict with the time-sensitive substantive reasons for which march-in is permitted, such as achieving practical application of the invention within a “reasonable time” and “alleviat[ing] health or safety needs.”²⁶⁶ They note, however, that judicial review should be preserved for these march-in cases, as the post-issuance exercise of march-in rights “disturbs settled expectations of grantees and licensees that may underlie investments,” which could lead to industry

260. *See id.* (citing 35 U.S.C. § 203(a), (b)).

261. *See id.* & n.35.

262. *Id.* at 310.

263. *Id.*

264. *Id.* (footnote omitted).

265. *See id.*

266. *Id.* at 311 (quoting 35 U.S.C. § 203(a)(1), (2) (2000 & Supp. II 2002)).

“becom[ing] wary of investing in university-based technology.”²⁶⁷

Armed with these two reforms, Professors Rai and Eisenberg believe, the NIH can determine which inventions should be patented and which should not, and control its funding recipients accordingly.

C. CRITIQUE OF THE SOLUTION

One initial critique of this solution is that the view Professors Rai and Eisenberg take is a narrow one. After all, after the fact one can always point to patented inventions, government-funded or not, that would have been developed even without the patent incentive. Rather, what is important is the overall effect on the technology transfer/invention development system of having patents available in the first place. Instead of viewing it as a failure, the success of Cohen-Boyer should be seen as a victory for the Bayh-Dole Act. The revenue made by Stanford and the University of California has made researchers and institutions much more aware of the value of watching for patented technology and getting it out of the labs, thereby serving the ultimate goals of Bayh-Dole.²⁶⁸ Furthermore, revenue from university-owned patents often goes toward funding more research, reducing the need for government funding²⁶⁹ and thereby funding research by taxing those using the technology, rather than the population in general.²⁷⁰

267. *Id.*

268. See Ramirez, *supra* note 105, at 376 (arguing that after Cohen-Boyer, “inventors and universities recognized the benefits of making the technology broadly available”); cf. Eisenberg, *supra* note 1, at 1712 (“Of course, universities would have no reason to cooperate in technology transfer on a royalty-free basis . . .”).

269. According to Professor Thomas Massaro at the University of Virginia School of Medicine:

It has become very logical—and in fact very necessary—for research universities to more aggressively seek the profits that may be generated through patents, licenses, and royalties. In this cash-dry environment, universities are enamored with the possibility of generating new revenues by commercializing the products of their research. We are trying to use the proceeds from the “downstream” results of research to feed back “upstream” research itself.

Massaro, *supra* note 5, at 1734.

270. Professor Massaro continues:

To the extent that universities are successful in feeding the “upstream” with “downstream” revenues, society is well served. The Bayh-Dole legislation's superordinate goals of getting new ideas into

However, the basic hypothesis advanced by Professors Rai and Eisenberg has merit: The Act provides important incentives for getting many inventions developed, but some inventions would have been developed even without the incentives of the Bayh-Dole Act, and such inventions should be made more widely available.²⁷¹ Nevertheless, their proposed solution—requiring the NIH to determine in advance which funding agreements will result in inventions that should be patented and which will result in inventions that should not be patented, and to act accordingly—is unworkable, for a variety of reasons.²⁷²

The basis of their proposal is that Congress should delete the “exceptional circumstances” language from §202(a)(ii), thereby giving the NIH broader discretion to determine whether each individual funding agreement should or should not permit the funding recipient to seek patents on any resulting inventions. If the agency decides that the funding agreement will result in an invention (or inventions) that needs the Act’s incentives for further development, the agreement should permit the funding recipient to obtain patents and grant exclusive licenses to the patents. If instead the agency decides that the funding agreement will result in an invention (or inventions) that will be better developed and used without the incentives, the agreement should require the funding recipients to forego patenting, and the invention should be dedicated to the public. However, the NIH (and other federal agencies) *had* exactly that discretion prior to Bayh-Dole, and their reluctance to permit funding recipients to obtain patents and grant

the marketplace is being met. . . . [Professor Eisenberg] suggests that from the point of view of the consumer, royalties paid to the university are just another tax. Of course at one level this is true. A more realistic view is that universities are government contract laboratories distinguished by the efficiency with which they can help defray their operating overhead by a form of “user fees.” Such royalty-derived user fees align the incentives of society and the university research community better than most other mechanisms in the sense that such fees are paid by a defined group that in principle benefits from the good (university research) more than the general public.

Id. (footnotes omitted).

271. Indeed, the Harbridge House report identified exactly this same issue thirty-five years earlier. *See supra* note 31 and accompanying text.

272. It must be noted that Professors Rai and Eisenberg do address many of the criticisms discussed in this part. However, they underestimate the actual difficulties they do address, and fail to consider others.

licenses (especially exclusive licenses) is what led to the passage of the Act in the first place.²⁷³ The authors address this criticism, arguing that the tide has turned in the last twenty-five years and that the NIH now understands and embraces its role in technology transfer.²⁷⁴ Although that may be true in the short term, it is entirely plausible that the NIH, freed from the shackles of Bayh-Dole, will eventually revert to its old instincts and again become reluctant to allow funding recipients to obtain patents and grant exclusive licenses.²⁷⁵

A more fundamental question is that of institutional competence. Simply put, will the NIH be any good at determining which funding agreements will result in inventions that should be patented (because they need further development) and which will result in inventions that should

273. See *supra* Part I.A.1 (discussing the history of the Bayh-Dole Act).

274. See Rai & Eisenberg, *supra* note 9, at 311.

275. Indeed, history suggests that the NIH might well do exactly that. As noted *supra* notes 39-42 and accompanying text, one of the events that led to the passage of the Bayh-Dole Act was that HEW (the agency that then had authority over the NIH), after ten years of stability, began reconsidering its licensing policies. To quote Professor Eisenberg:

Apparently the immediate trigger for introduction of the Bayh-Dole bill was frustration on the part of universities with changes in the way HEW and DoD handled patent rights in their inventions. The change at HEW followed a relatively harmonious decade after the agency responded in the late 1960s to sharp criticism from the General Accounting Office of its handling of patent rights in the NIH medicinal chemistry program. The agency response was to allow universities with approved technology transfer capabilities to retain title to patents and to grant exclusive licenses to industry under the terms of Institutional Patent Agreements ("IPAs"). IPAs conferred rights in universities on a prospective basis, without the need for case-by-case requests for a government waiver after an invention had been made, thereby eliminating uncertainty and bureaucratic delays for universities that sought patent rights.

Then, in a 1978 draft report, HEW's Office of General Counsel recommended that use of IPAs be reconsidered on the ground that they encourage exclusive licensing and thereby limit the agency's control over the availability and cost of HEW-supported inventions. Around the same time, the HEW general counsel's office began taking longer to review case-by-case requests for a waiver of government patent rights after inventions had been made. These developments caused concern that HEW might be reverting to its pre-1968 policies and created pressure for legislation that would make permanent and nondiscretionary the arrangements that the agency had previously implemented on a discretionary basis.

Eisenberg, *supra* note 1, at 1691-92 (footnotes omitted); cf. Heller & Eisenberg, *supra* note 132, at 700 ("[A] politically accountable government agency such as NIH may further its public health mission by using its intellectual property rights to ensure widespread availability of new therapeutic products at reasonable prices.").

not (because they do not need such development)? After all, the NIH is an institution established for the advancement of scientific knowledge, through direct research of its own and funding of other researchers nationwide.²⁷⁶ Most of the personnel consist of current or former research scientists who are not versed in the arcana of the invention-development literature. The skills needed to perform or to manage the funding of basic scientific research are quite different from those needed to make the very subtle determination of whether a particular discovery will be better developed with exclusive rights.²⁷⁷ Professors Rai and Eisenberg do suggest that the NIH could employ policy experts on innovation to help with this problem,²⁷⁸ but a handful of experts cannot overcome the institutional deficiency of the NIH personnel as a whole.

Furthermore, all those people at the NIH already have jobs to do—and so who, exactly, will make these patenting determinations? Even if funding could be found to hire some new personnel for this purpose, it is unlikely to be sufficient to the task. Ann Roberson, the former president of the University of Tennessee Research Corporation, calculates that it would require an “army” of at least 1000 new employees to do the job properly.²⁷⁹ However, the NIH is unlikely to receive funding to hire even one-tenth that number, even assuming such a number of qualified people actually existed and desired the job. The result will be a cadre of overworked analysts and a pile of underanalyzed funding agreements—not a formula likely to bring about the desired result.²⁸⁰

276. See National Insts. of Health, Questions and Answers About NIH, <http://www.nih.gov/about/FAQs.htm#NIH> (last visited Mar. 24, 2006).

277. Professors Rai and Eisenberg do spend considerable time justifying this role for the NIH. See Rai & Eisenberg, *supra* note 9, at 303-310. However, they discuss only NIH *as an institution*, not the individual people who make up the institution. The people are the ones who will ultimately need to make the relevant determinations, not the “institution.”

278. See *id.* at 312.

279. Personal Communication from Ann Roberson, Former President, Univ. of Tenn. Research Corp. (Feb. 10, 2004). In an interview, Dr. Mark Rohrbaugh, Director of the Office of Technology Transfer at the National Institutes of Health, seconded this view, at least in principal. Telephone Interview with Dr. Mark Rohrbaugh, Director, Office of Tech. Transfer, National Insts. of Health (Sept. 22, 2004) [hereinafter Rohrbaugh Interview].

280. Indeed, this is the very situation that plagues the Patent and Trademark Office (PTO)—too few personnel to handle the amount of work, meaning that examiners are rarely able to invest the time required to do a proper patentability analysis on each application. Thus, the PTO is routinely

Finally, there is the issue of institutional bias: What will be the tendencies of the NIH when deciding what gets patented and what does not? Professors Rai and Eisenberg discuss the public choice model in this context, noting that skeptics might fear that “our proposal would tempt agencies like NIH to use their discretion to justify an allocation of greater resources to expand their own roles,” using “ostensibly public-spirited arguments for public funding as a means of promoting widespread access to research results, when in fact these arguments would cover self-serving efforts to expand the scope of its own research, even in research areas where the private sector is already operating.”²⁸¹ They dismiss the concern, however, noting that the “public-spirited arguments” may well be persuasive in this context, even if their underlying source is simply the agency trying to enhance its power.²⁸² They do not, however, address what happens when the arguments are not persuasive and the agency makes decisions that are entirely self-serving based on pretextual “public-spirited arguments.” Furthermore, this argument would seem to undercut the entire rationale for the Bayh-Dole Act—if these “public-spirited arguments” are so persuasive, then why does the Act require the opposite result? If Professors Rai and Eisenberg truly believe this argument, then they should be arguing for the abolition of the Act, not its fine-tuning.²⁸³

A related concern about bias arises upon considering how the NIH is comprised. As noted above, most of the people at the NIH are scientists or former scientists, and as a consequence they largely share a particular ethos. Both Professor Eisenberg and Professor Rai have written about the “norms of science” that lead scientists to view their work as a piece of a larger endeavor to understand the world.²⁸⁴ This

criticized for the poor quality of many of the patents it issues. *See, e.g.*, NATIONAL RESEARCH COUNCIL, *supra* note 172, at 46-63 (chapter entitled “Seven Criteria for Evaluating the Patent System: Ensuring High-Quality Patents”); *id.* at 51-52 (subchapter entitled “Workload Pressures on the USPTO”).

281. Rai & Eisenberg, *supra* note 9, at 311-12.

282. *See id.* at 312.

283. *Cf. generally* Eisenberg, *supra* note 1 (attacking the underpinnings of Bayh-Dole and creating the impression that she would not be adverse to abolishing it, at least insofar as it covers universities and related nonprofit entities).

284. *See* Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 *YALE L.J.* 177 (1987); Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94

view leads them to favor widespread sharing of results, techniques, and reagents, and to view proprietary rights with great skepticism.²⁸⁵ Given the power to decide what should and should not be patented, these scientists are likely to show a bias toward finding that funding recipients should not be permitted to patent their inventions, in an attempt to move the scientific enterprise away from its modern emphasis on proprietary rights and bring it back to these norms of free sharing.

The authors also note the danger that “funding agencies such as NIH might use their expanded discretion over patenting decisions to respond to political pressures unrelated to the legitimate goal of mediating the tension between access and product development,” particularly in controversial areas such as research involving human embryos.²⁸⁶ Unable to dismiss this concern, they express the hope that judicial review of agency decisions will restrain this type of conduct.²⁸⁷ Given the extreme deference courts must give to discretionary agency decisions such as these that are highly fact-dependent and rely heavily on agency expertise,²⁸⁸ that hope seems wildly optimistic at best.

All of these problems are significant practical hurdles to the proposed review mechanism. However, the fundamental issue is whether *anyone* can make the kind of determinations required by the proposal. Even assuming that the NIH hires a large number of people who are experts in the field, who can overcome any institutional biases and political pressure, and

NW. U. L. REV. 77 (1999) [hereinafter Rai, *Norms of Science*]. Not everyone agrees with this picture of the scientific enterprise. See F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Response to Rai and Eisenberg*, 95 NW. U. L. REV. 691 (2001) (arguing this view of science is too abstract to be of use in setting patent policy). But see Arti K. Rai, *Evolving Scientific Norms and Intellectual Property Rights: A Reply to Kieff*, 95 NW. U. L. REV. 707 (2001) (countering Kieff by arguing that scientific norms are instructive in encouraging patents).

285. See generally Eisenberg, *supra* note 284; Rai, *Norms of Science*, *supra* note 284. This description is a vast oversimplification of a much more nuanced argument.

286. Rai & Eisenberg, *supra* note 9, at 313.

287. See *id.*

288. See 5 U.S.C. § 706 (2000) (setting out standards of review of agency actions under the Administrative Procedure Act); *Chevron USA, Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-45 (1984) (expounding the “*Chevron* doctrine” of deference to administrative agencies).

who have the best intentions of implementing the proposed scheme perfectly, can these experts make the correct decisions? The proposed reform requires in effect a two-step *ex ante* analysis at the time a funding agreement is drafted: (1) Predict what invention or inventions will be created under the funding agreement, and then (2) predict whether any such postulated invention(s) will be better developed with a patent or without one. Given the high frequency with which the actual direction of a research project diverges from the initial planned direction, even the first prognostication step is fraught with difficulty. The second, more difficult step then requires looking further into the future and predicting the course of development of the postulated invention and of subsequent inventions that might derive from the postulated invention. However, in all but the most obvious cases, this latter determination is almost impossible to make.²⁸⁹ Even a cursory glance at the invention development literature reveals both the wide range of viewpoints on the process of development and the lack of consensus of what will and will not lead to optimum development of inventions.²⁹⁰ Even in hindsight, determining whether a patent facilitated or hindered the development of an invention can be exceedingly difficult; making such a determination in advance promises to be almost impossible. Combining the two predictive steps makes an accurate determination virtually unattainable.

For these reasons, the Rai and Eisenberg proposal would

289. In a footnote, the authors appear to acknowledge this difficulty, but they have very little to say about its solution; indeed, the footnote only compares making *ex ante* decisions with making *ex post* decisions:

To be sure, action *ex ante* may be problematic to the extent that it may sometimes be difficult to determine at the outset whether particular research is best distributed broadly or under a regime of property rights. As discussed in the text, however, action *ex post* is problematic to the extent that it may disturb settled expectations of grantees and licensees.

Rai & Eisenberg, *supra* note 9, at 310-11, n.114.

290. See generally, e.g., Merges & Nelson, *supra* note 227 and references cited therein; NATIONAL RESEARCH COUNCIL, PATENTS IN THE KNOWLEDGE-BASED ECONOMY (Wesley M. Cohen & Stephen Merrill eds., 2003); Manfredi La Manna et al., *The Case for Permissive Patents*, 33 EUR. ECON. REV. 1427 (1989); Suzanne Scotchmer, *Patents as an Incentive System*, in ECONOMICS IN A CHANGING WORLD, VOL. 2: MICROECONOMICS (PROCEEDINGS OF THE TENTH WORLD CONGRESS OF THE INTERNATIONAL ECONOMICS ASSOCIATION—MOSCOW) 281 (Beth Allen ed., 1996); Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSP. 29 (1991).

fail in implementation. However, the goal that they advance is a desirable one, and so this Article proposes an alternative reform of the Bayh-Dole Act.

III. AN ALTERNATIVE PROPOSAL

A. THE PROPOSAL

To better implement the goals of the Bayh-Dole Act, the focus should shift from the potential patentee and his or her invention (the target of the proposed reform of Professors Rai and Eisenberg and many others) to the other end of the equation: the users of the technology.

The primary concern of Bayh-Dole critics, including Professors Rai and Eisenberg, tends to be the effect of the Act on research that is deemed basic or fundamental. Such fundamental research is typically susceptible to wide application in many avenues of further exploration, by a wide variety of other researchers who are also doing basic research.²⁹¹ In the United States, such basic research is primarily carried out by researchers using government funding.²⁹² Thus, most of the basic research that concerns the critics will have government funding. Conversely, the government does not, as a rule, fund truly commercial development.²⁹³ The commercial development that causes the critics less concern will therefore likely not have government funding. Categorizing the research as government-funded or non-government-funded thus serves as a rough proxy for the two categories of research that concern the critics.

The basic proposal is this: All researchers whose work is supported by federal funds should have a limited, royalty-free license to make and use for research purposes all inventions developed with federal funds.²⁹⁴ Such a system would address many of the problems identified by the critics, including

291. Indeed, with true breakthrough discoveries, the original inventor may be incapable of investigating all the avenues that the research opens up, or even imagining what all of those avenues are.

292. See, e.g., National Insts. of Health, About NIH, <http://www.nih.gov/about/> (last visited Mar. 25, 2006).

293. See Eisenberg, *supra* note 1, at 1663-64.

294. The license should not extend to the right to sell or otherwise commercialize the patented invention for reasons discussed *infra* Part III.C.2.a.

Professors Rai and Eisenberg. Since all government-funded researchers (that is, most basic researchers) would have a license to all government-funded patents, then almost all of those who need access to the basic technology covered by these patents will have it. Conversely, non-government-funded researchers (that is, commercial researchers) would still need to license the patents, as is proper for commercial enterprises. This solution does not suffer from the indicated drawbacks of Professors Rai and Eisenberg's proposed reform, and it would also be at least a partial implementation of other proposed reforms of patent law designed to solve other problems currently affecting this field of law.

One of the main advantages of such a solution is its simplicity: It puts fundamental inventions in the hands of most basic researchers without the need to have anyone review each funding agreement or to have a court battle over whether an invention should be patented or dedicated to the public domain. Moreover, it does not require that a particular research project be characterized as "basic" or "applied" (or with a related labeling scheme)—a distinction required in the implementation of many experimental use exemption proposals, but one that is often virtually impossible to make in practice. Instead, the only question is whether the research is funded by the government or not, a fact that is easily ascertained.

This proposal also provides at least a partial answer to one aspect of the "double paying" problem.²⁹⁵ As noted above, one of the lingering concerns over Bayh-Dole is that it forces the public to pay twice for inventions funded by the government: once when they subsidize the research with tax dollars and again when they must pay royalties on the patented invention. The broad argument is ultimately unpersuasive, since the real choice is between paying once and getting nothing, or paying twice and getting the innovation. However, the idea behind the argument has more force in the particular context of the government spending tax dollars to develop an invention, then spending more tax dollars (in the form of royalties) to use the invention in subsequent research it funds. If researchers funded by the government have a royalty-free license to use all government-developed technology for research purposes, then this second payment is eliminated.

As an example of the effect of the proposed license,

295. See *supra* notes 108-111 and accompanying text.

consider the case of human embryonic stem cells.²⁹⁶ Most cells in the human body are “differentiated,” meaning that they have developed in a way that enables them to perform a very specific task.²⁹⁷ Skin cells, blood cells, muscle cells, and nerve cells are all examples of differentiated cells.²⁹⁸ Stem cells, in contrast, are undifferentiated, and therefore retain the ability to become more than one type of differentiated cell.²⁹⁹ For example, blood stem cells (actually bone marrow stem cells) retain the ability to differentiate into a variety of types of blood cells, including red blood cells, white blood cells, and platelets.³⁰⁰ The stem cells in adults are of this type, retaining the ability to differentiate into a limited number of related differentiated cells.³⁰¹ The embryonic stem cell, however, retains the ability to differentiate into *any* type of cell found in the body.³⁰² In addition, most cells taken from the body have a very limited lifetime in tissue culture. Embryonic stem cells, on the other hand, can persist for a very long time in culture, which facilitates their study and use.³⁰³ Scientists believe that this ability to persist in culture for a long time and then differentiate into any type of body cell makes embryonic stem cells ideally suited for use in treating a wide variety of diseases.³⁰⁴ “Stem cells, directed to differentiate into specific cell types, offer the possibility of a renewable source of replacement cells and tissues to treat diseases including Parkinson’s and Alzheimer’s diseases, spinal cord injury, stroke, burns, heart disease, diabetes, osteoarthritis, and rheumatoid arthritis.”³⁰⁵ Embryonic stem cells may also be useful for screening new drugs and toxins, and understanding

296. As indicated above, access to these stem cells seems to be one of the primary concerns of Professors Rai and Eisenberg. *See supra* note 243. *See generally* Rai & Eisenberg, *supra* note 9.

297. *See* National Insts. of Health, Stem Cell Information: Stem Cell Basics <http://stemcells.nih.gov/staticresources/info/basics/StemCellBasics.pdf> (last updated Sept. 2002).

298. *See id.*

299. *See id.*

300. *See id.*

301. *See id.*

302. *See id.* In scientific terms, embryonic stem cells are said to be “pluripotent.” *Id.*

303. *See id.*

304. *See id.*

305. *Id.*

birth defects.³⁰⁶

Human embryonic stem cells were first isolated in 1998 by a team of researchers led by Dr. James Thomson at the University of Wisconsin–Madison.³⁰⁷ In earlier work supported by funding from the NIH, these researchers had isolated embryonic stem cells from rhesus monkeys and macaques.³⁰⁸ Based on these primate lines and pursuant to the Bayh-Dole Act, the university obtained a patent on primate embryonic stem cells—which included human embryonic stem cells.³⁰⁹ At the time, a moratorium was in place on federal funding of research into human embryonic stem cells, and so the researchers' further research into human embryonic stem cells was supported by Geron Corporation.³¹⁰ After the researchers successfully used the techniques developed with NIH funding to isolate human embryonic stem cells, they obtained a patent particularly claiming these cells as well.³¹¹ Rather than license the patent broadly, the university licensed many of the most important uses exclusively to Geron.³¹² This exclusive license gave Geron a potential stranglehold over much of the research involving human embryonic stem cells, with the power to determine who could perform even basic research with them.³¹³ As a consequence, many basic researchers desiring to research various aspects of the near-limitless uses of stem cells were at the mercy of Geron.³¹⁴

306. See *id.* at 3. For a thorough discussion of the science of stem cells, see NATIONAL INSTS. OF HEALTH, STEM CELLS: SCIENTIFIC PROGRESS AND FUTURE RESEARCH DIRECTIONS (2001), available at <http://stemcells.nih.gov/staticresources/info/scireport/PDFs/fullrptstem.pdf>.

307. See NATIONAL INSTS. OF HEALTH, *supra* note 306, at ES-4.

308. See Rai & Eisenberg, *supra* note 9, at 293 n.23.

309. See *id.* (citing Primate Embryonic Stem Cells, U.S. Patent No. 5,843,780 (filed Jan. 18, 1996)).

310. See *id.* at 293 n.23, 301.

311. See *id.* at 293 n.23 (citing Primate Embryonic Stem Cells, U.S. Patent No. 6,200,806 (filed June 26, 1998)).

312. The funding agreement in fact required that Geron receive an exclusive license to these areas. See *id.* at 301. The licensed uses were to six types of differentiated cells derived from embryonic stem cells: neural cells, heart cells, pancreatic islet cells (which produce insulin), bone cells, blood cells and cartilage cells. See Andrew Pollack, *University Resolves Dispute on Stem Cell Patent License*, N.Y. TIMES Jan. 10, 2002, at C11.

313. See Rai & Eisenberg, *supra* note 9, at 301 (“Exclusive licenses on research tools with potentially broad applications threaten to throttle scientific progress by limiting the number of players in a developing field.”).

314. The NIH was also concerned over this degree of control in a single company and persuaded Wisconsin and Geron to modify their agreement

Under my proposed Bayh-Dole license, however, Geron's power would have been greatly diminished. Any recipient of government funding wishing to study these embryonic stem cells would be free to do so, under the terms of the proposed license—the government funded the research leading to the patent, and thus subsequent researchers who are also funded by the government would have licenses to use the patented technology.³¹⁵ The researchers would also be excused from paying royalties to Geron, freeing tax dollars to support other research. Thus, the proposed license would remove many of the barriers erected by patents obtained under the Bayh-Dole Act.

B. POTENTIAL IMPACT

Before considering whether such a proposal should be implemented, its effects on the overall Bayh-Dole scheme, and patent law incentives generally, need to be explored. Of critical importance is how commercial entities will respond to the change in the Bayh-Dole Act, and whether they will be more reluctant to develop technology created with government funding if the market of potential users is thus limited by the removal of government-funded researchers with the royalty-free license. Also important, however, are its positive aspects, as the proposed license may be seen as at least a start in developing a more robust experimental use exemption and a biotechnology patent pool.

1. Potential Impact on Patent Incentives

Granting government-funded researchers a license to patents arising from government-funded inventions might have an adverse affect on licensing those patents for further development. In particular, the proposed Bayh-Dole license

(resolving a lawsuit by the university against the company). *See id.* at 301 n.65, 309-10. Geron ceded exclusive control over three of the differentiated cell types, retaining only neural cells, heart cells and pancreatic islet cells. *See* Pollack, *supra* note 312. Both Wisconsin and Geron also agreed to allow free use of the cells by academic and government scientists for research purposes, retaining rights only for commercial use. *See id.*

315. This of course ignores other restrictions on embryonic stem cell research, particularly President Bush's ban on using federal funding to perform research on stem cell lines other than those existing at the time the ban was implemented on August 9, 2001. *See* Press Release, The White House, Fact Sheet: Embryonic Stem Cell Research (Aug. 9, 2001), *available at* <http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html>.

raises the issue of whether the free use of the patented invention in research that eventually results in a commercial product will have a negative effect on the market for the patented invention and thus destroy the incentive to develop the patented invention—a result contrary to the purpose of the Bayh-Dole Act.

If the resulting commercial product contains the patented invention, and thus still infringes the patent, no problem arises—the patentee will still control commercial use of the final product since the proposed license does not include the right to sell.³¹⁶ For example, the hair restorer minoxidil was originally patented as a compound for treating high blood pressure (for which it is still used).³¹⁷ One of the side effects of its use as a high blood pressure treatment was hair growth, and this method of use was subsequently patented as well.³¹⁸ The original patent on the compound was still in effect at the time the later patent issued, however, and so anyone wishing to use minoxidil as a hair restorer needed to license the original patent.³¹⁹ Thus, the original patentee was able to collect royalties for the use of minoxidil to restore hair and was therefore compensated for the subsequent research on and use of its patented compound.³²⁰ Differentiated human embryonic stem cells used directly as a treatment would also fall into this category—they will still be covered by the original patent on

316. See *infra* Part III.C.2.a.

317. See [MedicineNet.com, Minoxidil - Oral](http://www.medicinenet.com/minoxidil-oral/), <http://www.medicinenet.com/minoxidil-oral/article.htm> (last reviewed Mar. 2, 2005) (describing use of minoxidil to reduce blood pressure); U.S. Patent No. 3,461,461 (filed Nov. 1, 1965) (covering the compound now known as minoxidil; indicated use is as hypertensive agent).

318. See [MedicineNet.com, Minoxidil](http://www.medicinenet.com/minoxidil/), <http://www.medicinenet.com/minoxidil/article.htm> (last reviewed Dec. 31, 1997) (describing history and use of minoxidil to restore hair growth); U.S. Patent No. 4,139,619 (filed Aug. 19, 1977) (covering the method of using minoxidil to restore hair growth).

319. This included the owner of the hair-growth-restoration method of use patent. See Norman M. Goldfarb, *When Patents Became Interesting in Clinical Research*, J. CLINICAL RES. BEST PRACS., Mar. 2006, at 1-2, <http://www.firstclinical.com/resources/journal/0603/Patents.pdf>. And conversely, the holder of the patent on minoxidil itself would need a license to the method of use patent to sell minoxidil for hair restoration. This is thus an example of a pair of blocking patents. See *supra* notes 126-128 and accompanying text.

320. In the case of minoxidil, The Upjohn Company was actually the assignee of both patents. See U.S. Patent No. 3,461,461 (filed Nov. 1, 1965); U.S. Patent No. 4,139,619 (filed Aug. 19, 1977).

the embryonic stem cells themselves, and therefore the patentee will be entitled to royalties on the commercial product. A similar situation arises when the eventual product is a mixture that still includes the patented invention as a component.³²¹

A problem regarding the incentives of the original patentee does arise, however, when a researcher uses the patented invention during development, but the invention is not present in the final commercial product. In this situation, the patentee has no control over sales of the non-infringing commercial product and thus cannot recover the costs of developing the original patent into a useful invention.

This problem can manifest itself in two ways.³²² First, researchers might use the patented invention to improve on, design around, or avoid the patent itself.³²³ For example, a researcher might use the patented invention as a point of comparison for judging the effectiveness of a new invention. Alternatively, the researcher might start with a patented device and then gradually modify it until a non-infringing (and possibly improved) competing device results. Some of the earliest versions are likely to infringe the patent, even if the final device does not. Such uses would be directly counter to the interests of the patentee, but they are nevertheless an important aspect of the purpose of experimental use and a fundamental part of the patent system—getting patented inventions into the hands of researchers so that they can be exploited in these ways.

Second, researchers might use the invention as a tool to further other research. Such research tools are one of the most difficult elements of experimental use (and therefore of the proposed license, insofar as it implements experimental use). For example, a researcher might use a patented DNA or protein product in an assay to find a novel pharmaceutical. The final pharmaceutical typically will not include the patented

321. See, e.g., Combinations of Retinoids and Minoxidil-type Compounds for Hair Growth, U.S. Patent No. 5,183,817 (filed Dec. 13, 1988); Minoxidil Gel, U.S. Patent No. 5,225,189 (filed Feb. 18, 1988); Stimulation of Hair Growth with Minoxidil and a 5 α -Reductase Inhibitor, U.S. Patent No. 5,578,599 (filed Jan. 20, 1995).

322. These two ways track the distinction between “experimenting on” and “experimenting with” the patented invention developed in the discussion of the experimental use exemption. See *supra* notes 182-197 and accompanying text.

323. See FTC INNOVATION REPORT, *supra* note 175, at ch. 4, at 36.

DNA or protein, and so will not itself infringe. Similarly, a researcher might use human embryonic stem cells to assess the efficacy and toxicity of a potential drug product. The final drug product will again not fall under the original patent because it does not include the human embryonic stem cells, and therefore the patentee will not be entitled to royalties on the commercial product. Some would view such a result as a desirable side effect of the license proposal, as it helps resolve some perceived problems of the current patent system.³²⁴ One potential way to alleviate some of the harm caused by this situation would be to allow the research to proceed without liability but then to require payment of a royalty once a commercial product is available.³²⁵ Many experimental use proposals exclude such research tools,³²⁶ but they would not be excluded from the proposed Bayh-Dole license.

Research tools do not present a problem with respect to development incentives if they do not need further development once they have been invented in the laboratory. The primary justification for the Bayh-Dole Act is to provide an incentive to get commercial development of government-funded inventions;³²⁷ the original government funding agreement provides the necessary incentive to make the invention in the first place. If no such further development is needed, then the Bayh-Dole incentive is similarly unnecessary, as the patentee has no development costs to recover—these costs were already paid by the government.³²⁸ Research tools also do not present a

324. Some of these problems are discussed *supra* Parts I.B.2 and I.B.3. Cf. Suzanne T. Michel, Comment, *The Experimental Use Exception to Infringement Applied to Federally Funded Inventions*, 7 HIGH TECH. L.J. 369, 407 (1992) (“If the experimental work by a non-licensee results in a product which designs around the basic research and does not infringe the original patent, then federal funds spurred more development at the private level, which is the point of government supported research. A licensee will be forced to accept the possibility of increased design around activity. In response, the licensee and licensor can account for the added risk through decreased royalty rates.”).

325. See *supra* note 192 (discussing proposals by Mueller, *supra* note 174, and Strandburg, *supra* note 174, for such a royalty system, as well as the difficulties in calculating such a royalty).

326. See, e.g., Eisenberg, *supra* note 174, at 1074.

327. See 35 U.S.C. § 200 (2000 & Supp. II 2002).

328. As a corollary, the proposed license should result in a reduction in patenting of this type of research tool. If a tool does not need further development and is easily used by subsequent basic researchers, then the original researcher will have no reason to patent it—most of those who need it will be able to use it under the proposed Bayh-Dole license without paying

problem if the further-developed product is itself patentable. In this case, the commercial developer is protected by the later patent, which, not having been developed with government funding, is not eligible for the proposed Bayh-Dole license.³²⁹

When research tools require further development in order to become commercial products but the further development is not itself patentable, they can be handled via other, non-license methods of appropriation. In the biotechnology context, this appropriation can commonly be accomplished through patenting of kits, where the biotechnology company assembles the necessary reagents for patented processes into the kits.³³⁰ These kits greatly ease the conduct of research, as the manufacturer takes the responsibility of making sure that each necessary solution has precisely the correct composition. Despite the fact that these kits typically cost more than the individual reagents in them, researchers use them because they are efficient, particularly when the time needed to mix the reagents (and the time lost in repeating experiments when the inevitable mistakes are made) is taken into account.³³¹

As an example, consider the polymerase chain reaction (PCR), one of the fundamental techniques of the modern molecular biology laboratory.³³² PCR allows scientists to start

royalties, effectively negating the benefits of the patent. The absence of a patent would then free up the tool for use by all, including those ineligible for the proposed license, which is good for research tools with wide application.

329. This analysis assumes that the subsequent development is not funded by the government—a reasonable assumption, as such development is usually funded by industry. See Eisenberg, *supra* note 1, at 1666. If the subsequent development is funded by the government, then the patent incentive should again be unnecessary, and so the proposed Bayh-Dole license is appropriate.

330. See, e.g., *CAFC Considers Validity of Marking with Patent Numbers*, 24 BIOTECHNOLOGY L. REP. 448, 449 (2005).

331. Researchers use such kits even when the underlying process is not patented, and so they are free to make use of the process/reagent. For example, in the early years of biotechnology research, graduate students often started their careers by purifying large quantities of a particular restriction enzyme (a protein molecule that operates like a pair of molecular scissors, cutting a DNA molecule at a precisely defined location). They would then trade with other students who had purified different restriction enzymes (ones that cut DNA in other precise locations). Personal Communication from Haynes W. Sheppard, Jr., Director of Research, IGB Products, Ltd. (1986). Once restriction enzymes became commercially available, this practice stopped; even though most of the enzymes were not patented, and so students were free to continue the practice, it was simply a waste of time to do so.

332. See Roche Molecular Diagnostics, PCR Explained, http://www.roche-diagnostics.com/ba_rmd/pcr_explained02.html (last visited Mar. 26, 2006).

with a very small amount of a particular piece of DNA and generate large amounts of that DNA rapidly and efficiently through a process often referred to as “gene amplification.”³³³ The basic chemical reagents needed to perform PCR—reaction buffers,³³⁴ nucleotides, magnesium chloride—are cheap and commonly found in any reasonably equipped laboratory.³³⁵ The primary enzyme required for performing PCR, *Taq* polymerase,³³⁶ is readily available from commercial sources (or an ambitious researcher could even produce his or her own enzyme). However, most researchers choose not to mix their own reagents, instead preferring to purchase a kit containing the necessary reagents, even though these kits often cost more than the sum of the individual reagents they contain.³³⁷ They

333. See *id.* (describing the basic PCR process in detail); see also Roche Molecular Diagnostics, Applications of PCR, http://www.roche-diagnostics.com/ba_rmd/pcr_applications.html (last visited Mar. 26, 2006) (describing some of the medical diagnostic uses of PCR); Roche Molecular Diagnostics, Chronology of PCR Technology, http://www.roche-diagnostics.com/ba_rmd/pcr_evolution.html (last visited Mar. 26, 2006) (showing a timeline of the development of PCR).

334. A “reaction buffer” is a solution containing the salts and other soluble elements needed to perform a particular biochemical process; the solution is typically “buffered” to maintain a particular pH. PCR Reaction Buffer consists of 100 mM Tris/HCl, 15 mM MgCl₂, 500 mM KCl, pH 8.3 (the concentration of MgCl₂ may be varied for different applications). See Roche Applied Science, Package Insert: PCR Core Kit (4th ver. July 2003), available at <http://www.roche-applied-science.com/pack-insert/1578553a.pdf>. These reagents are all commonly found in the molecular biology laboratory.

335. See Connie Veilleux, PCR Technology, http://www.accessexcellence.org/LC/SS/PS/PCR/PCR_technology.html (last visited Mar. 26, 2006).

336. Or a recombinant variant thereof. See, e.g., Roche Applied Science, Product Information: Taq DNA Polymerase, <http://www.roche-applied-science.com/fst/amplification.htm?/sis/amplification/pifs/enzymes/taq.htm> (last visited Mar. 26, 2006) (“Taq DNA Polymerase is the recombinant form of the enzyme from the thermophilic eubacterium *Thermus aquaticus* BM, expressed in *E. coli*.”); see also Roche Applied Science, Product Information: FastStart Taq DNA Polymerase, <http://www.roche-applied-science.com/fst/amplification.htm?/sis/amplification/pifs/enzymes/faststart.htm> (last visited Mar. 26, 2006) (“FastStart Taq DNA Polymerase is a thermostable, chemically modified form of recombinant Taq DNA Polymerase.”)

337. The popularity of this option is evidenced by the number of companies that sell such kits. See, e.g., Roche Applied Science, Product Information: PCR Core Kit, http://www.roche-applied-science.com/fst/amplification.htm?/sis/amplification/pifs/mixes_kits/pcr_core.htm (last visited Mar. 26, 2006); Sigma-Aldrich Co., Online Catalog: PCR Core Kit with Taq DNA Polymerase, <http://www.sigmaaldrich.com/catalog/search/ProductDetail/SIGMA/CORET> (last visited Mar. 26, 2006). Some companies have simplified the process even

can then simply add their own particular DNA templates and primers and perform the reactions quickly and easily. The kits free the researchers from the need to measure and mix all of these reagents individually, and also from concern over errors in measuring the reagents each time they need to be mixed.³³⁸ And with PCR, kits provide an additional advantage. DNA amplification by PCR is so powerful that even trace amounts of contaminating DNA can grow into large artifacts, compromising the integrity of the research. Companies certify that their kits are free of such contaminants.³³⁹

From the perspective of the company, kits generally allow patentees to recover costs from researchers without needing to sue or license them individually—the researchers pay a royalty built in to the price of the kit in exchange for a license to use the reagent or method embodied in the kit.³⁴⁰ Researchers are

further, mixing the reagents into a single tube. *See, e.g.*, Promega Corp., Online Catalog: PCR Master Mix, <http://www.promega.com/catalog/CatalogProducts.asp?catalog%5Fname=Promega%5FProducts&category%5Fname=PCR+Master+Mix&description%5Ftext=PCR+Master+Mix> (last visited Mar. 26, 2006); Invitrogen Corp., Online Catalog: PCR SuperMixes, <https://catalog.invitrogen.com/index.cfm?fuseaction=viewCatalog.viewProductDetails&productDescription=569&CMP=LEC-GCMSSEARCH&HQS=10572> (last visited Mar. 26, 2006). A Google search for “PCR Kit” reveals many more providers. *See* Google, Search Results, <http://www.google.com/search?hl=en&q=PCR+Kit> (last visited Mar. 26, 2006).

338. The advantage of the kits multiplies as the number of reagents increases and the degree of precision in amount of each reagent increases. For example, using the PCR to determine the order of the bases in a piece of DNA (PCR sequencing) requires many more reagent mixtures than the basic PCR. Furthermore, the exact amounts of the nucleotides and special terminator nucleotides are crucial, with even slight errors often resulting in failure of the process. For this reason, researchers rarely mix their own sequencing reagents, instead relying on commercial kits. *See, e.g.*, Promega Corp., Online Catalog: fmol[®] DNA Cycle Sequencing System, <http://www.promega.com/catalog/CatalogProducts.asp?catalog%5Fname=Promega%5FProducts&category%5Fname=fmol+DNA+Cycle+Sequencing+System&description%5Ftext=%3Ci%3Efmol%3C%2Fi%3E%3Csup%3E%26%23x00AE%3B%3C%2Fsup%3E+DNA+Cycle+Sequencing+System> (last visited Mar. 26, 2006); USB Corp., Online Catalog: Thermo Sequenase[™] Cycle Sequencing Kit, <http://www.usbweb.com/category.asp?cat=dna&id=78500#> (last visited Mar. 26, 2006).

339. *See* Roche Applied Science, *supra* note 334. Furthermore, unlike what is present in the researcher’s laboratory, any remaining contaminating DNA is unlikely to be the DNA the researcher is studying, reducing the likelihood that it will cause problems.

340. For example, the package insert for the Roche PCR kit contains the following language:

willing to pay the additional price for the convenience and reproducibility. Indeed, biotechnology patents (and others) often include specific claims directed to kits for performing the patented method, for just this reason.³⁴¹ Thus, kits let patentees recover their costs from researchers without having to worry about licensing them individually.

With kits, the true risk to the patentee is competitors who sell their own kits, potentially at a reduced cost,³⁴² drawing researchers away from the patentee's kit. If the kit is itself patented, the competitor can be sued directly for selling an

A license under U.S. Patents 4,683,202, 4,683,195, and 4,965,188 or their foreign counterparts, owned by Roche Molecular Systems, Inc. and F. Hoffmann-La Roche Ltd ("Roche"), has an up-front fee component and a running-royalty component. The purchase price of this product includes limited, nontransferable rights under the running-royalty component to use only this amount of the product to practice the Polymerase Chain Reaction ("PCR") and related processes described in said patents solely for the research and development activities of the purchaser.

Id. The Invitrogen PCR SuperMixes Product Manual and the Sigma-Aldrich PCR Core Kit Technical Bulletin contain identical language. See Invitrogen Life Techs., AccuPrime Pfx SuperMix (Oct. 15, 2004), available at http://www.invitrogen.com/content/sfs/manuals/accuprimepfxsupermix_man.pdf; Sigma-Aldrich Co., Technical Bulletin: PCR Core Kit with *Taq* DNA Polymerase (June 2002), available at <http://www.sigmaaldrich.com/sigma/bulletin/coretbul.pdf>. However, Promega Corp. has challenged the validity of the basic PCR patents, and so its PCR Master Mix Product Usage Information sheet does not include this language. Instead, the Information sheet states:

The PCR process is covered by patents issued and applicable in certain countries. Promega does not encourage or support the unauthorized or unlicensed use of the PCR process. Use of this product is recommended for persons that either have a license to perform PCR or are not required to obtain a license. . . . Certain applications of this product are covered by patents issued and applicable in certain countries. Because purchase of this product does not include a license to perform any patented application, users of this product may be required to obtain a patent license depending upon the particular application and country in which the product is used.

Promega Corp., Product Usage Information: PCR Master Mix (April 2004), available at <http://www.promega.com/tbs/9pim750/9pim750.pdf>.

341. See, e.g., Kits for Amplifying and Detecting Nucleic Acid Sequences, U.S. Patent No. 6,197,563 (filed Nov. 18, 1994); Method and Kit or [sic] Detecting Antibodies to Antigens of Human Immunodeficiency Virus Type 2 (Hiv-2), U.S. Patent No. 5,055,391 (filed Jan. 3, 1990); see also *In re Ngai*, 367 F.3d 1336 (Fed. Cir. 2004) (discussing the patentability of a kit for performing a new biotechnology method).

342. Competitors can typically undercut the patentee because they can ride on the coattails of the patentee, using the patentee's research to design the kit, and thus avoid incurring the patentee's research costs.

infringing kit.³⁴³ If the relevant patent claims only the method, however, the competitor is not directly infringing, because it is not itself practicing the method; it is simply selling a kit that allows *others* to practice the method and infringe the patent.³⁴⁴ However, in this situation, the patent law still provides a remedy: a suit against the competitor for contributory infringement or inducing infringement.³⁴⁵ Returning to the PCR example, because the technique is so important in the molecular biology laboratory, the owners of the patents covering various aspects of PCR have repeatedly sued the manufacturers of PCR kits for contributory infringement, rather than suing individual researchers for direct

343. See, e.g., *In re Cambridge Biotech Corp.*, 186 F.3d 1356, 1363 (Fed. Cir. 1999) (discussing a patent owner's suit against Cambridge Biotech for selling kits for detecting HIV-2 antibodies; some of the claims of one of the patents in suit, the '391 patent, *supra* note 341, covered kits). The patentee may also sue for direct infringement if the kit contains a component that is itself separately patented. See, e.g., *id.* (discussing the claims of another patent in suit, Peptides Related to Human Immunodeficiency Virus II (HIV-2), U.S. Patent No. 5,051,496 (filed Jan. 16, 1987), which covered only particular peptides used in the kits).

344. In these cases, the individual researchers are the ones actually infringing the patent by using the competitor's kits to perform the patented method. Thus, the patentee could theoretically sue these individual researchers for direct infringement. Patentees, however, are generally reluctant to sue individual researchers, in part because it is costly and impractical to sue so many parties and in part because the researchers are potential customers who are likely to be alienated if they are sued. See *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 188 (1980) (noting that the contributory infringement doctrine removed the need for "the patentee to undertake the almost insuperable task of finding and suing all the innocent purchasers who technically were responsible for completing the infringement"); SCHECHTER & THOMAS, *supra* note 117, at 293 (suggesting in a hypothetical that patentees prefer to sue the contributory infringer rather than the direct infringers, who "may be present or potential customers" of the patentee).

345. See 35 U.S.C. § 271(c) (2000) (providing cause of action for contributory infringement); *id.* § 271(b) (providing a cause of action for inducing infringement). The competitor will typically be liable for contributory infringement for providing a kit for which the only use is to infringe the patented method, and for inducing infringement for providing specific instructions for performing the infringing method. For examples of such suits in the biotechnology context, see *Hybritech Inc. v. Abbott Labs.*, 4 U.S.P.Q.2d (BNA) 1001, 1004 (C.D. Cal. 1987) (involving a defendant sued for selling diagnostic kits using antibodies and instructions for using them; claims of the patent in suit, *Immunometric Assays Using Monoclonal Antibodies*, U.S. Patent No. 4,376,110 (filed Aug. 4, 1980), covered only methods); and *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1371 (Fed.Cir.1986) (same).

infringement.³⁴⁶

Both because the Bayh-Dole license does not extend to sales of the patented invention³⁴⁷ and because the commercial competitor is not a researcher funded by the government, the sale of kits will not be covered by the Bayh-Dole license. Thus, the seller will remain liable for infringement, leaving the patentee with its desired remedy. One important caveat to this, however, is that both contributory and induced infringement require a direct infringement by someone. If the competitor sells the kit to a researcher who has a Bayh-Dole license, then the researcher is not directly infringing, and so the competitor cannot be indirectly infringing.³⁴⁸ The license therefore needs to be carefully drafted to exclude coverage for using a kit made by a competitor in a way that infringes the patent, at least in the case where the patentee itself provides such a kit commercially.³⁴⁹

A similar analysis pertains if performing the patented method requires a specialized apparatus—the provider of the apparatus will be liable for contributory infringement. For example, Professors Rai and Eisenberg discuss DNA sequencing machines as a technology that was properly patented under Bayh-Dole, because while the underlying research tool was created via government-funded research, developing the research tool into a commercial product required the exclusive licensee to make substantial commercial

346. See, e.g., *Hoffman-La Roche, Inc. v. Promega Corp.*, 33 U.S.P.Q.2d (BNA) 1641, 1642 (N.D. Cal. 1994); *E.I. du Pont de Nemours & Co. v. Cetus Corp.*, 19 U.S.P.Q.2d 1174 (N.D. Cal. 1990) (infringement counterclaim). The patents at issue in both of these suits, *Process for Amplifying, Detecting, and/or Cloning Nucleic Acid Sequences*, U.S. Patent No. 4,683,195 (filed Feb. 7, 1986), and *Process for Amplifying Nucleic Acid Sequences*, U.S. Patent No. 4,683,202 (filed Oct. 25, 1985), claim only methods.

347. See *infra* Part III.C.2.a.

348. See *Met-Coil Sys. Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 687 (Fed. Cir. 1986) (finding no direct infringement because alleged direct infringers had implied license to perform the claimed method, and therefore defendant could not, as a matter of law, be guilty of contributory infringement); *Saxe v. Hammond*, 21 F.Cas. 593, 594 (C.C.D. Mass. 1875) (“There is no evidence, in this record, of a sale to an unlicensed manufacturer” as would be required for direct infringement, and therefore no contributory infringement). Of course, as previously discussed, if the kit is directly covered by the patent or includes a component that is directly covered, then indirect liability is not needed—the patentee can sue the competitor directly on the kit claim.

349. Cf. 35 U.S.C. § 271(d)(5) (permitting patentee to condition license on purchase of a separate product).

investment.³⁵⁰ Under the proposed license, researchers *could* build their own sequencing machines without fear of infringement liability, but they are very unlikely to do so—they can much more efficiently buy the machines from the licensee than they can replicate the complex technology involved.³⁵¹ Therefore, the value in the patent is in the ability to prevent *competitors* from making and selling machines and undercutting the patentee on price, not in the ability to prevent researchers from making their own machines.³⁵² Thus, the real risk for this category of patented inventions is from market competitors making sales, not researchers using the invention for their research, and so the proposed Bayh-Dole license will not have an adverse affect on the patentee.³⁵³

Thus, the proposed license presents a problem only if a research tool (a) needs further development, but (b) the developer has no viable way to recover the cost of this development other than through direct licensing of the original patent. Although this category of research tools is problematic, it is likely to be quite small—most relevant research tools will be either simple enough to need no further development or else sufficiently complex to be themselves patentable or to require

350. See Rai & Eisenberg, *supra* note 9, at 302-03 & n.69.

351. See EFF Amicus Brief, *supra* note 223, at 29 n.21 (“Most scientists are not engaged in manufacturing and will readily purchase rather than make patented products—such as microscopes, reagents, or biological materials—when they meet specifications and are commercially available for a reasonable fee.”).

352. A similar point, in a slightly different context, is made by Professor Eisenberg. See Rebecca S. Eisenberg, *Technology Transfer and the Genome Project: Problems with Patenting Research Tools*, 5 RISK 163, 173 (1994) (“[P]rotection against competitors who would sell the product to researchers provides some measure of protection. So long as other large scale producers can be excluded from the market, the patent holder will be able to reap the benefits of any significant economies of scale in production of the research tool.”). *But see id.* (“The lack of a remedy against researchers who make the invention themselves would still set an upper bound on the ability of patent holders to charge full monopoly prices, since at a certain point researchers might find it cost effective to make the research tool themselves rather than to buy it from the patent holder.”).

353. Not surprisingly, similar suits have arisen in the PCR context, concerning the thermocycler apparatus required to perform PCR. Roche and its licensee, Applied Biosystems, sued a maker of competing thermocyclers for indirect infringement of the '195 and '202 patents on the basic PCR methods, *supra* note 346, as well as for direct infringement of certain patents on the thermocyclers themselves. See *Applied Biosystems v. MJ Research Inc.*, 372 F. Supp. 2d 233 (D. Conn. 2005).

reagents or apparatus that can be sold as a kit. Furthermore, recovering development costs in such cases is likely to be extremely difficult even without the proposed license. Because any infringement would be by individual researchers using specific techniques and reagents in their own laboratories, without the need to purchase anything commercially that is directly tied to the patent, the patentee would have to track down and sue each of these researchers individually—an endeavor that is likely to be impractical at best, and prohibitively expensive.³⁵⁴ One possibility might be to handle these inventions in a different way. For the small class of inventions that need further development but for which costs cannot be recovered because of the proposed license, then perhaps the government should fund such development directly via its normal funding channels, rather than leaving it to the market via the patent incentive.³⁵⁵

Another possible objection to the proposal is that a required licensing provision would limit the flexibility of the agencies to deny such licenses when they determine that such licenses would be contrary to the goals of the Bayh-Dole Act. As discussed below, Dr. Rohrbaugh indicated that the NIH was already implementing a similar scheme into its licenses,³⁵⁶ and he suggested that codification could possibly limit the options of the NIH.³⁵⁷ If desired, this objection could easily be addressed by incorporating flexibility into the implementing documents.

354. As noted by Professor Eisenberg:

Making and using a patented invention within a research laboratory is not very conspicuous and may never come to the attention of the patent holder. Even if the patent holder knows about the use, it might not be worth the trouble and expense of pursuing a lawsuit against a researcher who does not represent a significant threat to the patent holder's commercial interests.

Eisenberg, *supra* note 174, at 1071-72.

355. *Cf.* Eisenberg, *supra* note 1, at 1673 (describing a pre-Bayh-Dole proposal by the Attorney General that would have implemented this type of government-funded development scheme for all government inventions that industry was not willing to develop without an exclusive license).

356. Transcript of Committee on Intellectual Property in Genomic and Protein Research Innovation, National Academies 146 (Feb. 27, 2004), *available at* http://www7.nationalacademies.org/step/Genomics_Committee_Meeting_1_transcript.pdf (transcribing, among others, presentation by Dr. Mark Rohrbaugh, Director, Office of Technology Transfer, National Institutes of Health, discussing NIH policies on technology transfer in the biotechnology area, including interpretations of Bayh-Dole) [hereinafter Rohrbaugh Presentation].

357. *See* Rohrbaugh Interview, *supra* note 279.

However, such flexibility is neither necessary nor desirable.³⁵⁸ Given the logic behind the proposal, there seem to be no circumstances under which the license should be denied. Furthermore, making the requirement compulsory on the agencies gives them the leverage to demand the right—they need merely point to the requirement, without an exception, and the funding recipient has no room for argument. A codified right would also be much more resistant to changes in administrations (both at the level of the agency and at the level of the federal government as a whole). A codified requirement would have the additional advantage of applying to all federal agencies, not just the NIH.

2. Experimental Use

The proposed reform will implement a limited form of the common law experimental use exemption, as it lets government-funded researchers infringe certain patents in connection with their government-funded research without fear of liability. Its coverage is, of course, less broad than the traditional common law experimental use exemption, as it applies only to a limited group of patents and researchers, and therefore it does not meet all of the goals of experimental use. Nonetheless, the proposed Bayh-Dole license is a useful step in the right direction.

The proposed license does not require making a distinction between experimenting on the patented invention and using the patented invention as a tool for other research;³⁵⁹ the government-funded researcher exemption applies to *all* government-funded research that involves the use of inventions arising from government-funded research. However, one weakness of its limited scope is that it does not allow researchers to use research tools created with private funds, which in many instances may be the most important tools.³⁶⁰

358. See *infra* note 387 and accompanying text (discussing the advantages of uniform treatment of all patents under the proposed licensing scheme).

359. As discussed earlier, this can be a difficult distinction to make. See NATIONAL RESEARCH COUNCIL, *supra* note 239, at 114-15.

360. Dr. Rohrbaugh mentions particularly the *cre/lox* technology for generating specific gene mutations and the oncomouse technology for creating animal models to study human cancer. See Rohrbaugh Presentation, *supra* note 356, at 147 (“I would note that we already have a challenge in some cases in collaborating with industry in conducting research with proprietary materials when industry receives a benefit in terms of an option to license

Even so, it is a useful step in the right direction—and if it works well, it could serve as a “pilot program” to pave the way for broadening the experimental use exemption, either voluntarily via some sort of patent pool (as discussed in the next Section) or by legislative expansion.

3. Patent Pools

In addition to implementing a limited version of the common law experimental use exemption, the proposed Bayh-Dole licensing scheme might also be viewed as a rough patent pool. As described above, in a patent pool, individual patentees assign their patents to a single collective entity, in exchange for royalties and a license to use the other patents in the pool. Since the proposed license does not involve royalties, it would not be like a pool in this respect. However, in many instances, the main function of a patent pool is to provide access to the patents in the pool, not to make money directly from the patent royalties,³⁶¹ and in this respect the proposal is very much like a patent pool.

The proposed license could, of course, also be viewed (with considerable justice) as a compulsory license with royalty of zero.³⁶² However, the limited membership in the pool, coupled with its reciprocal nature—anyone who uses patents from the pool must be doing research funded by the government, and the funding would carry the obligation to license any patents generated from the research to others doing research funded by the government—makes the analogy to a patent pool valid, at least in a limited sense.

Many of the historical patent pools that have arisen to resolve blocking problems in various industries ultimately

inventions or rights to data. This is still a challenge. It is a challenge with Krilocks [sic, *cre/lox*] and oncomouse.”). Professors Rai and Eisenberg also discuss some of the problems with licensing these technologies, see Rai & Eisenberg, *supra* note 9, at 296 n.40, as do Professors Heller and Eisenberg, see Heller & Eisenberg, *supra* note 133, at 699-700.

361. See *supra* note 226 and accompanying text (discussing the airplane and automobile patent pools).

362. “The term ‘compulsory licensing’ refers to a governmental requirement that a patent owner permit another to perform otherwise infringing acts at a mandated rate.” MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW 1062 (2d ed. 2003). Compulsory licenses are rarely found in U.S. intellectual property law (there are exceptions in patent law for air pollution controls, 42 U.S.C. § 7608 (2000), and atomic energy inventions, 42 U.S.C. § 2183 (2000)), although they are more common under international regimes. See *id.*

required government intervention to get the pool started.³⁶³ Ideally, that is exactly what will happen under the proposed license: The NIH will in effect serve as the holder of the patent pool for the benefit of all its researchers.³⁶⁴ Such an outcome would advance the underlying goals of Bayh-Dole while ameliorating some of its undesired side effects.

If the proposed Bayh-Dole license is successful, it might even serve as the basis for a true patent pool. Perhaps the NIH could expand the pool to allow biotechnology companies doing research that is not funded by the government to join the pool. These companies would submit their patents for use by government-funded researchers in exchange for rights to use the other patents in the pool.³⁶⁵ If the pool did expand in this way, the NIH might be able to incorporate a limited royalty structure, under which the commercial members paid royalties for all uses (of patents from government-funded research and from other commercial members), while the government-funded members paid royalties only to the commercial members, retaining the free license to use patents from government-funded research.³⁶⁶ At this point, the license system would operate much like a real biotechnology patent pool, solving many of the blocking problems previously discussed, such as the problem of the anticommons. Even if the NIH license pool did not itself expand in this way, the industry might see that it works well, and thus it might provide the impetus (and mechanism) to implement a broad pooling system.³⁶⁷

363. See *Merges, supra* note 130, at 1356-57 & n.226 (discussing formation of the aircraft and synthetic rubber research patent pools at the behest of the government, triggered by U.S. entry in to World War I and II, respectively).

364. *Cf. id.* at 1356 (suggesting that “[t]he government should assist in some cases the formation of pools and other exchange mechanisms”).

365. Such an innovation might create the need for a screening mechanism for the submission of patents to the pool. Otherwise, companies would have an incentive to give worthless patents to the pool, in exchange for rights to the valuable patents in the pool, while holding back their own valuable patents and continuing to charge royalties. This situation might be addressed by requiring that *all* patents held by a company be assigned to the pool in exchange for access to the pool.

366. See *Merges, supra* note 130, at 1341-42 (“Typically, firms are required to license into the pool all patents covering technology of use to the industry. In exchange, pool members are permitted to use any other member’s technology for a set fee. Often these fees are calibrated to reflect the significance of the technology being licensed.” (footnote omitted)).

367. That the industry might be willing to join such pools, possibly even without royalties, is evidenced by IBM’s pledge to give 500-plus patents to the

C. PRACTICAL CONSIDERATIONS

The most efficient method of implementation would avoid the need for legislative action, if existing law permits; if not, then Congress would need to ascertain the best legislative solution. Further, the specific terms of the license need to be carefully constructed to implement the proposed license in a way that is most useful to researchers while interfering as little as possible with the rights of the patentees. Finally, the question of who, exactly, can participate in the license needs to be addressed.

1. Implementation

As noted above, the current Bayh-Dole Act reserves for the government a license to inventions developed with government funding:

With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable [sic], irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.³⁶⁸

The simplest method of implementing the proposal would be for the NIH to utilize this reserved license to allow anyone receiving government funds to use, in their research, all patented inventions made with government funding. The NIH could declare (either in a policy statement or possibly as a regulation) that it deems anyone funded by federal research dollars to be practicing the patented invention “on behalf of the United States” and therefore to be licensed to use the patent. A provision implementing such a license would become a

public domain for use in developing open source software. See Press Release, IBM, IBM Pledges 500 U.S. Patents to Open Source in Support of Innovation and Open Standards (Jan. 11, 2005), available at <http://www.ibm.com/press/PressServletForm.wss?MenuChoice=pressreleases&TemplateName=ShowPressReleaseTemplate&SelectString=t1.docid=7473&TableName=DataheadApplicationClass&SESSIONKEY=any&WindowTitle=Press+Release&STATUS=publish>; see also Rai & Eisenberg, *supra* note 9, at 298-99 (discussing the SNP Consortium, in which several corporations and other institutions agreed to make public their databases of small nucleotide polymorphisms (SNPs, which are important tools that help researchers pinpoint the locations of disease and other genes on the chromosomes), rather than protecting them with patents or other intellectual property). See generally Robert P. Merges, *A New Dynamism in the Public Domain*, 71 U. CHI. L. REV. 183 (2004) (discussing recent efforts of private parties to enrich the public domain, rather than appropriate knowledge via intellectual property).

368. 35 U.S.C. § 202(c)(4) (2000 & Supp. II 2002).

standard part of any government funding contract. Under the provision, the funding recipient would receive a license (in effect a sublicense of the government's license) to use all government-funded discoveries, while the government would specifically reserve the right to license other government-funded researchers to use any patents developed during the funding recipient's research.³⁶⁹

This method of implementation might, however, present certain difficulties.³⁷⁰ First, although to date there have been no judicial interpretations of the term "for or on behalf of the United States" in this statute,³⁷¹ thus allowing the agencies some leeway, the existing definitions of the means of funding research may create problems with adopting this interpretation. True contract work—which by definition is "to acquire . . . property or services for the direct benefit or use of the United States Government"³⁷²—can easily be viewed as "for or on behalf of the United States." Thus, work done pursuant to government contracts should already fall within the government's reserved license. However, the NIH and other agencies fund most research through grants, which by definition are used "to transfer a thing of value to the . . . recipient to carry out a public purpose of support or stimulation authorized by a law of the United States *instead of* acquiring . . .

369. Interestingly, in *Madey v. Duke University*, Duke asserted that it *had* such a license under the Bayh-Dole Act, pursuant to 35 U.S.C. § 202(c)(4), to use Madey's patented invention in its research projects. *Madey v. Duke University*, 266 F. Supp. 2d 420, 425, 428-29 & n.3 (M.D.N.C. 2001), *rev'd in part* by 307 F.3d 1351 (Fed. Cir. 2002). Duke argued that its research was "authorized by the Government, conducted for the Government, or funded by the Government" and therefore fell under the government's reserved Bayh-Dole license. *Id.* at 425. The District Court found that the experimental use exemption applied, so it did not reach this defense, although it did note the argument's basic plausibility. *See id.* at 428-29 & n.3. The Federal Circuit found the record on this point insufficient and remanded the issue to the District Court. *Madey v. Duke University*, 307 F.3d 1351, 1363-64 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003). On remand, the court rejected the defense as a matter of law, holding that it belonged to the government and could not be asserted by a private party. *Madey v. Duke University*, 2006 WL 267187 at *7-11 (M.D.N.C. Jan. 31, 2006). However, the failure of this defense has very little direct relation to my proposal, which requires at the very least that any such license must be written into the grant, which was not the case in *Madey*.

370. *See* Rohrbaugh Presentation, *supra* note 356, at 137-40.

371. *See id.* at 139-40.

372. 31 U.S.C. § 6303(1) (2000).

. property or services for the direct benefit or use of the United States Government,”³⁷³ and thus are more of an assistance mechanism directed at the recipient.³⁷⁴ Declaring work under a grant to be “on behalf of the United States” is therefore something of a leap, and it would probably be an inappropriate extension of the reserved right.³⁷⁵

Furthermore, declaring that research is “for or on behalf of the United States” has implications far beyond the simple issue of patent licenses.³⁷⁶ In general, such a declaration gives the government significant control over the funded project, far beyond that normally conveyed by a research grant.³⁷⁷ If a particular piece of research work is “for or on behalf of the United States,” then the agency will be looking for a specific type of result to fulfill a specific goal and so will want direct control over implementation, to ensure that it is getting that type of result. Most grantees would be very reluctant to cede such control to the agency, as they value their independence and look askance at any attempt by the government to control the direction of the research.³⁷⁸ Furthermore, the agency probably would not want control anyway—when it needs or desires such a directed result, it uses a requirements contract rather than a grant. In addition, the government might, by making such a declaration, open itself up to liability for patent

373. *Id.* § 6304(1) (emphasis added).

374. *See* Rohrbaugh Presentation, *supra* note 356, at 139-40.

375. *See* NIH RESEARCH TOOLS REPORT, *supra* note 193, at app. D (“It is not clear whether NIH’s retained license . . . allows NIH to authorize use of subject inventions by other recipients of NIH grants.”). The appendix also discusses the distinction between contracts and grants. *See id.*

376. *See* Rohrbaugh Presentation, *supra* note 356, at 139-40 (“There are a lot of implications that are negative with respect to working on or behalf of the U.S. government in receiving grants.”). In a subsequent interview, Dr. Rohrbaugh clarified that he was referring to the loss of control and loss of some rights that typically accompany working directly for the government. *See* Rohrbaugh Interview, *supra* note 279; *see also* NIH RESEARCH TOOLS REPORT, *supra* note 193, at app. D n.14 (“A broader interpretation of the retained license might also have implications for appropriations and grants law that neither the NIH nor other Federal agencies would welcome.”).

377. *See* 31 U.S.C. § 6304(2) (stating that a grant is used when “substantial involvement is not expected between the executive agency and the . . . recipient when carrying out the activity contemplated in the agreement”); Rohrbaugh Presentation, *supra* note 356, at 139-40.

378. *See* Rohrbaugh Presentation, *supra* note 356, at 139-40 (“But recipients of funding under grants, by and large, . . . are not acting on or behalf of the US government, and most of them don’t want to be considered as acting on or behalf of the US government.” (emphasis added)).

infringement by grantees.³⁷⁹ If the research is “for or on behalf of the United States,” then any infringement is also for the benefit of the United States, leading to potential liability for infringement damages.³⁸⁰ For similar reasons, this declaration might also have other tort liability consequences for the United States.³⁸¹ The United States would understandably not want to assume these liabilities for every grant it issues.³⁸²

One possible way to avoid these problems is for the Department of Commerce (which has responsibility for Bayh-Dole Act implementation³⁸³) to either adopt or permit individual agencies to adopt a special definition of “on behalf of the United States.”³⁸⁴ Commerce could limit the definition to implementation of the Bayh-Dole Act and no other contexts, specifically excluding things like patent infringement and tort liability.³⁸⁵ The agencies could then implement the proposed

379. *See id.* at 140 (“There is also increased liability and other issues that would pertain to the government, in which the government would not want these parties to be considered engaged in activities on behalf of the government.”). In our interview, Dr. Rohrbaugh clarified that he was referring to liability for patent infringement being attributed to the United States. *See* Rohrbaugh Interview, *supra* note 279.

380. *Cf.* 48 C.F.R. § 52.227-3 (2004) (providing clause to be used in contracts negotiated under the F.A.R. requiring contractors to indemnify the United States against liability for patent infringement, subject to certain exceptions); *cf. also id.* §§ 52.227-1, -2, -4 to -7 (providing related clauses); *id.* § 28.203 (giving instructions on when to use the various clauses). Note that the United States can be liable for damages for patent infringement, but injunctive relief is not available. *See* 28 U.S.C. § 1498(a) (2000).

381. In our interview, Dr. Rohrbaugh also clarified that he was referring to liability for torts being attributed to the United States. Rohrbaugh Interview, *supra* note 279. The federal government waived its sovereign immunity against tort claims, subject to certain conditions, in the Federal Tort Claims Act, Pub. L. No. 79-601, Title IV, 60 Stat. 843 (1946) (codified as amended in scattered sections of 28 U.S.C.).

382. *Cf.* 48 C.F.R. § 52.228-7 (providing clause to be used in contracts negotiated under the F.A.R. requiring contractors to maintain insurance against tort liability; United States will cover remaining uninsured tort damages, subject to certain exceptions); *id.* § 28.311 (giving instructions on when to use the clause).

383. *See* 35 U.S.C. §§ 202(b)(1), 207(b), 208 (2000 & Supp. II 2002).

384. Commerce has apparently to date declined to give the statute this interpretation. *See* Rohrbaugh Presentation, *supra* note 356, at 139 (“There has been an issue . . . that the license applies and should apply to our recipients of all funding, including our grantees. The government, the Department of Commerce, other agencies, have never taken that view in interpreting the words ‘for or on behalf of the US government’ . . . under Bayh-Dole.”).

385. The term “on behalf of the United States” appears in other places in

license pursuant to this definition.³⁸⁶

The options under this course raises the question of uniformity—that is, should the license policy be uniform throughout the government, or could it be enacted on an agency-by-agency basis? Ideally, the policy should be uniform, so that government-funded researchers do not have to be aware of the policy of every agency that funds research leading to patents that they might infringe. Part of the purpose of the license is to let researchers get on with the process of research, without worry over patent infringement of government-funded patents, and so seeing the magic words “this invention was made with Government support and . . . the Government has certain rights in the invention”³⁸⁷ in a patent should end the matter. This purpose would be severely undermined if not all government-funded patents fell under the proposed license, and thus researchers had to take the further step of identifying the funding agency and then researching its licensing policies.

the U.S. Code, but the contexts are so different that they should not create problems with using a special definition for purposes of the Bayh-Dole Act. *See, e.g.*, 16 U.S.C. § 403a (2000) (authorizing the Secretary of the Interior to accept, “on behalf of the United States,” title to the land that became Shenandoah and Great Smoky Mountains National Parks); 28 U.S.C. § 1404 (2000) (discussing transfer of proceedings in rem brought “by or on behalf of the United States”). Closer in context are some provisions in the tax code authorizing tax exemptions for work in certain industries done “for, or on behalf of, the United States,” but these appear to contemplate a typical government contractor relationship. *See, e.g.*, I.R.C. § 5851 (2000) (“The Secretary may relieve any person manufacturing firearms for, or on behalf of, the United States from compliance with any provision of this chapter [relating to special taxes on “Machine Guns, Destructive Devices, and Certain Other Firearms”] in the conduct of such business.”).

386. In his presentation, Dr. Rohrbaugh suggests that the NIH is already doing this on a limited basis: “[A]ll of our exclusive licenses have reserved the right for others to use the intellectual property, the research tool, to the extent there is one, for research purposes.” Rohrbaugh Presentation, *supra* note 356, at 146. However, he seems to be referring to patents owned by the NIH itself, arising out of its own intramural research. The NIH has much wider latitude in placing terms in licenses for the patents it owns than it does in imposing conditions on patents that will be owned by its funding recipients under the provisions of the Bayh-Dole Act.

387. 35 U.S.C. § 202(c)(6) (requiring this provision in all patents on inventions arising from federal funding). *But see* Coe A. Bloomberg, *Federal Funded Inventions and Bayh-Dole Act Compliance: Do You Really Own What You Think You Own?*, 16 NO. 2 J. PROPRIETARY RTS. 1, 4 (2004) (discussing a GAO survey of compliance with the requirements of Bayh-Dole, including the notice requirement, for patents on inventions arising from government-funded research, which found that compliance with these requirements was “dismal”; also noting that the government did not seem to be doing anything to enforce the requirements).

Nevertheless, if Commerce is unwilling to go that far, implementation by individual agencies would still be preferable to the current situation, and such a partial implementation could serve as the starting point for full implementation in the future. However, within each agency, the policy needs to be uniform, rather than addressing each contract individually, as the confusion noted above would be magnified dramatically if each patent required a separate inquiry. Case-by-case determinations would also suffer from all of the drawbacks noted above for the proposal advanced by Professors Rai and Eisenberg.

Another provision that might give the agencies the necessary power to implement the proposed change is found in the Act's opening statement of policy and objectives. This section identifies one of the goals of the Bayh-Dole Act as "to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise."³⁸⁸ However, in 2000, Congress passed an amendment that qualified this goal: "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*."³⁸⁹ Commerce (or possibly an individual agency) could declare that the current system was "unduly encumbering future research and discovery"³⁹⁰ and that it needed to be fixed by freeing future government-funded researchers to use patented technology that was developed with government funds. Although this section of the statute is really just a statement of purpose, Congress took the trouble to amend it in 2000, so the changed language should be given some practical effect.³⁹¹ The proposed Bayh-Dole license

388. 35 U.S.C. § 200.

389. *Id.* (emphasis added).

390. The agency would probably need to hold hearings and otherwise gather evidence to prove the point, but it should be able to do so adequately.

391. The history behind this amendment is rather obscure. It was enacted as part of the Technology Transfer Commercialization Act of 2000, H.R. 209, which was concerned primarily with the circumstances under which federal agencies should grant exclusive licenses to technology it owned. *See* H.R. REP. NO. 106-209, pt. 1, at 1 (1999). The version of the bill passed out of committee on May 6, 1999, did not contain this particular amendment to § 200. *See id.* at 2-5; 145 CONG. REC. H2919 (daily ed. May 6, 1999) (report of Rep. Sensenbrenner). The House of Representatives then took up the bill on May 11, 1999, and the version introduced then *did* contain this amendment. *See*

embodies the goal of the amended statutory language, and so might be enacted under its auspices.

Alternatively, Congress could simply add a new subsection to the Bayh-Dole Act that requires (or at least specifically allows) the agencies to grant such licenses. This is certainly the cleanest method, as it removes the possibility of disgruntled patentees challenging the action as beyond the power of the agencies. It would also implement a desirable uniform policy across all funding agencies. However, a mechanism that allowed the agency to make the change, rather than requiring congressional action, would be more expedient, as the agency is likely to be less resistant to this type of change, and indeed might even embrace it.³⁹² The agency would also likely be able to move more quickly on the matter.³⁹³

Whichever body institutes the change would have to pay close attention to timing issues. Suddenly changing the rules of who can freely use patents raises the specter of unwelcome takings claims under the Fifth Amendment.³⁹⁴ A patent is generally considered a strong property right, and thus a government-imposed restriction on against whom it can be asserted would almost certainly be resisted by patentees as a taking of a property right without compensation.³⁹⁵

The simplest way to address this concern would be to make the change prospective only. This solution would then raise the question of what should be the relevant event for the prospective cutoff. The most obvious event would be the patent application itself, applying the limitation only to applications

145 CONG. REC. H2941 (daily ed. May 11, 1999); *see also* 145 CONG. REC. S5041-42 (statement of Sen. Hatch) (documenting that the text of S. 999, the counterpart to H.R. 209, also contained the amendment). The record is silent as to how (and why) the text of the bill changed during this time.

392. *Cf. supra* notes 277, 284-285 and accompanying text (discussing the scientists in charge of the NIH).

393. *Cf. NATIONAL RESEARCH COUNCIL, supra* note 172, at 115 (“Realistically, the likelihood that Congress will pass research-exception legislation in the absence of compelling circumstances is small. Accordingly, we recommend consideration of administrative action.”).

394. U.S. CONST. amend. V.

395. Whether it would in fact be a taking raises some very interesting questions of takings law regarding what, exactly, has been taken and whether taking that causes the requisite level of harm to the property interest. Indeed, these are questions that would arise in any proposal that attempts to limit the patent right, such as implementing an expanded experimental use right; however, they do not seem to be addressed by such proposals. Further exposition of this issue is beyond the scope of this Article and is left for future development.

filed after the effective date of the implementing regulation (or legislation). However, at this point, the researcher will have already conducted the research leading to such applications pursuant to an earlier funding agreement. This earlier agreement will arguably have led the researcher to believe that any patent he or she obtained on the research would not contain such a limitation, and therefore the researcher would likely try to assert that this change in expectation was still a taking.³⁹⁶ To address this concern, the triggering event could be the approval of the grant application, with the exemption applying only to patents granted on inventions arising from research conducted pursuant to funding agreements made after the effective date of the implementing statute or regulation. On the other hand, given the language of §202(c)(4), an agency could certainly take the position that licensing “on behalf of the government” was part of the bargain when the patentee took title under the terms of the Bayh-Dole Act, and so the patentee has no grounds to complain—another advantage of using that provision rather than relying on congressional action.

2. Terms of the License

Another important consideration is the scope of the rights that the license should give to government-funded researchers (or, conversely, what limitations it should impose on patentees). The license should be limited to research activities, provide for certain limited sublicensing, require notification of the patentee where feasible, and address the issue of researchers giving away the patented invention to the public in a way that damages the economic position of the patentee.

a. Limitation on Rights Licensed

The most important feature of the license is that it needs to be strictly limited to the types of activities necessary to research and not extended to purely commercial activities.

The Patent Act defines infringement thus:

[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.³⁹⁷

396. Whether or not such an argument would be successful is well beyond the scope of this Article.

397. 35 U.S.C. § 271(a) (2000).

In general, the researcher should not need to offer to sell, sell, or import the patented invention to use it in research, so the license should not include these rights.³⁹⁸ The patentee should retain all these rights to commercialize the invention.³⁹⁹ Only the rights to make or use the patented invention for research purposes on the funded research project should be included in the license. This limitation would prevent researchers from using the research license to exploit the technology commercially.⁴⁰⁰

However, this limitation may create problems in certain situations. For example, a licensed researcher often will want to transfer particular research materials to another government-funded researcher who is also licensed. For instance, the licensed researcher might place a patented gene into a new expression vector⁴⁰¹ that makes it more useful (but still infringing). Other licensed researchers may also wish to use the new vector/gene system. Rather than trying to recreate the vector themselves, these latter researchers will commonly ask the first researcher to send them bacterial cells containing the new vector, which they can then propagate and use to obtain the expression vector as needed.

Normally, such a transaction will not raise any problems. However, if the material is expensive to create or to ship, the first researcher might desire to recover costs.⁴⁰² The introduction of money into the transfer arguably converts the transaction into a “sale,” which is not covered by the license. The license could address this issue in several ways. It could specify that such recovery of costs is not a “sale” for purposes of

398. As noted, patent rights are divisible, and so the proposed license may be constructed to exclude commercialization rights. See SCHECHTER & THOMAS, *supra* note 117, at 4.

399. Or, more precisely, to prevent others from commercializing it. The patent code makes clear that a patentee has only the right to exclude others from commercializing the invention, *see* 35 U.S.C. § 271; a patent gives the patentee no positive right to do anything. In the present context, the distinction is of little practical importance—assuming there is no other limitation on the sale of the technology, excluding others leaves the patentee as the sole seller of the technology.

400. See Mueller, *supra* note 174, at 58 (making a similar distinction).

401. An expression vector is a DNA construct that allows a gene cloned into it to be expressed as protein in a particular expression system. Such vectors are generally propagated in bacterial cells, allowing for easy creation of large quantities of the vector as needed.

402. This typically would not be the case for a simple DNA construct, but it might be true of, for example, a model organism such as a mouse or rabbit.

the license, or specifically grant the right to make this type of sale and no other. Alternatively, the license could simply exclude the right to make such sales and require that the licensees get specific permission for each such transfer.

b. Sublicensing

The license will also need to address the issue of sublicensing. The license should allow limited sublicensing when it is integral to advancing the research needs of the licensee, but not for commercialization.⁴⁰³ For example, the researcher should be allowed to sublicense an outside firm to custom manufacture a necessary piece of apparatus, but not to sell that apparatus to anyone else. And similar to the reimbursement issue discussed above, the licensee should be allowed to reimburse the sublicensee for the costs of making the apparatus. However, this right should be subject to an important limitation: A manufacturing subcontract should be allowed only if the patentee is not itself selling such a piece of apparatus; otherwise, the sublicense will have a direct adverse impact on the patentee.⁴⁰⁴ The sublicensing issue might also arise during clinical research, when the researcher requires subjects to perform some sort of infringing test or treatment on themselves as part of the research project. The license agreement should cover such uses, and the patentee should not be able to sue the subjects directly for infringement.⁴⁰⁵

c. Notice to the Patentee

Another licensing issue is notification of the patentee. The license could require the researcher to notify the patentee that he or she is using the patented method or device pursuant to the government license, so that the patentee can monitor

403. Of course, the latter limitation will largely be built into the license—since the researcher lacks the right to sell, it cannot sublicense that right to another party.

404. This limitation addresses the potential problems the proposed license might create for kits and apparatus in biotechnology research discussed above.

405. *But see* Kimberly Blanton, *Corporate Takeover: Exploiting the U.S. Patent System, a Single Company Has Gained Control over Genetic Research and Testing for Breast Cancer. and Scientists, Doctors, and Patients Have to Play by Its Rules*, BOSTON GLOBE, Feb. 24, 2002, § 2 (Magazine) (reporting on a commercial firm asserting that sharing the results of a clinical test with the patient makes the testing a commercial use, even if the use of the results for research use is not).

compliance with the license.⁴⁰⁶ However, while this requirement might make sense if the researcher knows that he or she is infringing, the researcher will often simply be unaware of the infringement. Indeed, one of the key advantages of the proposed license is that researchers will not have to keep close track of all government-funded patents that they might be infringing.⁴⁰⁷ The license could require notice anytime the researcher is aware of an infringement, but have no consequences for failure to notify when the researcher is unaware of the infringement, coupled with no affirmative duty on the part of the researcher to seek out patents that might be infringed.

d. Giving Away the Technology

One final issue is the potential problem of researchers giving away the patented technology to others (typically the public), because they believe that the commercial products are too expensive. For example, some researchers have complained that genetic tests for diseases are overpriced.⁴⁰⁸ A commonly cited example of this problem is the test for potentially dangerous mutants of the breast-cancer susceptibility genes BRCA1 and BRCA2.⁴⁰⁹ Myriad Genetics holds the patents on the tests and has been very aggressive about enforcing them.⁴¹⁰ Only a few laboratories approved by Myriad are allowed to perform the tests,⁴¹¹ and as a consequence the tests are very expensive.⁴¹² This situation has led to wide dissatisfaction in

406. See Mueller, *supra* note 174, at 58-59 (suggesting a notice scheme for the experimental use exemption).

407. This point is closely related to the discussion of government-wide unity presented earlier. See *supra* note 387 and accompanying text.

408. See, e.g., Anna Schissel, Jon F. Merz & Mildred K. Cho, *Survey Confirms Fears About Licensing of Genetic Tests*, 402 NATURE 118, 118 (1999) (criticizing exclusive licensing of genetic test patents as leading to their "being used to monopolize the testing services").

409. See generally Bryn Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH L.J. 123 (2002) (providing the history of the gene, its testing, and the controversy surrounding the patents on the gene and testing).

410. *Id.* at 136 ("Myriad holds patents on the two BRCA genes in the U.S., Europe, [and] Canada . . . Myriad has continued to aggressively enforce its patent rights in the U.S., and is also beginning to do so internationally, most recently in Canada and Europe.")

411. *Id.* at 136 ("Commercial laboratories . . . were systematically threatened with litigation until Myriad became the sole commercial provider of BRCA testing in the U.S.")

412. See *id.* at 133-34 (listing prices for various services); see also Jordan

the medical community, which feels that such important tests should be cheaper and more widely available.⁴¹³ Their dissatisfaction is furthered by the fact that initial identification of the gene was funded, in part, by the NIH.⁴¹⁴ The medical community has expressed similar dissatisfaction over a variety of patented tests for other disease genes.⁴¹⁵

Immunity from infringement liability would create a strong temptation for these disgruntled researchers to take direct action against the manufacturer by supplying the tests free of charge.⁴¹⁶ Such activity should not be protected by the proposed license, as it is not part of furthering the research enterprise but is merely an attempt to undercut the patentee's economic position, even though no direct "sale" is involved. On the other hand, if the funded research does in fact require such tests, then the researcher should be able to conduct them without liability.⁴¹⁷ The license terms should therefore clearly spell out what making and using is appropriate as research under the license and what is not.

Myriad's policies regarding research use of BRCA testing suggest one possible strategy. Myriad has a special license

Paradise, *European Opposition to Exclusive Control over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics BRCA Patent Controversy*, 59 FOOD & DRUG L.J. 133, 149 (2004) (discussing costs of the BRCA tests); Edward Weck, Note, *Exclusive Licensing of DNA Diagnostics: Is There a Negative Effect on Quantity and Quality of Healthcare Delivery that Compels NIH Rulemaking?*, 31 WM. MITCHELL L. REV. 1057, 1079-80 (2005) (same).

413. See Williams-Jones, *supra* note 409, at 137-38 (describing reactions against commercial testing); Blanton, *supra* note 405 (giving reactions of researchers and doctors to Myriad's patent policies).

414. See Williams-Jones, *supra* note 409, at 131 ("[The BRCA1] research was supported in part by funding from the pharmaceutical company Eli Lilly, but also from government agencies such as the NIH which provided Skolnick [one of Myriad's founders] with more than \$5 million specifically to look for BRCA1.").

415. See, e.g., Weck, *supra* note 412, at 1078-89 (describing several patented genetic tests and the reactions of professional medical organizations to them).

416. Indeed, the Canadian government feels so strongly on this point that it has refused to recognize the patents. See Williams-Jones, *supra* note 409, at 140-44. European groups have been similarly forceful in opposing the European versions of the patents. See *id.* at 138-40; Paradise, *supra* note 412, at 136-45.

417. Cf. Blanton, *supra* note 405 (describing research into the early stages of breast cancer that was halted because it required patient testing that would have infringed Myriad's patents).

program for NIH research, allowing researchers to perform tests as long as they do not charge the patients for them; alternatively, Myriad will perform the testing for the researchers at a greatly reduced cost.⁴¹⁸ A condition of the program is that the results not be given to the patient. According to Myriad, passing the results on to patients is the “very bright line” at which the testing crosses into the commercial realm and should be treated accordingly.⁴¹⁹ Alternatively, the license might define the right in terms of interference with the patentee’s economic position: If the researcher is simply replacing the patentee’s product, rather than using the invention to further his or her own research project, then the use is impermissible.⁴²⁰

In practice, this type of giving away of the patented invention may not turn out to be a problem, as performing the tests does involve costs to the tester that must be paid somewhere, and finding funding to cover these costs is likely to be difficult. Even if such funding is available, it is unlikely to come in the form of an NIH grant (since the hypothetical use is to undercut the patentee, not advance a research project), and so the license becomes irrelevant. However, given the strong resentment that many in the research community have against diagnostic testing patents, the license terms should plan for the possibility.

3. Participation

Another key issue under the proposed license is deciding who gets to benefit from the government license, and, as a corollary, who must license the patents arising out of their research to others who are eligible for the license. In many cases, funds from the government are insufficient to support the entire research project, and thus much research conducted with government funding is also supported by other funding sources.⁴²¹ One possibility is to set a percentage cut-off, below

418. *See id.* at 14, 27.

419. *Id.* at 20 (“[Dr. Gregory] Critchfield[, President of Myriad’s Laboratory Division,] explains, ‘If you give test results back to patients, it crosses over the line, and it’s no longer a simple research test.’ That, he says, ‘is really a very bright line.’”).

420. Intellectual property aficionados will note the analogy to the copyright fair use doctrine.

421. *See, e.g.,* Williams-Jones, *supra* note 409, at 131 (stating that Myriad’s BRCA1 research was funded by both Eli Lilly and government agencies).

which the researcher is exempted from the license.⁴²² These researchers would not be eligible to use patents covered by the proposed Bayh-Dole license, but they also would not have to subject any patents arising out of the research to it. However, a better approach is to make the system “all-or-nothing.” Any research project that receives *any* government funding is required to participate in the Bayh-Dole licensing scheme. Any other system would become a bureaucratic headache, with the NIH and researchers constantly trying to figure out which side of the line the project is on and whether it participates in the proposed license scheme.⁴²³

The potential impact of such broad participation is hard to evaluate. Broad participation might create an incentive for researchers always to attempt to get at least a small amount of government funding in order to take advantage of the right to use the patents under the proposed license. On the other hand, broad participation might cause some projects to steer clear of government funding to avoid subjecting any resulting patents to the proposed license. An “all-or-nothing” system lets researchers make the decision for themselves and then stick to it safely and easily.

D. RELATED PROPOSALS

Other commentators have made related proposals for giving basic researchers increased access to patented products and methods. One such proposal appears in the National Research Council’s recently completed comprehensive study of the future of the patent system, reported in a book entitled *A*

422. See Michel, *supra* note 324, at 408 (“A research project may be funded by both federal and private sources. Therefore it is necessary to set a minimum amount of government funding before the exception becomes applicable, perhaps 50%.”).

423. An example may help clarify the difficulty. Assume that the cutoff is set at 20%. A researcher receiving \$50,000 from the NIH and \$150,000 from an industrial partner would be eligible for the license (the NIH is providing 25% of the funding). Now, suppose the project is going well, and so the industrial partner provides another \$100,000. The NIH contribution is now only 17%, and so the researcher is no longer eligible for the license. Next, however, the NIH might renew the grant, providing another \$50,000. Now the researcher is again eligible for the license (the NIH is providing 29% of the funding). Assessing potential infringement liability in such a constantly shifting funding situation would be extremely difficult for the researcher to manage.

Patent System for the 21st Century.⁴²⁴ The report concludes with a chapter containing “Seven Recommendations for a 21st-Century Patent System.”⁴²⁵ One of the seven recommendations is presented in a subchapter that proposes to “Shield Some Research Uses of Patent Inventions from Infringement Liability.”⁴²⁶ This subchapter first discusses the Federal Circuit’s *Madey* decision⁴²⁷ and its possible consequences for basic researchers.⁴²⁸ It then explores some possible mechanisms for shielding basic researchers from patent infringement liability, including provisions in foreign law and scholarly proposals.⁴²⁹ However, the report concludes that, for various reasons, none of the proposals are feasible.⁴³⁰

As a solution, the report looks to an existing statute that in effect codifies eminent domain over patents.⁴³¹ Under the statute, when the United States infringes a patent, the patentee’s only remedy is a suit in the Court of Federal Claims for money damages; injunctive relief is not available against the federal government.⁴³² Furthermore, this limitation on liability extends to those entities doing work “for the Government and with the authorization or consent of the Government.”⁴³³ The report concludes that the government should explicitly extend this authorization and consent to all federally funded researchers.⁴³⁴ As a consequence, suits alleging infringement against these researchers would become suits against the United States, and would therefore be limited to money damages; research-threatening injunctions would not be available.⁴³⁵

The report then makes the same correlation made above:⁴³⁶ While distinguishing basic biotechnology research from applied biotechnology research is extremely difficult, receipt of federal

424. NATIONAL RESEARCH COUNCIL, *supra* note 172.

425. *Id.* at 81-129.

426. *Id.* at 108-17.

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

428. *See* NATIONAL RESEARCH COUNCIL, *supra* note 172, at 108-10.

429. *See id.* at 111-15.

430. *See id.*

431. *Id.* at 115-17 (citing 28 U.S.C. § 1498(a) (2000)).

432. *See* 28 U.S.C. § 1498(a).

433. *Id.*

434. *See* NATIONAL RESEARCH COUNCIL, *supra* note 172, at 115-16.

435. *See id.* at 116.

436. *See supra* note 291 and accompanying text.

funding can serve as a rough proxy indicating that the funded research is basic.⁴³⁷ Using government funding as a proxy lets the government extend its sovereign immunity to protect basic researchers from infringement liability. The cost, of course, is that the government must pay for any infringement damages. The report suggests that the Court of Federal Claims has historically limited damages against the government in patent cases under the statute, and that therefore the number of cases (and the damages awarded) should be relatively small.⁴³⁸

The report glosses over a small but key point in the statutory language. The government has the power to give its “authorization or consent” only when the research is “for the Government.”⁴³⁹ As discussed above in Part III.C.1, declaring an activity to be “for the Government” can have significant legal consequences, not all of which are desirable. The report does note that the authorization “should be carefully circumscribed to avoid conferring unrelated legal protections, for example, from tort liability.”⁴⁴⁰ However, it discusses neither how to achieve such a circumscription nor whether such limits on liability are even permissible under the statute. It also fails to address the implications of governmental control contained in declaring the research to be “for the Government.”⁴⁴¹

In a footnote, the report notes that the related language appearing in the Bayh-Dole Act regarding the government’s retained license in the research it funds might be an alternative mechanism for implementing its research shield.⁴⁴² It concludes that this approach would be less suitable because it would be less broad, applying only to patents on technology developed with government funding, rather than to all patents.⁴⁴³ However, the report fails to note the corresponding advantage of using the provisions of the Bayh-Dole Act. Under the statute, what the government receives in exchange for funding the research and allowing the funding recipient to

437. See NATIONAL RESEARCH COUNCIL, *supra* note 172, at 116.

438. See *id.*

439. 28 U.S.C. § 1498(a) (2000).

440. NATIONAL RESEARCH COUNCIL, *supra* note 172, at 116.

441. See *supra* notes 370-382 and accompanying text (discussing the implications of declaring research to be “for or on behalf of the United States”).

442. See *id.* at 115 n.53.

443. See *id.*

patent it is a *license* right.⁴⁴⁴ By having the government extend that license to the researchers that it funds, rather than using its eminent domain powers, the proposed Bayh-Dole license and the report's discarded suggestion would spare the government from having to defend *any* patent suits or pay any damages—they would all be subsumed under the license.

Dr. Suzanne Michel also makes a related proposal.⁴⁴⁵ Dr. Michel first discusses the traditional common law experimental use exemption and problems with its implementation.⁴⁴⁶ Next, she considers previous proposals for a codified broader experimental use exemption and explains why none of them is appropriate.⁴⁴⁷ She then makes a two-part proposal. The first part is “to grant [nonprofit] researchers [such as universities] the benefit of a clarified experimental use exception, which would exempt them from infringement when studying and improving a patented invention. The exemption should extend only to research use and not to commercialization of a product.”⁴⁴⁸ The second part (which the author says is intimately entwined with the first, so that the two should only be implemented in tandem⁴⁴⁹) is to “appl[y a] broad experimental use exception to patents resulting from federally funded research so that the patent can be used without liability for infringement up to the point of commercialization. The proposal exempts any researcher, whether for profit or not, from infringement when using a federally funded invention.”⁴⁵⁰

444. See 35 U.S.C. § 202(c)(4) (2000 & Supp. II 2002).

445. Michel, *supra* note 324.

446. See *id.* at 376-88.

447. See *id.* at 388-97.

448. *Id.* at 397-98.

449. See *id.* at 400.

450. *Id.* Professor Eisenberg, without much analysis, also makes a proposal similar to Dr. Michel's second part:

For example, one might add a research exemption to Bayh-Dole that would protect researchers who later use patented research tools developed with government funds from liability. Patent holders would still be able to enforce their rights against those who make, use or sell the inventions as commercial end products, including competitors who sell the invention to investigators for use as a research tool, but not against those who merely make and use the invention in their own research. Obviously, such an exemption would limit the value of patent rights in any government-sponsored invention that is useful primarily or exclusively as a research tool, although the protection against competitors who would sell the product to researchers provides some measure of protection.

Eisenberg, *supra* note 352, at 173.

Thus, Dr. Michel would implement a broader exemption than the proposed Bayh-Dole license: “Nonprofit” researchers can experiment on any patented invention,⁴⁵¹ while anyone can do non-commercial research on patents arising from government-funded research. While this broader exemption would encompass the proposed Bayh-Dole license and therefore have many of the same advantageous effects, its increased breadth might create new problems. Because it subjects a much larger group of patents to free use by a much wider range of users, its impact on the patent incentive is likely to be much more significant, and it may lead to a corresponding reduction in corporate research and development. Furthermore, the breadth of the exemption requires that Dr. Michel exclude research tools from its scope (otherwise, companies would have no incentive to create such tools, as they would be free to anyone).⁴⁵² The inclusion of research tools created with government funding is an important advantage of the proposed Bayh-Dole license.

The broader exemption also destroys the symmetry between government funding of the research leading to the patented research and government funding of the subsequent users of the technology, removing the equitable appeal of the proposed Bayh-Dole license and making it politically less palatable. In particular, the expansion of the license to allow *all* “nonprofit” researchers to experiment on *any* patent will almost certainly be opposed by patentees who funded their own research and do not wish to see it “given away” to potential rivals. When the government funded the inventions in the first place, however, subsequent licensees are in a much weaker position to make this argument. Similarly, the destruction of the symmetry removes the analogy to a patent pool, as the licensing is no longer reciprocal—researchers may get access to the pool without contributing to it, and contributing to the pool does not guarantee access to it. Thus, the advantages of creating a rough biotechnology patent pool are lost.

Professor Mike Mireles suggests a change to the Bayh-Dole Act that is related to the proposed Bayh-Dole license in a different way.⁴⁵³ Professor Mireles first examines the patent

451. Dr. Michel does exclude research tools from this exemption. See Michel, *supra* note 324, at 398 n.151.

452. See *id.*

453. Mireles, *supra* note 173.

system as it applies to biotechnology research.⁴⁵⁴ He next turns to an examination of the anticommons problem, focusing on whether empirical evidence supports the theoretical construct.⁴⁵⁵ He concludes that, although the evidence does not directly support the existence of an anticommons, it also cannot rule it out.⁴⁵⁶ Professor Mireles then proposes a solution to help prevent or mitigate any anticommons that might arise.⁴⁵⁷ After first proposing that the government commission a “Study of the Effect of Government Policy on Biotechnology Innovation” to resolve the issue of the existence of an anticommons,⁴⁵⁸ his solution then focuses on the use of industry-wide patent pools to facilitate the exchange of research tools, and government action to promote the formation of such pools.⁴⁵⁹ In particular, he first proposes that the government create a database of research tools so that those desirous of using the technology or forming a pool with it can find each other.⁴⁶⁰ Second, he proposes amending the government’s reserved license to patents obtained on government-funded inventions under the Bayh-Dole Act to make it transferable rather than non-transferable.⁴⁶¹ However, the license would be transferable only in very limited circumstances. Specifically, the government would have only the right to transfer the license to an industry-wide patent pool, and only when the patentee refused to put the patent into the pool itself and this refusal jeopardized the viability of the pool.⁴⁶²

Although Professor Mireles’s proposal and the proposed Bayh-Dole license share a view of patent pools as a valuable tool in facilitating biotechnology research, the two proposals focus on different ways of achieving the desired result. Professor Mireles sees the government as merely assisting the formation of the pools; the formation of the pools themselves is left to industry.⁴⁶³ Under the proposed Bayh-Dole license, on

454. *See id.* at 148-71.

455. *See id.* at 171-194. Professor Mireles also explores past proposed solutions for dealing with the anticommons problem. *See id.* at 194-224.

456. *See id.* at 192-94.

457. *See id.* at 225-34.

458. *See id.* at 225-30.

459. *See id.* at 230-31.

460. *See id.* at 231.

461. *See id.* at 231-33.

462. *See id.* at 233.

463. *See id.* at 230-34.

the other hand, the government *creates* a rough patent pool among recipients of government funding, with the hope that it might either be expanded into a true industry-wide patent pool or at least serve as the model for one. However, the two proposals are not really incompatible and might both be useful tools for improving access to patented research tools.

Finally, the proposal fits well with the NIH's recently introduced policy for facilitating the dissemination of results from NIH-sponsored research.⁴⁶⁴ The new data access policy requests (but does not require) that all NIH-funded researchers provide the NIH with electronic copies of all articles that result from funded research and are published in peer-reviewed scientific journals.⁴⁶⁵ After a suitable embargo period, these electronic copies are then placed in an online archive accessible to the public.⁴⁶⁶ The copyright in the research papers remains with its owner (either the researcher or the publishing journal); the NIH archive merely facilitates access to the research paper.⁴⁶⁷ According to the NIH, the purpose of the policy is to increase the public's access to the research results for which it paid.⁴⁶⁸ The proposed Bayh-Dole license is entirely consistent with this purpose: Both have the goal of increasing access to government-funded research (although the NIH data access policy is broader in that it encourages access to all the public, rather than just other government-funded researchers). Furthermore, both policies specifically limit this access to non-commercial uses—in both cases, the right holder retains all commercial rights. Thus, the proposed Bayh-Dole license

464. See Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research, 70 Fed. Reg. 6891, 6891 (Feb. 9, 2005) [hereinafter NIH Public Access Policy], available at http://publicaccess.nih.gov/Enhanced_Public_Access.pdf; Elias A. Zerhouni, *NIH Public Access Policy*, 306 SCIENCE 1895 (2004) (discussing the initial proposal for the policy).

465. See NIH Public Access Policy, *supra* note 464, at 6899. Recent data indicates that the policy has been largely ignored, leading to calls for the data access policy to be made mandatory. See Rick Weiss, *Government Health Researchers Pressed to Share Data at No Charge*, WASH. POST, Mar. 10, 2006, at A17 (discussing Congressional concerns and proposed legislation to address this failing).

466. See NIH Public Access Policy, *supra* note 464, at 6900.

467. See *id.* at 6897.

468. See *id.* at 6892 (“The Policy is intended to: . . . make published results of NIH-funded research more readily accessible to the public, health care providers, educators, and scientists.”).

comports nicely with the current trend of NIH policies on access to research.

IV. CONCLUSION

The Bayh-Dole Act has, in many respects, succeeded in its goal of getting the results of government-funded research into the hands of industry so that its fruits can be enjoyed by the taxpayers who paid for its creation. However, in some cases, that success has come at the cost of limiting or taxing future research, with no direct gain from such limits. Thus, many commentators have proposed various changes to the Act that will help avoid these costs without destroying the benefits.

One such proposal is made by Professors Arti Rai and Rebecca Eisenberg, who argue for a scheme under which the NIH (or, presumably, any funding agency) reviews each research funding agreement, predicts what invention or inventions might arise from it, and then decides whether any such inventions would be better utilized if they are covered by patent rights (giving private industry an incentive to develop them) or left in the public domain (so that all who desire have free access to technology that requires little or no further development). Depending on this assessment, the final funding agreement is then drafted to allow or forbid the funding recipient to seek patents on any resulting inventions. This proposal suffers from some serious drawbacks in implementation. In particular, the NIH does not have the expertise, resources, or appropriate personnel to perform such a task, and it is likely to succumb to a variety of biases in trying. More important, however, is the difficulty that *any* analyst would have in attempting to see into the future and make the necessary *ex ante* determinations as to which path is preferable. Thus, the proposed reform is likely to fail in practice.

Instead, this Article proposes an alternative reform: Allow all researchers whose work is funded by federal funds to have a limited, royalty-free license to make or use, for research purposes on the funded project, any patent for which the underlying invention was developed with federal funds. The license should be strictly limited to research activities and should not extend to the right to sell or otherwise commercialize the patented invention; the patentee should retain all rights to commercialize the invention. Under this proposed license, government funding serves as a proxy for

basic researchers, who need access to fundamental research that has broad application. This proposal should provide broad access to technology that was patented under the Bayh-Dole Act without significantly undermining patent incentives. Furthermore, it has the advantage of being simple to implement. It also serves to implement a limited experimental use exemption, and it could also serve as a rough patent pool that can pave the way to a future true patent pool for the biotechnology industry. Thus, the proposed Bayh-Dole license has many advantages and can help facilitate access to basic technology in the biotechnology field.