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Adoption of the Bayh-Dolye Act in Developed Countries: Added Presure for a Broad Research Exemption in the United States?

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Michael S. Mireles[*]

I. INTRODUCTION

Numerous developed countries, most if not all members of the Organisation of Economic Cooperation and Development (OECD), including Japan, France, the United Kingdom, Germany, Austria, Denmark, Norway, Portugal, Spain, and Finland, have or are considering adopting legislation similar to the Bayh-Dole Act.[1] These countries apparently believe that passage of legislation similar to the Bayh-Dole Act will lead to the transfer of government funded research results from the university laboratory to the marketplace and other economic activity. In the United States, the birthplace of the Bayh-Dole Act (the Act), it is not entirely clear whether its passage is the direct result or sole cause of the increase in patenting and licensing occurring after its passage. Much of this university patenting and licensing has been in the biotechnology field.

Some commentators believe that the purported positive consequence of the Act—increased patenting and licensing—would have occurred without the Act. While it is not entirely clear whether increased university patenting and licensing would have happened anyway, the Act does attempt to encourage technology transfer through several means. First, the Act provides an incentive structure to encourage participants in the technology transfer process—researchers, their employers, and potential licensees—to attempt to bring technology to market. The primary incentive to commercialize an invention is the ability of recipients of government funding for research to take title to patentable inventions resulting from that research. The exclusive rights provided by the patent allow the owner or licensor of that patent to possibly extract a supra-competitive price for the patented invention in the market. Second, the Act also provides a uniform government policy concerning the treatment of government funded inventions, which reduces transaction costs in obtaining ownership to government funded inventions. Third, the Act provides a strong signal to universities to patent and license government funded inventions. Finally, the Act places patenting costs with the entity in the best position to bear those costs—the university or private company—instead of the inventor.

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1. Bayh-Dole University and Small Business Patent Procedures Act of 1980, Pub. L. No. 96-517, 94 Stat. 3015 (codified as amended at 35 U.S.C. §§ 200-211 (2000)).

Some critics of the Act argue that it upsets the production and dissemination of scientific knowledge, particularly basic science, by the academic enterprise. Instead of academia serving as an independent arbiter of science, governed by Merton's norms and thus encouraged to spread knowledge widely for the public benefit, the Act has resulted in a divergence of research agendas from basic to applied science, conflicts of interest, increased secrecy amongst academic researchers, and a withholding of research materials or data. The Act is also criticized for requiring the public to pay twice for an invention: once by funding the invention through taxes, and again, by extracting a supra-competitive price in the market through patents. Also, the Act arguably reduces the amount of information directed to the public domain—the foundation of new innovation—and the consequential spillover of benefits by allowing the patenting of government funded inventions. Perhaps the most frequently raised criticism of the Act is that it is contributing to the development of a tragedy of the anticommons in biotechnology innovation. A tragedy of the anticommons occurs when too many property rights are granted in one particular piece of property, with the result that the holders of the rights are unable to transfer and aggregate those rights to use the property. There is currently conflicting empirical evidence on whether an anticommons has emerged in the biotechnology field in the United States.

This essay makes several points. First, the Bayh-Dole Act may not be successful in Europe and Japan—success judged by increased patenting and licensing—because of the differences in the history, practice, and structure of most European and Japanese university systems compared with the U.S. university system. It may take substantial change in the practice and structure of European and Japanese university systems for legislation similar to the Bayh-Dole Act to be successful. While European and Japanese university systems appear to be undergoing that change, it will likely take a substantial amount of time to modify long-standing practices and existing structure.

Second, assuming legislation similar to the Bayh-Dole Act is successful in Europe and Japan, it may make the development of an anticommons more likely in the United States because of increased patenting and licensing by European and Japanese research universities and spin-off companies in the biotechnology field in the United States. Finally, while an anticommons may be avoided in European countries and Japan, as those countries generally have a more robust research exemption to patent infringement, the increased patenting and licensing in the United States may result in an anticommons because of the limited common law research exemption. This may result in pressure for the United States to enact or develop, through the common law, a more robust exception similar to that of other developed countries.

Part II of this essay discusses the Bayh-Dole Act. Part III analyzes the adoption of legislation similar to the Bayh-Dole Act in European countries and Japan. Part IV reviews the anticommons theory as applied to biotechnology innovation, and Part V analyzes the pressure for a more robust experimental use exception in the United States. The last section offers some concluding thoughts.

II. THE BAYH-DOLE ACT

The passage of the Bayh-Dole Act represented a change in federal policy concerning the ownership of government funded patentable inventions.[2] Prior to passage of the Bayh-Dole Act in 1980, each federal agency and funding group had its own policy concerning whether a funding recipient could take title to an invention developed from that funding.[3] Generally, the policies of those funding groups either required the government to retain title or dedicate the results of federally funded research to the public domain. Instead of favoring ownership in the government or dedication of the invention to the public domain, the Bayh-Dole Act creates a uniform federal policy that favors the patenting of government funded invention and the ownership of those inventions by the recipient of federal funding. The grant of title purportedly provides the recipient with the necessary incentive to invest in the commercialization of the invention.

There are numerous arguments and supposed benefits of the Bayh-Dole Act; however, there are also a number of criticisms. [4] The primary argument in support of

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2. *See* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663 (1996). ALINE C. FLOWER, INTELLECTUAL PROPERTY TECHNOLOGY TRANSFER 12 (BNA 2006) (quoting 35 U.S.C. § 201(b)) ("The Bayh-Dole Act generally applies to all 'funding agreements,' which are defined as government contracts, grants, and cooperative agreements . . . 'for the performance of experimental, developmental, or research work.'"). Further,

> [t]he Act applies to "subject inventions," which are broadly defined as "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement . . . ." The term "invention" is further defined as "any invention or discovery which is or may be patentable or otherwise protectable under" federal patent law. Thus, the Act applies to invention and discoveries that can be patented, even if the contractor is not inclined to apply for a patent.

Id. at 15 (quoting 35 U.S.C. § 201(e)). The scope of the Act is thus quite broad. For example, "[a]n invention can be a 'subject invention' if the government spends little on its conception while the contractor pays entirely for its further development, including its reduction to practice" and "an invention can be a 'subject invention' when conceived by a contractor working with its own funds, but reduced to practice under a government funding agreement." *Id.* at 16. Thus, "the making of a simple note in a laboratory notebook while working under a funding agreement could be considered the conception of an invention to which the government would have rights, even if the invention was not further researched or developed during the term of the agreement." *Id.*

3. Eisenberg, *supra* note 2, at 1663.

4. The eight purposes of the Bayh-Dole Act are expressed in 35 U.S.C. § 200:

> It is the policy and objective of the Congress to use the patent system to [1] promote the utilization of inventions arising from federally supported research or development; [2] to encourage maximum participation of small business firms in federally supported research and development efforts; [3] to promote collaboration between commercial concerns and nonprofit organizations, including universities; [4] 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; [5] to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; [6] to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and [7] protect the public against nonuse or unreasonable use of inventions; and [8] to minimize the costs of administering policies in this area.

35 U.S.C. § 200 (2000). Recipients of federal funding who may receive ownership of the federally funded

the Bayh-Dole Act is that private industry requires patents on government funded inventions to justify the expenditure of resources to develop such an invention into a commercial application.[5] Before enactment of the Bayh-Dole Act, a substantial amount of research results funded by the federal government and subsequently patented were not licensed.[6] However, this group of patents covering government funded research results was subject to a selection bias.[7] Most of these patents covered inventions wherein the contractors were usually permitted to take title to those patents.[8] Thus, this group of patents had been rejected by private industry, and it should therefore not be surprising that other industry participants would also not want to obtain title to those patents.[9]

Another justification for the Act was a belief that companies based outside of the United States were benefiting from the results of the research funded by the U.S. government.[10] Policy makers also believed that the Bayh-Dole Act would "reinvigorate U.S. industry by giving it a fresh infusion of new ideas that would enhance productivity and create new jobs."[11] One of the benefits of the Act was the creation of a uniform policy concerning ownership of government funded inventions,

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invention include small businesses and nonprofit organizations, including universities. *See The University and Small Business Patent Procedures Act: Hearings on S. 414 Before the S. Comm. on the Judiciary*, 96th Cong. 1 (1979) (statement of Sen. Birch Bayh); *id.* at 30 (statement of Sen. Robert Dole); *id.* at 33 (statement of Sen. Orrin G. Hatch). *See also* Eisenberg, *supra* note 2, at 8-12 (discussing legislative history of Bayh-Dole Act); Gary Pulsinelli, *Share and Share Alike: Increasing Access to Government-Funded Inventions under the Bayh-Dole Act*, 7 MINN. J. L. SCI. & TECH. 393, 447-48 (2006) (discussing legislative history of Bayh-Dole Act). The Bayh-Dole Act also specifies the conditions under which federal agencies may apply for, obtain, and maintain patents, and license government funded innovation. 35 U.S.C. §§ 207-09. *See also* UNIVERSITY TECHNOLOGY TRANSFER: QUESTIONS AND ANSWERS, COUNCIL ON GOVERNMENTAL RELATIONS 1 (1996), [hereinafter COUNCIL ON GOVERNMENTAL RELATIONS,] *available at* http://206.151.87.67/docs/bayhdoleqa.htm ("Enactment of Bayh-Dole Act (P.L. 96-517) . . . on December 12, 1980, created a uniform patent policy among the many federal agencies that fund research. Bayh-Dole enables small businesses and nonprofit organizations, including universities, to retain title to materials and products they invent under federal funding."). By executive order and later congressional housekeeping legislation, the Bayh-Dole Act was extended to not only small businesses, but to all government contractors, including large businesses. *See* Exec. Order No. 12,591, 52 Fed. Reg. 13,414 (Apr. 10, 1987).

5. Eisenberg, *supra* note 2, at 1669-70.

6. COUNCIL ON GOVERNMENTAL RELATIONS, *supra* note 4, at 1. The motivation for passing the bill was stated as follows:

> One major impetus for the bill was the lack of a capability on the part of the federal government to transfer technologies for which it had assumed ownership. Hundreds of valuable patents were sitting unused on the shelf because the Government, which sponsored the research that led to the discovery, lacked the resources and links with industry needed for development and marketing of the inventions. Yet the government was unwilling to grant licenses to the private sector. The few federal agencies that could grant patent title to universities, were overregulated with conflicting licensing and patenting policies. Technology transfer under those conditions was operationally prohibitive for universities and made them reluctant to enter the technology area.

Id.

7. Eisenberg, *supra* note 2, at 1702.

8. *Id.*

9. *Id.* at 1703.

10. *Id.* at 1665.

11. *Id.* at 1664-65.

which simplified the technology transfer process. Another related benefit is that the Act cleared bureaucratic hurdles that existed prior to passage of the Act. Notably, the discussion concerning passage of the Bayh-Dole Act was silent regarding the impact of the Act on university contribution to innovation through academic presentations, academic publications, and the training of future industry workers.[12]

In achieving the broad purposes of commercialization and technology transfer from the laboratory to the market through the grant of title, the Act provides incentives to the parties involved in bringing technology to market. Those parties include the government, the public, the inventor of the technology, the employer of the inventor, follow-on innovators, and entities involved in the commercialization of the invention. Instead of providing ownership initially to the inventor, the Act provides ownership to the entity that is most likely to be able to bear the costs of patent prosecution: the university or other grant recipient. The transfer of technology often occurs between universities, recipients of government funding, and private industry.

Since the passage of the Act, there has been a dramatic increase in the patenting and licensing of government funded inventions by universities or other nonprofits, and the creation of other apparently related economic activity.[13] In 1980, fewer than 250 patents were issued to universities; in 2004, over 3,800 U.S. patents were issued to universities.[14] More than 3,100 new products have been brought to market based on university or nonprofit research since 1998.[15] Further, more than 4,500 companies have been created based on licenses from universities and nonprofits since passage of the Bayh-Dole Act,[16] and close to 200,000 U.S. residents are employed in the biotechnology field.[17] Also, "[b]etween 1991 and 1999, annual invention disclosures by university researchers increased 63% . . . , patent filings increased 77% . . . and new licenses/options increased 129%."[18]

Some commentators argue that the increase in patenting and licensing attributed to the passage of the Bayh-Dole Act would have occurred regardless.[19] These commentators point to an upswing in patenting by universities prior to the passage of

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12. David C. Mowery & Bhaven N. Sampat, *The Bayh-Dole Act of 1980 and University-Industry Technology Transfer: A Model for Other OECD Governments?*, 30 J. TECH. TRANSFER 115, 119 (2005).

13. *See* ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS, AUTM U.S. LICENSING SURVEY: FY 2004, at 2-3, *available at* http://www.autm.net/events/File/04AUTMSurveySum-USpublic.pdf.

14. *Id.* at i.

15. *Id.*

16. *Id.*

17. *Id.*

18. U.S. DEPARTMENT OF COMMERCE, THE ADVANCED TECHNOLOGY PROGRAM: REFORM WITH A PURPOSE 11 (2002), *available at* http://www.atp.nist.gov/secy_rept/contents.htm.

19. DAVID C. MOWERY, RICHARD R. NELSON, BHAVEN N. SAMPAT & ARVIDS A. ZIEDONIS, IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT 1 (2004). *See also* Jerry G. Thursby & Marie C. Thursby, *University Licensing under Bayh-Dole: What are the Issues and Evidence,?* 8 (2003), http://opensource.mit.edu/papers/Thursby.pdf. ("Does university licensing under Bayh-Dole satisfy the Act's intent? While it is unclear what might have transpired in the absence of the Bayh-Dole Act, it is clear that the Act has at least facilitated technology transfer from universities."); *cf.* Rebecca Henderson, Adam B. Jaffe & Manuel Trajtenberg, *Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting, 1965-1988*, 80 REV. OF ECON. & STAT. 119, 126 (1998) ("Clearly, the Bayh-Dole Act has been a success with respect to the second of these incentive effects. Both the rate of patenting and the extent of licensing have increased dramatically.").

the Act because of advances in life sciences research, the change in the legal treatment of the patentability of living organisms in the *Diamond v. Chakrabarty*[20] decision, and the creation of the U.S. Court of Appeals for the Federal Circuit.[21] The commentators further argue that, "[c]urrent research thus provides mixed support at best for a central assumption of the Bayh-Dole Act, i.e., the argument that patenting and licensing are necessary for the transfer and commercial development of university inventions."[22] Moreover, the Act is subject to criticism by many commentators because it arguably causes a shift in the research agendas of scientists from basic to applied science, requires the public to pay twice for an invention, contributes to the development of an anticommons, results in increased withholding of research materials and results, adds to increased conflicts of interest among academic researchers, and the provisions designed to protect the interests of the public have not been exercised as perhaps expected.[23]

III. COPYING THE BAYH-DOLE ACT IN DEVELOPED COUNTRIES

The purported success of the Bayh-Dole Act—an increase in patenting and licensing activity by universities along with other economic effects—has led other countries to adopt or consider adopting legislative schemes similar to the Bayh-Dole Act.[24] Some of these countries are members of the Organisation of Economic Cooperation Development.[25] For example, Japan, France, the United Kingdom, Germany, Austria, Denmark, Norway, Portugal, Spain, and Finland have adopted or are considering enacting legislation similar to the Bayh-Dole Act.[26] However, there is a substantial question as to whether similar legislation will have the same impact in the OECD countries as the Act arguably has had in the United States: increased patenting and licensing leading to increased economic benefits such as new companies and jobs.

In a recent article, Professors David Mowery and Bhaven Sampat argued that "efforts at 'emulation' of the Bayh-Dole policy elsewhere in the OECD are likely to have modest success at best without greater attention to the underlying structural differences among the higher education systems of these nations."[27] In the United States, before passage of the Bayh-Dole Act, there was a history of collaboration

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20. 447 U.S. 303 (1980).

21. MOWERY ET AL., *supra* note 19, at 2.

22. Mowery & Sampat, *supra* note 12, at 122.

23. *See, e.g.*, Michael S. Mireles, *States as Innovation Systems Laboratories: California, Patents, and Stem Cell Technology*, 28 CARDOZO L. REV. 1133 (2006).

24. Mowery & Sampat, *supra* note 12, at 115.

25. Ken Howard, *Global Biotech Expansion Taking Cues from Bayh-Dole*, 22 NATURE BIOTECHNOLOGY 919 (2004).

26. *Id.* Australia is another country examining its innovation policy. *See* ADVISORY COUNCIL ON INTELLECTUAL PROPERTY, PATENTS AND EXPERIMENTAL USE ISSUES PAPER, at i (Feb. 2004), http://www.acip.gov.au/library/patentsexpuse.PDF [hereinafter PATENTS AND EXPERIMENTAL USE ISSUES PAPER]. This paper points out that "Australia spends, through public and private sources, considerable funds on research and development, including bio-medical research. There has also been increasing concern that there has been insufficient return on this investment through commercialization of research and development in Australia and that inadequate use of the patent system may play a part in this." *Id.*

27. Mowery & Sampat, *supra* note 12, at 116.

between universities and industry, including technology transfer.[28] The historical link between universities and industry in Europe has been more attenuated than in the United States.[29] Moreover, the structure and scale of the U.S. university system is very different from that of most OECD countries and these different characteristics encouraged university and industry collaboration.[30] For example, the U.S. university system is very large, includes "a very heterogeneous collection of institutions, . . . lack[s] any centralized national administrative control, and encourage[s] considerable interinstitutional competition for students, faculty, resources, and prestige."[31] Before the Bayh-Dole Act, U.S. universities were reliant on local sources for political and financial support, which led to increased collaboration between researchers and industry.[32] Further, U.S. universities increased their patenting and some universities created technology transfer offices or hired technology transfer officers during the 1970s, prior to the passage of the Act.[33]

Professor Mowery has also argued that there must exist "a demand for industry for transfer as well as the processes to facilitate the transfer."[34] He and other commentators argue that a combination of features in the United States enable the transfer to happen, including: "venture capital, labor mobility between university and industry, large scale public funding for biomedical research, competition between universities for faculty and research money, lack of central government control and administrative autonomy of universities in addition to a comprehensive patent system."[35] Professors Mowery and Sampat have discussed the differences between the approaches of several countries in adopting parts of the Bayh-Dole Act.[36] For

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28. *Id.*

29. Yannis Caloghirou, Aggelos Tsakanikas & Nicholas S. Vonortas, *University-Industry Cooperation in the Context of the European Framework Programmes*, 26 J. TECH. TRANSFER 153, 153 (2001).

30. Mowery & Sampat, *supra* note 12, at 116.

31. *Id.* at 118.

32. *Id.*

33. *Id.* at 119.

34. Howard, *supra* note 25, at 919.

35. *Id.* at 920. Some authors have also specifically discussed the various differences between the U.S. and Japanese systems concerning "higher education and research funding, the venture-capital and IPO markets, cultural characteristics and incentive systems which impact scientists' entrepreneurialism, and tort-liability exposures." *See* Michael R. Darby & Lynne G. Zucker, *Star Scientists, Institutions, and the Entry of Japanese Biotechnology Enterprises* (Nat'l Bureau of Econ. Research, Working Paper No. 5795, 1996). An issue concerning the differences between U.S., European, and Japanese markets may be "that Japanese pharmaceutical companies tend to do more in-house basic research and to a lesser extent rely on alliances with biotechnology companies or universities" than their European and U.S. counterparts. ANNA S. NILSSON, HENRIK FRIDEN & SYLVIA SCHWAAG SERGER, SWEDISH INST. FOR GROWTH POLICY STUDIES, COMMERCIALIZATION OF LIFE-SCIENCE RESEARCH AT UNIVERSITIES IN THE UNITED STATES, JAPAN, AND CHINA 27 (2006), http://www.itps.se/Archive/Documents/Swedish/ Publikationer/Rapporter/Allm%C3% A4nna/A2006/A2006_006%20webb.pdf. This may be because of "organizational and operational structures within companies [and] restructuring of domestic pharmaceutical companies may lead to more interaction with universities." *Id.* Another commentator raises issues concerning whether European researchers are more risk adverse than U.S. researchers in commercializing their inventions because of the small number of positions in European universities, and whether there is a greater incentive in the United States to commercialize certain inventions because of the lack of price controls on prescription drugs than in many European countries where those price controls exist. Thomas J. Siepmann, *The Global Exportation of the U.S. Bayh-Dole Act*, 30 U. DAYTON L. REV. 209, 218 (2004).

36. Mowery & Sampat, *supra* note 12, at 123. Universities in Europe may be more involved in

example, some countries have allowed public research institutions such as universities to take title to government funded inventions instead of the inventors.[37] This is different from the U.S. experience with the Bayh-Dole Act, which moved the ability to take title from the government to universities, not from inventors to universities.[38] The granting of title to universities creates an obligation to disclose potentially patentable inventions to the university, allowing them the decision to patent and, more importantly, provides title to an entity with the motivation and ability to pay patent prosecution costs. The individual university inventor is unlikely to have the ability to front substantial patent prosecution costs. Professor Mowery and others have argued, however, that much of the effect of the Bayh-Dole Act, such as patenting and licensing, would have occurred without its passage.[39]

Professors Mowery and Sampat qualify their argument by stating that there may be some "modest success at best."[40] This "modest success" may be increased patenting and licensing activity by universities. Moreover, the authors state that there must be more attention to the underlying university structural differences between the United States and other OECD countries.[41] Members of the European Union and Japan have reformed or are currently reforming their university educational system and in some ways the reform appears to attempt to emulate the U.S. university system. For example, in Japan, the national universities, which received over three quarters of funding for basic research in Japan, have been converted into an independent administrative entity, called national university corporations.[42] Apparently, most of the results of research at the national universities prior to the change to national university corporations could be used by private firms "for free or a small amount of donation paid to individual researchers for their inventions."[43] University corporations are now

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patenting than indicated by some studies. *See* Bart Verspagen, *University Research, Intellectual Property Rights and European Innovation Systems*, 20 J. ECON. SURV. 607, 628 (2006) ("[T]he data suggest that European universities are already more heavily engaged in patenting than was believed on the basis of official patent statistics.").

37. Mowery & Sampat, *supra* note 12, at 123.

38. *Id.* For a discussion of how some OECD countries are reforming their legal treatment concerning government funded invention, see OECD, TURNING SCIENCE INTO BUSINESS: PATENTING AND LICENSING AT PUBLIC RESEARCH ORGANISATIONS 95-291 (2003) [hereinafter TURNING SCIENCE INTO BUSINESS].

39. Howard, *supra* note 25, at 990.

40. Mowery & Sampat, *supra* note 12, at 123.

41. *Id.*

42. Masuyuki Nishijima, *Effects of the Anticommons on R&D: The Case of University Corporation in Japan* 22-2 SETO, KANAZAWA-KU 3 (2004), *available at* http://repec.org/esFEAM04/up.2724.1080643531.pdf; *see also* Tabata Hirokuni, *The Incorporation and Economic Structural Reform of Japan's National Universities*, 8 SOC. SCI. JAPAN J. 91 (2005) (discussing the reform of national universities in Japan by the National University Corporations Law which converts national universities into corporate bodies); *Fifth Report to Leaders on US-Japan Regulatory Reform and Competition Policy Initiative* 14 (June 29, 2006), http://www.mofa.go.jp/region/n-america/us/report0606.pdf ("Japan is preparing to submit legislation to the Diet in FY2007. This legislation will expand the scope of Japan's Bayh-Dole system, making it possible for contractors to possess ownership rights to intellectual property created through government-sponsored development of information systems, including software."); Ashley J. Stevens & John Fraser, *Understanding the Importance of Bayh-Dole*, MANAGING INTELL. PROP., Dec. 2005/Jan. 2006, at 37 ("In Japan, the government is privatizing the entire university system in part because they want Japanese universities to become economic catalysts, like their U.S. counterparts.").

43. Nishijima, *supra* note 42, at 3.

allowed to earn income from the inventions their researchers develop and their funding is no longer guaranteed.[44] Moreover, university corporations are encouraged "to obtain patents of their inventions and engage in cooperative research activities with private firms."[45] This change also allows the national university corporations "to claim the rights to all inventions made by their employees."[46] The Japanese approach apparently attempts to create incentives for university corporations to generate income from patents.

The European Union has also been active in reforming its university system. The European Commission recently released a report entitled, "European Universities: Enhancing Europe's Research Base."[47] Notably, the report expressly states that "autonomy is a good orienting principle because there is no single model for the European University, just as there is no model for the American University [and t]he Forum believes that Universities should be given more freedom to respond to changes that are occurring . . . ."[48] The report includes several recommendations for European universities, including encouraging mobility of trained people between universities and industry; "build[ing] up concrete synergies between universities and surrounding society (companies, chambers of commerce, public authorities, etc.);" encouraging a "trans-disciplinary" approach to solving "scientific problems and those faced by society;"[49] encouraging universities to "take a leading role in regional and local development;" and improving their ability to raise funding to carry out research.[50] These recommendations appear to orient European universities to focus on solving

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44. *Id*; *see also* Flower, *supra* note 2, at 400 n.5 ("University researchers can now hold a concurrent post in the private sector, because civil service regulations no longer apply to universities.").

45. Nishijima, *supra* note 42, at 3; *see also* Flower, *supra* note 2, at 401 ("Currently, under Japanese Patent Law Section 35, national university corporations can acquire ownership of all work-related employee inventions."); Robert Kneller, *University-Industry Cooperation and Technology Transfer in Japan Compared with the United States: Another Reason for Japan's Economic Malaise?*, 24 U. PA. J. INT'L ECON. L. 329 (2003) (discussing ownership rules concerning government funded inventions prior to formation of national university corporations, and the changes and impact of new ownership rules).

46. NILSSON ET AL., *supra* note 35, at 26. Japan did enact the Industrial Vitalization Law, also called the Japanese Bayh-Dole Act, in 1999. *Id.* This law allowed the public research institution to own IP resulting from some government funding. *Id.* It did not apply to situations involving basic funding to the university professor and thus, in those circumstances, the university professor was entitled to retain title to those inventions. *Id.* Apparently, this situation led to possible under-reporting of inventions because "the researcher [had] to determine which results came from commissioned funding [under the Industrial Vitalization Law] or . . . basic funding." *Id.* This apparent problem has been solved for national universities in the legislation that has created the national university corporations. *Id.*

47. Forum on University-based Research, *European Universities: Enhancing Europe's Research Base* (European Commission 2005) [hereinafter *European Universities*], http://europa.eu.int/comm/research/conferences/2004/univ/pdf/enhancing_europeresearchbase_en.pdf.

48. *Id.* at 11.

49. The report on European Universities specifically points out scientific centers it calls "trans-disciplinary" in the United States at universities such as Berkeley, Chicago, Harvard, Princeton, and Stanford. *Id.* at 35.

50. *Id.* at 12-15. Interestingly, the report on European Universities, in discussing the role of universities in the creation of knowledge, states that universities have an entrepreneurial role "as sources of spin-offs and start-up companies. . . . Addressing this role is tremendously difficult, and is not solved merely by encouraging Universities to take out patents." *Id.* at 24. For more information concerning the policies and trends in the management of intellectual property generated at universities and other public research organizations, see TURNING SCIENCE INTO BUSINESS, *supra* note 38, at 3.

more practical problems as opposed to theoretical issues. Interestingly, Germany has recently restructured its university system to create centers of excellence somewhat modeled after the American university system's "Ivy League."[51]

In addition to changes in the structure of university systems in Europe and Japan to resemble some characteristics of U.S. universities, the governments in Europe and Japan have been and are continuing to encourage collaboration between universities and industry in those countries. In 1984, the European Union established European Framework Programmes (FWPs) that were designed to encourage collaboration in research and development in several fields between universities, industry, and other research institutions across Europe.[52] FWPs are the main mechanism through which the European Union distributes research funds and are a major part of the attempt to create a European Research Area.[53] The European Research Area is

> a vision for the future of research in Europe, based on an internal market for science and technology, which seeks to foster scientific excellence, competitiveness and innovation through the promotion of better co-operation and co-ordination between all relevant European actors at all levels. The creation of ERA aims to ensure the free movement of researchers, ideas and technology in Europe, to overcome the fragmentation of European research, and at co-ordinating national and European programmes and policies to avoid the duplication of resources and efforts.[54]

According to the authors of a study concerning research joint ventures formed pursuant to FWPs between 1983 and 1996, FWPs have been successful in developing a closer relationship between universities and industry in Europe.[55] In fact, the authors found that, "[u]niversities have been very active, participating in more than fifty percent of [research joint ventures] in all but one technology areas, the highest rate being in the area of biotechnology (92%)."[56] The impetus for this collaboration by industry has included "research synergies, keeping up with major technological developments and R&D cost sharing."[57] The most recent FWP, the Seventh Framework Programme, is designed to apply between 2007 and 2013 and has a budget of 53.2 billion euros.[58] Notably, 32.3 billion euros is allocated to "gaining leadership in key scientific and technology areas by supporting co-operation between universities, industry, research centres and public authorities across the EU and with the rest of the world."[59] Another portion of that fund is devoted to increasing the mobility of researchers between university and industry.[60]

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51. Charles P. Wallace, *Germany's Ivy League*, TIME, March 31, 2002.

52. Caloghirou et al., *supra* note 29, at 153-54.

53. European Commission, *Sixth Framework Programme, Frequently Asked Questions* 1, http://ec.europa.eu/research/fp6/pdf/faq_en.pdf (last visited April 9, 2007).

54. EurActiv.com, *European Research Area—Within Reach?*, http://www.euractiv.com/en/science/european-research-area-reach/article-162032 (last visited April 9, 2007).

55. Caloghirou et al., *supra* note 29, at 154.

56. *Id.* at 159.

57. *Id.* at 154.

58. European Commission, *The Seventh Framework Programme* 1, http://ec.europa.eu/research/fp7/pdf/fp7-brochure_en.pdf (last visited April 9, 2007).

59. EurActiv.com, *7th Research Framework Programme*, http://www.euractiv.com/en/science/7th-research-framework-programme-fp7/article-117494.

60. *European Research Area—Within Reach?*, *supra* note 54.

The Japanese government began to attempt to increase collaborations between universities and industry in the early 1980s by creating collaborative research programs, allowing universities to take on research projects using private funds, and developing a system of collaborative research centers at national universities.[61] While the efforts to increase collaboration did not increase patenting and licensing activity between the late 1980s and 1995, there was more collaboration between industry and universities during that time period.[62] For example, in 1985, there were 216 cooperative research and development projects involving 254 researchers; by 1995, there were 1704 cooperative research and development projects with 1843 researchers.[63] The total amount funded in commissioned research and development projects increased from 14.7 million dollars in 1985 to 150 million dollars in 1995.[64] There has also been an increase in the number of Cooperative Research Centers from three in 1985 to forty-nine in 1995.[65] In addition to those reforms, "the Japanese legislature in 1996 enacted the Science and Technology Basic Plan," which called for an increase in the amount of government funding for research in an attempt to come close to government funding for research in other industrialized countries.[66] The Second Science and Technology Basic Plan, enacted in 2001, is directed to increasing collaborations between universities, industry, and the government.[67]

Governments in Europe and the Japanese government are also attempting to encourage technology transfer and collaborations between industry and universities in other ways. For example, in 2001, the Japanese government lifted a ceiling on the amount of funds "that researchers at public universities are allowed to earn from government-held patents based on their work."[68] The ceiling was 50,000 dollars and now there is no limit.[69] The Japanese government also enacted the University Technology Transfer Promotion Law.[70] That law encourages universities to establish technology transfer offices directed to transfer technology from universities to industry.[71] The Japanese government also passed the Law to Strengthen Industrial Technology Capability in 2000, which "allows university professors to consult for private enterprises and take managerial positions with companies in which their research is used [and makes] it possible for researchers to gain economic benefits from such activities."[72]

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61. Steven Collins & Hikoji Wakoh, *Universities and Technology Transfer in Japan: Recent Reforms in Historical Perspective*, 25 J. TECH. TRANSFER 213, 216-17 (2000).

62. *Id.* at 217-18. However, patent applications in Japan by National Universities have risen from below 100 in 1995 to over 350 in 1999. *See* David Cyranoski, *Japan's Academics Get Green Light to Make Their Fortunes*, 410 NATURE 504 (2001).

63. Collins & Wakoh, *supra* note 61, at 216.

64. *Id.*

65. *Id.*

66. *Id.* at 219.

67. NILSSON ET AL., *supra* note 35, at 25.

68. Cyranoski, *supra* note 62, at 504.

69. *Id.*

70. Collins & Wakoh, *supra* note 61, at 219.

71. *Id.*

72. NILSSON ET AL., *supra* note 35, at 26.

In 2001, the Japanese government initiated the Knowledge Cluster Initiative as part of the Second Science and Technology Basic Plan and the Industrial Cluster Program.[73] Both programs have as part of their objective the development of regional technology systems.[74] The Knowledge Cluster Initiative is tasked with, among other things, "conducting joint research among universities, public research institutes and companies mainly at universities, [and] patenting and developing research results towards commercial use . . . ."[75] The Industrial Cluster Initiative is designed, in part, to provide "policy support for forming industry-academic-government networks."[76] In 2001, the Japanese government "set the goal of doubling the number of university-based companies to 1,000 in the next three years."[77] In 2004, the government announced that the "number had hit 1,000" and the government will spend 480 million dollars funding start-ups.[78] However, despite the large numbers of start-ups, those start-ups may have difficulty surviving because the Japanese venture capital market (1.6 billion) is substantially smaller than the United States (22 billion) or European market (13 billion).[79] Further, in Europe, at least one country is creating a government fund similar to a private venture capital fund to provide funding for commercialization that is apparently beyond funding for invention.[80]

Not only are governments attempting to encourage industry and university collaboration in Europe and Japan, but some universities are actively engaging in technology transfer and establishing contacts with industry and, importantly either taking an active role in early stage financing or engaging venture capital funds. For example, at least one major research institution in the United Kingdom, the Imperial College of Science, Technology, and Medicine (Imperial College) has been focused on technology transfer for almost twenty years.[81] In 1986, Imperial College formed Imperial Innovations Group P.L.C., which is a technology transfer company with the purpose of evaluating and licensing research results. As of April 20, 2006, "Imperial Innovations had equity holdings in 58 spin-out companies and has concluded over 100 intellectual property agreements arising from the College's research activity."[82]

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73. Masayuki Kondo, *Regional Innovation Policy and Venturing Clusters in Japan*, 14 ASIAN J. TECH. INNOVATION 2, 170-72 (2006).

74. *Id.* at 171-72.

75. *Id.* at 171.

76. *Id.* at 172. Kondo notes that there have been some problems with a low level of entrepreneurial activity by start-up companies in Japan and recommends the creation of "venture clusters" that "focus[] on the functions to create or assist creating start-ups." *Id.*

77. Ichiko Fuyuno, *Japanese Spin-offs Face Struggle for Survival*, 441 NATURE 280 (2006).

78. *Id.*

79. *Id.*

80. *See* Stevens & Fraser, *supra* note 42, at 37.

81. *See* Imperial College, London, *Imperial Innovations History*, http://www.imperialinnovations.co.uk/index.php?option=com_content&task=view&id=30&grp=4&Itemid=41 (last visited April 9, 2007); *see also* P. O'Brien, William A. Wakeham & J.T. Walsh, *University-Industry Strategic Alliance: A British Perspective*, *in* RESEARCH TEAMS AND PARTNERSHIPS: TRENDS IN THE CHEMICAL SCIENCES, REPORT OF A WORKSHOP 32 (1999), *available at* http://books.nap.edu/openbook.php?record_id=9759&page=28 (discussing function of Imperial Innovations).

82. *See* Imperial College, London, *Technology Transfer Company Established by Imperial College London to Float on the Alternative Investment Market of the London Stock Exchange* (2006), http://www.imperial.ac.uk/P7996.htm.

Interestingly, in July of 2006, Imperial Innovations raised 26 million pounds through offering shares on the London Stock Exchange, the first IPO of a "majority owned university technology transfer company in the UK."[83] Those funds will be used for continued investment in spin-off companies and technology transfer.[84] Imperial College also started IC Consultants in 1990, a consulting company consisting of academic staff that "markets the use of the college's scientific research facilities for use by industrial partners . . . ."[85] Imperial College also makes use of strategic alliances with industrial partners.[86] The strategic alliance includes a long term relationship between the university and an industrial partner.[87] An example includes the research center completely funded by Smithkline Beecham and Zeneca.[88] Another example of a university with a well-developed plan to commercialize university research is the University of Manchester. The University of Manchester built a biotechnology incubator building in 1999 that leases space to spin-off companies and has created a wholly owned subsidiary to manage that space, called The University of Manchester Incubator Company Limited.[89] The University of Manchester has also formed the University of Manchester Intellectual Property Limited to direct the commercialization of intellectual property managed and/or created by the university[90] and the Manchester Technology Fund which provides early stage equity funding for new spin-off companies.[91]

In Japan, Tokyo University researchers funded the Advanced Science and Technology Enterprise Corporation in 2001, which is an early-stage venture capital fund.[92] Hokkaido University has also developed a hybrid technology transfer and venture capital fund business that is designed to aid and form businesses built around the results of university research.[93] Interestingly, in a 2001 study, 59.3 percent of 241 researchers in Hokkaido responded to a questionnaire indicating that they were interested in starting up a company.[94] Tsukuba University has also formed the Tsukuba Advanced Research Alliance that is tasked with managing patents and licensing and

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83. *Id.*

84. *Id.*

85. *See* Imperial College, London, *Imperial College Consultants: About Us*, http://www.imperial-consultants.co.uk/page.php?id=2 (last visited April 9, 2007); O'Brien et al., *supra* note 81, at 32.

86. O'Brien et al., *supra* note 81, at 33.

87. *Id.*

88. *Id.*

89. University of Manchester Incubator Company, *Manchester Incubator Building*, http://www.umic.co.uk/manchester_technology_quarter/Manchester_Incubator_Building.php (last visited April 9, 2007).

90. University of Manchester, *University of Manchester Intellectual Property Limited: About Us*, http://www.umip.com/about (last visited April 9, 2007).

91. Manchester Technology Fund, *Manchester Technology Fund*, http://www.mantechfund.com (last visited April 9, 2007).

92. *See* Cyranoski, *supra* note 62, at 504; ASTEC, *About ASTEC*, http://www.ut-astec.com/en_about.html (last visited April 9, 2007).

93. Collins & Wakoh, *supra* note 61, at 220.

94. Kondo, *supra* note 73, at 176. Notably, Kondo states that "new start-ups including university start-ups are supported mentally by local communities [because] Hokkaido is the land of frontier spirit and openness to newcomers" and the author compares it to California. *Id.* at 178.

will "stay with funded companies until they go public."[95] Since 1992, the largest number of spin-off companies from universities in Japan have been life sciences companies.[96]

As discussed above, the differences in the structures of the European and Japanese university systems, among other factors,[97] make it unclear whether legislation similar to the Bayh-Dole Act would have an impact like that in the United States—increased patenting and licensing and other economic impact—in other developed countries that adopt similar provisions. However, some developed countries in Europe and Japan appear to be very focused on encouraging technology transfer and the economic benefits that apparently flow from the transfer of technology from universities to industry. The success of those countries in achieving the supposed benefits of the Bayh-Dole Act remains to be seen.[98]

IV. DEVELOPMENT OF AN ANTICOMMONS IN THE UNITED STATES

The tragedy of the anticommons theory asserts that if multiple patent rights are granted in a potential commercial application then those rights may block one another and then no one will have an effective right to use the commercial application or property.[99] Parties may transfer rights to overcome the anticommons, but they might be unable to if there are transaction costs, strategic behaviors, and cognitive biases that impede transfer.[100] This theory has been applied to biotechnology innovation and usually explains a problem where there are fragmented rights that need to be aggregated in order to use a particular commercial application.[101]

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95. Collins & Wakoh, *supra* note 61, at 220.

96. Kondo, *supra* note 73, at 175.

97. The existence of venture capital and its availability at early stages in the development of a start-up company in the biotechnology field is likely an important part of the success of the biotechnology industry in the United States. *See* Brigitte Haar, *Venture Capital Funding for Biotechnological Companies in an Integrated Financial Services Market: Regulatory Diversity within the E.C.*, 2 EUR. BUS. ORG. L. 585, 587 (2001). As previously discussed, some universities and funds exist in Europe, but according to a CEO of a biopharmaceutical company,

> the availability of venture capital, combined with the willingness of Wall Street to support companies with initial public offerings . . . has put the United States as much as five to ten years ahead of Europe and Japan in developing a biotechnology industry. Either venture capital was not available in those areas, or the ability to cash out as a venture capitalist into a public market was much more difficult.

Id.

98. How to avoid the potential negative impacts of legislation similar the Bayh-Dole Act in OECD and developing countries will be discussed in another article.

99. *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998); *but see* Richard A. Epstein & Bruce N. Kuhlik, *Is There a Biomedical Anticommons?*, REGULATION, Summer 2004 (criticizing the anticommons theory as applied to biotechnology innovation).

100. Heller & Eisenberg, *supra* note 99, at 698.

101. *Id.* at 698; *but see* David E. Adelman, *The Irrationality of Speculative Gene Patents, in* ADVANCES IN THE STUDY OF ENTREPRENEURSHIP, INNOVATION AND ECONOMIC GROWTH: UNIVERSITY ENTREPRENEURSHIP AND TECHNOLOGY TRANSFER 123 (Gary D. Libecap ed., JAI Press 2005) ("Once the premise of a finite, congested commons is abandoned, the potential for patent anticommons to emerge largely disappears and patents on most research tools pose far less of a threat than the typical public commons model predicts."); David E. Adelman, *A Fallacy of the Commons in Biotechnology Patent*

A related potential problem in biotechnology innovation and patenting involves the granting of a patent on an upstream biotechnology finding that may be a fundamental advance in the field and needed to conduct further research and development for multiple purposes.[102] This particular finding may be required by many researchers advancing different research agendas to continue their research, but may also be needed for development along with other patented research tools to create a particular commercial application. Evidence of the latter problem, an anticommons resulting from the need to aggregate multiple rights to develop a single commercial application, is conflicted.[103]

There are numerous conflicting studies on whether an anticommons exists.[104] For example, one particular influential study found that, "[n]one of [the] random sample of academics had stopped a project due to the existence of third party patents on research inputs"[105] while the American Association for the Advancement of Science found that 35 percent of biotechnology researchers experienced difficulties obtaining patented inventions necessary for their research.[106] Two recent studies also found a statistically significant anticommons effect.[107]

The adoption of legislation similar to the Bayh-Dole Act in OECD countries along with changes in university structures may lead to increased patenting and licensing by universities in OECD countries,[108] including the securing by those universities and spin-off companies of patent rights in the United States. This may contribute to the development of a biotechnology anticommons and stifle biotechnology innovation in

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Policy, 20 BERKELEY TECH. L.J. 985, 1020-30 (2005) (arguing that "the standard finite commons model is not representative of the essentially unbounded opportunities that exist at this early stage of development").

102. *See generally* JOHN P. WALSH, CHARLENE CHO & WESLEY M. COHEN, PATENTS, MATERIAL TRANSFERS AND ACCESS TO RESEARCH INPUTS IN BIOMEDICAL RESEARCH (2005), http://tigger.uic.edu/~jwalsh/NASReport.html.

103. *See* Charles McManis & Sucheol Noh, *Impact of the Bayh-Dole Act on Genetic Research and Development: The Empirical Evidence to Date* (manuscript on file with author).

104. *See, e.g.*, NAT'L INSTITUTES OF HEALTH, REPORT OF THE NATIONAL INSTITUTES OF HEALTH WORKING GROUP ON RESEARCH TOOLS (1998), http://www.nih.gov/news/researchtools/; NAT'L RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH (National Research Council 2006) [hereinafter REAPING THE BENEFITS]; AMERICAN ASS'N FOR THE ADVANCEMENT OF SCIENCE, THE EFFECTS OF PATENTING IN THE AAAS SCIENTIFIC COMMUNITY 7 (2006), http://sippi.aaas.org/survey/AAAS_IP_Survey_Report.pdf [hereinafter AAAS REPORT]; Fiona Murray & Scott Stern, *Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis* 6 (2005), http://www.nber.org/papers/w11465; Bhaven N. Sampat, *Genomic Patenting by Academic Researchers: Bad for Science?* 5-6 (2004), http://mgt.gatech.edu/news_room/news/2004/reer/files/sampat.pdf; John P. Walsh, Ashish Arora & Wesley M. Cohen, *Effects of Research Tool Patenting and Licensing on Biomedical Innovation, in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285 (Wesley M. Cohen & Stephen A. Merrill eds., National Research Council 2002); WALSH ET AL., *supra* note 102, at 2.

105. WALSH ET AL., *supra* note 102, at 2.

106. AAAS REPORT, *supra* note 104, at 2.

107. Murray & Stern, *supra* note 104, at 5; Sampat, *supra* note 104, at 26.

108. Nishijima, *supra* note 42, at 3. ("The transition of National University to University Corporation implies that results of basic research will suddenly change from public goods to private goods and that the anticommons problem will emerge in the product innovation where basic research and development of new products are complementary.").

the United States. While the causal link between the Bayh-Dole Act and increased patenting and licensing in the United States is not certain, the Act very well may have contributed to increased patenting and licensing. An additional group of universities in OECD countries with the means and ability to secure patent rights in the United States along with the creation of additional spin-off companies from those universities may very well increase the likelihood of the development of an anticommons in the United States. As discussed below, this is particularly troubling because of the lack of a robust experimental use exception in the United States. Notably, in 2000, the European Union and the United States expenditures for research at university laboratories were almost the same.[109]

As discussed above, whether the Bayh-Dole Act will be successful in some OECD countries is an open question; however, increased patenting and licensing may result. Moreover, the conditions that may contribute to an anticommons, e.g., heterogeneous interests, and lack of experience in fast-paced, market-oriented bargaining, may also be present in Europe.[110] Indeed, because of the lack of tradition in some countries of a close connection between academic institutions and industry, there may be more institutional resistance within European and Japanese universities to comply with industry requests for delays in publishing materials that may disclose patentable inventions. Negotiation over those types of provisions may result in substantial delays and disagreements concerning the licensing of university-generated patentable inventions, which could then result in a breakdown in the licensing of a particular patented invention in Europe or Japan, and in the United States. However, in the United States, industry is apparently not aggressively enforcing its patents against universities, infringement by researchers is very difficult to detect, and researchers are apparently ignoring patents.[111] It is unclear whether industry will continue its inaction

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109. EUROPEAN COMMISSION, THE EUROPE OF KNOWLEDGE 2020: A VISION FOR UNIVERSITY-BASED RESEARCH AND INNOVATION 10 (2004), http://ec.europa.eu/research/conferences/2004/univ/index_en.htm. Interestingly, "there are differences between Europe and the US in terms of output, not so much for the overall scientific production but for its impact. While the numbers of papers in peer-reviewed journals originating from European laboratories is equivalent to the American production, the latter seems to have an advantage when it comes to citation index, a crude measure of novelty and quality of the work." *Id.*

110. Heller & Eisenberg, *supra* note 99, at 700 (heterogeneous interests of rights holders may contribute to anticommons along with high transaction costs because of limited competence in fast-paced, market-oriented bargaining); *see Education: Commission Launches Debate on Future of Inventions*, EUROPEAN REPORT, Feb. 8, 2003, at 471 ("In a general sense, European universities have less well developed structures to manage research results than other research institutions. In addition, university staff are less familiar with economic realities and with matters of intellectual property rights.").

111. Richard J. Bauer, *Why Not Try the Experiment and Stop Pointing the Finger: Modern University Research Unaffected by a Narrow Experimental Use Exception*, 24 TEMP. J. SCI. TECH. & ENVTL. L. 121, 135 (2005) ("Yet in practice, industry is not aggressively suing universities for patent infringement despite both a university's greater than before vulnerability to patent infringement claims, and academic scientists' pervasive and routine disregard for intellectual property rights. In fact, academic research using patented research tools has mostly remained unmarred and scientific advancement even seems to be accelerating."); Katherine Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 85 (2004) ("*Madey* contradicted a belief widespread in the research community . . . that all nonprofit research was exempt from infringement liability."); *see also* Christina Weschler, *The Informal Experimental Use Exception: University Research After* Madey v. Duke University, 79 N.Y.U. L. REV. 1536 (2004) (arguing that there exists an informal experimental use exception because it is in the interest of the patent holder to allow infringing noncommercial use).

against university researchers for patent infringement as universities act more like private industry in enforcing their patents. Participants in the biotechnology industry continue to dedicate some potentially patentable inventions to the public domain, which contributes to reducing the likelihood that an anticommons may develop.[112] Moreover, the Federal Circuit's recent cabining of the experimental use exception may eventually result in university researchers avoiding the use of patented research tools or following research agendas in areas in which a proliferation of patents exist. The contribution of increased patenting and licensing in the United States by universities and spin-off companies in OECD countries may very well contribute to the development of an anticommons in the United States.

V. PRESSURE TO DEVELOP A ROBUST EXPERIMENTAL USE EXCEPTION IN THE UNITED STATES

This Article argues that as developed countries adopt legislation similar to the Bayh-Dole Act, increased patenting and licensing could result in both Europe and Japan, and in the United States. Consequently, the likelihood that a tragedy of the anticommons could develop in the United States is increased. This is particularly true because of the very narrow common law experimental use exception in the United States. Moreover, research and development may be pushed outside of the United States where researchers can take advantage of a more robust exception. It is less likely that a tragedy of the anticommons would develop in European Union countries despite the potential increase of patenting and licensing that could result from legislation similar to the Bayh-Dole Act because of the broader experimental use exception that exists in those countries. The possible development of a tragedy of the anticommons in the United States will likely place pressure on the United States to adopt an experimental use exception that resembles the exemption in the European Union.[113] One of the benefits of this change is the avoidance of a tragedy of the anticommons.

A potential solution to avoiding or mitigating the negative impact of a tragedy of the anticommons in biotechnology innovation is to adopt a robust experimental use exception. A robust experimental use exception to patent infringement may allow a researcher to engage in some use of the patented invention without having to obtain a license, thus avoiding transaction costs associated with obtaining the license and mitigating problems with hold-ups associated with a tragedy of the anticommons.

One potential problem with adoption of a robust experimental use exception to patent infringement is the negative effect on incentives to invent and innovate. A robust exemption may erode the economic value of a patented product or process and thus make it less likely that one would invest in the invention or commercialization of that patented product or process. This is particularly troublesome for research tools that may be the subject of research and investigation and follow-on research and

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112. Robert P. Merges, *A New Dynamism in the Public Domain*, 71 U. CHI. L. REV. 183 (2005).

113. This pressure could also result in changing provisions in the Bayh-Dole Act in the United States designed to ensure access to government funded inventions, such as the exceptional circumstances provision, the march-in provisions, or the adoption of a research exemption similar to that proposed by Professor Gary Pulsinelli. *See generally* Pulsinelli, *supra* note 4.

development, but are also commercial products and processes.[114] Moreover, with especially complicated research projects, the patented tool may be just one of many tools needed to advance a particular research agenda. In attempting to address issues concerning research tools and the experimental use exception, many commentators have advocated for changes to the experimental use exception, including expanding its coverage.

There are two experimental use exceptions to patent infringement in the United States: the common law experimental use exception and the statutory experimental use exception.[115] This essay will focus on the common law experimental use exception as that exception is most likely implicated with university research.[116] The statutory experimental use exception is directed to experimentation conducted for the purpose of regulatory review.[117] The common law experimental use exception was designed to allow experimentation with a patented invention for the "sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement . . . ."[118] If the use of the

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114. *See* Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457, 463 (2004). Dreyfuss states:

> The fruits of biotechnology . . . blur the core dichotomy between fundamental and end-use work. Inventions in this field—genomics and proteomics, for example—have immediate, commercial applications as diagnostics or treatments and thus they qualify for patent protection. At the same time, they are of crucial importance to researchers, and as such, they have enormous power. These "upstream" patents cover not just product markets but also innovation markets . . . , the ability to carry out fundamental research.

Id. See also David L. Parker, *Patent Infringement Exemptions for Life Science Research*, 16 HOUS. J. INT'L L. 615, 618 (1994) ("The dual role of biotechnological discoveries as research tools and as commercial products and processes, raises potentially significant issues related to whether early stage or laboratory scale developments . . . will receive broad protection or whether they will be made available for others to build upon."); *cf.* HAROLD C. WEGNER, THE POST-MADEY RESEARCH EXEMPTION 2 (2003), http://www.foley.com/files/tbl_s31Publications/FileUpload137/1588/post-madley%20whitepaper.pdf ("Use of a patented research tool for its intended purpose as a research tool should be carefully understood as not coming under an experimental use exemption.").

115. *See* 35 U.S.C.A. § 271(e)(1) (2001); Merck KGAA v. Integra Life Sciences I, Ltd., 545 U.S. 193, 193 (2005); Madey v. Duke Univ., 307 F.3d 1351, 1360 (Fed. Cir. 2002).

116. A broad interpretation of the recent United States Supreme Court decision in *Integra Lifesciences* may result in application of the statutory exemption to research conducted at universities. Moreover, university research "reasonably related" to regulatory approval may implicate the statutory exemption.

117. The statutory experimental use exempts conduct that would be infringing if conducted solely for uses reasonably related to the development and submission of information to the Food and Drug Administration. This exemption is particularly important to the generic pharmaceutical industry, but may be less relevant to academic researchers than the common law experimental use exception. Other countries have adopted similar statutory exceptions designed to enable generic pharmaceutical companies to use a patented invention for purposes related to providing information to regulatory agencies for the marketing of pharmaceuticals. For example, Canada has an exception that provides: "(1) Exception. It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product." Patent Act, R.S.C., ch. P 4, s. 55.2(1) (1985). In Europe, member countries of the European Union are required by Directive to introduce legislation adopting an exception for patent infringement for use of a patented invention to develop information for regulatory review. *See* European Union Directive, No. 2004/27/EC, Article 10.6.

118. Poppenhusen v. Falke, 19 F.Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279). For a discussion of the evolution of the United States experimental use exception, see Strandburg, *supra* note 111, at 93-100.

patented invention was for commercial use or with intent to profit, the use would not be exempted from infringement.[119] Apparently most academic researchers believe their use of a patented invention during research is exempt from infringement under this exception.[120] While academic researchers may continue to believe their conduct is exempt, it is clear that much of the use by academic researchers of patented inventions is now not exempt from patent infringement. In a recent Federal Circuit case, *Madey v. Duke University*,[121] the court determined that the experimental use exception did not apply to research that utilized a patented invention at a university if there is a remote commercial purpose, including a purpose consistent with a university's legitimate business objectives.[122] The court stated that the university's legitimate business objectives included, "educating and enlightening students and faculty participating in [noncommercial research projects]."[123] The court strictly limited the application of the common law experimental use exception to conduct that which is limited to or "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[124] The *Madey* court further stated that the "profit or nonprofit status of the user is not determinative."[125] The National Research Council recently stated that after *Madey* "formal research enjoys no absolute protection from infringement liability regardless of institutional venue, the purpose of the inquiry, the origin of the patented inventions, or the use that is made of them."[126] One scholar has stated that the interpretation of the experimental use doctrine is so narrow "that, for all practical purposes, the doctrine has become a nullity."[127] Some have argued that the *Madey* decision will have a chilling effect on academic research, particularly in the biotechnology field.[128]

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119. Sawin v. Guild, 21 F.Cas. 554, 555 (C.C.D. Mass. 1813)(No. 12,391), *see also* Dreyfuss, *supra* note 114, at 458 ("[T]o early jurists, a clear distinction could be made between using patented material to learn about the patented invention and using patented material for business or for commerce – between using the patent to satisfy curiosity or using it to turn a profit.").

120. REAPING THE BENEFITS, *supra* note 104, at 92.

121. 307 F.3d 1351 (Fed. Cir. 2007).

122. *Id.* at 1362.

123. *Id.*

124. *Id.* at 1653. Patent law scholar Harold Wegner has criticized contemporary courts for apparently not recognizing that "philosophical" in the Nineteenth century meant "scientific," so philosophical experiments were scientific experiments. WEGNER, *supra* note 114, at 3-4.

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

126. NATIONAL RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY 7 (Stephen A. Merrill et al eds., 2004), *available at* http://www.promotetheprogress.com/ptpfiles/patentreform/misc.NAS report.pdf..

127. Janice M. Mueller, *The Evenescent Experimantal Use Exemption from U.S. Patent Infringment Liability: Implication for University and Nonprofit Research and Development*, 56 BAYLOR L. REV. 917, 918 (2004); *see also* Sara Boettiger & Alan Bennett, *The Bayh-Dole Act: Implications for Developing Countries*, 46 IDEA 261, 268 (2006) ("The *Madey v. Duke University* decision . . . made it clear that effectively no research exemption exists in U.S. law and thereby created a precarious legal situation for U.S. universities.").

128. *See* MINISTRY OF ECONOMIC DEVELOPMENT, AN EXPERIMENTAL USE EXCEPTION FOR NEW ZEALAND'S PATENT LEGISLATION, AN OPTIONS PAPER 10 (2006), *available at* http://www.med.govt.nz/upload/31657/options-paper.pdf ("This decision is widely regarded as narrowing the experimental use exception in the United States to the point where most organizations carrying out research or experimental work involving patented inventions could find themselves liable for patent infringement.") *But see* Brief for the United States as Amicus Curiae at 14, Duke Univ. v. Madey, 539 U.S.

As discussed above, several studies have been conducted to test whether an anticommons has developed specifically with *Madey* in mind.[129] Those studies conflict with one another as to whether an anticommons has developed, but warn that the *Madey* decision may contribute to the development of an anticommons as patent owners begin to enforce their patent rights against academic researchers.[130] In spite of the inconclusive evidence, many have argued for an expanded experimental use exception in the United States, including an exception that resembles that of other developed countries.[131] In a recent OECD Working Paper entitled "Research Use of Patented Knowledge: A Review," the authors caution that, "there is reasonably strong evidence suggesting that patents may have some deleterious effects on scientific research."[132] However, the authors also caution that there is "insufficient empirical data at this stage to demonstrate that any particular form of the exemption will be more effective than others in guarding against future restrictions on scientific work."[133]

Some developed countries have more robust experimental use exceptions than the United States.[134] In some countries, an analog to the United States common law

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958 (2003) (No. 02-1007), *available at* http://www.usdoj.gov/osg/briefs/2002/2pet/6invit/2002-1007.pet.ami.inv.html ("Even assuming the Federal Circuit's decision substantially limits the availability of the experimental use defense, there are several reasons why the practical impact of that decision may not be as great as petitioner fears. . . .").

129. *See generally*, WALSH ET AL., *supra* note 102; REAPING THE BENEFITS, *supra* note 104.

130. REAPING THE BENEFITS, *supra* note 104; *see also* FEDERAL TRADE COMMISSION, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 35 (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf; *but see* AAAS REPORT, *supra* note 104; Mowery & Sampat, *supra* note 12; Murray & Stern, *supra* note 104.

131. *See* Dreyfuss, *supra* note 114, at 471. In this paper, Dreyfuss proposes the following system:

> [A] university or other nonprofit research institution that wants to use patented material and cannot obtain a license from the patentee on reasonable terms could use the technology without permission if it is willing to sign a waiver, [which] would require the institution to promptly publish the results of work conducted with the patented technology and to refrain from patenting discoveries made in the course of that work.

Id. See also Andrew Caruso, *The Experimental Use Exception: An Experimentalist's View*, 14 ALB. L.J. SCI. & TECH. 215 (2003); Rebecca S. Eisenberg, *Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989); Ted Hagelin, *The Experimental Use Exemption to Patent Infringement: Information on Ice, Competition on Hold*, 58 FLA. L. REV. 483 (2006); Robert A. Migliorini, *The Narrowed Experimental Use Exception to Patent Infringement and Its Application to Patented Computer Software*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 523 (2006); Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001); Mueller, *supra* note 127; Parker, *supra* note 114; Strandburg, *supra* note 111. *Cf.* Jordan P. Karp, *Note, Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169, 2179-2181 (1991) ("A system with a broad experimental use allowance would have a disparate impact on less well-financed inventors whose ability to conduct R&D may be limited in the short term when they are not able to convince possible investors of the potential commercial success of their patented inventions."); Heather Hamme Ramirez, *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); Elizabeth A. Rowe, *The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment*, 57 HASTINGS L.J. 921, 954 (2006).

132. CHRIS DENT, PAUL JENSEN, SOPHIE WALLER, & BETH WEBSTER, ORG. FOR ECON. CO-OPERATION & DEV., RESEARCH USE OF PATENTED KNOWLEDGE: A REVIEW 45 (2006), http://oberon.sourceoecd.org/vl=3531378/cl=19/nw=1/rpsv/cgi-bin/wppdf?file=5l9pscsjvnvl.pdf.

133. *Id.*

134. *See* REAPING THE BENEFITS, *supra* note 104, at 92 ("Many other nations provide somewhat broader

research exception may be in legislation or in case law.[135] Most European Union countries have enacted legislation implementing Article 27 of the Community Patent Convention.[136] The Community Patent Convention provides that "[t]he rights conferred by a Community patent shall not extend to: . . . (b) acts done for experimental purposes relating to the subject-matter of the patented invention."[137] This provision delineates between *experimenting on* a patented invention, which would be excused and *experimenting with* a patented invention, which would not be exempted.[138] Thus, the experimental use exception in those countries is not focused on whether there is a commercial or nonprofit purpose for the research, but on the nature of the research itself.[139] Research that may be permitted by a research

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exemptions [than the United States]."); WEGNER, *supra* note 114, at 10-11. Wegner explains that

> A liberal trend has been observed to favor a broader experimental use exception abroad. In contrast to the American view which is tinged with whether there is a commercial taint, the majority view around the world dismisses whether the invention was tested by a commercial operation or for commercial purposes and, instead, focuses upon the qualitative question of whether the use of the invention was to explore the nature of the invention itself (versus using the invention for its intended purpose).

Id. *See also* Hagelin, *supra* note 131, at 521 ("Although the scope of . . . foreign experimental use exemptions varies, they all provide at a minimum for the use of patent subject matter for the purpose of determining whether a patented invention is feasible, useful, or technically operable. Some of the foreign experimental use exemptions are considerably broader and allow for the use of patent subject matter even when the use is clearly commercially motivated."); ADVISORY COUNCIL ON INTELLECTUAL PROPERTY, PATENTS AND EXPERIMENTAL USE 2 (2005), http://www.acip.gov.au/reviews.htm (follow "Consideration of patents and experimental use" hyperlink; then follow "report" hyperlink) [hereinafter PATENTS AND EXPERIMENTAL USE] ("[T]he law on experimental use of patented inventions differs markedly around the world, and there is little movement to further rectify this.").

135. Some countries also have statutory experimental use exceptions similar to the United State exception that is directed to uses related to regulatory approval. Other countries have interpreted their non-statutory experimental use exception to apply to some uses related to regulatory approval. *See*, Mueller, *supra* note 127, at 969-71 (examining statutory experimental use exceptions in other countries); Peter Ruess, *Accepting Exceptions?: A Comparative Approach to Experimental Use in U.S. and German Patent Law*, 10 MARQ. INTELL. PROP. L. REV. 81, 97-101 (2006) (discussing German cases applying statutory exemption to clinical trials for regulatory review).

136. DENT ET AL., *supra* note 132. Japan adopted a similar experimental use exception. *See* Mueller, *supra* note 127, at 969-70.

137. Agreement Relating to Community Patents art. 27(b), Dec. 15, 1989, 89/695/EEC, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?=CELEX: 41989A0 695(01):EN:HTML [hereinafter Community Patent Convention]. *See also* DENT ET AL., *supra* note 132, at 18 n.44 ("Although the [Community Patent Convention] never came into force, it has had an influential role in the development of patent legislation in the EU member states. As a result, article 27(b) has been widely implemented into the national patent statutes of the EU member states, including those who are also OECD member countries.").

138. DENT ET AL., *supra* note 132, at 32. *See also* PATENTS AND EXPERIMENTAL USE ISSUES PAPER, *supra* note 26, at 18. This source explains

> [t]he distinction [between experimenting with or on a patented invention] seems consistent with the fundamental principles of the patent system in balancing the needs of the primary innovator with those of secondary innovators and end-users and is closely related to the disclosure requirements. As Eisenberg states "If the public had absolutely no right to use the disclosure without the patent holder's consent until after the patent expired, it would make little sense to require that the disclosure be made freely available to the public at the outset of the patent term."

Id. (quoting Eisenberg, *supra* note 131, at 1022).

139. WEGNER, *supra* note 114, at 12. *See also* PATENTS AND EXPERIMENTAL USE ISSUES PAPER, *supra*

exemption would include use of the patented invention to improve, study, or design around the patented invention.[140] The distinction between experimenting on and with a patented invention does not work well with research tools. Experimentation with a research tool uses the tool for its intended purpose—to conduct research. Allowing experimentation with a research tool without liability would eviscerate the economic incentive to invent those tools. Commentators have made some proposals to specifically address research tools and those proposals should be seriously considered because of the potential for patents on research tools to hinder follow-on research and development.[141]

Moreover, there are some difficulties associated with distinguishing between experimentation on and with an invention and the "language may provide false comfort to researchers, as it will ultimate[ly] be interpreted by legal experts, not technologists."[142] Some of the advantages of a statutory experimental use exception include improved clarity and thus, increased efficiency, and the "encourage[ment of] further secondary innovation by non-patent holders."[143] Another advantage includes encouraging peer review of the patented technology.[144] Some potential general problems with a statutory experimental use exception include a decrease in value of patents and the belief that exemptions are limited to those described in the statute. Thus "appropriate drafting would be crucial."[145]

The existence of robust experimental use exceptions may decrease the chance for the development of an anticommons in Europe and Japan. However, in countries without a robust experimental use exception, such as the United States, it is more likely

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note 26, at 18. The author states that

> [I]n contrast to the recent views of the American courts (as expressed in *Madey*) which are influenced by whether there is a 'commercial taint', the majority view around the world ignores whether the invention was tested by a commercial operation or for non-commercial purposes and, instead, focuses upon the qualitative question of whether the use of the invention was to explore the nature of the invention itself versus using the invention for its intended purpose. Thus the modern trend particularly in Europe is to draw a distinction based on whether the experimentation is *on the invention itself*—to determine how it operates, test it, and use it as a base to make different, improvement inventions—as opposed to *using* an invention *for its intended purposes*.

Id.

140. Strandburg, *supra* note 111, at 100.

141. *See generally*, Dreyfuss, *supra* note 114; Strandburg, *supra* note 111.

142. DENT ET AL., *supra* note 132, at 34; *see also* Strandburg, *supra* note 111, at 148-52 ("[I]t is probably impossible to produce a bright-line rule to distinguish between the two types of experimentation.").

143. DENT ET AL., *supra* note 132, at 33. *See also* PATENTS AND EXPERIMENTAL USE, *supra* note 134, at 2. This source explains:

> Under US case law experimental acts are only permitted if they are not in furtherance of the alleged infringer's legitimate business. This approach has been highly controversial and is considered by the [Advisory Council] as one best avoided because it does not appear to follow the principles of the patent system. There is at least some degree of harmony within Europe, where most countries have a statutory exemption that is worded very like the following: The rights conferred by a patent shall not extend to acts done for experimental purposes relating to the subject matter of the invention.

Id.

144. Dreyfuss, *supra* note 114, at 470.

145. DENT ET AL., *supra* note 132, at 33-34.

that an increased number of patents and licensing as a result of the adoption of legislation similar to the Bayh-Dole Act by other OECD countries may result in the development of a tragedy of the anticommons.[146] Moreover, even if OECD countries adopt research exemptions in their versions of the Bayh-Dole Act or broader so-called "march-in rights" than the U.S. version or interpretation of the Bayh-Dole Act, the benefits of those provisions may be unavailable to U.S. academic and industry researchers. Second, the lack of a robust experimental use exception may also lead to research and development work to be outsourced to countries with a robust experimental use exception.[147] Consequently, the United States may be pressured to adopt a more robust experimental use exception similar to other countries or as proposed by commentators.

VI. CONCLUSION

Whether legislation similar to the Bayh-Dole Act will result in increased patenting and licensing in the near future in Europe and Japan is unclear; however, changes made by countries in Europe and in Japan in university structure make it much more likely that the Bayh-Dole Act may cause increased patenting and licensing, including that activity in the United States. The pressure from increased patenting and licensing in the United States by universities and spin-off companies in Europe and Japan may result in the United States adopting a more robust common law experimental use exception to avoid a potential tragedy of the anticommons.[148]

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146. The existence of an experimental use exception that distinguishes between researching on and with a patented invention will not allow the access necessary to avoid an anticommons in every situation. For example, experimentation *with* research tools may be an infringement. A broader research exemption perhaps modeled after Professor Strandburg's proposal or Professor Dreyfuss's proposal may alleviate some of the concerns associated with research tools. *See generally* Strandburg, *supra* note 111; Dreyfuss, *supra* note 114. The existence of a broad research exemption may negatively impact the ability of some start-up biotechnology companies to obtain venture capital. *See* Mireles, *supra* note 23, at 1209-10.

147. *See* Migliorini, *supra* note 131, at 542 (arguing that the United States may lose parts of software industry to foreign markets with robust experimental use exception); Mueller, *supra* note 127, at 919 ("Without [a broader exemption], scientific research functions that require use of patented inventions are more likely to be shifted offshore to legally hospitable forums."); *see also* Hagelin, *supra* note 131, at 522 (Research exemptions in other countries that are broader than the U.S. exemption "could result in the migration of top researchers from the United States to other countries and deprive industry, as well as universities, of critical human resources.").

148. Another option may include adopting a research exemption available for recipients of government funding for use of government funded research results similar to the one proposed by Professor Pulsinelli. *See generally* Pulsinelli, *supra* note 4.