

ARTICLE

NONCOMPLIANCE, NONENFORCEMENT, NONPROBLEM? RETHINKING THE ANTICOMMONS IN BIOMEDICAL RESEARCH

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I. INTRODUCTION

A decade ago the biomedical research community was sounding alarm bells about the impact of intellectual property (IP) rights on the ability of scientists to do their work.¹ Controversies and delays in negotiating terms of access to patented mice² and genes,³ databases of scientific information,⁴ and tangible research materials⁵ all pointed toward the same conclusion: that IP claims were undermining traditional sharing norms to the detriment of science. Michael Heller and I highlighted one dimension of this concern: that too many IP rights in “upstream” research results could paradoxically restrict “downstream” research and product development by making it too costly and burdensome to collect all the necessary licenses.⁶ We called this phenomenon “the tragedy of the anticommons” in biomedical research, a phrase that has since become a buzzword

1. See, e.g., REPORT OF THE NATIONAL INSTITUTES OF HEALTH (NIH) WORKING GROUP ON RESEARCH TOOLS (1998), <http://www.nih.gov/news/researchtools/index.htm> (noting styming effects of certain licensing agreements on university and government research); Donald Kennedy, *Enclosing the Research Commons*, 294 SCIENCE 2249 (2001) (comparing private restrictions on research to the fencing in of the American frontier); Leon Rosenberg, *Major Pharmaceutical Company: Bristol-Myers Squibb*, in NAT'L RESEARCH COUNCIL, INTELLECTUAL PROPERTY RIGHTS AND THE DISSEMINATION OF RESEARCH TOOLS IN MOLECULAR BIOLOGY 61 (1997) (attributing IP restrictions to possible commercial interests).

2. Eliot Marshall, *DuPont Ups Ante on Use of Harvard's OncoMouse*, 296 SCIENCE 1212 (2002); Eliot Marshall, *NIH, DuPont Declare Truce in Mouse War*, 281 SCIENCE 1261, 1261–62 (1998); Sam Jaffe, *Ongoing Battle over Transgenic Mice*, SCIENTIST, July 19, 2004, at 46, 46–47 (2004), available at <http://www.the-scientist.com/article/print/14847/>.

3. Michael Balter, *Transatlantic War over BRCA1 Patent*, 292 SCIENCE 1818 (2001); Eliot Marshall, *Companies Rush to Patent DNA*, 275 SCIENCE 780, 780–81 (1997).

4. AM. ASS'N FOR THE ADVANCEMENT OF SCI., AAAS RESOLUTION: STATEMENT ON INTELLECTUAL PROPERTY PROTECTION FOR DATABASES (1997), http://archives.aaas.org/docs/resolutions.php?doc_id=446.

5. Eliot Marshall, *Need a Reagent? Just Sign Here . . .*, 278 SCIENCE 212, 212–13 (1997).

6. M.A. Heller & R.S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698–99 (1998); see also Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, in INNOVATION POLICY AND THE ECONOMY 119 (A. Jaffe & J. Lerner eds., 2000) 119, 124 (referring to the tragedy of the anticommons and its stifling effect on innovation).

for a broader range of potential detrimental effects of intellectual property.⁷

Since that time a number of studies have sought to put the anticommons theory to empirical tests. The largest of these studies have examined the impact of intellectual property on research scientists (primarily in academia)⁸ rather than its impact on downstream product development.⁹ The results suggest that, overall, intellectual property has presented fewer impediments to research than policymakers may have projected on the basis of early salient controversies.¹⁰ Most scientists report no difficulties in attempting to acquire IP-protected technologies, and only a small percentage report significant delays in research or having to abandon a project because of IP issues. Even in fields characterized by extensive patenting, many academic researchers seem to be either oblivious to the patents they might be infringing or unconcerned about potential infringement liability. More significant to researchers than patents as such have been practical restrictions on access to materials and data,

7. See, e.g., Fiona Murray & Scott Stern, *Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis* 25, 27 (Nat'l Bureau of Econ. Research, Working Paper No. 11465, 2005), available at <http://www.nber.org/papers/w11465> (finding negative impact of patent issuance on subsequent citations to corresponding publications).

8. See Part II.C–D (discussing studies of the impact of intellectual property on researchers in university, government, and public laboratories).

9. Some studies have included interviews with representatives of commercial firms. See, e.g., 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, 292–93 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) [hereinafter Walsh et al., *Effects of Research Tool Patents*] (examining the effect of intellectual property on research through interviews, including some interviews with personnel at pharmaceutical and biotech firms) (discussed *infra* at Part II.A); Dianne Nicol & Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* 64–71 (Univ. of Tasmania Ctr. for Law and Genetics, Occasional Paper No. 6, 2003), available at <http://www.lawgenecentre.org/Publication%20PDF/OccPaper%206.pdf> (detailing results of surveys and interviews to gather data from private sector companies) (discussed *infra* at Part II.E); see also JOSEPH STRAUS ET AL., GENETIC INVENTIONS AND PATENT LAW, AN EMPIRICAL SURVEY OF SELECTED GERMAN R&D INSTITUTIONS (Verlag Medien Design 2004) (discussed *infra* at notes Part II.B). Some commercial scientists were included among the survey respondents in AM. ASS'N FOR THE ADVANCEMENT OF SCI., INTERNATIONAL INTELLECTUAL PROPERTY EXPERIENCES: A REPORT OF FOUR COUNTRIES 6–8 (2007), available at http://sippi.aaas.org/Pubs/SIPPI_Four_Country_Report.pdf [hereinafter INT'L INTELLECTUAL PROP. EXPERIENCES] (discussed *infra* at Part I.D).

10. See Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECHNOLOGY 1091, 1092 (2006) (indicating gene patents have delayed scientific research among only 1% of biomedical researchers surveyed).

such as requirements for institutional assent to the terms of materials transfer agreements (MTAs).¹¹

Although still inconclusive in important respects, these results are clearly telling us something. Taken together, these findings point the way towards a more nuanced account of how a proliferation of IP claims affects future research and product development. As Heller & Eisenberg predicted, patents appear to have a greater impact on downstream product development than on upstream academic research.¹² But 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 property rights.¹³

With patents, the burden of inertia is on the property owner to identify infringers and to enforce the patent against them.¹⁴ When owners face high costs of detection and enforcement, it is unlikely that they will bother to pursue claims of relatively low value (such as claims against noncommercial academic researchers). In this context, high transaction costs work to the advantage of low-value users, mitigating rather than aggravating the risk of an anticommons. By contrast, with material transfer agreements and database access agreements, the burden of inertia is on the user to obtain access to a restricted resource.¹⁵ The owner need not incur costs to identify and pursue users, but may instead wait for prospective users to seek access.¹⁶ In this context, high transaction costs work to the detriment of low-value users, increasing the risk of an anticommons. In order to evaluate the risk of an anticommons, it is therefore necessary to consider not only the number of rights that potentially stand in the way of use and the level of transaction costs, but also whether it is the owner or the user who bears the initial burden

11. This finding is consistent with my own earlier observations in Rebecca S. Eisenberg, *Bargaining Over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?*, in EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 223, 225 (Rochelle Cooper Dreyfuss et al. eds., 2001).

12. Heller & Eisenberg, *supra* note 6, at 698.

13. See Eisenberg, *supra* note 11, at 231 (noting delays of research associated with MTAs).

14. Rebecca S. Eisenberg, *Patents and Data-Sharing in Public Science*, 15 INDUS. & CORP. CHANGE 1013, 1019 (2006).

15. *Id.* (noting a researcher cannot gain access to materials and data without the cooperation of a controlling third party).

16. *Id.*

of those transaction costs. These findings thus point towards a more crisp account of the relationship between property rights, transaction costs, and the risks of inefficient underuse. They also suggest that, without adjusting the underlying property rights, it might sometimes be possible to adjust the burden of inertia in order to shift the balance between upstream incentives and downstream anticommons effects.

II. WHAT THE DATA SHOW

A. *Walsh, Arora & Cohen Interviews in the U.S.*

Perhaps the most prominent empirical investigations of the impact of patents on biomedical research in the United States are those reported in a series of papers from John Walsh, Wesley Cohen, Charlene Cho, and Ashish Arora. In the first of these studies, reported in 2003, Walsh, Arora & Cohen explored the effects of research tool patents through seventy interviews with personnel at biotechnology firms, pharmaceutical firms, and universities in the United States.¹⁷ The interview respondents included attorneys, scientists, research managers, technology transfer professionals, and government and trade association personnel.¹⁸ Industry respondents reported that although the patent landscape had become more complex, and they might therefore need to consider hundreds of patents for potential in-licensing in connection with product development, in the end they would generally conclude that licenses were required for only a handful of these patents.¹⁹ The authors found almost no evidence of a breakdown in negotiations over rights leading to cessation of an ongoing R&D project.²⁰ Although respondents—particularly those in small biotechnology firms and universities—complained about the cost of access to research tools, they reported only one example in which royalty stacking actually caused a firm to terminate a project.²¹ On the other hand, patent attorneys for biotechnology firms reported that they evaluate the patent landscape very early on in deciding what projects to pursue, and that too many patents can be a “show stopper” if

17. Walsh et al., *Effects of Research Tool Patents*, *supra* note 9, at 292; John P. Walsh, Ashish Arora & Wesley M. Cohen, *Working Through the Patent Problem*, 299 *SCIENCE* 1021 (2003).

18. Walsh et al., *Effects of Research Tool Patents*, *supra* note 9, at 292.

19. *Id.* at 294–95.

20. *Id.* at 298.

21. *Id.* at 299.

identified at an early stage.²² One interviewee recounted a specific instance of patents on research tools dissuading a firm from undertaking a project.²³ But the presence of patents is only one of many factors that determine which projects a firm will pursue further, and probably not the most important factor.

Summarizing the interviews, Walsh, Arora & Cohen attributed the relatively small number of obstacles posed by patents to a variety of “working solutions” on the part of firms and universities to allow research to proceed (although at some cost), including licensing, inventing around patents, going offshore to do research beyond the reach of patents, developing public domain databases and research tools, challenging the validity of patents in court, and using patented technology without a license (i.e., infringing).²⁴

B. Straus, Holzapfel & Lindenmeir Interviews in Germany

Around the same time, the German government commissioned a study by Joseph Straus and colleagues on the effects of patents on genetic inventions in Germany.²⁵ The study involved interviews in a sample of twenty-five institutions in Germany, including four large pharmaceutical firms, nine small- and medium-sized biotechnology firms, seven biotechnological research institutions, and five clinical institutions associated with universities performing R&D in the field of genetic engineering.²⁶ The German respondents reported that patent owners were generally willing to license their inventions, but expressed some concern over royalty stacking. The authors summarized: “One to three licenses per marketable product could be tolerated, but increasingly often seven or more licenses were mandatory, endangering the commercialization of the final product.”²⁷ The respondents indicated that patents on research tools were infringed “behind locked laboratory doors,” that patentees were generally unaware of such infringements, and that scientists might not be aware of the legal implications of

22. *Id.* at 303.

23. *Id.*

24. *Id.* at 322–24, 328–29.

25. ORG. FOR ECON. CO-OPERATION & DEV. (OECD), GENETIC INVENTIONS, INTELLECTUAL PROPERTY RIGHTS AND LICENSING PRACTICES: EVIDENCE AND POLICIES 45–49 (2002) [hereinafter OECD GENETIC INVENTIONS]. For a more complete account of the results, see Straus et al., *supra* note 9. Professor Straus’s 2002 presentation of his data to the OECD is posted on the Internet at <http://www.oecd.org/dataoecd/36/22/1817995.pdf>.

26. The interviews were conducted over a seven month period in 2001–02. STRAUS ET AL., *supra* note 9, at 12–13, 47.

27. *Id.* at 21.

making or using patented research tools.²⁸ Companies were reluctant to pursue research in a field dominated by a competitor's patents, but if the research were far enough along, they would try to license or purchase any necessary patents.²⁹

C. Walsh, Cohen & Cho Survey of U.S. Biomedical Researchers

Walsh, Cohen & Cho followed the initial Walsh, Arora & Cohen small sample of interviews with a larger but more narrowly focused post-mail survey to a group of 414 biomedical researchers working in the patent-rich fields of genomics and proteomics in university, government, and nonprofit laboratories.³⁰ They supplemented these data with a further sample of scientists conducting research on one of three important signaling proteins characterized by different levels of patenting.³¹ In a series of papers, they draw on these survey results as well as the work of others to conclude that, despite widespread complaints, patents have rarely blocked academic research.³² They attribute this result to the fact that most scientists are oblivious to the patents they may be infringing,³³ and to the fact that most patent owners would not find it cost-effective to sue academic researchers for infringement.³⁴ Among the thirty-two respondents who were aware of relevant patents, twenty-four (75%) contacted the owner for permission to use the IP, four (13%) had to change their research approach because of difficulties in obtaining access, and five (16%) reported delaying their research for more than a month.³⁵ Expressed as a percentage of the total sample of respondents, approximately 6% sought permission from patent owners to conduct their research,

28. *Id.* at 26.

29. OECD GENETIC INVENTIONS, *supra* note 25, at 47.

30. John P. Walsh, Charlene Cho & Wesley M. Cohen, *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002, 2002 (2005) [hereinafter Walsh et al., *View from the Bench*]; 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, 5–6 (2008) (further analysis of same results).

31. Walsh et al., *View from the Bench*, *supra* note 30, at 2003.

32. Cohen & Walsh, *supra* note 30, at 9–10; Walsh et al., *Where Excludability Matters*, *supra* note 30, at 1191.

33. Only 8% of the respondents believed that their research in the past two years was covered by someone else's patents, and only 5% reported that they regularly check for patents that might cover their research activities. Walsh et al., *Where Excludability Matters*, *supra* note 30, at 1189–90.

34. Cohen & Walsh, *supra* note 30, at 12–13.

35. Walsh et al., *Where Excludability Matters*, *supra* note 30, at 1190.

1% reported either changing or significantly delaying their research plans as a result of patents, and none reported abandoning a line of research entirely.³⁶ Patents appeared to play a somewhat larger role in decisions about what research projects to pursue, with 7% of respondents according high importance to “inputs patent free” in a list of reasons for choosing a research project, 10% according high importance to “unreasonable terms,” and 3% according high importance to “too many patents” in a list of reasons for not pursuing a project.³⁷

More significant to researchers than patents were restrictions on access to tangible materials.³⁸ Seventy-five percent of the survey respondents had made at least one request for research materials in the last two years, and although most of these requests were fulfilled,³⁹ 19% of respondents “report[ed] that their most recent request for a material was denied.”⁴⁰ In the past two years, failure to receive requested materials from academic researchers led to reported delays of more than one month for 68% of respondents and to abandonment of a project for 22% of respondents, while failure to receive materials from scientists in industry led to delays of more than one month for 40% of respondents and to abandonment of a project for 27% of respondents.⁴¹ Comparing their data to previously reported results from other researchers,⁴² the authors suggest that noncompliance with requests for research materials may be increasing.⁴³

D. AAAS/SIPPI Multinational Survey of Scientists

The American Association for the Advancement of Science (AAAS), through its Project on Science and Intellectual Property in the Public Interest (SIPPI), has provided data from separate surveys of scientists in the United States, United Kingdom,

36. *Id.* at 1190. Respondents in the supplemental group of scientists working on important signaling proteins were much more likely to report that they needed access to a patent for their research and more likely to report having to abandon, modify, or delay a project because of patents, but the numbers were still small. *Id.* at 1199.

37. *Id.* at 1188 tbl.2, 1189 tbl.3.

38. *Id.* at 1190–91.

39. *Id.* at 1191. Of the requests to other academics, 18% were not fulfilled, and 33% of the requests to industry researchers were not fulfilled. *Id.*

40. Walsh et al., *View from the Bench*, *supra* note 30, at 2002.

41. Walsh et al., *Where Excludability Matters*, *supra* note 30, at 1192.

42. See generally Eric G. Campbell et al., *Data Withholding in Academic Genetics: Evidence from a National Survey*, 287 J. AM. MED. ASS'N 473, 479 (2002) (reporting survey results on data withholding in scientific research).

43. Walsh et al., *Where Excludability Matters*, *supra* note 30, at 1191–92.

Germany, and Japan to assess their experiences in acquiring, using, or creating intellectual property.⁴⁴ Survey respondents were drawn from professional societies of scientists, not limited to biomedical researchers, and invited by e-mail to complete a self-administered survey instrument over the Internet.⁴⁵ Although different investigators were responsible for the studies in different countries and their results are not entirely comparable, the authors of the SIPPI report found “very little evidence of an ‘anticommons problem’” in survey results from the United States and Japan.⁴⁶

In the U.S. survey, 33% of respondents reported having experienced difficulties in attempting to acquire IP-protected technologies, including 25% of academic respondents and 40% of industry respondents.⁴⁷ Of those who experienced difficulties, 60% complained that licensing negotiations were “overly complex,” and 38% reported a “breakdown of licensing negotiations.”⁴⁸ Yet among the respondents who experienced difficulties, 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.⁴⁹ More commonly, acquisition difficulties led to project delays or to changes such as “using different tools or technologies,” “‘inventing around’ a patented technology,” “chang[ing] the geographic location of the project,” or “chang[ing] project goals.”⁵⁰

In the Japanese survey, the universe of respondents was drawn exclusively from university and public laboratories and did not include scientists working in industry.⁵¹ Twelve percent

44. INT'L INTELLECTUAL PROP. EXPERIENCES, *supra* note 9, at 6.

45. *Id.* at 6–7.

46. *Id.* at 12. According to the authors, it was possible to make comparisons only between the U.S. and Japanese datasets. The number of people invited to take the German and U.K. surveys was not known, but the response rates were likely quite small. The authors concluded that these datasets could not be compared either to each other or to the U.S. and Japanese datasets. *Id.* at 7–8.

47. STEPHEN A. HANSEN, MICHAEL R. KISIELEWSKI & JANA L. ASHER, AM. ASS'N FOR THE ADVANCEMENT OF SCI., INTELLECTUAL PROPERTY EXPERIENCES IN THE UNITED STATES SCIENTIFIC COMMUNITY 24 (2007), available at http://sippi.aaas.org/Pubs/SIPPI_US_IP_Survey.pdf. Of the respondents, 44% reported difficulties in acquiring IP-protected technology from academia. Only 29% reported difficulties with acquisitions from industry, and 30% reported difficulties with acquisitions from the GNHC sector. *Id.*

48. *Id.* at 25.

49. *Id.* at 25, 61.

50. *Id.* at 25.

51. JOHN P. WALSH & HSIN-I HUANG, AM. ASS'N FOR THE ADVANCEMENT OF SCI., RESEARCH TOOL ACCESS IN THE AGE OF THE IP SOCIETY: RESULTS FROM A SURVEY OF JAPANESE SCIENTISTS 9 (2007), available at http://sippi.aaas.org/Pubs/SIPPI_Japan_IP_Survey.pdf.

said that “they had acquired patented technologies from outside [their laboratories] in the past five years,” and 11% of this subset reported difficulty in gaining access to a patented technology in the last five years.⁵² Of those reporting difficulties, 45% indicated that the royalty was too high; 27% indicated that negotiations were too complex; and less than 10% indicated that the patents could not be licensed, that the request for a license was denied, that negotiations broke down, or that royalties were required for multiple patents.⁵³ Only one respondent, or 0.1% of the entire universe of respondents, reported abandoning a project because of the difficulties.⁵⁴

The German study solicited respondents by e-mail from members of selected professional organizations of scientists.⁵⁵ Twenty percent reported that they had acquired IP-protected technology for use in their work.⁵⁶ Out of this subset, 23% (or 5% of all respondents) reported having difficulties in acquiring IP,⁵⁷ and less than 1% (or 0.1% of all respondents) reported having abandoned research due to these difficulties.⁵⁸ The most frequent reason reported for the difficulties in acquiring IP was “overly complex patent licensing negotiations” (50% of the subset of respondents who reported difficulties).⁵⁹ Next in order of frequency were “individual royalties were too high” (34% of the subset), “unable to determine the IP status of the technology” (34% of the subset), “licensing negotiations broke down” (22% of the subset), and “request for license denied” (19% of the subset).⁶⁰ Only two respondents, or 6% of the subset, checked “royalties required for multiple patents” as a reason for difficulties in acquiring IP.⁶¹

The U.K. study relied upon professional societies of scientists to forward e-mail invitations to their members to complete the survey.⁶² Twenty-seven percent of the respondents

52. *Id.* at 9–10.

53. *Id.* at 33 tbl.3-2.

54. *Id.* at 10.

55. S. WESTERBURG ET AL., AM. ASS'N FOR THE ADVANCEMENT OF SCI., INTELLECTUAL PROPERTY EXPERIENCES IN THE GERMAN SCIENTIFIC COMMUNITY 18 (2007), available at http://sippi.aaas.org/Pubs/SIPPI_Germany_IP_Survey.pdf.

56. *Id.* at 11.

57. *Id.* at 21 fig.10.

58. *Id.* at 21 fig.11.

59. *Id.* at 46.

60. *Id.*

61. *Id.*

62. MICHAEL R. KISIELEWSKI, JANA L. ASHER & STEPHEN A. HANSEN, AM. ASS'N FOR THE ADVANCEMENT OF SCI., INTELLECTUAL PROPERTY EXPERIENCES IN THE UNITED KINGDOM SCIENTIFIC COMMUNITY 30 (2007), available at <http://sippi.aaas.org/>

indicated that they had acquired IP-protected technology in the past five years,⁶³ and 25% of this subset reported having encountered difficulties in accessing the technology.⁶⁴ Of the group reporting difficulties, 61% indicated that “licensing negotiations were overly complex,” 26% indicated that “licensing negotiations had broken down,” and 21% indicated that “royalties were too high.”⁶⁵ The most common effects of the difficulties reported were that projects were delayed (37%) or that projects had to be changed (16%).⁶⁶ Only 8% of those experiencing difficulties reported abandoning a project as a result of the difficulties.⁶⁷

The AAAS–SIPPI data are limited in accordance with the focus of the project on the experience of research scientists, but within that context they suggest that IP has so far presented only limited problems. These results shed little light, however, on the impact of upstream IP on downstream product development.

E. Nicol & Nielsen Survey and Interviews in Australia

Dianne Nicol and Jane Nielsen studied the impact of patents on the Australian medical biotechnology industry through a combination of (1) written surveys mailed to research institutions, public and private biotechnology and pharmaceutical companies, and diagnostic genetic testing facilities, and (2) “semi-structured interviews” with participants in each of these sectors.⁶⁸ Respondents expressed mixed views as to the impact of patents on research, with the most sharply negative views coming from diagnostic facilities⁶⁹ and the most positive views coming from biotechnology and pharmaceutical companies.⁷⁰ Respondents from diagnostic laboratories were

Pubs/SIPPI_UK_IP_Survey.pdf.

63. *Id.* at 9.

64. *Id.* at 11.

65. *Id.* at 12.

66. *Id.*

67. *See id.* (reporting that 3 out of the 37 respondents had abandoned a project due to difficulties acquiring IP-protected technology).

68. Nicol & Nielsen, *supra* note 9, at x. The researchers found that “large scale patenting is not the norm in the Australian industry,” *id.* at 78, and that although respondents file for patents in Australia, they perceive Australian patents as less valuable than U.S., E.U., and Japanese patents. *See id.* at 80 (noting that respondents showed “a certain degree of ambivalence about the value of Australian patents”).

69. *See id.* at 83 (indicating that none of the respondents from diagnostic facilities believed that patents have a positive impact on research, 39% stated that patents have a negative impact, and 23% stated that the impact varies).

70. *See id.* (reporting that 68% of respondents from biotechnology and pharmaceutical companies stated that patents have a positive impact, 2% stated that they

particularly critical of the impact of patents on gene sequences and gene products.⁷¹

Asked about the impact of patents on their own work, 18% of respondents from industry reported that their company had changed its research program because of a patent that blocked access to key research tools or materials.⁷² In follow-up interviews, many respondents reported that they worked around blocking patents “by changing the direction of their research so as to avoid infringing the patent(s),” while others reached successful license agreements.⁷³ Of the interviews with respondents from private companies, 12% of companies “reported being refused a patent license,” while 9% of interview respondents from research institutions and none from the diagnostic laboratories reported that they had been refused a patent license.⁷⁴ Some respondents complained that patent owners, although willing to license, demanded unreasonable terms, and some respondents, particularly from universities, conceded that they used patented research tools without licenses.⁷⁵

Although 84% of companies, 50% of research institutions, and 23% of diagnostic facilities “routinely conduct patent searches to ensure that their research does not infringe patents held by others,”⁷⁶ interviews revealed that such searches typically await the discovery of something of commercial value.⁷⁷ Patent attorneys reported that, although an ever-growing number of patents must be analyzed to determine if they impact a research project, in most cases upon further investigation “the number of problematic patents can often be reduced to two to three.”⁷⁸ These attorneys further indicated that anything beyond that small number is a serious problem that may block the research from going forward.⁷⁹ Somewhat surprisingly, a higher percentage of the research institutions (52%) than of the companies (45%)

have a negative impact, and 17% stated that the impact varies).

71. See *id.* (noting that 77% of respondents from diagnostic facilities stated that patents on gene sequences have a negative impact and 69% stated that patents on gene products have a negative impact).

72. *Id.* at 140–41.

73. *Id.* at 143.

74. *Id.* at 145–46.

75. *Id.* at 147.

76. *Id.* at 178.

77. *Id.* at 180.

78. *Id.* at 183.

79. *Id.* at 182–83 (claiming that in most instances, there will be less than ten “problematic patents” and anything beyond that would be a “real problem”).

reported that they had in-licensed patented tools and/or materials for research purposes.⁸⁰ Roughly half of respondents reported no in-licensing activity at all, and interviews with those that were required to negotiate licenses suggested that generally no more than five licenses were necessary to achieve freedom to operate.⁸¹ The interviews suggested that if a project requires too many licenses it will simply not move forward into the development phase.⁸² However, the data did not allow Nicol & Nielsen to quantify how often patent obstacles led to abandonment of research projects.⁸³

F. DNA Diagnostics

Some of the reports summarized above note that patents seem to be more problematic in the area of DNA diagnostic product development than in other fields of biomedical research.⁸⁴ Empirical evidence in the United States suggests that patents on genes have impeded both the provision of genetic testing services and the development of new tests by diagnostic laboratories. Mildred Cho and collaborators conducted telephone survey interviews with 132 directors of laboratories that perform DNA-based genetic tests in the United States.⁸⁵ These laboratories were affiliated with companies, universities, government, nonprofit institutions, and hospitals.⁸⁶ Seventy-five percent of these laboratories held patent licenses, 65% had been “contacted by a patent or license holder regarding the laboratory’s potential infringement of a patent by performance of a genetic test,” 25% had stopped performing a clinical genetic test because of a patent or license, and 53% had decided not to develop a new clinical genetic test because of a patent or license.⁸⁷ Of those who had been contacted regarding potential infringement, laboratory directors at private companies were significantly more likely

80. *Id.* at 184.

81. *Id.* at 185–86.

82. *Id.* at 186–87.

83. *Id.* at 187.

84. See Walsh et al., *Effects of Research Tool Patents*, *supra* note 9, at 317–19 (finding that clinical research using DNA diagnostic tests is a major exception to the norm of “leaving university researchers alone”); see also Nicol & Nielsen, *supra* note 9, at 83 (noting negative views towards patents of interviewees from diagnostic laboratories); *id.* at 201 (noting that “many respondents expressed concern about the impact of gene patents on genetic testing services”).

85. Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 3 (2003).

86. *Id.* at 4 tbl.1.

87. *Id.* at 4–5.

than those at universities to report that they had been prevented from performing a test (71% of laboratories in companies versus 24% of those at universities).⁸⁸ The authors had previously obtained similar results in a case study of the impact of patents related to genetic tests for hereditary haemochromatosis.⁸⁹

It 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.⁹⁰ Some laboratories have apparently been stymied in their ability to offer particular genetic tests by the licensing practices of particular firms, such as Myriad Genetics in the case of breast cancer, that either own or have exclusive licenses to key patents.⁹¹ Whatever the implications of these difficulties for R&D and for clinical practice, the results do not inherently suggest an anticommons problem. On the other hand, some DNA diagnostic products, such as microarrays that include many different genes and mutations, could face an anticommons problem if the burden of negotiating many necessary licenses consumes too much of the expected value of the product. This may be why microarray developer Affymetrix has been an outspoken opponent of patents on DNA sequences.⁹²

G. Mouse Models

Another notorious example of difficulties in negotiating license terms for patented research tools from a single licensor is the case of genetically altered mice.⁹³ One firm, DuPont, obtained

88. *Id.* at 5.

89. See Jon F. Merz et al., *Diagnostic Testing Fails the Test: The Pitfalls of Patents Are Illustrated by the Case of Haemochromatosis*, 415 NATURE 577, 577-78 (2002) (indicating that patents kept 30% of laboratories that had the ability to develop and perform tests for hereditary haemochromatosis from doing so).

90. See Nicol & Nielsen, *supra* note 9, at 187 (acknowledging it can be difficult to measure problems that are potentially associated with the negotiation of multiple licenses because the project may be dropped after it becomes apparent that it would be difficult to negotiate a single license).

91. Sirpa Soini, Ségolène Aymé & Gert Matthijs, *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues*, 16 EUR. J. OF HUMAN GENETICS 10, 15 (2008).

92. See Barbara A. Caulfield, *Why We Hate Gene Patents*, LAW.COM, Dec. 30, 2002, <http://www.law.com/jsp/article.jsp?id=1039054490790> (noting, based on author's experience at Affymetrix, that the cost of licenses and litigation can grow exponentially when multiple patents are involved, leading to an inefficient allocation of resources); see also Dianne Nicol, *Navigating the Molecular Diagnostic Patent Landscape*, 18 EXPERT OPINION ON THERAPEUTIC PATENTS 461, 468 (2008) (noting that companies involved in microarray technology are likely to face the greatest complexity in securing freedom to operate).

93. See generally NAT'L RESEARCH COUNCIL, SHARING LABORATORY RESOURCES:

dominant patent rights as the exclusive licensee of Harvard University on both oncomice (i.e., mice that have been genetically engineered to be susceptible to cancer) and cre-lox technology for creating “knockout” mice (i.e., mice in which certain genes are deleted in specific tissues).⁹⁴ Oncomice and cre-lox mice are both important research tools.⁹⁵

In a series of papers, Fiona Murray has described the impact of patenting on the dissemination of the oncomouse and the response of the scientific community to licensing terms offered by DuPont.⁹⁶ This is a case study based on document review and interviews rather than on quantitative analysis of data, but because of the twenty-year timeframe and wide range of perspectives that Murray consulted, it offers an unusually rich account of this particular episode.⁹⁷ Although difficulties in negotiating with a single patent holder do not count as an anticommons, 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. The greater the number of essential licensors, the greater the total risk of bargaining breakdown.

In 1984, scientists at Harvard University created a mouse that was genetically engineered to have a predisposition to cancer.⁹⁸ The research had been sponsored by DuPont, and under the terms of the funding agreement, Harvard patented the invention and licensed it exclusively to DuPont.⁹⁹ By the time the first of the Harvard oncomouse patents issued, oncomice had become an important tool for the mouse research community,¹⁰⁰ and given the broad scope of the claims, there was little prospect of inventing around the patent. The patent claims purported to

GENETICALLY ALTERED MICE 3 (1994).

94. *Id.* at 21–22; see also Marshall, *NIH, DuPont Declare Truce in Mouse War*, *supra* note 2, at 1261.

95. NAT'L RESEARCH COUNCIL, *supra* note 93, at 18.

96. See Fiona Murray, *Patenting Life: How the Oncomouse Patent Changed the Lives of Mice & Men* (Sept. 2007) (unpublished manuscript, on file with the Houston Law Review), available at http://www.bus.wisc.edu/insite/events/seminars/documents/Oncomouse_Chapter_Short_09242007.doc [hereinafter Murray, *Mice & Men*]; Fiona Murray, *The Oncomouse that Roared: Resistance and Accommodation to Patenting in Academic Science* (Mar. 2006) (unpublished manuscript, on file with the Houston Law Review), available at http://web.mit.edu/fmurray/www/papers/THE%20ONCOMOUSE%20THAT%20ROARED_FINAL.pdf [hereinafter Murray, *The Oncomouse that Roared*].

97. See Murray, *The Oncomouse that Roared*, *supra* note 96, at 7 (concentrating analysis on how individual scientists deal with roadblocks to research that patents may present).

98. *Id.* at 1.

99. See Murray, *Mice & Men*, *supra* note 96, at 5–7.

100. *Id.* at 4–7.

reach any “transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal... at an embryonic stage.”¹⁰¹

DuPont offered the mice to researchers on terms that provoked outrage in the academic community.¹⁰² These terms included a \$50 price tag, a prohibition on any further sharing or breeding of the mice, annual disclosure to DuPont of research results, and a grant-back to DuPont of rights in any future discoveries arising from use of the mice.¹⁰³

Some scientists responded with “civil disobedience,” willfully ignoring the patent while creating their own mice and lobbying their universities to refuse to sign the DuPont agreement.¹⁰⁴ Mouse geneticists discussed strategic responses at scientific meetings, and the National Academy of Sciences (NAS) held a workshop and published a report on the topic.¹⁰⁵ The Director of the National Institutes of Health (NIH) became personally involved in negotiations with DuPont.¹⁰⁶ After *four years* of high level negotiations, DuPont and NIH finally signed 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.¹⁰⁷ These restrictions have proven to be an ongoing source of problems between DuPont and the scientific community, even years after the NIH Memorandum of Understanding.¹⁰⁸

On the other hand, the DuPont episode proved to be an important trigger for a variety of moves on the part of the scientific community to clarify and fortify its norms concerning the exchange of research materials and data. The NIH, the NAS, and the university technology transfer community each

101. U.S. Patent No. 4,736,866 col.9 1.35–col.10 1.2 (filed June 22, 1984).

102. Murray, *Mice & Men*, *supra* note 96, at 8–9.

103. *Id.* at 8.

104. Murray, *The Oncomouse that Roared*, *supra* note 96, at 27–28.

105. See NAT'L RESEARCH COUNCIL, *supra* note 93 (providing a summary of the National Academy of Sciences workshop, held March 23–24, 1993).

106. Murray, *The Oncomouse that Roared*, *supra* note 96, at 31.

107. *Id.*

108. See Sasha Blaug, Colleen Chien & Michael J. Shuster, *Managing Innovation: University-Industry Partnerships and the Licensing of the Harvard Mouse*, 22 NATURE BIOTECHNOLOGY 761, 762–63 (2004) (noting that some universities felt the Memorandum of Understanding alone should govern use of the oncomouse for research); Marshall, *DuPont Ups Ante on Use of Harvard's OncoMouse*, *supra* note 2, at 1212 (reporting that DuPont has increasingly sought to enforce its patent); Jaffe, *supra* note 2.

responded to this and other salient controversies by promulgating hortatory guidelines and “best practices”¹⁰⁹ that have had an impact on licensing practices, particularly on the part of universities.¹¹⁰ They may thereby have helped to minimize the transactional burden that might otherwise have confronted academic institutions, preventing potential anticommons problems in the future.

III. UNDERSTANDING THE DATA

What do these studies tell us about the validity of the anticommons hypothesis? To repeat, that hypothesis was that too many IP rights in “upstream” research results could restrict “downstream” research and product development by making it too costly and burdensome to collect all the necessary licenses.¹¹¹ Reviewing the evidence in an article in *Nature Biotechnology*, Timothy Caulfield, Robert Cook-Deegan, F. Scott Kieff, and John Walsh conclude that (1) “the effects predicted by the anticommons problem are not borne out in the available data;” and (2) the “effects are much less prevalent than would be expected if its hypothesized mechanisms were in fact operating.”¹¹²

A fairer reading of the evidence to date would be that: (1) most of the available data measure the effects IP rights have on “upstream” research itself rather than the predicted effects on “downstream” product development; (2) to the extent that the data shed light on “downstream” effects, they provide evidence that the hypothesized mechanism is indeed operating, although the effects so far may be less serious than predicted; and

109. See, e.g., Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72,090, 72,090 (Dec. 23, 1999) (attempting to promulgate guidelines to promote and facilitate the use of research tools in the field of biomedical technology); CAL. INST. OF TECH. ET AL., IN THE PUBLIC INTEREST: NINE POINTS TO CONSIDER IN LICENSING UNIVERSITY TECHNOLOGY 1–9 (2007), available at <http://news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf> (positing various approaches and solutions to apply in the area of technology sharing); COMM. ON RESPONSIBILITIES OF AUTHORSHIP IN THE BIOLOGICAL SCIS., NAT’L RESEARCH COUNCIL, SHARING PUBLICATION-RELATED DATA AND MATERIALS: RESPONSIBILITIES OF AUTHORSHIP IN THE LIFE SCIENCES 18 (2003) (revisiting core principles for sharing data and research in the scientific community); NAT’L RESEARCH COUNCIL, *supra* note 1.

110. See Lori Pressman et al., *The Licensing of DNA Patents by US Academic Institutions: An Empirical Survey*, 24 NATURE BIOTECHNOLOGY 31, 32 (2006) (studying to what extent academic institutions were already adhering to the suggestions published by the NIH).

111. Heller & Eisenberg, *supra* note 6, at 698.

112. Caulfield et al., *supra* note 10, at 1092.

(3) within “upstream” research, the hypothesized mechanism is more apparent for MTAs than for patents.

These are significant and interesting results that have important implications for the anticommons hypothesis, for further study, and for public policy. Intellectual property presents tradeoffs between *ex ante* incentives and *ex post* costs. The anticommons hypothesis highlights one dimension of those costs, and it is important to understand the magnitude of its effects in order to put in proper perspective the costs and benefits of enhanced IP protection for upstream research. If the costs associated with determining and clearing rights are relatively small and manageable, and the upstream benefits of IP incentives are relatively high, then perhaps the upstream expansion of intellectual property has been a good thing. Conversely, if the benefits are relatively small and the costs are significant, then perhaps the system could be improved. I consider separately the evidence with respect to “downstream” and “upstream” effects below.

A. *Downstream Effects*

The studies attempting to measure the anticommons effects have focused relatively little attention on downstream product development.¹¹³ Instead, the largest and most comprehensive of the studies have focused on the effects of upstream research itself, primarily from the perspective of individual scientists. This may be because the initiatives that have spawned the most extensive studies have come from the scientific community,¹¹⁴ or it may be because effects on product development are harder to measure.

To the extent that the studies compare effects in academia with those in industry, they suggest that patents impose greater costs on scientists in product developing firms than they impose on academic scientists (who generally ignore them).¹¹⁵ For

113. See *supra* Part II.

114. E.g., Walsh et al., *Where Excludability Matters*, *supra* note 30, at 1188 (background paper for NAS study of patents in genomics and proteomics); see also INT'L INTELLECTUAL PROP. EXPERIENCES, *supra* note 9, at 6 (noting that the AAAS-SIPPI study “arose out of concerns over the effects of IP protections on the conduct of scientific research”).

115. This is exactly as predicted in Heller & Eisenberg, *supra* note 6, at 700–01 (“Use of a patented invention in an academic laboratory or a small start-up firm may be inconspicuous, at least if not described in a publication or at a scientific meeting. Patent owners may be more reluctant to sue public sector investigators than they are to sue private firms. Differences in institutional cultures may make academic laboratories and biotechnology firms more tolerant of patent infringement than large pharmaceutical

example, the SIPPI data include some survey responses from scientists in industry.¹¹⁶ In the United States, difficulties in attempting to acquire IP-protected technologies were more common among industry respondents (40%) than among academic respondents (25%).¹¹⁷

Survey responses of individual scientists, even those in industry, may not be the best way to observe effects on product development. In the Nicol & Nielsen survey of Australian biotechnology and pharmaceutical firms, 18% of the firms that responded reported having changed their research programs because a patent blocked access to key research tools or materials.¹¹⁸ But the response rate was quite low (27%), and some of the firms that declined to fill out the survey preferred to participate through interviews.¹¹⁹

Institutional representatives such as lawyers or research managers may know more than working scientists about product development decisions and how they are made. Both the Walsh, Arora & Cohen study and the Nicol & Nielsen study included interviews with such representatives.¹²⁰ Although their small numbers raise questions about whether the responses are representative,¹²¹ both sets of interviews tell similar stories. The results suggest, as predicted by the anticommons hypothesis, that firms incur significant costs in culling through multiple patents to determine what licenses are necessary, and that these costs are greater in fields characterized by more patents.¹²² For example, a lawyer for a large pharmaceutical firm told Walsh,

firms.”)

116. See *supra* Part II.D (discussing the SIPPI survey and its results).

117. See *supra* note 47 and accompanying text.

118. Nicol & Nielsen, *supra* note 9, at 140–41.

119. *Id.* at 66.

120. Walsh et al., *Effects of Research Tool Patents*, *supra* note 9, at 292; Nicol & Nielsen, *supra* note 9, at 67.

121. Nicol & Nielsen conducted a total of forty interviews, including CEOs, IP personnel, and bench scientists from private industry; directors of research groups, bench scientists, and technology transfer personnel from research institutions; and directors of research groups in diagnostic testing facilities, as well as outside patent attorneys, licensing consultants, and government and trade representatives. Nicol & Nielsen, *supra* note 9, at 67–68. Walsh, Arora & Cohen conducted a total of seventy interviews, including twelve lawyers, three scientists, and nine business managers from the pharmaceutical industry; seven lawyers, four scientists, and seven business managers from the biotechnology industry; ten scientists and three business managers from universities; seven outside lawyers; five government and trade association personnel; and three additional scientists. Walsh et al., *Effects of Research Tool Patents*, *supra* note 9, at 293 tbl.1.

122. Walsh et al., *Effects of Research Tool Patents*, *supra* note 9, at 293–94; Nicol & Nielsen, *supra* note 9, at 156, 178–81.

Arora & Cohen that lawyers in the small molecule division in his firm are responsible for eight projects each, while those in the biotechnology division of the same firm are only responsible for about two projects each because of the greater complexity of the in-licensing issues that they must manage.¹²³ This is clear evidence that transaction costs are higher in fields characterized by more patents. It is less clear whether one lawyer for every two projects—or even one lawyer for every eight projects—is a large number or a small number in any meaningful sense. One Australian patent attorney told Nicol & Nielsen that ten times more patent searching is done now (i.e., in 2002–2003 when the interviews were conducted) than a decade earlier, while another reported that searching “has always been a headache” and is no more so now than in the past, given the availability of superior databases today.¹²⁴ Perhaps improvements in information technology have mitigated the anticommons problem somewhat by making it easier to search through large numbers of patents efficiently.¹²⁵ On the other hand, electronic searching may reveal more patents that require professional review to ensure freedom to operate, increasing transaction costs. Trends toward more aggressive claiming strategies may have further expanded the universe of potentially relevant patents.¹²⁶ A number of respondents told Nicol & Nielsen that because of the increasing breadth of patent claims, it is now necessary to analyze more patents in detail in order to determine whether they must be licensed; however, at the end of this analysis, the number of patents that prove to be potentially problematic generally remains small.¹²⁷

The need to review a large number of patents for freedom to operate, although plainly costly, does not necessarily pose an insurmountable obstacle to product development. A consistent story in the interviews is that the number of patents that require evaluation for freedom to operate purposes is much larger than the number that ultimately require licensing.¹²⁸ One Australian respondent estimated that a typical freedom to operate search might uncover anywhere from a dozen to thirty or forty patents that are relevant, but that upon closer analysis “there may be only one or two or a few more that are blocking,” and that

123. Walsh et al., *Effects of Research Tool Patents*, *supra* note 9, at 316.

124. Nicol & Nielsen, *supra* note 9, at 181.

125. *See id.* (discussing use of Derwent, a database, in the patent search).

126. *Id.* at 87–88, 182.

127. *Id.* at 182.

128. *Id.*

“[a]nything beyond three is probably too many.”¹²⁹ In their U.S. interviews, Walsh, Arora & Cohen heard larger numbers but similar ratios. Characterizing the reports of about ten industry respondents, the authors said that an initial search would turn up hundreds of patents that they would have to consider, a number that was surely higher than in the past, but that after analysis the number that they would need to address would range from zero to a dozen.¹³⁰

How many upstream patents does it take to derail a project? That evidently depends in part on how soon the patents are discovered. In both the United States and Australia, respondents indicated that numerous patents would be more likely to deter a firm from pursuing a project at the outset than to cause it to abandon a project once it was underway.¹³¹ A lawyer for a biotechnology firm told Walsh, Arora & Cohen that “[w]e start very early on . . . to assess the patent situation. When the patent situation looks too formidable, the project never gets off the ground. . . . Once you are well into development, you get patent issues, but not the show stopper that you would identify early on.”¹³² The authors nonetheless concluded that the patent landscape is a relatively minor consideration in determining which research projects to take into development.¹³³ By contrast, hearing similar stories from their Australian respondents, Nicol & Nielsen concluded that “it is vitally important to acknowledge that it is possible that a number of potentially anticommons-affected projects do not come onto the radar, because such projects will have been abandoned well before any difficulty of negotiating with multiple parties is encountered.”¹³⁴

These interviews offer qualified support for the anticommons hypothesis.¹³⁵ They suggest that the patent landscape for biomedical research is becoming more complex and that the cost of surveying that landscape and negotiating necessary licenses is rising, but that in most cases firms are able to work through the patent issues and find R&D projects to pursue that are not unduly burdened with IP rights. At the same time, they suggest that the risk of an anticommons, although perhaps smaller than

129. *Id.* at 183.

130. Walsh et al., *Effects of Research Tool Patents*, *supra* note 9, at 294.

131. *Id.* at 303; Nicol & Nielsen, *supra* note 9, at 186–87.

132. Walsh et al., *Effects of Research Tool Patents*, *supra* note 9, at 303.

133. *Id.*

134. Nicol & Nielsen, *supra* note 9, at 187.

135. Walsh et al., *Effects of Research Tool Patents*, *supra* note 9, at 303, 332; Nicol & Nielsen, *supra* note 9, at 187–90.

might have been feared a decade ago, is nonetheless quite real in the calculations of product-developing firms. If 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.¹³⁶

Larger studies focused on downstream freedom to operate practices within product-developing firms might help to clarify the magnitude of the costs, perceptions of the risk of bargaining breakdowns, the extent to which these costs and risks drive R&D decisions in firms, and the overall impact on R&D investments.

B. Upstream Effects

Although inconclusive with respect to downstream effects, the studies to date provide more data about the impact of IP rights on upstream research, particularly in academic laboratories. In that setting, the studies suggest that scientists typically ignore patents, and that for the most part, they get away with it.¹³⁷ Although actual infringement litigation against universities is not unheard of,¹³⁸ it is rare.¹³⁹ It is more common

136. It is not clear whether it promotes efficiency for firms to avoid R&D pathways that are characterized by more patents. Cohen & Walsh suggest that redirection of effort away from areas where there are 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.” Cohen & Walsh, *supra* note 30, at 11–12. This assumes that the presence of many patents indicates that other firms are working on the R&D pathway. 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.

137. See, e.g., Nicol & Nielsen, *supra* note 9, at 178 (quoting observation of respondent that most people in the academic field do not worry about patent infringement).

138. Recent examples that have generated appellate opinions include *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005) (patent infringement action against, *inter alia*, Scripps Research Institute based on use of patented molecules in preclinical research sponsored by pharmaceutical firm); *Baum Research & Development Co. v. University of Massachusetts at Lowell*, 503 F.3d 1367 (Fed. Cir. 2007) (patent infringement and breach of contract action against university licensee); *Pennington Seed, Inc. v. Produce Exchange No. 299*, 457 F.3d 1334 (Fed. Cir. 2006) (patent infringement action against university and university officials, including a faculty member); and *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002) (patent infringement action against university by former faculty member based on use of patented inventions in government-sponsored academic research). A 2001 U.S. General Accounting Office report on state immunity in infringement actions identified thirty-two infringement actions against state institutions of higher education that were brought in federal court and another five such actions that were brought in state court since 1985. U.S. GEN. ACCOUNTING OFFICE, INTELLECTUAL PROPERTY: STATE IMMUNITY IN INFRINGEMENT ACTIONS 10–11 (2001).

139. U.S. GEN. ACCOUNTING OFFICE, *supra* note 138, at 7.

for patent holders to require universities to get patent licenses.¹⁴⁰ There have been some notorious examples of patents on research tools that required enormous investments in transaction costs within the research community to work out acceptable license terms, including the oncomouse and cre-lox patents licensed exclusively to DuPont¹⁴¹ and patents on genes associated with breast cancer that were licensed exclusively to Myriad Genetics.¹⁴² But evidently most academic researchers do not find themselves on the receiving end of patent enforcement. Walsh, Cohen & Cho found that only 1% of survey respondents working in the fields of genomics and proteomics—fields characterized by extensive patenting—reported either changing or significantly delaying their research plans as a result of patents, and none reported abandoning a line of research entirely.¹⁴³

An important omission from the data is the perspective and experience of research-performing institutions, as distinguished from individual scientists.¹⁴⁴ Some rights holders, such as DuPont, may pursue site licenses from universities rather than pursuing individual scientists.¹⁴⁵ Short of litigation, universities may be facing enforcement measures such as letters advising them that faculty members are infringing patents and demanding that they enter into license agreements.¹⁴⁶ Demand letters could impose considerable transaction costs on

140. See Murray, *The Oncomouse that Roared*, *supra* note 96, at 24; Nicol & Nielsen, *supra* note 9, at 11, 48–49.

141. See *supra* notes 93–108 and accompanying text (explaining the history and problems of the oncomouse patent).

142. See *supra* note 91 and accompanying text.

143. Walsh et al., *Where Excludability Matters*, *supra* note 30, at 1190. Respondents in a supplemental group of scientists working on important signaling proteins were much more likely to report that they needed access to a patent for their research and having to abandon, modify, or delay a project because of patents, but the numbers were still small. *Id.* at 1199.

144. Walsh, Arora & Cohen conducted interviews with three “business managers” from universities but did not separately characterize the perspective of this subset of respondents, perhaps because of its small size. Walsh et al., *Effects of Research Tool Patents*, *supra* note 9, at 293 tbl.1.

145. Indeed, this may be a more cost-effective strategy for patent holders than pursuing individual infringers.

146. An example that caused considerable stir among university lawyers is a letter that Acacia Media Technologies sent to many universities in 2003 asserting that their online learning services were infringing its patent rights on the process of transmitting and receiving digital content over the Internet. See WESLEY D. BLAKESLEE, NAT’L ASS’N OF COLL. & UNIV. ATTORNEYS, *THE ACACIA PATENT CLAIMS AND OPTIONS FOR EDUCATIONAL INSTITUTIONS 1* (2004), available at <http://www.nacua.org/documents/Blakeslee-Acacia3.pdf> (describing Acacia’s infringement notice campaign). For a general discussion of demand letters and how to respond to them, see generally Gregory A. Duff et al., *Patent Trolls (and Other Bad News) Lurking in Your Mailbox: Handling Cease-and-Desist Letters in the USA*, 3 J. INTEL. PROP. L. & PRAC. 442 (2008).

universities even if they do not ultimately result in either litigation or licensing. Further research might shed light on how common such demand letters are, who sends them to universities, and what costs universities incur in responding. University scientists who infringe patents in academic laboratories may be unaware of the costs that their institutions are incurring to investigate charges of infringement and to clear any necessary rights.¹⁴⁷ One might surmise that, if individual scientists remain oblivious to these enforcement efforts as they go about their research, they have not reached the point of blocking research from going forward. On the other hand, it is possible that scientists who are denied access to patented materials do not know that a patent is involved or do not attribute the problem to patents.

In contrast to the perceived minimal impact of patents, scientists report that their work is interrupted with some regularity by the need to negotiate terms of access to proprietary materials or data.¹⁴⁸ In the Walsh, Cohen & Cho survey, 19% reported that their most recent request for materials was denied,¹⁴⁹ and many reported that in over a one-year period, failure to receive requested materials led to significant delays and even to abandonment of projects.¹⁵⁰

Cohen & Walsh explain the difference between patents, on one hand, and materials or data, on the other hand, largely in cost-benefit terms, citing the relative ease of excluding competitors from access to research inputs that cannot be readily replicated by other researchers and the relative costliness of tracking down patent infringers and suing them.¹⁵¹ Nonetheless, they find evidence of a sharing norm that retains some vitality in the willingness of most researchers to share data and materials with their competitors even when it is costly for them to do so.¹⁵² Observing significantly higher rates of withholding materials in their own data than in an earlier study,¹⁵³ Cohen & Walsh

147. See Eisenberg, *supra* note 11, at 240 (stating that the top priority of academic researchers is acquiring needed research materials, usually without much regard for infringement issues).

148. *Id.* at 225.

149. Walsh et al., *View from the Bench*, *supra* note 30, at 2002.

150. *Id.* at 2003.

151. Cohen & Walsh, *supra* note 30, at 13–14.

152. *Id.* at 18. Costs of sharing include the risk of losing future priority of discovery to a competitor as well as the immediate tangible costs of duplicating and providing materials. *Id.* at 15.

153. *Id.* at 15, 18 (“[T]he rate of withholding research materials appears to have increased from 10 percent of requests in the 1997 to 1999 period . . . to 18 percent . . . of requests in the 2003 to 2004 period, possibly reflecting a significant increase in a short

suggest an explanation for the apparent decline in sharing that has nothing to do with commercial practices: perhaps higher levels of NIH funding are to blame because they make exclusionary practices more advantageous as scientists compete more vigorously for larger grants.¹⁵⁴

Katherine Strandburg reviews the same studies and offers a somewhat different explanation.¹⁵⁵ Placing greater reliance on results of the AAAS-SIPPI study,¹⁵⁶ she observes a greater prevalence of difficulties in gaining access to intellectual property, particularly for scientists in industry.¹⁵⁷ Nonetheless, she also finds fewer problems with patented research tools than were previously feared and suggests that more is at work in the failure to enforce patents against researchers than “rational forbearance” from pursuing legal claims that are not cost-justified.¹⁵⁸ Strandburg sees the emergence of an “ignoring patents” norm alongside the traditional sharing norm in science.¹⁵⁹ Noting more problems with the transfer of tangible materials, she suggests that the difficulties arise primarily when industry researchers are involved.¹⁶⁰ Industry scientists, she argues, do not share the preferences that fortify sharing norms among academic scientists, or at least not to the same degree.¹⁶¹ Strandburg also notes that the costs of sharing tangible materials make it more difficult to enforce a sharing norm for these resources.¹⁶² Her normative story rests on an account of the preferences of academic scientists as rational actors, including a preference to learn the results of the collective research project.¹⁶³

time.”).

154. *Id.* at 20.

155. Katherine J. Strandburg, *Sharing Research Tools and Materials: Homo Scientificus and User Innovator Community Norms* 5–8 (May 23, 2008) (unpublished manuscript, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1136606).

156. *See supra* Part II.D and sources cited therein.

157. Strandburg, *supra* note 155, at 6–7.

158. *Id.* at 3.

159. *See id.* at 8–12.

160. *Id.* at 15–16.

161. *Id.* at 30–37.

162. *Id.* at 42–45.

163. Strandburg argues that:

the pervasiveness of the disregard for patents, its justification in normative terms, . . . the distinction between using a tool in research and “making a profit,” the use of reputational and shunning penalties to enforce forbearance and sharing, and the involvement of community organizations and high-status members as norm entrepreneurs in promoting it suggest that the “ignore research tool patents” is a positive social norm enforced within the community of academic and industrial researchers.

Id. at 12.

The cost-benefit account and the norms account are not entirely distinct. Costs and benefits lurk behind norms,¹⁶⁴ and norms factor into the costs and benefits of actions that violate or conform to those norms.¹⁶⁵ It seems likely that both norms and cost-benefit calculations play a role in the observed patterns of exchange. It is nonetheless useful to distinguish the two accounts in analyzing the implications of the studies reviewed herein for the anticommons hypothesis.

C. Cost-Benefit Analysis

The cost-benefit account offers a straightforward explanation for the most striking result in the studies reviewed herein—that exchanges of materials are more likely to give rise to research-impeding transaction costs and bargaining breakdowns than exchanges driven by patent rights.¹⁶⁶ This result may seem to present a challenge to the anticommons hypothesis, which predicts transaction costs and bargaining breakdowns as a consequence of too many property rights.¹⁶⁷ After all, patents are more like property rights than the combination of self-help and contract used to control access to materials and data. Patents confer a legal right to exclude all others—including researchers who make the same thing independently—from making, using, selling, or importing an invention without the permission of the patent owner.¹⁶⁸ By contrast, researchers are free to duplicate unpatented materials and data without legal liability. As property rights, patents might seem more likely to threaten an anticommons than the less absolute rights held by those in possession of unpatented materials and data.

But it is transaction costs and risks of bargaining failure that set the stage for an anticommons; what matters is thus not the property-like character of the underlying rights, but rather the need to negotiate multiple agreements. As a matter of law, a user needs to get permission from the patent owner before using a patented invention. But as a matter of practice, both owners and infringers routinely ignore patents in the context of

164. See *id.* at 18–22, 40–47.

165. Indeed, Cohen & Walsh find evidence of a sharing norm in the fact that sharing research materials and results is common even though it is costly and presents a risk of losing a competitive advantage. Cohen & Walsh, *supra* note 30, at 18.

166. *Id.* at 9–15 (concluding that while “patents have rarely blocked academic research,” the existence of secrecy among university researchers regarding unpublished findings and research materials can pose significant impediments to future research).

167. See Strandburg, *supra* note 155, at 2–3.

168. 35 U.S.C. § 271 (2000).

upstream research. Would-be users thus readily gain access to patented technology without having to engage first in costly bargaining, a fact that minimizes the risk of an anticommons arising from a proliferation of patents alone. On the other hand if, as the data also suggest, exchanges of materials and data are encumbered by costly negotiations and risks of bargaining breakdowns, then a proliferation of MTAs and database access agreements could potentially give rise to an anticommons even without patents.

Cohen & Walsh distinguish patent rights from what they call “practical excludability.”¹⁶⁹ With or without a patent, a scientist or institution may control access to a resource, such as a large private database or a transgenic mouse.¹⁷⁰ Those in control of such a resource hold the practical power to force other users to enter into an agreement before they will share it.¹⁷¹ Sometimes practical excludability and patent protection may both be present, as in the case of patented transgenic mice.¹⁷² But sometimes users have the capacity to duplicate patented inventions in their own laboratories without the cooperation of the patent owner,¹⁷³ and sometimes users need the cooperation of owners before they can gain access to unpatented materials and data.¹⁷⁴ Practical excludability has three notable attributes with interesting implications for the anticommons hypothesis.

First, the resource must be costly for users to recreate on their own. If users are able to duplicate the resource at reasonable cost in their own laboratories, they may not even become aware of purely legal obstacles such as patents. Strandburg explains that it may be more costly for users to duplicate materials because the materials embody considerable tacit knowledge about how to produce them or because of the

169. Cohen & Walsh, *supra* note 30, at 13.

170. *Id.*

171. *See id.* at 13–14 (describing ability of owners of restricted material to simply refuse to cooperate with those seeking access to it).

172. David Mowery and Arvids Ziedonis have examined MTAs at the University of Michigan and found that they are often complements to patents rather than substitutes. David C. Mowery & Arvids A. Ziedonis, *Academic Patents and Materials Transfer Agreements: Substitutes or Complements?*, 32 J. TECH. TRANSFER 157 (2007).

173. It is tempting to speculate that the patent law requirement for an enabling disclosure of how to make and use the invention, 35 U.S.C. § 112 (2000), forces inventors to codify their inventions and thereby puts researchers in possession of the invention without the need for further consultation with the inventor. But it seems from the studies reviewed herein that many researchers are infringing patents of which they are not aware, suggesting that they are learning how to make and use these inventions from sources other than patent disclosures. *See* Strandburg, *supra* note 155, at 8 (stating that only 5% of university researchers check for patents related to their research).

174. Cohen & Walsh, *supra* note 30, at 13–14.

importance of standardization for the research.¹⁷⁵ The same may be true of new methods or data. If it is costly for users to recreate the resource, it may also be costly for the owner to provide it,¹⁷⁶ although this is not a necessary feature of practical excludability. The costliness of sharing may make owners less willing to share; on the other hand, owners may be able to exchange the practically excludable resource for value that helps defray its costs.¹⁷⁷ As long as it is cheaper for the owner to share the resource than it is for the user to recreate it, there are potential gains from exchange that stand to be dissipated through transaction costs or lost through bargaining breakdowns.

Second, the owner must be able to exclude users from the resource at low cost. This is an important distinction between patents and practical excludability. Enforcement of a patent is a high cost endeavor; failure to share materials and data with users who cannot otherwise duplicate them may require little or no effort on the part of the owner.¹⁷⁸ Exclusion becomes more costly if the owner needs to share the resource to secure patents or other rewards,¹⁷⁹ or to avoid reputational penalties. When it is cheap for owners to exclude users, exclusion is more likely.

Third, and most interesting for the anticommons hypothesis, the burden of inertia rests on the user to overcome transaction costs before proceeding with the use. This is another important distinction between patents and practical excludability. If a patent is the only obstacle to use of a technology, the burden of inertia rests on the patent owner to detect and stop the infringing activity, generally after it is under way. The patent owner has a legal remedy, but this remedy is not self-executing. Infringement litigation is costly and fraught with risks. The cost and risk may seem worthwhile if market exclusivity in a lucrative product is at stake, but if the user is an academic researcher who is not close to developing a commercial product,

175. Strandburg, *supra* note 155, at 42.

176. It may consume costly materials and the time of skilled laboratory personnel to reproduce tangible materials and to ship them off, or to train the user to produce the materials independently. *Id.* at 42. Even in the case of data, it may be costly for the owner to provide access in a form that is readily usable by others or to explain how to use a database. Moreover, as Cohen & Walsh elaborate, sharing a resource with competitors may deprive the owner of a competitive advantage in future research, at the cost of losing future priority of discovery and attendant future rewards. Cohen & Walsh, *supra* note 30, at 4–6.

177. Payment may take many forms, including cash, acknowledgement in publications, collaboration on future research, or license rights to future discoveries.

178. Cohen & Walsh, *supra* note 30, at 9, 13–14.

179. See *supra* note 173. For inventions and discoveries that may be effectively disseminated in writing, it may be impossible to restrict dissemination after publication.

the owner may conclude that the costs of enforcement do not justify the potential gains. The higher the costs of enforcement, the less likely enforcement becomes. In this environment, researchers may feel that it is generally safe to proceed without a license, even when they are aware of the patents.

Compare the position of a researcher who wishes to use a tangible research tool that she cannot readily duplicate in her own laboratory. If it is cost-prohibitive to duplicate the tool, the burden of inertia rests on the user to persuade the party in control to agree to share it before proceeding with the use. The owner doesn't have to bring an infringement action in order to force researchers to pay, but can sit back and wait for users to seek access and then bargain over terms. The tool may or may not be covered by a patent, and the researcher who seeks access may or may not be aware of the patent if it exists. The obstacle that academic researchers take note of is not likely to be a patent, but instead a restriction on access to something that is costly to duplicate without a license. The need for *ex ante* cooperation from the owner requires the researcher to incur transaction costs before proceeding in a way that the remote future possibility of infringement liability does not.

This highlights an interesting dimension to the anticommons problem that Heller & Eisenberg did not address: the burden of inertia matters in predicting the likelihood of use in the presence of high transaction costs. When the burden of inertia to clear rights in advance is on users—as it is when researchers seek access to materials or data from someone else—high transaction costs work to the detriment of users, creating a risk of underuse. The user must incur these costs before using the resource, and if the transaction costs exceed the expected value of the use, it will not happen. But when the burden of inertia to enforce rights against infringers after the fact is on owners—as it is when users infringe patents—high transaction costs work to the detriment of owners, mitigating the risk of underuse. The more costly it is to enforce patents, the less likely it is that owners will go to the trouble, making it less risky for users to proceed without first bargaining for a license.

Of course, this dichotomous account of the burden of inertia is a simplified story that may not capture the nuances of every potential transaction. One can imagine circumstances in which the party whom I have pictured as free of the burden of inertia—the unlicensed user in the case of patents or the owner of the resource in the case of practical excludability—is unhappy with the status quo and motivated to seek a deal rather than to leave it up to the other party to make the first move. A patent infringer

may fear legal liability and want to secure a license before proceeding further with R&D, even though the patent owner is so far unaware of the infringing activity or willing to ignore it for now. As for material transfers, some owners may affirmatively want to disseminate their materials for profit and be motivated to seek out potential users as customers, incurring transaction costs along the way rather than leaving the burden of inertia on would-be users. Moreover, the burden of inertia may shift as the situation unfolds. If the patent owner takes action to enforce the patent, the infringer may need to incur significant costs to respond. Even if the user makes the first move, an owner of materials who wants to enter into a lucrative transfer will need to incur transaction costs in order to get to that point. But despite the plausibility of these alternative scenarios, the recurring observation in multiple studies that negotiations over transfer of materials are more likely to block research than patents suggests that the simplified account holds true much of the time. The result is, on one hand, to mitigate the risk of an anticommons arising from a proliferation of patents alone and, on the other hand, to aggravate the risk of an anticommons arising from a proliferation of resources that are characterized by practical excludability.

For purposes of refining the anticommons hypothesis, what matters is that high transaction costs to clear property rights do not necessarily lead to inefficient underuse. Not every property right is like a padlock on a door that cannot be opened without first tracking down the owner and negotiating to use the key. Some property regimes put the burden on the owner to identify and pursue those who have gained access without permission. In such a regime, the costlier it is to enforce property rights, the less likely it is that enforcement will occur, and the safer it is to proceed without a license.

The burden of inertia may provide an adjustable mechanism for shifting the balance between *ex ante* incentives for innovation and downstream risks of an anticommons without changing the underlying property rights. Where the burden of inertia lies may sometimes appear to be mere happenstance—a fortuitous consequence of the cost of replicating a particular resource, or an inadvertent byproduct of the costs of enforcing legal rights in a society that cares about due process. But the burden of inertia can sometimes be adjusted as a design feature of property regimes. Legal proceedings may be elaborate or simple. Burdens of proof may be on plaintiffs or defendants. The sheriff may lend owners a hand or leave them to fend for themselves.

Consider the case of patents. As noted, ordinarily the burden of inertia to enforce patents rests on patent owners.¹⁸⁰ But in the case of patented drugs, Congress has shifted some of that burden from owners to infringers. Under the Drug Price Competition and Patent Term Restoration Act of 1984, sometimes known as the Hatch–Waxman Act,¹⁸¹ patent owners who seek to exclude generic competitors from the market are not limited to the slow and costly process of seeking a judicial remedy for infringement but may use their patents to defer FDA approval of a generic version of a patented drug.¹⁸² The statute requires the manufacturer of a generic version of a previously approved drug to certify to the FDA that its product does not infringe any valid patents, even if it otherwise meets the FDA’s standards for approval.¹⁸³ If the generic manufacturer challenges the patent, the owner may file a lawsuit to establish that the patent is valid and infringed.¹⁸⁴ But the owner need not await a judicial remedy to get relief. While the lawsuit is pending, and without evaluating its merits, the FDA will enter an automatic 30-month stay of approval of the generic product.¹⁸⁵ The net effect is similar to a preliminary injunction against the generic product, but without the usual burden on the patent owner to demonstrate a likelihood of success on the merits, irreparable harm, a balance of hardships in its favor, and impact on the public interest.¹⁸⁶ Although this enhanced benefit to patent owners gains leverage from a legal regime outside the patent system, it is hardly an inadvertent byproduct of FDA regulation. The statute explicitly directs the FDA to consider patent protection and the status of infringement litigation in determining the effective date of product approval.¹⁸⁷ The result is a significant shift in the burden of inertia from the patent owner to the alleged infringer.

A similar shift in the burden of inertia has occurred between copyright owners and creators of academic coursepacks as a consequence of judicial decisions holding commercial copy centers

180. Cohen & Walsh, *supra* note 30, at 9, 14.

181. Drug Price Competition and Patent Term Restoration (Hatch–Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 [hereinafter Hatch–Waxman Act] (codified as amended in scattered sections of 15 U.S.C., 21 U.S.C., and 35 U.S.C.).

182. 21 U.S.C. § 355(b), (c), (j) (2006).

183. 21 U.S.C. § 355(j) (2006).

184. 21 U.S.C. § 355(j)(4)(B)(iii) (2006).

185. 21 U.S.C. § 355(j)(2)(C)–(D) (2006); *see also* Apotex, Inc. v. Thompson, 347 F.3d 1335, 1352 (Fed. Cir. 2003) (holding that the Hatch–Waxman Act does not require the FDA to review patents for validity and infringement).

186. *See, e.g.,* Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1374 (Fed. Cir. 2006) (reciting standards for preliminary injunctions).

187. 21 U.S.C. § 355(b), (c), (j) (2006).

liable for making and selling photocopies of copyrighted materials for classroom use.¹⁸⁸ Although the copyright statute explicitly permits fair use of a copyrighted work, including “reproduction in copies . . . for purposes such as . . . teaching (including multiple copies for classroom use),”¹⁸⁹ the courts have held that a for-profit copy center that makes such copies for sale to students is not entitled to claim fair use.¹⁹⁰ Fearing liability for infringement, many copy centers thereafter began requiring that professors obtain licenses to reproduce all copyrighted works before they would make copies of coursepacks.¹⁹¹ The result has been a dramatic shift in the burden of inertia from copyright owners onto professors who use copyrighted works in teaching materials.¹⁹²

If policymakers were so inclined, one could also imagine ways of shifting the burden of inertia from the owners of patents on research tools onto infringers of those patents. The studies reviewed herein suggest that academic researchers often get away with patent infringement,¹⁹³ and those who fear that patents could impede academic research might consider that a good thing. But suppose one believed that the high costs of patent enforcement were preventing owners of research tool patents from receiving adequate compensation for their innovations from the researchers who use them.¹⁹⁴ One might try to lighten the burden of inertia on patent owners by making it easier for them to get preliminary injunctions against unauthorized use of their

188. See, e.g., *Princeton Univ. Press v. Mich. Document Servs.*, 99 F.3d 1381, 1388–91 (6th Cir. 1996) (determining that copy shop’s preparation of student “coursepacks” did not satisfy the fair use test); *Basic Books, Inc. v. Kinko’s Graphics Corp.*, 758 F. Supp. 1522, 1535–36, 1547 (S.D.N.Y. 1991) (concluding that Kinko’s was not entitled to a fair use defense when it copied and sold excerpts of copyrighted works destined for classroom use).

189. 17 U.S.C. § 107 (2006).

190. *Princeton*, 99 F.3d at 1389.

191. See STANFORD UNIV. LIBRARIES & ACADEMIC INFO. RES., COPYRIGHT & FAIR USE (2007), http://fairuse.stanford.edu/Copyright_and_Fair_Use_Overview/chapter7/7-a.html.

192. See, e.g., *id.* (“It is the instructor’s obligation to obtain clearance for [copyrighted] materials used in class.”); UNIV. OF TEX. SYS., FAIR USE OF COPYRIGHTED MATERIALS (2005), <http://www.utsystem.edu/ogc/Intellectualproperty/COPYPOL2.HTM> (promulgating “Rules of Thumb” to aid students and professors in their understanding of fair use and recommending that off-campus copy shops obtain permission before copying materials for academic coursepacks).

193. See *supra* notes 32–34 and accompanying text.

194. For a defense of the importance of providing effective protection for research tool patents, see *Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1348, 1352–53 (Fed. Cir. 2007) (Rader, J., dissenting in part and concurring in part). For an argument that exemptions from infringement liability should be narrowly construed, see Elizabeth A. Rowe, *The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?*, 57 HASTINGS L.J. 921, 923, 945–48 (2006).

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inventions in research. Or, one might borrow the power of federal research sponsors over grantees to facilitate enforcement by patent owners, much as Congress has borrowed the power of the FDA over drugs to reduce the burden on owners of drug patents.¹⁹⁵ Research sponsors might, for example, require grantees to promise to exercise due diligence to avoid patent infringement or to affirm that the work for which they seek funding will not infringe patents. They might also retain the right to suspend grant funding for patent infringers.

Of course, each of these shifts in the burden of inertia benefits owners rather than users, thereby tending to aggravate the risk of an anticommons. If policymakers are more worried about creating an anticommons than they are about fortifying upstream R&D incentives, they might have quite the opposite impulse. Rather than making patent enforcement cheaper, policymakers might make it more costly. In fact, federal funding agencies have shown little political inclination to strengthen the hand of patent owners against their own grantees. Quite the contrary, NIH has instead used its influence as a research sponsor to reduce transaction costs that impede access to proprietary research tools and to minimize the impact of patents on academic research.¹⁹⁶ After the Court of Appeals for the

195. See *supra* notes 181–187 and accompanying text (examining the effects of the Hatch–Waxman Act).

196. See, e.g., Best Practices for the Licensing of Genomic Inventions: Final Notice, 70 Fed. Reg. 18,413, 18,415 (Apr. 11, 2005) (advocating a licensing regime which allows greater access to patented material and technology); Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72,090, 72,090–93 (Dec. 23, 1999) (setting forth conditions for recipients of NIH funding to “facilitate further biomedical research” and accelerate development); Memorandum of Understanding Between E.I. DuPont de Nemours & Company and Public Health Service (July 1, 1999), available at <http://www.ott.nih.gov/pdfs/oncomouse.pdf> (granting Public Health Service the right to use patented materials for noncommercial purposes); Memorandum of Understanding Between DuPont Pharmaceuticals Company and Public Health Service 1–2 (July 1, 1998), available at <http://www.ott.nih.gov/pdfs/cre-lox.pdf> (allowing DuPont to receive value for its patent rights without significantly burdening health research conducted by Public Health Service).

The Supreme Court extended further protection from infringement liability for upstream research with its decision in *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 201–08 (2005), broadly construing a statutory exemption from infringement liability to cover industry-sponsored research in a university laboratory on a patented molecule. The statutory exemption was added as part of the Hatch–Waxman Act to permit clinical testing of generic versions of patented drugs during the patent term in order to facilitate prompt market entry thereafter. See H.R. REP. NO. 98-857(II), at 5 (1984). The statutory language provides more broadly:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information

Federal Circuit squarely held that nonprofit research in universities is not categorically exempt from infringement liability,¹⁹⁷ the NAS put a research exemption from patent infringement on its legislative agenda for patent law reform.¹⁹⁸

Given the reported infrequency of patent enforcement against universities and academic researchers, it is interesting that the scientific community remains concerned about this issue.¹⁹⁹ Perhaps, as suggested earlier, the institutional perspective of universities is different than the individual perspective of researchers as revealed in the reported studies.²⁰⁰ Universities may feel little confidence that past patterns of nonenforcement of patents will continue indefinitely. Public universities appear for now to enjoy sovereign immunity from patent infringement actions,²⁰¹ but there are signs that the Supreme Court may be retreating from its prior robust concept of state sovereign immunity.²⁰² Patent infringement exposes both

under a Federal law which regulates the manufacture, use, or sale of drugs
35 U.S.C. § 271(e)(1) (2000). The statutory basis for the exemption was not that the research occurred in a university setting, but rather that it was related to the development and submission of information to the FDA, a condition that commercial research can more easily satisfy than academic research. See *Merck KGaA*, 545 U.S. at 202.

197. See *Madey v. Duke Univ.*, 307 F.3d 1351, 1361–63 (Fed. Cir. 2002) (“[The] correct focus should not be on the non-profit status of Duke but on the legitimate business Duke is involved in.”).

198. A PATENT SYSTEM FOR THE 21ST CENTURY 82 (Stephen A. Merrill et al. eds., 2004).

199. See ASS’N OF AM. UNIVS. ET AL., COMMENTS ON H.R. 1908 AND S. 1145, THE PATENT REFORM ACT OF 2007, at 5 (2007), http://www.nacua.org/documents/PatentReformAct_Comments.pdf (advocating for the “inclusion of an experimental research exemption in any patent reform legislation that is enacted”).

200. See *supra* notes 144–145 and accompanying text.

201. See *Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 683–84, 691 (1999) (overruling the constructive waiver doctrine in holding that Florida neither abrogated nor waived its sovereign immunity to suit under the Lanham Act by engaging in interstate commercial activities).

202. See *Coll. Sav. Bank*, 527 U.S. at 691 (upholding Florida’s sovereign immunity); *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 645–48 (1999) (holding that the Patent Remedy Act violated Section 5 of the Fourteenth Amendment); *Seminole Tribe of Fla. v. Florida*, 517 U.S. 44, 72–73, 76 (1996) (holding that suits brought to enforce federal legislation pursuant to the Indian commerce clause are barred by the “background principle of state sovereign immunity embodied in the Eleventh Amendment”). For a critique of these decisions in the context of patent infringement by universities and a suggestion that the federal government should condition receipt of federal research funds on a waiver of sovereign immunity for patent infringement, see Jennifer Polse, *Holding the Sovereign’s Universities Accountable for Patent Infringement after Florida Prepaid and College Savings Bank*, 89 CAL. L. REV. 507 (2001). Recent evidence suggests a possible retreat from the robust version of sovereign immunity by the Supreme Court. See *Cent. Va. Cmty. Coll. v. Katz*, 546 U.S. 356, 379 (2006) (holding that Congress has authority to abrogate state sovereign immunity in bankruptcy cases). The Supreme Court recently sought the views of the solicitor general

researchers and their institutions to risks of liability, but academic institutions have endowments that might make them more attractive targets of enforcement than individuals, and they may be more patent-savvy and better able to appreciate the magnitude of the liability risk.²⁰³ Universities are generally risk-averse institutions, and they may find it challenging even to evaluate risks of patent infringement liability. Liability risks, as well as freedom to operate costs, increase with the number of relevant patents, which might tempt risk-averse institutions to curtail research in areas characterized by extensive patents.²⁰⁴ Traditions of academic freedom make it difficult for university administrators to control the behavior of scientists in order to control liability risks. Perhaps a research exemption that eliminates the risk seems like a good way out of this bind.

D. *Sharing Norms*

Katherine Strandburg offers a norms-based account of the lack of enforcement of patents in academic research.²⁰⁵ According to this account, the research community has responded to a proliferation of patents in upstream research by adapting its traditional norms, which in the past called for sharing and not patenting, so that they now permit patenting but also call for ignoring patents in the context of university research.²⁰⁶ She finds evidence that norms play a role in the dissemination of research tools in the efforts of prestigious scientific institutions, such as the NAS²⁰⁷ and the

on a petition for certiorari in a case that could call into question the scope of state sovereign immunity in the patent law context. *See* *Biomedical Patent Mgmt. Corp. v. Ca. Dep't of Health Servs.*, 128 S. Ct. 2076 (2008) (mem.) (inviting the Solicitor General to “file a brief . . . case expressing the views of the United States” in a patent infringement action brought against the California Department of Health Services that was dismissed on sovereign immunity grounds). For the decision below, see *Biomedical Patent Management v. California Department of Health Services*, 505 F.3d 1328 (Fed. Cir. 2007).

203. Rebecca S. Eisenberg, *Patent Swords and Shields*, 299 *SCIENCE* 1018, 1018–19 (2003).

204. *See supra* notes 123–130 and accompanying text (discussing costs of evaluating freedom to operate in the private sector).

205. Strandburg, *supra* note 155, at 8–9.

206. *Id.* at 8; *cf.* Murray, *The Oncomouse that Roared*, *supra* note 96, at 6 (recounting the scientific community’s response to oncomouse, including more patenting by universities to preserve freedom to operate).

207. *See, e.g.*, COMM’N ON LIFE SCIENCES, NAT’L RESEARCH COUNCIL, *FINDING THE PATH: ISSUES OF ACCESS TO RESEARCH RESOURCES*, at vi–xiii (1999); COMM. ON RESPONSIBILITIES OF AUTHORSHIP IN THE BIOLOGICAL SCIENCES, NAT’L RESEARCH COUNCIL, *SHARING PUBLICATION-RELATED DATA AND MATERIALS: RESPONSIBILITIES OF AUTHORSHIP IN THE LIFE SCIENCES* 33–34 (2003) (concluding that the scientific

NIH,²⁰⁸ to encourage sharing and to preserve freedom to operate in the scientific community, especially in the context of biomedical research.²⁰⁹ Empirical evidence suggests that universities have sought to abide by the guidelines established by these institutions in licensing their own patents.²¹⁰

One difficulty with this account is that it is not obvious as a normative matter why the scientific community would embrace an “ignore patents” norm that is more robust than its sharing norms for materials and data.²¹¹ Strandburg suggests that it is more challenging for the scientific community to maintain sharing norms for these resources because it is more costly to share them and because there are greater benefits to be gained by not sharing.²¹² Cohen & Walsh see evidence of a possible sharing norm for materials in the fact that, despite the costs of sharing and the benefits of not sharing, most requests for materials and data are fulfilled.²¹³ It is possible that patents lurk behind some instances of failure to share materials, and that withholding of patented materials pending completion of a MTA functions as a low-cost means of enforcing rights to these inventions against academic researchers.²¹⁴ Further empirical work might help to illuminate what the relevant norms are, how they are enforced, and how much work they do.

The norms account has some explanatory power in understanding counterexamples in which patents have actually

community supports certain standards for sharing data and materials).

208. See Principles for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Request for Comments, 64 Fed. Reg. 28,205, 28,206 (May 25, 1999); U.S. DEP’T OF HEALTH & HUMAN SERVS., NIH DATA SHARING POLICY AND IMPLEMENTATION GUIDANCE (2003), http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm (listing positive effects of promoting data sharing in the scientific community).

209. Strandburg, *supra* note 155, at 10–11.

210. Pressman et al., *supra* note 110, at 34–35; see also CAL. INST. OF TECH. ET AL., *supra* note 109, at 5 (hortatory statement signed on behalf of nine research universities and the American Association of Medical Colleges encouraging universities to license inventions in accordance with normative principles).

211. Perhaps the relevant normative distinction has less to do with sharing than with norms and traditions of free inquiry, particularly in academic research, which is where all scientists begin their careers. Hauling researchers into court to get them to stop their experiments may feel like an aggressive violation of their right of free inquiry, while failing to send off a transgenic mouse may seem more like failing to make a charitable contribution.

212. Strandburg, *supra* note 155, at 42–43.

213. Cohen & Walsh, *supra* note 30, at 18.

214. In a study conducted at the University of Michigan, Mowery & Ziedonis find that the use of MTAs often precedes the filing of a patent application and increases the likelihood that the university will patent the invention. Mowrey & Ziedonis, *supra* note 172, at 167.

been enforced. To the extent that nonenforcement of patents depends on the operation of social norms, one might expect that those norms would be more effective among members of a close-knit, homogeneous community who share the same norms and who interact with each other enough that they anticipate reciprocal claims and feel vulnerable to reputational consequences if they depart from the norms.²¹⁵ Such community members know that in the next round, the positions of owner and user may be reversed, making owners more likely to treat users as they would hope to be treated themselves. Conversely, one might expect less compliance with norms by outsiders or fringe members of the community who have fewer concerns about reputation and reciprocity.

This theory may explain why DuPont was relatively undeterred by sharing norms when it sought to enforce the oncomouse and cre-lox patents. Controversy over the licensing of these patents is sometimes presented as a clash between corporate and academic cultures.²¹⁶ But few corporate–academic interactions in biomedical research have been as protracted and difficult as this one. Perhaps DuPont, whose core business is chemistry,²¹⁷ was less concerned about the traditional sharing norms of biomedical research than firms from the biopharmaceutical industry that had more pervasive interactions with academic biomedical scientists. If the “ignore patents” norm is more effective within the biomedical research community than it is between community members and nonmembers, the community may have reason to be concerned about the future. As biomedical research draws increasingly on research from other fields, such as information technology²¹⁸ and nanotechnology,²¹⁹ researchers may find themselves at greater risk of trespassing

215. Strandburg, *supra* note 155, at 41–42.

216. See Murray, *The Oncomouse that Roared*, *supra* note 96, at 1 (“The Oncomouse is a prominent example of the increasingly common collision between two institutions—academic and commercial science.”).

217. For a history of R&D at DuPont, see DAVID A. HOUNSHELL & JOHN KENLY SMITH, JR., *SCIENCE AND CORPORATE STRATEGY: DUPONT R&D 1902–80* (1988).

218. See NAT’L INSTS. OF HEALTH, *RECOMMENDATIONS OF THE BIOMEDICAL INFORMATION SCIENCE AND TECHNOLOGY INITIATIVE IMPLEMENTATION GROUP 5* (2000), http://www.bisti.nih.gov/bisti_recommendations.cfm (recommending the creation of a consortium to facilitate “the sharing of information across the NIH on emerging scientific opportunities in biocomputing”).

219. See Kelly Y. Kim, *Research Training and Academic Disciplines at the Convergence of Nanotechnology and Biomedicine in the United States*, 25 *NATURE BIOTECHNOLOGY* 359, 361 (2007) (noting the mix of curriculum that tends to produce nanobiotechnologists); see also NIH BIOENGINEERING CONSORTIUM, *NANOSCIENCE AND NANOTECHNOLOGY: SHAPING BIOMEDICAL RESEARCH (SYMPOSIUM REPORT)* (2000) (on file with the Houston Law Review).

upon patents held by institutions outside the biomedical research community who feel less constrained to observe the community's sharing norms.

Community norms might also be ineffective at deterring infringement actions against universities by disgruntled faculty members. We have already seen an example in the case of *Madey v. Duke*.²²⁰ Patents have so far played a relatively small role in intra-academic disputes. But a patent infringement claim worked for Professor Madey, and it would not be surprising to see other unhappy professors play that card in the future.²²¹ Although typically universities own the patents on inventions made by faculty, faculty members sometimes obtain patents on inventions that universities have elected not to pursue.²²² If the faculty member later leaves the institution under unhappy circumstances, that patent may be a valuable weapon in any ensuing legal dispute.²²³ In the context of such disputes, aggrieved faculty members could be motivated to pursue a winning legal theory even though it is not cost-justified and violates traditional norms.

To the extent that the scientific community relies on sharing norms to forestall anticommons problems, one might wonder about the durability of those norms looking forward. Fiona Murray and Scott Stern have suggested that the impact of intellectual property on the scientific community may shift over time as legal rules and social norms interact.²²⁴ In the past decade the biomedical research community has taken numerous measures to fortify its sharing norms in the face of perceived

220. *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002). Professor Madey owned patents on laboratory equipment that he used to perform research at Duke University. After his relationship with Duke unraveled and Duke replaced him as principal investigator on a grant, Professor Madey sued on a variety of legal theories, including patent infringement. *Id.* at 1352–53. For a review of the implications of *Madey* for university patent infringement liability, see Eisenberg, *supra* note 203.

221. *Madey*, 307 F.3d at 1364; *see also* Eisenberg, *supra* note 203, at 1019.

222. If a university that is receiving federal funding does not elect to retain title to an invention, U.S. law provides that “the Federal agency may consider and after consultation with the [university] grant requests for retention of rights by the inventor.” 35 U.S.C. § 202(d) (2000).

223. Although Professor Madey's lawsuit remains unusual, a front page article in the *Wall Street Journal* in 2006 predicted more legal disputes between universities and faculty in the future as universities become more businesslike in their management of research on campus, intervening more in decisions about research rather than deferring to faculty autonomy. Bernard Wysocki, Jr., *Ivory Power: Once Collegial, Research Schools Now Mean Business*, WALL ST. J., May 4, 2006, at A1.

224. Fiona Murray & Scott Stern, *Learning to Live with Patents: Assessing the Dynamic Adaptation to the Law by the Scientific Community* (Apr. 2008) (unpublished manuscript, available at <http://imio.haas.berkeley.edu/WilliamsonSeminar/murray041708.pdf>).

incursions by conflicting incentives to protect and enforce intellectual property.²²⁵ These measures have had some success in influencing the behavior of universities as licensors of patents,²²⁶ but they have been less successful in influencing the behavior of scientists as providers of research materials and data. If anything, it appears that restrictions on dissemination of these “practically excludable” resources are becoming more common over time,²²⁷ suggesting that sharing norms may be weakening. The studies reviewed herein all occurred close together in time,²²⁸ making it difficult to project with confidence how the observed behavior patterns, and the norms on which they rest, will persist in the future.

If there is indeed an “ignore patents” norm within the scientific community that serves to forestall potential anticommons problems arising from a proliferation of patents in biomedical research, it might make sense to adjust the patent laws to reflect that norm rather than relying upon noncompliance and nonenforcement under the current law. Widespread disregard of patent laws in respectable institutions like universities threatens to engender disrespect for the patent laws, to the detriment of patent owners. If you live in a community in which patent infringement is pervasive and practiced on a regular basis by all of your competitors and collaborators, when the occasional outlier (such as DuPont or Myriad Genetics) decides to enforce a patent, the patent laws seem arbitrary and unfair. An obvious parallel is the widespread disregard of the copyright laws by young music listeners.²²⁹ Sporadic enforcement efforts by the recording industry have been largely ineffective and have failed to arrest the decline in respect for the copyright laws.²³⁰ Perhaps copyright owners would be better served by a narrower set of rights that were more widely respected.²³¹ If the proliferation of patent rights in biomedical research has led to widespread patent infringement by academic scientists, it is

225. See *supra* notes 205–214 and accompanying text.

226. See Pressman et al., *supra* note 110, at 38–39.

227. See Cohen & Walsh, *supra* note 30, at 17–18 (comparing their results to those of earlier studies).

228. See sources cited *supra* notes 205–214.

229. Yuval Feldman & Janice Nadler, *The Laws and Norms of File Sharing*, 43 SAN DIEGO L. REV. 577, 582 (2006).

230. *Id.* at 589–91.

231. Cf. Mark F. Schultz, *Fear and Norms and Rock & Roll: What Jambands Can Teach Us About Persuading People to Obey the Copyright Laws*, 21 BERKELEY TECH. L.J. 651, 680–82 (2006) (describing norms against copying that are widely respected within the jamband community).

worth considering whether patent owners would be better served by a patent system that drew boundaries that prestigious institutions, such as universities, could abide by and respect.

IV. CONCLUSION

Over the past decade, empirical studies have investigated whether a growing number of IP claims have caused a tragedy of the anticommons in biomedical research. These studies have focused primarily on the effects of intellectual property on the research science community itself, limiting their value as a test of the Heller & Eisenberg hypothesis that too many upstream IP claims could impede downstream product development. Reports of interviews with attorneys suggest that product-developing firms face a growing burden of transaction costs to identify and clear rights, and that too many patent rights will deter product development if identified at an early stage. But the data are more extensive with respect to the impact of patents and other proprietary restrictions on the activities of working scientists. Survey results from scientists suggest that, although commercial scientists face more obstacles from intellectual property than academic scientists, in both settings it is rare for an ongoing project to be stopped because of patents. Within the academy, scientists generally ignore patents and rarely face patent enforcement. Perhaps this reflects the continuing vitality of sharing norms in academic science, or perhaps patent owners conclude that enforcement of patents against academic researchers is not worth the cost. On the other hand, scientists in both academic and commercial laboratories report more problems in gaining access to “practically excludable” resources such as tangible materials and data that they cannot readily duplicate in their own laboratories.

These results point to an important qualification of the anticommons hypothesis. As framed by Heller & Eisenberg, the risk of underuse in an anticommons arises when too many property rights lead to excessive transaction costs and risks of bargaining failures. But bargaining and transaction costs do not always precede the use of resources that are protected as property. Sometimes, as in the case of patents, the burden of inertia is on the owner of the property right to detect violations of its rights and sue for infringement. In this context, high transaction costs make enforcement less likely, and unauthorized use more likely, mitigating the risk of an anticommons. On the other hand, when it is easy for owners to exclude users from access to resources, as in the case of “practically excludable”

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materials and data, the burden of inertia is on users to persuade owners to permit access, whether or not the resource is covered by formal property rights such as patents. In this context, high transaction costs make use less likely, aggravating the risk of an anticommons. The burden of inertia might sometimes be adjusted in the design of legal rules, offering another mechanism for calibrating the balance between the costs and benefits of property rights.