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**The Impact of the Bayh-Dole Act on Genetic Research and Development:  
Evaluating the Arguments and Empirical Evidence to Date**

By  
Charles R. McManis\*  
& Sucheol Noh\*\*

The past two decades have witnessed a growing debate in the United States over patenting genetic products and processes. At the heart of the debate are two interrelated questions—1) whether granting patents on the results of “upstream” genetic research<sup>1</sup> undermines the norms of the biological research community; and 2) whether such patenting promotes or retards biomedical innovation, technology transfer, and/or the development of downstream commercial products and processes. Much of this debate has focused on the impact of a 1980 piece of legislation codified as a chapter of the U.S. patent statutes and commonly known as the Bayh-Dole Act.<sup>2</sup>

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\* Thomas & Karole Green Professor of Law, Director of the Intellectual Property & Technology Law Program, and Director of the Center for Research on Innovation & Entrepreneurship, Washington University. I am indebted to Dr. Wei-Ling Wang, J.S.D. Washington University, 2004, whose dissertation, *TECHNOLOGY TRANSFER FROM ACADEMIA TO PRIVATE INDUSTRY: A CRITICAL EXAMINATION OF THE BAYH-DOLE ACT* (2004), helped shape my understanding of the Bayh-Dole Act and greatly facilitated the research for this Chapter. I am also grateful to Professor Jay Dratler and the law faculty at the University of Akron for inviting me to deliver the 2005 Albert & Vern Oldham Intellectual Property Law Lecture, “Bridging the Gown-Town Gap: Bringing Academic Research to Market,” April 18, 2005, just as I was beginning my own research effort. Moreover, neither this research project nor the Center’s inaugural November 4-6, 2005 academic conference on the topic, “Commercializing Innovation,” would have been possible without the generous financial support that the Ewing Marion Kauffman Foundation and Washington University’s own Skandalaris Center for Entrepreneurial Studies, Center for Interdisciplinary Studies, and Whitney R. Harris Institute of Global Legal Studies have provided for the directed research activities of the Center for Research on Innovation & Entrepreneurship. Nor would the conference or this volume have come to pass, were it not for my colleagues, Professors Scott Kieff and Troy Paredes, who organized and co-chaired the conference and were also responsible for the editing and publication of this volume. I am also indebted to my co-author for his meticulous research and editorial assistance throughout this project. Finally, I am grateful for having had the opportunity to present this paper and receive feedback at the 2006 Intellectual Property Scholars Conference, held at the University of California-Berkeley, on August 10-11, 2006. See <http://www.law.berkeley.edu/institutes/bclt/ipsc/about.html>.

\*\* Visiting Fellow, Center for Research on Innovation & Entrepreneurship, Washington University, 2005-2006; J.S.D. Washington University of Law, 2001.

<sup>1</sup> “Upstream research” and “upstream technologies” are terms commonly used to refer to a basic-science research tools. See, e.g. David A. Adelman, *The Irrationality of Speculative Gene Patents*, [hereinafter Adelman, *Speculative Gene Patents*] in *UNIVERSITY ENTREPRENEURSHIP AND TECHNOLOGY TRANSFER: PROCESS, DESIGN, AND INTELLECTUAL PROPERTY* 123, 125 (Gary Libecap, ed.)(2005)[hereinafter Libecap]; David A. Adelman, *A Fallacy of the Commons in Biotech Patent Policy*, 20 *BERKELEY TECH. L. J.* 985, 989 (2005)[hereinafter Adelman, *Fallacy of the Commons*]. For a discussion of the controversy over the patenting of research tools, and the impact of such patenting on the norms of the biological research community, biomedical innovation, technology transfer, and the development of downstream products, see *infra* notes 6- 7 and accompanying text, and Parts II and III of this Chapter.

<sup>2</sup> Act of Dec. 12, 1980, Pub. L. No. 96-517, § 6(a), 94 Stat. 3018-3028 (1980) (codified as amended at 35 U.S.C. §§ 200-212 (1994)). For a brief introduction to the major provisions of the Bayh-Dole Act, see

The Bayh-Dole Act effected a major change in U.S. policy with respect to the ownership of intellectual property rights in federally funded research, and was designed to promote technology transfer by allowing universities, small businesses and other research institutions, in the absence of special circumstances, to retain ownership of the patent rights resulting from federally funded research, subject to a number of obligations, including an obligation on the part of universities and other non-profit institutions to share royalties with the actual inventor.<sup>3</sup> Prior to the Bayh-Dole Act, patent rights were in principle retained by the federal funding agencies themselves, though actual patent policies of federal funding agencies varied considerably, with some agencies allowing universities to patent publicly funded research discoveries under certain circumstances.<sup>4</sup> Although the Bayh-Dole Act governs the patenting of federally-funded research in all fields of technology, university patenting and licensing pursuant to the Act have thus far overwhelmingly involved the life sciences.<sup>5</sup>

Proponents of the Bayh-Dole Act argue that the Act was necessary because prior to 1980 many inventions resulting from federally-funded scientific research were not being commercialized, and that the Act has provided an effective framework for federal

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Association of University Technology Managers, Bayh-Dole Act [hereinafter AUTM, Bayh-Dole Act], available at [http://www.autm.net/aboutTT/aboutTT\\_bayhDoleAct.cfm](http://www.autm.net/aboutTT/aboutTT_bayhDoleAct.cfm). For a more detailed summary of the legislative history of this Act, see Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1688-1695 (1996)[hereinafter Eisenberg, Public Research and Private Development]. See also *infra* note 3.

<sup>3</sup> For a summary of the major provisions of the Act, see AUTM, Bayh-Dole Act, *supra* note 2. The legislative history of the Bayh-Dole Act states that the Act:

provides for a uniform policy governing the disposition of patent rights in government funded research . . . [replacing] the 26 different agency policies now in effect . . . with two patent policies . . . [1] Non-profit research institutions and small businesses are given preferential treatment. [2] The legislation establishes a presumption that ownership of all patent rights in government funded research will vest in any contractor who is a non-profit research institution or a small business. H. R. Rep. No. 96-1307 (Part I) at 5, 1980 U.S. CODE CONG. & ADMIN. NEWS 6464 (1981). The Bayh-Dole Act requires contractors to: 1) disclose of inventions “within a reasonable time”; 2) inform the government of an intent to patent; 3) file for patents within reasonable times and include a statement specifying that the invention was made with Government support and that the Government has certain rights to the invention; and 4) provide periodic reporting, as required by the funding agency. 35 U.S.C. § 202 (c)(1)-(6). Non-profit organizations must, among other things, share royalties with the inventor and apply the balance of royalties “for the support of scientific research or education.” 35 U.S.C. § 202(c)(7)(B) &(C). For additional powers that the Act vests in federal agencies, see *infra* note 119. In 1983, President Reagan directed heads of executive departments and agencies to extend the benefits of the Bayh-Dole Act to all government contractors, though subject to a statutory obligation to give preference to small businesses in licensing such patents. Memorandum to the Heads of Executive Departments and Agencies: Government Patent Policy, Pub. Papers 248 (Feb. 18, 1983). Congress acquiesced to this extension in a 1984 housekeeping amendment to the Act, Trademark Clarification Act of 1984, § 501(13), Pub. L. 98-620, codified at 35 U.S.C. §210(c).

<sup>4</sup> See *supra* note 3. See generally DAVID C. MOWERY, RICHARD R. NELSON, BHAVEN N. SAMPAT, & ARVIDS A. ZIEDONIS, IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT IN THE UNITED STATES 87-93 (2004)[hereinafter Mowery et al.].

<sup>5</sup> See, e.g. Council on Governmental Relations, The Bayh-Dole Act: A Guide to the Law and Implementing Regulations 8 (Oct. 1999), available at [http://www.cogr.edu/docs/Bayh\\_Dole.pdf](http://www.cogr.edu/docs/Bayh_Dole.pdf). (noting that a 1997 survey of the Association of University Technology Managers reports that 70% of the active licenses of responding institutions are in the life sciences).

technology transfer, producing tremendous economic benefits not just for universities and private industry, but for the U.S. economy as a whole.<sup>6</sup> Critics of the Bayh-Dole Act, on the other hand, question the theoretical and empirical assumptions on which the Bayh-Dole Act is based, and go on to argue that the use of patents in such areas as basic biological research may frustrate basic norms of “open science” in the research community, and that the failure to distinguish between downstream inventions that lead directly to commercial products and fundamental research discoveries that broadly enable further scientific investigation may hinder rather than accelerate biomedical research, creating the risk of both “blocking” patents on foundational discoveries or indispensable research tools and “patent thickets,” or a “tragedy of the anti-commons,”<sup>7</sup> where basic research discoveries necessary for subsequent downstream development are owned by a large number of entities, thus impeding downstream development.

Over the past five years, both Congress and the National Institutes of Health (NIH), one of the federal agencies most involved in funding biomedical research, have taken tentative (some would say timorous) steps to respond to criticisms of the Bayh-Dole Act. In 2000, Congress amended the Act, specifying among other things that the objective of the Bayh-Dole Act is to be carried out “without unduly encumbering future research and discovery.”<sup>8</sup> The NIH, for its part, has issued a number of informal policy

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<sup>6</sup> See, e.g., H.R. Rep. No. 106-129 (Part I) at 6, 2000 U.S. CODE CONG. & ADMIN. NEWS 1799, 1800 (2000), noting that prior to 1980 “many discoveries resulting from federally-funded scientific research were not commercialized for the American public’s benefit,” and that the Bayh-Dole Act is “widely viewed as an effective framework for federal technology transfer,” citing by way of example to a 1996 study conducted by the Association of University Technology Managers, which concluded that the law garnered tremendous economic benefits not just for the universities and private industry directly involved in each partnership, but more importantly for the United States as a whole.

<sup>7</sup> See, e.g. Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L. J. 177 (1987)[hereinafter Eisenberg, *Proprietary Rights and the Norms of Science*]; Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. L. REV. 77 (1999)[hereinafter Rai, *Regulating Scientific Research*]; Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289 (2003)[hereinafter Rai & Eisenberg]. Professors Rai and Eisenberg identify three types of proprietary barriers to biomedical research and development: Patents on upstream discoveries hinder subsequent research by 1) permitting owners to charge a premium of the use of discoveries that might otherwise be more cheaply available in a competitive market or in the public domain; 2) giving a single entity monopoly control of basic research discoveries that enable subsequent investigation across a broad scientific territory; and 3) creating a danger of a “patent thicket,” or anti-commons, when basic research discoveries necessary for subsequent work are owned, not by one entity, but by a number of different entities. *Id.* 295-298. Whereas the first two types of problems may result from one or more “blocking” patents on a foundational discovery or indispensable research tool, patent thickets are the result of too many patents in a particular field of technology. See NATIONAL RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 119 (2005)[hereinafter NRC Report, *Reaping the Benefits*] (distinguishing between “blocking” patents and patent “thickets”).

<sup>8</sup>Technology Transfer Commercialization Act of 2000, P.L. 106-404, §§ 5-6, 114 Stat. 1742, 1745 (2000) (codified as amended at 35 U.S.C. §§ 200, 202(e))(amending the policy and objectives provision of the Bayh-Dole Act, 35 U.S.C. § 200, and adding § 202(e), authorizing a federal agency, employing a co-inventor of any invention made under a funding agreement with a non-profit organization or small business, to consolidate rights--either by licensing, assigning, or acquiring rights--in the invention).

statements designed to constrain its grantees in pursuing intellectual property rights.<sup>9</sup> While these NIH initiatives have been characterized as consistent with the stated goal of the Bayh-Dole Act to promote the utilization of inventions arising from federally supported research or development, they have also been criticized as arguably being beyond the scope of the agency's statutory authority.<sup>10</sup> In 2000, the NIH began developing "best practices" guidelines for genomic inventions, and in April 2005 the revised final guidelines were published in the Federal Register,<sup>11</sup> recommending that recipients of NIH funding strongly consider broad and nonexclusive licensing of genomic inventions, with allowance for cases when exclusive licensing is needed to induce large investment in post-discovery commercial development.<sup>12</sup>

A particularly dismaying feature of the debate among legal scholars over the impact of the Bayh-Dole Act—at least according to one outside observer of a recent round in that debate—is the widespread reliance on what might charitably be called “anecdotal,” and an “evident lack of concern (let alone embarrassment) about the dearth of empirical evidence on the subject in question.”<sup>13</sup> To this outside observer, the problem is

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<sup>9</sup> See Rai & Eisenberg, *supra* note 7, at 306-308 (summarizing a variety of “hortatory efforts” on the part of NIH to constrain its grantees in pursuing intellectual property rights, including promulgating a general statement of “Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources,” adopted by NIH in December 1999, 64 FED. REG. 72,090 (Dec. 23, 1999), available at [http://www.nih.gov/od/ott/RTguide\\_final.htm](http://www.nih.gov/od/ott/RTguide_final.htm)).

<sup>10</sup> Rai & Eisenberg, *supra* note 7, at 308.

<sup>11</sup> “Best practices for the licensing of genomic inventions,” 70 Fed. Reg. 18413 (2005).

<sup>12</sup> See Lori Pressman, Richard Burgess, Robert M. Cook-Deegan, Stephen J. McCormack, Io Nami-Wolk, Melissa Soucy & LeRoy Walters, *The licensing of DNA patents by US academic institutions: an empirical survey*, 24 NATURAL BIOTECHNOLOGY 31 (2006)[hereinafter Pressman et al.].

<sup>13</sup> David A. Hyman, *An Outsider Perspective on Intellectual Property Discourse*, PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 275-285, 276, 278 (F. Scott Kieff, ed.) (2003) [hereinafter Hyman] (commenting on the absence of empirical evidence offered by legal scholars at a 2002 academic conference on legal implications of the Human Genome Project in support of assertions that research and clinical treatment are being hampered by the existence of property rights in genes and DNA sequences). See also Adelman, *supra* note 1, at 126 (commenting on the division among intellectual property scholars into two camps, one optimistic, the other pessimistic, about whether licensing and other market agreements can deal with patent thicket problems, with optimists appealing to experience in established industries and pessimists focusing on anecdotal evidence and other incipient signs that aggressive patenting is threatening biomedical research and development). This is not to suggest that no relevant empirical research exists. In fact, a substantial amount of empirical research has been done on the impact of the Bayh-Dole Act and the effectiveness of university technology transfer more generally. See, e.g. Donal S. Siegel & Phillip H. Phan, *Analyzing the Effectiveness of University Technology Transfer: Implications for Entrepreneurship Education*, Libecap, *supra* note 1, 8-9 (summarizing the results of eleven empirical studies of university technology licensing and patenting). However, legal scholars have developed little of their own empirical data to support their arguments for or against the Bayh-Dole Act, and have tended to ignore, or at least to minimize, empirical studies that undercut their arguments. See, e.g. Rai & Eisenberg, *supra* note 7, at 298, n. 49, where the authors, in the course of challenging the market-based argument that patent pools and other institutions for bundling intellectual property rights will reduce transaction costs and avert a tragedy of the anti-commons as “an empirical claim that has not yet been borne out by the experience of the biomedical research community,” cite to an early draft of John P. Walsh, Ashish Arora & Wesley M. Cohen, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285 (Wesley M. Cohen & Stephen A. Merrill, eds., 2003)[hereinafter Walsh, Arora & Cohen], a study that Rai and Eisenberg themselves concede offers empirical evidence undercutting their own criticism of the Bayh-Dole Act, as Walsh, Arora & Cohen conclude that examples

not unique to the debate among legal scholars over patenting of biotechnology products or processes; rather, it results from the selection and socialization process that produces lawmakers, lawyers, judges, and law professors, together with the incentive structure under which they operate.<sup>14</sup> In short, says this observer, members of the legal profession “prefer anecdotes to tables.”<sup>15</sup> Thus, while critics of the Bayh-Dole Act are quick to point out that little in the way of hard evidence “has been produced to support the argument that patenting and licensing of university inventions are necessary to support the transfer of technology to industry and commercial development of these inventions,”<sup>16</sup> some of these same critics (notably those from within the legal profession) are equally quick to suggest legislative solutions for what are, at best, potential problems in the operation of the Act.<sup>17</sup>

To be sure, in 1998 and again in 2003, just as the number of issued DNA patents peaked,<sup>18</sup> two widely publicized empirical studies on the specific question of the effect of research-tool patents on biomedical innovation were proffered.<sup>19</sup> Unfortunately, however, the two studies were said to offer apparently conflicting conclusions on the question,<sup>20</sup> and both have been criticized for not having disclosed the interview protocols

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of projects actually being stopped because of the sorts of anti-commons difficulties that concern Rai and Eisenberg and lead them to suggest revisions of the Bayh-Dole Act, are in fact “rare.” Having conceded this point, however, Rai and Eisenberg have little further to say about the Walsh Arora & Cohen study, other than to point out where it could be said to support their position.

<sup>14</sup> Hyman, *supra* note 13, at 278.

<sup>15</sup> *Id.* at 279, quoting Maurice Rosenberg, *Federal Rules of Civil Procedure in Action: Assessing Their Impact*, 137 U. PA. L. REV. 2197, 2211 (1989). For a more general critique of the tendency of legal scholarship to proceed “with little awareness of, much less compliance with, many of the rules of inference, and without paying heed to the key lessons of the revolution in empirical analysis that has been taking place over the last century in other disciplines,” see Lee Epstein & Gary King, *The Rules of Inference*, 69 U. CHI. L. REV. 1 (2003). Cf. Frank Cross, Michael Heise & Gregory C. Sisk, *Above the Rules: A Response to Epstein and King*, *id.* at 135; Jack Goldsmith & Adrian Vermeule, *Empirical Methodology and Legal Scholarship*, *id.* at 153; Richard L. Revesz, *A Defense of Empirical Legal Scholarship*, *id.* at 169; Lee Epstein & Gary King, *A Reply*, *id.* at 191.

<sup>16</sup> Mowery et al., *supra* note 4, at 1.

<sup>17</sup> See Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J. L. REFORM 141-235, 146 (2004)[hereinafter Mireles](who notes that a number of commentators, including Rai & Eisenberg, *supra* note 7, have proposed solutions to a lurking “tragedy of the anti-commons” in biotechnology innovation, but goes on to argue that, in view of the ambiguity of the empirical research, before any substantial changes are made to existing patent law, Congress enact a law similar to the proposed Genomic Science and Technology Innovation Act of 2002, H.R. 3966, 107<sup>th</sup> Cong. (2d Sess. 2002), requiring the U.S. Government to conduct a study regarding the effect of government policy on biotechnology innovation).

<sup>18</sup> See Pressman et al., *supra* note 12, at 35, Fig. 2 (Number of US DNA patents issued 1971-2005). DNA patents are defined in Pressman et al. as those patents containing at least one claim that includes a nucleic acid-specific term. Between 1998 and 2003, the number of DNA patents retrieved using the study’s search algorithm exceeded 3500 per year, a number not equaled in any year before or since.

<sup>19</sup> REPORT OF THE NATIONAL INSTITUTES OF HEALTH WORKING GROUP ON RESEARCH TOOLS (1998), available at <http://www.nih.gov/news/researchtools/> [hereinafter NIH Working Group Report]; Walsh, Arora & Cohen, *supra* note 13.

<sup>20</sup> Mireles, *supra* note 17, at 144, citing the NIH Working Group Report, *supra* note 19, and Walsh, Arora & Cohen, *supra* note 13. The Chair of the NIH Working Group was Professor Rebecca S. Eisenberg, one of the leading legal critics of the Bayh-Dole Act, see *supra* note 7, and the NIH Working Group Report tends to echo many of her concerns. The Walsh, Arora & Cohen study, by contrast, which was conducted

followed in conducting the interviews on which the studies were based, thus raising the possibility that the questions may have driven the conclusions.<sup>21</sup> As one economist notes, a more fundamental problem with the effort to develop empirical evidence concerning the impact of the Bayh-Dole Act is that it is “inextricably encumbered by the problem of documenting a counterfactual assertion in the form: if we had not done that, the world would now be different.”<sup>22</sup> Thus, “rhetorical victories tend to go to the side that can shift the burden of proof to the shoulders of their opponents—simply because conclusive proof of a counterfactual assertion will be elusive.”<sup>23</sup>

At the same time, as Stephen Toulmin reminds us,<sup>24</sup> a demand for “conclusive proof” of a proposition may itself simply reflect a preoccupation with a narrow mathematical form of reasoning modeled on the scientific method, and a futile quest for certainty where certainty is not possible. In many situations (particularly those involving the evaluation of human conduct and the formulation of public policy), the best that can be obtained--after determining who should bear the burden of proof on a particular point, how weighty the available evidence is, and which way it seems to preponderate—is a reasonable probability that a given proposition is true or false. These sorts of

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by a team of two economists and a sociologist and was funded by a grant from the National Science Foundation, found little evidence that university research has been impeded by concerns about patents on research tools. Mireles himself argues that the two studies can be viewed as consistent, as the NIH Working Group Report, *supra* note 19, arguably provides support only for the conclusion that certain conditions exist that may allow an ant-commons to develop, while Walsh, Arora & Cohen, *supra* note 13, basically concede this point, but argue that these conditions have not substantially impeded drug discovery.

<sup>21</sup> 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)[hereinafter David], available at <http://siepr.Stanford.edu/papers/pdf/02-30>, cited in Mireles, *supra* note 17, at 145, 192-193. Note, however, that Walsh, Cho and Cohen subsequently delivered a more detailed report to the National Academy of Sciences Committee on Intellectual Property Rights in Genomic and Protein-Related Inventions, see John P. Walsh, Charlene Cho & Wesley M. Cohen, *Patents, Material Transfers and Access to Research Inputs in Biomedical Research*, (Sept. 20, 2005) [hereinafter Walsh, Cho & Cohen] available online at <http://tigger.uic.edu/~jwalsh/NASReport.html>, in which they reported the results of a more expansive survey and essentially reiterated their earlier conclusions. This study, in turn, was relied on in a forthcoming study by the National Research Council. See The National Academies, News Release, “Intellectual Property Rights Must Be Balanced With Research Needs To Realize Full Potential of Biomedical Research,” <http://www4.nationalacademies.org/news.nsf/isbn/0309100674?OpenDocument> announcing the imminent publication (and pre-publication distribution) of NRC Report, *Reaping the Benefits*, *supra* note 7. These two reports will be discussed in more detail, *infra* Part III, notes 152-184 and accompanying text.

<sup>22</sup> David, *supra* note 21, at 16.

<sup>23</sup> *Id.* Note, however, that because a workable system of allocating the burden of proof and weighing evidence in contested cases can be found in the modern legal system, these questions are readily amenable to resolution. See *infra* notes 25-26 and accompanying text.

<sup>24</sup> STEPHEN TOULMIN, *RETURN TO REASON* 2, 204-214 (2001), who argues that the centuries-old dominance of *rationality*, a mathematical form of reasoning modeled on scientific method and the quest for absolute certainties, has diminished the value of *reasonableness*, a system of humane judgments based on personal experience and practice. Note, however, that the system of humane judgments based on personal experience and practice to which Toulmin refers is essentially embodied in the modern system of civil (i.e. non-criminal) justice, where in contrast to the criminal law’s demand for “proof beyond a reasonable doubt,” the law requires only that a party bearing the burden of persuasion in civil cases convince the decision maker that it is more probable than not that the party’s contentions are true. See *infra* note 25 and accompanying text.

determinations, in turn, tend to be precisely the stock-in-trade of the present-day legal system and profession,<sup>25</sup> which routinely grapple, for example, with such practical evidentiary problems as how to go about proving (or avoiding having to prove) a counterfactual assertion.<sup>26</sup>

Thus, while legal academics do need to look more carefully and dispassionately at all of the available empirical evidence with respect to the impact of the Bayh-Dole Act--including a bevy of empirical studies unveiled just within the past two years<sup>27</sup>--the debate

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<sup>25</sup> As indicated *supra*, notes 23-24, the modern system of civil justice has devised a workable system for determining who has the burden of proof (which consists of both a burden of producing evidence and a burden of persuasion). Normally, the burden of persuasion falls on the party having the burden of production, and in ordinary civil cases for monetary relief the party bearing the burden of persuasion must convince the decision maker that it is more probable than not that the party's contentions are true. In exceptional civil cases, where injunctive relief is sought, the applicable burden of persuasion is typically described as "clear and convincing evidence." Only the criminal burden of persuasion requires "proof beyond a reasonable doubt." The only general rule said to have "any real content" with respect to the allocation of the burden of production and persuasion "is that . . . moving parties [i.e. proponents of a change in the status quo] . . . should be required to demonstrate a justification for the request." Ronald J. Allen, *Presumptions, Inferences and Burden of Proof in Federal Civil Actions—An Anatomy of Unnecessary Ambiguity and a Proposal for Reform*, 76 NW. L. REV. 892, 896 (1982) (noting that while the Federal Rules of Evidence are generally so well formulated that their impact may come to rival the Federal Rules of Civil Procedure, the treatment of presumptions is nevertheless ambiguous and needs further refinement). The general rule concerning the allocation of the burden of proof may be subject to exceptions, however, where specific issues are "are peculiarly within the knowledge" of one of the parties to a dispute. *Id.* at 899. Thus, the burden of proving that a particular piece of legislation is needed or has achieved its intended purpose would normally seem to be on the proponents of the legislation. On the other hand, the burden of proving a counterfactual would seem most appropriately to fall on the party making a counterfactual assertion.

<sup>26</sup> For example, after years of judicial efforts to resolve a variety of factual causation issues (such as the problem of independently created but conjoining causes, such as fires) by creating exceptions to the well-known, but problematic *sine qua non*, or but-for test of causation, which requires proof of a counterfactual (namely, that but for the defendant's conduct, plaintiff's injury would not have occurred), the courts have largely eliminated these problems by articulating a more practicable "substantial factor" test, which merely requires proof that defendant's conduct was (more probably than not) a substantial factor in bringing about plaintiff's injury. *See generally* RESTATEMENT, SECOND, TORTS § 431 (1965). Similarly, the counterfactual assertion noted in text accompanying note 18 *supra*, could perhaps best be resolved by reformulating the question in the form: "If we [the United States] had not done x, our situation would probably be similar to that of country y or z, as they seem to have pursued the main policy alternatives to x." For evidence of just that sort, *see infra* text following note 53.

<sup>27</sup> For examples of the tendency on the part of legal academics to skew empirical evidence to support their particular policy arguments, rather than analyzing it carefully and dispassionately, *see supra* note 13 and *infra* notes 93, 95, 99 and 136. Among the most important recently released empirical studies are: 1) Bhaven N. Sampat, "Genomic Patenting by Academic Researchers: Bad for Science?" [http://mgt.gatech.edu/news\\_room/news/2004/reer/files/sampat.pdf](http://mgt.gatech.edu/news_room/news/2004/reer/files/sampat.pdf) [hereinafter Sampat]; 2) Fiona Murray & Scott Stern, "Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis," National Bureau of Economic Research Working Paper 11465 <http://www.nber.org/papers/w11465> (June 2005)[hereinafter Murray & Stern]; 3) Paula E. Stephan, Shiferaw Gormu, A.J. Sumell, & Grant Black, "Who's Patenting in the University? Evidence from the Survey of Doctorate Recipients," available at [http://www2.gsu.edu/~ecosgg/research/pdf/sgsb\\_eint.pdf](http://www2.gsu.edu/~ecosgg/research/pdf/sgsb_eint.pdf) (July 2005)[hereinafter Stephan et al.]; 4) Walsh, Cho & Cohen, *supra* note 21; 5) NRC Report, Reaping the Benefits, *supra* note 7; 6) Pressman et al., *supra* note 12; 7) STEPHEN HANSEN, AMANDA BREWSTER, JANA ASHER & MICHAEL KISIELEWSKI, THE EFFECTS OF PATENTING IN THE AAAS SCIENTIFIC COMMUNITY (2006)[hereinafter Hansen et al.]; 8) Pierre Azoulay, Waverly Ding, and Toby Stuart, "The Impact of

over patenting upstream genetic research and vesting presumptive patent ownership in the recipients of federally funded research may ultimately turn as much on arguments as to the appropriate allocation of the burden of proof on these two questions and a rough judgment as to the weight of the available evidence as it does on the conclusiveness of the empirical evidence as such. Accordingly, this Chapter will summarize the theoretical arguments for and against patenting upstream genetic research and vesting presumptive patent ownership in the recipients of federally funded genetic research, with a view to determining who should bear the burden of proof on specific aspects of these two questions, and will also evaluate the weight of the available empirical evidence, with a view to determining how that evidence seems to preponderate at the moment. Part I will discuss the theoretical underpinnings of the Bayh-Dole Act and the empirical evidence regarding its role in stimulating university patenting and licensing. Part II will discuss the impact of the Bayh-Dole Act on the research mission of U.S. universities. Part III will discuss the impact of upstream university patenting of genetic research on downstream innovation. Part IV concludes.

### **Part I: Theoretical Underpinnings of the Bayh-Dole Act and its Role in Stimulating University Patenting and Licensing**

As a starting point, it seems appropriate to impose upon proponents of the Bayh-Dole Act, as with any other legislative initiative, the initial burden to establish that the legislation is based on sound theoretical foundations and has in fact or is likely to achieve its stated objectives. This is particularly urgent in the case of the Bayh-Dole Act, as critics of the Act, even decades after its enactment, persist in characterizing the policies underlying the Act as “counterintuitive”<sup>28</sup> and “in need of significant reform.”<sup>29</sup> At the heart of these criticisms is the argument that, while the purpose of granting patent protection is ostensibly to create incentives to innovate, recipients of federal funds arguably need no additional incentive to innovate.<sup>30</sup> Thus, allowing private parties to

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Academic Patenting on the Rate, Quality, and Direction of (Public) Research,” National Bureau of Economic Research Working Paper Series, Working Paper 11917 (Jan. 2006), available at <http://www.nber.org/papers/w11917> [hereinafter Azoulay et al.], an earlier version of which is available at <http://www2.gsb.columbia.edu/divisions/finance/seminars/fo/Azoulay.pdf> (June 15, 2004); 9) Kira R. Fabrizio, “Opening the Dam or Building Channels: University Patenting and the Use of Public Science in Industrial Innovation,” available at <http://gbspapers.library.emory.edu/archive/00000255/01/GBS-OM-2006-001.pdf> (Jan. 30 2006)[hereinafter Fabrizio]; 10) David B. Audretsch, Taylor Aldridge, and Alexander Oettl, “The Knowledge Filter and Economic Growth: The Role of Scientist Entrepreneurship, Preliminary Draft Prepared for the Ewing Marion Kauffman Foundation (March 29 2006)[hereinafter Audretsch et al.], available at <http://ideas.repec.org/p/esi/egpdis/2006-11.html>; and 11) David E. Adelman & Kathryn DeAngelis, “Mapping the Scientific Commons: Biotechnology Patenting from 1990 to 2004,” unpublished paper presented at the Nov. 4-6, 2005 Conference on “Commercializing Innovation,” Washington University [hereinafter Adelman & DeAngelis]. For a discussion of these studies, see *infra* notes 55-58, 114, 116, 124, 141-215 and accompanying text.

<sup>28</sup> See Eisenberg, Public Research and Private Development, *supra* note 2, at 1666.

<sup>29</sup> See Brett Frischmann, *Innovation and Institutions: Rethinking the Economics of U.S. Science and Technology Policy*, 24 VT. L. REV. 347 (2000)[hereinafter Frischmann, Innovation and Institutions](arguing that “the intellectual underpinnings upon which our current innovation policy is based are inaccurate and in need of significant reform.”).

<sup>30</sup> See Eisenberg, Public Research and Private Development, *supra* note 2, at 1666. *But cf. infra* notes 36-37 and accompanying text.

hold exclusive rights to inventions that have been generated at public expense seems to require the public to pay twice for the same invention.<sup>31</sup>

On the other hand, a number theoretical justifications for the current U.S. patent system traditionally have been proffered, and the above-mentioned “incentive to innovate” justification is but one of them.<sup>32</sup> Thus, one must begin by identifying and critically examining the specific theoretical underpinnings of the Bayh-Dole Act itself.

#### A. Theoretical Underpinnings of the Bayh-Dole Act

Arguably, the theory most relevant to the patenting of upstream genetic research and vesting presumptive patent ownership in the recipients of federally funded research is one referred to as the “commercialization” theory. This is so because the Bayh-Dole Act itself clearly seems to embrace this theory.<sup>33</sup>

One of the principal academic proponents of the commercialization theory, emphasizing the shortcomings in any view of the patent system that focuses only on incentives to engage in inventive activity, argues that the current patent system is primarily necessary 1) to facilitate investment in the complex, costly, and risky commercializing activities required to turn nascent inventions into new goods and services, and 2) to help society decide which inventive activities are worth protecting in

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<sup>31</sup> *Id.* But cf. *infra* notes 36-37 and accompanying text.

<sup>32</sup> The two most often cited justifications for the U.S. patent system are that it creates an incentive to invent and an incentive to disclose the invention. See F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697, 742 (2001)[hereinafter Kieff, *Property Rights and Property Rules*], citing Giles S. Rich, *The Relation Between Patent Practices and the Anti-Monopoly Laws* (pts. 1-2), 24 J. PAT. OFF. SOC’Y 85, 159, 175-177 (1942)[hereinafter Rich, *Patent Practices and the Anti-Monopoly Laws*]. Rich recognizes that these two justifications for the U.S. patent system may be extrapolated from Article I section 8 clause 8 of the U.S. Constitution, which authorizes Congress to “promote the Progress of . . . the useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries,” but goes on to argue that the same can be said of a third type of inducement, the inducement to commercialize the invention, which “is by far the greatest in practical importance.” *Id.* at 177. See also F. Scott Kieff, *The Case for Registering Patents and the Law and Economics of Present Patent-Obtaining Rules*, 45 BOSTON C. L. REV. 55, 61 (2003)[hereinafter Kieff, *Registering Patents*](alluding to a fourth incentive created by the U.S. patent system—namely an incentive to design around a patented invention).

<sup>33</sup> The introductory section of the Bayh-Dole Act states that the policy and objective of the Act is, *inter alia*, “to use the patent system to promote the utilization of inventions arising from federally supported research and development” and “to promote the commercialization and public availability of inventions made in the United States by United States industry and labor . . . .” 35 U.S.C. §200. Critics of the Bayh-Dole Act have suggested that the commercialization justification for patent protection has less support in the constitutional text authorizing Congress to enact patent protection than does the incentive to invent rationale. See, e.g., Rai, *Regulating Scientific Research*, *supra* note 7, at 166 n. 215. However, while the language of the U.S. Constitution, Art. I § 8, cl. 8, clearly enunciates a utilitarian, rather than a natural rights justification for patent protection, it nevertheless seems sufficiently capacious to embrace a variety of utilitarian inducements, including the inducement to commercialize. See, e.g., Rich, *Patent Practices and the Anti-Monopoly Law*, *supra* note 32, at 175-177. Indeed, without an implicit inducement to commercialize, it is difficult to understand how the constitutionally authorized exclusive rights would create any initial incentive to invent.

the first instance.<sup>34</sup> The commercialization justification for patent protection is also said to be the theory that in fact operated to inform and motivate the framers of the current U.S. patent system.<sup>35</sup>

The commercialization justification for patent protection is particularly important in the debate over patenting genetic products and processes because it overcomes the two objections to vesting the recipients of federal funds with presumptive patent ownership in federally funded genetic research noted above—namely 1) that recipients of federal funds need no additional incentive to innovate; and 2) that allowing private parties to hold exclusive rights to inventions that have been generated a public expense seems to require the public to pay twice for the same invention.<sup>36</sup> The commercialization theory calls attention to the fact that innovating to the point of qualifying for patent protection is not necessarily synonymous with innovating to the point of producing a commercially viable product or process. This being so, providing federal funding for basic genetic research and early stage development does not necessarily render the incentives of the patent system superfluous, nor is the public necessarily being made to pay twice for the same invention; rather, the public may simply be paying for two distinct phases of the innovative process—namely the early-stage “proof-of-concept” phase (generated by public funding) and the subsequent commercialization phase (generated by the incentives of the patent system). On this point, the available empirical evidence seems to confirm that university technologies are generally early stage technologies, with only a small percentage being “ready for practical use.”<sup>37</sup>

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<sup>34</sup> Kieff, *Property Rights and Property Rules*, *supra* note 32, at 703. While critics of the Bayh-Dole Act tend to equate the commercialization justification with the “prospect” theory of Professor Edmund Kitch, *see* Rai, *Regulating Scientific Research*, *supra* note 7, at 120-121, citing Edmund Kitch, *The Nature and Function of the Patent System*, 20 J. L. & ECON. 265 (1971), Kieff distinguishes between Kitch’s prospect theory, as well as the related “rent dissipation” theory of Professors Grady and Alexander, *see* Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305 (1992), and his own commercialization theory, which emphasizes how the right to exclude promotes commercialization by facilitating the social ordering and bargaining around inventions that are necessary to generate output in the form of information about the invention, a product of the invention, or a useful embodiment of the invention, *see* Kieff, *Registering Patents*, *supra* note 32, at 67, notes 52 & 53 (“whereas the prospect theory can be seen to focus on coordination among competing users of an invention, the commercialization theory can be seen to focus on coordination among complementary users.”). *See also* Kieff, *Property Rights and Property Rules*, *supra* note 32, at 707, note 47.

<sup>35</sup> Kieff, *Property Rights and Property Rules*, *supra* note 32, 736-746.

<sup>36</sup> *See* Eisenberg, *Public Research and Private Development*, *supra* note 2, at 1666-1667, who argues that the policy underlying the Bayh-Dole Act is counterintuitive for four interrelated reasons: 1) By allowing private firms to hold exclusive rights to inventions that have been generated at public expense, it seems to require the public to pay twice for the same invention; 2) by calling for exclusive rights in inventions that have already been made through public funding (and thus, presumably, without the need for a profit incentive), it contravenes the conventional wisdom that patent rights on existing inventions result in a net social loss *ex post*, a loss that we endure only to preserve *ex ante* incentives to make future patentable inventions; 3) by promoting the private appropriation of federally-sponsored research discoveries as a matter of routine, it calls into question the public goods rationale for public funding of research; and 4) by providing incentives to patent and restrict access to discoveries made in institutions that have traditionally been the principal performers of basic research, it threatens to impoverish the public domain. For a response to these four criticisms, *see infra* notes 44-72, 84-110, 132-230 and accompanying text.

<sup>37</sup> Jerry G. Thursby & Marie C. Thursby, “University Licensing under Bayh-Dole: What are the Issues and Evidence?” 6 NBER Working Paper No. W9734. <http://ssrn.com/abstract=412881> (May 2003)[hereinafter

While the United States was quite successful, prior to passage of the Bayh-Dole Act, in expanding the frontiers of basic science, other countries, such as Germany and Japan, were more effective at refining and diffusing technologies into existing industry and thus experienced greater growth during the 1980s.<sup>38</sup> In so doing, they also incidentally demonstrated two important economic truths—namely, that productivity gains rely primarily on diffusing and refining technology, and a market economy alone is not sufficient to permit natural diffusion of innovation to the market, as the private sector generally under-invests in commercializing the results of basic research.<sup>39</sup>

Economists and legal commentators also emphasize that the innovative process is not simply a linear process in which innovations result from advances in basic scientific knowledge that are then applied by industry to products and processes.<sup>40</sup> Rather, important feedbacks occur at each level of the innovative process, particularly in “middle-ground” research projects. These are defined as applied research projects that have commercial applications, but where the results are too general to make them attractive to private companies, thus creating the risk of a technology and funding “gap,” or “valley of death,” in the innovative process.<sup>41</sup> At least one economic study has concluded that a government-funded, targeted approach to increasing middle-ground research is not particularly effective,<sup>42</sup> while another economic study concludes that the Bayh-Dole Act represents a more efficient method of stimulating middle-ground research, by offering the incentives needed to support investment in developing offices that could facilitate commercialization of university research and attract more research funding to the university.<sup>43</sup>

## B. The Role of the Bayh-Dole Act in Stimulating Patenting and Licensing

Although proponents of the Bayh-Dole Act thus appear to have offered a plausible theoretical justification for the Act, critics have nevertheless raised two further criticisms, the first challenging some of the empirical assumptions underlying the Bayh-Dole Act, and the second questioning the overall role of the Act in stimulating university patenting and licensing. Some critics of the Act, for example, question the empirical basis for the claim that prior to 1980 many inventions resulting from federally funded scientific research were not being commercialized, thus justifying granting contractors

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Thursby and Thursby 2003](noting that based on their survey, 45% of university licenses are for technologies that are only a “proof of concept” while only 12% are “ready for practical use.” See also Jerry G. Thursby & Marie C. Thursby, *Pros and Cons of Faculty Participation in Licensing*, in Libecap, *supra* note 1, at 190 (noting that university inventions tend to be embryonic, and that in two surveys conducted by the authors, 88% and 84% of the respective licensed university inventions required further development).

<sup>38</sup> Douglas W. Jamison & Christina Jansen, *Technology Transfer and Economic Growth*, 12 J. OF ASS’N. OF U. TECH. MANAGERS 24, 35 (2000)[hereinafter Jamison & Jansen].

<sup>39</sup> *Id.*

<sup>40</sup> *Id.* See also Frischmann, *Innovation and Institutions*, *supra* note 29, 349-351.

<sup>41</sup> Jamison & Jansen, *supra* note 38, at 35.

<sup>42</sup> LINDA R. COHEN & ROGER G. NOLL, *THE TECHNOLOGY PORK BARREL* (1991), cited in Jamison & Jansen, *supra* note 38, at 35.

<sup>43</sup> Jamison & Jansen, *supra* note 38, at 35.

title to federally funded inventions.<sup>44</sup> Other commentators, while not explicitly questioning the theoretical underpinnings of the Act, argue that proponents of the Act have exaggerated the role of the Bayh-Dole Act in spawning university patenting and licensing over the past twenty-five years, and claim that even without the Bayh-Dole Act, university patenting would have grown significantly during the 1980s and 1990s.<sup>45</sup>

To be sure, the oft-repeated assertion that of the 28,000 to 30,000 patents that the federal government held in 1978, less than 4 to 5 percent were ever successfully licensed,<sup>46</sup> was apparently based on flawed data, and thus never should have been cited as evidence that the results of government-sponsored research were languishing in federal archives.<sup>47</sup> Likewise, commentators are correct that the emphasis on the Bayh-Dole Act as the primary catalyst stimulating university patenting and licensing since 1980 may have been exaggerated, as proponents tend to ignore a number of other contemporaneous catalyzing factors contributing to the upsurge in university patenting and licensing,<sup>48</sup> and also ignore a long history in the U.S., extending back to the early decades of the 20<sup>th</sup> Century, of university patenting, licensing, and collaboration with industry.<sup>49</sup>

On the other hand, most commentators agree that university patenting “exploded” in the U.S. during and after the period in which the Bayh-Dole Act was enacted.<sup>50</sup> As several commentators point out, whereas in 1965, a mere 28 universities received just 96 patents, and in 1980, 25 universities received just 150 patents,<sup>51</sup> by 1992, 150 universities received nearly 1,500 patents—an increase of over 1500% for a period when overall U.S.

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<sup>44</sup> See Eisenberg, Public Research and Private Development, *supra* note 2, 1702-1705. See also Mowery et al., *supra* note 4, at 90-91.

<sup>45</sup> See Mowery et al, *supra* note 4, at 1 & 7. See also David C. Mowery, *The Bayh-Dole Act and High-Technology Entrepreneurship in U.S. Universities: Chicken, Egg, or Something Else?* [hereinafter Mowery], Libecap, *supra* note 1, at 41, 48-49.

<sup>46</sup> See, e.g. Hearings on S. 414 Before the Senate Comm. On the Judiciary, 96<sup>th</sup> Cong., 1<sup>st</sup> Sess., at 2 (opening statement of Sen. Birch Bayh)(“Of the 30,000 patents that the Government presently holds, less than 4 percent are ever successfully licensed”); *id.* at 28 (opening statement of Sen. Robert Dole)(“of the 28,000 inventions funded by the Government, only about 5 percent have been used”).

<sup>47</sup> See Eisenberg, Public Research and Private Development, *supra* note 2, at 1702-1703. For a recent article that nevertheless relies on this flawed data, see Clifton Leaf, *The Law of Unintended Consequences*, 152 FORTUNE No. 6, 250-268, at 258 (September 19, 2005).

<sup>48</sup> See, e.g., Mowery, *supra* note 45, at 51, noting that both the 1982 establishment of the Court of Appeals for the Federal Circuit as the exclusive court of appeals in patent matters and the 1980 decision of the U.S. Supreme Court in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), upholding the validity of a patent on a genetically modified organism, were equally important catalysts to university patenting and licensing.

<sup>49</sup> Mowery, *supra* note 45, at 41, 48-49. See also Mowery et al., *supra* note 4, at 1.

<sup>50</sup> See, e.g., Robert W. Hahn, “The Economics of Patent Protection: Policy Implications From The Literature,” (Oct. 30, 2003), at 23, available at <http://ssrn.com/abstract+467489> [hereinafter Hahn], citing Rebecca Henderson, Adam B. Jaffe, and Manuel Trajtenberg, *Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting, 1965-1988*, 80 REVIEW OF ECON. & STAT., No. 1, 119 (Feb. 1988)(originally National Bureau of Economic Research Working Paper No.5068, available at <http://www.nber.org/papers/w5068>)[hereinafter Henderson, Jaffe & Trajtenberg], who refers to an “explosion” in university patenting since 1965). See also Katherine J. Strandburg, *Curiosity-Driven Research and University Technology Transfer* [hereinafter Strandburg, Curiosity-Driven Research and University Technology Transfer], in Libecap, *supra* note 1, at 94 (noting that there is clear evidence “that patenting at universities has increased drastically over the past 30 years).

<sup>51</sup> Jamison & Jansen, *supra* note 38, at 35.

patenting rose by less than 50%.<sup>52</sup> While it is true that the increase in university patenting began before 1980, it also seems clear that after 1980 there was a dramatic rise in the “propensity to patent” on the part of universities that had never applied for patents before and that universities that had always patented began to do so more intensely.<sup>53</sup>

Further empirical support for the conclusion that the patent system in general and the Bayh-Dole Act in particular played an important role in stimulating university patenting and licensing in the U.S. can be found in studies comparing the experience of universities in the U.S. with experience elsewhere in the world during the same time period. For example, it has often been stressed that the lack of adequate patent protection was a major obstacle to the development of the biotechnology industry in Europe.<sup>54</sup> Moreover, in a comparison of U.S. and Swedish innovation systems that affect the commercialization of university technology generally, the authors of a 2002 study note that “the U.S. model is very much focused on creating (economic) incentives for universities to commercialize their research output,” whereas “the Swedish model, which is similar to most European Union countries’ models in some respects, is very much an attempt by the government to directly create mechanisms that facilitate commercialization.”<sup>55</sup> They conclude: “[I]n light of our analysis we believe that it is unlikely that Sweden is harvesting the full commercial potential of its research output as successfully as the U.S.”<sup>56</sup> To be sure, the innovation and technology transfer system in Sweden and elsewhere in Europe is not exactly analogous to the situation in the U.S. prior to and following the Bayh-Dole Act, as the Swedish system, like others in Europe, may not have adequately protected biotechnology and in any event awards patent rights to publicly funded research directly to the academic inventor.<sup>57</sup> The European experience

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<sup>52</sup> See, e.g. Henderson, Jaffe & Trajtenberg, *supra* note 50, at \_\_\_; Hahn, *supra* note 50, at 23.

<sup>53</sup> Henderson, Jaffe & Trajtenberg, *supra* note 50, at \_\_\_.

<sup>54</sup> See, e.g., Ernst & Young, “Biotechnology in Europe,” ERNST & YOUNG ANNUAL REPORT (1994); Rebecca Henderson, Luigi Orsenigo, & Gary P. Pisano, *The Pharmaceutical Industry and the Revolution in Molecular Biology: Interactions Among Scientific, Institutional, and Organizational Change* [hereinafter Henderson et al.], in SOURCES OF INDUSTRIAL LEADERSHIP: STUDIES OF SEVEN INDUSTRIES 267, 302 (D.C. Mowery & R.R. Nelson, eds., 1999)(citing the Ernst & Young Report and noting, first, that the grace period introduced in the United States is not available in Europe, with the result that any discovery that has been published is not patentable, and, second that “the interpretation has prevailed that naturally occurring entities, whether cloned or uncloned, cannot be patented”).

<sup>55</sup> Brent Goldfarb and Magnus Henrekson, “Bottom-Up vs. Top-Down Policies towards the Commercialization of University Intellectual Property,” SSE/EFI Working Paper Series in Economics and Finance No. 463, 1-2 (Feb. 25, 2002). *But cf.* Audretsch et al., *supra* note 27, emphasizing that two paths to commercialization exist in the U.S.—the *technology transfer office* route and the *entrepreneurial route*--and exploring the extent to which U.S. academic scientists choose not to assign patents to their universities and commercialize their inventions via technology transfer offices (TTO), but rather follow a more entrepreneurial route to commercializing their research. This study establishes that 30 % of the top 20 % of university scientists funded by the National Cancer Institute choose not to assign their patents to the university TTO, but rather follow the more entrepreneurial route to commercializing their research, and concludes that scientific entrepreneurship is “an important and prevalent mode of commercialization of university research.” *Id.* at Executive Summary and 61.

<sup>56</sup> *Id.* at 2.

<sup>57</sup> *Id.* See also H. NORMAN ABRAMSON, JOSE ENCARNAÇÃO, PROCTOR R. REID & ULRICH SCHMOCH (eds.), TECHNOLOGY TRANSFER SYSTEMS IN THE UNITED STATES AND GERMANY: LESSONS AND PERSPECTIVES 19 (1997)[hereinafter Abramson et al.], noting that as of 1997, under German law, the right to exploit inventions resulting from university-based research supported by institutional base funds rested exclusively

is nevertheless instructive, as the innovation and technology transfer systems in place there have until quite recently involved an attempt by government to directly create mechanisms that facilitate commercialization, rather than vesting this function in the universities.<sup>58</sup>

The differing results, particularly in biotechnology, are striking. In Germany, while most universities are equipped with technology transfer offices, their primary function, at least until recently, has been “to build relationships between small and medium-sized enterprises and faculty members, not to license patents.”<sup>59</sup> Most universities have “neither funds nor infrastructure to support patenting and licensing activities; inventions resulting from federally funded academic research generally can only be licensed on a non-exclusive basis to interested industrial partners; and a portion of any licensing income earned from inventions developed with federal government funds must go to the funding agency”<sup>60</sup>—a situation that is roughly analogous to that in the U.S. prior to the enactment of Bayh-Dole.<sup>61</sup> Thus, “with the option of establishing or

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with the individual professor or inventor involved, not with the inventor’s host institution. *But cf.* Breschi S., Lissoni F. and F. Montobbio, “Open Science and University Patenting: A Bibliometric Analysis of the Italian Case,” at 2, available at <http://epip.dk/papers/20041001/paris/papers/Montobbio.pdf>. (Oct. 2004) [hereinafter Breschi et al.], noting that, by 2004, “[f]ascinated by the impressive growth of patents granted by US academic institutions . . . many European governments have both reformed national IPR legislation concerning academic research and encouraged universities to undertake pro-active technology transfer policies.” This paper goes on to note that the German legislature, in 2002, abolished the so-called “professor’s privilege,” and the Scandinavian countries are considering abolishing it, though ironically, “more or less at the same time, the Italian government introduced a law going in the opposite direction, thus establishing the “professor’s privilege” in a country where it had never existed before, with the declared intention of finally providing the right economic incentives for individual scientists to undertake ‘useful’ (that is ‘patentable’) research.” *Id.* See generally Rebecca Henderson et al., *supra* note 54, at 267, 302 (noting that the lack of adequate patent protection was a major obstacle to the development of the biotechnology industry in Europe: “First, the grace period established in the United States is not available: any discovery that has been published is not patentable. Second, the interpretation has prevailed that naturally occurring entities, whether cloned or uncloned, cannot be patented.”). Prior to 1980, however, it was equally unclear whether U.S. patent law extended to living organisms. See *supra* note 48 and accompanying text. For evidence that academic researchers in the U.S. sometimes choose not to assign their patent rights to their university, but follow a more entrepreneurial route in commercializing their research, see Audretsch et al., *supra* note 27, discussed *supra* note 55.

<sup>58</sup> See, e.g., Abramson et al., *supra* note 57, at 20, noting that, as of 1997, inventions resulting from federally funded research in Germany generally could only be licensed on a non-exclusive basis to interested industrial partners, and a portion of any licensing income earned from inventions developed with federal government funds must go to the funding agency. *But cf.* Breschi et al., *supra* note 57, noting that in 2002, Germany reformed its national intellectual property legislation concerning academic research, and among other things, abolished the so-called “professor’s privilege.” See also Lorelei Ritchie de Larena, “The Price of Progress: Are Universities Adding to the Cost?” SSRN\_ID917367\_code485586.pdf, at 67-70 [hereinafter Ritchie de Larena] (describing recent legislative changes and proposed changes in Europe, Japan, Australia, and India). For evidence that academic researchers in the U.S. sometimes choose not to assign their patent rights to their university, but follow a more entrepreneurial route in commercializing their research, see Audretsch et al., *supra* note 27, discussed *supra* note 55, who note that these scientists “exhibit a higher likelihood of starting a new firm but a lower propensity to license.” *Id.* at 62.

<sup>59</sup> Abramson et al., *supra* note 57, at 19. For a summary of recent changes in Germany IP legislation, see *supra* notes 57-58.

<sup>60</sup> *Id.* at 19-20.

<sup>61</sup> See *supra* note 4 and accompanying text.

working for a high-tech start-up company, U.S. academic researchers have an additional important vehicle through which they can transfer as well as have a direct hand in commercializing the results their own research or technologies originating elsewhere—a vehicle largely unavailable to their German counterparts.”<sup>62</sup>

Consequently, whereas the majority of American biotechnology start-ups were “tightly linked to university departments, and the very strong state of American molecular biology clearly played an important role in facilitating the wave of start-ups that characterize the 1980s,”<sup>63</sup> new technology-based firms (NTBFs) working in biotechnology in Germany are said to have played “a negligible role; they represent barely 10 percent of the roughly 300 NTBFs created per year” in Germany.<sup>64</sup> In the development of pharmaceutical products, the German market has been “dominated by a dozen multinational, German-based concerns primarily in the chemical and pharmaceutical industry,” which because of that industry’s success in traditional pharmaceutical development, “almost ignored the potential of genetic engineering for many years, although many German experts were already emphasizing its importance in the 1970s.”<sup>65</sup> Although German scientists “contributed many discoveries, new methods, and processes to the world’s knowledge of biotechnology,” many of them “went to the United States to establish spin-off companies.”<sup>66</sup> Since the middle of the 1980s, the large German pharmaceutical companies “began to acknowledge the potential of biotechnology and started a catch-up strategy,” which consisted primarily of cooperating “with external scientific institutions, the building of internal research capacity, and the acquisition of SMEs [small and medium enterprises] abroad.”<sup>67</sup>

In short, the available empirical evidence seems to rebut both the argument that the Bayh-Dole Act was based on fundamentally flawed theoretical premises,<sup>68</sup> and the

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<sup>62</sup> Abramson et al., *supra* note 57, at 20.

<sup>63</sup> Ian Cockburn, Rebecca Henderson, Luigi Orsenigo, & Gary P. Pisano, *Pharmaceuticals and Biotechnology*,” D.C. MOWERY (ed.) U.S. INDUSTRY IN 2000: STUDIES IN COMPETITIVE PERFORMANCE 388 (2000)[hereinafter Cockburn et al.]

<sup>64</sup> Abramson et al., *supra* note 57, at 344.

<sup>65</sup> *Id.*

<sup>66</sup> *Id.* One explanation for this phenomenon could be the availability of more adequate patent protection in the U.S. for biotech inventions after 1981. *See supra* notes 48, 57-58.

<sup>67</sup> *Id.* at 344-345.

<sup>68</sup> *See, e.g.,* Eisenberg, Public Research and Private Development, *supra* note 2, at 1666 (describing the policy underlying the Bayh-Dole Act as “counterintuitive”) and Frischmann, Innovation and Institutions, *supra* note 29 (arguing that “the intellectual underpinnings upon which our current innovation policy is based are inaccurate and in need of significant reform.”). For a critique of Eisenberg’s criticisms, *see supra* note 36-37 and accompanying text and *infra* notes 125-226 and accompanying text. Frischman concedes that facilitating technology transfer from government to industry may be accomplished by awarding intellectual property rights to federally funded researchers, but argues that the social costs seem unnecessarily high when alternative institutional mechanisms, such as selective tax incentives and cooperative R & D are considered. *Id.* at 353. He goes on to identify three sources of market failure that arise during the transfer of technology from the government to domestic industry, but argues that “only foreign misappropriation of federally funded research presents a sufficient justification for mixing IP with grants when alternative corrective institutions are considered.” *Id.* at 355, 407-409. *But see infra* notes 70-71 and accompanying text, indicating that one important objective of the Bayh-Dole Act was precisely to reinvigorate U.S. industry in the face of increased foreign competition and to ensure that federally funded

argument that much of the post-1980 upsurge in university patenting and licensing would have occurred without the Act.<sup>69</sup> Even critics of the Bayh-Dole Act recognize that one important objective of the Act was to reinvigorate U.S. industry in the face of increased foreign competition and to ensure that federally funded 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.”<sup>70</sup> At least one of these critics concedes that “foreign misappropriation of

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research discoveries were developed by U.S. firms rather than foreign competitors. Frischmann also argues that, “given the starting point of patentable innovation, it seems unlikely that the class of derivative innovations for which success depends on grantee-innovator involvement is expansive [given that] the patent disclosure enables other researchers ‘skilled in the art’ to practice the invention.” *Id.* at 409. *But see infra* note 72 and accompanying text (noting that because most university inventions are embryonic when first disclosed, and require significant additional development before they can be commercially useful, giving title to universities will create incentives for inventors and institutions to become actively involved in the development and commercialization of embryonic inventions; and that, at least in the early years, the exploitation of biotechnology required the mastery of a considerable body of tacit knowledge that could not be easily acquired from the literature).

<sup>69</sup> See Mowery et al., *supra* note 4, at 7, arguing that “Much of the post-1980 upsurge in university patenting and licensing . . . would have occurred without the Act and reflects broader developments in federal policy and academic research.” See also Mowery, *supra* note 45, at 48-49, citing both to evidence that private universities in particular expanded their patenting and licensing rapidly during the 1970s, and to evidence that U.S. research university lobbying was one factor behind passage of the Act in 1980, as support for his conclusion that the Bayh Act should be considered as much an effect as a cause of expanded university patenting and licensing. Note, however, that Mowery et al. are asserting a counterfactual—namely that “much” of the post-1980 upsurge in university patent and licensing would have occurred even if the Bayh-Dole Act had not been enacted. As we have suggested, the party asserting a counterfactual arguably should bear the burden of proof. See *supra* note 25. While Mowery et al. present persuasive evidence that at least some universities were patenting prior to 1980, and that causes other than the Bayh-Dole Act also contributed to the upswing in university patenting after 1980, their evidence falls short of proving the counterfactual being asserted, as even they concede that “the Bayh-Dole Act accelerated the growth of university patenting and resulted in the entry into patenting and licensing by many universities during the 1980s” (Mowery et al., *supra* note 4, at 36); that “[a]ggregate university ‘patent propensity’ does increase after 1981” (*id.* at 48); that an important factor that “affected growth in patenting by universities during the 1970s was the negotiation of IPAs [Institutional Patent Agreements] with federal research funding agencies” (*id.* at 51); and that “prior to 1980, federal policy remained ambivalent toward university licensing, [as] evidenced in the debates over the appropriateness of exclusive licensing under IPAs” (*id.* at 57). As Douglas Jamison and Christina Jansen add, while it was possible to retain title to university inventions prior to 1980, “it was done on a case-by-case basis, and universities had to petition the federal government [;] for the majority of universities, growth in university technology really exploded only after 1980[; ] [p]rior to 1980, fewer than 250 patents were issued to universities each year and only about 25 institutions engaged in technology transfer . . .” Jamison & Jansen, *supra* note 38, at 24, 35 (2000). In response to Mowery’s argument that the Bayh-Dole Act was “as much an effect as a cause” of expanded university patenting and licensing, another team of economists cautions that “It is impossible to assign roles of “cause” and “effect” to these different trends[;] [t]he increase in university patenting predates the passage of Bayh-Dole, but continued exponential growth probably could not have been sustained without removal of cumbersome barriers to patents from federal research.” Henderson, Jaffe & Trajtenberg, *supra* note 50.

<sup>70</sup> See, e.g. Eisenberg, Public Research and Private Development, *supra* note 2, at 1664-1665. For a detailed discussion of this point, see RICHARD J. BRODY, EFFECTIVE PARTNERING: A REPORT TO CONGRESS ON FEDERAL TECHNOLOGY PARTNERSHIPS 8, 20-22 (April 1996)[hereinafter Brody](offering three reasons for the loss of U.S. competitiveness in the 1970s and 1980s: First, as the technical sophistication of major competitors of the U.S. grew, they too were able to appropriate the output of U.S. government basic and mission research, which reduced the relative impact of these public investments on American economic

federally funded research presents a sufficient justification for mixing [intellectual property] with [federal] grants when alternative corrective institutions are considered.”<sup>71</sup> Likewise, commentators who claim that proponents of the Bayh-Dole Act have exaggerated its role in stimulating university patenting and licensing nevertheless seem to concede that supporters of the bill did indeed anticipate the conclusions of subsequent empirical studies in emphasizing that, because most university inventions are embryonic when first disclosed, and require significant additional development before they can be commercially useful, giving title to universities will create incentives for inventors and institutions to become actively involved in the development and commercialization of embryonic inventions.<sup>72</sup>

However, it is precisely this objective and outcome of the Bayh-Dole Act that some critics find to be most objectionable, as they claim the Act is undermining the norms of the biological research community, is changing the focus of university research by diverting academic scholars from basic to applied research activities, and generating other potential conflicts of interest within the academic research community. It is to this set of criticisms that we now must turn.

## **Part II: The Impact of the Bayh-Dole Act on the Research Mission of U.S. Universities**

A perennial criticism of the Bayh-Dole Act is that it is undermining norms of “open science” in the biological research community, changing the focus of academic research by diverting academic researchers from basic to applied research, and is generating other potential conflicts of interest within the academic research community. The norms most frequently identified with “open science” are said to include: 1) universalism—meaning that the veracity of claimed scientific observations should be determined by universal criteria without regard to the particular attributes of the claimant,

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competitiveness; second, traditional mechanisms of technology transfer, development and diffusion took too long in an era of accelerating private sector product development; and third, as foreign R & D increased, U.S. government R & D represented a declining world share). *See also* David C. Mowery & Bhaven N. Sampat, *University Patents and Patent Policy Debates in the USA, 1925-1980*, 10 *INDUSTRIAL & CORPORATE CHANGE* 781, 796 (2001).

<sup>71</sup> Frischmann, *Innovations and Institutions*, *supra* note 29, at 355, 407-409. *See generally* Brody, *supra* note 70, at 20-22.

<sup>72</sup> *See* Mowery et al., *supra* note 4, at 91, citing both to S. REP. 96-480, accompanying a forerunner of the Bayh-Dole Act, namely the University and Small Business Patent Procedures Act (1979) (“Virtually all experts in the innovation process stress very strongly that . . . involvement by the inventor is absolutely essential, especially when the invention was made under basic research where it is invariably in the embryonic stage of development”), and to Richard Jenson & Marie Thursby, *Proofs and Prototypes for Sale: The Licensing of University Inventions*, 91 *AM. ECON. REV.* 240-258 (2001) (offering survey evidence and economic arguments in support of the view that unless universities have the right to license out patentable inventions, many results from federally funded research would never be transferred to industry). *See also* Cockburn et al., *supra* note 63, at 388-389 (noting that the majority of the American biotechnology start-ups during the 1980s “were tightly linked to university departments;” that “the very strong state of American molecular biology clearly played an important role in facilitating the wave of start-ups that characterize the 1980s;” and that “the American lead appears to have been particularly important because the exploitation of biotechnology in the early years required the mastery of a considerable body of tacit knowledge that could not be easily acquired from the literature”).

such as reputation, institutional affiliation, or nationality; 2) Communalism—meaning that scientific advances should be a product of and for the benefit of the community; 3) Disinterestedness—meaning that scientific effort should be expended for the purpose of seeking generally applicable scientific truth, rather than some personal interest; and 4) Organized skepticism—meaning that scientific observations should be subject to empirical scrutiny.<sup>73</sup> Two additional norms have also been suggested—namely: 5) Independence—meaning that scientists should be free to set their own research agendas and to criticize the work of others; and 6) Invention—meaning that scientists should make original contributions to the common stock of knowledge.<sup>74</sup>

Whether any of these general norms gave rise to a more specific pre-1980 norm that “discouraged the assertion of intellectual property rights in scientific invention or discovery,” however, is hotly contested.<sup>75</sup> Moreover, while there may be some critics of the Bayh-Dole Act who continue to embrace a “utopian vision” of a pre-1980 basic biological research community “characterized by specific prescriptive norms against intellectual property generally and patents in particular,”<sup>76</sup> the most prominent legal critics of the Bayh-Dole Act appear to agree with proponents that, whether or not that specific norm ever actually existed,<sup>77</sup> the more general prescriptive norms of open

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<sup>73</sup> See ROBERT MERTON, *The Normative Structure of Science*, in *THE SOCIOLOGY OF SCIENCE* 267 (1973); Eisenberg, *Proprietary Rights and the Norms of Science*, *supra* note 7, 183; Rai, *Regulating Scientific Research*, *supra* note 7, 89-90. See generally Strandburg, *Curiosity-Driven Research and University Technology Transfer*, *supra* note 50, 104-107.

<sup>74</sup> Rai, *Regulating Scientific Research*, *supra* note 7, 91-92. See generally Strandburg, *Curiosity-Driven Research and University Technology Transfer*, *supra* note 50, 104-107.

<sup>75</sup> Compare Rai, *Regulating Scientific Research*, *supra* note 7, at 88, with F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Response to Rai and Eisenberg*, 95 NW. L. REV. 691, 694 (2001)[hereinafter Kieff, *Response to Rai*].

<sup>76</sup> The quoted words are those of Professor Scott Kieff, a major proponent of the commercialization theory, see *supra* notes 34-35 and accompanying text, who ascribes this position to Professor Arti Rai, a major critic of the Bayh-Dole Act. See, Kieff, *Response to Rai*, *supra* note 75, at 697. But see Arti Kauer Rai, *Evolving Scientific Norms and Intellectual Property Rights: A Reply to Kieff*, 95 NW. L. REV. 707 (2001)[hereinafter Rai, *Reply to Kieff*], denying that she intended her description of pre-1980 norms to be, as Kieff had claimed, “a benchmark against which to measure the relative performance of that same community today.” Rather, she states that this part of her article was merely designed to describe, not to endorse, those pre-1980 norms. *Id.* at 707-708. Indeed, Rai claims that the norms she endorses are those of the *current* regime, which she claims are quite different from those that existed prior to 1980, but which are nevertheless imperiled by the over-aggressive patenting of upstream research. For a discussion of that point, see *infra* Part III. Kieff, on the other hand, seems to be claiming that in any event Rai is inaccurately describing pre-1980 norms in the biological research community--see Kieff, *Response to Rai*, *supra* note 75 at 692—a claim that Rai likewise denies, arguing that her statement that academic scientists did not seek patents before 1980 (a claim for which there is evidence) is not to be taken as a claim that scientists were, or are, altruistic and selfless human beings. See Rai, *Reply to Kieff*, *supra*, 708-709. But see *infra* note 77.

<sup>77</sup> The debate between Kieff and Rai, for example, seems to boil down to a dispute over whether a specific norm existed in the pre-1980 biological research community that discouraged researchers from asserting intellectual property rights. See *supra* note 76. While it is clear that academic patenting prior to 1980 was not nearly so common as it would become after 1980, a variety of alternative explanations have been proffered for why that was so—including lingering doubts about the validity of patents on living organisms, as well as a continuing ambivalence in federal policy toward university patenting of federally funded research. See *supra* note 48 and accompanying text. It has also been shown that university patenting began to grow as a share of U.S. patenting a full decade prior to the Bayh-Dole Act. See *supra* notes 48-49 and

science do not necessarily conflict with the policies furthered by federal patent law,<sup>78</sup> but neither are the norms of open science necessarily efficient,<sup>79</sup> and for that reason they may have been appropriate candidates for change via legislative intervention. Most proponents and critics of the Bayh-Dole Act likewise appear to agree that the purpose of the Bayh-Dole Act was precisely to affect a norm change in the scientific research community in an effort to promote the more efficient commercialization of federally funded research.

The more urgent and controversial question is whether this legislatively generated norm change in the scientific research community in the United States has generated any inefficiencies of its own. The two most common sets of concerns raised about the Bayh-Dole Act are: 1) that university patenting and licensing in general may have restricted dissemination of academic research, diverted faculty from basic to more applied research, contributed to research misconduct and/or academic mismanagement of federal research funds, or created conflicts of interest in the basic research mission of U.S. universities; and 2) that the patenting and licensing of basic upstream genetic research tools in particular threaten to create both “blocking patents” on key technologies and “patent thickets,” thus retarding biomedical innovation, technology transfer, and the development of downstream commercial products and processes. The first set of concerns will be discussed below, while the second will be the subject of Part III of this Chapter. Before addressing these two specific sets of concerns, however, it bears noting that because those who raise them are explicitly or implicitly arguing that the policies underlying the Bayh-Dole Act are in need of significant reform,<sup>80</sup> the burden of proof on both issues would appear to be on the critics to offer the same kind of theoretical arguments and empirical evidence in support of their position as was initially demanded of the proponents of the Bayh-Dole Act in Part I of this Chapter.<sup>81</sup>

The strongest theoretical criticism raised against the Bayh-Dole Act is that, in providing incentives to patent and restrict access to discoveries made in institutions that have traditionally been the principal performers of basic, or “curiosity-driven,” research,

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accompanying text. Thus, drawing any definitive conclusions about whether a specific academic norm against patenting genetic research existed prior to 1980 is difficult.

<sup>78</sup> See Eisenberg, *Proprietary Rights and the Norms of Science*, *supra* note 7, 229-231 (concluding that while trade secrecy is an undesirable strategy for protecting basic research discoveries, patent law is in many respects more congruent with scientific norms, as it is premised on disclosure, but arguing that the fit between the patent system and the norms and incentive systems of the biological research community is not perfect, and patent law may threaten the interests of the research community in the free use and extension of new discoveries unless certain adjustments are made).

<sup>79</sup> See, e.g. Rai, *Regulating Scientific Research*, *supra* note 7, 85-88.

<sup>80</sup> See, e.g., *id.* 144-151 (suggesting specific legal changes that would reinforce efficient research norms as a mechanism for balancing privatization and the public domain); Rai & Eisenberg, *supra* note 7, at 291 (arguing that the Bayh-Dole Act should be amended to give funding agencies greater discretion to determine when to require that publicly-funded research discoveries be dedicated to the public domain); Strandburg, *supra* note 50, at 95 (arguing that a strengthened experimental use exemption to patent infringement liability is important to redirect the patenting behavior of basic researchers in a more socially beneficial direction); Frischmann, *Innovations and Institutions*, *supra* note 29, at 347 (arguing that current innovation policy is in need of significant reform).

<sup>81</sup> For a rationale for the allocation of the burden of proof, see *supra* note 25.

the Act threatens to impoverish the public domain that has long been an important resource for researchers in both the public and private sectors,<sup>82</sup> and may threaten the functioning of the curiosity-driven research enterprise itself.<sup>83</sup> The remainder of Part II of this Chapter will address the argument that university patenting and licensing may be restricting dissemination of academic research, diverting faculty from basic to more applied research, contributing to research misconduct or academic mismanagement of federal research funds, or creating conflicts of interest in the basic research mission of U.S. universities. Part III will consider the impact of “upstream” university patenting on curiosity-driven research and downstream innovation.

#### A. The Impact of the Bayh-Dole Act on Dissemination of Academic Research

While citing to what is described as “considerable evidence of increasing secrecy and delays in the dissemination of genetic research results,” one critic of the Bayh-Dole Act nevertheless concedes that “the evidence with respect to a connection between the increasing secrecy and delays and university patenting is less clear.”<sup>84</sup> Among the empirical studies most frequently cited as evidence of increasing secrecy and delays in dissemination of research results, moreover, two of these studies--Blumenthal *et al.* (1997), and Campbell *et al.* (2002)--conclude that actual withholding of research results is not a widespread phenomenon among life science researchers, at least as measured by self-reports of faculty.<sup>85</sup>

The earlier of these two studies (Blumenthal *et al.*), based on a survey conducted between October 1994 and April 1995, also finds that withholding among life science faculty is more common among the most productive and entrepreneurial faculty,

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<sup>82</sup> See Eisenberg, Public Research and Private Development, *supra* note 2, at 1667.

<sup>83</sup> See Strandburg, Curiosity-Driven Research and University Technology Transfer, *supra* note 50, 107-111.

<sup>84</sup> See *id.* at 94, citing to Eric Campbell, Brian R. Clarridge, Manjusha Gokhale, Lauren Birenbaum, Stephen Hilgartner, Neil A. Holtzman, & David Blumenthal, *Data Withholding in Academic Genetics: Evidence From a National Survey*, 287 JAMA 473, 478 (2002)[hereinafter Campbell *et al.* (2002)]; David Blumenthal, Eric Campbell, M.S. Anderson, Nancyanne Causino, and Karen S. Louis, *Withholding Research Results in Academic Life Science*, 277 JAMA 1224 (1997)[hereinafter Blumenthal *et al.* (1997)]; Jeremy M. Grushcow, *Measuring Secrecy: A Cost of the Patent System Revealed*, 33 J. LEGAL STUD. 59 (2004)[hereinafter Grushcow], which is critiqued *infra* note 99, and J. H. Reichman & Paul F. Uhlir, *A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment*, 66 L. & CONTEMP. PROB. 315 (2003), an article focusing primarily on the threat posed by the extension of exclusive intellectual property rights to collections of data themselves, in which the discussion of the Bayh-Dole Act, *id.* 341-343, 398-399, 402-404, is largely derived from Rai & Eisenberg, *supra* note 7; Frischmann, *Innovations and Institutions*, *supra* note 29; Eisenberg, *Public Research and Private Development*, *supra* note 2; Eisenberg, , *Proprietary Rights and the Norms of Science*, *supra* note 7; Rai, *Regulating Scientific Research*, *supra* note 7; and other scholarship of these same critics of Bayh-Dole.

<sup>85</sup> Blumenthal *et al.*, *supra* note 84, at \_\_\_ ; Campbell *et al.*, *supra* note 84, at 478. Note that the two studies have one author (David Blumenthal) in common. The authors of both reports concede that faculty may have underreported engaging in behaviors that they viewed as contrary to accepted norms of practice and may have overreported reasons for their withholding behavior that they viewed as socially acceptable. Blumenthal *et al.* (1997) at \_\_\_ ; Campbell *et al.* (2002) at 479. For three later studies that appear to confirm that actual withholding of research results is not a widespread phenomenon among life science researchers, see *infra* notes 96-97, 101-104 and accompanying text.

suggesting that highly productive faculty may be more burdened with requests and thus more likely at some point to be unable to comply, and also that data withholding may be important to assuring priority in publication.<sup>86</sup> The study goes on to distinguish between two discrete types of withholding behavior: 1) refusals to share data, which appear to be motivated by a desire by scientists to protect their scientific priority,<sup>87</sup> and 2) delays in publication, which are more a product of commercial considerations and relationships with industry.<sup>88</sup> The report notes that university involvement in an academic-industry research relationship is associated with publication delays but not with refusal to share research results upon request, and that the most commonly cited reason for delay in publication (46% of those who experienced delays) was the need to allow time for filing patent applications.<sup>89</sup> The report thus concludes that “both the natural competitiveness of scientists and the influences of the outside world may play a role in compromising the . . . norm of communalism, and . . . the comparative importance of such factors may differ by the type of withholding behavior.”<sup>90</sup> A slightly earlier study by Blumenthal and others, for example, cautioned that secrecy is more common in industrially *supported* academic research, as higher levels of secrecy result in part from the policies and expectations of the industrial partners, than in research supported otherwise (e.g. through federal funding).<sup>91</sup>

The later study (Campbell *et al.*), which is based on a survey conducted between March and July 2000, finds that only 12% of geneticists reported denying requests from other academicians for information, data, and materials,<sup>92</sup> but the study also notes that the impact may be much more widespread, as almost half of all geneticists who made a request of another academic for information, data, or materials related to published research reported having had that request denied.<sup>93</sup> On the other hand, while more than

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<sup>86</sup> Blumenthal *et al.* (1997), *supra* note 84, at \_\_\_. Of those refusing to share, 46% reported doing so to protect their scientific lead, 27% because of the limited supply or high costs of the materials requested, 18% because of a previous informal agreement with a company, 6% to protect the financial interest of the university, 4% because of a formal agreement with a company, and 2% to protect their own financial interests. See also Campbell *et al.* (2002), *supra* note 84, at 479 (noting that data withholding “may paradoxically occur most commonly during extremely rapid progress, since scientists are generating large numbers of new findings that stimulate much jockeying for scientific priority.”).

<sup>87</sup> See *supra* note 86.

<sup>88</sup> Blumenthal *et al.* (1997), *supra* note 84.

<sup>89</sup> *Id.* The report goes on to note that the delays reported by faculty exceeded 6 months, far longer than the 60 days the National Institutes of Health considers acceptable. *But cf. infra* notes 97-100 and accompanying text.

<sup>90</sup> *Id.*

<sup>91</sup> David Blumenthal, Nancyanne Causino, Eric Campbell, & Karen S. Louis, *Relationship Between Academic Institutions and Industry in the Life Sciences—An Industry Survey*, 334 NEW ENG. J. MED. 368, 372 (1996).

<sup>92</sup> Campbell *et al.* (2002), *supra* note 84, at 478. The authors concede that because they relied on self-reporting, this figure “likely constitutes a lower bound estimate of the proportion who actually participate in this behavior, since respondents are often reticent to admit engaging in behavior that may be perceived as less than desirable.” *Id.* at 479.

<sup>93</sup> *Id.* Rai & Eisenberg, *supra* note 7, at 295, note 38, point out that the 47% figure represents a “substantial increase” over the 34% figure reported in Blumenthal *et al.* (1997), *supra* note 84. However, the two studies appear to have been based on slightly different populations. In Blumenthal *et al.* (1997), the study was derived from a stratified random sample of 4000 life-science faculty from 50 universities that received the most research funding from the National Institutes of Health (NIH) in 1993, and included faculty from

one third (35%) of the geneticists surveyed believe that data withholding is becoming more common in their field, 51% believe that the willingness to share data remains unchanged, while 14% believe that the willingness to share data had actually increased.<sup>94</sup> The study also notes that data withholding “may paradoxically occur most commonly during extremely rapid progress, since scientists are generating large numbers of new findings that stimulate much jockeying for scientific priority,” that scientists are most likely to encounter refusals when they approach other academic investigators for access to biomaterials, and that at least some of these refusals are likely to stem from the scarcity of the materials or human subjects concerns.<sup>95</sup>

A more recent study--Walsh & Hong (2003)—compared two surveys of experimental biologists, mathematicians and physicists, conducted about thirty years apart, and seemed to confirm that the increasing commercialization of academic science has led to an increase in secrecy, particularly among experimental biologists.<sup>96</sup> However, the study is also said to show that secrecy is strongly predicted by scientific competition (measured as concern over having one’s research results anticipated), while the effects of commercial activity are quite mixed, as industry funding is associated with greater

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all life-science departments and graduate programs at these institutions. Campbell *et al.* (2002), *supra* note 84, on the other hand, was based on a sample of 3000 life scientists from the 100 U.S. educational institutions that received the most NIH funding in 1998, but was limited to departments and programs in genetics and human genetics, together with three additional randomly-selected life science departments and programs from lists of clinical and non-clinical departments. Blumenthal *et al.* (1999), *supra* note 84, found that investigators in the field of genetics are more likely than others in the life sciences to engage in data-withholding behaviors. However, Campbell *et al.* (2002) compared the response of geneticists with 600 other life scientists and found that while the odds of geneticists making or receiving requests for information, data, and materials were significantly higher than for other life scientists, geneticists were no more likely than other life scientists to deny requests or to have their requests denied. *Id.* at 477-478. The two factors significantly associated with an increased likelihood of geneticists denying others’ requests were having received a high number of requests in the last 3 years and having engaged in commercial activities. *Id.*

<sup>94</sup> Campbell *et al.*, *supra* note 84, at 478.

<sup>95</sup> *Id.* at 479. The study also notes that “it may be that material transfer agreements have become so complex and demanding that they inhibit sharing.” *Id.* Rai & Eisenberg, *supra* note 7, at 295, note 38, cite Campbell *et al.* (2002) for the proposition that scientists are most likely to encounter refusals when they approach other academic investigators for access to biomaterials, and for the proposition that material transfer agreements may have become so complex and demanding that they inhibit sharing, but they do not mention the study’s reference to the scarcity of materials or human subjects concerns as likely explanations for withholding biomaterials. Nor do they refer to the observation that data withholding “may paradoxically occur most commonly during extremely rapid progress, since scientists are generating large numbers of new findings that stimulate much jockeying for scientific priority.”

<sup>96</sup> John P. Walsh & Wei Hong, “Secrecy is increasing in step with competition,” 442 NATURE 801-802 (2003)[hereinafter Walsh & Hong (2003)]. Interestingly, however, the study notes that even in 1966, only 50% of 1,042 respondents reported feeling safe in talking with others about their current research, and then goes on to report that by 1998, when the authors surveyed 202 scientists in the same three fields, the equivalent number was 26%, while a mere 14% of experimental biologists were willing to talk openly about their current research. Given the mixed evidence concerning the effects of commercial activity, the authors caution that “[a]lthough it is right to raise concerns about the negative effects of publication restrictions associated with industry funding, we should not conclude that university-industry linkage per se produces unhealthy levels of secretiveness among academic scientists. Instead, it may be better to focus on alleviating some the negative effects of scientific competition.” *Id.* at 802.

secrecy, but having industry collaborators is associated with less secrecy, and patenting is said to have no effect at all.<sup>97</sup>

All but the last of these findings appear to be consistent with those of the earlier Blumenthal and Campbell studies. Moreover, the apparent discrepancy between Walsh & Hong's last finding and the earlier study of Blumenthal *et al.*, which had found a connection between delays in publication and the need to allow time to file patent applications, has at least two possible explanations. The first is that the Walsh and Hong study does not appear to have distinguished between refusals to share data and delays in publication, but rather dealt with secrecy generically, and thus may have failed to disaggregate the impact of patenting on refusals to share data and on delays in publication. A second, more intriguing (albeit somewhat more speculative), possibility is that a change in U.S. patent law, which was made after the data was collected for the Blumenthal study and was designed to reduce the incentive to delay publication pending completion of research and filing of a patent application, may in fact have begun to achieve its purpose by the time of the Walsh and Hong study.

In 1994, three years before the second of the two surveys utilized by Walsh & Hong, the U.S. Patent Act was amended to permit the filing of provisional patent applications, which effectively doubled the time that researchers have to complete their research before being required to file actual patent claims with the Patent Office.<sup>98</sup> The data of Blumenthal *et al.* was collected prior to the effective date of that amendment.<sup>99</sup> This amendment of the Patent Act may well have affected a significant change in university patenting behavior, as at least one commentator, discussing how to maximize

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<sup>97</sup> *Id.*

<sup>98</sup> See 35 U.S.C. § 111(b), the authoritative Statement of Administrative Action for the amendment of which notes that the amendment “will provide applicants who take advantage of this section a period of up to twelve months in which to file a formal application but claim priority based on the provisional application filed in the United States, which period will not be included in the calculation of the patent term.” Pub. L. No. 103-465, § 532(b)(1), 108 Stat. 4809, 4985 (1994). One purpose of provisional patent applications is to “place domestic applicants on an equal footing with foreign applicants as far as the measurement of term is concerned because the domestic priority period, like the foreign priority period, is not counted in determining the endpoint of the patent term.” US PTO Final Rule Making, 60 Fed. Reg. 20195, 20205 (April 25, 1995)(noting that “[I]n accordance with [Article 4*bis* of] the Paris Convention for the Protection of Industrial Property, the term of patent cannot include the Paris Convention priority period”). Another stated purpose of the provisional patent application process, however, is “to provide easy and inexpensive entry into the patent system.” *Id.*

<sup>99</sup> A similar problem affects yet another study, published in 2004, but based on data collected between 1980 and 1990. See Grushcow, *supra* note 84. This study, which purports to show that academic scientists seeking to patent their work withhold the presentation of their data until their work is substantially complete, is premised on the assumption that the U.S. Patent Act's limited one year grace period for filing a patent application after the invention is described in a printed publication, 35 U.S.C. § 102(b), creates an incentive to withhold publication until work is substantially complete and ready for patenting, but the study inexplicably fails to consider what effect the provisional patent application process might have had on that incentive. See *supra* note 98 and accompanying text. Indeed, the study assumes that a cost of the patent system is “increased secrecy,” citing to Eisenberg, Proprietary Rights and the Norms of Science, *supra* note 7, at 216, an article that, like the data the study relies on, predates the adoption of the provisional patent application process. In short, while Grushcow presents an interesting study of the secrecy costs of the patent system as it existed in 1980-1990, his study tells us little if anything about the impact of the current patent system on publication of research results.

the benefits of the provisional patent application process, recommends among other things that applicants immediately file on conception of the invention rather than wait for an actual reduction to practice.<sup>100</sup>

In any event, two of the most recent empirical studies are likewise supportive of the conclusions of the earlier Blumenthal, Campbell, and Walsh & Hong studies. In one, Walsh, Cho and Cohen (2005) determined that only 1 % of a random sample of 398 academic respondents involved in biomedical research reported suffering a project delay of more than a month due to patents on knowledge inputs necessary for their research.<sup>101</sup> None of the random sample of academics had stopped a project due to the existence of third party patents on research inputs. On the other hand, Walsh, Cho and Cohen found that access to tangible property in the form of material transfers is more likely to impede research, as 19 % of their respondents did not receive materials in response to their last request, and a comparison with an earlier study suggests this number has increased since the late 1990s.<sup>102</sup> However, the major stated reasons for academics not sharing materials is the time and cost of providing these materials and scientific competition, rather than patents or concern over commercial returns.<sup>103</sup> On the other hand, in a related article, Walsh, Cho & Cohen do note that the number of scientific researchers who are being subjected to threatening "notification letters" has increased since the *Madey* decision.<sup>104</sup> They also note scientists do appear to be foregoing or delaying their research as a result of patents, although still at relatively low levels.<sup>105</sup>

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<sup>100</sup> See Peter G. Dilworth, *Some Suggestions for Maximizing the Benefits of the Provisional Application*, 78 J. PAT. & TM OFFICE SOC'Y 233, 234 (1996). See also Charles E. Van Horn, *Practicalities and Potential Pitfalls When Using Provisional Patent Applications*, 22 AIPLA Q. J. 259, 296-301 (1994)(noting that among the many benefits that can be obtained by filing a provisional patent application are 1) that the patent term does not start with the filing date; 2) that filing a provisional application provides a quick and relatively inexpensive entry into the patent system, as the formal and legal requirements are fewer and provide greater flexibility than a non-provisional patent application, fees are significantly lower, examination may be deferred, postponing costs and providing an opportunity for an inventor to see financial assistance for patent prosecution or product development, while having the security of a patent application on file with the US PTO; 3) where a patent eventually issues on a non-provisional application claiming the benefit of a provisional application, the filing date of the provisional application is likely to be considered the effective date for prior art purposes under section 102(e) and (g), as long as the provisions of section 371 (governing the national stage of Patent Cooperation Treaty filings) are avoided; 4) the filing of a provisional application will establish, as of the time of the filing date, a constructive reduction to practice of the invention described in the application, which is critical for obtaining patents in countries with first-to-file systems, but can also provide important advantages in the U.S. first-to-invent system; and 5) filing a provisional application provides a mechanism for protecting absolute novelty in Paris Convention countries that do not provide a grace period for filing after publication.

<sup>101</sup> See Walsh, Cho & Cohen, *supra* note 27, at 2.

<sup>102</sup> *Id.*, 2-3.

<sup>103</sup> *Id.* See also *infra* notes 110, 124, and accompanying text, suggesting how the absence of patent protection might aggravate, rather than facilitate, sharing of both data and research materials.

<sup>104</sup> See John P. Walsh, Charlene Cho & Wesley M. Cohen, *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002 (2005)[hereinafter Walsh et al.] (increase from 3% to 5%); see also *id.* (notification by scientists' own institutions to respect patent rights has increased from 15% to 22%).

<sup>105</sup> *Id.* (of those aware of potentially applicable patents, 4 of 32 scientists (12.5%) changed their research approach, and 5 of 32 (15.6%) were delayed by at least a month).

The second study, conducted by the Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation, National Research Council of the National Academies, and relying in part on the Walsh, Cho, and Cohen study, found that the number of research projects abandoned or delayed as a result of difficulties in technology access is reported to be small, as is the number of occasions in which investigators revise their protocols to avoid intellectual property issues or in which they pay high costs to obtain intellectual property, and that for the time being, at least, it appears that access to patented inventions or information inputs into biomedical research rarely imposes a significant burden for biomedical researchers.<sup>106</sup>

Finally, two other recent studies have found that only a minority of university-based discoveries are being patented to begin with, as only about 15 % of university-based genetic discoveries are patented, with the vast majority going into the public domain without intellectual property protection.<sup>107</sup> Moreover, one of these studies reveals that universities have substantially different patenting strategies than those representing commercial entities.<sup>108</sup> Private firms reported both a “blocking” strategy designed to keep others out of an intellectual property area, and a “defensive” strategy designed to defend a stake in an area by filing patent applications on all inventions and then dropping technologies later if there is no commercial interest.<sup>109</sup> By contrast, non-profit institutions appear to be more selective, filing only where inventions demonstrably meet the requirements of novelty, usefulness, and non-obviousness.<sup>110</sup> Moreover, non-profit institutions were more likely than firms to report careful market analysis to ensure a patent would be licensed even prior to filing for a patent application.<sup>111</sup>

Thus, while there is at least some evidence suggesting increasing secrecy and delays in the dissemination of genetic research results over the past two decades, it is not at all clear that the concomitant increase in university patenting and licensing necessarily bears any causal relation with the increase in secrecy or continuing delays in disseminating research results, or that university patenting is significantly diminishing the public domain. Indeed, to the extent that increased university patenting and licensing of

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<sup>106</sup> See NRC Report, *Reaping the Benefits*, *supra* note 7, at 2. However, this report also concludes that there are several reasons to be cautious about the future—reasons that will be discussed in more detail in Part III of this article, *infra* notes 164-182 and accompanying text.

<sup>107</sup> See Walsh, Arora & Cohen, *supra* note 13, at 309, citing to David C. Mowery, Richard R. Nelson, Bhavan N. Sampat & Arvids A. Ziedonis, *The Growth of Patents and Licensing by U.S. Universities*, 30 RESEARCH POLICY 99 (2001)[hereinafter Mowery, Nelson, Sampat & Ziedonis], which constitutes an early version of Mowery et al., *supra* note 4; and M. R. Henry, M.K Cho, M.A. Weaver & J. Merz, *DNA Patenting and Licensing*, 297 SCIENCE 1279 (Aug. 23, 2002). See also Michelle R. Henry, Mildred K. Cho, Meredith A. Weaver, and Jon F. Merz, *A Pilot Survey on the Licensing of DNA Inventions*, 31 J. L. MED. & ETHICS 442, 443 (2003)[hereinafter Henry et al.].

<sup>108</sup> Henry et al., *supra* note 105, at 443.

<sup>109</sup> *Id.*

<sup>110</sup> *Id.* The difference in selectivity is said to be evident in the number of invention disclosures received compared with the number of patent applications survey respondents had filed on nucleic acid sequence inventions in the prior two-year period. Whereas companies reported an average of 37 invention disclosures and filed an average of 32 patent applications (86%), non-profit research organization received an average of 163 invention disclosures and filed an average of 24 applications (15%). *Id.*

<sup>111</sup> *Id.* at 444.

upstream research results has strengthened the bargaining position of universities in relation to private industry and compensates in part for the decline in the federal government's share of financial support for academic R & D,<sup>112</sup> any reduction in the ability of universities to patent such research may actually aggravate, rather than alleviate, the problem of secrecy and delays in dissemination of research results.

## B. Diversion of Research, Research Misconduct and Mismanagement, and Conflicts of Interest

Critics also generally acknowledge that the evidence is mixed with respect to whether university scientists have shifted toward more applied research as a result of increased patenting opportunities.<sup>113</sup> Among the most commonly cited empirical studies on this point are those of two economists, Jerry G. Thursby and Marie C. Thursby.

In a study partially funded by a National Science Foundation grant, Thursby and Thursby report that: "While some evidence shows an increase in applied research in the 1990s to suggest changes in the direction of faculty research, much of the available evidence suggests that faculty have not been diverted from their traditional role in the creation of knowledge."<sup>114</sup> Specifically, they find "in a study of over 3400 faculty at 6

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<sup>112</sup> See <http://www.nsf.gov/statistics/seind02/c4/c4s1.htm#c4s112>, noting that:

In recent years, the Federal Government has contributed smaller shares of the nation's R&D funding. The Federal Government had once been the main provider of the nation's R&D funds, accounting for 53.9 percent in 1953 and as much as 66.8 percent in 1964. Its share of R&D funding first fell below 50 percent in 1979 and remained between 44 and 47 percent from 1980 to 1988. Since then, its share has fallen steadily to 26.3 percent in 2000, the lowest ever recorded in the history of the NSF's R&D data series. This decline in the Federal Government share, however, should not be misinterpreted as a decline in the actual amount funded. Federal support in 2000 (\$69.6 billion), for example, actually reflects a 0.8 percent increase in real terms over its 1999 level. Because industrial funding increased much faster . . . , Federal support as a proportion of the total has continued to decline.

The report goes on to note (<http://www.nsf.gov/statistics/seind02/c5/c5s1.htm#c5s112>) that:

Although the Federal Government continues to provide the majority of [R&D] funds [to U.S. universities], its share has declined steadily since reaching a peak of slightly more than 73 percent in 1966. In 2000, the Federal Government accounted for an estimated 58 percent of the funding for R&D performed in academic institutions, its lowest share since the late 1950s.

The percentage of academic R & D funds provided by the federal government for the life sciences declined from 66.3% in 1973 to 57.2% in 1999. The percentage of federal R & D funds for the medical sciences declined from 75.3% in 1973 to 60.7% in 1999. See *id.* Appendix table 5-7. The report also notes that:

In 2000, industry provided an estimated 8 percent of academic R&D funding. The funds provided for academic R&D by the industrial sector grew faster than funding from any other source during the past three decades, although industrial support still accounts for one of the smallest shares of funding.

See <http://www.nsf.gov/statistics/seind02/c5/c5s1.htm#c5s112a>.

<sup>113</sup> See Strandburg, *supra* note 50, at 94, citing to Jerry G. Thursby and Marie C. Thursby, "University Licensing Under Bayh-Dole: What are the Issues and Evidence?," (May 2003)[hereinafter Thursby and Thursby May 2003], available at <http://opensource.mit.edu/papers/Thursby.pdf>; Thursby and Thursby 2003, *supra* note 37; Jerry G. Thursby and Marie C. Thursby, *Who is Selling the Ivory Tower: The Sources of Growth in University Licensing*, 48 MANAGEMENT SCIENCE, NO. 1, 90 (2002).

<sup>114</sup> Thursby and Thursby May 2003, *supra* note 111, at 6. See also Stephan et al., *supra* note 27, at 4, who analyze the Survey of Doctorate Recipients, and find "strong complementarity between patenting and publishing"; Azoulay et al., *supra* note 27, which analyzes a comprehensive, longitudinal dataset,

major research universities that the basic/applied split in research did not change over the period 1983-1999 even though licensing had increased by a factor greater than 10.”<sup>115</sup> They also indicate that their conclusion is generally consistent with two other sets of case studies of licensed technologies of prominent research universities, which are summarized respectively as having found “no evidence that financial returns played a significant role in the motivation behind research,” and having concluded “that there has been little effect on the content of academic research.”<sup>116</sup> These conclusions are also consistent with at least two other academic studies,<sup>117</sup> as well as data contained in two National Science Board studies, which show that in 1989, basic research constituted 68% of total academic research, applied research accounted for 25%, and developmental research for just 6%, while in 2000, basic research accounted for 69% of total academic research, applied research accounted for 24%, and developmental research for 7%.<sup>118</sup>

Even though the evidence of a diversion of research is at best mixed, a related concern is that the Bayh-Dole Act might be contributing to research misconduct,

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consisting of a prospective, 3,862-person random sample drawn from the population of life scientists in academia between 1967 and 1999, and concludes that “academic scientists who patent are more productive than otherwise equivalent scientists that are not listed as inventors on patents, but that publication quality appears similar in the two groups. Thus, the evidence appears to reject the assertion that the increase of patenting in academe has come at the cost of diverting researchers’ time, interest, and attention from their traditional focus on standard scientific research. However, we also find that scientists alter the content of their research after they patent in ways that make their output more relevant to questions of commercial interest.” *Id.* at 29. *Accord:* Kira R. Fabrizio & Alberto DiMinn, *Commercializing the Laboratory: Faculty Patenting and the Open Science Environment*, available at <http://gsbpapers.library.emory.edu/archive/00000254/01/GBS-OM-2005-004.pdf> (Aug. 12, 2005)[hereinafter Fabrizio & DiMinn].

<sup>115</sup> Thursby and Thursby May 2003, *supra* note 111, at 6, citing to Jerry G. Thursby & Marie C. Thursby, “Patterns of Research and Licensing Activities of Science and Engineering Faculty,” presented at May 21, 2003 meeting of the Cornell Higher Education Research Institute (2002).

<sup>116</sup> Thursby and Thursby May 2003, *supra* note 111, at 6, citing, respectively, J. Colyvas, M. Crow, A. Gelijns, R. Mazzoleni, R. Nelson, N. Rosenberg & B. Sampat, *How Do University Inventions Get Into Practice*,” 48 *MANAGEMENT SCIENCE*, NO. 1, 61 (2002); and Mowery, Nelson, Sampat & Ziedonis, *supra* note 105. *But cf.* Azoulay et al., *supra* note 27, discussed *supra* note 112, who, while they find that “both the flow and the stock of scientists’ patents are positively correlated to subsequent publication rates,” and that “this increase in output does not come at the expense of the quality of the published research,” nevertheless conclude that “patenting has had real effects on the direction of scientific research,” as they produce evidence that among those academics who patent, “patenting induces a moderate shift in the content of scientists’ research.” *Id.* at 2.

<sup>117</sup> See Richard Nelson, *Observations on the Post-Bayh-Dole Rise of Patenting at American Universities*, 26 *J. OF TECH. TRANS.* 13, 14 (2001)(noting “no evidence that research has become any less fundamental than it used to be”); and Arvid A. Ziedonis, *The Commercialization of University Technology* 156, 171 (2001)(unpublished Ph.D. dissertation on file with the Berkeley University Library)(noting that “the primary effect of the Bayh-Dole Act on academic patent quality was to promote previously inactive universities to establish technology transfer operations, rather than encourage experienced universities to shift their research, patenting, and licensing agendas from basic to more applied work”), *cited in* Wei-Ling Wang, *Technology Transfer From Academia to Private Industry: A Critical Examination of the Bayh-Dole Act 177-178, 218* (2004)(unpublished J.S.D. dissertation on file at Washington University School of Law and with the authors)[hereinafter Wang]. *But cf.* Azoulay et al., *supra* note 27, discussed *supra* notes 112, and 114.

<sup>118</sup> See Wang, *supra* note 117, at 218, citing to NATIONAL SCIENCE BOARD, *SCIENCE & ENGINEERING INDICATORS 1990*, AT 108 (1989), and NATIONAL SCIENCE BOARD, *SCIENCE & ENGINEERING INDICATORS 2002*, at 95-100 (2002).

mismanagement of research funds, or institutional or individual conflicts of interest in academia. A recent study, for example, recounts numerous instances of research misconduct and university mismanagement of federal research funds over the past 25 years (including a number of instances between 2003 and mid-2005 alone, in which six major-research universities paid substantial civil fees to the government to settle charges of improper diversion of federal-research funds), but concedes that the problem of research misconduct and university management of federal funds predated passage of the Bayh-Dole Act and persists in part because the federal government apparently lacks the will or the ability to enforce key provisions of the Act.<sup>119</sup>

Perhaps the most troubling example of an institutional conflict to date was the widely publicized story concerning the death in September, 1999, of an 18 year old patient of the Institute for Human Gene Therapy at the University of Pennsylvania, who had voluntarily accepted a trial therapy, even though his liver disease was already under control, having been informed that this trial might not help cure his disease, but apparently not having been informed that the gene therapy was still at such an early stage that there was no proof of its efficacy and that in earlier experiments with monkeys, the monkeys had died.<sup>120</sup> Later reports revealed that the therapy was developed by a biotechnology company that had been co-founded by the director of the institute (who was also the principal investigator of the project) and the University of Pennsylvania itself, and that the biotechnology company contributed approximately 20% of the annual research budget for the principal investigator's lab, in return for an exclusive right to develop the results of the research into commercial products, from which both the principal investigator and the university would profit significantly if the therapy was successful.<sup>121</sup> Soon after the family of the deceased patient filed suit against the university, the institute, and the principal investigator, the university settled the case out of court for an undisclosed sum, said to be between \$5-10 million, and the U.S. Food and Drug Administration issued an order halting 8 human gene therapy experimental trials at the university.<sup>122</sup>

There has also been at least one highly publicized example at the University of Pennsylvania of an individual conflict of interest, involving both a financial conflict and a

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<sup>119</sup> See Ritchie de Larena, *supra* note 58, at 32-43 (detailing the “harsh reality” of misuse and mismanagement of federal research funds), and 19-32 (detailing the “dormant” powers of the federal government, including the authority of federal funding agencies to: 1) “march-in” and take control of a federally funded invention, 35 U.S.C. § 203; 2) assert a “nonexclusive, nontransferable, irrevocable paid-up license to practice or have practiced for or on behalf of the U.S. any subject invention throughout the world,” 35 U.S. § 202(c)(4); and 3) claim actual title to an invention if reporting formalities are not properly observed, 35 U.S.C. § 202(c)(1). Agencies are also authorized in “exceptional circumstances” to determine that “restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of [the Act],” 35 U.S.C. § 202(a)(ii).

<sup>120</sup> Wang, *supra* note 117, at 158, citing to Jennifer Washburn, *Informed Consent?*, THE WASHINGTON POST, December 30, 2001, W 16 [hereinafter Washburn]. Wang defines a conflict of interest as “a conflict between the private interests and the official responsibilities of a person whose professional judgment is unduly influenced,” distinguishes between individual and institutional conflicts, and further divides individual conflicts into financial conflicts and conflicts of commitment. *Id.* at 157-162.

<sup>121</sup> *Id.* at 158-159, citing Washburn, *supra* note 118.

<sup>122</sup> Wang, *supra* note 117, at 159.

conflict of commitment. In that case, a faculty member who was the inventor of Retin-A, a chemical compound used to treat acne, and who had assigned his patent rights to the University of Pennsylvania (which had made \$15 million from licensing the invention), later discovered that Retin-A had great potential as an anti-wrinkle cream, filed for and received a patent on this new use, and sold these patent rights to a pharmaceutical company, without notifying the university, which upon learning of the transaction sued and eventually settled with the faculty member and the company.<sup>123</sup>

As troubling as these incidents are, however, the more fundamental question is whether, in vesting universities with presumptive ownership of patent rights resulting from federally funded research, thereby encouraging cooperation and interaction between academic researchers and private industry, the Bayh-Dole Act is creating or aggravating the risks of research misconduct, mismanagement of research funds, or institutional or individual conflicts of interest in academia. According to the research of David Blumenthal, an authority in the area of conflicts of interest who has investigated the prevalence of industry funding of academic research at four different points over the last two decades, the conflict of interest problem is not as serious as it is sometimes made out to be, nor does it appear to be a burgeoning problem in academia, as the amount of industry funding and faculty equity interest in companies connected to their research has remained moderate and has not substantially changed over time, with academic researchers receiving somewhere between 21-28 % of their funding from private industry, and approximately 7-8% of academics reporting that they held equity in a company related to their research.<sup>124</sup> Moreover, Blumenthal found that faculty receiving moderate amounts (i.e. less than two-thirds) of their funding from the private sector for a single project tended to be the most productive researchers in terms of the rates of publication in peer reviewed journals, while there tended to be a decline in publication rates as the amount of industry funding exceeded 66%, and researchers who received no industry funding produced the fewest number of publications.<sup>125</sup>

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<sup>123</sup> *Id.* at 160-161, citing to *University Patents, Inc. v. Kligman*, 762 F. Supp. 1212 (E.D. Pa. 1991); *Penn Settles Patent Suits on Retin-A*, PHILA. INQUIRER, Mar. 6, 1992, cited in Sunil R. Kulkarni, *All Professors Created Equally: Why Faculty Should Have Complete Control over the Intellectual Property Rights in Their Creations*, 47 HASTINGS L.J. 221, note 206 (1995). For the European experience relating to the contention stated in the title of the latter work, see *supra* notes 54-67 and accompanying text.

<sup>124</sup> Wang, *supra* note 117, citing to David Blumenthal, *Conflicts of Interest in Biomedical Research*, 12 HEALTH MATRIX 377, 378-379 (2002)[hereinafter Blumenthal]. See also Walsh, Cho & Cohen, *supra* note 27, at 2, who likewise found substantial commercial activity among a sample group of academic biomedical researchers, but also note that their study does not reflect much of a change over the last five years. They report that 19 % of their respondents reported receiving industry funding for their research (accounting for 4 % of their total research funding), while 43 % have applied for a patent at least once over the course of their career, with 22 % having applied in the last two years.

<sup>125</sup> Wang, *supra* note 117, at 163-164, citing to Blumenthal, *supra* note 124, 385-386. See also Stephan et al., *supra* note 27, discussed *supra* notes 112 & 123, who find a “strong complementarity between patenting and publishing”; Fabrizio & DiMinn, *supra* note 114; and Azoulay et al., *supra* note 27, discussed *supra* notes 112, 114, 115 & 123, who conclude that “scientists who patent are more productive than otherwise equivalent scientists that are not listed as inventors on patents, but that publication quality appears to be similar in the two groups. Thus, the evidence appears to reject the assertion that the increase in patenting in academe has come at the cost of diverting researchers’ time, interest, and attention from their traditional focus on standard scientific research.” However, Azoulay et al. also find that “scientists

Indeed, the strongest conclusion that can be drawn from the foregoing studies is arguably that continuing federal funding for basic scientific research, together with the continuing opportunity for universities to patent and license any commercially feasible applications of that basic research (subject to enhanced oversight by the NIH and other federal funding agencies), may well be critical to maintaining the autonomy of the research mission of U.S. universities, as this will minimize university reliance on the private sector to fund basic or applied research.<sup>126</sup> The final question to be considered, however, is whether the opportunity to patent and license upstream genetic research will itself retard downstream biomedical innovation or impoverish the public domain. It is to this question that we now turn.

### **Part III: The Impact of Upstream University Patenting on Downstream Innovation**

At the heart of the debate over patenting upstream genetic products and processes and allowing universities, small businesses, and other research institutions to retain presumptive ownership of the patent rights resulting from federally funded research is the concern that these two public policies may hinder rather than accelerate biomedical research, creating the risk of both blocking patents on particular foundational discoveries or indispensable research tools and more widespread “patent thickets,” or a “tragedy of the anti-commons,” where basic research discoveries necessary for subsequent downstream development are owned by a large number of entities.<sup>127</sup> The specific concern is that these patent thickets will impoverish the public domain that has long been an important resource for researchers in both the public and private sectors, and will potentially threaten the functioning of the curiosity-driven research enterprise itself.<sup>128</sup>

On this point, as in Part II of this Chapter, the burden of proof should be on critics to offer the same kind of theoretical arguments and empirical evidence in support of their concerns as was initially demanded of the proponents of the Bayh-Dole Act in Part I of

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alter the content of their research after they patent in ways that make their output more relevant to questions of commercial interest.” *Id.* at 29.

<sup>126</sup> For a sampling of suggestions for how the NIH, other federal funding agencies, the courts, or Congress itself might enhance agency oversight of federally funded research, see Rai & Eisenberg, *supra* note 7, at 310-313 (summarizing efforts of the NIH to regulate university patenting and licensing and suggesting two legislative modifications of the Bayh-Dole Act: 1) elimination of the “exceptional circumstances” language in 35 U.S.C. § 202(a)(ii), which currently creates a presumption that agencies should exercise their power to restrain patenting only infrequently; and 2) elimination of the requirement that the “march-in” authority vested in agencies by 35 U.S.C. § 203 be held in abeyance pending exhaustion of all court appeals by the government contractor); NRC Report, *Reaping the Benefit*, *supra* note 7 (making 13 specific recommendations for improved NIH, US PTO, and Congressional oversight of patenting and licensing of federally-funded research); and Ritchie de Larena, *supra* note 58, at 72-79 (suggesting that the management of the transfer of federally-funded technology be shifted to a national technology transfer center that would manage the disposition of intellectual property on all federally funded inventions). For data concerning the relative roles that federal and private sector funding currently play in academic R & D, see *supra* note 112 and accompanying text.

<sup>127</sup> See *supra* note 7 and accompanying text.

<sup>128</sup> See *supra* notes 82-83 and accompanying text.

this Chapter.<sup>129</sup> To date, however, little hard empirical evidence has been produced to substantiate their concerns, and most—though by no means all—of the most recently unveiled empirical studies suggest that these concerns are exaggerated.<sup>130</sup> Moreover, the author of at least one of these recent studies has also joined other patent law scholars in calling into question the theoretical assumptions on which concerns over blocking patents and patent thickets in upstream genetic research are based.<sup>131</sup> The balance of this Chapter will thus evaluate both the accumulating empirical evidence and the theoretical assumptions underlying the concern over blocking patents and patent thickets in upstream biomedical research.

#### A. The Empirical Evidence to Date

As was noted at the outset of this Chapter, two of the most widely cited empirical studies on the effect of research-tool patents on biomedical innovation, one published in 1998 and the other in 2003, came to seemingly conflicting conclusions.<sup>132</sup> On the one hand, a 1998 report of the NIH Working Group on Research Tools, chaired by one of the leading academic critics of the Bayh-Dole Act, reported that scientist and institutions involved in biomedical research are frustrated by growing difficulties and delays in negotiating the terms of access to research tools,<sup>133</sup> thus prompting the research arm of the National Academy of Sciences (NAS) to commission a study on the effects of patenting in the biomedical sciences.<sup>134</sup> On the other hand, however, the 2003 study commissioned by the NAS (hereinafter Walsh, Arora & Cohen) found “little evidence of routine breakdowns in negotiations over rights,” although the study cautioned that research tool patents do “impose a range of social costs and there is some restriction of access.”<sup>135</sup> The latter study also concluded that access to foundational upstream discoveries “has not yet impeded biomedical innovation significantly,” though it cautioned that “ongoing scrutiny is warranted.”<sup>136</sup>

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<sup>129</sup> See *supra* text preceding note 28.

<sup>130</sup> See *infra* notes 166-215 and accompanying text.

<sup>131</sup> See *infra* notes 216-230 and accompanying text.

<sup>132</sup> See *supra* notes 18-21 and accompanying text.

<sup>133</sup> See NIH Working Group Report, *supra* note 19, at 2.

<sup>134</sup> See Adelman, Fallacy of the Commons, *supra* note 1, at 998.

<sup>135</sup> See Walsh, Arora & Cohen, *supra* note 13, at 289. For a discussion of restrictions on access and the reasons therefore, see *supra* notes 84-112 and accompanying text.

<sup>136</sup> *Id.* For skewed summaries of the findings of this study by legal critics of the Bayh-Dole Act, see Rai & Eisenberg, *supra* note 7, discussed *supra* note 13; and Amy Kapczynski, Samantha Chaifetz, Zachary Katz & Yochai Benkler, *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031, 1054 (2005), citing to the study for the proposition that there is evidence that patents cause scientists to redirect their research efforts towards “areas with more intellectual property freedom.” The foregoing quote, however, is lifted from the abstract, which states only that there have been “cases in which research is redirected to areas with more intellectual property (IP) freedom,” while the Walsh, Arora & Cohen study itself states that “it was relatively rare for firms to move to a new research area . . . because of concerns over one or more research tools”; that of the 11 industry respondents who did mention IP as a cause for redirecting their research, seven “were primarily concerned with IP on compounds, not on research tools”; and that the findings of this study are “consistent with the notion that there are relatively few cases where otherwise commercially promising projects are not undertaken because of IP on research tools.” See Walsh, Arora & Cohen, *supra* note 13, at 303.

While at least one commentator argues that the 1998 and 2003 studies can be viewed as consistent,<sup>137</sup> both studies have also been criticized for not having disclosed the interview protocols followed in conducting the interviews on which the studies were based, thus raising the possibility that the questions may have driven the conclusions.<sup>138</sup> However, the controversy surrounding these two studies is rapidly diminishing in importance, as a rash of more recent studies, deploying a variety of research approaches, have largely corroborated the conclusions reached in the Walsh, Arora & Cohen study.<sup>139</sup> At the same time, however, at least three other recent studies, comparing patterns of citations to scientific articles, find respectively that 1) the grant of a patent that is a part of a paper-patent pair is associated with a significant but modest decline in knowledge accumulation as measured by forward citations; and 2) backward citation lags in industrial patents are increasing on average as university patenting increases, suggesting a slowdown in the pace of firm knowledge exploitation with increasing university patenting.<sup>140</sup>

Although these studies present results that are characterized as “robust,”<sup>141</sup> it does not follow that these results constitute evidence of a decline of knowledge accumulation or support an anti-commons hypothesis. In the first of these studies, for example, Fiona Murray and Scott Stern state their version of the anti-commons hypothesis as follows: “[I]f the grant of intellectual property hinders the ability of researchers to build (in the public domain) on a given piece of knowledge, then the citation rate to the scientific publication disclosing that knowledge should be lower than for scientific publications with no IP and should fall after formal property rights are granted.”<sup>142</sup> Then, having produced robust empirical data, based a sample of published scientific research articles appearing in a top-tier research journal specializing in dual knowledge discoveries,<sup>143</sup> that arguably meets the second part of their “If-then” hypothesis, Murray and Stern suggest that this data can be interpreted to establish the first part of the hypothesis.<sup>144</sup> But while the deductive syllogism “If x then y; x; therefore y” is both logically valid and (assuming

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<sup>137</sup> See *supra* note 20.

<sup>138</sup> See *supra* notes 18-21 and accompanying text.

<sup>139</sup> See *supra* note 27 and accompanying text.

<sup>140</sup> See *infra* notes 140-151 and accompanying text.

<sup>141</sup> E-mail communication from Wesley M. Cohen, referring to Murray & Stern, *supra* note 27, and Sampat, *supra* note 27 (April 4, 2006)(on file with the author). See also *infra* notes 143-144 and accompanying text.

<sup>142</sup> Murray & Stern, *supra* note 27, at 5.

<sup>143</sup> *Id.* at 14. Their sample consisted of 340 peer reviewed articles appearing in the research journal, *Nature Biotechnology*, between 1997 and 1999.

<sup>144</sup> *Id.* at 5: “[T]here is robust evidence for a quantitatively modest but statistically significant anti-commons effect; across different specifications, the article citation rate declines by 9 to 17 % after a patent grant.” Ultimately, however, the authors qualify their conclusion, stating only that their evidence suggests that “the granting of IPR is associated with a significant but modest decline in knowledge accumulation as measured by forward citation (emphasis added).” *Id.* at 30. The authors concede that published articles associated with formal IP are more highly cited than those whose authors choose not to file for patents (though they argue that this “can largely be accounted for by observed characteristics such as author location and number of authors on the article”). *Id.* at 5. They also concede that “scientific citations are by no means a perfect measure of the impact of a specific article,” though they go on to claim that citations provide a “useful (if noisy) index of the relative salience of research in follow-on research which is also disclosed in scientific publications.” *Id.* at 16.

the persuasiveness of the major and minor premises) highly persuasive, the converse inductive argument—“If x then y; y; therefore x”—is inherently less conclusive and loses much of its persuasive force where multiple plausible hypotheses can be propounded to explain y.

One reason to doubt that a drop in the citation rate in the academic literature for a given piece of knowledge once a patent issues represents a decline in knowledge accumulation or indicates that the issued patent “hinders the ability of researchers to build (in the public domain) on a given piece of knowledge” is that the issued patent may simply be serving a “signaling” function,<sup>145</sup> notifying academic researchers that they should fish in less crowded waters.<sup>146</sup> Another plausible explanation (consistent with the first) is that, with the publication of a patent, communication among researchers might to some extent shift from the scientific literature to the patent record, with the issued patent becoming a focus of citations both in the scientific literature and in subsequent patent applications of academic researchers seeking to distinguish their follow-on innovation from the prior art.<sup>147</sup> Only if there are no less-crowded waters in which academic researchers might fish, and no alternative medium (such as the patent record) whereby the value of fish might be ascertained, would a drop in forward citations in the scientific literature convincingly signal a decline in knowledge accumulation or a significant hindrance to follow-on research. As we shall see, the emerging empirical evidence with respect to biotechnology patenting and licensing suggests that this is far from the case.<sup>148</sup>

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<sup>145</sup> See generally Clarisa Long, *Patent Signals*, 69 U. CHIC. L. REV. 625 (2002). See also F. Scott Kieff, *Perusing Property Rights in DNA*, PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT (F. Scott Kieff, ed.) 125, 138-140 (2003)[hereinafter Kieff, *Perusing Property Rights in DNA*].

<sup>146</sup> For evidence establishing the abundance of “less crowded waters” in genomic research, see *infra* notes 220-225 and accompanying text. So abundant are these waters that one commentator, at least, argues that speculative gene patents are essentially irrational. See *infra* note 222 and accompanying text. In any event, such abundance tends to undercut the argument that a drop in forward citations in the scientific literature once a patent issues indicates that follow-on research is being significantly inhibited. See also Stephen et al., *supra* note 27, discussed *supra* note 112, finding a “strong complementarity between patenting and publishing”; and Azoulay et al., *supra* note 27, discussed *supra* notes 112, 114, 115, and 123, which finds that “academic scientists who patent are more productive than otherwise equivalent scientists that are not listed *supra* note 27, as inventors on patents,” and that publication quality appears similar in the two groups, though their study also suggests that “scientists alter the content of their research after they patent in ways that make their output more relevant to questions of commercial interest.” *Id.* at 29.

<sup>147</sup> See *infra* text following note 151. See also *Integra Lifesciences I. Ltd. V. Merck KGaA*, 331 F.3d at 875 (Newman, J., dissenting), noting that the “information contained in patents is a major source of scientific as well as technologic knowledge.”

<sup>148</sup> See *infra* notes 208-214, 220-225 and accompanying text. Another potential problem with the Murray and Stern study is its claim to have established the comparability of the selected scientific articles that are part of patent-paper pairs and other selected articles that are not part of a patent-paper pair, based on a review of the latter articles by an experienced intellectual property lawyer, who is said to have determined that, of the articles submitted for review, “more than 75% (27 out of 34) were considered to be obviously patentable; of the remaining, most obtained at least some potential for patentability.” The authors’ description of what this review consisted of—namely, an “examination of publication abstracts” and a “conservative” determination of whether the research findings included a “potentially patentable discovery”—fails to say whether and how extensively the patent attorney searched the prior art in making the determination of “potential patentability.” Although a review of article abstracts might enable a patent attorney to determine that the article discloses patentable subject matter, it would be difficult to assess whether an invention meets the patent standard of non-obviousness specified in 35 U.S.C. § 103 in the

The same observations are equally applicable to a paper by Bhaven N. Sampat, who reports the results of a study of citations to genomic discoveries and inventions by academic researchers who were funded by the National Institutes of Health.<sup>149</sup> In this study, which compares citations to articles with patents at a given point of time to citations to non-patented articles,<sup>150</sup> Sampat finds that genomic articles that are part of a patent-paper pair receive approximately 8 percent fewer U.S. citations than similar articles that are not yet related to an issued patent, and also finds that the effect is apparently driven by patented sequences, as non-sequence genomic discoveries (“techniques”) result in no statistically significant decline in citations after patents issue, while for genomic articles published after 1990 (though apparently not for genomic articles published prior to 1990<sup>151</sup>), patents on sequences are said to “cause” a 14 percent decline in citations, all else being equal.<sup>152</sup> However, Sampat concedes that a potential pitfall in using variation in the grant lag to identify the effects of patents on citations is the potential for unobserved heterogeneity across articles.<sup>153</sup>

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absence of a thorough examination of the prior art. Moreover, given at least some empirical evidence that universities and other non-profit research organizations tend to follow a more selective patenting strategy than do companies, reportedly conducting careful market analysis to ensure a patent will be licensed even prior to the filing of a patent application, *see supra* notes 108-109 and accompanying text, it could be argued that the experienced IP attorney’s comparability determination is not only incomplete, as it apparently does not consider comparability of licensing potential, but also somewhat suspect, as it suggests that universities and other non-profit institutions are acting more irrationally than selectively in making patenting decisions. While this may indeed be the case, such evidence would also tend to support the argument that speculative gene patenting may itself be irrational, *see infra* note 206 and accompanying text.

<sup>149</sup> Sampat, *supra* note 27, at 9. Unlike the Murray & Stern study, all of the articles in Sampat’s dataset, which is based on 590 genomic patents funded by the National Institutes of Health, are eventually the subject of a patent; thus, he cannot directly estimate the lifetime difference in citations of an article with and without patents. Rather than rely upon a non-patented control sample, as Murray and Stern do, Sampat simply treats the timing at which a patent “hits” an article as exogenous, and compares citations to articles with patents at a given point in time to citations to non-patented articles, after controlling for average article quality via article-specific fixed effects. *Id.*

<sup>150</sup> *Id.* For a critique of Sampat’s references to “patented” and “non-patented” articles, *see infra* note 152.

<sup>151</sup> While Sampat does not speculate as to why a statistically significant decline in academic citations to patented genetic sequences is observed only for articles published after 1990 and not before, one plausible explanation is that some environmental learning is occurring, as more and more academic researchers become familiar with the patent system. While other studies suggest that the number of academic biomedical researchers who regularly consult the patent record continues to be modest, *see infra* text accompanying note 174, the results of Sampat, Murray and Stern’s own studies suggest that such environmental learning is occurring, as the decline in citations in the academic literature they observe after a patent issues strongly suggests that at least some academics are consulting the patent record, recognizing the connection between an issued patent and a previously published article, and adjusting their research goals accordingly.

<sup>152</sup> *Id.* at 26. While Sampat himself speaks of “articles which are patented” and “similar articles on which patents have not yet issued,” I have paraphrased his findings, as it is hardly correct to say that articles as such can be patented; rather, he is comparing articles that disclose genomic inventions or discoveries that are later patented versus articles that disclose genomic inventions or discoveries that are not yet the subject of an issued patent. Bhaven states that his data show that patents on sequences disclosed in post-1990 articles “cause a 14 percent decline in citations, all else equal”—though he later qualifies that assertion, conceding that his finding that patents on genomic sequences “cause” declines in citations rests on the validity of his assumption that the timing of the patent grant is not otherwise systematically related to trends in citations, after controlling for the age and importance of an invention. *Id.* at 26, 28.

<sup>153</sup> *Id.* at 20.

As we have seen in evaluating the Murray and Stern paper, one potential unobserved heterogeneity--hiding in plain sight, as it were--may be that articles that are a part of a patent-paper pair disclose information that is available in both the article and the patent and can be cited both in the scientific literature and in the patent record, as the information in question begins to migrate from one forum to the other. By contrast, articles that are not currently the subject of a patent-paper pair disclose information that is available only in the scientific literature and, at least until a patent issues, will continue to be of interest primarily in that forum. In other words, for the comparison of citations of articles in the scientific literature to provide a meaningful measure of knowledge accumulation or the ability of researchers to build on a given piece of knowledge, one must also take into account whether and to what extent the patent is being cited in the scientific literature and whether and to what extent either the article or the patent is being cited in the patent record, as the patent record is just as much a repository of accumulated public domain knowledge on which researchers may rely and build as the scientific literature is. If a decline in citations in the scientific literature to an article that is part of a patent-paper pair can be shown to be offset by citations in the scientific literature to the corresponding patent and/or by citations to either the article or the patent in follow-on patent applications of academic researchers, then it would be difficult to conclude that the Sampat, Murray and Stern data accurately measure an overall decline in knowledge accumulation or that academic researchers are in fact being hindered in their ability to build (in the public domain) on a given piece of knowledge that is disclosed in a patent-paper pair.

A third study, by Kira R. Fabrizio, examines the relationship between the change in university patenting and changes in firm citation of public science, as well as changes in the pace of knowledge exploitation by firms, as measured by changes in the distribution of backward citation lags in industrial patents.<sup>154</sup> This study concludes that backward “citation lags in industrial patents are increasing on average as university patenting increases, suggesting a slowdown in the pace of firm knowledge exploitation with increasing university patenting.”<sup>155</sup> Fabrizio speculates that “this may be due to the reduced availability of an important input to the industrial R & D process: university-based science,” and that the “reduction or delay in availability may stem from reduced dissemination, restricted use, or more time consuming and costly negotiated access to university science.”<sup>156</sup>

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<sup>154</sup> See Fabrizio, *supra* note 27, (abstract). Fabrizio’s study is based on patents applied for in the U.S. between 1975 and 1995 in 626 international technology classes, which she proceeds to divide into high or low university patenting classes, according to the change in the percent of patent assigned to universities in that class. *Id.* at 13. The “low university patenting” group accounts for 69% of the patents and 79% of the technology classes in her dataset, while the “high university patenting” group accounts for 31% of the patents and 21% of the technology classes. *Id.* at 13-14.

<sup>155</sup> *Id.* at 4.

<sup>156</sup> *Id.* at 27. Fabrizio also finds an increasing variance across firms in citations to public science as university patenting increases, but concludes that the increase is associated with the increased reliance of industry innovation on public science, not the increase in patenting per se. *Id.* at 3. In particular, she finds that “non-U.S. inventors have decreased their citation of public science relative to U.S. inventors in the same technology class.” *Id.* at 18. As we have seen, however, one important objective of the Bayh-Dole Act was to reinvigorate U.S. industry in the face of increased foreign competition and to ensure that

Accepting for the moment Fabrizio's speculation as to what her data might mean, her conclusion is hardly surprising. If university patenting is increasing, and what was once freely available in the public domain must now be licensed, one would expect to see growing citation lags such as this. After all, the patent system is not cost-free, and if the Bayh-Dole Act is in fact encouraging universities to file patents, someone down the line will inevitably have to absorb the associated transaction costs (both financial and temporal). The more fundamental question, however, is whether Fabrizio's particular interpretation of her data is the only plausible explanation for what she observes and, if so, whether the transaction costs outweigh the benefits that society at large receives from university patenting. Fabrizio herself concedes that her study "says nothing about the amount, importance, or value of the innovations being patented or the costs of the indicated delays."<sup>157</sup> However, she does believe that her data "highlight one [of the] potentially detrimental consequences of intellectual property policy associated with increasing patenting of university-based research outputs."<sup>158</sup>

Fabrizio concedes that one alternative explanation for her data may be that, if "university research is opening up more basic, difficult, or new areas of innovation in which the progress is slower, this might produce a positive correlation between an increase in university patenting and an increase in the lag between patented inventions in a technology class."<sup>159</sup> However, she cites an earlier study demonstrating that the average backward citation lag of a patent is negatively correlated with the measures of "basicness" examined, and concludes that this evidence "contradicts the assumption that more basic inventions have longer average backward citation lags."<sup>160</sup> In addition, she hypothesizes that "if university patenting were in slower areas within a technology class, the backward citation lags of university patents would be larger than other patents in the same technology class."<sup>161</sup> To the contrary, however, "not only do the technology classes in which university patents are concentrated have on average shorter lags, but within the technology class the university patents have shorter lags."<sup>162</sup> Moreover, university patents "also have relatively shorter backward citation lags when compared to a matched

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federally funded research discoveries are developed by U.S. firms rather than by foreign competitors who "too often come to dominate world markets for products based on technologies pioneered by the United States." See *supra* notes 70-71 and accompanying text.

<sup>157</sup> *Id.*

<sup>158</sup> *Id.*

<sup>159</sup> *Id.* at 25.

<sup>160</sup> *Id.*, citing to Manuel Trajtenberg, Rebecca Henderson, and Adam Jaffe, *Universities vs. Corporate Patents: A Window on the Basicness of Innovations*, 5 *ECONOMICS OF INNOVATION AND NEW TECHNOLOGY* 19-50 (1997)[hereinafter Trajtenberg et al.], who develop a variety of forward and backward looking measures for the "basicness" of patented research. The forward measures include 1) the importance of patents, based on the number of subsequent citations and *their* respective importance (using the same measure); 2) the generality of subsequent patent citations; 3) the distance between the patented innovation and its descendants, measured both by time and technology classes; and 4) the ownership structure of an innovation's descendants. The backward measures include 1) the importance of previous patents cited; 2) the originality of the patented innovation, based on the breadth of the technological roots of the underlying research; 3) the predominance of scientific sources over technological ones; and 4) the distance between cited prior art and the patented innovation, measured both by time and technology classes.

<sup>161</sup> *Id.*

<sup>162</sup> *Id.*

sample of corporate patents.”<sup>163</sup> Thus, she concludes that “the explanation of increasing patent lags being due to increasing basicness of research associated with increasing university patenting is questionable from the start.”<sup>164</sup>

However, Fabrizio’s data is susceptible to yet another plausible explanation. As we have seen, an equally salient characteristic of university patents is that they tend to be early-stage, “proof of concept” patents, with only a small percentage being “ready for practical use.”<sup>165</sup> If one substitutes this characteristic of academic patenting for “basicness,” it arguably offers a plausible explanation for why citation lags in industrial patents are increasing on average as university patenting increases, even though technology classes in which university patents are concentrated have on average shorter lags and university patents within those technology classes have shorter citation lags. Just as *cited* university patents tend to be early-stage, “proof of concept” patents, the same is also likely to be true for university patents *citing to* previous university patents. Thus, when Fabrizio notes that university patents have relatively shorter backward citation lags when compared to a matched sample of corporate patents, she may in fact be comparing apples and oranges. Moreover, her data may demonstrate nothing more than that, as university patenting increases, backward citations in technology classes in which there is an increasing reliance on public science to such early-stage, “proof of concept” patents in industrial patents will experience a greater lag than will be the case for backward citations to that same prior art in other early-stage, “proof of concept” academic patents or for backward citations to prior art more generally. This alternative explanation for Fabrizio’s data undercuts her conclusion that increasing citation lags in industrial patents as university patenting increases is necessarily the result of a slowdown in the pace of firm knowledge exploitation with increasing university patenting.

In any event, offsetting the conclusions of the foregoing studies are at least five other recent studies, utilizing a variety of research methodologies, that all seem to corroborate the earlier conclusions reached by Walsh, Arora, and Cohen, though with some qualifications. The first of these recent studies, an expanded study and report to the NAS by Walsh, Cho, and Cohen,<sup>166</sup> considers in greater depth and with greater generality some of the questions considered in the earlier Walsh, Arora & Cohen study, and also goes on to examine the impact of intellectual property on incentives, knowledge flows, material transfers among bench scientists working in upstream biomedical research, the willingness of researchers to share materials and data with one another, the terms of exchange, and the factors that might condition such exchanges, including intellectual

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<sup>163</sup> *Id.*, citing to Trajtenberg et al., *supra* note 160.

<sup>164</sup> *Id.*

<sup>165</sup> See *supra* note 37 and accompanying text.

<sup>166</sup> Walsh, Cho & Cohen, *supra* note 21. Whereas the Walsh, Arora & Cohen study was based on 70 interviews with attorneys, business managers, and scientists from 10 pharmaceutical firms and 15 biotech firms, as well as university researchers and technology transfer officers from 6 universities, in addition to patent lawyers and government and trade association personnel, Walsh, Arora & Cohen, *supra* note 13, at 292, the Walsh, Cho & Cohen study was based on a survey of 1125 academic researchers and 563 industry researchers, as well as 299 academic and industry researchers who were conducting research on one of three signaling proteins. Walsh, Cho & Cohen, *supra* note 21, at 2.

property.<sup>167</sup> While they confirm that commercial activity is widespread among their academic respondents,<sup>168</sup> they do not find much of a change in the level of that commercial activity in the past five years.<sup>169</sup> Nor do they find evidence that patenting limits research activity significantly, particularly among those doing basic upstream research.<sup>170</sup> Only 1 % of their random sample of 398 academic respondents report suffering a project delay of more than a month due to patent on knowledge inputs necessary for their research, and none had stopped a project due to the existence of third party patents on research inputs.<sup>171</sup> However, they caution that one reason for the negligible impact of patents on the conduct of academic biomedical research is that researchers tend not to be aware of them. Even in the wake of the highly visible 2002 decision in *Madey v. Duke University*,<sup>172</sup> which Walsh, Cho and Cohen describe (not altogether accurately) as affirming the absence of any research exemption shielding universities from patent infringement liability,<sup>173</sup> only 5 % of their academic respondents check regularly for patents on research inputs.<sup>174</sup> In a related article, however, Walsh, Cho & Cohen do note that the number of scientific researchers who are being subjected to threatening "notification letters" has increased since the *Madey* decision.<sup>175</sup> Moreover, scientists do appear to be foregoing or delaying their research as a result of patents, although still at relatively low levels.<sup>176</sup>

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<sup>167</sup> *Id.* at 6. One reason that Walsh, Cho and Cohen decided to expand on their earlier research project was that shortly after the fieldwork for this earlier study was completed, the court in *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002), held that Duke University's use of patented equipment in the physics lab of a former faculty member did not fall within the judicially developed experimental use exemption. *See infra* notes 172, 185-189 and accompanying text. The Walsh, Arora & Cohen study had concluded that one reason research tool patents had not interfered with research was that academic researchers routinely ignored intellectual property rights in the course of their research. *See* Walsh, Arora & Cohen, *supra* note 13, at 324. The highly visible decision in *Madey* thus raised the question whether academics would continue to disregard patents on research tools. The expanded Walsh, Cho & Cohen Study concludes that so far, at least, academic researchers continue to ignore patents on research inputs. *See infra* note 174 and accompanying text. However, for biomedical researchers, at least, the more recent Supreme Court decision in *Merck KGaA v. Integra*, 125 S.Ct. 2373 (2005) should assuage at least some of the concern spawned by the decision in *Madey*. *See infra* notes 175-179 and accompanying text.

<sup>168</sup> Walsh, Cho & Cohen Study, *supra* note 21, at 2 (19 % currently receive industry funding for their research, representing 4 % of their total research funding; 43 % have applied for a patent at least once of the course of their career, with 22 % having applied in the last two years; 30 % have engaged in negotiations over rights in their inventions; 11 % have at least begun developing a business plan or other groundwork for starting a firm; 8 % have actually started a firm; 13 % report the commercialization of a product or process based one of their inventions; 18 % had some licensing income; and about 5 % received more than \$10,000 in total licensing income).

<sup>169</sup> *Id.*

<sup>170</sup> *Id.* at 3.

<sup>171</sup> *Id.* at 2.

<sup>172</sup> 307 F.3d 1351 (Fed. Cir. 2002). *See supra* note 153.

<sup>173</sup> Walsh, Cho & Cohen, *supra* note 21, at 6. For a discussion of the holding in *Madey*, *see infra* notes 185-189 and accompanying text.

<sup>174</sup> Walsh, Cho & Cohen, *supra* note 21, at 2. For evidence that at least some scientists *are* regularly checking the patent record, however, *see supra* notes 140-153 and accompanying text, summarizing the the studies of Murray & Stern, *supra* note 27, and Sampat, *supra* note 27.

<sup>175</sup> *See* Walsh et al., *supra* note 104, at 2002 (increase from 3% to 5%; notification by scientists' own institutions to respect patent rights has increased from 15% to 22%).

<sup>176</sup> *Id.* (of those aware of potentially applicable patents, 4 of 32 scientists (12.5%) changed their research approach, and 5 of 32 (15.6%) were delayed by at least a month).

The Walsh, Cho & Cohen study also finds that difficulties in gaining access to tangible research results through material transfers are more likely to impede research, but concludes that the major stated reasons for academics not sharing materials is evidently the time and cost of providing those materials and scientific competition, not patents or concerns over commercial returns.<sup>177</sup> This conclusion is hardly surprising, as one of the constitutionally mandated purposes of the patent system is to overcome the proclivity of commercially-minded innovators to cloak their innovations in secrecy.<sup>178</sup> Thus, if academic researchers are resisting making research results publicly available, this behavior strongly suggests that they are either motivated by factors other than a concern over commercial returns or have come to a strategic conclusion that secrecy will yield greater commercial returns than patenting. As was suggested in Part II of this Chapter, placing restrictions on the existing ability of academic researchers to patent upstream research results is thus likely to exacerbate, rather than alleviate, the problem of withholding access to research results, as it will simply drive still more academics to keep their research results secret.<sup>179</sup>

The second recent study on the effect of research-tool patents on biomedical innovation is a report just issued by the National Research Council of the National Academies (hereinafter the NRC Report), which relies in part on the Walsh, Cho and Cohen study.<sup>180</sup> This report, too, finds that “the number of projects abandoned or delayed as a result of difficulties in technology access is reported to be small, as is the number of occasions in which investigators revise their protocols to avoid intellectual property issues or in which they pay high costs to obtain intellectual property.”<sup>181</sup> Accordingly, the report concludes that, “for the time being, it appears that access to patented inventions

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<sup>177</sup> Walsh, Cho & Cohen, *supra* note 21, at 2-3. The study notes that these results are very similar to those of Campbell et al., *supra* note 84, discussed *supra* notes 92-95 and accompanying text, but also notes that there may be some response bias on this item, given that commercial motives may be viewed as less legitimate than excessive demands or scientific competition. Walsh, Cho & Cohen, *supra* note 21, at 28. However, after conducting a negative binomial regression predicting the number of requests denied, Walsh, Cho & Cohen conclude that, while commercial activity does have a negative effect of a scientist’s willingness to share research inputs, scientific competition and the burden associated with the effort are important, independent predictor of refusals to comply with requests for materials, and the patent status of the material has no independent effect. *Id.*

<sup>178</sup> See generally *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966) (“Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must ‘promote the Progress of \* \* \* useful Arts.’ This is the *standard* expressed in the Constitution and it may not be ignored.”)(emphasis in original); *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 489 (1974) (“If a State, through a system of [trade secret] protection, were to cause a substantial risk that holders of patentable inventions would not seek patents, but rather would rely on the state protection, we would be compelled to hold that such a system could not constitutionally continue to exist.”); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989) (“ . . . the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure.”).

<sup>179</sup> See *supra* text accompanying note 110.

<sup>180</sup> NRC Report, *Reaping the Benefits*, *supra* note 7, at xii (thanking John Walsh, Charlene Cho, and Wesley Cohen “for developing and conducting the survey of research scientists that added much to our understanding of intellectual property from the perspective of the biomedical research bench.”).

<sup>181</sup> *Id.* at 2.

or information inputs into biomedical research rarely imposes a significant burden for biomedical researchers.”<sup>182</sup>

However, the NRC Report also concludes that there are several reasons to be cautious about the future, particularly as the lack of substantial evidence for a patent thicket or a patent-blocking problem “is associated with a general lack of awareness or concern among academic investigators about existing intellectual property.”<sup>183</sup> The Report notes that this situation could change “dramatically and possibly even abruptly” if research institutions take more active steps to regulate researcher behavior or patent holders take more active steps to assert their patents against universities, either through infringement proceedings or via demands for licensing fees, grant-back rights, and other terms that are burdensome to research.<sup>184</sup>

The obvious concern here is over the potential impact of the decision of the Court of Appeals for the Federal Circuit (CAFC) in *Madey v. Duke University*.<sup>185</sup> However, while the *Madey* decision did describe the judicially-developed experimental use defense as “very narrow and limited to actions performed ‘for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry’,”<sup>186</sup> there was nothing particularly new in this formulation, as that statement can be traced back to early nineteenth century opinions of U.S. Supreme Court Justice Joseph Story.<sup>187</sup> In *Madey* itself, the court specifically held only that Duke University’s use of patented equipment in the physics lab of a former faculty member was not protected under the judicially-developed experimental use exemption because the use was in “keeping with the alleged infringer’s legitimate business,” as the research was in furtherance of the institution’s educational and research objectives.<sup>188</sup> In other words, while Duke University may have been conducting

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<sup>182</sup> *Id.*

<sup>183</sup> *Id.* at 3. Here, the NRC Report is obviously relying on the Walsh, Cho & Cohen study. See *supra* note 174 and accompanying text. For evidence that at least some scientists *are* regularly checking the patent record, however, see *supra* notes 140-153 and accompanying text, summarizing the the studies of Murray & Stern, *supra* note 27, and Sampat, *supra* note 27.

<sup>184</sup> *Id.* But see *infra* notes 201-202 and accompanying text.

<sup>185</sup> 307 F.3d 1351 (Fed. Cir. 2002). See *supra* note 158 and accompanying text.

<sup>186</sup> 307 F.3d at 1362

<sup>187</sup> See, e.g. *Sawin v. Guild*, 21 Fed. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391), in which Justice Story distinguished “the making with an intent to use for profit, and not for the mere purpose of philosophical [i.e. scientific] experiment, or to ascertain the verity and exactness of the specification.” See also *Whittemore v. Cutter*, 29 Fed. Cas. 1120, 1121 (C.C.D. Mass. 1813)(No. 17,600), in which Justice Story remarked that “it could never have been the intention of the legislature to punish a man who constructed a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.” For a modern interpretation of this judicially-developed experimental use privilege, see 331 F.3d at 874-875 (Newman, J., dissenting), discussed *infra* notes 194-195 and accompanying text.

<sup>188</sup> 307 3d at 1362. As one commentator has noted:

It is not difficult to understand why the court did not want to extend the research exemption to the University’s activities. The experimentation in this case was not trying to understand or experimenting on the equipment; rather, the experimentation was the economic purpose of the equipment. Extending the research exemption to such use would effectively immunize all academic institutions from infringing any patents on laboratory equipment.

Tanuja V. Garde, *Supporting Innovation in Targeted Treatments: Licenses of Right to NIH-funded Research Tools*, 11 MICH. TELECOMM. & TECH. L. REV. 249, 262 (2005). However, this same commentator

experimental research *with* the patented invention, it was not conducting experimental research *on* the patented invention, and consequently would not be entitled to assert even a broadly defined experimental use privilege.<sup>189</sup>

As the NRC Report itself later seems to recognize,<sup>190</sup> at least some of the anxiety spawned among biomedical researchers by the *Madey* decision should be assuaged by the Supreme Court's later decision in *Merck KGaA v. Integra Lifesciences I, Ltd.*,<sup>191</sup> which held there to be a broad statutory experimental use privilege under 35 U.S.C. § 271(e)(1)<sup>192</sup> to use patented compounds in preclinical studies as well as clinical trials, even with respect to drugs that are not ultimately the subject of submissions to the Food and Drug Administration (FDA), so long as 1) the researcher has a reasonable basis for believing that a patented compound may work through a particular biological process to produce a particular physiological effect; and 2) uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA. The Supreme Court's opinion in *Merck* admittedly did not discuss the judicially-developed experimental use privilege that had been in issue in *Madey*. The Court also carefully avoided expressing any view about whether, or to what extent, § 271(e)(1) exempts from infringement the use of "research tools" in the development of information for the regulatory process, noting only that Judge Newman's dissent in the lower court decision in *Merck* cautioned that "[u]se of an existing tool in one's research is quite different from study of the tool itself."<sup>193</sup> However, Judge Newman's dissenting opinion did offer a

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goes on to criticize the court's decision in *Madey* as "having been made much broader by its failure to differentiate between experimenting on patented technology and experimenting with patented technology." *Id.* See also *infra* note 194-195 and accompanying text.

<sup>189</sup> See *supra* note 188. See also *infra* notes 194-195 and accompanying text.

<sup>190</sup> See NRC Report, Reaping the Benefits, *supra* note 7, 94-95 discussing the Supreme Court's decision in *Merck KGaA v. Integra Life Sciences I, Ltd.*, 125 S.Ct. 2373 (2005). Notwithstanding the *Merck* decision, however, the Report expresses continuing concern, see NRC Report, Reaping the Benefits, *supra* note 7, 94-95, over the Court's observation at 125 S. Ct. 2382 that "Basic scientific research on a particular compound, performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce, is surely not 'reasonably related to the development and submission of information' to the FDA." On the other hand, the CAFC's earlier decision in *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002), does not eliminate the possibility that this research might nevertheless fall within the judicially-developed experimental use privilege, which is precisely what Judge Newman argues in her dissent to the CAFC's decision in *Merck v. Integra*. See *infra* notes 194-195 and accompanying text.

<sup>191</sup> 125 S.Ct. 2373 (2005).

<sup>192</sup> 35 U.S.C. § 271(e)(1) states that: "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product as those terms are used in the Federal Food, 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."

<sup>193</sup> 125 S.Ct. at 2382, n. 7, citing to 331 F.3d at 878 (Newman, J., dissenting). In its statement of the facts of the case, the Court noted that the Court of Appeals had held that *Integra*'s patents covered certain RGD peptides developed by *Merck*, see 125 S.Ct. at 2378, n. 3; that the patented RGD peptide sequence promotes cell adhesion by attaching to certain receptors commonly located on the outer surface of certain endothelial cells, 125 S.Ct. at 2377; and that the Scripps scientist whose research *Merck* was funding discovered that was possible to inhibit the growth of new blood vessels critical in many diseases, such as

trenchant discussion of the judicially-developed experimental use exemption, in which she argued that any “prohibition of all research into patented subject matter is as impractical as it is incorrect,” and emphasized in particular that a “rule that [the information contained in a patent] cannot be investigated without permission of the patentee is belied by the routine appearance of improvements on concepts that are patented.”<sup>194</sup> Support for Judge Newman’s argument may be found in the language of the Patent Act itself, which apparently envisions experimenting on the patented inventions of others in order to make independently patentable improvements of those inventions.<sup>195</sup> In short, while the precise parameters of the judicially-developed experimental use privilege remain murky, the *Madey* decision did little other than affirm that the judicially-developed research exemption does not altogether shield universities from potential patent infringement liability.

Perhaps most importantly, the Report concludes, is that results of the survey conducted with the support of the committee revealed substantial evidence of a more immediate and potentially remediable burden on research stemming from difficulties in accessing proprietary research materials, whether patented or unpatented.<sup>196</sup> Echoing the Walsh, Cho & Cohen study, the Report found that impediments to the exchange of

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solid tumor cancers, diabetic retinopathy, and rheumatoid arthritis, by blocking integrins on proliferating endothelial cells, and thus directed *in vitro* and *in vivo* experiments on RGD peptides provided by Merck. 125 S.Ct. at 2378. The Court noted that Integra had “never argued that the RGD peptides were used by the scientist as research tools, and that it was “apparent from the record that they were not.” 125 S.Ct. at 2382, n. 7. In her earlier dissent, Judge Newman had stated that her colleagues on the court of appeals panel appeared to view the Integra patents as a patent on a “research tool,” which she believed to be a “misdefinition,” as the Integra patents were not “a tool used in research, but simply new compositions having certain biological properties.” However, the CAFC majority had merely characterized the Merck-sponsored research as “general biomedical research to identify new pharmaceutical compounds,” 331 F.3d at 866, and went on to state that “expansion of § 271(e)(1) to include the Scripps Merck activities would effectively vitiate the exclusive rights of patentees owning biotechnology tool patents,” 331 F.3d at 867, but did not explicitly characterize Integra’s patented invention as a research tool. In any event, Merck did provide, and the scientist whose research Merck was funding did use RGD peptides held to be covered by Integra’s patents in his research. Whether this constituted “experimenting on” or “experimenting with” the patented invention (or both) appears to be a close question. Judge Newman herself characterizes the research activities of Scripps Merck as making “improvements” on Integra’s patented invention, and concludes that while the “threshold invention may (as here) exact tribute from or enjoin commercial and pre-commercial activity, the patent does not bar all research that precedes such activity.” 331 F.3d at 876.

<sup>194</sup> 331 F.3d at 878 (Newman J., dissenting). See 35 U.S.C. § 101 (“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 therefor, subject to the conditions and requirements of this article [emphasis added].”); *Smith v. Nichols*, 88 U.S. (21 Wall.) 112, 118-119 (1875) (“A new idea may be ingrafted upon an old invention, be distinct from the conception which preceded, and be an improvement. In such case it is patentable. The prior patentee cannot use it without the consent of the improver, and the latter cannot use the original invention without the consent of the former.”). In the absence of an implicit experimental use privilege to improve the patented inventions of others, the statutory right to make patentable improvements of a patented invention would become a dead letter for all but the initial patent holder, as making any unauthorized improvements of another’s patentable invention could be said to constitute an infringing “use” of the patented invention. For a detailed discussion of what constitutes infringing “use” of another’s invention, see 5 DONALD S. CHISUM, CHISUM ON PATENTS § 16.02[4].

<sup>195</sup> See *supra* note 194.

<sup>196</sup> NCR Report, Reaping the Benefits, *supra* note 7, at 3.

biomedical research materials remain prevalent and may be increasing.<sup>197</sup> On the basis of these findings, the NRC Report makes a number of recommendations to facilitate the free exchange of materials and data. Among these recommendations is an endorsement of the NIH *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources*<sup>198</sup> and *Best Practices for the Licensing of Genomic Inventions*,<sup>199</sup> and a recommendation that the NIH require recipients of a variety of forms of NIH funding to adhere to and comply with these guidance documents.<sup>200</sup>

On the other hand, a third recent study—namely a federally funded survey of licensing practices at 19 of the 30 U.S. academic institutions that have received the largest number of DNA patents—reveals that the licensing practices at these large and experienced academic institutions are already largely in agreement with the NIH guidelines for research tools.<sup>201</sup> This same study also observes that 1) the number of DNA patents has declined each year since 2001; 2) that patent prosecution, maintenance and management costs—estimated by respondents as between \$20,000 and \$30,000 per patent—militate against patenting inventions that are unlikely to recover those costs, thus encouraging greater selectivity in what gets patented in academia; and 3) that technology transfer offices report a continuing “rational forbearance” on the part of private companies with respect to bringing patent infringement lawsuits against universities.<sup>202</sup> As we have seen, the empirical data to date confirms that universities generally follow a far more selective patenting strategy than do private firms, and a substantial majority of university research continues to fall into the public domain.<sup>203</sup>

Likewise, a fourth recent study, surveying the effects of patenting in the American Association for the Advancement of Science (AAAS) scientific community, reveals that, although patents are the most common means used by the respondents to protect intellectual property, licensing those patented technologies is not the primary means by which respondents within academia acquire or disseminate technology.<sup>204</sup> Rather, the

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<sup>197</sup> *Id.*

<sup>198</sup> See *supra* note 9 and accompanying text.

<sup>199</sup> See *supra* note 11 and accompanying text.

<sup>200</sup> NRC Report, Reaping the Benefits, *supra* note 7, at 8.

<sup>201</sup> Pressman et al., *supra* note 12, at 31, 38-39. Respondents are said to have frequently referred to the NIH licensing guidelines. *Id.* at 34. Two respondents reported that their institution preferred to license research tools or patents more generally on a non-exclusive basis. *Id.* at 35. The study also accumulated evidence that universities are increasingly retaining a transferable research-use right, even in exclusive, all fields of use licenses. *Id.*

<sup>202</sup> *Id.* at 35, 39. Pressman et al. report a decline in issued DNA patents (i.e. those patents containing at least one claim that includes a nucleic acid-specific term) from a high of approximately 4500 in 2001 to approximately 2500 through the first eleven months of 2005, *id.* at 35 (fig. 2), or a projected 2954 for the 2005 as a whole. *Id.* at 33. Moreover, university technology transfer offices report that private firms continue an informal policy of rational forbearance with respect to bringing patent infringement lawsuits against universities, in part because such academic use may improve their invention, in part because they wish to maintain goodwill and ensure access to future academic inventions, and in part because damages are likely to be very small. *Id.* at 35.

<sup>203</sup> See *supra* notes 107-111 and accompanying text.

<sup>204</sup> Hansen et al., *supra* note 27, at 8. This study was based on a 2005 survey of a random, stratified sample of 4,017 individuals drawn from AAAS membership. A total of 1,111 AAAS members, or 28%, responded,

greatest overall proportion of those responding to the AAAS survey reported acquiring their last patented technology through the use of a material transfer agreement (MTA).<sup>205</sup> Exclusive licensing was one of the least-used methods of technology transfer.<sup>206</sup> Indeed, this study tentatively concludes that academia has been less affected than industry by more restrictive and formal licensing practices in the acquisition and distribution of patented technologies necessary for research, as difficulties reported by bioscience industry respondents in attempting to access patented technologies outnumbered those of bioscience academic respondents by a ratio of more than 2:1.<sup>207</sup>

Finally, in an as-yet unpublished study, based on a dataset comprised of biotechnology patents granted in the United States from January 1990 through December 2004 (more than 52,000 patents in all), and apparently the most comprehensive empirical analysis to date of U.S. biotechnology patents generally, David E. Adelman and Kathryn L. DeAngelis find little evidence that the recent growth in biotechnology patenting is threatening innovation.<sup>208</sup> Based on several complementary methods, including studies of broad patent trends, patterns of patent ownership, the distribution of patents across U.S. Patent and Trademark Office (US PTO) patent subclasses, and two preliminary investigations of patenting in two discrete areas of biotechnology research and development,<sup>209</sup> the data of Adelman and DeAngelis reveal 1) a striking rise and fall in biotechnology patenting; 2) surprisingly diffuse and expanding patent ownership; and 3) a broad distribution of patents by subject matter.<sup>210</sup> Even the largest companies, on

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76% of which reported that they were actively conducting or managing research or specializing in IP. *Id.* at 5.

<sup>205</sup> *Id.* at 6.

<sup>206</sup> *Id.*

<sup>207</sup> *Id.*

<sup>208</sup> Adelman & DeAngelis, *supra* note 27, at 1-2.

<sup>209</sup> *Id.* at 2. The database consists of 52,039 biotechnology patents issued between January 1990 and December 2004, selected from an unambiguously overinclusive database of biotechnology-related patents drawn from 49 general US PTO classes and then pared down by examining the US PTO subclasses in which well-established biotechnology companies were obtaining patents, identifying the subclasses the US PTO treats as biotechnology fields, and independently assessing potentially relevant subclasses to determine their relevance. The final database consists of patents whose primary US PTO classification falls under one of 704 subclasses. *Id.* at 5-6. For comparative purposes, the dataset was divided into five distinct areas of biotechnology research and development—1) measuring and testing processes; 2) polypeptide and protein sequences; 3) nucleotide sequences; 4) immunological processes and compounds; and 5) genetically modified organisms (GMOs)—and into three categories of assignees (i.e. owners)—1) federal government; 2) universities; and 3) corporations. *Id.* at 7-8. The analyses of general trends were supplemented by two studies designed to evaluate the distribution of biotech patenting among patent owners and across distinct areas of research and development. *Id.* at 9.

<sup>210</sup> *Id.* at 60. Specifically, the data reveals that 1) the number of biotechnology patents issued per year peaked at 5977 patents in 1998 and then declined to 4324 patents (a 29% drop) by 2004 (this same basic trend can be tracked through each of the authors' five technology areas, specific large-population US PTO subclasses within four technology groups, the 30 subclasses with the largest number of patents, and the three categories of assignees), *id.* at 10; 2) while corporate ownership of patents dominates (accounting for 80% of the patents issued versus 20% for the federal government and universities), university and government patenting increased from 15% of biotechnology patents in 1990 to 20% from 1994 onward, representing a ten-fold increase in patent issued to universities and the federal government between 1990 and 1998-99, and the division of ownership is similar among four of the authors' five biotechnology subfields, GMOs being the one area of substantial divergence, with universities and the federal government

average, are granted fewer than thirty patents per year, and the number of entities obtaining biotechnology patents has consistently increased over the fifteen years covered by the dataset.<sup>211</sup>

According to Adelman and DeAngelis, the lack of concentrated control, the rising number of patent applications, and the continuous record of new market entrants are all positive signs that biotechnology patenting is not adversely affecting innovation.<sup>212</sup> Moreover, while the large number and broad-based ownership of biotechnology patents among different entities raises the specter of a fragmented “anti-commons” emerging, the broad distribution of biotechnology patents across US PTO subfields suggests that in most areas of biotechnology research and development, the density of patenting is too low to provide any support for this concern.<sup>213</sup> On the basis of this data, Adelman and DeAngelis conclude that the lack of concentrated control, the rising number of patent applications, and the continuous influx of new patent owners suggests that overall biotechnology innovation is not being impaired by the growth in patents issued each year.<sup>214</sup>

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receiving 29% of the patents, though the absolute numbers of patents are relatively low in this subfield, as the largest number of patents by far (almost 50%) is consistently to be found in the measuring and testing subfield throughout the 15 year period, followed by protein sequences (26%), immunological inventions (12%), nucleotide sequences (9%) and GMOs (3%), with patents on protein and polypeptide sequences experiencing a 50% drop in their relative share over the 15 year period, while GMOs, nucleotide sequences and immunological almost tripled their share of biotech patents during the same period, *id.* at 14-16; and 3) biotechnology patents are spread broadly across and expanding number of patent owners, *id.* at 17-18. The authors find economic disruptions do not appear to explain the late-1990s drop in biotechnology patenting and that the US PTO’s decision to strengthen the utility requirements in 1999 is the most significant legal development that could explain the rapid leveling off of biotechnology patenting. *Id.* at 12.

<sup>211</sup> *Id.* at 3.

<sup>212</sup> *Id.*

<sup>213</sup> *Id.* at 28.

<sup>214</sup> *Id.* at 60. A more narrowly focused study of gene patenting reports that nearly 20% of human genes, representing 4382 of the 23,688 genes in the National Center for Biotechnology Information gene database, are claimed as U.S. intellectual property, and notes that while large expanses of the human genome are unpatented, the distribution of gene patents is non-uniform, as specific regions of the genome constitute “hot spots” of heavy patent activity. *See* Kyle Jensen and Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 *SCIENCE* 239-240 (2005). However, this study also notes that 1) these genes are claimed in 4270 patents owned by 1156 different assignees, 63% of which are owned by private firms and 28% are owned by governments, schools, universities, research institutions, and hospitals; 2) at least 3000 have only a single IP rights holder; and 3) the two genes with the most fragmented ownership were PSEN2, the amyloid precursor protein (8 assignees for 9 patents), and BRCA1, the early onset breast cancer gene (12 assignees for 14 patents). While the authors note that such fragmentation raises the possibility that innovators may incur considerable costs securing access to genes, they present no evidence of any resulting anti-commons effect. Moreover, while Pressman et al., *supra* note 12, at 31, acknowledge this study, they go on to show that issued DNA patents have declined precipitously since 2001. *See supra* note 202 and accompanying text. *See also supra* note 210 and accompanying text, noting Adelman & DeAngelis’s similar finding of a striking rise and fall of biotechnology patents more generally during that same time period. As Adelman and DeAngelis also point out, notwithstanding the attention patents on nucleotide sequences have received, they account for only 9% of biotechnology patents; the number of gene and protein patents currently being issued “appears to be relatively unthreatening”; and the relatively low numbers of patents on genetic and protein sequences “suggest that worries about excessive patenting of genes and proteins are overblown.” Adelman & DeAngelis, *supra* note 27, at 15-17. *See also infra* notes 216-230 and accompanying text, discussing the arguable “irrationality” of speculative gene patents.

In addition to providing empirical evidence that biotechnology patenting is not adversely affecting innovation, Professor Adelman has joined others<sup>215</sup> in offering a cogent theoretical critique of the concern over blocking patents and an emerging anti-commons problem in biotechnology research. It is to this critique that we will now turn and conclude.

## B. A Theoretical Critique of Blocking Patents and an Emerging Anti-Commons in Biotechnology Research

In a recent pair of papers, Professor Adelman has questioned the theoretical assumptions underlying the concerns of critics of the Bayh-Dole Act, noting that legal commentators “have been surprisingly indifferent to whether the traditional model of the public commons accurately reflects the conditions of innovation in the biological sciences.”<sup>216</sup> This indifference, he argues, proves to be a critical one, for it obscures a central fallacy in the anti-commons argument—namely the assumption that the commons for biomedical science is finite and congested.<sup>217</sup> Adelman argues that “the uniquely open-ended nature of biomedical science requires a reassessment of how patenting affects biotech research and innovation.”<sup>218</sup> He also notes the importance of recognizing that two distinct types of genomic research tool exist: 1) the relatively small number of common-method research tools (e.g. the Cohen-Boyer, Kohler-Milstein, and PCR processes); and 2) problem-specific tools that are quite plentiful (e.g., ESTs, SNPs, and drug targets).<sup>219</sup>

Adelman’s underlying insight is that while biotechnology research “has produced vast quantities of genetic data, which are often useful research tools (for example, drug targets and genetic probes),”<sup>220</sup> the translation of this knowledge into new products has been far less impressive, creating an environment in which “research opportunities far exceed the capacities of the scientific community,” thus making “biotech science, in important respects, an effectively unbounded, uncongested common resource.”<sup>221</sup> This unbounded commons, in turn, largely negates the value of speculative gene patents, particularly of such research tools as genetic probes, putative drug targets, and uncharacterized genetic sequences, thus making patenting of such research tools

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<sup>215</sup> See, e.g. Kieff, *Perusing Property Rights in DNA*, *supra* note 143.

<sup>216</sup> Adelman, *Fallacy of the Commons*, *supra* note 1, at 985; Adelman, *Speculative Gene Patents*, *supra* note 1, at 124. See also Adelman & DeAngelis, *supra* note 27, at 1.

<sup>217</sup> Adelman, *Fallacy of the Commons*, *supra* note 1, 985-86.

<sup>218</sup> *Id.* at 986; See also Adelman, *Speculative Gene Patents*, *supra* note 1, at 124; Adelman & DeAngelis, *supra* note 27, at 1.

<sup>219</sup> Adelman, *Fallacy of the Commons*, *supra* note 1, at 1020; Adelman, *Speculative Gene Patents*, *supra* note 1, at 139.

<sup>220</sup> Adelman, *Fallacy of the Commons*, *supra* note 1, at 987. See also Adelman, *Speculative Gene Patents*, *supra* note 1, at 124.

<sup>221</sup> Adelman, *Fallacy of the Commons*, *supra* note 1, at 986. See also Adelman, *Speculative Gene Patents*, *supra* note 1, at 124. See also Kieff, *Perusing Property Rights in DNA*, *supra* note 143, quoted *infra* notes 206, 212.

essentially “irrational.”<sup>222</sup> Adelman notes that his theoretical argument is consistent with recent trends toward dedicating these types of research tools to the public domain.<sup>223</sup> He also finds support for his theoretical argument in the fact that few of the predictions made or the solutions advocated by legal scholars are borne out consistently by empirical studies of biotech patenting,<sup>224</sup> and concludes that, “contrary to the fears of many legal commentators, there are few signs that biotech patenting has impeded biomedical innovation.”<sup>225</sup>

To be sure, Adelman joins other commentators in recognizing that “patents on common-method research tools do present potentially significant risks to innovation and warrant continuing scrutiny.”<sup>226</sup> However, this is not an anti-commons problem, but rather a blocking patent problem. While the risks posed by patents on common-method research tools are substantial, even here, “several intrinsic scientific factors mitigate this event,” as the relatively small number of “powerful common-method research tools typically have many nonrivalrous uses.”<sup>227</sup> Adelman’s underlying insight here is that “the broader the range of applications for a research tool, the less likely a patent owner will be able to exploit its research potential and the greater the market-size incentives will be to make the technology broadly available.”<sup>228</sup> As a consequence, access to research tools of broad importance to biomedical research and development “is unlikely to be

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<sup>222</sup> Adelman, *Fallacy of the Commons*, *supra* note 1, at 1022 (“[T]he current state of biotech research and development represents the worst conditions for strategic patenting.”); Adelman, *Speculative Gene Patents*, *supra* note 1, at 124 (“[S]peculative biotech patenting, particularly of genetic probes, putative drug targets, and uncharacterized genetic sequences, is irrational.”) *See also id.* at 125 (“It is this basic dynamic [in which research opportunities far exceed the capacities of the scientific community] that makes biotech science, in important respects, an uncongested common resource and that negates the value [of] speculative biotech patenting.”); Kieff, *Perusing Property Rights in DNA*, *supra* note 143, 138-139 (noting that patents on gene sequences are “much less likely to cause the pernicious clogging of downstream innovation than originally feared because . . . such downstream activities would not infringe most such valid claims for a number of interrelated reasons [including the Federal Circuit’s “strong reading” of the written description requirement to put the public on clear notice of what will infringe and what will not.]”); *id.* at 141 (noting that if the utility of a speculative gene patent is uncertain, “the patentee has an incentive to license it broadly, so as to increase the chance of being able to extract some part of whatever utility is later uncovered.”); *id.* at 147 (noting that uncertainties over the appropriate valuation of patents “may also have a positive impact because broad patent licensing may be a way to increase the chance that at least some licensee generates some value from which the patentee can extract a share.”). For reasons why universities and others might “irrationally” pursue speculative gene patents, *see* Sabrina Safrin, “Chain Reaction: How Property Begets Property,” <http://www.law.berkeley.edu/institutes/bclt/ipsc/papers2/Safrin.doc>.

<sup>223</sup> Adelman, *Speculative Gene Patents*, *supra* note 1, at 140.

<sup>207</sup> Adelman, *Fallacy of the Commons*, *supra* note 1, at 988.

<sup>225</sup> *Id.* *See also supra* note 128.

<sup>226</sup> Adelman, *Fallacy of the Commons*, *supra* note 1, at 1024.

<sup>227</sup> *Id.* Adelman notes that whereas rivalrous uses would involve applications of patented technology in the same market(s), nonrivalrous applications would arise in a distinct market. For example, uses of certain proteins “can span completely different disease categories.” *Id.*, note 187. *See also* Kieff, *Registering Patents*, *supra* note 32, at 67, notes 52 & 53, noting that the patent system promotes coordination among complementary users of a patented invention.

<sup>228</sup> Adelman, *Fallacy of the Commons*, *supra* note 1, at 1029. *See also* Kieff, *Perusing Property Rights in DNA*, *supra* note 143, at 147 (noting that patents “covering some of the most basic technologies in the field of modern basic biological science—such as hybridomas and calcium phosphate transfection—are widely licensed for free to academic scientists,” while other patents, “such as the one covering the process of PCR, are licensed to anyone who buys from the patentee a machine for performing the process.”).

restricted.”<sup>229</sup> While patent premiums could still function as de facto restrictions on access, Adelman concludes that concern about this occurrence is allayed somewhat by the lack of corroborating evidence.<sup>230</sup>

#### IV. Conclusion

In short, while neither the foregoing theoretical arguments nor the empirical evidence examined in this Chapter are likely to put an end to the fractious debate over patenting the results of upstream genetic research and vesting presumptive patent ownership in the recipients of federally funded genetic research, both the theoretical arguments and the empirical evidence to date clearly seem to preponderate in favor of the proponents of patenting upstream genetic research and vesting presumptive patent ownership in the recipients of federally funded genetic research. Indeed, very little empirical evidence has been produced to date to support the argument that granting patents on the results of “upstream” genetic research undermines the norms of the biological research community or retards biomedical innovation, technology transfer, or the development of downstream commercial products and processes.

To be sure, this situation could change “dramatically and possibly even abruptly,” as the NRC Report cautions,<sup>231</sup> if research institutions do indeed begin to take more active steps to regulate researcher behavior or patent holders take more active steps to assert their patent rights against universities, either through infringement proceedings or via demands for licensing fees, grant-back rights, and other terms that are burdensome to research. However, notwithstanding insistent warnings over the past decade that patenting upstream genetic research and vesting presumptive patent ownership in the recipients of federally funded genetic research might well be undermining the norms of the biological research community and retarding, rather than promoting, biomedical innovation, critics have thus far failed to carry their burden of proof that this is in fact happening. To the contrary, the preponderance of the empirical evidence produced to date seems to suggest that, by vesting presumptive patent ownership in the recipients of federally funded genetic research, the Bayh-Dole Act is indeed achieving not only its statutory purpose but also the larger, constitutionally mandated requirement that the U.S. patent system “promote the Progress of Science and the useful Arts.”<sup>232</sup>

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<sup>229</sup> Adelman, Fallacy of the Commons, *supra* note 1, at 1029. See also *supra* notes 2227-2228.

<sup>230</sup> *Id.*, citing to Walsh, Arora & Cohen, *supra* note 13. Indeed, the rash of empirical studies unveiled just during the past year, including Adelman’s own as-yet unpublished empirical study, tend to corroborate the theoretical conclusions of Adelman and others. See *supra* notes 166-214 and accompanying text.

<sup>231</sup> See *supra* note 184 and accompanying text. But see *supra* notes 201-202 and accompanying text, for evidence that universities are increasingly retaining a transferable research-use right in their own patent licensing, and private companies are continuing to display “rational forbearance” with respect to asserting patent rights against universities.

<sup>232</sup> U.S. Constitution, Article 1, § 8, cl. 8.