University of Michigan Journal of Law Reform

Volume 38

2004

An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation

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AN EXAMINATION OF PATENTS, LICENSING, RESEARCH TOOLS, AND THE TRAGEDY OF THE ANTICOMMONS IN BIOTECHNOLOGY INNOVATION

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The continued development of and affordable access to potentially life saving pharmaceuticals, gene therapies and diagnostics is unquestionably a socially important issue. However, crafting government policy to encourage the development of and allowing affordable access to those services and products is difficult. On one hand, the development of those services and products requires a large investment of funds because of the complexity, collaborative nature, and uncertainty of the development of those products and services. Accordingly, investors require the safety of strong and stable patent rights to ensure a return on their investment in the development of a commercial end-product or a research tool. On the other hand, patents may foreclose competition for a particular product or service and enable a company to exact a supra competitive price for that product or service, thus denying access to people unable to afford that product or service. In arriving at that supra competitive price, the company selling the commercial end product may have to include in that price a number of additional costs imposed by holders of patented research tools needed in the development of the commercial end-product.

This Article examines whether the development of pharmaceuticals, gene therapies or diagnostics is being stifled by the inability of companies to access proprietary research tools needed for the development of those important products and services. This Article also evaluates proposals for alleviating problems in accessing proprietary research tools, and proposes recommendations to aid in the efficient transfer of that technology. First, this Article recommends that Congress enact a law similar to the proposed Genomic Science and Technology Innovation of Act of 2002, which requires the government to conduct a study of the effect of government policy on biotechnology innovation. Second, this Article recommends that the government encourage public and private parties to enter patent pools to efficiently transfer rights in biotechnology inventions. The government, in conjunction with private and public institutions, should create a publicly available database of proprietary research tools and licenses concerning those tools. The government should also modify the provision of the Bayh-Dole Act concerning reservation of a non-exclusive right to practice any patented invention created with federal funding. The modification would allow the government to transfer a non-exclusive license to a patented research tool developed with government funding to a patent pool created by industry participants if it is demonstrated that the owner of the patented research tool is unreasonably withholding the license of that tool from the pool. Any

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royalties resulting from the licensing of the research tool in the patent pool will be distributed to the owner of the patented research tool.

Part I of this Article provides definitions for research tools and commercial applications. Part II discusses the costs, benefits, and purposes of patent law. Part III reviews university and private research and development, including the influence of the Bayh-Dole Act. Part IV examines the development of commercial applications of biotechnology research, including the role of venture capital and the use of licensing provisions requiring reach through royalties and exclusivity. Part V evaluates problems that may occur in attempting to develop commercial applications and licensing patents. Part VI reviews the Tragedy of the Anticommons theory. Part VII discusses research and analysis concerning the existence of the anticommons problem. Part VIII examines and analyzes potential solutions for solving the Tragedy of the Anticommons in biotechnology. Finally, Part IX offers recommendations for addressing an existing or developing Tragedy of the Anticommons.

INTRODUCTION

The complex and uncertain nature of biotechnology innovation[1] results in an increasing need for collaborations between multiple public and private institutions to share costs, proprietary technology, and specialized skills to develop commercial applications such as pharmaceuticals, gene therapies, and diagnostics.[2] A single

1. Josh Lerner & Robert P. Merges, *The Control of Technology Alliances: An Empirical Analysis of the Biotechnology Industry*, 46 J. INDUS. ECON. 125, 126 (1998); FEDERAL TRADE COMMISSION, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 3, p. 16 (October 2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf (on file with the University of Michigan Journal of Law Reform) [hereinafter FTC REPORT] ("R&D is particularly lengthy for biotechnology firms, because biotechnology innovation is more uncertain than innovation in other industries.").

2. ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD), GENETIC INVENTION, INTELLECTUAL PROPERTY RIGHTS AND LICENSING PRACTICES ch. 1, p. 7 (2002), *available at* http://www.oecd.org/dataoecd/42/21/2491084.pdf (on file with the University of Michigan Journal of Law Reform) [hereinafter OECD REPORT] ("Biotechnology is a fast-moving field in which new products and services are developed from an increasingly complex and cumulative set of underlying technologies."); REPORT OF THE NATIONAL INSTITUTES OF HEALTH WORKING GROUP ON RESEARCH TOOLS 3, *available at* http://www.nih.gov/news/researchtools/ (on file with the University of Michigan Journal of Law Reform) [hereinafter NIH REPORT] ("Biomedical researchers increasingly chose to collaborate with entrepreneurial companies that understood and valued basic science . . . ."); Richard Florida, *The Role of the University: Leveraging Talent, Not Technology*, *in* AAAS SCIENCE AND TECHNOLOGY POLICY YEARBOOK 2000 366 (Albert H. Tecih et al., eds., 1999), *available at* http://www.aaas.org/spp/yearbook/2000/ch31.pdf (on file with the University of Michigan Journal of Law Reform) ("Joint university-industry research centers have . . . grown dramatically, and a lot of money is being spent on them."); Arti K. Rai, *Regulating*

pharmaceutical may cost as much as $800 million[3] and require numerous proprietary inputs, owned or subject to a tax by multiple parties, to develop. Accordingly, the ability of public and private entities to efficiently transfer proprietary technology is critical to the development of socially beneficial commercial applications. This Article explores whether public and private entities are encountering difficulties in transferring proprietary rights necessary to develop commercial applications. This Article also evaluates proposals for alleviating problems in accessing proprietary technology, such as research tools, and proposes recommendations to aid in the efficient transfer of that technology.

Patent law provides the principal legal protection for biotechnology innovation. In 1980, the United States Supreme Court decided *Diamond v. Chakrabarty*, which paved the way for the patenting of biotechnological products and processes.[4] That decision, along with the passage of the Bayh-Dole Act,[5] which allowed universities and small companies to retain title in inventions developed with government funding, created the biotechnology industry and the resulting flood of patent applications and issued patents for biotechnological inventions such as genes and gene fragments.[6] Patent protection for those inventions allowed biotechnology companies to obtain much needed capital to fund research and development.[7]

Scientific Research: Intellectual Property Rights and the Norms of Science, 94 NW. U. L. REV. 77, 110 (1999) ("[T]he legal developments of the 1980s and 1990s have generated a large variety of academic-industrial relationships .... [S]ome academic-industrial relationships resemble commercial joint ventures."); Lynn E. Nimtz et al., *University-Industry Partnerships: Meeting the Challenges with High Tech Partner*, SRA JOURNAL, Fall 1995, at 9 ("Today's knowledge-based, technological society demands much from higher education and the corporate world—demands that often can be met through effective university—industry partnerships."); DAVID M. EPSTEIN, ECKSTROM'S VOL. 2 LICENSING IN FOREIGN AND DOMESTIC OPERATIONS § 11.3 (2003) ("University research costs—the costs of acquiring, maintaining and operating equipment necessary to conduct state-of-the-art research—have been increasing rapidly ....").

3. TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT, *Post-approval R & D raises total drug development costs to $897 million*, IMPACT REPORT, May/June 2003, *available at* http://csdd.tufts.edu/infoservices/impactreportpdfs/impactreportsummarymayjune2003.pdf (on file with the University of Michigan Journal of Law Reform).

4. Diamond v. Chakrabarty, 447 U.S. 303 (1980).

5. The Government Patent and Policy Act of Dec. 12, 1980, Pub. L. No. 96-517, 94 Stat. 3015–28 (codified as amended at 35 U.S.C. §§ 200–211, 301–307 (1994)).

6. BIOTECHNOLOGY INDUSTRY ORGANIZATION, BIOTECHNOLOGY INDUSTRY FACTS, *available at* http://www.bio.org/er/statistics.asp (on file with the University of Michigan Journal of Law Reform) (stating that 2,160 biotechnology patents were granted in 1989 compared to 7,763 biotechnology patents granted in 2002).

7. FTC REPORT, *supra* note 1, at ch. 2, p. 1 ("Biotechnology start-ups rely on their ability to patent their innovations to attract investment and continue innovating ....");

Patent law is designed to correct a market failure wherein too few inventions are created because copyists may easily free-ride on the efforts of inventors.[8] Patent law provides a right to exclude others from making, using, selling, offering to sell, or importing the patented invention to incentivize the creation and disclosure of inventions.[9] Patents also provide an incentive for capitalists to invest in the commercialization, including the further innovation, of patented technology.[10] In a perfect world, patent law doctrine would reflect the most efficient mechanism to incentivize invention, the disclosure of inventions, and innovation, while at the same time ensuring the existence of a public domain upon which additional inventions may be built. However, in reality, patent law may create roadblocks to the development of commercial applications, particularly when applied to a new technology, such as biotechnology.

In 1998, Professors Michael Heller and Rebecca Eisenberg asserted that biotechnology innovation may be stifled because too many property rights in biotechnology had been granted, resulting in a situation called a "Tragedy of the Anticommons," wherein no one party can collect those rights to develop a commercial application.[11] Heller and Eisenberg further argued that transaction costs, including costs associated with bundling rights, strategic behavior, and the cognitive biases of biotechnology industry participants, will prevent parties from transferring rights to avoid a Tragedy of the Anticommons.[12]

Two studies have offered apparently conflicting conclusions as to whether a Tragedy of the Anticommons exists or may develop in biotechnology. In one study, the National Institutes of Health

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Bruce Lehman, *Major Biotechnology Issues for the U.S. Patent and Trademark Office*, 33 CAL. W. L. REV. 49, 50 (1996) ("[P]atenting is a very important part of commercializing biotechnology. The biotechnology industry requires considerable capital expenditure .... That capital is essential and the ability to get that capital is very much dependent upon the capacity to get patent protection for a prospective product.").

8. ROGER E. SCHECHTER & JOHN R. THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS § 13.4 (2003) [hereinafter INTELLECTUAL PROPERTY].

9. 35 U.S.C. § 154(a)(1) (1994); Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. OF LEGAL STUD. 247, 247, 267 (1994); Stanley M. Besen & Leo J. Raskind, *An Introduction to the Law and Economics of Intellectual Property*, 5 J. ECON. PERSP. 3, 5–6 (1991).

10. Rebecca S. Eisenberg, *Eisenberg: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1045–46 (1989). *See generally* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977).

11. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (May 1, 1998).

12. *See* Heller & Eisenberg, *supra* note 11, at 700.

("NIH") found that scientists in academia and industry, university technology transfer professionals, and members of private firms expressed concerns about the difficulties and delays associated with licensing proprietary rights in biotechnology research tools.[13] Several years later, a second study conducted by Professors Walsh, Arora, and Cohen, collected information from intellectual property attorneys, business managers, and scientists from biotechnology and pharmaceutical firms; university researchers and technology transfer officers; patent lawyers; government personnel; and trade personnel.[14] The researchers in the Walsh study also examined archival data.[15] The purpose of this study was to analyze how changes in patenting practices and law have affected biotechnology innovation.[16] The researchers concluded that despite an increase in the number of patents on research tools and conditions conducive to the creation of a Tragedy of the Anticommons, the data collected demonstrate that, "drug discovery has not been substantially impeded by these changes."[17]

In a recent article, Professor Paul David argues that the Walsh Study is flawed in several respects.[18] First, David criticizes the study for failing to describe the interview protocol followed in the survey.[19] David notes that the form of the questions can result in responses from interviewees indicating that there is not a problem.[20] Second, David asserts that rational actors would not report abandoned projects that otherwise might have been undertaken if patenting practices and law had not changed. Accordingly, David argues that a search for evidence of a Tragedy of the Anticommons is difficult because the researcher is attempting to prove a counterfactual: if something had not happened, then something else would have resulted.[21]

Based on research and analysis concerning the presence of a Tragedy of the Anticommons, it is unclear whether the Tragedy

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13. *See* NIH REPORT, *supra* note 2.

14. JOHN P. WALSH ET AL., *Research Tool Patenting and Licensing and Biomedical Innovation, in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285 (W.M. Cohen & S. Merrill eds., 2002).

15. *Id.*

16. *Id.*

17. *Id.* at 285, 293–97.

18. Paul A. David, *The Economic Logic of "Open Science" and the Balance between Private Property Rights and the Public Domain in Scientific Data and Information: A Primer*, 13–15 (2003), *available at* http://siepr.stanford.edu/papers/pdf/02-30.pdf (on file with the University of Michigan Journal of Law Reform).

19. *Id.* at 13–14.

20. *Id.* at 14.

21. *See id.* at 16.

exists or will exist in the biotechnology sector. A number of commentators, however, have proposed solutions to the Tragedy of the Anticommons; these solutions include making the utility requirement more stringent,[22] broadening the scope of the experimental use exception to patent infringement,[23] creating a fair use exception to patent infringement,[24] and using patent pools.[25] Because of the ambiguity of research concerning the existence of a Tragedy of the Anticommons, this Article argues against a substantial change in patent law doctrine that may undermine the incentives provided by patents to invent, disclose, and innovate. The capital intensive nature of the biotechnology industry requires stable and strong property rights to justify investment in research and development.[26] However, recent Federal Circuit cases narrowly interpreting the experimental use exception upset the expectations of academic scientists that the use of patented technologies for university research is exempt from patent infringement.[27] These new cases may increase the likelihood that a Tragedy of the Anticommons will develop.

Accordingly, this Article recommends that certain actions be taken to determine if a Tragedy of the Anticommons exists or will develop and to alleviate the effects of an existing or a developing Tragedy of the Anticommons. First, this Article recommends that Congress enact a law similar to the proposed Genomic Science and Technology Innovation Act of 2002,[28] which requires the government to conduct a study regarding the effect of government policy on biotechnology innovation. Second, this Article recommends that the government encourage public and private parties to enter patent pools to efficiently transfer rights in biotechnology inven-

22. *See, e.g.*, Teresa M. Summers, *The Scope of Utility in the Twenty-First Century: New Guidelines for Gene-Related Patents*, 91 GEO. L.J. 475, 477–478 (2003).

23. Eisenberg, *supra* note 10; Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 9 (2001).

24. *See* Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000).

25. *See* JEANNE CLARK ET AL., UNITED STATES PATENT AND TRADEMARK OFFICE, PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS? (Dec. 5, 2000), *at* http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf (on file with the University of Michigan Journal of Law Reform) [hereinafter White Paper].

26. *See* BIOTECHNOLOGY INDUSTRY ORGANIZATION ON BAYH-DOLE AND TECHNOLOGY TRANSFER BEFORE THE PRESIDENT'S COUNCIL ON SCIENCE AND TECHNOLOGY OFFICE AND TECHNOLOGY POLICY 1 (Apr. 11, 2002), *available at* http://www.bio.org/ip/pdf/bd20020509.pdf (on file with the University of Michigan Journal of Law Reform).

27. *See* Madey v. Duke University, 307 F.3d 1351 (Fed. Cir. 2002); Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860 (Fed. Cir. 2003).

28. H.R. 3966, 107th Cong. (2d Sess. 2002).

tions. The government, in conjunction with private and public institutions, should create a publicly available database of proprietary research tools and licenses concerning those tools. The government should also modify the provision of the Bayh-Dole Act concerning reservation of a non-exclusive right to practice any patented invention created with federal funding. The modification would allow the government to transfer a non-exclusive license to a patented research tool developed with government funding to a patent pool created by industry participants if it is demonstrated that the owner of the patented research tool is unreasonably withholding the license of that tool from the pool. Any royalties resulting from the licensing of the research tool in the patent pool would be distributed to the owner of the patented research tool.

This proposal attempts to provide increased access to research tools while balancing the relative interests of the public and the owners of proprietary technology. The public interest is protected as greater access to research tools may result in the creation of more commercial applications that benefit the public health. Moreover, the public has already paid once for the research tool and should be not taxed again at a high rate because a company with government funded proprietary technology has chosen to hold things up. In addition, one of the primary justifications for the Bayh-Dole Act is the need for title in inventions to vest in private firms to encourage the commercialization of inventions created with government funding.[29] However, with research tools, a market already exists, and the creator of a research tool often may not use or be equipped to use that tool to develop a commercial application. Thus, providing title to an invention created with government funding may be unnecessary for the continued commercialization of the research tool itself. Furthermore, the licensor's rights are still protected and should be protected enough to allow continued investment in the development of research tools. The license is to be used whenever the licensor is engaged in behavior that unfairly stifles innovation and only when the licensor refuses to join a patent pool. In addition, the licensor is still entitled to recover royalties.

This Article is comprised of eleven parts. Part I provides definitions for research tools and commercial applications. Part II discusses the costs, benefits, and purposes of patent law. Part III reviews university and private research and development, including the influence of the Bayh-Dole Act. Part IV examines the

29. *See infra* notes 108–27 and accompanying text.

development of commercial applications of biotechnology research, including the role of venture capital and the use of licensing provisions requiring reach through royalties and exclusivity. Parts V and VI evaluate problems that may occur in attempting to develop commercial applications and licensing patents. Part VII reviews the Tragedy of the Anticommons theory. Part VIII discusses research and analysis concerning the existence of the anticommons problem. Part IX and X examine and analyze potential solutions for solving the Tragedy of the Anticommons in biotechnology. Finally, Part XI offers recommendations for addressing an existing or developing Tragedy of the Anticommons.

I. DEFINING RESEARCH TOOLS AND COMMERCIAL APPLICATIONS

Developments in molecular biology in the last decade have increased our understanding of the cause and development of incurable diseases, thus enabling us to develop products and services for the treatment of those diseases. The nature of the development of those products and services, however, is increasingly cumulative and collaborative due to the complex and uncertain nature of biotechnology research and development.[30] Increasing numbers of so-called research tools are needed to develop much needed products and services that will directly impact the health of the public. Because most of these research tools are patentable, a "patent thicket" could arise to retard innovation and the subsequent development of publicly beneficial commercial applications. "The term 'patent thicket' has been coined to characteri[z]e a technological field where multiple patent rights are owned by multiple actors.[31] The numerous rights that may need to be brought together for work in this field might possibly impede research and development because of the difficulty or cost of assembling the necessary rights."[32]

This Article distinguishes between commercial applications and research tools. However, from the perspective of the developer of the product or service, the definitions of commercial applications

30. FTC REPORT, *supra* note 1, at ch. 2, p. 17 ("Innovation is often an ongoing, cumulative process, with each generation of innovations building on what came before.").

31. OECD REPORT, *supra* note 2, at 92.

32. *Id.*

and research tools can differ.[33] Both the fact that research tools may be developed by the same entity that is developing a commercial application and the fact that research tools may be developed by public entities as well as private entities complicate the distinction. An additional complication exists because research tools may be included in the commercial application sold to the end-user. For purposes of this Article, a commercial application includes a pharmaceutical drug, a gene therapy, or a diagnostic product. Meanwhile, "[a] research tool is a technology that is used by pharmaceutical and biotechnology companies to find, refine, or otherwise design and identify a potential product or properties of a potential drug product. As such, it serves as a springboard for follow-on innovation."[34] The main distinguishing characteristic between a commercial application, thus defined, and a research tool is the market for the product or service.[35] Though the market for research tools consists of public and private scientists who use those tools in the development of products and services,[36] the market for commercial applications consists of the general public.

Some examples of research tools include a fragment of a gene, a gene, "cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines."[37] Research tools are critical to the efficient development of commercial applications, especially pharmaceutical drugs.[38] Research tools can greatly reduce the "costs and time required for the clinical trial phases, which are the most 'expensive part' of the drug development process."[39]

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33. NIH REPORT, *supra* note 2.

34. FTC REPORT, *supra* note 1, at ch. 3, p. 18.

35. *Id.*

36. *See Genomania Meets the Bottom Line; Genomics for Profit*, 291 SCIENCE 1193 (2001)

> [T]oolmakers . . . sell the machines, chemicals, chips, and computer codes that make it possible to sequence raw DNA, characterize gene expression, and search for meaningful patterns in the data. Among these are Affymetrix . . ., which makes gene chips that give researchers the ability to screen the activity of scores of genes at a time, sequencing machine-maker Applied Biosystems . . ., and bioinformatics software developer Informax . . . .

Id.

37. Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts, 64 Fed. Reg. 72,090, 72,092 n.1 (Dec. 23, 1999).

38. FTC REPORT, *supra* note 1, at ch. 3, p.19 ("[R]esearch tools have led to a considerable reduction in the cost and time required for the targeting of therapeutic antibodies during the initial stages of new drug research.").

39. FTC REPORT, *supra* note 1, at ch. 3, p. 20.

Examples of commercial applications include gene therapies, diagnostic products, and pharmaceutical drugs. Gene therapy involves replacing malfunctioning genes, which can cause diseases, with functioning genes.[40] Genetic diagnostic testing can include: "diagnosing a disease; providing prognostic information; permitting early intervention in asymptomatic, high-risk individuals; predicting the future risk of disease; and designing patient-specific therapeutic regimens."[41] The production of human insulin to treat diabetes is an example of a drug created through the use of recombinant DNA technology.[42] "During its first two decades of existence, the biotechnology industry created more than 75 FDA-approved drugs, vaccines, and diagnostic tests that have completely changed the practice of medicine and generated billions in sales revenues."[43]

II. COSTS, BENEFITS, AND PURPOSES OF PATENT LAW

The United States Constitution allows Congress to enact patent law for the purpose of promoting scientific progress.[44] In the evaluation of how patents promote scientific progress, courts and commentators have focused on several theories: an incentive to invent, an incentive to disclose, and an incentive to innovate.[45] The incentive to invent rationale focuses on the patent grant as provid-

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40. Human Genome Project Information, *available at* http://www.ornl.gov/TechResources/Human_Genome/elsi/patents.html (on file with the University of Michigan Journal of Law Reform) [hereinafter Human Genome Project Information]; *Gene Medication or Genetic Modification? The Devil is in the Details*, 21 NATURE BIOTECHNOLOGY 11, 1280 (November 2000).

41. Laurie L. Hill, *The Race to Patent the Genome, Free Riders, Hold Ups, and the Future of Medical Breakthroughs*, 11 TEX. INTELL. PROP. L.J. 221, 228 (2003). Once a gene or several genes are discovered which predispose a person to a certain disease, complementary gene tests are created to determine whether people have that gene or genes. *See* Human Genome Project Information, *supra* note 40.

42. Mary Breen Smith, Comment, *An End to Gene Patents? The Human Genome Project Versus the United States Patent and Trademark Office's 1999 Utility Guidelines*, 73 U. COLO. L. REV. 747, 753 (2002).

43. Cynthia Robbins-Roth, *Buy or Die*, FORBES ASAP, Apr. 3, 2000, *at* http://www.Forbes.com/asap/2000/0403/153.html (on file with the University of Michigan Journal of Law Reform).

44. U.S. CONST. art. I, § 8, cl. 8; *see* Eisenberg, *supra* note 10, at 1025–26; *see also* Dam, *supra* note 9, at 248 ("[Patent] law is based squarely on an economic policy articulated in the Constitution.").

45. Eisenberg, *supra* note 10, at 1036–37. Courts have primarily focused on the first two theories: an incentive to invent and incentive to disclose. *See id.*

ing encouragement for developers to invent.[46] The incentive to disclose theory promotes scientific progress by ensuring that the patented invention is publicly disclosed, enabling someone skilled in the art to practice the invention.[47] The incentive to innovate theory focuses on how patent rights encourage commercialization or development after the patent issues.[48] Each theory has been substantially discussed and criticized in economics literature.[49] The analysis below will discuss each theory and several criticisms of the theories.

A. Incentive to Invent

The creation or invention of new knowledge is economically beneficial because it leads to the production of new products or processes.[50] However, in a competitive market system, the public goods nature of knowledge leads to a market failure.[51] Because a public good is nonrival in consumption and is nonexcludable, an inventor may bear the costs to develop an invention but may be unable to recoup the investment made in research and development of the invention.[52] Others can easily free-ride on the efforts of the inventor without having incurred the costs of invention.[53] This problem leads to a competitive market system that may provide

46. *See infra* notes 50–68 and accompanying text.

47. *See infra* notes 69–76 and accompanying text.

48. *See infra* notes 77–85 and accompanying text.

49. Eisenberg, *supra* note 10, at 1024–30 (discussing criticisms of theories).

50. *See* Dam, *supra* note 9, at 252 ("In high-technology industries . . . investment in research and development is itself a major form of competition and leads directly to consumer benefits in the form of new products and lower prices."); Corrine Langinier & GianCarlo Moschini, *The Economics of Patents: An Overview*, (Center for Agricultural and Rural Development, Iowa State University, Working Paper, February 2002), *at* http://www.econ.iastate.edu/research/webpapers/paper_2061.pdf (on file with the University of Michigan Journal of Law Reform).

51. INTELLECTUAL PROPERTY, *supra* note 8, at 7; *See also* David, *supra* note 18, at 2 ("[I]t follows from the nature of pure public goods that *competitive* market processes will not do an efficient job of allocating resources for their production and distribution, simply because where such markets work well they do so because the incremental costs and benefits of using a commodity are assigned to the users.").

52. *Id.* A public good has two characteristics: it is nonrivalrous, meaning that one person's use of the good does not affect the amount of it available for consumption by others; and it is nonexcludable, meaning that it is impossible to exclude others from using the public good once it is available. *Id.* at 1. *See* 1 HERBERT HOVENKAMP ET AL., IP AND ANTITRUST 1.1 (2003).

53. INTELLECTUAL PROPERTY, *supra* note 8, at 288.

ineffective incentives to invent and, thus, too few inventions.[54] From an economic perspective, the patent system is designed to correct this market failure by awarding a property right in a discovery, allowing inventors or innovators to exclude others from making, using, or selling their discoveries.[55] The patent system generally is designed to increase consumer and public welfare by encouraging inventors to create inventions that otherwise would not have been created because of the market failure discussed above.[56]

There are, however, costs associated with providing proprietary rights in discoveries.[57] The potential monopoly power that a patent provides allows the patentee to increase a patented invention's price beyond the competitive market price, thus reducing the supply of the patented invention.[58] Moreover, it is unclear whether it is "necessary to endure the output-restricting effects of patent monopolies in order to stimulate invention."[59] A desire to obtain a competitive advantage by being first in the market or to keep up with the progress of competitors may provide sufficient incentive to invent.[60] Moreover, market barriers to entry unrelated to patents may insulate the inventor from competition long enough to justify expenditures in research and development.[61]

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54. *See* Dam, *supra* note 9, at 247 ("[T]he primary problem that the patent system solves . . .—often called the 'appropriability problem'—is that, if a firm could not recover the costs of invention because the resulting information were available to all, then we could expect a much lower and indeed suboptimal level of innovation."); Langinier & GianCarlo, *supra* note 50, at 3; Yusing Ko, Note, *An Economic Analysis of Biotechnology Patent Protection*, 102 YALE L.J. 777, 791–92 (1992).

55. *See* Dam, *supra* note 9, at 247 ("[T]he patent system prevents others from reaping where they have not sown and thereby promotes research and development . . . investment in innovation. The patent law achieves this laudable end by creating property rights in inventions.").

56. U.S. CONST. art. I, § 8, cl. 8. The United States Constitution provides Congress the "[p]ower to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." *Id.*

57. *See* David, *supra* note 18, at 2 ("But imposing restrictions on the uses to which ideas may be put also saddles society with the inefficiencies that arise when monopolies are tolerated; a point harped upon by economists ever since Adam Smith.").

58. JANICE M. MUELLER, AN INTRODUCTION TO PATENT LAW, 20 (2003); Dam, *supra* note 9, at 248 ("[S]ince patent law gives the patentee the power to exclude others from practicing the invention, a monopoly may be created, leading to restriction of production, a supracompetitive price, and what economists call an efficiency or deadweight loss.").

59. Eisenberg, *supra* note 10, at 1026.

60. *Id.* at 1026–27; Ko, *supra* note 54, at 792.

61. Eisenberg, *supra* note 10, at 1027. *Contra* Ko, *supra* note 54, at 794 (arguing that "[t]ypical non-patent means of appropriation," such as head start, trade secrets, sales and service efforts, are unreliable nonpatent barriers in the biotechnology industry).

Generally, only the inventor firm can obtain a patent for its discovery; the competing firms will not receive a patent even though they may have invested considerable sums of money attempting to win the race to invent.[62] Accordingly, the benefit to society of having the invention is dissipated "by the cost of numerous, redundant, development efforts."[63] Moreover, patents might cause rivals seeking to solve the same problem to waste resources by either moving faster than necessary to invent first or duplicating research efforts.[64]

Additional costs may include the presence of patents that discourage others from improving patented inventions.[65] This problem is exacerbated where a questionably invalid patent has been issued.[66] Alternatively, patents may also encourage inventor attempts to design around patents, thus yielding inventions serving the same purpose as the patented invention.[67] Furthermore, competitors might become concerned about potential patent infringement, or even the threat of patent infringement, which can lead to conduct that wastes resources.[68]

B. Incentive to Disclose

The patent system provides another benefit in that it increases the storehouse of public knowledge by requiring a patentee to provide a disclosure, which enables others to make and use the patented invention without undue experimentation.[69] This

62. MUELLER, *supra* note 58, at 20–21. *See generally* Matthew Erramouspe, *Staking Patent Claims on the Human Blueprint: Rewards and Rent Dissipating Races*, 43 UCLA L. REV. 961 (1996) (arguing patent system's mechanisms to minimize rent dissipation, but those mechanisms appear to be failing in race to find and claim commercially valuable genes). *Contra* Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305, 308 (1992) (reviewing rent dissipation theory and how cases appear to have adopted rules of decision that minimize rent dissipation in the pioneer development stage as well as in the improvement stage).

63. Grady & Alexander, *supra* note 62, at 308.

64. Eisenberg, *supra* note 10, at 1027.

65. *Id.*

66. MUELLER, *supra* note 58, at 20–21.

67. Eisenberg, *supra* note 10, at 1027–28.

68. MUELLER, *supra* note 58, at 20–21. *See* FTC REPORT, *supra* note 1, at ch. 2, p. 8 ("The threat of being sued for infringement by an incumbent—even on a meritless claim—may 'scare . . . away' venture capital financing.").

69. *See* 35 U.S.C. § 112 ¶ 1 (2000); MUELLER, *supra* note 58, at 20; Eisenberg, *supra* note 10, at 1027. *See also* Ko, *supra* note 54, at 796 (arguing that the incentive to disclose

enabling disclosure is generally made publicly available eighteen months after a patent application is filed.[70] "[P]atents create legal rights that permit disclosure, enabling sales negotiations or licensing of the patented product or technology."[71] Accordingly, the public can access the information in the application or in the issued patent, which otherwise might have been kept secret.[72]

Some critics object to this theory because "[s]ecrecy is not always a practical strategy for protection, and often secret technologies can eventually be uncovered through reverse engineering."[73] Moreover, it may be more desirable to keep an invention perpetually secret, rather than settling for twenty years of patent protection.[74] Finally, critics also claim that patents do not provide sufficient information to competitors.[75] If an invention is kept secret, it may be difficult to detect infringement of the patent.[76] Accordingly, an inventor might prefer to conceal an invention rather than allow competitors to secretly practice the invention.

C. Incentive to Innovate

Patents also provide an incentive to "induce firms to invest in 'innovation'—i.e., putting existing inventions to practical use."[77] Significant investment may be required to bring a patentable invention to market, whether those costs include constructing a new plant, advertising, or distribution.[78] "[T]he incentive to innovate theory gives existing patents an ongoing role in preserving the incentives of patent holders to invest in development during the patent term."[79] The patent provides a basis for possibly earning more than ordinary returns, permitting "innovators to secure the financial backing of capitalists and to bid productive resources

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theory holds that without patent protection, inventors would conceal their inventions in order to prevent exploitation by competitors).

70. MUELLER, *supra* note 58, at 22.

71. Ko, *supra* note 54, at 796.

72. MUELLER, *supra* note 58, at 21.

73. Eisenberg, *supra* note 10, at 1029. *See also* Ko, *supra* note 54, at 796.

74. *Id.*

75. *Id.*

76. *Id.*

77. Eisenberg, *supra* note 10, at 1036–37.

78. Eisenberg, *supra* note 10, at 1037; Ko, *supra* note 54, at 799.

79. Eisenberg, *supra* note 10, at 1038. ("Reducing the strength of existing patent monopolies might thus have the effect of undermining incentives to put existing technologies into use.").

away from their current uses."[80] This theory is usually associated with the work of Joseph Schumpeter on economic development.[81] In contrast to the other two theories, the incentive to innovate theory is concerned with *ex post* activity.[82]

The patent system arguably provides an additional benefit when a broad patent is issued for a pioneering development, because the patentee is able to efficiently direct multiple firms to allocate resources to develop follow-on innovations.[83] "The patent owner is thus in a position to cause researchers to share information and thereby avoid duplicative research efforts."[84] This theory is known as the "prospect theory."[85]

III. UNIVERSITY AND PRIVATE RESEARCH AND DEVELOPMENT: THE INFLUENCE OF THE BAYH-DOLE ACT

Since the 1980s, biotechnology research and development have increasingly become a collaborative effort between the public and private sector.[86] A primary reason for increased collaboration involves the passage of the Bayh-Dole Act, a major shift in government policy.[87] The Bayh-Dole Act allows universities to take title to inventions developed with government funding.[88]

The Bayh-Dole Act has a tremendous effect upon the appropriation of technology because the federal government is the largest source of funding for research and development in the United

80. *Id.* at 1039.

81. *Id. But see* Ko, *supra* note 54, at 800 ("Empirical studies testing Schumpeter's assumption—that monopolistic conditions created by patents more readily induce innovation than do competitive conditions—have proved inconclusive.").

82. Eisenberg, *supra* note 10, at 1038.

83. Kitch, *supra* note 10, at 266. *But c.f.* Ko, *supra* note 54, at 803 ("Biotechnology's unpredictability confounds the prospect theory's central notion of coordination.").

84. Eisenberg, *supra* note 10, at 1041–42.

85. Kitch, *supra* note 10, at 266. *But c.f.* Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 843–44 (1990) ("Without extensively reducing the pioneer's incentives, the law should attempt at the margin to favor a competitive environment for improvements, rather than an environment dominated by the pioneer firm. In many industries the efficiency gains from the pioneer's ability to coordinate are likely to be outweighed by the loss of competition for improvements to the basic invention.").

86. EPSTEIN, *supra* note 2, at § 11.2.

87. *See id.*

88. *See id.*

States for universities.[89] The federal government currently spends about twenty-six percent of the total funding for research and development in the United States.[90] The government spends almost sixty percent of all funding for research and development in universities in the United States.[91] Private industry funds about seventy-six percent of research and development in the United States.[92] Prior to the passage of the Bayh-Dole Act, less than four percent of all government funded research was commercialized.[93]

As a result of the increased collaboration, the Association of University Technology Managers reported in 2000 that "$29.5 billion was spent in sponsored university research expenditures—this included $18.1 billion from the federal government and $2.7 billion from private industry"; and sponsored research yielded "13,032 new technology disclosures; 6,375 new U.S. patent application filings; 3,764 U.S. patents issued; 4,362 new options and licenses granted—50 percent of all options licenses granted were exclusive licenses[,] 454 of all options and licenses were granted to new start-ups; $1.3 billion adjusted gross income was generated."[94] The Association of University Technology Managers also reported that "347 new products resulting from academic research were introduced in 2000[,] and in 1999[,] university-private industry collaboration contributed $41 billion to the United States economy, supporting 270,000 jobs and producing $5 million in tax revenue."[95]

Although there are apparently benefits to the increased collaboration of universities and the private sector, there are critics to

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89. Joshua A. Newberg & Richard L. Dunn, *Keeping Secrets in the Campus Lab: Law, Values and Rules of Engagement for Industry-University R&D Partnerships*, 39 AM. BUS. L.J. 187, 193 (Winter 2002) (citing NAT'L SCI. BD., *National Patterns of R&D Resources: 2000 Data Update*, Table 1A, *at* http://www.nsf.gov/sbel.srs/nsf01309/start.htm) (on file with the University of Michigan Journal of Law Reform).

90. ALBERT H. TEICH, AAAS REPORT XXVII: RESEARCH & DEVELOPMENT, R&D IN THE FEDERAL BUDGET: FREQUENTLY ASKED QUESTIONS 2 (2003) *available at* http://www.aaas.org/ssp/rd/03pch1.htm (on file with the University of Michigan Journal of Law Reform).

91. *Id.*

92. *Id.*

93. EPSTEIN, *supra* note 2, at § 11.12 (citing Lobenstein, *Future of University-Industry Licensing*, 25 LES NOUVELLES 138 (1990)).

94. *Id.* at §§ 11.36–.37. (citing BERNMEN & DENIS, UNIVERSITY LICENSING TRENDS AND INTELLECTUAL CAPITAL, BIOTECHNOLOGY LAW 2002: BIOTECHNOLOGY PATENTS & BUSINESS STRATEGIES 551 (PLI 2002)).

95. *Id.* at § 11.16 (citing BERNMEN & DENIS, UNIVERSITY LICENSING TRENDS AND INTELLECTUAL CAPITAL, BIOTECHNOLOGY LAW 2002: BIOTECHNOLOGY PATENTS & BUSINESS STRATEGIES 551 (PLI 2002)).

collaboration.[96] Some critics state that the purpose of commercializing university research is in direct conflict with the purpose of university research: to seek knowledge.[97] Other critics argue that the collaboration will unduly influence the academic freedom of researchers to pursue whatever projects they deem important, which traditionally have centered on basic research—research geared toward understanding fundamental principles.[98] Instead, universities and their researchers will be swayed by desires for financial gain and might thus focus on applied research.[99] Moreover, the desire to obtain proprietary rights in technology in the private sector conflicts with traditional academic goals of immediate publication and dissemination of research.[100] The private sector might encourage academics to withhold publication and dissemination of research until proprietary rights are established in that research.[101] As a result, there may be too little basic research available for other researchers to build upon.[102]

Proponents of increased collaboration argue that notwithstanding thee above-stated criticisms, universities and private industry benefit from the relationship.[103] For example, universities have a new source of funding to support increasingly expensive high-technology research.[104] Moreover, financial benefits may encourage researchers to remain at universities rather than leaving for private companies.[105] In addition, university research students may receive valuable practical training and employment opportunities with private firms.[106] Private industry might also benefit from increased competition in new technologies, objectivity in research with access to better research talent and facilities, and opportunities to hire highly qualified research students.[107]

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96. *Id.* at § 11.3.
97. *Id.*
98. *Id.* at § 11.7.
99. *Id.*
100. *Id.* at §§ 11.7–8.
101. *Id.*
102. *Id.* at § 11.8.
103. *Id.* at §§ 11.3–.6.
104. *Id.* at §§ 11.9–.16 ("[A]t around the same time that Congress enacted legislation permitting universities to retain title to inventions generated by federally-funded research, the amount of federal research funding available to universities began to decrease." *Id.* at § 11.11 (citing Lobenstein, *Future of University-Industry Licensing*, 25 LES NOUVELLES 138 (1990)).
105. *Id.* at § 11.10.
106. *Id.*
107. *Id.* at §§ 11.9–.10.

A. The Bayh-Dole Act

The issue of whether title to inventions created with government funding should vest in the government or private companies has been debated since the 1940s.[108] In 1947, the United States Attorney General recommended that the ownership of technology developed with the use of government funds, even in collaboration with private firms, should vest in the government.[109] However, each agency instituted its own policies concerning the rights the government retained in technology developed with the use of government funds.[110] In 1963, a presidential memorandum attempted to achieve a greater degree of uniformity in government patent policy.[111] The memorandum allowed the government to generally retain title to inventions developed with the use of government funds but also allowed contractors to acquire rights greater than exclusive licenses if "necessary . . . to call forth private risk capital and expense to bring the invention to the point of practical application."[112] In 1971, President Nixon issued a revised presidential memorandum and policy statement on government patent policy, which facilitated the allocation of exclusive rights in government funded inventions to private firms.[113]

In the late 1970s and early 1980s, the federal government recognized that significant investment was needed to commercialize innovations developed with government funds and that private firms were unwilling to invest in commercializing innovations unless those firms received a proprietary interest in the end product.[114] Thus, the

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108. Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government Sponsored Research*, 82 VA. L. REV. 1663, 1671–1691 (1996).

109. EPSTEIN, *supra* note 2, at § 14.4. (citing U.S. DEPT. OF JUSTICE, REPORT AND RECOMMENDATIONS OF THE ATTORNEY GENERAL TO THE PRESIDENT, INVESTIGATION OF GOVERNMENT PATENT PRACTICES AND POLICIES (1947)); *see* Eisenberg, *supra* note 108, at 1676–77 ("Agencies . . . had considerable discretion to choose whatever patent policy best suited their missions. Not surprisingly, there was considerable variation in the policies adopted by the different agencies.").

110. EPSTEIN, *supra* note 2, at § 14.4.

111. Eisenberg, *supra* note 108, at 1677.

112. *Id.* at 1678.

113. *Id.* at 1684.

114. EPSTEIN, *supra* note 2, at § 14.4; Eisenberg, *supra* note 108, at 1689 ("Further support for legislation to promote the private appropriation of government-sponsored research results came from the Domestic Policy Review on Industrial Innovation, initiated by President Carter in 1978 to identify and recommend Government actions to encourage increased industrial productivity and innovation."). *Id.* at 1669.

government determined that technology developed with government funds should be transferred to the private sector for further research, development, and investment to commercialize that technology.[115] The new strategy served several goals: "ensure [the] effective transfer and commercial development of discoveries that would otherwise languish in government and university archives"; "reinvigorate U.S. industry by giving it a fresh infusion of new ideas that would enhance productivity and create new jobs"; and "ensure that U.S.-sponsored research discoveries were developed by U.S. firms, rather than by foreign competitors who had too often come to dominate world markets for products based on technologies pioneered in the United States."[116] The government's policy shift concerning the commercialization of innovations resulted in changes in government practices and the law.[117]

The Government Patent Policy Act of 1980, known as the Bayh-Dole Act, went into effect in 1981.[118] The Act concerned the ownership of technology developed with the use of federal funds by small businesses, universities, research institutions, nonprofit scientific or educational institutions, and hospitals.[119] The purpose of the Bayh-Dole Act was "to promote the utilization of inventions arising from federally supported research and development, to encourage the maximum protection of small business firms . . . [, and] to promote collaboration between commercial concerns and nonprofit organizations including universities . . . ."[120] By presidential memorandum in 1983, the government extended the Act to entities such as large corporations.[121]

> [F]urther investment is necessary to refine it, test it, build the necessary facilities for production on a commercial scale, and find or create a market for it. Throughout this development process a substantial risk of failure remains. These follow-on investments may greatly exceed the value of the initial investment that created the invention in inchoate form. The government lacks the expertise and facilities to do this development work itself, and therefore needs to turn the invention over to industry at this point. Firms may only be willing to invest in the development of an invention if they hold exclusive rights, either in the form of title or an exclusive license, under a patent.

Id. at 1669.

115. EPSTEIN, *supra* note 2, at § 14.4.

116. Eisenberg, *supra* note 108, at 1664–65.

117. EPSTEIN, *supra* note 2, at §§ 14.4–.5.

118. 35 U.S.C. §§ 200–211 (1994); EPSTEIN, *supra* note 2, at § 13.46.1.

119. EPSTEIN, *supra* note 2, at § 13.46.1.

120. 35 U.S.C. § 200 (1994); EPSTEIN, *supra* note 2, at §§ 13.46.1–.2.

121. EPSTEIN, *supra* note 2, at § 13.46.1 (citing President's Memorandum to the Heads of the Executive Departments and Agencies on Government Patent Policy, 19 WEEKLY

Although the Act reserves certain rights to the government, the Act allows a qualifying organization to elect to retain title to any technology developed with the use of federal funds.[122] The rights reserved by the government include a non-exclusive right to practice the invention worldwide[123] and limited "march in" rights to require the granting of a license if the invention is not practiced within a reasonable time period.[124] The Act also provides that in "exceptional circumstances" an agency may limit or restrict the right of a recipient of federal funds to elect title if the agency determines that restriction or elimination of that right will better promote the policy and objectives of the Act.[125]

As a result of the Act, universities are encouraged to take a proprietary position in any technology that is developed with federal funds. The Act also encourages private commercial organizations to collaborate with universities funded with federal monies because those commercial concerns may be able to take an exclusive proprietary position in that technology. The number of patent applications filed by qualifying biotechnology organizations increased by more than 300 percent in the first five years after the enactment of the legislation, as compared with the five years prior

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COMP. PRES. DOC. 252 (Feb. 18, 1983)). The Act was originally intended to benefit small firms which were viewed as:

> innovative, adaptive, risk-taking, entrepreneurial and competitive, yet consistently underrated by funding agencies in their allocations of research dollars and patent rights. Large business, by contrast, was pictured as short-sighted, risk-adverse, and predatory, more likely to suppress new technologies than to adopt them, yet savvy and powerful in their dealings with government agencies and therefore more successful than their more worthy small business competitors in garnering government research contracts and securing patent rights in the results.

Eisenberg, *supra* note 108, at 1696.

122. EPSTEIN, *supra* note 2, at § 13.46.2.

123. 35 U.S.C. § 202 (1994). "Some grantees have taken the position that the statute provides protection from infringement only, and have refused to provide samples of the materials in question to facilitate the actual use." NIH REPORT, *supra* note 2. It is also not clear whether the retained license allows the government to authorize use of subject inventions by other recipients of government funding. *Id.*

124. 35 U.S.C. §§ 202(c)(2), 203 (1994). The government can only exercise "march-in" rights if the government fulfills certain requirements: (1) meets the requirements for "'public use;'" (2) determines that the requirements for public use have not been met; (3) provides the contractor with an opportunity within a reasonable time to demonstrate that the license should not be granted. EPSTEIN, *supra* note 2, at § 14.6.

125. 35 U.S.C. § 202(a) (1994). For an extensive discussion of "march in" rights and the "exceptional circumstances" provisions in the Bayh-Dole Act with proposals for reform, see Arti K. Rai & Rebecca S. Eisenberg, *The Public Domain: Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289 (2003).

to the passage of the Act.[126] "[B]iotechnology patent applications constituted 22 percent of all patent applications filed by these institutions."[127]

B. University Licensing

Most, if not all, universities have developed policies directed toward research and development collaborations between private industry and the university.[128] Those policies attempt to strike a balance between the desire to use university research to bring products to market, create revenue streams for the university, which generate additional funding for university research, and maintain the ability of university researchers to pursue basic research.[129] The policies also state the university's stance toward university-private industry licensing and define the rights and duties of the inventor, the university, and the outside entity.[130] In addition to a policy, most universities will establish administrative procedures for evaluating prospective patented inventions, obtaining and securing patents and other intellectual property rights, and transferring rights to entities outside the university.[131] An outside technology transfer firm, a university foundation, or an "in house" technology transfer office typically do the administration and transfer of a university's property rights.[132] Some universities use a combination of those approaches.[133] An example of a combination of a university foundation and an outside technology firm is the Triangle Universities Licensing Consortium, which manages and negotiates on behalf of Duke University, the University of North Carolina—Chapel Hill, and North Carolina State University.[134]

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126. EPSTEIN, *supra* note 2, at §§ 13.45–.46.

127. *Id.* (citing U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS—SPECIAL REPORT (OAT 13A) at 337 (Washington, D.C. Government Printing Office 1987)).

128. *Id.* at 11–16. For a detailed discussion concerning the Bayh-Dole Act and technology transfer offices, see Kenneth Sutherlin Dueker, *Biobusiness on Campus: Commercialization of University-Developed Biomedical Technologies*, 52 FOOD DRUG L.J. 453 (1997).

129. EPSTEIN, *supra* note 2, at S 11.16.

130. *Id.* (citing COUNCIL ON GOVERNMENTAL RELATIONS, PATENTS AND COLLEGES AND UNIVERSITIES, GUIDELINES FOR THE DEVELOPMENT OF POLICIES 8–9 (1985)).

131. *Id.* at 11-17-18.

132. *Id.* at 11–18.

133. *Id.*

134. *Id.* at 11–23.

University patent policies often require that the university researcher assign her rights in an invention to the university.[135] University policies also require the inventor or discoverer to disclose most potentially patentable inventions or discoveries to the appropriate administrative body, which will evaluate the patentability of any such invention or discovery.[136] Policies include provisions to distribute any income from the licensing and subsequent commercialization of any patented invention between the university and the inventor.[137] Moreover, though some universities do not require the disclosure of all inventions or discoveries, the university will reserve the right to acquire title in any invention the inventor wishes to commercialize.[138]

IV. BIOTECHNOLOGY COMPANIES AND VENTURE CAPITAL

The meeting in 1975 between a young venture capitalist and a researcher at the University of California at San Francisco led to the formation of Genentech and marked the birth of a new relationship between venture capital and the biotechnology market.[139] Since that time, venture capital has played a significant role in the development of the biotechnology market.[140] Venture capital is the primary source of funding for biotechnology start-ups.[141] Venture capital is defined as high risk financing, generally in the form of common stock or debentures convertible from common stock, often provided to companies that do not qualify for other forms of

135. *See* University of Colorado Patent Policy (December 1997) (on file with the University of Michigan Journal of Law Reform); University of Minnesota Patent Policy (October 1986) (on file with the University of Michigan Journal of Law Reform); Yale University Patent Policy (September 1989) (on file with the University of Michigan Journal of Law Reform).

136. *Id.*

137. *Id.*

138. *See* University of Minnesota Patent Policy (October 1986) (on file with the University of Michigan Journal of Law Reform); Yale University Patent Policy (September 1989) (on file with the University of Michigan Journal of Law Reform).

139. Terry C. Bradford, *Evolving Symbiosis—Venture Capital and Biotechnology*, 21 NATURE BIOTECHNOLOGY 983 (September 2003).

140. *Id.*

141. *Id.* at 984 ("[B]iotechnology has been and will remain the mainstay that defines US VC high-risk, high-return investment."); Mary Breen Smith, Comment, *An End to Gene Patents? The Human Genome Project Versus the United States Patent and Trademark Office's 1999 Utility Guidelines*, 73 U. COLO. L. REV. 747, 758 ("A start-up biotechnology or genomics company, not having any profits with which to fund development, is dependent on outside capital.").

financing.[142] Venture capitalists generally require a potential for exceptionally high rates of return in exchange for funding.[143]

Once a company establishes that a market is valid and important, a key factor to venture capitalists in determining whether to invest in a company includes the company's ability to defend its market advantage in technology through patents.[144] The patent position of a biotechnology company may determine whether that company will close its doors or continue in business.[145]

Generally, small biotechnology start-up companies do not plan to use the technology that they develop.[146] Often, the small start-up companies do not have the expertise or funds necessary to bring a product to market, especially considering the expensive and time-consuming clinical trials involved.[147] Thus, most start-up

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142. STEPHEN C. BLOWERS ET AL., GUIDE TO THE IPO VALUE JOURNEY 284 (1999).

143. *Id.*

144. FTC REPORT, *supra* note 1, at ch. 2, p. 1 ("Biotechnology start-ups rely on their ability to patent their innovations to attract investment and continue innovating."); *see* Rebecca S. Eisenberg, *Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 FORDHAM L. REV. 477, 479 (2003) ("Biotech firms say that they need patents in order to raise capital from investors to conduct their research and in order to get pharmaceutical firms to partner with them to use their research platforms to develop new products.").

145. FTC REPORT, *supra* note 1, at ch. 3, p. 18. ("The venture capital accessed through patents thus enables not-yet-profitable companies to 'sustain . . . innovation through massive investments in research and development.'"); Eisenberg, *supra* note 10, at 1039 ("[T]he prospect of earning more than an ordinary return permits innovators to secure the financial backing of capitalists and to bid productive resources away from their current uses."); Lehman, *supra* note 7, at 50 (1996):

> [P]atenting is a very important part of commercializing biotechnology. The biotechnology industry requires considerable capital expenditure, not only for the initial research and development, but also to go through the regulatory approval process necessary to get a product—particularly a pharmaceutical product—on to the market. That capital is essential and the ability to get that capital is very much dependent upon the capacity to get patent protection for a prospective product.

Id.

146. HAROLD EINHORN & THOMAS J. PARKER, PATENT LICENSING TRANSACTIONS 6A-3 (Release no. 59, April 2004).

147. *See id.*; Biotech Strategies, *at* http://practice.findlaw.com/feature-0104.html (on file with the University of Michigan Journal of Law Reform):

> On the R&D side, life science companies have long lead times and large development costs to get the drugs and products from the research and development stage to market. Unlike other industries, most of [sic] drugs must endure huge clinical trials and obtain FDA approval before the product can even be marketed. Most smaller start up companies simply do not have the financial resources to even complete the development process. Thus, they and [sic] are required to partner with other companies even to get the technology required to finish their R&D. . . . [O]n the distribution side, once the product is developed, most smaller companies do not have

biotechnology companies seek to license their technology to large pharmaceutical companies.[148]

From 1999 to 2002, venture capitalists invested over $8.5 billion in biotechnology companies.[149] After the burst of the Dot Com bubble, conventional wisdom suggested that venture capitalists were no longer investing in biotechnology.[150] However, through the first half of 2003, venture capitalists invested $1.177 billion in biotechnology.[151] In fact, the total number of deals has remained constant despite the relative weakness in the United States economy.[152]

V. IMPORTANT PROVISIONS IN LICENSES OF RESEARCH TOOLS

A large part of the biotechnology industry concerns the development of commercial applications through the use of research tools.[153] Research tools can be developed in-house by a company, acquired by purchasing the assets of a company, or licensed.[154] However, the cost involved in developing research tools in-house or acquiring the assets of a company can be very high.[155] Licensing is the most cost-effective method of acquiring the rights to

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the resources for the large-scale commercialization that needs to happen. The distribution channels are controlled by a few large companies that have access to the hospitals through purchasing organizations, doctors, offices[,] and pharmacies around the country.

Id. See generally Phillipe Ducor, *New Drug Discovery Technologies and Patents*, 22 RUTGERS COMPUTER & TECH. L.J. 369 (1996) (describing drug development process).

148. EINHORN & THOMAS, *supra* note 146, at 6A-3. "[L]icenses are merely instruments through which the licensee receives from the licensor, for an agreed upon consideration, the right to enjoy something the licensor has the right to grant, without interference by the licensor." EPSTEIN, *supra* note 2, at § 1.1.

149. Bradford, *supra* note 139, at 983.

150. *Id.* at 984.

151. *Id.* at 983.

152. *Id.* at 984.

153. EINHORN & THOMAS, *supra* note 146, at 6A-9.

154. *Id.*

155. *Id.* Notably, a patent need not be issued at the time of execution of a license. EPSTEIN, *supra* note 2, at § 3.4. Moreover, assuming there is a patent, most patent license agreements do not only include the licensed patent. *See id.* at § 3.3. It is beneficial to the licensor to structure the agreement as a transfer of information and technical assistance that includes the patent rights to reduce the chances that a licensee may successfully attack the agreement on the basis of fraud in the inducement, mistake, failure of consideration, and patent validity. *Id.*

use a research tool.[156] Licensing can be defined as a waiver of the right to exclude the licensee from practicing the claimed invention.[157] However, as discussed below, there are numerous issues involved in the licensing of research tools that may lead to an inefficient or ineffective use of the tools, or even a Tragedy of the Anticommons.[158] Two important provisions in licenses of research tools concern the valuation of the research tool and the nature of the exclusivity of the license.

A problem that arises in licensing research tools is determining the value of the research tool.[159] This problem exists because at the time of licensing the research tool it is difficult to accurately gauge the ultimate value of the product or service developed from use of the research tool or whether any commercial application will be developed at all.[160] Thus, the cost of the license for the basic research tool is not simply the cost of development of the research tool; it is also the value of the right to use the technology.[161] The reach-through royalty provision is a common remedy in research tool licensing agreements .[162] The reach-through royalty provision usually allows a licensor to capture a percentage of the sales of the commercial application developed from use of the research tool, even though the commercial application does not per se include the licensed patented technology.[163]

A problem may arise in the development of a new commercial application if it is necessary to use multiple research tools, each of which requires a different license with a separate reach-through

156. EINHORN & THOMAS, *supra* note 146, at 6A-9.

157. BRIAN G. BRUNSVOLD & DENNIS P. O'REILLY, DRAFTING PATENT LICENSE AGREEMENTS 14 (1998).

158. *See infra* notes 208–31 and accompanying text.

159. EINHORN & THOMAS, *supra* note 146, at 6A-9. "The value to a licensee of research tools lies, in part, in the point at which those tools are employed in the drug development continuum. A research tool enabling the identification of a drug candidate during high throughput screening, for instance, may supply more value to the ultimate invention than a research tool used to confirm an already recognized drug candidate's safety or efficacy." *Integra*, 331 F.3d at 871.

160. EINHORN & THOMAS, *supra* note 146, at 6A-9.

161. *Id.*

162. *Id.* at 6A-10; *see* Stephen G. Kunin et al., *Reach Through Claims in the Age of Biotechnology*, 51 AM. U. L. REV. 609, 618 (2002) ("For example, an agreement might specify that the supplier of a new receptor will provide the receptor to a researcher for use in seeking new hormones so long as the supplier receives reach-through royalties on any new hormone discovered or invented by the researcher.").

163. *Id.*; *see* Mueller, *supra* note 23, at 61 ("The premise underlying reach-through royalties is that the true value of the patented research tool will be determined by the ultimate marketplace success of the new product developed through use of the tool.").

royalty clause.[164] The royalties assigned to various licensors may severely erode profit potential, creating a disincentive for companies that require numerous research tools to develop specific commercial products or services.[165] Moreover, a company might abandon developing a commercial product or service that proves unprofitable or not profitable enough for that particular company to continue developing. Some firms have attempted to overcome this problem with a clause that places a ceiling on the total amount of reach-through royalties collected to develop a particular commercial application.[166] Thus, "[i]f a third party royalty must be paid, previous rates are adjusted downwards to stay below the limit."[167]

A second important issue in the licensing of biotechnology research tools concerns the licensee's desire to obtain some exclusivity in the technology.[168] Exclusivity of a research tool provides a competitive advantage to the licensee.[169] Exclusivity allows the licensee to prohibit a potential competitor from using the same research tool.[170] Exclusivity can take the form of exclusive use of the research tool in a specific niche market or particular field of use.[171] If an exclusive license is granted to the licensor, other parties who need to use that research tool may be prohibited from using that tool.[172] A potential problem is that the party best situated to develop a commercial product from the research tool may not possess the rights to use that tool.[173] Because of reach-through royalties, however, the licensor has an incentive to license the research tool to the party that is best positioned to develop a particular commercial application. Although the licensor may not be paid until the commercial application is sold, it is not uncommon for licenses to include positive or negative milestone

164. *See infra* notes 208–31 and accompanying text.

165. *Id.*

166. OECD REPORT, *supra* note 2, at 62.

167. *Id.*

168. EINHORN & THOMAS, *supra* note 146, at 6A-10.

169. *Id.* The grant of an exclusive license can raise antitrust concerns. BRUNSVOLD & O'REILLY, *supra* note 157, at 19.

170. BRUNSVOLD & O'REILLY, *supra* note 157, at 18. ("The express grant of an exclusive license conveys an implied promise by the patent owner not to practice under the patent and not to grant any further licenses.").

171. EINHORN & THOMAS, *supra* note 146, at 6A-10.

172. EPSTEIN, *supra* note 2, at 3–16. An exclusive license can take many forms including a license exclusive to all but the licensee and all other pre-existing licensees, a license providing exclusive rights limited to a particular territory, a license providing exclusive rights for a limited period of time, or a hybrid of the above-types of licenses. *Id.* at 3-16-17.

173. *See* ROBERT C. MEGANTZ, TECHNOLOGY MANAGEMENT: DEVELOPING AND IMPLEMENTING EFFECTIVE LICENSING PROGRAMS 83 (2002).

payments or other incentives to ensure that the licensee uses the research tool to develop a commercial product.[174] For example, a licensor might request a higher reach-through royalty rate, minimum royalty rate, or large positive or negative milestone payments.[175] A licensor might also request that a licensee pay a larger up-front fee.[176]

Exclusivity, however, as discussed above, also means that the licensee will have to pay a premium to obtain exclusive rights.[177] The licensee will have to convince the licensor that she is best positioned to develop a commercial application from the research tool, because the licensor can issue multiple non-exclusive licenses to competitors of the licensee, thus increasing the likelihood that a company will develop an application.[178] The licensor may receive a lesser reach-through royalty rate, and negative and positive milestones, but may increase her chances that a commercial application will be developed.[179] Moreover, multiple party competition using the research tool to develop a commercial application may lead to the development of a particular application sooner than if only one party were using the tool.

VI. LICENSING PATENTED RESEARCH TOOLS

Part VI discusses various issues arising because of the cumulative and collaborative nature of the development of commercial applications in the biotechnology industry. This Part reviews blocking patents, complementary patents, hold-ups, royalty stacking, and problems that may arise in licensing patented research tools.

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174. A license may also contain a minimum annual royalty provision that allows the licensor to terminate the license if minimum royalties are not met or a conversion to a nonexclusive license provision to protect the licensor. BRUNSVOLD & O'REILLY, *supra* note 157, at 22–24. However, a termination provision is a very severe sanction, and one that is likely not to be accepted by a licensor. *Id.* Moreover, either a duty to provide "best efforts" will be expressly provided for in the contract or it may be implied in some cases. *Id.*

175. EPSTEIN, *supra* note 2, at § 3.17. An additional potential benefit of entering an exclusive license for the licensor is that the costs associated with administering one license are potentially less than several non-exclusive licenses. *Id.*

176. EINHORN & THOMAS, *supra* note 146, at 6A-10.

177. *Id.*

178. *Id.* "If, for example, one company has a large market share compared to its competitors in a particular technology field, it may be more profitable to have a single exclusive license with that company .... For this reason, the licensee may seek an exclusive license even if it must pay a higher royalty." EPSTEIN, *supra* note 2, at § 3.18; MEGANTZ, *supra* note 173, at 83–84.

179. MEGANTZ, *supra* note 173, at 83.

A. Blocking Patents

Blocking patents result from the incremental nature of innovation.[180] The United States Patent and Trademark Office ("USPTO") may grant a broad, pioneer patent.[181] If a second inventor improves an invention covered by the first patent, the second inventor may receive a patent for her invention, assuming her invention fulfills the requirements for patentability.[182] However, the improvement patent cannot be practiced without infringing the first patent.[183] Similarly, the inventor of the pioneering invention cannot practice the second inventor's patented invention.[184] The second inventor's patent blocks the first inventor from practicing the improvement.[185] The improvement patent is deemed the "subservient patent," and the first patent is the "dominant patent."[186] The first inventor must obtain a license from the second inventor to practice the improvement. The second inventor must also secure a license from the first inventor to use the improvement.

B. Complementary Patents

Complementary patents cover technology that is useless without a license to another patented invention.[187] Complementary patents can occur where different inventors have patented components of a larger invention.[188] Absent cooperation between owners of complementary patents, commercial applications may be blocked from development because of competing patent claims.[189] Thus, to develop a particular commercial application the owners of

180. Steven C. Carlson, Note, *Patent Pools and the Antitrust Dilemma*, 16 YALE J. ON REG. 359, 362 (1999).

181. *Id.* at 364.

182. *Id.* at 363.

183. *Id.*; *see* Robert P. Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75, 75 (1994) (discussing the problem of blocking patents and the reverse doctrine of equivalents as a "judicial response to the likelihood of a breakdown in bargaining between inventors who pioneer a new technology and those who later develop key improvements").

184. Carlson, *supra* note 180, at 363.

185. *Id.*

186. *Id.*

187. *Id.* at 364.

188. *Id.* at 364–65.

189. *Id.*

complementary patents must license their respective rights to one another or to a third party.

C. Hold-Ups

A hold-up may result if a developer, unaware of a particular patent, uses the patented technology to create a commercial application. Assuming, on the other hand, that a developer has both knowledge of a patent that potentially blocks the creation of a commercial application and also sufficient lead-time, he may invest in designing around the patent.[190] Any royalty that the patentee may exact from the developer is likely slight.[191] The patentee is in a very weak negotiating position;[192] however, if the developer, without knowledge of the patent, has invested substantial resources in creating a commercial application using the patented technology, he is also in a weak negotiating position.[193] The patentee can demand higher royalties, "very likely backed up with the threat of shutting down the [developer] if the court finds the patent valid and infringed and grants injunctive relief."[194] Though the developer might go back and attempt to redesign the product, to do so "could well require a major redesign effort and/or cause a significant disruption to production," "would still leave potential liability for any products sold after the patent issued before the redesigned products are available for sale," "and could present compatibility problems with other products or between different versions of this product."[195] For these reasons, the developer is susceptible to being held up by the patentee.[196] An example of a potential hold-up in the biotechnology industry includes a developer that uses an already privately patented gene sequence from a public database.[197]

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190. Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting* 6–7, *in* INNOVATION POLICY AND THE ECONOMY (Adam Jaffe et al., eds., 2001), *available at* http://haas.berkeley.edu/~shapiro/thicket.pdf (on file with the University of Michigan Journal of Law Reform).

191. *Id.*

192. *Id.*

193. *Id.*

194. *Id.*

195. *Id.*

196. *Id.*

197. Human Genome Project Information, *supra* note 40. "[A] demand for payment after lock in can compel the downstream actor to pay the patentee a 'far greater' royalty rate. That higher rate . . . can be passed along to consumers in the form of higher prices. [T]he threat of hold up may reduce overall levels of innovation, because some companies will

D. Royalty Stacking

Royalty stacking can occur with blocking or complementary patent situations. Royalty stacking can arise with blocking patents where there are multiple layers of improvement on a pioneering invention. For example, multiple licensees may have a right to a royalty for every sale of a commercial application.

Complementary patents may also produce a royalty stacking problem. Royalty stacking can occur when a single genomic sequence is patented in different ways, for example, when an EST, a gene, and a SNP are each patented.[198] Thus, in order to practice a commercially useful invention, such as gene therapy, which uses one or several genes, a company will have to obtain multiple licenses to those patents.[199] The company developing the gene therapy will likely have to pay royalties to each and every owner of the patents for each EST, gene, and SNP needed to practice the therapy.[200] The value of the commercial development or the profitability of the commercial development may be substantially decreased because of the amount of royalties paid for each research tool, or part of a gene, or several genes used in a commercial application.[201] Thus, there may be a disincentive for companies to research and develop commercial applications in areas where there is a patent thicket.

Royalty stacking can also occur when a research tool or multiple tools are needed to conduct research for and development of a particular commercial application even though the application does not include the patented research tool or tools. "Stacking royalty obligations can make a significant dent in the profit expectations of firms that might develop [commercial applications], thereby undermining the commercial attractiveness of potential applications."[202]

'refrain from introducing certain products for fear of holdup.'" FTC REPORT, *supra* note 1, at ch. 2, p. 29.

198. Human Genome Project Information, *supra* note 40, at 8.

199. *Id.*

200. *Id.*

201. WALSCH ET AL., *supra* note 14, at 299.

202. NIH REPORT, *supra* note 2.

E. Transaction Costs and Impediments to Efficient Licensing

There are numerous costs associated with licensing patents.[203] For example, there are costs in analyzing what patents apply or cover a commercial application[204] and in determining ownership of upstream inputs.[205] There are also numerous impediments to the licensing of biotechnology research tools: inexperienced parties attempting to license patents; differing goals of licensors and licensees, such as universities versus private industry; time constraints, such as research agendas and funding issues; and difficulty valuating the research tool.[206] Moreover, "uncertainty or disagreement as to the value of the patented invention, the likely outcome of the research project, and the validity and scope of the patent claims might also make it difficult for the parties to agree on a price for a license."[207]

VII. THE TRAGEDY OF THE ANTICOMMONS

In 1998, Professors Michael Heller and Rebecca Eisenberg identified a potential problem involving patents and biomedical research described as a "Tragedy of the Anticommons."[208] The "Tragedy of the Anticommons" theory is a mirror image of the metaphor "Tragedy of the Commons," which has been used to explain overpopulation, air pollution, and species extinction.[209] The Tragedy of the Commons theory states that if people hold

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203. Human Genome Project Information, *supra* note 40, at 8.

204. *Id.*

205. *Id.*

206. Rebecca S. Eisenberg, *Bargaining over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?* in EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 223–50 (R.C. Dreyfuss et al., eds., 2001); Merges, *supra* note 183, at 89 ("Where high uncertainty attends the valuation of assets to be exchanged, bargaining can be difficult.").

207. Eisenberg, *supra* note 10, at 1073.

208. Heller & Eisenberg, *supra* note 11, at 698. For a more detailed analysis of the anticommons theory as it applies generally to property, see Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621 (1998). *See also* Michael A. Heller, *The Boundaries of Private Property*, 108 YALE L. J. 1163 (1999). For a criticism of the anticommons theory, see Richard A. Epstein & Bruce N. Kuhlik, *Navigating the Anticommons for Pharmaceutical Patents: Steady the Course on Hatch-Waxman*, *available at* http://www.law.uchicago.edu/lawecon/index.html (2004).

209. Heller & Eisenberg, *supra* note 11, at 698.

property in common, and no person has a right to exclude other persons from using that property, those people tend to overuse the property because there is no incentive to conserve the property.[210] The solution to the Tragedy of the Commons is to provide private property rights to individuals using the former commons property.[211] Meanwhile, the Tragedy of the Anticommons theory holds the opposite: if too many people own private property rights in a piece of property, then the rights may block one another, and thus, no one person has an effective right to use the property.[212] This problem leads to under-use of the property.[213] Heller and Eisenberg apply this theory to biomedical research and assert: "[a] proliferation of intellectual property rights upstream may be stifling life-saving innovations further downstream in the course of research and product development."[214]

Heller and Eisenberg believe that an anticommons can arise either through "creating too many concurrent fragments of intellectual property rights in potential future products or by permitting too many upstream patent owners to stack licenses on top of the future discoveries of downstream users."[215] Heller and Eisenberg provide two examples of ways in which the government might create too many fragments of intellectual property rights in upstream research.[216] The first involves potential patents in gene fragments or genes.[217] The second involves potential patents in gene receptors, which are useful to screen potential pharmaceutical products.[218] In both examples, the developer of a commercially useful end product, such as therapeutic proteins or genetic diagnostic tests, might need to obtain multiple licenses to gene fragments, genes, or receptors to use the downstream innovation.[219] Heller and Eisenberg assert that reach-through royalty license agreements "may lead to an anticommons as upstream owners stack overlapping and inconsistent claims on potential downstream products," which may provide "each upstream owner a continuing

210. *Id.*
211. *Id.*
212. *Id.*
213. *Id.*
214. *Id.*
215. *Id.* at 699.
216. *Id.*
217. *Id.*
218. *Id.*
219. *Id.*

right to be at the bargaining table as a research project moves downstream toward product development."[220]

Heller and Eisenberg recognize Coase's theorem, which posits that, assuming costless transactions, a tragedy can be avoided so long as people transfer and trade their rights.[221] Moreover, the researchers recognize that even in situations without costless transactions, owners of intellectual property rights have solved potential anticommons problems by bundling licenses to multiple rights, whether through patent pools or collective rights organizations such as ASCAP or BMI.[222] However, they argue that because of transaction costs in bundling rights, strategic behavior, and cognitive biases of the participants involved in the transfer of intellectual property rights in upstream biomedical research, a tragedy nonetheless may result.[223]

Heller and Eisenberg state that some of the difficulties in bundling rights include public institutions with limited resources for absorbing transaction costs and limited competence in fast-moving, market-orientated bargaining; difficulties in valuing a diverse set of techniques, reagents, DNA sequences, and instruments, which can impede the development of a standard distribution scheme; the heterogeneity of interests among private and public patent owners may complicate or defeat attempts to create standard licensing terms, which may lead to case-by-case negotiation of licensing terms; and licensing transaction costs may occur at the research and development stage when it is unclear whether the potential project will be successful.[224] They also argue that antitrust law may provide a disincentive for firms to bundle rights through patent pools.[225]

Heller and Eisenberg raise the heterogeneous interests of the rights holders as another potential impediment to solving the anticommons problem through collective action.[226] They argue that often private and public rights holders will have different goals in licensing patents.[227] For example, a public institution may be more concerned about the widespread dissemination of a publicly beneficial technology, whereas the private institution may be concerned

220. *Id.*
221. *Id.* at 698.
222. *Id.* at 700–701.
223. *Id.*
224. *Id.*
225. *Id.*
226. *Id.*
227. *Id.*

solely with financial gain.[228] Lastly, they believe that bargaining can break down between firms that want to bundle their rights because rights holders will overvalue their discoveries.[229]

Heller and Eisenberg conclude that because an anticommons is likely to arise and endure in biomedical research, "privatization must be carefully deployed to preserve the public goals of biomedical research."[230] They suggest that "[p]olicy-makers should seek to ensure coherent boundaries of upstream patents and to minimize restrictive licensing practices that interfere with downstream product development."[231]

VIII. RESEARCH AND ANALYSIS CONCERNING THE TRAGEDY OF THE ANTICOMMONS

This Part describes and analyzes several studies relevant to whether a Tragedy of the Anticommons exists that impedes biotechnology innovation. This Part also reviews an example of the anticommons phenomena in agricultural biotechnology.

A. Report of the NIH Working Group on Research Tools

In response to increasing difficulties in licensing or transferring proprietary rights in research tools—because owners and users are unable to agree on fair terms or negotiations are difficult and cause delays—the NIH formed a Working Group on Research Tools ("Group").[232] The Group was charged to "[i]nquire into problems encountered by NIH-funded investigators in obtaining access to patented research tools, including refusals to license, onerous royalty obligations, restrictions on the dissemination of materials and information, restrictions on the ability to collaborate with commercial firms, and advance commitments regarding intellectual property rights in future discoveries."[233] The Group was also directed to "[i]dentify and assess possible NIH responses in light of the competing interests of intellectual property owners and re-

228. *Id.*
229. *Id.*
230. *Id.* at 701.
231. *Id.*
232. NIH REPORT, *supra* note 2.
233. *Id.*

search users and the role of NIH as a public institution and research sponsor."[234] The Group focused its analysis on the terms of access to research tools in transactions involving NIH grantees.[235] The Group examined the issues from the perspective of the three stakeholders involved in transactions of research tools: bench scientists, university technology transfer office professionals, and private firms.[236]

The Group questioned bench scientists who import and export research tools.[237] The Group found a "rising frustration" among academic and industry bench scientists concerning delays caused by negotiating the transfer of IP rights in research when attempting to import research tools.[238] In addition, industry scientists expressed frustration concerning delays in access to research tools created by NIH-funded or taxpayer-funded research.[239] Scientists in academia and industry would like "access to research tools streamlined, expedited, and rationalized."[240] Interestingly, bench scientists who export research tools had two divergent opinions concerning the ease of access and availability of those research tools.[241] Some believe that research tools should be readily available and freely distributed, consistent with their desire for access to the tools that others have developed.[242] Others desire to "capture the market value of research tools that they have developed for themselves and their institutions through the terms of patent licenses . . . ."[243] Moreover, scientists who develop new research tools tend to overvalue those tools, often undervaluing the number of other tools necessary to research a biological problem.[244] Additionally, the value of a tool is difficult to predict and agree upon.[245] There is no consensus among scientists on how to distribute and value research tools, leading to increased frustration.[246]

The Group also questioned university technology transfer professionals concerning issues raised in importing and exporting

234. *Id.*
235. *Id.*
236. *Id.*
237. *Id.*
238. *Id.*
239. *Id.*
240. *Id.*
241. *Id.*
242. *Id.*
243. *Id.*
244. *Id.*
245. *Id.*
246. *Id.*

research tools.[247] The Group noted that responses focused on problems of importing research tools from universities and, particularly, private institutions.[248] Some of those problems include: increased administrative burden of reviewing and negotiating an increasing number of transfer agreements; limitations on publication or dissemination of the results of research;[249] ownership of or access to rights to future discoveries made when using the licensed research tools;[250] restrictions on how research tools may be used, which may prohibit sharing materials with other researchers, sending them to other institutions, using them for commercial purposes, or using them in research that another firm has funded;[251] and agreements that require universities to indemnify providers against liability arising from use of research tools.[252] Notably, the Group found that universities often used transfer agreements with terms similar to those discussed below when exporting research tools.[253]

Finally, the Group questioned private firms concerning access to research tools.[254] The Group notes that the perspectives of private

247. *Id.*

248. *Id.*

249. *Id.* The Group notes:

> Many universities have policies that limit their ability to agree to restrictions on publication of research results .... Objectionable terms in proposed agreements include: confidentiality provisions that are so far-reaching in their coverage as to interfere with effective publication of research results, presentations at conferences, or validation of results by other investigators; requirements for approval from the provider prior to submission of manuscripts for publication; and unreasonable delays in publication .... Some universities will not agree to any restrictions or delays in publication, but most will agree to delays of 30, 60, or even 90 days to permit the provider to request deletion of company confidential information that it supplied or to get a patent application on file.

Id.

250. *Id.* This is a particularly thorny issue. *Id.* Universities are confronted with violating obligations to current and past research sponsors by contracting away rights to future discoveries developed using a proprietary research tool. *Id.* Moreover, universities "fear that precommitments to license future discoveries of research tools, interfere with future technology transfer to other firms, and conflict with the university's stewardship of its inventions for the public benefit." *Id.* "Options or rights of first refusal to license future discoveries raise some of the same problems as precommitted licenses." *Id.* "Some universities ... mortgage their speculative future intellectual property so that the research may go forward, while others are unable to arrive at mutually agreeable terms and have to tell their scientists to forego use of certain research tools entirely." *Id.*

251. *Id.*

252. *Id.*

253. *Id.*

254. *Id.*

firms on the issue of access to research tools differs depending on the nature of the tool, the relationship between the firm's business strategy and the tool, and the importance to the firm of university-based research using the tool.[255] Some biotechnology firms hope to sell pharmaceuticals to consumers, and thus align consumer interests somewhat with those of pharmaceutical companies.[256] However, other biotechnology firms market and sell research tools to other firms as part of their business strategy.[257] Whether a private firm is willing to make research tools available to universities or others at all depends on the competitive advantage that the tool provides to the firm.[258] If the firm allows others to license the research tool, it likely will reserve a high degree of control over dissemination, use, and disclosure, along with an ability to recover some value in return.[259]

The Group found that private firms realize some benefits in providing access to research tools.[260] Some of these benefits include: goodwill developed between the private firm and the public sector, which may lead to opportunities to collaborate with university scientists;[261] an opportunity to learn more about the firm's products from experts in a particular area;[262] and discoveries with potential commercial applications from which a firm might profit.[263] The Group also found that private firms realize risks in providing access to research tools as well.[264] Some of those risks include: their own proprietary tools might be used in ways to advance the interests of a competitor, which can include a university scientist with a similar research agenda;[265] future intellectual property rights in discoveries

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255. *Id.*

256. *Id.*

257. *Id.*

258. *Id.*

259. *Id.*

260. *Id.*

261. *Id.* Firms often need to collaborate with the public sector "to further the interests of their research scientists, to obtain certain research capabilities and expertise, and to stay abreast of the most important advances in science." *Id.* Moreover, many firms were birthed in academia and feel a strong pressure from their scientists to maintain ties to academia. *Id.*

262. *Id.* ("Biotechnology firms often have limited internal research capabilities for exploring the fundamental biology questions related to their products and potential products, and even large pharmaceutical companies find that academic scientists can sometimes perform research that they are not set up to handle in-house.").

263. *Id.* ("Some firms have not yet obtained a commercially valuable discovery from a university as a result of providing a research tool, but many firms count this possibility as an essential quid pro quo for providing their proprietary tools to a university free of charge.").

264. *Id.*

265. *Id.* ("People from other firms noted that they had been 'burned' by scientists who entered into deals with multiple companies. Many firms try to manage this risk by

that university scientists make using proprietary research tools will be licensed to competitors of the owner of the tools;[266] losing proprietary rights through disclosure by academics;[267] and the risk of liability for harm caused by the use of tools by scientists and institutions that they cannot control.[268]

Additional risks concern specific tools.[269] For example, firms are concerned about licensing proprietary therapeutic compounds for scientists to use in research because a university may discover and patent a new use for the compound, thereby blocking the private firm's development of the compound.[270] Moreover, loss of control over how the compound is used and what is done with the compound because of concerns related to discovering information could affect whether the compound receives FDA approval.[271] Firms are also concerned about licensing a research tool such as a molecule (for example, a receptor) that plays a role in a disease pathway that is not fully understood, because if the patent on the molecule itself does not cover the ultimate therapeutic product, "the firm [may] quickly lose its competitive advantage."[272]

The licensing of research tools that may have a broad application to many research problems also provides substantial risks to private firms.[273] These risks involve appropriating some value from licensing that particular tool.[274] A major risk arises when those tools are made available to academic researchers, as it may undermine sales to paying customers by causing them to "use the data generated by the academic researchers rather than buying the tool for use in their own internal research."[275]

The Group noted that private firms concurred in complaining that a university's position on fair terms of access to research tools depended on whether the university was importing or exporting

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forbidding the use of their tools in research that is subject to licensing obligations to other firms.").

266. *Id.*

267. *Id.*

268. *Id.*

269. *Id.*

270. *Id.* ("A typical mechanism for managing this risk is to seek a grant-back of a nonexclusive, royalty-free license to any improvements and new uses of the proprietary materials."). Many firms, however, desire an exclusive license to improvements. *Id.*

271. *Id.*

272. *Id.* ("If the firm makes the molecule available to a university scientist, the only way to ensure that it is not undermining its own proprietary advantage may be to secure some form of reach-through rights to future discoveries.").

273. *Id.*

274. *Id.*

275. *Id.*

tools.[276] As one lawyer for a small biotechnology start-up stated, "'[u]niversities want it both ways. They want to be commercial academic environments when it comes to accessing technology that others have developed. . . .'"[277] Private firms also complained that universities distort the value of their research tools and fail to comprehend the costs and risks related to product development,[278] and are unduly slow and cautious in negotiating deals.[279] "Many companies complained about universities granting exclusive licenses for government-funded research tools, arguing that such tools should be made broadly available on 'reasonable' terms."[280] Firms also complained about university demands of shared ownership of future discoveries and reach-through royalties on future products.[281] "Virtually every firm . . . believed that restricted access to research tools is impeding the rapid advance of research and that the problem is getting worse."[282]

The Group concluded its analysis by recommending various steps that the NIH could take to provide greater access to research tools.[283] These steps include: promotion of "free dissemination of research tools without legal agreements whenever possible, especially when the prospect of commercial gain is remote";[284] promotion of use of the Uniform Biological Materials Transfer Agreement "and the development of other standard agreements to reduce the need for case-by-case review and negotiations";[285] development and dissemination of "guidelines for recipients of NIH funds as to what terms are reasonable in licenses and MTAs, addressing both importing of research tools owned by other institutions and exporting of research tools created with NIH funds";[286] review of "policies with regard to dissemination of research tools generated under its intramural and extramural

276. *Id.*
277. *Id.*
278. *Id.*
279. *Id.*
280. *Id.* ("One firm that has long taken the position that research tools should be licensed nonexclusively noted that universities seem to be coming around to this view, although another major pharmaceutical firm observed a growing problem of universities granting exclusive licenses on research tools to firms that refuse to grant sublicenses.").
281. *Id.* ("[S]tacking royalty obligations can make a significant dent in the profit expectations of firms that might develop and market the end products themselves, thereby undermining the commercial attractiveness of potential products.").
282. *Id.*
283. *Id.*
284. *Id.*
285. *Id.*
286. *Id.*

funding, and revise and strengthen those policies consistent with the recommendations in this report";[287] and promotion of "the establishment of a research tools forum for the biomedical research and development community."[288]

B. Research Tool Patenting and Licensing and Biomedical Innovation

In a recent study, Professors Walsh, Arora, and Cohen gathered information, primarily through interviews with IP attorneys, business managers, and scientists from ten pharmaceutical firms and fifteen biotech firms, as well as university researchers and technology transfer officers from six universities, patent lawyers, government and trade association personnel, and archival data, to analyze how changes in patenting practices and in the law have affected innovation in the biotechnology sector.[289] Their article concludes that "drug discovery has not been substantially impeded"[290] regardless of an increase in the number of patents on research tools in the biotechnology industry and certain conditions in the biotechnology industry increasing the likelihood that an anticommons will develop. The article also finds that the patenting of research tools has not stifled university research.[291] The authors note, "the vast majority of respondents say that there are no cases in which valuable research projects were stopped because of IP problems relating to research inputs."[292]

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287. *Id.*

288. *Id.*

289. WALSCH ET AL., *supra* note 14, at 285.

290. *Id.* at 285, 293–97. The authors argue that several preconditions exist which may facilitate an anticommons in the biotechnology sector. These conditions are: a rapid growth of biotechnology patents over the past 15 years; the numbers and diversity of entities involved in the biotechnology sector has grown; and the number of patents on research tools has increased. *Id.*

291. *Id.* at 285. The article notes that there is evidence that patents are interfering with university research with restrictions on the use of patented genetic diagnostics. *Id.* The article also notes that "there is, also, some evidence of delays associated with negotiating access to patented research tools, and there are areas in which patents over targets limit access and where access to foundational discoveries can be restricted." *Id.* at 286. Moreover, university research is impacted because research is redirected to areas where there does not exist a thicket of patents. *Id.*

292. *Id.* at 286. The authors state that "Although we have no systematic data on projects never pursued, our findings on the absence of breakdowns is consistent with the notion that there are relatively few cases where otherwise commercially promising projects are not undertaken because IP on research tools." *Id.* at 303.

The authors examined the impediments to drug discovery that an anticommons in biotechnology may cause.[293] The authors specifically examined three potential problems: breakdowns in negotiations over rights, royalty stacking, and excessive licensing schemes.[294] The authors found no evidence of breakdowns in negotiations concerning the licensing of patent rights that lead to the end of a research and development effort.[295]

The authors also found that "royalty stacking did not represent a significant or pervasive threat to ongoing R&D projects .... Although about half of respondents complained about licensing costs for research tools, nearly all of those concerned about licensing costs also went on to say that the research always went forward."[296] According to the authors, three primary factors contribute to the above result: (1) the total amount of royalty or licensing fees that are accumulated do not result in a project becoming a loss; (2) if the amount of the royalty or licensing fee does push the project into a loss, then the participants will negotiate an off-set to the royalty amount to allow the project to go forward; and (3) in the few cases where such a problem might occur, the problem is anticipated.[297]

Finally, the authors found that the productivity gains from the licensing of research tools outweighed industry participant concerns over heightened licensing fees resulting from the boom in the

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293. *Id.* at 297.

294. *Id.*

295. *Id.* at 298. The authors note:

> Numerous respondents reported that they did not initiate or had dropped projects if they learned another firm had already acquired a proprietary position on a drug they were considering developing—that is, on the output of a drug discovery and testing process. But that is quite different from other firms having IP for the research tools—the inputs into the discovery process.

Id.

296. *Id.* at 299. The authors note:

> One of our other biotechnology respondents suggested, however, that 'the royalty burden can become onerous' and that the stacking of royalties 'comes up pretty regularly now' with the proliferation of IP [, however, even in that case,] respondent said that no projects had ever been stopped because of royalty stacking .... [Additionally] one respondent, an IP lawyer, ... said that [in cases with too many claimants of royalty percentages] projects were stopped existed, but client privilege prevented the respondent from giving details.

Id.

297. *Id.* at 300.

patenting of research tools.[298] The authors also found, however, that small start-up firms and universities find the licensing fees for research tools prohibitively expensive.[299] The authors note that there are non-economic costs such as publication restrictions for university researchers.[300]

The authors distinguish their analysis of the need for multiple rights to invent a commercially viable product—the anticommons problem—from the need for a foundational upstream discovery, e.g., one particular research tool that is critical for the development of a commercially viable downstream product.[301] The authors examine whether restricted access to a particular research tool, such as exclusive licensing, provides an obstacle to biotech innovation.[302] In a National Research Council report titled, "Intellectual Property Rights and Research Tools in Molecular Biology," the authors review several examples of situations involving restricted access.[303] These examples, particularly the polymerase chain reaction ("PCR") technology, CellPro, and the Geron embryonic stem cell matter, appear to demonstrate that restrictive licensing terms may reduce access to research tools and impede the development of commercial products.[304] The authors note, however, that "[e]ven where universities employ restrictive licensing terms . . ., it is not clear that such a practice diminishes follow on discovery, at least when applied to smaller firms."[305]

The authors also examine transaction costs related to the increasing number of research tool patents, such as negotiations, litigation, inventions around patented inventions, overseas research, and the monitoring of the use of a firm's intellectual

298. *Id.* at 301.

299. *Id.* at 302. "Some firms (particularly genomics firms) holding rights over research tools did, however, offer discounted terms for university and government researchers." *Id.*

300. *Id.* The authors are unsure of whether these costs apply to license agreements between industry and university participants concerning inputs to academic research. *Id.*

301. *Id.* at 305.

302. *Id.*

303. *Id.*

304. *Id.* at 305–309.

305. *Id.* at 309. The authors also discuss widespread complaints from universities, biotechnology firms and pharmaceutical firms over patentholders' assertion of exclusivity over an important class of research tools, namely 'targets,' which refers to any cell receptor, enzyme, or other protein implicated in a disease, thus representing a promising locus for drug intervention. *Id.* at 310. While the authors note that they do not have systematic data on the frequency of the limitations of access to targets, the authors state that "[f]rom interviews and secondary sources . . ., we heard of a number of prominent examples of firms' being accused of asserting exclusivity over (or allowing only limited access to) a target." *Id.* at 312. However, the authors report that while there is "some evidence of researchers being excluded, we do not find a failure to exploit a target." *Id.* at 314.

property.[306] The authors report that a third of all respondents stated that transaction costs cause delays and add to the overall cost of research.[307] Moreover, the average litigation costs are between $1–10 million per side and, thus, are likely to be a significant cost related to licensing patents in the biomedical field.[308] Additionally, the opportunity costs are likely to be large considering the time-intensive burden of litigation on firm managers and scientists.[309] The authors state that for large firms the real out-of-pocket costs and opportunity costs are low relative to the large firm budget for research and development.[310] However, the authors note that those costs for small firms could be a significant burden.[311]

The authors report that there is "only limited support for the idea that negotiations over rights stymie precommercial research conducted in universities."[312] The authors highlight one notable exception: "the case of clinical research based on diagnostic tests using patented technologies."[313] In fact, "one study found that 25 percent of laboratory physicians reported abandoning a clinical test because of patents."[314] The authors concluded, however, that while some firms are willing to assert patents against universities performing patented diagnostic tests and "at least some labs are stopping their testing as a result," the majority of labs are continuing to test.[315]

The authors review government response and private firm and university strategies dealing with the relatively high level of patenting of research tools.[316] First, contracting is not difficult.[317]

306. *Id.*

307. *Id.*

308. *Id.* at 315.

309. *Id.* The authors also note the significant time loss involved in researching and examining potentially relevant patents to the proposed research project: "One attorney responsible for evaluating research tool IP from a large pharmaceutical firm provided estimates for the time attorneys were occupied with evaluating the IP of third parties and the time associated with actual negotiations that implied a total of $2 million in annual expenses." *Id.*

310. *Id.* at 316.

311. *Id.*

312. *Id.* at 317.

313. *Id.*

314. *Id.* at 318.

315. *Id.* The authors report that another potential problem includes the costs associated with delays in negotiating access to research materials or material transfer agreements. *Id.* at 319. As to that issue, the authors conclude that "to the degree that the patenting of biomedical discoveries may impose additional costs and delays in material transfers it is largely because Bayh-Dole and related acts have provided university administrations, and especially their technology transfer offices, a vested commercial interest in the disposition of intellectual property." *Id.*

316. *Id.* at 322.

317. *Id.*

Firms often deal with only a handful of patents on inputs.[318] Second, firms and universities can often ignore patents, especially because infringement of research tool patents is difficult to detect.[319] The authors report that some firms may be reluctant to file patent infringement actions against universities involved in non-commercial research for fear of low damage awards or negative press.[320] Moreover, firms often will not aggressively enforce their patents because of the cost of litigation.[321] Third, some firms may use patented technology offshore to avoid infringement.[322] Fourth, some firms may invent-around the claims in the patents.[323] The authors conclude that between contracting and current practices, "firms were able to greatly reduce the complexity of the patent landscape."[324]

The authors also review institutional responses by firms, the NIH, the USPTO, and courts designed to increase access to research tools.[325] Firms, along with other institutions, have co-

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318. *Id.* The authors report that,

> Several companies with patents on targets noted that, in addition to trying to develop their own therapeutics, they include the liberal and broad licensing of those targets to others as part of their business model, reflecting a belief on the part of some holders of target patents that by giving several firms a nonexclusive license they increase the chances that one will discover a useful drug .... Liberal licensing practices are also encouraged to the extent that inventing around tool patents is feasible, ... [u]nder such circumstances, patentholders are more willing to license on reasonable terms assuming the prospective user does not invent around to begin with.

Id. at 323.

319. *Id.* at 324. University researchers often will rely upon a "research exemption," however, the Federal Circuit in Madey v. Duke University has interpreted the exemption very narrowly. *Id.* at 325 (citing 307 F.3d 1351 (Fed. Cir. 2002)). Additionally, the authors found that a third of industrial respondents, and all university or government lab respondents, "acknowledged occasionally using patented research tools without a license, and most respondents suggested that infringement by others is widespread." *Id.* at 327. Also, researchers stated that partly because there is a belief that research tools are invalid or very narrow, researchers would be willing to challenge the patents in court. *Id.* at 328. Finally, "because of the long drug development process, the 6-year statute of limitations may expire before infringement is detected." *Id.*

320. *Id.* at 325. Moreover, members of the university community may sanction overly aggressive behavior and are consumers of the products or services of the private firms. *Id.* Also, private firms and universities have an incentive to develop good relationships because of the need to exchange information. *Id.* However, private firms will enforce their patents against universities that become competitors. *Id.*

321. *Id.* at 328.

322. *Id.*

323. *Id.*

324. *Id.*

325. *Id.*

sponsored public and quasi-public databases of information.[326] The NIH has championed the cause of obtaining access to research tools for university scientists.[327] The USPTO has heightened the requirement for satisfying the utility obligation for patentability.[328] Furthermore, the authors report that respondents cite several recent Federal Circuit cases that have either invalidated research tool patents or limited the scope of the claims of those patents.[329]

The authors state that the anticommons has not emerged as especially problematic.[330] The authors also state that access to foundational upstream discoveries has not yet emerged as a problem, but there is a prospect that a problem might develop and "ongoing scrutiny is warranted."[331] Finally, the authors conclude that "the biomedical enterprise seems to be succeeding, albeit with some difficulties, in developing an accommodation that incorporates both the need to provide strong incentives to conduct research and development and the need to maintain free space for discovery."[332]

C. The Preservation of Open Science

Professor David proposes that public policy should ensure that the Republic of Science and the Regime of Technology remain distinct and that a productive balance be maintained between them.[333] David criticizes both Walsh's attempt to find evidence of a "Tragedy of the Anticommons" and Walsh's interpretation of that evidence.[334] David asserts that those who desire broader intellectual property rights should bear the burden to demonstrate that the expansion of existing rights will not be economically damaging.[335]

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326. *Id.*
327. *Id.*
328. *Id.* at 329.
329. *Id.* at 330.
330. *Id.* at 331.
331. *Id.*
332. *Id.* at 335–36. The authors note that as technology changes and new court decisions, such as *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002), are published, the issues reviewed in this Article may need to be revisited. WALSCH ET AL., *supra* note 14, at 336.
333. David, *supra* note 18, at 5. Professor David makes an important distinction between "business support for academic style R&D—as distinguished from industrial contracting for university based applications oriented research with intellectual property rights assigned to the sponsoring firms . . . ." *Id.* at 8.
334. *Id.* at 15–16.
335. *Id.* at 16.

The Republic of Science consists of basic science researchers who receive funding from public sources searching for knowledge.[336] The Regime of Technology includes private firms that seek to develop commercial products and acquire proprietary interests in applied technology.[337] David states that several trends—university patenting of research tools spurred by the passage of the Bayh-Dole Act, the "concerted effort by all parties to secure copyright protection for the electronic production and distribution of information," and "growing efforts to assert and enforce intellectual property rights over scientific and technological knowledge"—have given greater control of technology to private interests at the expense of the public domain.[338]

The conditions that support the Regime of Technology are not conducive to the development of reliable knowledge.[339] The purpose of the Regime of Technology is to generate stock wealth through profits from "existing data, information[,] and knowledge, and therefore requires the control of the knowledge through secrecy, or exclusive possession of the right to its commercial exploitation."[340]

David notes that the following norms govern the Republic of Science: communalism, universalism, disinterestedness, originality, and skepticism.[341] These norms recognize that the development of knowledge is a social process.[342] Specifically, knowledge is developed in a cooperative manner through the open disclosure of new knowledge and peer testing of that knowledge.[343] The incentive provided to members of the Republic of Science relates to the development of "collegiate reputations and . . . material and nonpecuniary rewards. . . ."[344] In addition, the temptation to free-ride on the works of others exists within the Republic of Science, just as it does in the Regime of Technology; however, the system of norms in the Republic of Science has withstood the free-rider problem and has conveyed "some positive, functional value" to a substantial

336. *Id.* at 5.

337. *Id.*

338. *Id.* at 9.

339. *Id.* at 5.

340. *Id.*

341. *Id.* at 3. For a further discussion of the norms of science, see Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987).

342. David, *supra* note 18, at 3.

343. *Id.*

344. *Id.* The benefits can include "reputational standing and the esteem of colleagues, enhanced access to research resources, formal organizational recognition through promotions accompanied by higher salary, accession to positions of authority and influence within professional bodies and public institutions, [and] the award of prizes and honors." *Id.* at 4.

number of scientists working in the Regime and, consequently, has benefited the public through the creation and distribution of knowledge.[345] David also extols the benefits of an incentive system based on good reputation and openness because this system encourages the "rapid validation of findings, and reduces excess duplication of research efforts."[346] A proprietary rights system that encourages secrecy and a race to priority will potentially have a problem with validating findings and managing duplicative research efforts.[347] Meanwhile, the wide sharing of information helps to place information in the possession of the people who can best use it, even if these people are not the original discoverer or inventor.[348] Moreover, because the incentive structure largely consists of peer-provided benefits, researchers will choose to investigate problems that others have reviewed, thereby achieving appreciation among peers.[349] This results in a bias toward "'research spillovers,' rather than 'product-design spillovers' in the sphere of commercial innovation."[350]

David asserts that the structure and purposes of the Republic of Science are better suited to develop reliable knowledge, and the Republic of Science must remain distinct from the Regime of Technology.[351] David explores the ways that "public expenditures for the support of open science serve to enhance the value of commercially-oriented R&D as a socially productive and privately profitable form of investment."[352]

David discusses the Tragedy of the Anticommons in the context of the Walsh Study's attempt to gather empirical evidence to determine whether a serious Tragedy of the Anticommons had emerged.[353] The "thrust of their 'findings' was that while there were

345. *Id.* at 3.
346. *Id.* at 4.
347. *Id.*
348. *Id.*
349. *Id.*
350. *Id.*
351. *Id.* at 5.
352. *Id.* David points to the spillovers of applied technology which have originated from basic research such as, "airline reservation systems, packet switching for high-speed telephone traffic, the Internet communication protocols, the Global Positioning System, and computer simulation methods for the visualization of molecular structures." *Id.* at 5–6. David also points to the benefit of having an expansive knowledge base developed from basic research. *Id.* A knowledge base that often informs the applied researcher whether a specific research agenda is plausible or not, which results in certainty in investment. *Id.* at 7. David also states that universities engaged in basic research provide an excellent training ground for young researchers that are often employed by private firms. *Id.*
353. *Id.* at 13.

a few isolated instances of serious difficulties in working out the IPR arrangements among firms, and between firms and universities, their interviews disclosed nothing resembling a 'tragedy.'"[354] David criticizes the study for failing to describe the interview protocol followed in the survey.[355] David notes that the form of the questions may compel an interviewee to state that there is no problem when in fact there is one.[356] For example, survey respondents may have stated that rights holders do not enforce their rights against potential infringing firms and, thus, there is no problem.[357] David argues that this conclusion is misleading because there merely has not been a cause.[358] "The proper conclusion is: We can't say what the effect of the IPR regime will be in this instance, except that when a cease and desist injunction is brought against one of these professors, and her university is charged with patent infringement and sued for damages . . ., it is going to be a big shock."[359]

David states that interpreting the evidence can be problematic where the interpretation depends on whether the researcher approaches the Tragedy of the Anticommons in an economically naïve or sophisticated manner.[360] A naïve approach would be to believe that

> [P]arties to a potentially productive coalition will see only the value of cooperating for a common benefit, and will ignore the possible costs of contracting. So, if IPR has the effect of raising the parties [sic] valuation of their own contribution to the collective project, and makes it possible for them to deny others access to that contribution, the negotiation of cooperative agreements will be surprisingly difficult, and frequently these will fail. One should be able to find records, or elicit testimony of such failures. Look for them in order to test the 'anti-commons' hypothesis.[361]

According to David, a sophisticated analysis begins with Coase's theorem that "institutional arrangements that assigned property rights to some agents would only affect the efficiency of resource

354. *Id.* at 14.
355. *Id.*
356. *Id.*
357. *Id.*
358. *Id.*
359. *Id.*
360. *Id.*
361. *Id.* at 14–15.

allocation among them if there were zero 'costs of transacting,' of arriving at a contract in which the gains from trade would be secured for the collectivity and distributed among them."[362] David asserts that parties will consider ex ante the benefit of entering into any such contract, including the right to any rent streams and the costs of negotiating that contract.[363] A party conducting this analysis will take into consideration any institutional change that may alter the property rights of the parties and the consequent "affect of this on the nature of the contracting process and its costs."[364] If an institutional change occurs, it may modify each party's expectations of the benefits received from the transaction.[365] This, in turn, might raise the costs of the transaction to a point that renders some transactions foolish to complete, especially those projects that would result in a lower expected rate of return and those that are of a higher commercial or scientific risk.[366] Consequently, rational agents will avoid serious consideration of certain financially risky projects.[367] According to David, a rational agent would not report any higher frequency of blocked or abandoned projects after the institutional change than it would before such change.[368] Thus, in order to determine the effect of the institutional change, one must determine what might occur in a counterfactual world: "what projects that were not seriously considered, would have been considered."[369] Project consideration would likely shift then to those projects in which

> The distribution of initial property rights among the participating [parties] was already highly asymmetric[,] and the relative disparity in bargaining power would not be materially changed by the altered property rights regime, so the estimated transaction costs wouldn't be significantly affected; . . . [t]he private expected rate of return was higher than the norm for the previously undertaken projects, and so could justify the higher contracting costs of putting the collaboration

362. *Id.*
363. *Id.*
364. *Id.*
365. *Id.*
366. *Id.*
367. *Id.*
368. *Id.* This assumes that the rational agent is in possession of the information to make the decision that a particular transaction will or will not fail. For example, the perceived value of a particular research tool by the owner of the IP rights in the research tool is not known until the negotiations begin.
369. *Id.*

> together [and] . . . [t]he risk-return ratios for the projects undertaken are found to have been lower than those among the projects previously undertaken.[370]

Thus:

> [the] institutional change that raises the marginal costs of transactions of a particular kind need not actually increase the amount of resources consumed by such transactions; rather[,] it may push resources into other channels, and leave a gap between the marginal rates of return that the realized projects in that area yield (gross of negotiation expenses) and the rates of return on the other kinds of projects. That gap is a measure of the social burden of 'royalty stacking,' 'blocking patents,' etc.[371]

The gap of lost opportunities likely cannot be measured exactly because a different group of projects will be present after the institutional shift.[372]

David concludes that a search for evidence of a Tragedy of the Anticommons is difficult because the researcher is searching for counterfactual evidence.[373] She attempts to prove that if something had not happened, then something else would have happened that would have caused the world to be different than it is today.[374] David questions why the burden of proof to demonstrate the anticommons must be on the critics questioning the effect of the institutional shift.[375] David notes that the assumption that "competitive markets and well-defined private property rights can support a socially optimal equilibrium in the allocation of resources, . . . ceases to hold [true] in the realm of information and knowledge."[376] David would require those in favor of a stronger intellectual property rights regime to demonstrate that

the moves already made in that direction have not been economically damaging; that further encroachments into the public domain of scientific data and information would not be still more

370. *Id.*

371. *Id.*

372. *Id.* David suggest that, in principle, one could "examine the characteristics of the entire portfolio of research projects that were being undertaken before and after the institutional innovation." *Id.*

373. *Id.* at 16.

374. *Id.*

375. *Id.*

376. *Id.*

harmful; [and] that society would not benefit by adopting a policy that was just the opposite of the one they support.[377]

D. A Tragedy of the Anticommons in Biotechnology and Agriculture: The Golden Rice Problem

While not in the biomedical arena, a recent anticommons problem has arisen in the biotechnology and agriculture field. This anticommons example helps clarify the interaction between technology development, the patent thicket, and attempts to create products that are socially beneficial. Researchers at the Swiss Federal Institute of Technology transplanted certain genes from the daffodil plant into rice, creating a type of rice that is capable of producing a precursor chemical to vitamin A.[378] This so-called "golden rice" has the potential to alleviate life-threatening vitamin A deficiency in disadvantaged children throughout the world.[379] However, to create the rice, researchers had to use university-patented technology that had since been licensed to private agricultural biotechnology companies.[380] More than forty patents and contractual obligations associated with material transfer agreements presented obstacles to producing golden rice.[381] The private companies initially were unreceptive to providing licenses to the researchers and almost caused researchers to abandon the project.[382] However, because of the public debate in Europe concerning genetically modified crops, several private companies seized the "golden rice" opportunity to demonstrate that genetically modified crops can help the poor.[383] Consequently, the private companies transferred the necessary rights to the researchers so that they could develop and produce the crops.[384]

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377. *Id.*

378. Justin Gillis, *Researchers to Keep Some Biotech Rights*, WASH. POST, July 11, 2003, at E5.

379. *Id.*

380. *Id.*

381. Richard C. Atkinson et al., *Public Sector Collaboration for Agricultural IP Management*, 301 SCIENCE 174, 174 (July 11, 2003).

382. Gillis, *supra* note 378.

383. *Id.*

384. *Id.*

E. Analysis of Research

The NIH Study and the Walsh Study apparently reach conflicting results. The NIH Study finds "a rising frustration among scientists concerning delays in obtaining licenses for IP rights" and that "[v]irtually every [private] firm believe[s] that restricted access to research tools is impeding the rapid advance of research and that the problem is getting worse."[385] Moreover, the NIH Study reveals that technology transfer professionals have told scientists to forgo the use of some research tools when a university has been unable to agree with other parties on the terms of licenses for access to research tools.[386] In contrast, the Walsh Study asserts that "the vast majority of respondents say that there are no cases in which valuable research projects were stopped because of IP problems related to research inputs."[387] The Walsh Study also indicates that the anticommons has not emerged as particularly problematic.[388]

The two studies can be viewed as consistent. While the Walsh Study recognizes that certain conditions conducive to creating an anticommons exist, these conditions have not substantially impeded drug discovery.[389] The NIH Study might merely provide support for the conclusion that certain conditions exist that may allow an anticommons to develop.[390] Moreover, the Walsh Study occurred several years after the NIH Study. Perhaps the lessons learned from the NIH Study, combined with several additional years of experience in between the two studies, allowed industry participants to reduce the transaction costs involved in licensing patented research tools.

Professor David criticizes the Walsh Study for several reasons.[391] First, David wonders whether the questions drove the conclusions in the Walsh Study, particularly since the report does not provide the form of the questions.[392] The same criticism can be directed at the NIH Study. David further criticizes the Walsh Study for failing to accurately measure the impact of the Tragedy of the

385. NIH REPORT, *supra* note 2.
386. *Id.*
387. WALSCH ET AL., *supra* note 14, at 286.
388. *Id.*
389. *Id.* at 295–97.
390. *See generally* NIH REPORT, *supra* note 2.
391. David, *supra* note 18, at 13–15.
392. *Id.* at 13–14.

Anticommons.[393] David argues that rational actors will ignore certain projects—those yielding a low expected rate of return or carrying high scientific or commercial risk—that might otherwise be considered absent blocking patents and royalty stacking.[394] David points out that it is difficult to measure exactly how many projects a rational actor did not pursue simply because he would never consider such project in the first place. Accordingly, David argues that a search for evidence of a Tragedy of the Anticommons is difficult because the researcher must prove a counterfactual: that if something had not happened, then something else would have resulted.[395] The Walsh Study provides some support for this argument by noting that royalty stacking did not present a significant impediment to ongoing R&D projects, because in the few cases in which a problem did occur, the problem was anticipated.[396] Moreover, as described *infra*, the golden rice problem, albeit in agricultural biotechnology, provides an example of how easily an anticommons can develop for a commercial application that rational actors may not consider commercially viable yet may provide significant social benefits. As David argues, that particular type of breakdown may not be reported because a rational actor may never seriously consider development of that commercial application.[397]

An additional problem is that neither study provides the specific number of interviewees that responded in a particular way to a particular question. Thus, the amount of support provided for each conclusion in both studies is unclear.

Because of ambiguous findings concerning the existence of a Tragedy of the Anticommons, this Article suggests that additional studies be conducted to consider this potential problem. The Walsh Study, which suggests that an anticommons problem may develop and that ongoing scrutiny is warranted, supports this conclusion. Further study is especially important in light of recent Federal Circuit cases that clarify the limited scope of the experimental use exception to patent infringement.[398] Additionally, in a

393. *Id.* at 14–15.

394. *Id.*

395. *Id.* at 16.

396. WALSCH ET AL., *supra* note 14, at 300. The authors note that, "[o]ur interviews suggest that the main reasons why projects were not undertaken reflected considerations of technological opportunity, demand, and internal resource constraints, with expected licensing fees or 'tangles' or rights on tools playing a subordinate rule, salient for only those projects which were commercially less viable." *Id.* at 304.

397. David, *supra* note 18, at 14–15.

398. WALSCH ET AL., *supra* note 14, at 331, 335–36.

recent report entitled "Genetic Inventions, Intellectual Property Rights and Licensing Practices," the OECD recommended the continued monitoring of patenting and licensing of genetic inventions.[399] The OECD also recommended the collection and analysis of robust economic data to ensure that access does not become problematic.[400]

IX. POTENTIAL PROPOSED SOLUTIONS TO THE TRAGEDY OF THE ANTICOMMONS

This section describes and analyzes proposed solutions to the Tragedy of the Anticommons. Commentators have proposed changes in the utility requirement for patentability, a fair use exception to patent law, expansion of the experimental use exception, and the use of patent pools or collective rights organizations to overcome a Tragedy of the Anticommons.

A. Heightened Utility Requirement

1. Utility—Along with patent eligible subject matter, nonobviousness, and novelty, utility is a statutory prerequisite for an invention to be patentable.[401] At least one author has suggested that the utility requirement for patentability be used to curtail the number of patents issued on biotechnology inventions and research tools.[402] The Supreme Court, the Federal Circuit, and the USPTO have gone back and forth on restricting and expanding the use of the utility requirement as a device to allow or disallow

399. OECD REPORT, *supra* note 2, at 78.

400. *Id.*

401. 35 U.S.C. § 101 (2000) ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.").

402. Summers, *supra* note 22. *But see* Julian David Forman, Comment, *A Timing Perspective on the Utility Requirement in Biotechnology Patent Applications*, 12 ALB. L.J. SCI. & TECH. 647 (2002) (arguing that more restrictive PTO guidelines will hamper the progress of biotechnology invention by delaying patent protection until later stages of invention resulting in less investment in high-risk research and development).

patents on chemical or biotechnological inventions.[403] Most recently, the USPTO issued examination guidelines that set forth an arguably more restrictive view of utility than courts have previously required.[404]

The utility requirement ensures that the public receives an invention that is useful in exchange for the limited right to exclude others from practicing the invention.[405] An invention is useful if it "perform[s] some function of positive benefit to society," or achieves some practical utility.[406] Courts divide the utility requirement into three parts when analyzing whether an invention possess the requisite statutory utility: general utility, specific utility, and moral utility.[407] "An invention that possesses general utility is one that is operable, or capable of doing something."[408] "A finding of specific utility requires that the invention provide a solution to a stated problem."[409] "Courts may then question whether an invention is beneficial to society or if there is an absence of immoral purposes."[410] In the past, courts have laxly enforced the utility requirement, demanding that inventors meet only a very low threshold for patentability.[411]

The utility requirement is easily met for some types of inventions, i.e., mechanical or electrical inventions; however, the utility requirement is often a "problem with chemical compounds and

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403. *See* Brenner v. Manson, 383 U.S. 519 (1966); *In re* Brana, 51 F.3d 1560 (Fed. Cir. 1995); USPTO Utility Examination Guidelines, 66 Fed. Reg. 1092 (2001) [hereinafter 2001 Utility Examination Guidelines].

404. 2001 Utility Examination Guidelines, *supra* note 403.

405. *Brenner*, 383 U.S. at 534 ("The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.").

406. DONALD S. CHISUM, CHISUM ON PATENTS 4–2 (2003). *See also* INTELLECTUAL PROPERTY, *supra* note 8, at 315 ("Utility ordinarily presents a minimal requirement that the invention be capable of achieving a pragmatic result."); MUELLER, *supra* note 58, at 156 ("United States patent law requires that patentable inventions possess 'practical utility.' In other words, to be patentable an invention must have some real world use.").

407. ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 163 (2000); *see also* Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial DNA Sequences*, 23 AIPLA Q.J. 1, 5–6 (1995); Forman, *supra* note 402, at 650 ("The utility inquiry can be divided conceptually into three parts: general utility, specific utility, and moral (or beneficial) utility.").

408. Forman, *supra* note 402, at 650, n.16; *see* MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW 141 (2003) ("Courts, as well as the Patent and Trademark Office, have also employed the utility requirement to reject wholly inoperable inventions.").

409. Forman, *supra* note 402, at 650, n.16.

410. *Id.*

411. Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1007 n.78 (1997).

processes—particularly pharmaceutical compounds[,]" and biotechnology.[412] "In these fields, inventors sometimes synthesize compounds without a precise knowledge of how they may be used to achieve a practical working result."[413] Thus, a particular isolated and purified DNA sequence may have multiple potential downstream uses that are unknown to the researcher.[414] The only cited utility of an isolated and purified DNA sequence may be its use as an object of further research.[415]

In *Brenner v. Manson*, the Supreme Court examined the utility requirement as applied to chemical processes.[416] The examiner denied Manson's application, and the Board of Appeals later affirmed, on the ground that there was a failure to disclose any utility for the chemical compound that the process had produced.[417] The Court of Customs and Patent Appeals (CCPA)[418] reversed the Board of Appeals, stating, "'where a claimed process produces a known product it is not necessary to show utility for the product,' so long as the product 'is not alleged to be detrimental to the public interest.'"[419] The Supreme Court reversed the CCPA.[420] The Court rejected Manson's arguments that the applicant had demonstrated utility by showing one of the following: (1) that the claimed process produced a product under investigation by serious scientific researchers, (2) that the process produces the intended product, or (3) that an adjacent homologue[421] of the steroid that the applicant's process produces has tumor-inhibiting effects in mice.[422] The Court held that "[u]nless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad

412. CHISUM, *supra* note 406, at 4–2; INTELLECTUAL PROPERTY, *supra* note 8, at 315.

413. INTELLECTUAL PROPERTY, *supra* note 8, at 315.

414. Summers, *supra* note 22, at 478–479.

415. *Id.* at 479.

416. *Brenner*, 383 U.S. at 534.

417. *Id.* at 521.

418. The Court of Customs and Patent Appeals (CCPA) was the predecessor court of the U.S. Court of Appeals for the Federal Circuit.

419. *Brenner*, 383 U.S. at 522. (quoting *In re* Manson, 333 F.2d 234, 237–238 (1964)).

420. *Id.*

421. "'A homologous series is a family of chemically related compounds, the composition of which varies from member to member by CH[2] (one atom of carbon and two atoms of hydrogen) .... Chemists knowing the properties of one member of a series would in general know what to expect in adjacent members.'" *Id.* at 522 n.3 (quoting Application of Henze, 181 F.2d 196, 200–201 (1950)). The Court noted that there is a "'greater known unpredictability of compounds'" in the field of steroids. *Id.* at 532.

422. *Id.* at 531–533.

field."[423] The Court expressed concern that if a patent were allowed to issue on a claimed process, yielding a product with unknown utility, then the patent might encompass unknown areas of scientific development without providing the benefit to society—the substantial utility—that is at the heart of the quid pro quo that Congress had contemplated.[424] The Court stated, "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."[425]

The Supreme Court in *Brenner* clearly set forth a restrictive view of the utility doctrine, at least as applied to chemical processes. A patentee, under *Brenner*, can obtain a patent only after demonstrating a specific benefit from the patentee's claimed invention. The Federal Circuit in *In re Brana* examined the utility requirement in the context of pharmaceuticals and established a more lenient approach.[426] The court reversed a decision of the Board of Patent Appeals and Interferences, affirming an examiner's rejection of a patentee's claims because the claimed compounds lacked utility as antitumor substances.[427] The court framed the issue on appeal by asking "with regard to pharmaceutical inventions, what must the applicant prove regarding the practical utility or usefulness of the invention for which patent protection is sought[?]"[428] The court stated that applicants must provide sufficient evidence to convince a person skilled in the particular art that the invention possesses the asserted utility.[429] In this case, the evidence included a declaration with test results showing that several compounds within the scope of the claims exhibited significant antitumor activity against

423. *Id.* at 534–535.

424. *Id.*

425. *Id.* at 536.

426. *Brana*, 51 F.3d at 1560–61.

427. *Id.* at 1565. The Board of Patent Appeals and Interferences, in *In re Brana*, based its affirmance of the examiner's rejection on a lack of utility which violated 35 U.S.C. § 112, ¶ 1, not 35 U.S.C. § 101. *Id.* at 1564. Section 112, paragraph 1, of 35 U.S.C. states:

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, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Id. at 1564. The Federal Circuit thus reviewed the Board's affirmance based on section 112. *Id.*

428. *Id.* at 1564.

429. *Id.* at 1566–1567. The Court initially held that the PTO failed to carry its initial burden of challenging the presumptively correct assertion of utility. *Id.* at 1566. The Court considered the applicant's rebuttal evidence as an alternative basis for its holding that the claimed invention satisfied any utility requirement. *Id.* at 1567.

the standard tumor model in vivo.[430] Moreover, the court rejected the Commissioner's argument that in vivo tests in animals are insufficient to demonstrate utility because such tests are not reasonably predictive of the success of the compounds in treating cancer in humans.[431] The court stated that "[u]sefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development . . . [and t]he stage at which an invention in this field becomes useful is well before it is ready to be administered to humans."[432] The court noted that "[w]ere we to require [Food and Drug Administration] Phase II (significant testing on humans) in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures [to diseases]."[433]

In 1995, the same year in which the Federal Circuit issued *In re Brana*, the USPTO released the 1995 Examination Guidelines.[434] The Guidelines and *In re Brana* apparently represented an interpretation of the utility requirement that was much more lenient than that which the *Brenner* court had contemplated. Subsequently, a flood of patent applications covering so-called "ESTs" were submitted to the USPTO. ESTs are fragments of genes, usually with unknown biological function. In response to industry, academic, and government outcry concerning the patenting of ESTs, the USPTO released the 2001 Utility Examination Guidelines.[435] The 2001 Utility Examination Guidelines require a well-established utility in the art, i.e., a utility that a person of ordinary skill in the art would immediately appreciate or a demonstration of a specific, credible, and substantial utility.[436] The requirement that an invention have a specific, credible, and substantial utility excludes "nonspecific," "throw-away," or "insubstantial" utilities, "such as the use of a complex invention as landfill."[437] At least one author argues that the new guidelines will prevent the patenting of genes.[438]

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430. *Id.* at 1568.
431. *Id.* at 1568–1569.
432. *Id.* at 1569.
433. *Id.*
434. USPTO Utility Examination Guidelines, 60 Fed. Reg. 36,263 (July 14, 1995).
435. 2001 Utility Examination Guidelines, *supra* note 403.
436. *Id.*
437. *Id* at 1098.
438. Smith, *supra* note 42, at 749–50 (arguing that new guidelines will prevent the patenting of genes and deter investment in biotechnology companies).

2. Proposed Heightened Utility Requirement and Analysis—One author advocates adoption of a utility requirement that is more stringent than that set forth in the 2001 Utility Examination Guidelines.[439] The author states that broad patents in basic biotechnology research are improper because the development of today's patent law fails to account for two trends in modern biotechnology.[440] The first trend is that biotechnology research is unveiling science at an increasingly rudimentary level while patent law is becoming broader, thus threatening to remove fundamental building blocks of science from the public domain.[441] The second trend involves the Bayh-Dole Act, which provides an incentive for discoverers—particularly public discoverers—of rudimentary upstream research tools to patent those tools and license them to downstream commercial innovators.[442] The author reviews philosophical and economic rationales for patent law and concludes that those rationales support an even narrower utility requirement in light of the cited trends.[443] The proposed narrower utility requirement, for example, would require an applicant for a gene patent to disclose the encoded protein along with the function of that protein.[444]

Early patenting in the biotechnology innovation process is important to the continued growth and development of the industry. Biotechnology research and development is risky, complex, and uncertain, and heavily reliant upon venture capital funding.[445] A biotechnology start-up often has no revenue to fund research and development except through outside sources.[446] Patents provide biotechnology firms assets, often their only assets, with which to

439. Summers, *supra* note 22, at 477–78.

440. *Id.* at 476.

441. *Id.*

442. *Id.*

443. *Id.* at 477. The author asserts that the incentive to invent theory fails to justify a broad utility requirement because the traditional public sector is motivated by increasing the storehouse of public knowledge, not by potential patent rights, and the patentee of a patent directed to a DNA sequence which does not disclose the function of the protein it encodes will free ride on the efforts of subsequent researchers that discover that function. *Id.* at 487. The author also asserts that the incentive to disclose theory does not justify a broad utility requirement because a patent directed to a DNA sequence fails to disclose the uses of a research tool, and the information often disclosed is already known or will be publicly disclosed. *Id.* at 488. Finally, the author asserts that the incentive to innovate theory fails to justify a broad utility requirement because the "commercial value in biotechnology lies not in isolating a gene sequence, but further downstream once the gene's function has been determined." *Id.* at 491.

444. *Id.* at 480–81.

445. *See supra* notes 139–52 and accompanying text.

446. *Id.*

secure venture capital funding.[447] Without a patent, venture capitalists may be unwilling to invest in biotechnology research and development.[448] Furthermore, the FDA requires a bevy of clinical trials to test a compound, amounting to a significant investment of time and effort on the part of researchers. [449] Consequently, researchers in the pharmaceutical field have an interest in patenting pharmaceutical compounds early in the development process, even when the specific properties of that compound are not fully understood; a broader utility requirement may frustrate that interest. [450] Patents also are a valuable commodity to trade to potential partners who have the expertise to further develop a product or who are able to get a product past any regulatory hurdles and release it to the market.[451] Accordingly, patents provide an incentive for venture capitalists to invest in the continued development and commercialization of biotechnology commercial applications.[452]

Heightening the utility requirement may make sense for ESTs with a minimal disclosed utility given the use of techniques such as high-throughput sequencing. However, the utility requirement should not prevent the patenting of research tools whose only purpose relates to the development or research of commercial applications. Some biotechnology companies *only* create research tools, and a market for those tools has developed.[453] Moreover, if research tools are not patentable, developers of those tools may use them in secret rather than disclosing them publicly.[454] Without public disclosure of the tools, competing firms may waste signifi-

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447. *Id.*

448. *Id.*

449. INTELLECTUAL PROPERTY, *supra* note 8, at 318:

> The utility requirement should be viewed in light of the considerable incentives chemists and biochemists possess to obtain patent protection on compounds of interest as soon as possible .... [I]n the case of pharmaceutical compounds, food and drug authorities require considerable product testing before the pharmaceutical can be broadly marketed. Before investing further time and effort on laboratory testing and clinical trials, actors in the pharmaceutical filed desire to obtain patent rights on promising compounds even where their particular properties are, as yet, not well understood. But when patent applications are filed too close to the laboratory bench, chemists and biotechnicians have discovered that the ordinarily dormant utility requirement has posed considerable obstacles.

Id.

450. *Id.*

451. *See supra* notes 139–52 and accompanying text.

452. *Id.*

453. NIH REPORT, *supra* note 2.

454. Forman, *supra* note 402, at 661.

cant resources duplicating research in order to develop a previously invented tool.[455]

Because of the ambiguous evidence of a Tragedy of the Anticommons, the utility requirement should not be heightened. A more stringent utility requirement may disrupt the valuable incentives that patents provide to invent, disclose, and innovate.

B. A Fair Use Exception to Patent Infringement

Professor Maureen O'Rourke argues that, because of several recent developments, current patent law doctrine fails to strike the proper balance between the grant of exclusive rights to encourage innovation and the maintenance of a vibrant public domain.[456] These developments include: fast-paced high technology, an expanded definition of patent eligible subject matter, the PTO issuing patents at a record rate, the impact of the Federal Circuit holding patents valid more often than prior courts, and an increased likelihood of situations in which the grant of a patent would be socially beneficial but a breakdown in bargaining is likely to result.[457] O'Rourke advocates the adoption of a fair use exception in patent law—similar to that in copyright law—to address any anticommons effects when the costs for any one entity to accumulate all the required licenses to develop a socially beneficial product or service is prohibitive.[458]

O'Rourke recognizes that though patent law does not have a broad scope limiting doctrine similar to that found in copyright law, patent law has other scope limiting doctrines.[459] Those doctrines include: the ability to reevaluate a patent's validity, the ability to construe claims, the reverse doctrine of equivalents, the doctrine of blocking patents, the experimental use exception, and

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455. *Id.* (arguing that the issuance of patents will deter rent seeking because the issuance of a patent itself communicates to firms that a particular problem has been solved and competitors should stop expending R&D dollars to solve that particular problem).

456. O'Rourke, *supra* note 24, at 1178–79.

457. *Id.*

458. *Id.* at 1177–79. The fair use exception to copyright infringement generally provides a privilege for one to use a copyrighted work in a reasonable manner without the owners consent. *Id.* at 1188. Effectively, the fair use exception "imposes a limited royalty-free compulsory license on the copyright owner: The party asserting the defense has infringed, but that infringement is excused." *Id.*

459. O'Rourke specifically references *Sony Corp. of America v. Universal City Studios, Inc.*, wherein the Supreme Court held that the fair use doctrine applied to excuse allegedly infringing copying of copyrighted broadcasts. *Id.* at 1188–1189 (citing 464 U.S 417 (1984)).

patent misuse.[460] O'Rourke notes that patent law may not have a broad fair use doctrine because, in contrast to the almost negligible costs of obtaining copyright protection, obtaining a patent can be very costly.[461] O'Rourke argues that even a combination of the above doctrines fails to match the prowess of the copyright fair use defense, which rectifies market failures that would render "exclusive rights overbroad and prevent socially efficient and desirable uses of the copyrighted work from occurring." [462] Market failures occurring in copyright law fall within three categories: "(i) high transaction costs that frustrate private bargaining[, including identifying, contacting, and contracting with multiple rights holders]; (ii) positive externalities that prevent the infringer from being able to pay the copyright owner's price for the license; and (iii) the failure of any market for the particular use to develop."[463]

According to O'Rourke, market failures are occurring more often in markets for patentable products.[464] O'Rourke relies upon domestic scholars and international movements to point to specific market failures that current patent doctrine does not remedy but that a fair use exception would remedy.[465] The market failures include: the liability of a researcher who infringes a patent in the course of verifying the functionality of the patented invention; subjecting a researcher who develops an improvement or alternative to a patented invention to liability, including an injunction; liability for infringing conduct such as teaching or research, wherein the infringer advances research without harming the patentee; and liability for a researcher who uses a patented invention to develop a non-infringing product.[466]

O'Rourke identifies five factors relevant to determining whether a fair use exception should apply to patent infringement: (1) the nature of the advance that the infringement represents,[467] (2) the

460. *Id.* at 1188–89.

461. *Id.* at 1185–1186.

462. *Id.* at 1187.

463. *Id.* at 1188.

464. *Id.* at 1187.

465. *Id.* at 1198–1202. O'Rourke also relies upon provisions of the Trade-Related Aspects of Intellectual Property Rights Agreement as providing "a strong international norm in favor of allowing socially beneficial infringements to occur" to justify adoption of a fair use exemption. *Id.* at 1202.

466. *Id.* at 1200.

467. *Id.* at 1205. This factor focuses on whether the infringing work is a major or minor advance in the art. *Id* at 1206. If the work is a major advance, then the public welfare is likely substantially improved and thus, the work is more likely a fair use. *Id.*

purpose of the infringing use,[468] (3) the nature and strength of the market failure that prevents a license from being concluded,[469] (4) the impact of the use on the patentee's incentives and overall social welfare,[470] and (5) the nature of the patented work.[471] Similar to the fair use analysis in copyright law, the court should balance the fair use factors to determine whether the fair use exception should apply to patent infringement.[472] Finally, if the court determines that the use is fair, then the court must determine whether the infringer should compensate the patentee with a royalty.[473]

O'Rourke applies the fair use factors to specific industries, including the software industry[474] and the biotechnology industry.[475] Specifically, O'Rourke reviews Heller and Eisenberg's Tragedy of the Anticommons theory and concludes that the doctrine of fair use can be used to excuse some infringement and alleviate anticommons concerns.[476] O'Rourke suggests that fair use "could be used to excuse infringement by researchers attempting to invent around the patent even when the eventual end product is to be marketed commercially."[477] She also states that fair use could be

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468. *Id* at 1205. This factor determines whether the use is non-commercial, indirectly commercial or commercial. *Id.* at 1206. A finding of commercial use increases the likelihood that fair use does not exist. *Id.*

469. *Id.* at 1205. This factor examines the specific market defect and how it impacts the market. *Id.* at 1206–07.

470. *Id.* at 1205. This factor focuses on whether widespread infringing use would adversely impact the market for the patented invention. *Id.* at 1207. Particularly, this factor examines the "social benefit to be gained by allowing the infringement balanced against the cost to the patentee, including the impact on incentives to invent." *Id.* "Harm to the patentee is likely to be greater when the infringement leads to a competitive product and it will be greatest when that product is also directly infringing." *Id* at 1207-08. Moreover, "[t]he courts should focus on the nature of both R&D and product-market competition in the particular industry." *Id* at 1208.

471. *Id.* at 1205. This factor examines whether the work is a pioneering work or a smaller advance over the prior work. *Id.* at 1208. If the work is pioneering, then the fair use right should be narrow. *Id.*

472. *Id.* at 1209. "The most important factors are the third and fourth which emphasize the reality of market conditions and the impact on the intellectual property balance. As in copyright law, no one factor would be determinative and fair use would be an equitable and affirmative defense with the burden of proof on the infringer." *Id.*

473. *Id.*

474. *Id* at 1211. O'Rourke argues that the fair use defense is needed to excuse reverse engineering to produce software compatible with the dominant operating system. *Id.* at 1212. She asserts that a fair use approach would allow the court with doctrinal latitude to consider policy concerns without contorting "existing patent doctrine to achieve a desirable result." *Id.* at 1230.

475. *Id.* at 1236-39.

476. *Id.* at 1237-38.

477. *Id* at 1238.

used in situations wherein a developer of a product has gathered almost all of the necessary licenses to bring a product to market, but because of a hold-out, is unable to license the final piece of technology needed.[478] The fair use doctrine might allow the developer of a product to move forward without the license from the holdout.[479] Finally, O'Rourke states that the mere presence of a fair use doctrine "may make patentees more willing to form institutions to decrease transaction costs."[480]

O'Rourke's suggested proposal for a fair use exception fills in the gaps between several patent law doctrines, including the experimental use exception and the reverse doctrine of equivalence, and attempts to preserve the incentive to invent that the patent grant provides. However, a broad, uncertain exception might erode the incentives that patents provide to invent, innovate, and disclose inventions. This outcome is particularly likely in the biotechnology industry, where research and development is uncertain and complex.[481] As discussed above, the biotechnology industry is capital intensive and relies upon the influx of funding from venture capitalists to continue innovating.[482] Strong and stable patent rights provide the necessary incentive for venture capitalists to invest in biotechnology companies.[483] A broad exception, the scope of which is determined only after litigation, may undermine the incentive to invest that stable and certain patents provide.

Moreover, a broad exception to copyright infringement may be justified because of the low threshold for obtaining, and the ease of securing, copyright protection for a work of authorship. Patent protection is only granted after a relatively extensive USPTO review. Furthermore, patents are subject to USPTO reexamination and court invalidation. The expense and time involved in obtaining a patent for a non-pioneering, yet patentable, invention may not be justified if a broad fair use defense is available. Notably, it is in precisely this type of case that the fair use defense may apply.[484] In these situations, an inventor may decide to keep an invention secret instead of attempting to obtain patent protection.[485] In addition, the effectiveness of the fair use exception for market failures

478. *Id.*
479. *Id.*
480. *Id.*
481. *See infra* Introduction.
482. *See infra* Part IV.
483. *See infra* Part IV.
484. O'Rourke, *supra* note 24, at 1208.
485. *See supra* notes 69–76 and accompanying text.

in copyrighted works may be overstated as the market still needs collective rights organizations such as BMI and ASCAP to address numerous failures.[486]

Professor O'Rourke provides the example of using the fair use doctrine to prevent a potential licensor from refusing to license to a product developer that has amassed almost all of the necessary licenses to bring a product to market.[487] At least one problem with the application of the fair use doctrine in this case is that the licensor may be refusing to license simply because the license fees are not acceptable. If the court applies the fair use doctrine, it must determine whether the requested license fees are reasonable.[488] The court is put in the position of valuing a piece of intellectual property and determining the appropriate amount of a license fee.[489] Though a court can determine a license fee, a collective rights organization or a patent pool is arguably better equipped to determine the value of a piece of intellectual property.[490]

As reviewed above, the evidence of a Tragedy of the Anticommons is, at best, unclear. Accordingly, it is unnecessary to weaken patent rights, a move that may undermine the incentives that patents provide to invent, disclose, and innovate.

C. The Experimental Use Exception

In a series of decisions, courts developed a common law exception to patent infringement relating to experimental use.[491] The exception recognized that "an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee."[492] Accordingly, if the researcher had a commercial intent or, in other words, an intent to profit, then the researcher's use of

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486. Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293, 1328 (1996).

487. O'Rourke, *supra* note 24, at 1239.

488. Merges, *supra* note 486, at 1317 ("Unless a special 'rate court' were established to administer these [licensing] disputes, each judge in each case would have to be educated about the industry, about appropriate [intellectual property rights] valuation ranges, and the like. These costs would clearly be large . . . .").

489. *Id.*

490. *Id.* Professor O'Rourke argues that in the biotechnology industry some players may be repeat players, but there is rapid market turnover which imposes negative externalities on the public. O'Rourke, *supra* note 24, at 1245.

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

492. Poppenhusen v. Falke, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279).

the patented invention would not be exempted from infringement.[493] Justice Story stated the rationale for the exception: "[i]t 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."[494] In recognition of the need to bring generic pharmaceuticals to market quickly, Congress enacted a statutory experimental use exception.[495] The exception is limited to pharmaceuticals and medical devices and use of the patented invention while preparing for clinical trials.[496] University scientists using patented research tools to further their research often rely upon these common law and statutory exceptions.[497] However, because of the very narrow scope of the exception, it is not clear that all the actions of those claiming the exception should be exempted from infringement. In recent years, because of the expansion of patentable inventions to research tools and the merger of public and private research, commentators have called upon Congress and the courts to broaden the experimental use

493. Sawin v. Guild, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813):

> "[T]he 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 (citation omitted). In other words, that the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.

Id. See also Ruth v. Stearns-Roger Mfg. Co., 13 F. Supp. 697, 703 (D. Colo. 1935); Chesterfield v. United States, 159 F. Supp. 371, 375–376 (Cl. Ct. 1958).

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

495. 35 U.S.C. § 271(e)(1) (1994). This section was enacted in response to *Roche Products v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), which held that Bolar's use of Roche's patented active ingredients of Dalmane for equivalency testing to satisfy federal requirements before marketing of the generic drug was not exempted from infringement. *Id.* at 867.

496. 35 U.S.C. § 271(e)(1) (1994).

497. *See* Biotech Strategies, *supra* note 147 ("[A National Academies of Sciences] survey showed that almost 80% of scientists at academic institutions and companies believed their research activities were immune under the [research use] exemption."); John W. Schlicher, *Biotechnology and the Patent System; Patent Law and Procedures for Biotechnology, Health Care and Other Industries*, 4 U. BALT. INTELL. PROP. L.J. 121, 139 (1996):

> While the words in the cases seemed somewhat narrower, most patent owners either understood (or operated under the implicit assumption) that others could conduct research using their inventions, when that research was designed to make other inventions, whether complementary or substitute, or to do research simply for the sake of doing research, historically the function of our universities.

Id.

exception.[498] However, in a recent Federal Circuit decision, the court interpreted the common law exception extremely narrowly.[499] Moreover, the Federal Circuit limited the reach of the already narrow statutory exception.[500]

1. Madey v. Duke University—In *Madey v. Duke University*, the Federal Circuit made clear that the common law experimental use defense did not apply to the use of patented inventions in university research that has even a remote commercial purpose, including merely furthering the university's legitimate business objectives.[501] The Federal Circuit reversed the district court's grant of summary judgment in favor of Duke, and held that the experimental use exception did not apply to Duke's use of Plaintiff Madey's patented laser technology.[502] Plaintiff Madey, a successful researcher in the laser research field, had joined Duke as a lab director and had moved his laser research laboratory there.[503] Madey owned two patents used in some of the equipment in the laboratory.[504] Duke eventually removed Madey as lab director, and Madey subsequently resigned from Duke.[505] Duke continued to use the lab equipment after Madey's resignation.[506] Madey then sued Duke for patent infringement.[507] The district court granted summary judgment to Duke, reasoning that Madey failed to raise a genuine issue of material fact as to whether Duke commercially benefited or intended to benefit commercially with respect to either patent.[508] The district court held that the experimental use exception applied to Duke's use of the patented inventions.[509]

On appeal, Madey asserted that the district court committed three errors: (1) the district court improperly shifted the burden of

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498. Eisenberg, *supra* note 10; Mueller, *supra* note 23; David L. Parker, *Patent Infringement Exemptions for Life Science Research*, 16 HOUS. J. INT'L L. 615 (1994); Israelsen, *Making, Using, Selling Without Infringing: an Examination of 35 U.S.C.(e) and the Experimental Use Exception to Patent Infringement*, 16 AIPLA Q.J. 457 (1989); Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051 (1988).

499. *Madey*, 307 F.3d 1351; *See* Jennifer Miller, *Sealing the Coffin on the Experimental Use Exception*, 2003 DUKE L. & TECH. REV. 12 (2003).

500. *Integra*, 331 F.3d 860. For further analysis of the *Madey* and *Integra* decisions, see MARTIN J. ADELMAN, 3-3 PATENT LAW PERSPECTIVES § 3.6(2) (2003).

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

502. *Id.*

503. *Id.*

504. *Id.*

505. *Id.* at 1353.

506. *Id.*

507. *Id.*

508. *Id.* at 1357.

509. *Id.*

proof to Madey to prove that Duke's use was not experimental; (2) the district court applied an overly broad version of the narrow experimental use exception; and (3) the district court relied upon overly general evidence not indicative of the specific propositions and findings of the experimental use exception.[510] The Federal Circuit agreed with Madey that the district court improperly shifted the burden of proof, had an overly broad conception of the experimental use exception, and relied on overly general evidence to support its finding of experimental use.[511]

Specifically, the Federal Circuit criticized the district court's formulations of the experimental use defense as overly broad. The district court stated that the experimental use defense applied to uses that "were solely for research, academic, or experimental purposes," and covered uses that were "made for experimental, non-profit purposes only."[512] The Federal Circuit stated that the defense was "very narrow and strictly limited [to] . . . actions performed 'for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.'"[513] "Further, use does not qualify for the experimental use defense when it is undertaken in the 'guise of scientific inquiry' but has 'definite, cognizable, and not insubstantial commercial purposes.'"[514] "[U]se is disqualified from the defense if it has the 'slightest commercial implication' [and] use in keeping with the legitimate business of the alleged infringer does not qualify for the experimental use defense."[515] The Federal Circuit reasoned that although major universities "often sanction and fund research projects with arguably no commercial application whatsoever . . . these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects, [increasing] the status of the institution[] and lur[ing] lucrative research grants, students and faculty."[516] The Federal Circuit concluded that the district court overemphasized Duke's non-profit nature and stated that the correct

510. *Id.* at 1361. *Madey* also argues that the experimental use exception no longer exists because it is inconsistent with *Warner-Jenkinson Co. v. Hilton-Davis Chem. Co.*, 520 U.S. 17 (1997), which held that intent plays no role in the application of the doctrine of equivalents. *Id.* at 1360. The Federal Circuit disagreed with Madey and concluded that the experimental use defense persists. *Id.* at 1361.

511. *Id.* at 1361–1363.

512. *Id.* at 1361 (quoting district court opinion at 9).

513. *Id.* at 1362 (quoting Embrex, Inc. v. Service Engineering Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000).

514. *Id.* at 1362 (quoting *Embrex*, 216 F.3d at 1349).

515. *Id.* (quoting *Embrex* at 216 F.3d at 1349 and Pitcairn v. United States, 547 F.2d 1106, 1125–26 (Ct. Cl. 1976)).

516. *Id.* at 1363.

focus should be "on the legitimate business Duke is involved in and whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[517]

The Federal Circuit, notwithstanding the call of commentators to broaden the experimental use exception, has interpreted the experimental use exception very narrowly and has clearly sent the following message to universities: unlicensed research using a patented invention constitutes an unexcused infringement if the research furthers the institution's legitimate business objectives.[518] Given the court's extremely broad definition of legitimate business objectives, neither applied nor basic university research is exempted from liability for patent infringement.[519] The decision makes no distinction between private-public collaborations for applied research, government-funded university research, and university research conducted for purely basic research purposes, i.e., the quest for knowledge. The Federal Circuit's decision can contribute to the anticommons phenomena, as university researchers must either find and license patents to basic research tools or risk liability for patent infringement.[520]

2. Integra Lifesciences I, Ltd. v. Merck KGaA—In *Integra Lifesciences I, Ltd. v. Merck KGaA*, the Federal Circuit narrowly interpreted 35 U.S.C. § 271(e)(1)—the safe harbor provision for the use of patented inventions reasonably related to the development and submission of information—to satisfy the requirements of the Food and Drug Administration Act.[521] Section 271(e)(1) is part of the Drug Price Competition and Patent Term Restoration Act of 1984, which was a compromise between the makers of generic drugs and research-based pharmaceutical companies.[522] Through the Act, Congress sought to restore the patent term to the drug maker because of the regulatory delays that result from time-consuming testing of a new drug prior to approval to sell the drug, and ensure that a patentee's rights do not de facto extend beyond the statutory period because a generic drug maker could not enter the market without regulatory approval.[523] Section 271(e)(1) allows a generic

517. *Id.*
518. *Id.*
519. *Id.*
520. In *Integra*, Judge Newman, in a dissent, criticizes the *Madey* majority opinion as failing to "distinguish between investigation into patented things, as has always been permitted, and investigation using patented things, as has never been permitted." *Id.* at 878.
521. 331 F.3d 860.
522. *Id.* at 865.
523. *Id.*

drug manufacturer to use a patented drug in preparation for regulatory approval.[524] Section 271(e)(1) provides:

> It shall not be an infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) 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 or veterinary biological products.[525]

The Federal Circuit noted the legislative history concerning section 271(e)(1), stating that pre-market approval activity involves "'a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute,'" while ensuring that the "'nature of the interference with the rights of the patent holder' not be 'substantial,' but 'de minimus [sic].'"[526]

In *Integra*, the Federal Circuit affirmed the district court's holding that 35 U.S.C. section 271(e)(1) did not immunize Merck against liability for infringement of several patents.[527] The issue, as the court framed it, was whether section 271(e)(1) embraces the development and identification of new drugs that will, in turn, be subject to FDA approval, not merely experiments to supply information for submission to the FDA.[528] According to the court, Merck needed to demonstrate that its activities were "'solely for uses reasonably related to the development and submission of information'" to the FDA.[529] The court noted that "[t]he focus of the entire exemption is the provision of information to the FDA" and that "[a]ctivities that do not directly produce information for the FDA are already straining the relationship to the central purpose of the safe harbor."[530] The court rejected an interpretation of

524. *Id.*

525. 35 U.S.C. § 271(e)(1) (1994).

526. *Integra*, 331 F.3d at 865 (quoting H.R. Rep. No. 857 at 8, *reprinted in* 1984 U.S.C.C.A.N. at 2692).

527. *Id.* at 868.

528. *Id.* at 866.

529. *Id.* (quoting 35 U.S.C. § 271(e)(1)).

530. *Id.*

section 271(e)(1) that would have expanded the phrase "reasonably related" to include the development of new drugs needing FDA approval; in other words, section 271(e)(1) does not immunize exploratory research that "may rationally form a predicate for future FDA clinical tests."[531] Notably, the court stated that a broad interpretation of § 271(e)(1) would vitiate the exclusive rights of owners of biotechnology tool patents, because patented tools often facilitate general research to identify candidate drugs.[532] Accordingly, the court held that the research was not "solely the uses reasonably related" to supplying information to the FDA, because Merck's activities involved only general biomedical research to identify new drugs.[533] Thus, *Integra* preserves the value of research tool patents by narrowly interpreting the statutory experimental use exception[534] and arguably contributes to the development of a Tragedy of the Anticommons.[535]

3. Proposals for a Broader Experimental Use Exception—Prior to the Integra and Madey decisions, several commentators, including Professors Eisenberg and Janice M. Mueller, advocated for a broader experimental use exception.[536] In a 1989 article, Professor

531. *Id.* at 867.

532. *Id.* at 866.

533. *Id.* (quoting 35 U.S.C. § 271(e)(1)).

534. *Id.* at 867.

535. Judge Newman, in a dissenting opinion, argues that the *Integra* majority decision "disapproves and essentially eliminates the common law research exemption." *Id.* at 873. She states:

> The subject matter of patents may be studied in order to understand it, or to improve upon it, or to find a new use for it, or to modify or 'design around' it. Were such research subject to prohibition by the patentee the advancement of technology would stop, for the first patentee in the field could bar not only patent-protected competition, but all research that might lead to such competition, as well as barring improvement or challenge or avoidance of patented technology. Today's accelerated technological advance is based in large part on knowledge of the details of patented inventions and how they are made and used. Prohibition of research into such knowledge cannot be squared with the framework of patent law .... [The Author not] undertake to define the boundaries of the research exemption for all purposes and activities, other than to observe that there is a generally recognized distinction between 'research' and 'development,' as a matter of scale, creativity, resource allocation, and often the level of scientific/engineering skill needed for the project; this distinction may serve as a useful divider, applicable in most situations. Like 'fair use' in copyright law, the great variety of possible facts may occasionally raise dispute as to particular cases. However, also like fair use, in most cases it will be clear whether the exemption applies.

Id. at 875–76 (footnote omitted).

536. *See supra* note 23. One commentator advocates for the adoption of "a limited research exemption for the public sector (e.g., university), non-commercial research in which

Eisenberg relies upon literature in sociology, history, and the philosophy of science to reason that free access to discoveries might promote technological progress more effectively than an exclusive rights scheme, given the continuing merger of basic and applied science.[537] Eisenberg argues that a three-prong model for the experimental use exception should be adopted to achieve a balance between the traditional free access model in basic science and the proprietary model in applied science.[538] First, Eisenberg proposes that the experimental use exception should apply to research use of a patented invention to check the adequacy of the written description and the validity of the claims.[539] Second, the exception should not apply to "[r]esearch use of a patented invention with a primary or significant market among research users . . . when the research user is an ordinary consumer of the patented invention."[540] Finally, "[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."[541] However, "it might be appropriate . . . to award a reasonable royalty after the fact to be sure that the patent holder receives an adequate return on the initial investment in developing the patented invention."[542]

In a 2001 article, Mueller expands upon Eisenberg's thesis, taking into account the substantial increase in transaction costs since 1989, primarily attributable to stacking royalties.[543] According to Mueller, and contrary to one of Eisenberg's assumptions, research

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a researcher engages in research with a tool or seeks to better understand how the tool itself works," and the elimination of reach-through royalties. Natalie M. Derzko, *In Search of a Compromised Solution to the Problem Arising from Patenting Biomedical Research Tools*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 347, 409–10 (2004). While reach-through royalties provisions may create an anticommons, they also provide a useful measure of the contribution of a research tool to the development of a commercial application. Moreover, the effect of most reach-through royalty clauses has been diminished through the use of contract clauses which restrict the total amount of reach-through royalties. Patent pools provide a better measure to allow parties to value tools. In addition, attempting to define what is non-commercial versus commercial is difficult and that uncertainty could lead to less investment in the development of research tools. The continued merger of the public and private spheres will make it increasingly difficult to continue to define what is non-commercial and commercial. *See* NIH REPORT, *supra* note 2.

537. Eisenberg, *supra* note 10, at 1017.

538. *Id.*

539. *Id.* at 1078.

540. *Id.*

541. *Id.*

542. *Id.*

543. Mueller, *supra* note 23, at 57.

tools are not readily available, with minimal transaction costs, to "ordinary users."[544] Mueller's article extends Eisenberg's thesis to permit non-consensual use of research tools that are not readily available for licensing on reasonable terms or via an anonymous marketplace purchase.[545] Mueller argues that where significant transaction costs are associated with licensing patented research tools to develop downstream commercial products, the experimental use doctrine should exempt from infringement the non-consensual use of those tools, even if for ultimately commercial purposes.[546] She recommends that a "liability rule" be adopted that prohibits the patent owner from enjoining the non-consensual use of the research tool, but compensates the patent owner with an ex post royalty set by the market value of any commercial product developed with the tool.[547]

Mueller further argues that because of the increased collaboration between the public and private sectors, the traditional view that experimental use does not insulate from infringement research with some commercial purpose using a patented invention is no longer viable.[548] According to Mueller, the current inflexibility of the experimental use exception, which seeks to categorize research as either for a commercial purpose on the one hand or merely to satisfy philosophical interest on the other hand, must be reevaluated.[549] "The involvement of a for-profit firm in the use of patented research tools to develop new products should not be treated as per se outside the scope of the experimental use doctrine."[550] Mueller relies upon foreign patent systems as examples of legal rules that exempt experimental or research use of a patented invention from infringement.[551] For instance, the Federal Supreme Court of Germany interpreted an exemption for experimental use of a patented invention to include clinical trials of a patented pharmaceutical, even though "the trials were conducted for the purpose of finding new applications for the pharmaceutical."[552]

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544. *Id.*

545. *Id.* at 58.

546. *Id.* at 9.

547. *Id.* at 9–10.

548. *Id.* at 36. Undoubtedly, Mueller would not be supportive of *Madey v. Duke University*, which did not even involve public and private collaboration, but concerned almost purely university research.

549. *Id.*

550. *Id.* at 37.

551. *Id.* at 37–40.

552. *Id.* at 38. (citing Wolfgang von Meibom & Johann Pitz, *Experimental Use and Compulsory License Under German Patent Law*, PATENT WORLD, June/July 1997, at 29).

Mueller cites the NIH Working Group on Research Tools, which concluded that "foreign patent systems properly distinguish between 'experimenting on the patented invention—i.e., using a patented invention to study the underlying technology or perhaps to invent around the patent,' and 'experimenting with a patented invention to study something else.' "[553] Mueller argues that if transaction costs are severe enough to impede the development of new commercial products, then the line drawing between "experimenting on" and "experimenting with" is no longer justified. While Mueller recognizes that the NIH Working Group's concern about undermining incentives to produce and disseminate research tools is valid if all non-consensual users of tools are exempted from liability, an approach that Mueller believes will preserve incentives is to impose a liability rule, i.e., the patent owner can obtain "an ex post royalty based on the marketplace valuation of products developed through use of the tool."[554] According to Mueller, the researcher's "access problem is alleviated because a license need not be negotiated prior to the use and an appropriate level of royalty to the patent holder will ensure that incentives to innovate are not significantly decreased."[555] In Mueller's model, the proposed user of the patented research tool will have to provide notice to the owner of the patent prior to use or be subject to treble damages if infringement is eventually proved.[556]

4. Analysis of the Proposal for a Broader Experimental Use Exception— Extension of the experimental use exception to include uses of research tools for some or any commercial purpose would effectively destroy the market for those tools, thus removing any incentives to create research tools.[557] Even an extension that does not completely end the market for research tools could impair the

553. *Id.* at 39 (quoting NIH REPORT, *supra* note 2.)
554. *Id.* at 40.
555. *Id.*
556. *Id.* at 58–59.
557. NIH REPORT, *supra* note 2:

> It is difficult to imagine how a broader research exemption could be formulated without effectively eviscerating the value of patents on research tools. Researchers are ordinary consumers of patented research tools, and if these consumers were exempt from infringement liability, the patent holder would have nowhere else to turn to collect patent royalties. An excessively broad research exemption would eliminate incentives for private firms to develop and disseminate new research tools, which on balance do more harm than good to the research enterprise.

Id. See also Eisenberg & Merges, *supra* note 407, at 19 (arguing that withholding patent protection from research tools could undermine their creation and distribution).

incentive to invent that the patent grant provides.[558] This is especially true in the biotechnology industry, where patents are necessary for companies to obtain venture capital funding.[559] Venture capitalists that currently invest in biotechnology companies may stop investing, because the value of the intellectual property portfolio of a company will be severely impacted if the company has no effective ability to exclude others from using its patented invention or if the company's ability to exclude others is uncertain.[560] The boundaries of the exclusive right would not be known until the experimental use exception had been litigated. It is difficult to value or set the royalty for use of a research tool, especially one that arguably does not contribute directly to the creation of a commercially successful product. For example, if a user utilizes a research tool to determine that a particular research course is a failure, but ultimately develops a commercially successful product, does the owner of the research tool receive a royalty? The user clearly has received some value. If the court applies the experimental use exception, the court must determine the amount of the royalty ex post;[561] in other words, the court must set the license fee.[562] While a court can determine a license fee, a patent pool is

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558. Eisenberg, *supra* note 10, at 1074 ("An exemption from infringement liability for research users would deprive patent holders of some of the social value of their inventions, thereby reducing the value of patents and weakening patent incentives. Whether such an exemption is nonetheless desirable in the interest of promoting continuing scientific progress is ultimately an empirical question.").

559. *See supra* notes 139–52 and accompanying text.

560. 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. If larger, well-funded competitors are able to utilize the patented inventions of smaller inventors to develop their own patented alternatives, these smaller inventors will be less able to raise funds for R&D. The experimental use exception, thus, could very well have a dampening effect on small scale, highly speculative R&D inventive endeavors, which scholars have recognized as comprising a substantial portion of the overall innovative activity in the United States.

Id. at 2183 (citing F.M. Scherer, Industrial Market Structure and Economic Performance 416–17 (2d ed. 1980) and J. Lowe & N. Crawford, Innovation & Technology Transfer for the Growing Firm 33 (1984)).

561. *Cf.* Merges, *supra* note 486, at 1317 ("Unless a special 'rate court' were established to administer these [licensing] disputes, each judge in each case would have to be educated about the industry, about appropriate [intellectual property rights] valuation ranges, and the like. These costs would clearly be large . . . .").

562. *Id.*

arguably better equipped to deal with such a matter.[563] Accordingly, a broad exemption encompassing the use of research tools for commercial purposes, by failing to ensure the patent owner's ability to recoup investments in research and development, could disable the incentives to invent and innovate that patents provide.[564]

A broad experimental use exception might also result in public disclosure of fewer research tools. Inventors may desire to keep research tools secret instead of disclosing those inventions through patents. This is especially likely because research tools are rarely disclosed through the sale of the patented commercial applications developed using the tools. Moreover, there are several beneficial non-infringing uses of information contained in a patent or a patented invention. For example, a researcher may study a patent, take good ideas from a patent, and verify an invention for operability, proof of principle, and proof of verification.[565] Accordingly, researchers may decide not to disclose research tools and rely on trade secret law for protection, and this would hurt scientific progress by not allowing other researchers to study patents or adopt good ideas from patents.

D. Collective Rights Organizations

Historically, institutions have used collective rights organizations, such as patent pools, to overcome transactional hurdles involved in accumulating the numerous intellectual property rights necessary to create a commercial application.[566] "A 'patent pool' is an agreement by two or more parties to license one or more patents to one another or to third parties."[567] A patent pool also can be defined as "the aggregation of intellectual property rights which are the subject of cross-licensing, whether they are transferred directly by patentee to licensee or through some medium, such as a joint venture, set up specifically to administer the patent pool."[568]

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563. *Id.* at 1296.

564. Karp, *supra* note 560, at 2180.

565. *See* Biotech Strategies, *supra* note 147; Karp, *supra* note 560, at 2179–81.

566. Merges, *supra* note 486, at 1342–1352 (describing patent pools in automobile and aircraft industries). *See also* Carlson, *supra* note 180, at 373.

567. White Paper, *supra* note 25.

568. Joel I. Klein, *An Address to the American Intellectual Property Association on the Subject of Cross-Licensing and Antitrust Law* (May 2, 1997), *available at* http://www.usdoj.gov/atr/public/speeches/1123.htm (on file with the University of Michigan Journal of Law Reform):

A few recently successful patent pools include the MPEG-2 pool and two pools related to Digital Versatile Discs.[569] Additionally, in the golden rice problem discussed below, several institutions[570] formed an initiative called the "Public Sector Intellectual Property Resource for Agriculture" ("PIPRA").[571] One of PIPRA's goals is to create shared technology practices, including "the possibility of pooling specific public-sector technologies, making technology 'packages' available to member institutions and to the private sector for commercial licensing or, at the very least, for designated humanitarian or special use."[572]

> All patent pools share one fundamental characteristic: they provide a regularized transactional mechanism that takes the place of the statutory property rule baseline requiring an individual bargain for each transaction. But in most other respects, their characteristics vary. They range from huge, industry-wide institutions with dozens of members and hundreds of patents, to relatively simple arrangements that look like nothing more than multilateral relational contracts.

Id. Merges, *supra* note 486, at 1342.

569. Robert P. Merges, *Institutions for Intellectual Property Transactions: The Case of Patent Pools* 28–37 (1999), *available at* http://www.law.berkeley.edu/institutes/bclt/pubs/merges/pools.pdf (on file with the University of Michigan Journal of Law Reform). (describing DVD pools and MPEG-2 pools approved by the Antitrust Division of the Department of Justice).

570. The institutions include: University of Wisconsin-Madison; University of California System; University of California-Davis; University of California-Riverside; University of Florida; The Ohio State University; Rutgers, The State University of New Jersey; North Carolina State University; Michigan State University; Cornell University; Boyce Thompson Institute for Plant Research; Donald Danforth Plant Science Center; Rockefeller Foundation and McKnight Foundation. *See* PUBLIC SECTOR INTELLECTUAL PROPERTY RESOURCE FOR AGRICULTURE, *at* http://www.pipra.participants.php (on file with the University of Michigan Journal of Law Reform).

571. Atkinson, *supra* note 381, at 174–175. In forming PIPRA, the institutions recognized that "[w]hen IP rights for agricultural materials and technologies are held by multiple public- and private-sector owners, this fragmentation produces situations where no single institution can provide a commercial partner with a complete set of IP rights to ensure freedom to operate . . . with a particular technology." *Id.* at 174. PIPRA participants believe that, if public sector institutions would collaborate in gathering information about and in the use of agricultural IPRs, the collaboration would make it easier for them to fulfill part of their public missions by speeding the creation and commercialization of improved staple and specialty crops. *Id.* at 175.

572. *Id.* at 175; *see also* Public Sector Intellectual Property Resource for Agriculture, *supra* note 570. PIPRA is also exploring the development of pilot projects, developing a business model for PIPRA, proving information, engaging other organizations, and stimulating discussions. It is unclear whether PIPRA as currently formed will be a success or not. Serious issues remain such as to whom will technology packages be licensed and for what purpose. Moreover, there is an open question as to what rights will be reserved by the universities. However, it serves as a model for the possible pooling of biomedical research tools by the public sector. A requirement to retain rights for later pooling for specific purposes can also be used in the biomedical field. While those rights are likely only the rights gathered from public institutions, those practices will somewhat relieve the pressure from a potential anticommons. At least for some rights, instead of gathering rights from 10 parties,

1. Guidelines for Licensing Intellectual Property—While patent pools can be used to overcome transactional barriers, they are nonetheless subject to antitrust review.[573] Patent pools have served as fronts for suspect collusive behavior, such as price fixing and preserving invalid patents.[574] Those practices have led federal regulators and courts to view licensing practices, including patent pools, with suspicion.[575] Recently, however, federal regulators and courts have recognized that patent law and antitrust law serve complementary purposes: "'both are aimed at encouraging innovation, industry and competition.'"[576] The largest impediment to the formation of patent pools includes antitrust scrutiny of patent pool arrangements.[577]

In 1995, the Federal Trade Commission and the Department of Justice jointly issued the Antitrust Guidelines for the Licensing of Intellectual Property ("Guidelines").[578] The Guidelines "describe the agencies' current complementary approach to applying anti-

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a developer may only need to license rights from 3 parties. The collective pressure from universities may encourage private companies to join in these pools.

573. White Paper, *supra* note 25, at 5.

574. 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, 244–246 (2002).

575. The trend towards narrowing the types of conduct exempt from antitrust scrutiny culminated in the 1970s with a now-infamous government policy called the 'Nine No-Nos' that was first articulated in a speech by a DOJ official. The Nine No-Nos were certain types of conduct that the Department always regarded as suspect and likely to unreasonably harm competition.

Sheila F. Anthony, *Antitrust and Intellectual Property Law: From Adversaries to Partners*, 28 AIPLA Q.J. 1, 5 (2000). The Nine No-Nos included: a patentee requiring a licensee to grant back patented improvements to the licencee's original technology; setting of royalty payments in amounts unrelated to sales volume of patented product; tying of unpatented supplies; post-sale restrictions on resale by purchasers of patented products; tie-outs; licensee veto power over the licensor's grant of future licenses; mandatory package licensing; restrictions on sales of unpatented products made by a patented process; and specifying the prices a licensee could charge upon resale of licensed products. *Id.* at 6.

576. Anthony, *supra* note 575, at 7. (quoting Atari Games Corp. v. Nintendo of America, Inc., 897 F.2d 1572, 1576 (Fed. Cir. 1990)).

577. Shapiro, *supra* note 190, at 144:

> We can ill afford to further raise transaction costs by making it difficult for patentees possessing complementary and potentially blocking patents to coordinate to engage in crosslicensing, package licensing, or to form patent pools. Yet antitrust law can potentially play such a counterproductive role, especially since antitrust jurisprudence starts with a hostility toward cooperation among horizontal rivals. . . . [T]he Federal Trade Commission . . . arguably is making it more difficult for firms to engage in crosslicenses, to offer package licenses, or to form pro-competitive patent pools.

Id.

578. Anthony, *supra* note 575, at 7.

trust principles in cases involving intellectual property rights."[579] Moreover, the Guidelines specifically apply the principles of particular licensing practices, such as cross-licensing arrangements, pooling, or the acquisition of intellectual property rights.[580]

The Guidelines specify that intellectual property pooling may provide "procompetitive benefits by integrating complementary technologies, reducing transaction costs, clearing blocking positions, and avoiding costly infringement litigation."[581] Moreover, "[b]y promoting the dissemination of technology, cross-licensing and pooling arrangements are often procompetitive."[582] Pooling arrangements, however, can be anticompetitive if: "the excluded firms cannot effectively compete in the relevant market for the good incorporating the licensed technologies, the pool participants collectively possess market power in the relevant market, and the limitations on participation are not reasonably related to the efficient development and exploitation of the pooled technologies."[583] Additionally, "[a]nother possible anticompetitive effect of pooling arrangements may occur if the arrangement deters or discourages participants from engaging in research and development, thus retarding innovation."[584] "However, such an arrangement can have procompetitive benefits, for example, by exploiting economies of scale and integrating complementary capabilities of the pool members (including the clearing of blocking positions), and is likely to cause competitive problems only when the arrangement includes a large fraction of the potential research and development in an innovation market."[585] The Guidelines are collapsed

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579. *Id.*

580. *See id.* at 8.

581. U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 5.5 (1995), *available at* http://www.usdoj.gov/atr/public/guidelines/ipguide.htm (on file with the University of Michigan Journal of Law Reform). [hereinafter ANTITRUST GUIDELINES].

582. *Id.*

583. White Paper, *supra* note 25, at 7 (quoting Letter from Joel I. Klein, Assistant Attorney General, U.S. Dep't of Justice, Antitrust Div., to Carey Ramos, Esq. (June 10, 1999), *available at* http://www.usdoj.gov/atr/public/busreview/2485.htm (on file with the University of Michigan Journal of Law Reform)).

584. ANTITRUST GUIDELINES, *supra* note 581, at § 5.5.

585. *Id.*

> The Justice Department has applied these guidelines in considering and approving three proposed patent pools. Its first review set forth the following additional guidelines: (1) the patents in the pool must be valid and not expired, (2) no aggregation of competitive technologies and setting a single price for them, (3) an independent expert should be used to determine whether a patent is essential to complement technologies in the pool, (4) the pool agreement must not disadvantage competitors

into two questions: (1) "'whether the proposed licensing program is likely to integrate complementary patent rights'"; and (2) "'if so, whether the resulting competitive benefits are likely to be outweighed by competitive harm posed by other aspects of the program.'"[586]

X. PROPOSALS FOR USING PATENT POOLS TO OVERCOME THICKETS OF PATENTS

Professor Merges argues that collective rights organizations, such as patent pools, are better suited to overcome thickets of intellectual property rights than are compulsory licenses because knowledgeable industry participants set the rules of exchange, including valuation and royalty rates, which are both more likely to represent market bargains.[587] Merges argues that patent pools are more likely to form when industry participants are required to transact with one another multiple times and when participants can work out a scheme more consistent with their needs than a congressional one-size-fits-all solution.[588] Merges specifically discusses the application of patent pools to solve patent thicket issues in the multimedia industry.[589] Moreover, commentators argue that patent pools may be used to overcome a potential Tragedy of the

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in downstream product markets, and (5) the pool participants must not collude on prices outside the scope of the pool, e.g., on downstream products.

Id. White Paper, *supra* note 25, at 7.

586. White Paper, *supra* note 25, at 7.

> In analyzing these issues, the Justice Department focused on the patents to be licensed (i.e., an independent expert in the relevant technology determines that they are "essential" to complementing the central technology in the pool), the joint licensing arrangement (i.e., collusion is unlikely, access to technology is enhanced), and the positive effects on innovation (e.g., the pool participants are required to license to each other "essential" patents they obtain *in the future*, less of a chance for future "blocking" patents, newer patents weigh heavier in calculating royalties to patent owners).

Id.

587. *See* Merges, *supra* note 486, at 1294–1300. Professor Merges argues that intellectual property rights are property rule entitlements and the high costs of transferring those rights leads to the creation of a liability rule-like regime based on collective valuation by firms. *Id.* at 1302–03.

588. *See id.* at 1299. "[R]epeat-play makes it easier to reach agreement on any particular issue, because disparities tend to balance out over many transactions." *Id.* at 1341.

589. *See id.* at 1373–90.

Anticommons in biotechnology.[590] The USPTO also advocates the use of patent pools to overcome the access problems that excessive biotechnology patents pose.[591]

In a white paper issued by the USPTO, the authors argue that a patent pool can eliminate problems associated with blocking patents or stacking licenses, while simultaneously encouraging cooperative efforts needed to effect true economic and social benefits of biotechnology invention.[592] Pools also potentially remove licensing transaction costs such as litigation, which provides certainty of patent rights and saves businesses time and money, especially small business that cannot survive costly litigation.[593] Pools also create an efficient mechanism for obtaining patented technologies, removing the opportunity for the last party with necessary rights to holdout for a substantially higher royalty than other licensees.[594] Patent pools also efficiently distribute risk because the pool provides an incentive for further innovation by enabling its members to share risks associated with research and development.[595] Pools ensure that all participants recover some of its costs for research and development efforts.[596] Finally, pools provide a way for the free sharing of technical information related to patented technology between members and the pool's licensees.[597] Members are also less likely to engage in overlapping efforts because of their greater access to information.[598]

The authors also address some of the criticisms of patent pools.[599] The first common criticism is that patent pools may include patented alternatives that could compete with a certain technology.[600] According to the authors, this criticism can be addressed through the careful evaluation of patent pool participants

590. *See* Heller & Eisenberg, *supra* note 11, at 700. *See also* Shapiro, *supra* note 190; Lawrence M. Sung, *Greater Predictability May Result in Patent Pools*, NAT'L L.J., June 22, 1998, at C2, *available at* http://www.ftc.gov/opp/intellect/020417lawrencemsung1.pdf (on file with the University of Michigan Journal of Law Reform) (arguing that Federal Circuit decisions limiting the scope of seemingly broad claims issued by the USTPO may result in more institutions participating in patent pools).

591. White Paper, *supra* note 25, at 2.

592. *Id.* at 8.

593. *Id.* at 8–9.

594. *Id.* at 9.

595. *Id.*

596. *Id.*

597. *Id.* at 10.

598. *See id.*

599. *Id.* at 10–11.

600. *Id.* at 10.

to ensure that the patents are truly blocking.[601] The second common criticism is that pools can shield potentially invalid patents.[602] If a pool shields a potentially invalid patent, then consumers may pay royalties for products with patents that courts would have otherwise invalidated.[603] The authors argue that an independent expert can review and select the patents to be added to the pool.[604] Moreover, the Department of Justice and the Federal Trade Commission provide some oversight of patent pools.[605] Finally, patent pools are criticized as detrimental to competition because they encourage collusion and price fixing.[606] The authors argue that careful evaluation of patent pools under the Guidelines, and the threat of antitrust violations and treble damages, should discourage the formation of anticompetitive patent pools.[607]

The work of Professor Carl Shapiro supports the white paper's recommendations.[608] Professor Shapiro cautions:

> we can ill afford to raise transaction costs by making it difficult for patentees possessing complementary and potentially blocking patents to coordinate to engage in cross-licensing, package licensing, or to form patent pools. Yet antitrust law can potentially play such a counterproductive role, especially since antitrust jurisprudence starts with a hostility towards cooperation among horizontal rivals.[609]

Patent pools provide a solution to the Tragedy of the Anticommons problem and preserve the incentives to invent, disclose, and innovate. Patent pools reduce transaction costs and potential litigation costs associated with bargaining with multiple parties to obtain rights.[610] Importantly, patent pools allow industry participants to select experts to evaluate licenses, more nearly representing a market valuation than a court or legislative determination.[611] In addition, patent pools may reduce the possibility of hold-ups after

601. *Id.*
602. *Id.*
603. *Id.*
604. *Id.*
605. *Id.*
606. *Id.* at 11.
607. *Id.* The White Paper also discusses three recent successful patent pools: MPEG-2 Standard (1997), DVD-ROM and DVD-Video Formats I (1998), and DVD-ROM and DVD-Video Formats II (1999). *Id.* at 13–15.
608. Shapiro, *supra* note 190, at 28.
609. *Id.* at 28.
610. Merges, *supra* note 486, at 1296–1301.
611. *See id.* at 1295–96.

the formation of the pool. However, hold-ups may still occur at the initial formation of the pool. Pools also reduce the likelihood that parties participating in the pool will engage in overlapping research efforts.

While the threat of antitrust liability and treble damages might provide a deterrent to the use of patent pools for anticompetitive purposes, government regulators and courts should approach and review patent pools with care to ensure that pools are not being used improperly. Improper purposes may include shielding invalid or unenforceable patents, or naked price-fixing.[612] If an arrangement is being used solely for the purpose of naked price-fixing, a per se, or "quick look," analysis is warranted.[613] Otherwise, patents pools should be analyzed under a rule of reason.[614] The rule of reason analysis identifies anticompetitive effects and balances these effects against procompetitive benefits.[615] As discussed above, anticompetitive effects can include "price-fixing, anticompetitive exclusionary practices, and the foreclosure of competition in related markets. Procompetitive benefits include the clearing of blocking positions, the advantages flowing from integrating complementary technologies, and the cost savings from avoiding litigation."[616]

If anticompetitive effects exist, the analysis [inquires] whether the arrangement is reasonably necessary to achieve procompetitive benefits that outweigh the anticompetitive effects. One important factor in determining whether a restraint is 'reasonably necessary' is to consider whether the parties could have achieved the procompetitive efficiencies through the use of significantly less restrictive alternatives.[617]

Though pools can have anticompetitive effects, pooled patented technologies can be carefully evaluated to ensure that those patents are complementary or blocking, and not competing.[618] However, patented research tools are not always blocking or complementary in the sense that the research tool is included within the commercial application itself. Research tools may be needed to conduct or simplify the research and development of a commercial application. Thus, independent experts, regulators, and the courts

612. *See* Hovenkamp et al., *supra* note 52, at § 34.4a.
613. *Id.* at § 34.4a n.2.
614. *See id.* at § 34.4a.
615. *See id.*
616. *Id.* at § 34.4a2.
617. *Id.*
618. *See id.* at § 34.4b1.

must ensure that a research tool is "necessary" for the particular research and development agenda of the pool at the time of the formation of the pool. The definition of "necessary" must be evaluated in light of the purpose or use of the particular patented research tool. At the time of the formation of the pool, however, it may be unclear whether a tool is needed to develop a particular commercial application because of the uncertain nature of biotechnology research and development.[619] Accordingly, where research tools used to develop a product are neither blocking nor complementary but are still needed to efficiently develop a particular commercial application, regulators and courts should not determine that a patent pool has anticompetitive effects that outweigh its procompetitive benefits. The use of a research tool to determine that a particular research and development agenda will not produce a useful commercial application provides a benefit to all members of the patent pool, even though that particular tool is not "necessary" to develop a commercial application. In determining whether a patent pool with patented research tools fails or passes the rule of reason test, regulators and courts should consider the realities of the market, including the uncertainty and complexity of biotechnology research and development, the transaction costs in licensing numerous patents directed to research tools, and the necessity of using numerous research tools to develop a single commercial application. In addition, pools of patented research tools allowing the licensing of the pooled technologies to parties outside the pool should be viewed as procompetitive.[620] Meanwhile, patent pools allowing veto rights over licensing of pooled technologies are more likely to have anticompetitive effects.[621]

Patent pools can be used to overcome a Tragedy of the Anticommons that exists or may develop in the biotechnology sector. Patent pools including patented research tools can have procompetitive effects and can withstand antitrust scrutiny. As discussed below, government policy makers should encourage biotechnology industry participants to enter patent pools.

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619. In addition, new patented technologies added to the pool after its initial formation must be carefully evaluated to ensure the technology is necessary to develop a particular commercial application.

620. *See* HOVENKAMP ET AL., *supra* note 52, at § 34.4b2.

621. *See id.*

XI. RECOMMENDATIONS

Because it is unclear whether a Tragedy of the Anticommons exists or will develop, this Article recommends against a change in patent law doctrine that may upset the incentives that patent law provides to invent, disclose, and innovate. A weakening of the patent grant might discourage investment in uncertain and expensive biotechnology research and development, which, in turn, will result in fewer socially useful commercial applications being brought to market. Weaker patent rights may also discourage firms from entering the biotechnology market because those firms will not be able to obtain venture capital funding.

This Article proposes two recommendations. First, this Article recommends that the government commission a study similar to that described in House Bill 3966.[622] Second, this Article recommends that the government take certain actions to facilitate the entering of patent pools by public and private institutions.

A. Study of the Effect of Government Policy on Biotechnology Innovation

Because of the conflicting nature of prior studies concerning the presence of a Tragedy of the Anticommons in biotechnology, and the importance of biotechnology innovation to the public health and economic welfare of the United States, the government should commission a study of the effect of government innovation policy on science and technology innovation in the biotechnology industry. In 2002, Representative Lynn N. Rivers of Michigan introduced a bill, the "Genomic Science and Technology Innovation Act of 2002" ("Genomic Act") in the House of Representatives, which "provides for an in-depth study by the White House Office of Science and Technology Policy on the impact of Federal policies, especially patent policies, on the rate of innovation, the cost, and the availability of genomic technologies."[623] However, Congress failed to enact the Genomic Act. This Article proposes that Congress should enact a slightly modified version of the Genomic Act. The changes in the

622. H.R. 3966, 107th Cong. (2002), *available at* http://thomas.loc.gov/home/c107query.html (on file with the University of Michigan Journal of Law Reform).

623. 148 CONG. REC. E354 (daily ed. Mar. 14, 2002) (statement of Rep. Rivers).

proposed Act ensure that the study include an examination of the impact of the patenting of research tools on biotechnology innovation and an analysis of government policies, including the Bayh-Dole Act, both of which affect innovation. The following sections provide the recommended changes to the Genomic Act:

SECTION 1. SHORT TITLE

This Act may be cited as the "~~Genomic~~ [Biotechnology] Science and Technology Innovation Act of ~~2002~~ [2004]." [Ed.: The title sounds redundant—Biotechnology Technology.]

SECTION 2. FINDINGS.

The Congress finds the following:

(1) ~~Genomic science~~ [Biotechnology] promises a revolution in the development of new and effective ~~genomic~~ [biotechnology] techniques and other innovations, and it is in the national interest to speed the development and deployment of these new technologies through policies that promote innovation in the field of ~~genomic~~ [biotechnology] science and technology.

(2) While Federal innovation policies can help stimulate innovation by attracting capital investment to the development of commercial products, such policies can also inhibit basic research and hinder sharing of information that is the basis of scientific progress, thereby slowing the innovation process.

(3) Intellectual property policies for ~~genomic~~ [biotechnology] science and technology products are being implemented without an adequate understanding and consideration of the net impact of such policies on the innovation process.

(4) Decisions about intellectual property policy being made now are likely to have significant impacts on basic research and the development of ~~genomic technology~~ [biotechnology] for decades to come.

(5) The Office of Science and Technology Policy is uniquely positioned to lead the development of a coordinated, inter-

agency policy to promote innovation in ~~genomic science and technology~~ [biotechnology]. A definitive study coordinated by the Office of Science and Technology that identifies the impacts of Federal innovation policy on the innovation pipeline for ~~genomic technology~~ [biotechnology] and includes recommendations for policies, including any statutory changes needed to optimize the ~~genomic technology~~ [biotechnology] innovation pipeline, would contribute significantly to the development of the policy.

SECTION 3. STUDY

(a) Requirement. The Director of the Office of Science and Technology Policy shall conduct, or may contract with the National Academy of Sciences to conduct, a study that assess the impact of Federal policies, including intellectual property policies, on the innovation process for ~~genomic technologies~~ [biotechnology].

(b) Consultation. In conducting the study, the Director of the Office of Science and Technology Policy shall consult with the National Science and Technology Council, the National Science Foundation, the Secretary of Energy, the Secretary of Commerce, the Secretary of Health and Human Services, and other agencies or divisions of agencies the Director considers appropriate.

(c) Advisory Committee. In conducting the study, the Director of the Office of Science and Technology Policy shall consult with a committee, organized as a subcommittee of the President's Committee of Advisors on Science and Technology, that shall include balanced membership from research universities, [including technology transfer professionals and research scientists;] non-profit research institutions; industry, [including members from the pharmaceutical and biotechnology industry]; economists[;] legal experts[;] bioethicists[;] clinicians and clinical scientists[;] genetic practitioners[;] and advocacy groups.

(d) Contents. The study shall—

(1) identify and quantify, to [the] extent possible, the actual and reasonably expected effects of innovation policy on ~~genomic science and technology~~ [biotechnology] innovation;

(2) explicitly consider various alternative levels of intellectual property protection ~~genomic~~ [biotechnology] materials may receive and the likely impact of the various levels of protection of each element of the innovation pipeline, including—

(A) fundamental ~~genomic~~ [biotechnology] research carried out at universities and other nonprofit research institutions;

(B) commercial ~~genomic~~ [biotechnology] research at universities, nonprofit research institutions, and for-profit institutions, including the expected effects on intra-company investment and external private capital;

(C) development of commercial ~~genomic technologies~~ [biotechnologies and research tools], including the expected effects on investment capital; and

(D) access to ~~genomic technologies~~ [biotechnology products,] ~~and~~ processes[, and research tools]; and

(3) include an assessment of the net impact of Federal innovation policies on innovation for ~~genomic technologies~~ [biotechnologies], including an assessment of—

(A) researchers' access to ~~genomic~~ [biotechnology] materials [and research tools];

(B) the rate of innovation;

(c) the quality of innovation;

(D) the cost of new ~~genomic~~ [biotechnology and research tools];

(E) the impact of restricted access to [biotechnology] diagnostics on evaluation, improvement, and clinical utilization;

(F) the cost and availability of innovative technology;

(G) whether Federal innovation policies create barriers to research through denial of use of a research tool, increased costs of licensing, legal and litigation costs, transaction costs, or the perception of increased legal liability, or hinder the access of researchers to ~~genomic~~ [biotechnology] materials and to databases of genomic sequence information;

(H) whether Federal innovation policies affect the choice of area of research conducted by researchers or institutions or provide positive benefits to such research, including additional funding from private sector partners; and

(I) the range of incentives providing motivation for genetics research and technology development other than intellectual property protection.

SECTION 4. REPORT

The Director of the Office of Science and Technology Policy shall, within 270 days after the date of enactment of this Act, transmit a report to Congress that—

(1) contains the findings of the study conducted under section 3; and

(2) makes recommendations for policies, including legislative changes, needed to optimize the ~~genomic technology~~ [biotechnology] innovation pipeline.

SECTION 5. COORDINATED POLICY

After the report is transmitted to Congress under section 4, the Director of the Office of Science and Technology Policy shall incorporate the policy recommendations into a coordinated interagency policy to promote innovation in ~~genomic science and technology~~ [biotechnology], including the sound use of intellectual property policy.

SECTION 6. DEFINITIONS

For the purposes of this Act—

(1) the term "~~genomic~~ [biotechnology] materials" means any material containing a human or human pathogen polynucleotide sequence other than genetic probes and markers and transgenic organisms;

(2) the term "~~genomic technology~~" ["biotechnology"] means any genetic diagnostic methods or kits, tools, probes, or markers, and any pharmaceutical or therapy ~~uses or incorporates~~ [developed with, using, or incorporating genomic materials];

(3) [the term "research tools" shall include, but is not limited to a fragment of a gene, a gene, cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry, and DNA libraries, clones and cloning tools, methods, laboratory equipment, and machines;] and

(3) the term "innovation policy" includes intellectual property protection and policies, [including, but not limited to, the Bayh-Dole Act].

B. Facilitate Creation of Patent Pools

The complex nature of the development of commercial applications in the biotechnology sector often requires multiple private and public firms to collaborate and exchange specialized skills and proprietary inputs. If transaction costs for transferring patented research tools are not minimized, these firms may be unable to assemble the necessary rights to bring a product or service to market. Patent pools provide a way to minimize transaction costs and facilitate the transfer of proprietary rights. Moreover, patent pools represent a solution that likely does not undermine the incentives for investment in biotechnology research and development, and is

consistent with the desire of scientists in academia and industry to streamline access to research tools.[624]

Government policy should encourage the creation of patent pools in two ways. First, the government, in collaboration with universities and private firms, should create a public database that contains information concerning proprietary and public domain research tools, including the identity of the owner, licensor, and/or licensee of each proprietary research tool; and a description of those tools. The information concerning research tools that are kept as trade secrets can be minimal, merely identifying the owner, contact information, and a very brief description of the tool.[625] Information concerning research tools that are patented can be more detailed, and include the patent. Similarly, the database can describe in detail research tools dedicated to the public domain.

The database would reduce transaction costs in determining whether a particular technology is subject to a proprietary right and in searching for the identity and contact information for the potential licensor. Through the use of a public database, participants would be able to quickly determine which rights are necessary to develop a particular commercial application or follow a particular research agenda. The public database would also allow researchers to determine whether a particular research tool has been developed, thus providing notice to researchers not to waste valuable resources pursuing development of an existing tool.[626] Moreover, as a result of the golden rice problem discussed above, universities and foundations now realize the benefits of a public database and are forming one to overcome any anticommons in the development of agricultural products.[627] The PIPRA database, if successful, could serve as a model.

Second, the Bayh-Dole Act should be amended to allow the government to retain a nonexclusive license to any patented technology developed with the use of federal funding. The Bayh-Dole Act currently provides that the government may either limit the recipient's right to elect title to an invention or retain title itself "in exceptional circumstances when it is determined by the agency

624. *See* NIH REPORT, *supra* note 2.

625. This may create the added benefit of creating a market for research tools maintained as trade secrets.

626. *See* Grady & Alexander, *supra* note 62, at 307–08 (discussing rent dissipating races to develop same technology by competing firms). *See also* Ko, *supra* note 54, at 795–96 ("Secrecy can also lead to waste to the extent that competitors duplicate research.").

627. Atkinson, *supra* note 381, at 174 (discussing goal of forming a collective public IP asset database, "so that public-sector researchers can be informed about FTO [freedom to operate] obstacles at the initiation of their research").

that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter."[628] The policy and objectives of the Act include:

> [T]o use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.[629]

As currently drafted, the Bayh-Dole Act requires the government to designate a case of exceptional circumstances at the time of the government's award of funding, which could be difficult.[630] At that time, the government may not know whether particular federally funded research will result in a research tool or not.[631] The NIH Working Group recommends that the NIH use this authority as a means to ensure broad dissemination of research tools.[632] However, adopting a policy that requires the government to retain title for all inventions created with federal funding may provide disincentives for public and private collaborations to develop research tools with federal funding. Prior to the passage of the Bayh-Dole Act, less than four percent of all government-funded research was commercialized.[633] Moreover, a blanket policy reserving title to the

628. 35 U.S.C. § 202(a)(ii) (2000).
629. 35 U.S.C. § 200.
630. *See id.* at § 202(a)(ii); *see also* NIH REPORT, *supra* note 2.
631. *See* NIH REPORT, *supra* note 2.
632. *See id.*
633. *See* EPSTEIN, *supra* note 2, at § 11.7 (citing Lobenstein, *Future of University—Industry Licensing*, 25 LES NOUVELLES 138 (1990)).

government may result in less commercialization of innovations that are not research tools.

The Bayh-Dole Act also currently provides that in all inventions created with government funding, the government retains "a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world . . . ."[634] This license allows the government to use any patented research tool in the course of federally sponsored research without liability for patent infringement.[635] It is unclear whether this provision applies to samples of research materials and whether the government can authorize use of subject inventions by other recipients of NIH grants.[636]

These two sections, along with the limited "march in" rights that the government retains, provide evidence of current government policy to secure for the government limited rights to patented inventions created with federal funding. To facilitate the ability of parties to enter patent pools, the Act should be revised to state that the government retains "a non-exclusive, transferable, license to make, use, offer to sell, sell, and import the patented invention throughout the world." However, the Act should specify that the government will only exercise that right if it is necessary to license those rights to a patent pool to ensure dissemination of a research tool. The Act should further state that the research tool is to be licensed only if the exclusive licensor unreasonably withholds the license from a patent pool. The question of unreasonableness will depend upon whether the potential licensor is attempting to hold up the potential licensees, whether the potential licensor's right is the last of several rights needed to create a commercial application, and whether the licensor is currently using the technology to develop an application. A patent pool would be defined as the need to pool two or more patented technologies in order to develop a commercial application or follow a particular research agenda to create a commercial application. The government would pay any proceeds from the patent pool to the party holding out. Both the Federal Trade Commission or the Department of Justice is well equipped to evaluate whether a potential licensor is unreasonably withholding a license to a patented research tool from a patent pool.[637]

634. 35 U.S.C. § 202(c)(4) (2000).

635. *See* NIH REPORT, *supra* note 2.

636. *See id.*

637. The DOJ and FTC are particularly well-suited to perform this task considering the current conflict of interest scandal at the National Institutes of Health. *See* David Labrador,

These changes are justifiable for several reasons. One of the primary justifications for the Bayh-Dole Act is the need for title to inventions to vest in private firms to encourage commercialization of an invention created with government funding.[638] However, with research tools, there already exists a market for those tools, and often the creator of a research tool may not use or be equipped to use that tool to develop a commercial application. Thus, providing title to an invention created with government funding might be unnecessary for the continued commercialization of the research tool itself. In addition, the public has already paid once for the research tool and should not be taxed again at a high rate simply because a company that refuses to license government funded proprietary technology has chosen to hold things up. Moreover, the licensor's rights are still protected and should be protected enough to allow continued investment in the development of research tools. The license is only to be used whenever the licensor is engaged in behavior that unfairly stifles innovation and only when the licensor is refusing to join a patent pool. Additionally, the licensor is still entitled to recover royalties, a factor that should somewhat dampen any disincentive to invent.

The effect of this proposal is substantial because the government currently funds approximately 26% of total research and development in the United States and 58% of research and development in U.S. colleges and universities.[639]

The proposals of creating a public database and modifying the Bayh-Dole Act promise to provide increased access to research tools to public and private researchers. These proposals should encourage public and private entities to enter patent pools. Patent pools provide an effective, flexible mechanism to transfer rights by limiting valuation, litigation, and enforcement costs.

CONCLUSION

Perhaps no technological advance in human history promises to provide as much benefit to humanity as recent developments in

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Damage Control: A Crackdown to Prevent Conflicts of Interest at the NIH, 291 Scientific American 18–20 (November 2004).

638. *See* 35 U.S.C. § 200.

639. NEWBERG & DUNN, *supra* note 89, at 193 (citing NAT'L SCI. BD., NATIONAL PATTERNS OF R&D RESOURCES: 2000 DATA UPDATE Table 1A *at* http://www.nsf.gov/sbel/srs/nsf01309/start.htm) (on file with the University of Michigan Journal of Law Reform)

biotechnology. Some of the promises include biotechnological solutions to countless diseases that plague us, such as cancer and heart disease, and to world hunger. However, the very mechanism that spurs development in the biotechnology industry should not be weakened without adequate empirical evidence. A heightened utility requirement, an expanded experimental use exception, or a fair use exception for patent law will undermine the incentives that patents provide to invent, disclose, and innovate.

At best the question of whether a Tragedy of the Anticommons exists or will develop is unclear. However, studies indicate that conditions conducive to the development of an anticommons exist. Accordingly, additional study to determine the effect of government policy on biotechnology innovation is warranted. Moreover, the government should revise the Bayh-Dole Act to encourage biotechnology sector participants to pool patent rights, thus ensuring that government funded technology is accessible, and preserving incentives to invent, disclose, and innovate.