

## THE BAYH-DOLE ACT AND THE ANTICOMMONS HYPOTHESIS: ROUND THREE

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### INTRODUCTION

Over the past fifteen years a debate has raged in the United States over the impact of the Bayh-Dole Act<sup>1</sup> on genetic research and development. The Bayh-Dole Act, enacted in 1980, 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.<sup>2</sup> Retention of owner-

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<sup>1</sup> Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 28 U.S.C. §§ 200-12 (2012)). For a brief introduction to the major provisions of the Bayh-Dole Act, see *Bayh-Dole Act*, ASS’N OF U. TECH. MANAGERS, [http://www.autm.net/Bayh\\_Dole\\_Act.htm](http://www.autm.net/Bayh_Dole_Act.htm) (last visited Apr. 1, 2014) [hereinafter AUTM, *Bayh-Dole Act*]. 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, 1684-95 (1996).

<sup>2</sup> For a summary of the major provisions of the Act, see AUTM, *Bayh-Dole Act*, *supra* note 1. 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. This . . . replace[s] 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, pt. 1, at 5 (1980), *reprinted in* 1980 U.S.C.A.N. 6460, 6464. The Bayh-Dole Act requires contractors to: 1) “disclose . . . invention[s] . . . within a reasonable time”; 2) inform the government of an intent to patent; 3) file for patents within a reasonable time 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). Nonprofit 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* notes 153-159 and accompanying text. 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

ship was subject to a number of limitations and obligations, including an obligation on the part of universities and other nonprofit institutions to share royalties with the actual inventor and to provide a royalty-free nonexclusive license to the U.S. government.<sup>3</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>4</sup>

At the heart of the debate over the Bayh-Dole Act's impact on genetic research and development have been two interrelated questions: (1) whether granting patents to universities on the results of "upstream" genetic research<sup>5</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 or processes. A specific thesis of critics of the Bayh-Dole Act traces to a 1998 article in which Professors Michael A. Heller and Rebecca S. Eisenberg posed what has come to be called the "tragedy of the anticommons" or "anticommons hypothesis"—namely, that too many intellectual property rights in "upstream" research results could paradoxically restrict "downstream" research and product development by making it too costly and burdensome to collect all of the necessary licenses.<sup>6</sup> A contemporaneous and related concern in this debate is that the use of patents in such areas as basic biological science could undermine the basic sharing norms of "open science" in the academic research community, and that the failure of U.S. patent law to distinguish between downstream innovations that lead directly to commercial products and fundamental research discov-

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statutory obligation to give preference to small businesses in licensing such patents. Memorandum on Government Patent Policy, 1 PUB. PAPERS 248 (Feb. 18, 1983). Congress acquiesced to this extension in a 1984 housekeeping amendment to the Act, Trademark Clarification Act of 1984, Pub. L. No. 98-620, § 501(c), 98 Stat. 3335, 3367-68 (codified at 35 U.S.C. §§ 210(c)). For a discussion of the obligation to provide the U.S. government with a royalty-free, non-exclusive, worldwide license, see *infra* note 159 and accompanying text.

<sup>3</sup> Vicki Loise, *The Bayh-Dole Act Turns 30*, LES NOUVELLES, Dec. 2010, at 185, 185, available at [http://www.bu.edu/otd/files/2011/02/The\\_Bayh-Dole\\_Act\\_Turns\\_30.pdf](http://www.bu.edu/otd/files/2011/02/The_Bayh-Dole_Act_Turns_30.pdf).

<sup>4</sup> See, e.g. COUNCIL ON GOVERNMENTAL RELATIONS, THE BAYH-DOLE ACT: A GUIDE TO THE LAW AND IMPLEMENTING REGULATIONS 8 (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").

<sup>5</sup> "Upstream research" and "upstream technologies" are terms commonly used to refer to basic-science research tools. See, e.g., David E. Adelman, *The Irrationality of Speculative Gene Patents*, in 16 ADVANCES IN THE STUDY OF ENTREPRENEURSHIP, INNOVATION AND ECONOMIC GROWTH: UNIVERSITY ENTREPRENEURSHIP AND TECHNOLOGY TRANSFER: PROCESS, DESIGN, AND INTELLECTUAL PROPERTY 123, 125 (Gary D. Libecap ed., 2005) [hereinafter Adelman, *Speculative Gene Patents*]; David E. Adelman, *A Fallacy of the Commons in Biotech Patent Policy*, 20 BERKELEY TECH. L.J. 985, 989 (2005) [hereinafter Adelman, *Fallacy of the Commons*].

<sup>6</sup> See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698-701 (1998).

eries that broadly enable further scientific investigation could hinder rather than accelerate biomedical research.<sup>7</sup>

Since Heller and Eisenberg propounded the anticommons hypothesis in 1998, the legal debate over the impact of the Bayh-Dole Act has proceeded in three distinct rounds. Round One, which occurred from 1998 to 2004, was dominated by legal scholars and focused primarily on the theoretical justifications for the Bayh-Dole Act and theoretical critiques of its impact on upstream research and downstream development. One dismaying feature of this round of the debate—at least according to one outside observer—was the widespread reliance by legal scholars on what might charitably be called “anec-data,” as well as an “evident lack of concern (let alone embarrassment) about the dearth of empirical evidence on the subject in question.”<sup>8</sup> To this observer, the problem was largely traceable to the selection and socialization process of members of the legal profession as a whole, which trains members to “prefer anecdotes to tables.”<sup>9</sup>

Fortunately for legal scholars, from 2004 to 2008 (and continuing on up to the present) social scientists rushed in to fill the empirical void, unveiling a bevy of empirical studies and thus touching off Round Two of the debate. As one economist cautioned at the outset of Round Two, however, a 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

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<sup>7</sup> See Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 HOUS. L. REV. 1059, 1098-99 (2008).

<sup>8</sup> David A. Hyman, *An Outsider Perspective on Intellectual Property Discourse*, in PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 275, 276-79 (F. Scott Kieff ed., 2003) (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, *Speculative Gene Patents*, *supra* note 5, at 125-26 (commenting on the division among intellectual property scholars into two camps—one optimistic, the other pessimistic—with regard to 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).

<sup>9</sup> Hyman, *supra* note 8, 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, 1 (2002). See also Frank Cross, Michael Heise & Gregory C. Sisk, *Above the Rules: A Response to Epstein and King*, 69 U. CHI. L. REV. 135, 135-36 (2002); Lee Epstein & Gary King, *A Reply*, 69 U. CHI. L. REV. 191, 191-93 (2002); Jack Goldsmith & Adrian Vermeule, *Empirical Methodology and Legal Scholarship*, 69 U. CHI. L. REV. 153, 153 (2002); Richard L. Revesz, *A Defense of Empirical Legal Scholarship*, 69 U. CHI. L. REV. 169, 169 (2002).

form: if we had not done that, the world would now be different.”<sup>10</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>11</sup> Thus, for all the empirical studies produced in Round Two of the debate, the evidence of the impact of the Bayh-Dole Act on genetic research and product development remains far from conclusive.

At the same time, as the late British philosopher and educator Stephen Toulmin warned, 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 may be a futile quest where certainty is not possible.<sup>12</sup> In many situations, particularly those involving the evaluation of human conduct and the formulation of public policy—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—the best result that can be obtained is a reasonable probability that a given proposition is true or false. These sorts of determinations, in turn, tend to be precisely the stock-in-trade of the present-day legal system and profession, which routinely grapple, for example, with such practical evidentiary problems as how to go about proving (or avoiding having to prove) a counterfactual assertion.

Thus, Round Three of the debate over the Bayh-Dole Act and the anticommons hypothesis has focused primarily on evaluating the empirical evidence produced during Round Two and reframing the theoretical terms of the debate in light of this empirical evidence, while at the same time prognosticating about the U.S. Supreme Court’s ultimate decision in two important upstream gene patent cases—*Mayo Collaborative Services v. Prometheus Laboratories, Inc.*<sup>13</sup> and *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*<sup>14</sup> Round Three was initiated by a particularly important article, published in 2008 and authored by Professor Eisenberg. As one of

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<sup>10</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* 16 (Stanford Inst. for Econ. Policy Research, Discussion Paper No. 02-30, 2003), available at <http://www.stanford.edu/group/siepr/cgi-bin/siepr/?q=system/files/shared/pubs/papers/pdf/02-30.pdf>.

<sup>11</sup> *Id.*

<sup>12</sup> STEPHEN TOULMIN, RETURN TO REASON 204-214 (2001) (arguing 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 perceived 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).

<sup>13</sup> 132 S. Ct. 1289 (2012).

<sup>14</sup> 133 S. Ct. 2107 (2013).

the original proponents of the anticommons hypothesis, Professor Eisenberg reviews the most significant of these empirical studies.<sup>15</sup> Although Eisenberg notes that “the largest of these studies have examined the impact of intellectual property on research scientists (primarily in academia), rather than its impact on downstream development,”<sup>16</sup> she does identify four major series of studies that included interviews with representatives of commercial firms.<sup>17</sup>

In evaluating the impact of these empirical studies on the anticommons hypothesis, Eisenberg concedes “that, overall, intellectual property has presented fewer impediments to research than policymakers may have projected on the basis of early salient controversies.”<sup>18</sup> One important caveat to that conclusion, however, is the assertion that “[m]ore significant to researchers than patents as such have been practical restrictions on access to materials and data, such as requirements for institutional assent to the terms of material transfer agreements (‘MTAs’).”<sup>19</sup> The article also claims that patents appear to have had a greater impact on downstream product development than on upstream academic research.

The central insight of the article is that

the findings that practical restrictions on access to materials and data are more frequently problematic than patents as such point to a further refinement of the anticommons hypothesis that may have broader implications for the design of property regimes: the burden of inertia matters in determining the practical impact of transaction costs associated with intellectual property rights.<sup>20</sup>

In short, whereas with patents the burden of inertia is on the property owner to identify infringers and to enforce the patent against them, with MTAs and database access agreements the burden of inertia is on the user to obtain access to the restricted resource.

This insight has a number of implications for the continuing debate over the Bayh-Dole Act and the anticommons hypothesis. Perhaps the most important is that, whereas Round One of the debate was concerned that a proliferation of university patenting of upstream research would restrict downstream research and development by making it difficult to collect all the necessary patent licenses, the empirical studies produced in Round Two seem to have shifted the focus of Round Three, where the debate has moved from patents and patent licenses as such to material MTAs and database access agreements. In practice MTAs and database access agreements have often served as complements to university efforts to obtain, enforce, and

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<sup>15</sup> See Eisenberg, *supra* note 7, at 1060-62.

<sup>16</sup> *Id.* at 1061 (footnote omitted).

<sup>17</sup> *Id.* at 1061 n.9.

<sup>18</sup> *Id.* at 1061.

<sup>19</sup> *Id.* at 1061-62.

<sup>20</sup> *Id.* at 1062.

license patent rights in upstream genetic research.<sup>21</sup> However, it is conceptually important to understand that these two forms of agreement could in theory serve as contractual substitutes for the current system of patenting and patent licensing of upstream genetic research as the form of legal protection being invoked amounts to a kind of genetic trade secret protection wherein a party maintains proprietary control over genetic materials or data.

The modest aim of this Article is to summarize and update an earlier paper evaluating the arguments and empirical evidence with regard to the impact of the Bayh-Dole Act on genetic research and development. Part I of this Article will summarize Round One of the debate, which focused primarily on the theoretical underpinnings of the Bayh-Dole Act and the anticommons hypothesis developed to critique the Act's role in stimulating university patenting and licensing. Part II will summarize Round Two of the debate, which produced a plethora of empirical evidence said to both confirm and undermine the anticommons hypothesis. Part III will summarize and evaluate the issues dominating Round Three of the debate.

## I. THEORETICAL UNDERPINNINGS OF THE BAYH-DOLE ACT AND ITS ROLE IN STIMULATING UNIVERSITY PATENTING AND LICENSING

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

Even before the anticommons hypothesis was propounded, critics of the Bayh-Dole Act persisted in characterizing the policies underlying the Act as “counterintuitive”<sup>22</sup> and “in need of significant reform.”<sup>23</sup> At the heart of these criticisms was the argument that, while the purpose of granting patent protection is ostensibly to create incentives to innovate, recipients of federal funds need no additional incentive to innovate.<sup>24</sup> Thus, allowing private parties to hold exclusive rights to inventions that have been generated at public expense requires the public to pay twice for the same invention.<sup>25</sup>

However, a number of traditional theoretical justifications for the current U.S. patent system have been proffered, and the “incentive to innovate”

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<sup>21</sup> See David C. Mowery & Arvids A. Ziedonis, *Academic Patents and Materials Transfer Agreements: Substitutes or Complements?*, 32 J. TECH. TRANSFER 157, 171-72 (2007) (concluding that MTAs and patents are often complements rather than substitutes).

<sup>22</sup> See Eisenberg, *supra* note 1, at 1666.

<sup>23</sup> Brett Frischmann, *Innovation and Institutions: Rethinking the Economics of U.S. Science and Technology Policy*, 24 VT. L. REV. 347, 347 (2000) (arguing that “the intellectual underpinnings upon which our current innovation policy is based are inaccurate and in need of significant reform”).

<sup>24</sup> See Eisenberg, *supra* note 1, at 1666.

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

justification is but one of them.<sup>26</sup> Arguably, the theory most relevant to the patenting of upstream genetic research and the vesting of presumptive patent ownership in the recipients of federally funded research is the “commercialization” theory, which 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.<sup>27</sup> Thus, the public may simply be paying for two distinct phases of the innovative process—the early-stage “proof-of-concept” phase (generated by public funding of academic research) 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>28</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 which are then applied by industry to products and processes.<sup>29</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

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<sup>26</sup> The two most often cited justifications for the U.S. patent system are that it creates an incentive to invent and that it creates 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) (citing Giles S. Rich, *The Relation Between Patent Practices and the Anti-Monopoly Laws*, 24 J. PAT. OFF. SOC'Y 159, 175-77 (1942)). 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 Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries,” U.S. CONST. art. I, § 8, cl. 8, 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.” Rich, *supra*, at 177; see also F. Scott Kieff, *The Case for Registering Patents and the Law and Economics of Present Patent-Obtaining Rules*, 45 B.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>27</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.” Bayh-Dole Act, Pub. L. No. 96-517, § 200, 94 Stat. 3015, 2019 (codified as amended at 35 U.S.C. § 200 (2012)).

<sup>28</sup> See, e.g., Jerry G. Thursby & Marie C. Thursby, *Pros and Cons of Faculty Participation in Licensing*, in 16 ADVANCES IN THE STUDY OF ENTREPRENEURSHIP, INNOVATION AND ECONOMIC GROWTH: UNIVERSITY ENTREPRENEURSHIP AND TECHNOLOGY TRANSFER: PROCESS, DESIGN, AND INTELLECTUAL PROPERTY 187, 190 (Gary D. Libecap ed., 2005) (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 require[d] further development”); Jerry G. Thursby & Marie C. Thursby, *University Licensing*, 23 OXFORD REV. ECON. POL'Y 620, 625 (2007).

<sup>29</sup> Douglas W. Jamison & Christina Jansen, *Technology Transfer and Economic Growth*, 12 AUTM J. 23, 33-34 (2000).

private companies, thus creating a risk of a technology and funding “gap,” or “valley of death,” in the innovative process.<sup>30</sup> At least one early commentator concluded that a government-funded, targeted approach to increasing middle-ground research had not been particularly effective,<sup>31</sup> while a later economic study concluded 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 which could facilitate commercialization of university research and attract more research funding to the university.<sup>32</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 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, questioned 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 title to federally funded inventions.<sup>33</sup> Other commentators argued that proponents of the Act had exaggerated the role of the Bayh-Dole Act in spawning university patenting and licensing over the previous twenty-five years, and claimed that even without the Bayh-Dole Act university patenting would have grown significantly during the 1980s and 1990s.<sup>34</sup> To be sure, critics attacked the oft-repeated assertion that less than 4 to 5 percent of the 28,000 to 30,000 patents held by the federal government in 1978 were ever successfully licensed, alleging the assertion was based on flawed data,<sup>35</sup> but this criticism itself later came under attack as flawed.<sup>36</sup>

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<sup>30</sup> *Id.* at 33.

<sup>31</sup> *Id.* at 34 (citing LINDA R. COHEN & ROGER G. NOLL, *THE TECHNOLOGY PORK BARREL* 50 (1991)).

<sup>32</sup> *Id.* at 34-35.

<sup>33</sup> See Eisenberg, *supra* note 1, at 1702-05; see also DAVID C. MOWERY ET AL., *IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT IN THE UNITED STATES* 90-91 (2004).

<sup>34</sup> See MOWERY ET AL., *supra* note 33, 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?* in 16 *ADVANCES IN THE STUDY OF ENTREPRENEURSHIP, INNOVATION AND ECONOMIC GROWTH: UNIVERSITY ENTREPRENEURSHIP AND TECHNOLOGY TRANSFER: PROCESS, DESIGN, AND INTELLECTUAL PROPERTY* 39, 41-49 (Gary D. Libecap ed., 2005) [hereinafter Mowery, *Chicken, Egg, or Something Else?*].

<sup>35</sup> See, e.g., 126 Cong. Rec. 1,985, 2,001 (statement of Sen. Chafee) (“[W]e now have a situation where less than 4 percent of 30,000 patents held by the Government have been successfully licensed.”); *id.* at 1,991 (statement of Sen. Robert Dole) (“[O]ut of the 28,000 inventions it funded, only about 5 percent have been used.”).

Likewise, commentators were correct that the emphasis on the Bayh-Dole Act as the primary catalyst stimulating university patenting and licensing since 1980 might have been exaggerated. Proponents tended to ignore a number of other contemporaneous catalyzing factors contributing to the upsurge in university patenting and licensing.<sup>37</sup> They also ignored a long history in the United States, extending back to the early decades of the twentieth century, of university patenting, licensing, and collaboration with industry.<sup>38</sup>

On the other hand, most commentators agree that university patenting “exploded” in the United States during and after the period in which the Bayh-Dole Act was enacted.<sup>39</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.”<sup>40</sup> The rise was seen among universities that had never applied for patents before and those that had always patented but began to do so more intensely.<sup>41</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 United States can be found in studies comparing the experience of universities in the United States with experiences elsewhere in the world during the same period. For example, it was often stressed that the lack of adequate patent protection was a major obstacle to the development of the biotechnology industry in

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<sup>36</sup> For the original criticism, see Eisenberg, *supra* note 1, at 1702-03. For a critique of Eisenberg’s argument, see Howard Bremer, Joseph Allen & Norman J. Latker, *The Bayh-Dole Act and Revisionism Redux*, LIFE SCI. L. & INDUS. REP., Sept. 11, 2009, at 1, 4-6, available at [http://www.allen-assoc.com/documents/Bayh\\_DoleRevisionism.pdf](http://www.allen-assoc.com/documents/Bayh_DoleRevisionism.pdf).

<sup>37</sup> See, e.g., Mowery, *Chicken, Egg, or Something Else?*, *supra* note 34, at 51 (noting that both the 1982 establishment of the Court of Appeals for the Federal Circuit as the exclusive court of final 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 for university patenting and licensing).

<sup>38</sup> Mowery, *Chicken, Egg, or Something Else?*, *supra* note 34, at 41, 46-48; see also MOWERY ET AL., *supra* note 33, at 1.

<sup>39</sup> See, e.g., Robert W. Hahn, *The Economics of Patent Protection: Policy Implications from the Literature* 23 (Oct. 30, 2003) (unpublished manuscript), available at <http://ssrn.com/abstract+467489> (citing Rebecca Henderson, Adam B. Jaffe & Manuel Trajtenberg, *Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting, 1965-1988*, 80 REV. ECON. & STAT. 119, 119 (1988)); see also Katherine J. Strandburg, *Curiosity-Driven Research and University Technology Transfer*, in 16 ADVANCES IN THE STUDY OF ENTREPRENEURSHIP, INNOVATION AND ECONOMIC GROWTH: UNIVERSITY ENTREPRENEURSHIP AND TECHNOLOGY TRANSFER: PROCESS, DESIGN, AND INTELLECTUAL PROPERTY 93, 94 (Gary D. Libecap ed., 2005) (“There is clear evidence . . . that patenting at universities has increased drastically over the past 30 years . . .”).

<sup>40</sup> Henderson et al., *supra* note 39, at 119 (internal quotation marks omitted).

<sup>41</sup> *Id.* at 125.

Europe.<sup>42</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 noted that “[t]he US 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>43</sup> These commentators concluded that “in 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 US.”<sup>44</sup> By 2004 European commentators were noting that many European governments, “[f]ascinated by the impressive growth of patents granted to US academic institutions, . . . have both reformed national IPR [intellectual property rights] legislation concerning academic research and encouraged universities to undertake pro-active technology transfer policies.”<sup>45</sup>

In short, the theoretical justification and available empirical evidence produced in Round One of the debate over the Bayh-Dole Act seems to

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<sup>42</sup> See, e.g., Rebecca Henderson, Luigi Orsenigo & Gary P. Pisano, *The Pharmaceutical Industry and the Revolution in Molecular Biology: Interactions Among Scientific, Institutional, and Organizational Change*, in SOURCES OF INDUSTRIAL LEADERSHIP: STUDIES OF SEVEN INDUSTRIES 267, 302 (David C. Mowery & Richard R. Nelson eds., 1999) (noting, “First, 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, “[s]econd, the interpretation has prevailed that naturally occurring entities, whether cloned or uncloned, cannot be patented”).

<sup>43</sup> Brent Goldfarb & Magnus Henrekson, *Bottom-Up vs. Top-Down Policies Towards the Commercialization of University Intellectual Property*, 32 RES. POL’Y 639, 640 (2002). *But cf.* David B. Audretsch, Taylor Aldridge & Alexander Oetl, *The Knowledge Filter and Economic Growth: The Role of Scientist Entrepreneurship* (Max Planck Inst. of Econ., Discussion Papers on Entrepreneurship, Growth and Public Policy, Paper No. 1106, 2005), available at <http://ideas.repec.org/p/esi/egpdis/2006-11.html> (emphasizing that two paths to commercialization exist in the United States—the technology transfer office (“TTO”) 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 TTOs, but rather to follow a more entrepreneurial route to commercializing their research). The Audretsch, Aldridge, and Oetl study establishes that 30 percent of the top 20 percent of university scientists funded by the National Cancer Institute choose not to assign their patents to the university TTO, but instead 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.” Audretsch, Aldridge & Oetl, *supra*, at 3, 13, 60-61. Although the Bayh-Dole Act applies to all federally funded research, nothing in the Act itself requires individual faculty recipients of federal research grants to assign their patent rights to their employers. Rather, such assignments are typically required as a condition of employment, but at least some faculty members apparently have sufficient bargaining power that they are able to retain rights to patent the results of their research.

<sup>44</sup> Goldfarb & Henrekson, *supra* note 43, at 640.

<sup>45</sup> S. Breschi, F. Lissoni & F. Montobbio, *Open Science and University Patenting: A Bibliometric Analysis of the Italian Case 2* (Oct. 2004) (paper presented at the Fourth EPIP Conference held at Paris Dauphine University, Paris, France, on Oct. 1-2, 2004), available at <http://epip.dk/papers/20041001/paris/papers/Montobbio.pdf>.

have rebutted the argument that the Bayh-Dole Act was based on fundamentally flawed theoretical premises.<sup>46</sup> Empirical data have also countered the argument that much of the post-1980 surge in university patenting and licensing would have occurred without the Act.<sup>47</sup>

## II. THE IMPACT OF THE BAYH-DOLE ACT ON THE RESEARCH MISSION OF U.S. UNIVERSITIES AND DOWNSTREAM INNOVATION

The two most common sets of concerns raised about the Bayh-Dole Act during Round One of the debate were: (1) that university patenting and licensing in general may have restricted dissemination of academic research and undermined academic norms of the biological research community by diverting faculty from basic to more applied research; and (2) that the patent and licensing of basic upstream genetic research tools in particular

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<sup>46</sup> See, e.g., Eisenberg, *supra* note 1, at 1666 (describing the policy underlying the Bayh-Dole Act as “counterintuitive”); Frischmann, *supra* note 23, at 347 (“[T]he intellectual underpinnings upon which our current innovation policy is based are inaccurate and in need of significant reform.”).

<sup>47</sup> See MOWERY ET AL., *supra* note 33, at 7 (“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, *Chicken, Egg, or Something Else?*, *supra* note 34, at 48–49 (citing both to evidence that “[p]rivate 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. While they present persuasive evidence that at least some universities were patenting prior to 1980, and that causes besides the Bayh-Dole Act also contributed to the upswing in university patenting after 1980, their evidence falls short of proving the counterfactual, and even they concede several facts: 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 33, 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

prior to 1980 it was possible to retain title to university inventions[,] . . . it was done on a case-by-case basis, and universities had to petition the federal government. . . . [F]or the majority of universities, growth in university technology transfer really exploded only after 1980. Prior 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 29, at 35. 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 “[i]t is clearly impossible to assign roles of ‘cause’ and ‘effect’ to these different trends. The increase in university patenting predates the passage of the Bayh-Dole Act, 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 39, at 122.

threaten to create both “blocking patents” on key technologies and a tragedy of the anticommons, and/or its close cousin, “patent thickets,”<sup>48</sup> thus retarding biomedical innovation, technology transfer, and the development of downstream commercial products and processes. It is to these two questions that we now turn.

A. *The Impact of the Bayh-Dole Act on the Research Mission of U.S. Universities*

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, [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>49</sup> and that it may threaten the functioning of the curiosity-driven research enterprise itself.<sup>50</sup> However, the empirical evidence on this point is, at best, mixed. One critic of the Bayh-Dole Act, while citing to what is described as “considerable evidence of increasing delays and secrecy in dissemination of research results,” nevertheless concedes that “the evidence with respect to a connection between the increasing secrecy and delays and university patenting is less clear.”<sup>51</sup>

Turning to that evidence, the empirical data generated during Round Two of the debate over the Bayh-Dole Act and the anticommons hypothesis can be divided into two types, based on “[t]wo research methodologies, two sets of findings, and two conflicting answers to the anticommons hypothesis.”<sup>52</sup> The first type of empirical study consists of opinion surveys and interviews,<sup>53</sup> while the second employs various forms of citation analysis.<sup>54</sup> Although the opinion surveys mainly examined the impact of intellectual property on research scientists (primarily in academia), rather than its impact on downstream development, it will be recalled that four major studies included interviews with representatives of commercial firms as well as

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<sup>48</sup> For a discussion of the similarities and differences between the “tragedy of the anticommons” and “patent thickets,” see DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* 75-78 (2009); see also *infra* note 72 and accompanying text.

<sup>49</sup> See Eisenberg, *supra* note 1, at 1667.

<sup>50</sup> See Strandburg, *supra* note 39, at 107-08, 110-11.

<sup>51</sup> See *id.* at 94 & n.8 (citing David Blumenthal et al., *Withholding Research Results in Academic Life Science: Evidence From a National Survey of Faculty*, 277 JAMA 1224, 1224 (1997); Eric G. Campbell et al., *Data Withholding in Academic Genetics: Evidence From a National Survey*, 287 JAMA 473, 478 (2002)).

<sup>52</sup> Matthew Herder, *Choice Patents*, 52 IDEA 309, 326 (2012).

<sup>53</sup> *Id.* at 326.

<sup>54</sup> *Id.* at 329-331.

academic researchers.<sup>55</sup> The citation analysis studies, by contrast, are concerned primarily with the impact of upstream patents on downstream knowledge dissemination.

Among the most widely cited opinion surveys are a series conducted by Professor John P. Walsh and various colleagues.<sup>56</sup> As to these surveys, even Professor Eisenberg, coauthor of the original anticommons hypothesis, concedes: “In a series of papers, [Walsh and colleagues] draw on these survey results as well as the work of others to conclude that, despite widespread complaints, patents have rarely blocked academic research.”<sup>57</sup> In the words of this critic, Walsh and colleagues “attribute this result to the fact that most scientists are oblivious to the patents they may be infringing, and to the fact that most patent owners would not find it cost-effective to sue academic researchers for infringement.”<sup>58</sup>

More significantly, the studies by Walsh and colleagues found that difficulties in gaining access to tangible research results through material transfers were more likely to impede research; however,

[r]estrictions on access . . . do not appear to turn on whether the material is itself patented. Rather, such restrictions are more closely associated with scientific competition, the cost of providing materials, a history of commercial activity on the part of the prospective supplier, and whether the material in question is itself a drug.<sup>59</sup>

Interestingly, and by way of illustrating the positive social response bias inherent in such surveys, Walsh and colleagues found that respondents, who had acted as both “suppliers” and “consumers” of research materials, claimed that 18 percent of their material requests went unheeded by other academic scientists, while admitting to failing to deliver materials only 6 percent of the time.<sup>60</sup>

Two earlier studies found that only a minority of university-based discoveries had been patented to begin with, as “only about 15 percent of university-based genetic discoveries are patented, with the vast majority going

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<sup>55</sup> See *supra* notes 11, 15-17 and accompanying text.

<sup>56</sup> John P. Walsh, Charlene Cho & Wesley M. Cohen, *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002, 2002 (2005); John P. Walsh, Wesley M. Cohen & Charlene Cho, *Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research*, 36 RES. POL'Y 1184, 1185-86 (2007) [hereinafter Walsh et al., *Where Excludability Matters*]; see generally Wesley M. Cohen & John P. Walsh, *Real Impediments to Academic Biomedical Research*, 8 INNOVATION POL'Y & ECON. 1, 10-11 (2007) (further analysis of the same results). For a discussion of these results, see Eisenberg, *supra* note 7, at 1063-66.

<sup>57</sup> Eisenberg, *supra* note 7, at 1065.

<sup>58</sup> *Id.* (footnote omitted).

<sup>59</sup> Walsh et al., *Where Excludability Matters*, *supra* note 54, at 1185.

<sup>60</sup> *Id.* at 1191.

into the public domain without [intellectual property] protection.”<sup>61</sup> Moreover, one of these studies reveals that universities employ substantially different patenting strategies than commercial entities.<sup>62</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 for all inventions and then dropping technologies later if there was no commercial interest.”<sup>63</sup> By contrast, non-profit institutions appear to be more selective, filing only where inventions demonstrably meet the requirements of novelty, utility, and non-obviousness.<sup>64</sup> Moreover, “[n]on-profits 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>65</sup>

Thus, while there is at least some evidence suggesting increased 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. Nor is it clear that university patenting and licensing are significantly diminishing the public domain. Indeed, to the extent that increased university patenting and licensing of upstream research results have strengthened the bargaining position of universities in relation to private industry and compensate in part for the decline in the federal government’s share of financial support for academic research and development (“R&D”), any reduction in the ability of universities to patent such research may actually aggravate,

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<sup>61</sup> See 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, 309 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) [hereinafter Walsh et al., *Effects of Research Tool Patents*] (citing David C. Mowery et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RES. POL’Y 99, 100 (2001) (representing an early version of MOWERY ET AL., *supra* note 33)); Michelle R. Henry et al., *DNA Patenting and Licensing*, 297 SCIENCE 1279, 1279 (2002); see also Michelle R. Henry et al., *A Pilot Survey on the Licensing of DNA Inventions*, 31 J.L. MED. & ETHICS 442, 443 (2003) [hereinafter Henry et al., *Pilot Survey*]. For a recent article that deconstructs the source of the widely cited contention that 20 percent of human genes are patented in a manner that would necessarily result in infringement by whole genome sequencing, see Christopher M. Holman, *Will Gene Patents Derail the Next Generation of Genetic Technologies?: A Reassessment of the Evidence Suggests Not*, 80 UMKC L. REV. 563, 570-72 (2012).

<sup>62</sup> Henry et al., *supra* note 61, at 443.

<sup>63</sup> *Id.*

<sup>64</sup> *Id.* The “difference in selectivity is evident when the number of invention disclosures received is compared to the number of patent applications [survey] respondents had filed on nucleic acid sequence inventions in the prior two-year period.” *Id.* Whereas companies reported an average of 37 invention disclosures and filed an average of 32 patent applications (86 percent), nonprofit research organizations received an average of 163 invention disclosures and filed an average of 24 applications (15 percent). *Id.*

<sup>65</sup> *Id.* at 444.

rather than alleviate, the problem of secrecy and delays in disseminating results.<sup>66</sup>

The empirical evidence to date also undercuts the concern that university scientists may have shifted toward more applied research because of increased patenting opportunities. Among the most commonly cited studies on this point are those of two economists, Jerry G. Thursby and Marie C. Thursby, who have produced a number of studies considering whether university patent licensing, afforded by the Bayh-Dole Act, has diverted universities away from their basic research mission. In the first of their two most recently published studies, and based on data from eleven major U.S. universities, they conclude that their research results “lend credence to the notion that, rather than diverting faculty research, licensing is part of a flurry of activities that can be associated with fundamental discoveries from fairly basic research.”<sup>67</sup> In the second of these studies, based on earlier theoretical work comparing simulations of university research in which faculty cannot license their inventions to simulations in which licensing income is possible, they purport to

have gone beyond the typical arguments that the Bayh-Dole Act has had no effects on the research enterprise (the status quo hypothesis) or that it has had a detrimental effect (the nega-

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<sup>66</sup> See 1 NAT'L SCI. FOUND., SCIENCE AND ENGINEERING INDICATORS 2002, at 4-9 to -10 (2002), available at <http://www.nsf.gov/statistics/seind02/pdf/c04.pdf> (“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.” (citation omitted)). The report goes on to note 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.

*Id.* at 5-9, available at <http://www.nsf.gov/statistics/seind02/pdf/c05.pdf>.

<sup>67</sup> Jerry Thursby & Marie Thursby, *University Licensing: Harnessing or Tarnishing Faculty Research?*, 10 INNOVATION POL’Y & ECON., 159, 183 (2010). Their data consist of the research, demographic, and disclosure profiles of all faculty scientists and engineers in PhD-granting departments at 11 major universities: California Institute of Technology, Cornell University, Georgia Institute of Technology, Harvard University, Massachusetts Institute of Technology, Purdue University, Stanford University, Texas A&M University, University of Pennsylvania, University of Utah, and University of Wisconsin at Madison.

*Id.* at 169-170.

tive hypothesis) to add the possibility that the effects have been positive in that they might have increased basic research effort (along with an increase in applied effort).<sup>68</sup>

Their results, using a database of faculty research at eight major U.S. universities over the years immediately following passage of the Bayh-Dole Act, “are quite clear in that [they] never find support for the negative hypothesis [and] the results tend to be consistent with the positive hypothesis rather than the status quo hypothesis.”<sup>69</sup>

#### B. *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.<sup>70</sup> The concern is that patenting upstream genetic products creates a risk of, first, blocking patents on particular foundational discoveries or indispensable research tools and, second, a more widespread “tragedy of the anticommons” where basic research discoveries necessary for subsequent

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<sup>68</sup> Jerry G. Thursby & Marie C. Thursby, *Has the Bayh-Dole Act Compromised Basic Research?*, 40 RES. POL’Y 1077, 1083 (2011).

<sup>69</sup> *Id.* The universities that were studied included all of the universities from their earlier study except California Institute of Technology, Cornell University, and Harvard University.

<sup>70</sup> See, e.g., Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987); Heller & Eisenberg, *supra* note 6; Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 L. & CONTEMP. PROBS. 289, 295-98 (2003); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77 (1999). 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 for 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 over basic research discoveries that enable subsequent investigation across a broad scientific territory; and 3) creating a danger of a “patent thicket,” or anticommons, when basic research discoveries necessary for subsequent work are owned not by one entity but by a number of different entities. *Id.* 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 NAT’L RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 119 (2006) (distinguishing between “blocking” patents and patent “thickets”). Some commentators further distinguish between anticommons problems, which require the aggregation of multiple inputs to create a single product, and patent thickets, which occur when multiple overlapping patents cover the same technology and can thus choke an industry. See, e.g., BURK & LEMLEY, *supra* note 48, at 75-78; Sabrina Safrin, *Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life*, 98 AM. J. INT’L L. 641, 669 (2004).

downstream development are owned by a large number of entities.<sup>71</sup> Similarly, there is also a concern about the creation of “patent thickets,” produced by overlapping and overbroad patent claims.<sup>72</sup> A related concern is that these adverse consequences will impoverish the public domain that has long been an important resource for researchers in both the public and private sectors, and that they may threaten the functioning of curiosity-driven research itself.<sup>73</sup>

To date, however, little hard empirical evidence has been produced to substantiate these concerns, and most of the survey-based empirical studies unveiled during Round Two of this debate suggest that these concerns are exaggerated.<sup>74</sup> At the same time, however, a number of contemporaneous studies, comparing patterns of citations to scientific articles, found respectively that: (1) the grant of a patent that is 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 that increased university patenting is accompanied by a slowdown in the pace of firm knowledge exploitation.

In the first of these studies, for example, Professors Fiona Murray and Scott Stern stated their version of the anticommons 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>75</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>76</sup>—that arguably meet the second part of their “if-then” hypothesis, Murray and Stern suggest that these data can be interpreted to establish the first part of the hypothesis.<sup>77</sup> But while the de-

<sup>71</sup> BURK & LEMLEY, *supra* note 48, at 75-77.

<sup>72</sup> *Id.* at 77-78.

<sup>73</sup> See *supra* notes 49-51 and accompanying text.

<sup>74</sup> See, e.g., Eisenberg, *supra* note 7, at 1060 (essentially conceding this point); see *supra* notes 49, 54-56 and accompanying text.

<sup>75</sup> Fiona Murray & Scott Stern, *Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis*, 63 J. ECON. BEHAV. & ORG. 648, 650 (2007).

<sup>76</sup> Their sample consisted of 340 peer-reviewed articles appearing in the research journal *Nature Biotechnology* between 1997 and 1999. *Id.* at 661.

<sup>77</sup> *Id.* at 651 (“[T]here is robust evidence for a quantitatively modest but statistically significant anti-commons effect; across different specifications, the article citation rate declines by approximately 10 to 20 percent 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 statistically significant but modest decline in knowledge accumulation as measured by forward citations.” *Id.* at 683 (emphasis

ductive syllogism “If x, then y; x; therefore y” is both logically valid and (assuming 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 explanatory hypotheses can be propounded.

One reason to doubt that a post-patent issuance drop in citation rate within the academic literature for a given piece of knowledge 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>78</sup> by notifying academic researchers that they should fish in less crowded waters.<sup>79</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. As a result, the issued patent becomes 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>80</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

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added). 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 651. 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 relative salience of research in follow-on research that is also disclosed in scientific publications.” *Id.* at 659.

<sup>78</sup> See generally Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625 (2002); see also F. Scott Kieff, *Perusing Property Rights in DNA*, in PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 125, 138-140 (F. Scott Kieff ed., 2003).

<sup>79</sup> For evidence establishing the abundance of “less crowded waters” in genomic research, see *infra* notes 99-121 and accompanying text. So abundant are these waters that one commentator, at least, argues that speculative gene patents are essentially irrational. See *infra* note 118 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 Pierre Azoulay, Waverly Ding & Toby Stuart, *The Impact of Academic Patenting on the Rate, Quality and Direction of (Public) Research Output*, 57 J. INDUS. ECON. 637, 668, 670 (2009) (finding that “academic scientists who patent produce more public scientific outputs than do otherwise equivalent non-patenters,” and that publication quality appears similar in the two groups, though their study also suggests that scientists “may modestly shift the content of [their research] towards questions of commercial interest”); Paula E. Stephan et al., *Who’s Patenting in the University? Evidence from the Survey of Doctorate Recipients*, 16 ECON. INNOVATION & NEW TECH. 71 (2007) (finding a strong complementarity between patenting and publishing).

<sup>80</sup> See *infra* note 188 and accompanying text; see also *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 875 (Fed. Cir. 2003) (Newman, J., concurring in part, dissenting in part) (“The information contained in patents is a major source of scientific as well as technologic knowledge.”), *vacated*, 545 U.S. 193 (2005).

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 neither a decline in accumulated knowledge nor a hindrance of follow-on research has occurred.<sup>81</sup>

A 2005 report of the National Research Council, while noting that the findings of Murray and Stern are “intriguing,” nevertheless concludes that “for a host of methodological reasons” their studies “should be interpreted with caution.”<sup>82</sup> One particular reason for caution is that a comparison of these findings with the opinion surveys conducted by Walsh and colleagues reveals what is described as a paradox. “If we accept that scientists are generally ignorant of patents, then why do we observe a decrease in citations to papers belonging to patent-paper pairs post-patent grant?”<sup>83</sup> While we will discuss one possible explanation for this paradox in Part III of this Article,<sup>84</sup> the 2005 National Research Council Report concludes that the effect Murray and Stern observe, “if real, ultimately may be more on citation behavior than research conduct.”<sup>85</sup> Not surprisingly, the coauthor of the anticommons hypothesis, Professor Eisenberg, omits specific discussion of the citation

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<sup>81</sup> See *infra* notes 99-121 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, “[o]f the articles submitted for review, more than 75 percent (27 out of 34) were considered to be obviously patentable; of the remaining, most contained at least some potential for patentability.” Murray & Stern, *supra* note 75, at 663. 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.” *Id.* 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 absence of a thorough examination of the prior art. Moreover, given at least some empirical evidence that universities and other nonprofit 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, 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 nonprofit institutions are acting more irrationally than selectively in making patenting decisions. See *supra* notes 62-63 and accompanying text. While universities may indeed be *irrationally* selective in their patenting decisions, such evidence would also tend to support the argument that speculative gene patenting may itself be irrational. See *infra* note 118 and accompanying text.

<sup>82</sup> NAT’L RESEARCH COUNCIL, *supra* note 70, at 127-128.

<sup>83</sup> Herder, *supra* note 52, at 330-331.

<sup>84</sup> See *infra* note 185 and accompanying text.

<sup>85</sup> NAT’L RESEARCH COUNCIL, *supra* note 70, at 128.

analysis literature as support for the anticommons hypothesis when surveying the empirical evidence generated in Round Two of the debate.<sup>86</sup>

A second study by Professor 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>87</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>88</sup> Fabrizio speculates that “[t]his may be due to the reduced availability of an important input to the industrial R&D process: university-based science,” and that “[t]he reduction or delay in availability may stem from reduced dissemination, restricted use, or more time consuming and costly negotiated access to university science.”<sup>89</sup>

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

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<sup>86</sup> Although Eisenberg cites to Fiona Murray’s series of papers describing the impact of patenting on the dissemination of the Harvard oncomouse and the response of the scientific community to licensing terms offered by DuPont, Eisenberg, *supra* note 7, at 1073 nn.96-100, she does not cite to Murray and Stern’s papers on citation analysis.

<sup>87</sup> See Kira R. Fabrizio, *Opening the Dam or Building Channels: University Patenting and the Use of Public Science in Industrial Innovation* (Jan. 30, 2006) (unpublished manuscript), available at <http://citeseerx.ist.psu.edu/viewdoc/summary?doi=10.1.1.128.3109>. Fabrizio’s study is based on patents applied for in the United States 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 patents assigned to universities in that class. *Id.* at 13. “[T]he ‘low university patenting’ group . . . accounts for 69% of the patents and 79% of [the technology classes in her dataset],” while “the ‘hi university patenting’ group” accounts for “approximately 31% of the patents . . . [and] 21% of the technology classes.” *Id.* at 13-14.

<sup>88</sup> *Id.* at 4.

<sup>89</sup> *Id.* at 27. Fabrizio also finds an increasing variance across firms in citations to public science as university patenting increases, but she 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 U.S.-sponsored research discoveries were developed by U.S. firms, rather than by foreign competitors who had too often come to dominate world markets for products based on technologies pioneered in the United States.” Eisenberg, *supra* note 1, at 1664-65.

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>90</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>91</sup>

Fabrizio also concedes that one alternative explanation for her data may be that, "[i]f 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>92</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 "[t]his evidence contradicts the assumption that more basic inventions have longer average backward citation lags."<sup>93</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>94</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>95</sup> Moreover, "[u]niversity patents also have relatively shorter backward citation lags when compared to a matched sample of corporate patents."<sup>96</sup> Thus, she concludes that "the explanation of increasing patent lags being due to

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<sup>90</sup> Fabrizio, *supra* note 87 at 27.

<sup>91</sup> *Id.*

<sup>92</sup> *Id.* at 25.

<sup>93</sup> *Id.* (citing Manuel Trajtenberg, Rebecca Henderson & Adam Jaffe, *University Versus Corporate Patents: A Window on the Basicness of Innovations*, 5 ECON. INNOVATION & NEW TECH. 19, 26-29 (1997) (developing 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. Trajtenberg et al., *supra*, at 26-29. 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. *Id.* at 29-30.

<sup>94</sup> Fabrizio, *supra* note 87, at 25.

<sup>95</sup> *Id.*

<sup>96</sup> *Id.* (citing Trajtenberg et al., *supra* note 93).

increasing basicness of research associated with increasing university patenting is questionable from the start.”<sup>97</sup>

However, Fabrizio’s data are susceptible to yet another plausible explanation: she may be comparing apples to oranges. 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>98</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 two dissimilar types of patents: early-stage, “proof of concept” patents versus late-stage, commercial patents. Moreover, her data may merely demonstrate that backward citation lags in industrial patents for technology classes increasingly reliant upon early-stage, “proof of concept” patents will experience a greater lag due to increases in university patenting than backward citations to that same prior art in other early-stage, “proof of concept” academic patents, or than 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 are necessarily the result of a slowdown in the pace of firm knowledge exploitation with increasing university patenting.

In any event, offsetting the results of the foregoing three citation analysis studies, a number of other studies published during Round Two of the debate seem to corroborate the conclusions reached by Walsh and colleagues. For example, as the coauthor of the anticommons hypothesis notes, the American Association for the Advancement of Science, through its Project on Science and Intellectual Property in the Public Interest (“SIPPI”) provided data from separate surveys of scientists, including commercial scientists, in the United States, the United Kingdom, Germany, and Japan. While only the U.S. and Japanese surveys were sufficiently similar to draw comparative conclusions, “the SIPPI report found ‘very little evidence of an “anticommons problem”’ in survey results from the United States and Ja-

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<sup>97</sup> *Id.* at 25.

<sup>98</sup> *See supra* note 27 and accompanying text.

pan.”<sup>99</sup> It is true, however, as the coauthor of the anticommmons hypothesis points out, that the U.S. SIPPI data indicate that difficulties in attempting to acquire IP-protected technologies were more common among industry respondents (40 percent) than among academic respondents (25 percent).<sup>100</sup> On the other hand, the SIPPI report on the U.S./Japan comparative data concludes that “the vast majority of researchers largely have been unaffected by others’ patented technologies.”<sup>101</sup> That result is said to be especially remarkable because “the survey included both pure IP acquisition (a license to use a patented technology) and research materials that are patented (e.g., a cell line or genetically engineered mouse), which should produce somewhat higher rates of adverse effects than pure IP alone.”<sup>102</sup>

Finally, in a study published in 2007 that was based on a dataset comprising 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, Professors David E. Adelman and Kathryn L. DeAngelis found “little evidence that the rise in biotechnology patenting is adversely affecting innovation.”<sup>103</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 (“USPTO”) patent subclasses; and two preliminary investigations of patenting in two discrete areas of biotechnology research and development<sup>104</sup>—

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<sup>99</sup> See Eisenberg, *supra* note 7, at 1066-1067 (quoting AM. ASS’N FOR THE ADVANCEMENT OF SCI., INTERNATIONAL INTELLECTUAL PROPERTY EXPERIENCES: A REPORT OF FOUR COUNTRIES 7 (2007)).

<sup>100</sup> *Id.* at 1067.

<sup>101</sup> AM. ASS’N FOR THE ADVANCEMENT OF SCI., *supra* note 99, at 12.

<sup>102</sup> *Id.*

<sup>103</sup> David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 TEX. L. REV. 1677, 1678 (2007); see also Carl E. Pray & Anwar Naseem, *Intellectual Property Rights on Research Tools: Incentives or Barriers to Innovation? Case Studies of Rice Genomics and Plant Transformation Technologies*, 8 AGBIOFORUM 108, 108 (2005) (concluding that patents were important in inducing private firms to develop two platform technologies—namely, “plant transformation techniques and the mapping of the rice genome”).

<sup>104</sup> Adelman & DeAngelis, *supra* note 103, at 1681. The “database consists of 52,039 [biotechnology] patents that were issued between January 1990 and December 2004 . . . collected from a larger patent database consisting of all patents” drawn from 49 general USPTO classes and then pared down by examining the USPTO subclasses in which well-established biotechnology companies were obtaining patents, identifying the subclasses the USPTO treats as biotechnology fields, and independently assessing potentially relevant subclasses to determine their relevance. *Id.* at 1741. The final database consists of patents whose primary USPTO classification falls under one of 704 subclasses. *Id.* at 1702. For comparative purposes, the dataset was divided into five distinct areas of biotechnology research and development—“(1) measuring and testing processes (MET); (2) polypeptide (i.e., short protein sequences) and protein sequences (PSQ); (3) nucleotide (i.e., DNA, gene) sequences (NSQ); (4) immunological processes and compounds (IGG); and (5) genetically modified organisms (GMO)” —and into “three categories of assignees” (i.e. owners)—(1) federal government; (2) universities; and (3) corporations. *Id.* at 1687, 1743 (footnotes omitted). The analyses of general trends were supplemented by two studies

the data of Adelman and DeAngelis reveal: (1) a “striking rise and fall in biotechnology patenting”; (2) a “surprisingly diffuse [and expanding] pattern of patent ownership”; and (3) a “consistent influx of new entrants conducting . . . research and development.”<sup>105</sup> “Even the largest companies, on average, are granted fewer than thirty biotechnology patents per year, and the number of entities obtaining biotechnology patents has consistently increased over the fifteen years covered by the data set.”<sup>106</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>107</sup> Moreover, while the large number and broad-based ownership of biotechnology patents among different entities raises the specter of a fragmented “anticommons,” the broad distribution of biotechnology patents across USPTO subfields suggests that in most areas of biotechnology research and development the density of patenting is too

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designed to evaluate the distribution of biotech patenting among patent owners and across distinct areas of research and development. *Id.* at 1687-1698.

<sup>105</sup> *Id.* at 1678. Specifically, the data reveal three trends. First, “the number of biotechnology patents issued per year peaked at 5,977 patents in 1998 and then declined to 4,324 patents (a twenty-nine percent drop) by 2004.” (This same basic trend can be tracked through each of the authors’ five technology areas, specific large-population USPTO subclasses within four technology groups, the thirty subclasses with the largest number of patents, and the three categories of assignees.) *Id.* at 1687. Second, “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.” Charles R. McManis & Suheol Noh, *The Impact of the Bayh-Dole Act on Genetic Research and Development: Evaluating the Arguments and Empirical Evidence to Date* 47 n.210 (Wash. Univ. in St. Louis Sch. of Law, Legal Studies Research Paper Series, Paper No. 11-05-04, 2011), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1840639##](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1840639##). This shift represented

a ten-fold increase in patents 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 receiving 29% of the patents.

*Id.* The absolute numbers of patents are relatively low in this subfield, however, as the largest number of patents by far (almost 50 percent) is consistently to be found in the measuring and testing subfield throughout the fifteen-year period, followed by protein sequences (26 percent), immunological inventions (12 percent), nucleotide sequences (9 percent) and GMOs (3 percent), with patents on protein and polypeptide sequences experiencing a 50 percent drop in their relative share over the fifteen-year period, while GMOs, nucleotide sequences and immunological technologies almost tripled their share of biotech patents during the same period. Adelman & DeAngelis, *supra* note 103, at 1735 fig. 7. Third, “biotechnology patents are spread broadly across an expanding number of patent owners.” *Id.* at 1695. The authors find economic disruptions do not appear to explain the late-1990s drop in biotechnology patenting and that the USPTO’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 1689-90.

<sup>106</sup> *Id.* at 1681.

<sup>107</sup> *Id.* at 1678.

low to provide any support for this concern.<sup>108</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>109</sup>

In addition to providing empirical evidence that biotechnology patenting is not adversely affecting innovation, Professor Adelman has joined others<sup>110</sup> in offering a cogent theoretical critique of the concern over blocking patents and an emerging anticommons problem in biotechnology research. In a 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>111</sup> This indifference, he argues, “proves to be a critical one, for it obscures a central fallacy [in the anticommons argument]—[namely the assumption] that the commons for

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<sup>108</sup> *Id.* at 1696-97.

<sup>109</sup> Adelman & DeAngelis, *supra* note 103, at 1729. A more narrowly focused study of gene patenting reported that nearly 20 percent of human genes, representing 4,382 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 & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 *SCIENCE* 239, 239 (2005). For a recent deconstruction of this study, which is the source of the widely cited contention that “20 percent of human genes are patented in a manner that would necessarily result in infringement” by whole genome sequencing, see Holman, *supra* note 61, at 564. The Jensen and Murray study itself notes that (1) these genes are claimed in 4,270 patents owned by 1,156 different assignees, 63 percent of which are owned by private firms and 28 percent of which are owned by governments, schools, universities, research institutions, and hospitals; (2) at least 3,000 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). McManis & Noh, *supra* note 105, at 47 n.214. 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 anticommons effect. *Id.* “Moreover, while Pressman et al. acknowledge this study, they go on to show that issued DNA patents have declined precipitously since 2001.” McManis & Noh, *supra* note 105, at 45 n.214 (citation omitted) (citing Lori Pressman et al., *The Licensing of DNA Patents by US Academic Institutions: An Empirical Survey*, 24 *NATURE BIOTECH.* 31, 31 (2006)); see also *supra* note 105 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 percent of biotechnology patents; the number of gene and protein patents currently being issued appears to be relatively unthreatening; and “[t]he relatively low numbers of patents on genetic and protein sequences suggest that worries about excessive patenting of genes and proteins may be overblown.” Adelman & DeAngelis, *supra* note 103, at 1692-94; see also *infra* note 117 and accompanying text (discussing the arguable “irrationality” of speculative gene patents).

<sup>110</sup> See, e.g., Kieff, *supra* note 78, at 127.

<sup>111</sup> Adelman, *Fallacy of the Commons*, *supra* note 5, at 985; see also Adelman, *Speculative Gene Patents*, *supra* note 5, at 124; Adelman & DeAngelis, *supra* note 103, at 1678.

biomedical science is finite and congested.”<sup>112</sup> Adelman argues that “[t]he uniquely open-ended nature of biomedical science requires a reassessment of how patenting affects biotech research and innovation.”<sup>113</sup> He also notes the importance of recognizing that “two types of [genomic] research tools exist: (1) the relatively small number of common methods research tools (for example, Cohen-Boyer, Kohler-Milstein, and PCR processes); and (2) problem-specific tools that are quite plentiful (for example, ESTs, SNPs, and drug targets).”<sup>114</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>115</sup> the translation of this knowledge into new products has been far less impressive, “creat[ing] an environment in which research opportunities far exceed the capacities of the scientific community,” thus making “biotech science, in important respects, an uncongested common resource.”<sup>116</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 essentially “irrational.”<sup>117</sup> Adelman notes that his theoretical

<sup>112</sup> Adelman, *Fallacy of the Commons*, *supra* note 5, 985-86.

<sup>113</sup> *Id.* at 986; *see also* Adelman, *Speculative Gene Patents*, *supra* note 5, at 124; Adelman & DeAngelis, *supra* note 103, at 1678.

<sup>114</sup> Adelman, *Fallacy of the Commons*, *supra* note 5, at 1020; Adelman, *Speculative Gene Patents*, *supra* note 5, at 139. For a case study of two platform technologies—i.e., plant transformation technologies and the mapping of the rice genome—see Pray & Naseem, *supra* note 103, at 108.

<sup>115</sup> Adelman, *Fallacy of the Commons*, *supra* note 5, at 987; *see also* Adelman, *Speculative Gene Patents*, *supra* note 5, at 124.

<sup>116</sup> *See* Adelman, *Speculative Gene Patents*, *supra* note 5, at 124-25; *see also* Adelman, *Fallacy of the Commons*, *supra* note 5, at 986; Kieff, *supra* note 78, at 147.

<sup>117</sup> Adelman, *Fallacy of the Commons*, *supra* note 5, at 1022 (“[T]he current state of biotech research and development represents the worst conditions for strategic patenting.”); Adelman, *Speculative Gene Patents*, *supra* note 5, 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, *supra* note 78, at 138-39 (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 (footnote omitted)); *id.* at 141 (“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*, 82 NOTRE DAME L. REV. 1917, 1921 (2007).

argument “is consistent with recent trends toward dedicating these types of research tools to the public domain.”<sup>118</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>119</sup> and concludes that, “contrary to the fears of many legal commentators, there are few signs that biotech patenting has impeded biomedical innovation.”<sup>120</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>121</sup> However, this is not an anticommons 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>122</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. As a consequence, access to research tools of broad importance to biomedical research and development is unlikely to be restricted.<sup>123</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>124</sup>

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<sup>118</sup> Adelman, *Speculative Gene Patents*, *supra* note 5, at 140.

<sup>119</sup> Adelman, *Fallacy of the Commons*, *supra* note 5, at 988.

<sup>120</sup> *Id.*; see also *supra* note 109 and accompanying text.

<sup>121</sup> Adelman, *Fallacy of the Commons*, *supra* note 5, at 1024. For a case study suggesting that concerns over patents on two “platform technologies” may be exaggerated, see Pray & Naseem, *supra* note 103, at 108.

<sup>122</sup> Adelman, *Fallacy of the Commons*, *supra* note 5, at 1024. Adelman notes that whereas rivalrous uses “would involve applications of patented technology in the same market(s), . . . nonrivalrous application would arise in a distinct market. Uses of certain proteins, for example, can span completely different disease categories.” *Id.* at 1024 n.187; see also Kieff, *Registering Patents*, *supra* note 26, at 67 & n.53 (noting that the patent system promotes coordination among complementary users of a patented invention).

<sup>123</sup> Adelman, *Fallacy of the Commons*, *supra* note 5, at 1029; see also Kieff, *supra* note 78, at 147 (noting that “patents . . . cover[ing] 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 “[o]ther 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”).

<sup>124</sup> Alderman, *Fallacy of the Commons*, *supra* note 5, at 1029. Indeed, the bevy of empirical studies unveiled between 2004 and 2007, including Adelman’s own empirical study, generally tend to corroborate the theoretical conclusions of Adelman and others. See *supra* notes 43-96 and accompanying text. In September 2008, the International Expert Group on Biotechnology, Innovation and Intellectual

Adelman's argument has been criticized as "confus[ing] the average case with individual ones"—the claim being that his "argument is essentially equivalent to claiming that New York and San Francisco will not become congested or experience soaring property values because of all the open space available in Montana and the Dakotas."<sup>125</sup> However, it should be noted that the Adelman and DeAngelis empirical study concluded that in *most* areas of biotechnology research and development—not simply in the average case—the density of patenting is too low to provide support for the anticommons concern.<sup>126</sup> Adelman also recognizes that patents on the relatively small number of common-method research tools "do present potentially significant risks to innovation and warrant continuing scrutiny," but goes on to distinguish these cases from the far more plentiful examples of problem-specific tools and explains why an anticommons is unlikely to develop in either case.<sup>127</sup>

### III. THE BAYH-DOLE ACT, ACCESS TO DATA, AND MATERIAL TRANSFER AGREEMENTS

This final Part of this Article will consider how, in Round Three of the debate over the Bayh-Dole Act and the anticommons hypothesis, the terms of the debate have been reframed in light of the bevy of empirical studies introduced during Round Two. Part III will also consider the relevance of three recent (i.e., Round Three) empirical studies to this ongoing debate.

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Property, chaired by Professor Richard Gold, a member of the law faculty at McGill University in Montreal, Canada, issued a report that was said to have found that "[t]he drive to accumulate and defend patents is stifling innovation, particularly in biotechnology and healthcare." Clive Cookson, *Patent Wars Hurting Life Sciences*, FINANCIAL TIMES (Sept. 23, 2008, 4:44 PM), <http://www.ft.com/intl/cms/s/0/805560d6-8985-11dd-8371-0000779fd18c.html#axzz2xIVMSPyM>; see INT'L EXPERT GRP. ON BIOTECH., INNOVATION & INTELLECTUAL PROP., CTR. FOR INTELLECTUAL PROP. POLICY, TOWARD A NEW ERA OF INTELLECTUAL PROPERTY: FROM CONFRONTATION TO NEGOTIATION (2008) [hereinafter CIPP REPORT], available at <http://cdm266901.cdmhost.com/cdm/ref/collection/p266901coll4/id/1710>. The actual findings of the report, however, are more modest than the news report cited above would suggest. The report asserts that the "old IP" era, "in which companies and universities seek ever greater amounts of IP in order to protect themselves from others," is on the wane, CIPP REPORT, *supra*, at 8, but it notes that "[t]he twilight of Old IP does not signal the end of the importance of IP . . . [but rather the beginning of an] era in which IP is used to sustain and maintain collaborations and partnerships so that knowledge gets to those who need it most to produce and disseminate new products and services." *Id.* at 9. The report concedes that "[t]here is a lack of empirical data on such critical questions as to whether, how and when IP increases levels of investment in research and development." *Id.* at 10. This issue, however, is far broader than the subject of this Article, which is narrowly concerned with the impact of university patenting on the research mission of universities and on the development of downstream products. About that specific issue, the report offers no new insights.

<sup>125</sup> See BURK & LEMLEY, *supra* note 48, at 152.

<sup>126</sup> See *supra* note 109 and accompanying text.

<sup>127</sup> See *supra* note 122 and accompanying text.

A. *Reframing the Debate over the Anticommons Hypothesis*

In light of the empirical evidence adduced in the course of Round Two of the debate over the Bayh-Dole Act's impact on genetic research and development, Professor Eisenberg concedes "that, overall, intellectual property has presented fewer impediments to research than policymakers may have projected on the basis of early salient controversies."<sup>128</sup> Nevertheless, Professor Eisenberg claims that the empirical data support the original anticommons hypothesis in two important respects: First, with regard to the impact of university patenting of genetic products and processes on upstream research, she argues that practical restrictions on access to materials and data have had more impact on researchers than patents.<sup>129</sup> Second, with regard to the impact of university patenting of genetic products and processes on downstream development, she argues that patents appear to have a greater impact on downstream product development than on upstream academic research.<sup>130</sup>

1. Upstream Effects—Access to Materials and Data

In addressing Eisenberg's first claim, it should be noted that the problem of "practical excludability" made possible by restrictions on access to materials and data is more analogous to the problem of blocking patents than it is to the anticommons problem or its first cousin, patent thickets.<sup>131</sup> Moreover, practical excludability (at least in theory) does not depend on the existence of an upstream patent. As Eisenberg notes, "[w]ith or without a patent, a scientist or institution may control access to a resource, such as a large private database or a transgenic mouse."<sup>132</sup> Indeed, three early "salient controversies"—i.e., the "anec-data" that contributed to Round One of the debate over the impact of the Bayh-Dole Act on genetic research and development<sup>133</sup>—illustrate precisely this kind of practical excludability.

The first salient controversy arose in the context of the sequencing of the human genome by the public Human Genome Project ("HGP") and the private firm Celera and subsequent access to data. As noted in a recent empirical study examining that controversy, "[b]etween 2001 and 2003, Celera used a contract law-based form of IP to protect genes sequenced by Celera

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<sup>128</sup> See Eisenberg, *supra* note 7, at 1061.

<sup>129</sup> *Id.* at 1060, 1080-1084.

<sup>130</sup> *Id.* at 1062, 1076-1080.

<sup>131</sup> For the distinction between an anticommons and a patent thicket, see *supra* note 70 and accompanying text.

<sup>132</sup> Eisenberg, *supra* note 7, at 1085.

<sup>133</sup> See *supra* note 8 and accompanying text.

but not yet sequenced by the public effort.”<sup>134</sup> While one may question the author’s assumption that a contract-based legal right is properly characterized as a “property” right,<sup>135</sup> it is nevertheless true that Celera’s control over access to its proprietary database invested it with a practical ability to license access to its data for substantial fees and potential “reach through” royalties “for any resulting commercial discoveries, even though it was publicly known at the time that all of Celera’s genes would be sequenced by the public effort, and thus be in the public domain, by 2003.”<sup>136</sup> It is also true that Celera was actively pursuing gene patent applications for genes in its database, though it is also worth noting that “ex post, most of these applications were not granted patents.”<sup>137</sup> In other words, Celera was availing itself of a classic form of trade secret protection, premised on the assumption that access to its proprietary data offered a sufficiently valuable lead time advantage prior to 2003 for anyone willing to pay the price, and thereby helping to offset Celera’s overall research costs in developing the data.<sup>138</sup>

Although the controversy over Celera’s proprietary database subsided once the underlying data entered the public domain in 2003, two other early salient controversies illustrating the phenomenon of practical excludability have been more enduring. Both of these controversies involved restricted access to materials—namely, restrictions on access to DNA diagnostics and mouse models—both of which Eisenberg discusses in her 2008 article.<sup>139</sup> In that article Eisenberg first describes the empirical studies documenting problems of access to DNA-based genetic tests, but concedes that “[i]t is not clear whether the difficulties documented in these studies arise from the challenge of negotiating multiple licenses in the face of a proliferation of patents, as distinguished from the inability to reach agreement with a single obstreperous patent holder.”<sup>140</sup> Certainly the most egregious of these cases is an example of the latter cause cited by Eisenberg. Myriad was the exclusive licensee of the University of Utah with respect to key patents, and Myriad’s licensing practices deterred laboratory efforts meant to offer ge-

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<sup>134</sup> Heidi L. Williams, *Intellectual Property Rights and Innovation: Evidence from the Human Genome*, 121 J. POL. ECON. 1, 2 (2013).

<sup>135</sup> See, e.g., *ProCD, Inc. v. Zeidenberg*, 86 F.3d 1447, 1454 (7th Cir. 1996) (distinguishing the exclusive rights of copyright and contract rights, noting that “[a] copyright is a right against the world. Contracts, by contrast, generally affect only their parties; strangers may do as they please, so contracts do not create ‘exclusive rights’”).

<sup>136</sup> Williams, *supra* note 134, at 2.

<sup>137</sup> *Id.* at 11.

<sup>138</sup> As we shall see, although this assumption was reasonable, as various pharmaceutical companies, universities, and nonprofit research organizations apparently paid the price for early access to Celera’s database, it was not a sustainable business model for Celera, given the eventual public disclosure of the data. See *infra* notes 173-174 and accompanying text.

<sup>139</sup> Eisenberg, *supra* note 7, at 1071-75.

<sup>140</sup> *Id.* at 1072 (emphasis omitted).

nostic tests for breast cancer.<sup>141</sup> However, Eisenberg concedes that difficulties with gaining access to DNA diagnostics “do not inherently suggest an anticommons problem”<sup>142</sup> and that such a problem would only arise in the case of DNA diagnostic products, such as microarrays, that include many different genes and mutations.

Eisenberg also discusses another notorious example of difficulties in negotiating license terms, this one involving DuPont’s exclusive license from Harvard University on dominant patent rights to two important mouse models—namely oncomice (genetically engineered to be susceptible to cancer) and cre-lox, or “knockout,” mice (genetically engineered to delete certain genes in specific tissues).<sup>143</sup> Here, too, however, she concedes that “difficulties in negotiating with a single patent holder do not count as an anticommons,”<sup>144</sup> though she does argue that “close consideration of such a salient episode can illuminate perceptions of the risk of bargaining breakdowns when an institution contemplates the need to negotiate with multiple licensors.”<sup>145</sup> But Eisenberg also goes on to describe how the reactions of individual academic scientists, universities, and the National Academy of Sciences resulted in the director of the National Institutes of Health (“NIH”) becoming “personally involved in negotiations with DuPont,” which eventually led to “a Memorandum of Understanding that permitted academic scientists to use oncomice without cost for noncommercial purposes, but did not permit them to transfer the mice to scientists at other institutions without using a DuPont MTA, nor to use them in industry-sponsored research.”<sup>146</sup>

Although Eisenberg describes the foregoing restrictions as having “prove[n] to be an ongoing source of problems between DuPont and the scientific community,”<sup>147</sup> a subsequent paper in a series to which she cites found that the level and type of follow-on research using the oncomice in question experienced a “significant increase” after the NIH-induced changes occurred.<sup>148</sup> Eisenberg’s account of the controversy thus seems to underestimate what another commentator (an insightful 2009 law graduate) explicitly identified as an explanation for why an anticommons has not emerged in the biotechnology realm: the fact that “most upstream research

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<sup>141</sup> *Id.*

<sup>142</sup> *Id.*

<sup>143</sup> *Id.* at 1072-76.

<sup>144</sup> *Id.* at 1073.

<sup>145</sup> Eisenberg, *supra* note 7, at 1073.

<sup>146</sup> *Id.* at 1074.

<sup>147</sup> *Id.*

<sup>148</sup> See generally Fiona Murray et al., *Of Mice and Academics: Examining the Effect of Openness on Innovation* (Nat’l Bureau of Econ. Research, Working Paper No. 14819, 2009), available at [http://www.nber.org/papers/w14819.pdf?new\\_window=1](http://www.nber.org/papers/w14819.pdf?new_window=1).

is structured and funded by the public sector, led by the [NIH].”<sup>149</sup> It is also noteworthy that since 2000 the NIH has been operating in light of an amendment to the Bayh-Dole Act in which Congress stated that the objective of the Bayh-Dole Act is to be carried out “without unduly encumbering future research and discovery.”<sup>150</sup> While some might argue that the NIH has taken only timorous steps to respond to criticisms of the Bayh-Dole Act and implement the foregoing congressional objective, the NIH did issue in 2005 a set of “best practices” guidelines for genomic inventions. The guidelines recommend that recipients of NIH funding strongly consider broad and nonexclusive licensing of genomic inventions, with allowance for cases where exclusive licenses are needed to induce large investment in post-discovery commercial development.<sup>151</sup> Had the University of Utah and Harvard University either realized on their own or been cajoled by the NIH to recognize that they needed to take a more nuanced approach in their licensing of these early upstream genetic patents, the controversies over DNA diagnostics and mouse models might well have been averted.<sup>152</sup> In any event, with respect to the DuPont knockout mouse controversy, once the licensing terms were modified, “the NIH moved to create its own line of knockout mice, . . . obtained licenses from two major private industry partners for their existing lines of knockout mice, as well as provided funding to create additional lines.”<sup>153</sup> “The NIH Knockout Mouse Project (KOMP) [in] seek[ing] to produce a series of knockout mice lines, one for each gene in the mouse genome, for distribution in research . . . can [thus] be thought of as a reaction to a potential anticommons problem.”<sup>154</sup>

Not only does the NIH wield the power of the purse, it is also a substantial patent holder and patent licensee in its own right. As the aforementioned 2009 law student-authored article describes in more detail, “[t]he

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<sup>149</sup> Chester J. Shiu, *Of Mice and Men: Why an Anticommons Has Not Emerged in the Biotechnology Realm*, 17 TEX. INTELL. PROP. L.J. 413, 415 (2009).

<sup>150</sup> See 35 U.S.C. § 200 (2012).

<sup>151</sup> Best Practices for the Licensing of Genomic Inventions: Final Notice, 70 Fed. Reg. 18,413 (Apr. 11, 2005); see Pressman et al., *supra* note 109, at 32. Note also that, in January 2008, pursuant to the Consolidated Appropriations Act of 2008, Pub. L. No. 110-161, § 218, 121 Stat. 1844, 2187 (2007), the NIH issued its Revised Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research, NOT-OD-08-033, revising what had previously been a voluntary public access policy to make it mandatory. See *Revised Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research*, NAT’L INSTS. OF HEALTH, <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html> (last visited Apr. 2, 2014).

<sup>152</sup> See, e.g., Robert Cook-Deegan, Subhashini Chandrasekharan & Misha Angrist, *The Dangers of Diagnostic Monopolies*, 458 NATURE 405, 405 (2009) (critiquing, inter alia, the exclusive licensing practices of Myriad Genetics, the exclusive licensee of the University of Utah’s BRCA patents). For a recent example of how a university’s failure to obtain an initial assignment of patent rights from a researcher resulted in the university’s loss of those rights, see *Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 131 S. Ct. 2188, 2199 (2011).

<sup>153</sup> Shiu, *supra* note 149, at 437.

<sup>154</sup> *Id.* at 430 (footnote omitted).

U.S. government is the second largest holder of DNA-based patents, behind only the University of California system.”<sup>155</sup> This same article points out that, “as of 2006 the NIH had 1,364 active licenses and held approximately 4,000 issued or pending patents.”<sup>156</sup> It also notes that “in recent years, the NIH has required researchers applying for more than \$500,000 in funding . . . to submit a plan for data-sharing in their grant applications,” thus reducing the likelihood that a Celera-like problem of restricted access to genetic information will occur in the future.<sup>157</sup> The article also notes that “[w]hile Celera certainly spurred [the public HGP] to work faster, in the end Celera was not able to profit by patenting genes or licensing databases or gene sequences, . . . [as] that plan was largely undercut by the free public availability of equivalent information, courtesy of the HGP.”<sup>158</sup> Finally, while much academic debate has been devoted to whether the NIH ought to be more aggressive in the exercise of its statutory “march-in” rights (in effect, the power to engage in compulsory licensing of patented inventions funded by the NIH) under section 203 of the Patent Act, less attention has been paid to section 202(4), which specifies that the federal agency providing the funding “shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.”<sup>159</sup>

To be sure, other commentators, such as Professors Dan Burk and Mark Lemley, in their 2009 book, *The Patent Crisis and How the Courts Can Solve It*, join Rebecca Eisenberg in “suggest[ing] that the risk of anticommons in biotechnology patents remains a concern.”<sup>160</sup> However, it bears emphasizing that Burk and Lemley are arguing that it is the patent system itself, and not the Bayh-Dole Act as such, that is broken. Their specific prescription for how the risk of anticommons in biotechnology patents can best be avoided is by proper judicial modulation of the patent standards for obviousness and disclosure.<sup>161</sup> “Under [their] approach, because there will be relatively few patents, the problem of patent thickets should not arise.”<sup>162</sup> They claim that “[t]his calibration of patent frequency and scope seems to be the proper response to the anticommons concern found in much of the biotechnology literature.”<sup>163</sup> They differ from Eisenberg primarily in

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<sup>155</sup> *Id.* at 428.

<sup>156</sup> *Id.*

<sup>157</sup> *Id.* at 429.

<sup>158</sup> *Id.* at 436-37.

<sup>159</sup> 35 U.S.C. § 202(4) (2012).

<sup>160</sup> See BURK & LEMLEY, *supra* note 48, at 152.

<sup>161</sup> See *id.* at 151 (“Our alternative approach—a fairly high obviousness threshold coupled with a fairly low disclosure requirement—will produce a few very powerful patents in uncertain industries. It will therefore solve the anticommons problem often identified with DNA while at the same time boosting incentives to innovate by giving stronger protection to significant inventions.”)

<sup>162</sup> *Id.* at 152

<sup>163</sup> *Id.* at 152-53.

their concern “that the alternative solution [to the anticommons concern]—favoring greater government control of inventions supported by public funds over unfettered intellectual property rights—might unacceptably reduce the incentive for biotechnology companies to move beyond invention to innovation and product development.”<sup>164</sup>

For purposes of evaluating the impact of the Bayh-Dole Act on genetic research and development, however, one need not choose between these two prescriptions for reducing the risk of an anticommons in biotechnology patenting and licensing. The Eisenberg and Burk and Lemley approaches, in reality, propose solutions to two different problems. Burk and Lemley, after all, are not concerned with correcting for any flaw in the policy underlying the Bayh-Dole Act as such, but rather with reforming the patent system as a whole. Eisenberg, by contrast, is specifically concerned with ensuring that university patenting of upstream research will not contribute to an anticommons.

At the same time, one consideration that counsels caution in adopting Burk and Lemley’s prescription as the sole response to the anticommons risk is that reducing the number of upstream gene patents may simply exacerbate the problem of “practical excludability.” While, as we have seen, the practical excludability achieved by use of data access and MTAs often serves, in practice, as a complement to patent protection, such agreements may also serve as a substitute when patent protection is unavailable.<sup>165</sup> In other words, the reduction of patent protection will not necessarily result in an enhanced public domain; it can also result in enhanced reliance on trade secret protection. Indeed, one of the underlying policies promoted by patent law, in addition to incentivizing invention and downstream commercialization, is to encourage public disclosure of inventions.<sup>166</sup> Thus, even if the courts do step up to the plate, as Burk and Lemley recommend, and tailor the disclosure and non-obviousness requirements of patent law to resolve the larger “patent crisis,” there will still be a need for the NIH to develop and maintain policies that foster the norms of open science, encourage less restrictive licensing, and discourage contractual practices that confer “practical excludability” advantages for federally funded producers of sub-patentable innovation.

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<sup>164</sup> *Id.* at 153.

<sup>165</sup> See *supra* notes 59-60 and accompanying text.

<sup>166</sup> See 35 U.S.C. § 112 (2012); Application of Hogan, 559 F.2d 595, 606 (C.C.P.A. 1977) (“[B]asic inventions’ have led to ‘basic patents,’ which amounted to real incentives, not only to invention and its disclosure, *but to its prompt, early disclosure.*” (emphasis added)).

## 2. Downstream Effects

With regard to downstream effects, Eisenberg concedes that relatively few of the Round Two empirical studies focused attention on downstream product development, but she argues that “[t]o the extent that [they do], they suggest that patents impose greater costs on scientists in product developing firms than they impose on academic scientists (who generally ignore them).”<sup>167</sup> However, she argues that the empirical evidence supports her point—e.g., the SIPPI surveys of scientists in industry in the United States suggesting that “difficulties in attempting to acquire IP-protected technologies” were more common among industry respondents (40 percent) than among academic respondents (25 percent)—while failing to reiterate her own earlier observation that “only 11% of both industry and academic respondents, or about 1% of the total universe of over 2,000 survey respondents, reported abandoning a research project.”<sup>168</sup>

Likewise, while Eisenberg emphasizes that the empirical studies of Walsh and colleagues suggest that “[i]f a potential anticommons is identified at an early enough stage, the risk of bargaining breakdowns sometimes leads firms to avoid R&D pathways that would call for too many licenses in favor of projects for which the IP landscape is clearer,”<sup>169</sup> she relegates to a footnote the observation of Walsh and colleagues “that redirection of effort away from areas where there are too many patents presents a tradeoff between the loss associated with ‘having fewer people work on a problem and a potential gain from having a . . . more diverse research portfolio.’”<sup>170</sup> She argues that “[t]his assumes that the presence of many patents indicates that other firms are working on the R&D pathway.”<sup>171</sup> However, a less optimistic possibility is that, if the patents are held by universities or by other institutions that are not themselves engaged in product development, no firm, or too few firms, will be willing to pursue an otherwise promising R&D project. However, in such cases, the value of the patents and the leverage of the patent holders in license negotiations will inevitably be reduced to the point that the effort to patent such genes and leverage their value in licensing negotiations will prove to be, as Adelman suggests, essentially irrational.<sup>172</sup>

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<sup>167</sup> Eisenberg, *supra* note 7, at 1076.

<sup>168</sup> *Id.* at 1067.

<sup>169</sup> *Id.* at 1080.

<sup>170</sup> *Id.* at 1080 n.136 (alteration in original) (quoting Cohen & Walsh, *supra* note 56, at 11-12).

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

<sup>172</sup> See *supra* note 117 and accompanying text.

## B. *Round Three Empirical Studies*

Two recent empirical studies have produced evidence said to be relevant to the debate over the impact of university patenting and licensing on access to data and research tools, while a third empirical study purports to contribute to the debate over the impact of academic entrepreneurialism on the university research enterprise.

### 1. The Impact of Database Access Agreements on Downstream Research and Development

Although we have alluded to the early controversy between Celera and the HGP as illustrative of how contractual restrictions placed on nonpublic databases can affect follow-on research, an empirical study published as recently as 2013 offers a deeper examination of the impact this “Human Genome War” had on downstream research and product development.<sup>173</sup> At the time of its inception, the HGP was heralded as a project that would put a vast amount of foundational scientific knowledge into the hands of scientists across the world.<sup>174</sup> As we have seen, a controversy quickly arose over the role of intellectual property in the project. On one side of the debate, Craig Venter argued that patenting genome sequences would incentivize follow-on research and ultimate development of downstream medical products. On the other side, Francis Collins argued that free and unrestricted access to the genetic sequences would allow for maximal research across the entire scientific community. Amid this controversy, Dr. Venter left the HGP and founded Celera, which sequenced the genome using the same technology as the NIH, thus beginning the “Human Genome War.” In 2001, both the Venter-led private group and the Collins-led public group published a rough draft, or map, of the human genome. Neither group, as it turned out, was able to sequence every single one of the 27,882 currently

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<sup>173</sup> For an account of this war, see generally JAMES SHREEVE, *THE GENOME WAR: HOW CRAIG VENTER TRIED TO CAPTURE THE CODE OF LIFE AND SAVE THE WORLD* (2004), an executive summary of which, by Benjamin Yang, is available online. Benjamin Yang, *Executive Summary of a Book—The Genome War: How Craig Venter Tried to Capture the Code of Life and Save the World*, *DISCOVERY MED.* (June 17, 2009), <http://www.discoverymedicine.com/Benjamin-Yang/2009/06/17/executive-summary-of-a-book-the-genome-war-how-craig-venter-tried-to-capture-the-code-of-life-and-save-the-world/>.

<sup>174</sup> The National Human Genome Research Institute notes: Of course, information is only as good as the ability to use it. Therefore, advanced methods for widely disseminating the information generated by the HGP to scientists, physicians and others, is necessary in order to ensure the most rapid application of research results for the benefit of humanity. Biomedical technology and research are particular beneficiaries of the HGP.

*An Overview of the Human Genome Project*, NAT'L HUMAN GENOME RESEARCH INSTITUTION, <http://www.genome.gov/12011238> (last visited Apr. 2, 2014).

known genes. By 2001, however, Celera had sequenced 1,682 genes that the public project had not.<sup>175</sup> After the 2001 publications, Celera ceased sequencing and turned to a business model in which it sold access to its sequence database. Meanwhile, the NIH was completing its sequencing of the entire genome in precise detail. By 2003, the NIH's efforts were complete, and the 1,682 genes initially sequenced only by Celera were made publicly available.

In her 2013 empirical study, Professor Heidi Williams sought to discover whether downstream research and development based on those 1,682 Celera genes were hindered or helped by Celera's restricted access business strategy. To accomplish this, she looked at three primary metrics: the total number of publications about the gene, the number of publications that linked the gene to a specific disease or phenotype, and the number of gene-based tests commercially available to the consumer. Based on a combination of these metrics, Williams ultimately concluded that Celera's restricted-access model led to a 20 to 30 percent reduction in subsequent research and development when compared to the genes that were always freely available.<sup>176</sup>

To be sure, the Williams study can be seen as illustrating how restricting access to fundamental scientific information can impede subsequent research and development. However, she does not empirically prove, as the title of her study suggests, that intellectual property rights per se (i.e., underlying patent rights, as opposed to Celera's reliance on trade secrecy) impeded biomedical research.<sup>177</sup> Because Celera was not pursuing patent protection for all of the 1,682 genes that only it had sequenced by 2001, and because many of its patent applications were ultimately rejected, the presence of patent protection cannot serve as an independent variable in her study. Nor does Williams's study of the impact of Celera's access contracts on innovation shed any particular light on the impact of federally funded university patenting on downstream development. As we have seen, Celera was a private company directly competing with the publicly funded HGP and relying more on trade secret than potential patent protection to do so. Finally, Celera's licensing practices are not even a particularly good example of a company's ability to rely on trade secret protection as a substitute

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<sup>175</sup> See Sorin Istrail et al., *Whole-Genome Shotgun Assembly and Comparison of Human Genome Assemblies*, 101 PROC. NAT'L ACAD. SCI. 1916, 1916 (2004).

<sup>176</sup> Williams, *supra* note 134, at 16-17. "Between 2002 and 2009, there were . . . an average of 2.116 publications [per] non-Celera gene and an average of 1.239 publications [per] Celera gene." *Id.* at 16 n.21. The probability of a non-Celera gene having a diagnostic test on the market was 0.054, and the probability of a Celera gene having a diagnostic test was 0.030. *Id.* By assuming that the Celera genes would have had publication and genetic tests produced at the same rate as the non-Celera genes but for Celera's restricted access from 2001-2003 and controlling for inherent propensity for follow-on research, Williams calculated the 20 to 30 percent reduction rate. *Id.* at 16 & n.16.

<sup>177</sup> *Id.* at 24 ("Celera's IP led to reductions in subsequent scientific research and product development on the order of 20-30 percent.").

for patenting, as it was known at the time that Celera's data were not going to be secret for more than two years. Indeed, from 2001 to 2003 HGP made its data freely available, thereby diminishing the value of Celera's proprietary data and rendering its access fees completely avoidable; by January 2002 Craig Venter stepped down as the CEO of Celera so the company could pursue a different business model;<sup>178</sup> and Celera then went on to focus on high-definition sequencing for intricate diseases such as Alzheimer's and developing diagnostic tests and therapeutics.<sup>179</sup> Whatever impact Celera's contracting practices may have had on subsequent innovation, the Celera story merely illustrates the potentially adverse effects of a company's decision to rely on trade secret protection as a potential substitute for patent protection.

Despite the aforementioned limitations, the Williams study has been relied upon in recent gene patent controversies. It was cited in one amicus brief and expert documents submitted to the Supreme Court in *Myriad*.<sup>180</sup> Additionally, it was listed as a positive piece of evidence against gene patenting in a review of the *Myriad* decision in the *New England Journal of Medicine*, one of the elite medical journals.<sup>181</sup> The preceding analysis, however, suggests that the significance of the Williams study as it relates to broad issues of upstream patenting should be tempered. To be sure, the study reveals important data about the scientific repercussions of Celera's business strategy of restricting access to data: fewer publications and genetic tests have been released on the Celera genes. However, Williams's study should not be read as a sweeping condemnation of the role of intellectual property in biomedical research. Certainly, it cannot be read as a condemnation of the role of patents or the Bayh-Dole Act in hindering biomedical research. If the Williams study has any relevance at all to the impact of the Bayh-Dole Act on upstream research and downstream development, it is to confirm the wisdom of the NIH policy requiring researchers applying for more than \$500,000 in federal funding to submit a plan for data sharing in their grant applications.

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<sup>178</sup> Andrew Pollack, *Scientist Quits the Company He Led in Quest For Genome*, N.Y. TIMES, Jan. 23, 2002, at C1.

<sup>179</sup> *About Us*, CELERA, <https://www.celera.com/celera/history> (last visited Mar. 10, 2014).

<sup>180</sup> Brief for Amici Curiae International Center for Technology Assessment et al. in Support of Petitioners at 17, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (No. 12-398), 2013 WL 417732 at \*17; Declaration of Joseph E. Stiglitz, Ph.D. at 14 n.4, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09-4515 (RWS)), 2010 WL 2643075.

<sup>181</sup> Aaron S. Kesselheim et al., *Gene Patenting—The Supreme Court Finally Speaks*, 369 NEW ENG. J. MED. 869, 870 n.18 (2013).

## 2. The Impact of Licensing and Material Transfer Agreements on Upstream Research and Downstream Development

A more important set of Round Three empirical studies are those of Professor David C. Mowery and colleagues, studying the impact of academic patenting, licensing, and MTAs on the flow of knowledge and research inputs among scientists.<sup>182</sup> The earlier of their two studies “undert[ook] a preliminary analysis of the role of MTAs in the biomedical research enterprise at the University of Michigan . . . [by] examin[ing] the relationship among invention disclosures, patenting, licensing, and the presence or absence of an MTA.”<sup>183</sup> Although this study was “limited by the small size of [their] sample,” they concluded that the increased assertion of property rights by universities does not appear to impede the commercialization of university research through patenting and licensing.<sup>184</sup> However, in a subsequent study, analyzing data on invention disclosures, patents, and licenses from the University of California, Mowery and colleagues came to more disturbing conclusions. Although they found that, in general, licenses are associated with an increase in journal citations to related scientific publications, they found the opposite effect of licensing on citations to related scientific publications when the underlying discovery is a research input, which they identify through the use of MTAs.<sup>185</sup> In the latter case, related scientific publications experience a significant decline in citations following the execution of the license. Thus, they conclude that while licensing of academic patents does not limit scientific communication linked to patented academic research, such licensing may restrict the flow of inputs to further scientific research among researchers, potentially harming scientific progress in that area.<sup>186</sup> This conclusion is at variance with the earlier and more limited University of Michigan study.

Although both studies utilize the same type of forward citation analysis that the National Research Council warned should be interpreted with caution, the results of the second of these studies are of concern for two reasons. First, unlike the citation analyses discussed in Part II of this Article,<sup>187</sup> the studies of Mowery and colleagues align quite closely with the survey evidence produced by Walsh and colleagues, rather than reaching a

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<sup>182</sup> Neil C. Thompson, David C. Mowery & Arvidis A. Ziedonis, Does University Licensing Facilitate or Restrict the Flow of Knowledge and Research Inputs Among Scientists? (Aug. 28, 2013) (unpublished manuscript) (on file with author).

<sup>183</sup> Mowery & Ziedonis, *supra* note 21, at 159-60.

<sup>184</sup> *Id.* at 160.

<sup>185</sup> Thompson et al., *supra* note 182, at 18-20.

<sup>186</sup> *Id.* at 21.

<sup>187</sup> *See supra* Part II.B.

disparate result.<sup>188</sup> The findings of Mowery and colleagues that, in general, licenses are associated with an increase in journal citations undercuts (or at least qualifies) the conclusions of the Round Two studies of Murray and Stern, who found that the grant of a patent that is part of a paper-patent pair is associated with a significant but modest decline in knowledge accumulation as measured by forward citations. The findings of Mowery and colleagues also support earlier Round Three research suggesting that academic licenses may act as positive signals or research potential in the licensed technological area.<sup>189</sup> But as Mowery and colleagues note in their most recent study, their conclusions on the impact of MTAs align with the survey results of Walsh in 2007, which as we have seen indicate that denials of access to materials or results by one researcher that are inputs to the experiments of other researchers “can impose significant costs and delays on the scientific work of other researchers, costs and delays that according to these authors, exceed those associated with patents.”<sup>190</sup>

The second reason for concern is that the results of Mowery and colleagues may explain the paradox that was discussed in Part II of this Article. As Mowery and Ziedonis put it, in the earlier University of Michigan study, “[i]f researchers are (purposely or otherwise) unaware of the existence of patents on a given area of research, what may cause them to shift their research agenda away from topics for which patents have been issued to other researchers?”<sup>191</sup> One possible explanation for the apparently conflicting findings that were discussed in Part II of this Article can be found in “the difficulties that researchers encounter in seeking access to essential research materials (biological materials or research tools) from other researchers on results covered by patents.”<sup>192</sup>

Thus, the findings of Mowery and colleagues in their latest study suggest that the NIH would do well not only to strengthen guidelines governing the licensing of federally funded, university-patented research but also to continue its efforts, such as KOMP, to maintain the ready availability of research tools that might otherwise be constrained by MTAs.

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<sup>188</sup> Thompson et al., *supra* note 182, at 20 (“The apparently more rapid appearance of the negative effects on citations observed in the MTA sample is broadly consistent with the delays and project abandonment observed in the surveys by Walsh, Cho, and Cohen (2007) and Lei, et al. (2009) . . .”).

<sup>189</sup> Kyriakos Drivas, Zhen Lei & Brian D. Wright, *Academic Patent Licenses: Roadblocks or Signposts for Unlicensed Innovators?* (2013) (unpublished manuscript) (on file with author) (finding that executing an exclusive license actually increased the amount of citations to that invention by non-licensees in future patent applications).

<sup>190</sup> Thompson et al., *supra* note 180, at 5 (discussing the results of Walsh et. al., *supra* note 54).

<sup>191</sup> Mowery & Ziedonis, *supra* note 21, at 159.

<sup>192</sup> *Id.*

### 3. The Impact of Patenting on Subsequent Scientific Collaboration and Research Diversity Among Basic Scientific Researchers

With the shift in attention toward restricted access to research inputs, the normative behavior of scientists has again garnered scrutiny. This attention is of heightened importance in the area of academia since the Bayh-Dole Act resulted in a large uptick in university patenting.<sup>193</sup> Especially in nascent biological fields with seemingly vast commercial upside, the prospect of an anticommons or practical exclusion of other scientists is a looming specter. Professor Matthew Herder sought to explore how the behavior of scientists in such a field—cancer epigenetics—was affected by efforts to commercialize research. He hypothesized that researchers “would become more insular in terms of who they collaborate with and more entrenched in their chosen line of research inquiry” once they began seeking patents.<sup>194</sup> This phenomenon was given the term “patent canalization.”

Herder sampled the most prolific scientists in the budding field of cancer epigenetics by searching the MEDLINE database for publications in the field. He compiled a list of fifty-two scientists whose patenting and subsequent publication record could be easily elucidated.<sup>195</sup> In order to ascertain the scientists’ research behavior before applying for a patent application, Herder searched PubMed Central and ISI Web of Science by author name to obtain a list of all the author’s publications. This list was ordered chronologically and categorized by subject matter of the research. Next, Herder “search[ed] the Delphion database for all patent applications filed or granted for each [of the fifty-two] scientist[s].”<sup>196</sup> Both applications and grants were used as a measure of “participation in commercialization.”<sup>197</sup> Herder had two outcome measurements or dependent variables: the level of scientific collaboration and the subject diversity of the scientist’s research. In order to test the level of scientific collaboration of each of the fifty-two scientists, Herder “measured the total number of new co-author relationships that a scientist formed over time.”<sup>198</sup> To quantify research diversity, he tracked the “‘Key Words Plus’ field associated with every research article

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<sup>193</sup> See *supra* note 101 and accompanying text.

<sup>194</sup> Herder, *supra* note 52, at 309-10.

<sup>195</sup> Because of researchers with very common surnames and initials, as well as authors who inconsistently used their middle initial, the pool of authors was limited to those with fewer than 500 publications to their name. Additionally, preference was given to U.S.-based researchers because it was easier to verify biographical information. *Id.* at 354-55.

<sup>196</sup> *Id.* at 356. Any publication that was not an original research article that was based on experimental data was excluded. For example, an editorial about the shortfalls of research funding, while an important contribution to the scientific community, is not an indication of research area per se. Abstracts, reviews, and commentaries were also excluded. *Id.* at 355-56.

<sup>197</sup> *Id.* at 357.

<sup>198</sup> *Id.* at 358.

produced by each scientist in the pool” over time.<sup>199</sup> Thus, he was able to track how both interpersonal collaboration and research subject diversity for each scientist developed throughout his or her career and how each measure changed after applying for or being granted a patent.

Herder found statistically significant results for both of his measures of patent canalization. As a general principle, patenting resulted in scientists “becom[ing] more insular in their research (reflected as less new co-authoring relationships) and more entrenched in their lines of research inquiry (reflected as less new keywords associated with each publication).”<sup>200</sup> Herder’s confirmation of patent canalization provides important insight into the normative behavior of scientists participating in the commercialization of biomedical research. Specifically, it dovetails with the Round Two debate between Adelman and Burke and Lemley about the bounds of the subject areas in which basic researchers could conduct their work.<sup>201</sup> While Adelman argued that the scientific landscape was unbounded and thus could be freely explored even when certain areas were blocked by intellectual property, Burke and Lemley argued that certain areas were more attractive than others. Herder’s patent canalization theory seems to suggest that both are correct. The landscape of potential biomedical research projects is vast, allowing scientists to explore basic questions freely. Once a scientist finds his or her niche and begins the process of commercialization in that niche, however, he or she becomes canalized.

## CONCLUSION

In short, neither the foregoing assortment of theoretical arguments nor the empirical evidence examined in this article is 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. However, both the theoretical arguments and the empirical evidence to date do 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 under-

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<sup>199</sup> *Id.*

<sup>200</sup> Herder, *supra* note 52, at 359. These conclusions are given with Herder’s explicit acknowledgement of two confounding factors that could not be controlled. “First, there are a number of . . . factors [other than patenting] that may limit collaboration and research diversity, including access to funding, new technology, available human resources, and access to clinical information.” *Id.* at 353. Second, relying exclusively on published papers may not fully capture the amount of “collaboration or research diversity” by each scientist. *Id.* It is completely possible that a scientist conducted a new line of research with a new collaborator but that study simply was not published. *Id.* at 353-54.

<sup>201</sup> *See supra* notes 103-124.

mines 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 National Research Council report cautions,<sup>202</sup> if research institutions do indeed begin to take more active steps to regulate researcher behavior or if patent holders take more active steps to assert their patent rights against universities. Recent research reveals that imposing access restrictions either through infringement proceedings or via demands for licensing fees, grant-back rights, and other terms, such as restrictive MTAs, is burdensome to research. However, and notwithstanding insistent warnings over the past fifteen years that patenting upstream genetic research and vesting presumptive patent ownership in the recipients of federally funded genetic research might undermine the norms of the biological research community, critics have thus far failed to carry their burden of proof that this is in fact happening.

Interestingly, in two recent articles, Professor Liza Vertinsky proposes that “[i]nstead of marginalizing the university role once discovery has been made, as both past law and present proposals do, universities should instead be put in charge of managing the destiny of their inventions.”<sup>203</sup> She argues that universities share three unique characteristics that, if properly harnessed, can “provide them with a comparative advantage over government agencies and the market in managing” the post-invention development process: “(1) they are constructed as specialized entities with public knowledge functions; (2) they have an autonomous, decentralized governance structure; and (3) their decisions are shaped by multiple stakeholders invested in different aspects of public knowledge production and consumption.”<sup>204</sup>

In any event, 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 useful Arts.”<sup>205</sup>

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<sup>202</sup> See NAT’L RESEARCH COUNCIL, *supra* note 70, at 2. *But see supra* notes 153-154 and accompanying text (providing 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>203</sup> Letter from Liza S. Vertinsky, Assoc. Professor of Law, Emory Univ. Sch. of Law, to Author (Aug. 16, 2013) (on file with author); see Liza Vertinsky, *Making Knowledge and Making Drugs? Experimenting with University Innovation Capacity*, 62 EMORY L.J. 741, 744 (2013).

<sup>204</sup> Liza Vertinsky, *Universities as Guardians of Their Inventions*, 4 UTAH L. REV. 1949, 1954 (2012).

<sup>205</sup> U.S. CONST. art. I, § 8, cl. 8.