Nonprofit Commercialization under Bayh-Dole and the Academic Anticommons

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NOTES

NONPROFIT COMMERCIALIZATION UNDER BAYH-DOLE AND THE ACADEMIC ANTICOMMONS

The tragedy of the anticommons describes a scenario in which early "upstream" patenting of minor discoveries or research tools negatively impacts future "downstream" discovery.¹ Under this scenario, barriers to research and invention arise when a single, novel discovery relies on multiple patented inventions or research tools. The increased transaction costs resulting from upstream patenting may impede or even prevent downstream research, invention, and patenting. The tragedy of the anticommons is the topic of much scholarly debate, as it has central relevance to the biotechnology industry, which relies heavily on patents. Moreover, the pyramidal nature of biomedical research is such that future research builds upon past research, and new inventions stem from prior discoveries.

One of the greatest contributors to upstream patenting is the Bayh-Dole Act, passed in 1980, which encourages nonprofit research institutes and universities to patent and commercialize inventions resulting from federally funded research. The purpose of the Bayh-Dole Act is to increase the public's access to federally funded research by enabling the transfer of intellectual property rights from academia to industry where they can be commercialized and made more readily available to the public.² Bayh-Dole allows nonprofit

research institutes and universities to retain the patent rights to these inventions, thus encouraging academic researchers to patent earlier and more frequently.

In addition to promoting upstream patenting in the academic setting through the conferment of intellectual property rights, Bayh-Dole implies a duty to commercialize inventions for the benefit of the public and promotes relationships between nonprofit and university researchers and industry. These resulting commercial relationships can have both positive and negative effects on academic research. For instance, patent rights are granted to incentivize researchers to pursue patentable discoveries, and the monetary rewards resulting from partnerships with industry confer such incentives. The trade-off is that academic researchers are no longer perceived as non-competitive, cerebral academics. In many instances, academic-industrial partnerships are built during early stages of research and development, making the academic researcher a direct competitor within his partner’s field. For instance, a researcher at a university who is developing a synthetic hormone funded by a large pharmaceutical company is in direct competition with other companies that are developing or selling hormone-based therapies.

Being perceived as a competitor within the industry may have serious consequences for a researcher under the tragedy of the anticommons scenario. Two empirical studies have tested the putative tragedy of the anticommons as it relates to the biotechnology industry. Both studies identified certain “working solutions” employed by researchers confronted with upstream patents that enable them to work around or simply ignore patents while pursuing their research goals. “Working solutions” include licensing, inventing around third-party patent claims, ignoring or willfully infringing patents, going offshore to use patented technologies without licensing, creating and using public databases, and challenging patents in court. The nonprofit and university researchers commonly ignore or infringe third-party patents, which they justify under the theory of a “research exemption.”

The “working solutions” that academic researchers utilize are unique to the nonprofit/academic setting and rely on the universal

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perception of academic researchers as non-competitors.\textsuperscript{5} Although these studies failed to identify clear impediments that upstream patenting imposes on downstream research, it is unclear whether this is because the surmised barriers do not exist or whether they exist and are easily surmounted by “working solutions” that the industry utilizes in response to upstream patents.\textsuperscript{6} For-profit firms traditionally do not regard the nonprofits as competitors and typically do not enforce their patent rights against nonprofit researchers because of negative press and lack of recoverable damages. This benign neglect may change as nonprofits and universities increase patenting and commercialization of competing inventions under the Bayh-Dole Act. Thus, commercialization under the Bayh-Dole Act may undermine the “working solutions” that nonprofits and universities have adapted to deal with upstream patenting of research tools, resulting in a tragedy of the anticommons that uniquely affects nonprofits and universities.

This Note addresses the implications of post-Bayh-Dole commercialization on the tragedy of the anticommons as it specifically applies to nonprofit and academic research. Part I of this Note provides a review of the debate concerning the potential harms associated with upstream patenting in biotechnology. Section A reviews the current debate surrounding upstream patenting and the tragedy of the anticommons theory. Section B summarizes the empirical studies that have sought to address the effects of upstream patenting on downstream invention in biotechnology.

Part II provides a review of the evolution of upstream patenting of biotechnology in academia and industry in the United States. Section A summarizes the effect of the market on the compartmentalization of biotechnology research and development in academia and industry prior to the enactment of the Bayh-Dole Act. Section B addresses the effects of the Bayh-Dole Act on biotechnology research, patenting, and commercialization in academia and the advent of nonprofit research institutes.

Part III analyzes the effect of upstream patenting in biotechnology on research conducted in nonprofit institutes and academia compared with for-profit firms. Section A summarizes the “working solutions” that researchers have employed to surmount barriers caused by


\textsuperscript{6} Walsh et al., supra note 4, at 322.
upstream research-tool patents. Section B discusses how these “working solutions” vary between nonprofit institutes and academia compared with for-profit firms.

Part IV discusses the implications of the Bayh-Dole Act on commercialization of the nonprofit sector. Section A addresses the implications of commercialization in regard to nonprofit competition with for-profits firms. Section B discusses the implications of nonprofit commercialization for “working solutions” to upstream research-tool patenting.

I. What Are the Downstream Effects of Upstream Patenting in Biotechnology?

A. The Debate: Biotechnology and the Tragedy of the Anticommons

1. Incentives of the Patent System

A patent confers a short-term monopoly over a novel invention to incentivize research and promote public disclosure of the invention. There is a trade-off between restricting the public’s use of the discovery and providing an incentive to people to invest time, effort, and money in the research leading to the invention. Additionally, patent rights provide downstream incentives by promoting investment in commercialization of the invention, making it more widely available to the public. A patent grants the holder the right to prevent others from practicing the patented invention during the term of the monopoly; however, a patent holder may sell a license to make or sell the invention. There is frequent debate about how best to insure that patent rights create incentives without unduly limiting the public’s use of new technology. This debate is particularly significant in the area of biotechnology because of the nature of biomedical research and the increasing trend toward patenting upstream inventions or research tools. One concern is that prolific patenting of upstream inventions could have a detrimental effect on future research and discovery.

2. Tragedy of the Anticommons

“Tragedy of the commons” describes the phenomenon by which people overuse resources held in common because individuals have no incentive to conserve.\(^7\) According to this theory, a resource is

\(^7\) See Garrett Hardin, The Tragedy of the Commons, 162 Sci. 1243 (1968)
prone to overutilization when too many owners possess a privilege of use, but no one has a right to exclude others.\(^8\) In considering the trends in biotechnology patenting, a converse phenomenon has been hypothesized. Heller and Eisenberg first introduced the metaphor "tragedy of the anticommons" to describe the scenario in which a scarce resource is prone to underutilization when multiple owners have the right to exclude others from the resource, and no one possesses an effective privilege of use.\(^9\) In this scenario, privatization and proliferation of patent rights may lead to significant barriers to future research, rather than increased incentives.

This scenario is not unique to the biotechnology industry, but Heller and Eisenberg claim that the field of biotechnology is particularly vulnerable to this tragedy of the anticommons.\(^10\) It is common knowledge in the field of intellectual property law that patents matter more to the biotechnology industry than to any other because reverse engineering allows competitors to copy discoveries such as genes, molecules, and drugs without undue effort.\(^11\) Thus, researchers in biotechnology cannot rely on trade secrets to preserve their market share as they can in other industries. Researchers hoping to commercialize their inventions are encouraged to patent early and often. The Bayh-Dole Act gives researchers at academic and nonprofit institutes incentives to patent all upstream discoveries and research tools, including genes, expressed sequence tags, receptors, reagents, devices, transgenic animals, and cell lines. This proliferation of patents on research tools creates a patent thicket.\(^12\) In addition, the United States Patent and Trademark Office (USPTO) and the Court of Appeals for the Federal Circuit have extended the scope of patentable subject matter to include novel, nonobvious, and useful research tools.\(^13\)

(explaining that examples of this phenomenon include overpopulation, pollution, deforestation, and extinction).

\(^8\) Heller & Eisenberg, supra note 1, at 698–99.
\(^9\) Id.
\(^10\) Id. Market failure, resulting from a breakdown of the patent system and failure to license, has occurred in several industries, such as radio technology and aviation, while in the semiconductor industry the market has evolved through cross-licensing to promote future discovery and commercialization. See Walsh et al., supra note 4, at 290.
\(^12\) Walsh et al., supra note 4, at 287; see Scott lyama, Comment, The USPTO’s Proposal of a Biological Research Tool Patent Pool Doesn’t Hold Water, 57 STAN. L. REV. 1223, 1225 (2005).
\(^13\) lyama, supra note 12, at 1225; Walsh et al., supra note 4, at 290; see also Diamond v.
The evolutionary nature of scientific discovery is particularly apparent in biomedical science, where future discoveries build upon past discoveries. Each fundamental scientific discovery acts as a building block and is often the result of piecing together earlier discoveries to create a novel invention. Progress in biomedical research has become even more cumulative in nature with advances in molecular biology and genomics, automated sequencing, microarray technology, and high-throughput screening of small molecules. Finally, in applied biomedical research, patent holders are unlikely to fully exploit their patented discoveries, and licensing becomes even more critical to promote downstream applications. For example, multiple researchers may pursue a drug targeted at a particular molecule implicated in a disease. If the molecule is patented and unlicensed, drug development may be limited to a single avenue of research that may not yield the most effective treatment.

The lack of substitutes for certain discoveries, including patented genes, receptors, model systems (i.e., transgenic animals or cell lines), techniques (i.e., polymerase chain reaction [PCR]), or the inability to invent around a critical patent may result in additional barriers to downstream invention.

Under Heller and Eisenberg's model, complex barriers to research and invention arise when a researcher needs access to multiple patented inventions or technologies to conduct research leading to a single, novel discovery. Barriers to downstream research result from increased transactions, costs necessary to obtain the rights to use the necessary research tools. Transaction costs increase with the number of required tools and the number of patent holders with whom licenses must be negotiated. Increased costs can slow or impede discovery, and where the sum of the costs exceed the expected return, avenues of research may be left unexplored, leading to loss of inventions. Thus, upstream patenting of research tools creates a disincentive or barrier to downstream research. Under this theory,


Iyama, supra note 12; see also Carl Shapiro, Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting, 1 Innovation Pol'y & Econ. 119 (2001).


See Walsh et al., supra note 4, at 291.

See Heller & Eisenberg, supra note 1, at 698–99.

Iyama, supra note 12, at 1226–29.
research tools will continue to be developed, but these tools will be under-utilized, and the short-term patent monopolies on these tools may actually impede applied research in areas such as drug discovery and clinical research.

The tragedy of the anticommons describes several types of barriers to downstream research raised by a plethora of upstream patenting. First, many upstream patent owners are public institutions with limited resources for absorbing transaction costs and limited competence in commercial bargaining.\textsuperscript{19} Therefore, increased transaction costs associated with obtaining licenses to use upstream patents are likely to exceed the ultimate value of a given downstream discovery.\textsuperscript{20} These licensing transaction costs are likely to arise early in the course of research and development when the outcome of a project is still uncertain, and it is not clear that value of downstream products justifies the trouble of overcoming the anticommons.\textsuperscript{21}

Second, in an ideal market, patent holders and potential licensees would agree on the value of a patent, thus facilitating licensing negotiations and utilization of the patented invention. However, patent holders may overestimate the value of their patents and demand more than the probabilistic value of the patent. Conversely, patent holders may undervalue the patents of others and reject reasonable offers.\textsuperscript{22} Patent holders' overestimating the value of their patents or undervaluing the patents of others' leads to inefficient bargaining, which interrupts negotiations for user rights and impedes downstream research.\textsuperscript{23} Lack of substitutes may also increase the leverage of certain patent holders, leading to a holdout situation in which a single upstream patent blocks downstream research.\textsuperscript{24} This may occur if the patent holder is unwilling to license or if licensing costs are prohibitive. In addition, if numerous licenses are need to pursue an avenue of research, the rights involved may cover a diverse set of techniques and tools, and it may be very difficult to compare the values of these patents. Patent thickets arise because of widely distributed, concurrent, and sometimes overlapping exclusive rights.\textsuperscript{25} Researchers wanting to use multiple upstream discoveries or tools must navigate through a thicket of patent rights and licensing agreements, where they run into barriers in assembling the rights for

\textsuperscript{19} Heller & Eisenberg, \textit{supra} note 1, at 700.
\textsuperscript{20} Iyama, \textit{supra} note 12, at 1227.
\textsuperscript{21} Heller & Eisenberg, \textit{supra} note 1, at 700.
\textsuperscript{22} \textit{Id.} at 701.
\textsuperscript{23} \textit{Id.}
\textsuperscript{24} \textit{Id.}
\textsuperscript{25} Shapiro, \textit{supra} note 14, at 119; Iyama, \textit{supra} note 12, at 1225.
each research tool required for a particular research project.\textsuperscript{26} This barrier becomes even more difficult to surmount when different types of institutions hold the necessary patents rights.\textsuperscript{27}

Third, the heterogeneity of interests, resources, agendas, and business norms among academic and commercial rights-holders may increase transactions costs.\textsuperscript{28} This heterogeneity may complicate the emergence of standard licensing terms and lead to costly case-by-case negotiations.\textsuperscript{29} When owners have conflicting goals, each can use his rights to block the strategies of the others, and they may not reach an agreement for the development of downstream research.\textsuperscript{30} More subtle conflicts in agendas arise between patent holders pursuing applied, end-product development and focusing primarily on upstream research. Differences in their tolerance for transaction costs may further complicate the emergence of informal licensing. Academic researchers may rely on outdated or obsolete public domain technologies and may find themselves losing grant competitions or unable to scientifically compete.\textsuperscript{31}

Patent owners are also likely to differ in their willingness and ability to infringe the patents of others, leading to disparate motivations in cross-licensing. Generally speaking, nonprofit and academic researchers may infringe with impunity. Use of patented invention in an academic or small start-up environment may be inconspicuous unless published. Therefore, researchers may only pursue licenses once a patented invention is determined essential to downstream invention. This leads to licensing of only a fraction of the patents that are being infringed.\textsuperscript{32} Commercial patent owners may be more reluctant to sue academic researchers, compared with commercial researchers, because of limited remedies and the potential for negative publicity. Cultural differences in nonprofit settings may make nonprofit or academic patent holders more tolerant of patent infringement than large pharmaceutical companies.\textsuperscript{33}

Lastly, long delays in the patent filing and prosecution process may lead to substantial uncertainty at the time of licensing as to the

\textsuperscript{26} Iyama, supra note 12, at 1225.
\textsuperscript{27} Walsh et al., supra note 4, at 290. Different types of institutions include pharmaceutical firms, biotechnology firms, nonprofit institutes, and government laboratories. Each institution has its own agenda, goals, and funding restraints that may not be compatible with the licensing requirements of other types of institutions.
\textsuperscript{28} Heller & Eisenberg, supra note 1, at 700.
\textsuperscript{29} Id.
\textsuperscript{30} Id.
\textsuperscript{31} Id.
\textsuperscript{32} Id.
\textsuperscript{33} Id. at 700–01.
scope of patent rights that will ultimately issue. Corporations and universities may enter into licensing agreements based on pending patent applications. These licenses are based on putative rights that may be larger than the actual rights that the PTO eventually confers, and these overlapping patent filings may compound the obstacles to developing new inventions. Additionally, the use of reach-through license agreements that grant the patent holder rights in subsequent downstream applications may lead to upstream patent holders with overlapping and inconsistent claims on downstream discoveries.

Thus, according to Heller and Eisenberg, in the field of biotechnology, there are numerous, overlapping barriers to downstream research that upstream patenting may raise. Furthermore, within the biotechnology field, nonprofit and academic researchers face unique barriers based on limited funding and legal and commercial experience. This is somewhat balanced by the willingness and ability of nonprofit and academic researchers to infringe patents with relative impunity. These researchers are insulated by the cultural norms surrounding the academic community that are in contrast with the regulated environment of for-profit researchers.

B. Empirical Studies: Effects of Research Tool-Patenting in Biotechnology

1. The Walsh Study

The National Academy of Sciences commissioned a study on the effects of upstream patenting in biotechnology that was first published in Science and later expanded in a second paper. The study sought to determine whether access to upstream inventions that are essential to future innovation actually create barriers to downstream research and patenting. Walsh et al. interviewed professionals within the biotechnology industry. These
interviews focused on changes in patenting, licensing, the relationship between pharmaceutical firms, biotechnology ventures, and nonprofit research institutes, and how policy changes have affected firm behavior.

In summary, Walsh et al. reported that, although searching for third-party patents has become more time consuming and expensive, and the number of licenses that must be obtained for a research project has increased in the past twenty years, that number is usually manageable. Approximately one-third of respondents claimed to be increasing their patenting of gene sequences, assays, and other tools in response to the increased patenting in the industry at large, in order to ensure freedom to operate. However, Walsh et al. found no evidence of an anticommons. Respondents reported that negotiations over access to necessary IP rights, royalty stacking, or excessive licensing fees rarely led to projects' cessations. Furthermore, respondents reported relatively few cases in which concerns regarding the costs related to third-party patents preempted researchers from pursuing a specific project. Walsh et al. reported several examples where restricted access to one critical research tool, such as a drug target, was an impediment to research. However, numerous scientific studies report using these tools despite restricted access, raising a question as to whether the patents serve as true impediments.

Interestingly, Walsh et al. found that researchers have managed to limit the negative effects of research-tool patents on research and innovation through a variety of "working solutions." In addition to traditional practices of licensing and inventing around third-party patent claims, respondents admit to commonly ignoring patents, going offshore to use patented technologies, creating and using public databases, and challenging patents in court. Apparently, these strategies effectively enable researchers in the biomedical sciences to surmount any barriers that upstream patents pose.

trade association personnel.

41 Id. at 294–95.
42 Id. at 295–96; see also M. R. Henry et al., DNA Patenting and Licensing, 297 Sci. 1279 (2002) (providing a comprehensive statistical overview and survey).
43 Walsh et al., supra note 4, at 298.
44 Id. at 305–09.
45 Id. at 322.
46 Id. at 324–29.
2. The Straus Study

In a similar study, "Genetic Inventions and Patent Law," which the German government commissioned, Professor Joseph Straus addressed the effects of upstream patenting in biotechnology. The responses elicited in the Straus study were generally in line with the Walsh study. There was no evidence suggesting an anticommons. There was little evidence of breakdowns in negotiations over IP rights or evidence that biomedical research has slowed. Patents on research tools had no discernible effect on the cost or pace of research in Germany. Respondents claimed that intellectual property rights did not unduly hamper research cooperation agreements. Exceptions were the exclusive licensing of certain research tools so that the licensee could benefit from a period of exclusivity to capitalize on his investment and the costs that royalty stacking imposed. All respondents indicated that they were vigilant in examining the validity of their competitor's patents and determining if their research projects are likely to infringe third-party patents.

Straus also suggested several reasons for the lack of effect of upstream patenting on downstream research, including the difficulty in detecting infringement and the prevalence of licensing in the biotechnology industry in Germany. German interviewees also reported "working solutions," which allow them to continue to innovate relatively unimpeded. These solutions included licensing negotiations, inventing around the patent, ignoring or infringing patents, challenging patents, moving offshore, and putting innovations in the public domain. Access to patented research tools did not appear to be a barrier to downstream research as long as firms were able to take advantage of these working solutions.

Neither the Walsh study nor the Straus study supported the existence of an anticommons in the field of biotechnology. It remains unclear whether Heller and Eisenberg's anticommons exists only as a theory or is in fact present and surmountable via "working solutions" devised within the industry itself. This question ceases to be moot.

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47 ORG. FOR ECON. CO-OPERATION & DEV., supra note 5, at 46. The results of the study were reported at the OECD Working Party on Biotechnology workshop, "Genetic Inventions, IPR, and Licensing Practices," on January 24–25, 2002. Strauss interviewed four large pharmaceutical companies, nine small and medium-sized specialist biotechnology companies, seven public research institutions, and five genetic testing centers in Germany.

48 Id. at 47.

49 "Royalty stacking" refers to the need to take out licenses under numerous patents, resulting in a series of royalty payments to the respective patent holders that may be crippling to the user.

50 ORG. FOR ECON. CO-OPERATION & DEV., supra note 5, at 46.

51 Id. at 50.
when researchers are potentially faced with an insurmountable anticommons resulting from the breakdown of current "working solutions."

II. PATENTING BIOTECHNOLOGY

A. Academia and Industry: Pre-Bayh-Dole

In the 1960s and 1970s, there was a clear division of research between large for-profit companies that conducted applied research focused on drug development, and nonprofit research institutions, including government labs, universities, research institutes, and teaching hospitals, which did curiosity-driven basic research. Clear institutional boundaries between nonprofit and commercial research did not prevent a significant movement of ideas, information, and scientists between nonprofit and for-profit research institutions; however, legal constraints and a strong set of social norms served to limit interactions between the two sectors. Most commercial pharmaceutical research was conducted in-house, and almost all firms were large and fully integrated for drug discovery, clinical development, regulatory affairs, manufacturing, and marketing. Nonprofit researchers concentrated largely on fundamental science and filed very few patents. Research funding was driven by peer-reviewed competition for grants on the basis of scientific merit and the reputation of individual researchers.

Prior to the enactment of the Bayh-Dole Act, the federal government sponsored pre-market "upstream" research through education and research grants to researchers at academic and nonprofit institutes and encouraged broad dissemination of resulting

53 Id. at 5 ("Many drug companies invested significant resources in ‘blue sky’ basic research, and specialist for-profit research boutiques generated and sold technology to large firms. Public sector institutions conducted screening programs for drug candidates, and many academic researchers had close financial and contractual links with drug companies through individual consulting arrangements and institutional research grants and contracts.").
54 Id. at 4. Drug discovery was primarily based upon large-scale, random screening of compounds rather than directed at specific targets. Thus, the large firms had limited requirements for building upon basic scientific knowledge about fundamental physiological processes at the molecular level.
55 Id. at 5 ("The importance of establishing priority and reputation drove early and extensive publication of results, and social norms (and requirements of granting agencies) promoted routine sharing of research materials.").
Fundamental research discoveries became part of the public domain through scientific scholarship and publications. Unpatented “upstream” discoveries in biotechnology were freely available as research tools and could be incorporated in “downstream” discoveries.

In order to provide for commercialization, the federal government retained title to these inventions and made them available through easily obtained nonexclusive licenses. Under this system, there were no exclusive rights available to companies wanting to invest in the development and marketing of new products, and there was no government-wide policy regarding ownership of inventions that government contractors and grantees under federal funding made. Federally-funded research discoveries were the sole property of the funding agencies, which were reluctant to permit ownership of inventions to vest in universities and nonprofit institutions. Policies regarding ownership and licensing of new technologies varied among the various funding agencies, resulting in very limited commercialization of government-funded inventions because petitions for property rights had to move through a lengthy and difficult waiver process. In 1980, the federal government held title to approximately 28,000 patents, of which fewer than 5 percent were licensed to industry for development and commercialization. Thus, although the federal government was supporting nonprofit research, taxpayers were not realizing any benefits resulting from the research or the economic development that would have occurred with the commercialization of research products.

Furthermore, there was no incentive for industry to invest in nonprofit research. Industrial research partners could not count on investment returns such as patent rights or exclusive licenses because of the complexity of research funding, which typically involved multiple funding sources, including federal grants. Prior to

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57 Heller & Eisenberg, supra note 1, at 698–99.
58 Id.; Cockburn, supra note 52, at 4 (“Upstream technology was largely acquired either 'for free' by reading journals and attending conferences, or by purchasing tangible inputs and services, such as instruments or highly skilled graduates.”).
59 Heller & Eisenberg, supra note 1, at 698–99.
61 Id. at 2.
62 Id. at 1.
63 Id.
64 Id.
65 Id. (citing U.S. GOV'T ACCOUNTING OFFICE, REPORT TO CONGRESSIONAL COMMITTEES, TECHNOLOGY TRANSFER, ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES (May 7, 1998)).
Bayh-Dole, investments in research occurring at an academic or nonprofit institution would likely end in the federal government retaining the intellectual property rights. Without exclusive rights to the manufacture or sale of the resulting products, there was nothing to prevent competitors from free-riding on a company’s investment after a product was brought to market. This lack of incentive made industry reluctant to commercialize government-owned inventions.

Finally, Congress provided for academic of nonprofit institutions to retain property rights to inventions, with the purpose of promoting funding from interested industry research partners and ensuring commercialization of research inventions that federal funding supports. In 1980, Congress passed the Bayh-Dole Act in an effort to encourage the development and commercialization of inventions emerging from academic and nonprofit research institutions. Under the Bayh-Dole Act, universities, nonprofit research institutes, and small businesses could elect ownership of inventions made under federal funding. The Bayh-Dole Act provided for certainty of title to inventions made under federal funding, implementation of uniform patenting and licensing procedures, and the ability of universities to grant exclusive licenses. By encouraging universities and other nonprofit research institution to patent discoveries from research arising from federally-funded research and development, this policy benefited the public and the national economy by promoting innovation and accelerating the development and manufacture of new products within the United States.

B. The Response to Bayh-Dole

In response to the Bayh-Dole Act, major research universities and research institutions such as the National Institutes of Health created technology-transfer offices to promote and oversee the patenting of scientific research discoveries. In many cases, institutions that had not been actively patenting or seeking to commercialize inventions began to establish entirely new technology-transfer offices, consisting of consultants with legal, business, and scientific backgrounds. University technology-transfer offices perform a wide variety of functions including, patenting and licensing of inventions, building

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66 Id. at 2.
67 Id.
68 35 U.S.C. §§ 200-11, 301-07 (1994); see also COUNCIL ON GOVERNMENTAL RELATIONS, supra note 60, at 5.
69 Id.
70 See Heller & Eisenberg, supra note 1, at 698-99.
71 COUNCIL ON GOVERNMENTAL RELATIONS, supra note 60, at 2-3.
relationships with industry partners, and negotiating the exchange of research materials and research tools.\textsuperscript{72} In 1980, approximately twenty-five to thirty universities were actively engaged in patenting and licensing inventions, and it is estimated that there was approximately a ten-fold increase in the number of these institutions from 1980 to 1999.\textsuperscript{73}

The number of patents, licenses, and start-up companies coming out of university technology-transfer offices following the enactment of the Bayh-Dole Act continues to increase annually. Evidence of this is reflected in the fact that the membership of the Association of University Technology Managers (AUTM) increased from 691 in 1989 to 2,178 in 1999. In 1979, the year before passage of the Bayh-Dole Act, the Association counted only 113 members.\textsuperscript{74} The Bayh-Dole Act has also provided a strong incentive for university-industry research collaborations.\textsuperscript{75} "In 1997, federal agencies provided an estimated $14.3 billion or about 60% of total support for research performed at universities. Academic institutions provided $4.5 billion of their funds. State and local governments and nonprofit organizations each contributed $18.1 billion and industry $1.7 billion. Although the proportion of academic research and development expenditures funded by industry has risen steadily, it represents only a fraction (7%) of total academic research and development support."\textsuperscript{76}

A national survey that AUTM conducted reports that 70 percent of the active licenses of responding institutions are in the life sciences, most of which federal funding supports.\textsuperscript{77} The AUTM survey summarizes the increase in commercialization of inventions at academic institutions post-Bayh-Dole: (1) academic institutions were granted more than 8,000 U.S. patents between 1993 and 1997; (2) over 2,200 new companies have been formed since 1980 that were based on the licensing of an invention from an academic institution; (3) approximately thirty billion dollars of economic activity each year, which supports 250,000 jobs, can be attributed to the commercialization of new technologies from academic institutions; (4) more than one thousand products currently on the market are based on university licensed discoveries; and (5) technologies

\textsuperscript{72} Id. at 3.
\textsuperscript{73} Id. at 9.
\textsuperscript{74} Id. at 3; see also THE ASS’N OF UNIV. TECH. MANAGERS, SURVEYS – BAYH-DOLE ACT, FISCAL YEAR 1991–1995 AND SUBSEQUENT YEARS, available at http://www.autm.net/pubs/survey/facts.html [hereinafter AUTM SURVEYS].
\textsuperscript{75} COUNCIL ON GOVERNMENTAL RELATIONS, supra note 60, at 3.
\textsuperscript{76} Id. at 12 n.4.
\textsuperscript{77} AUTM SURVEYS, supra note 74, at Fiscal Year 1997.
licensed from academia have been instrumental in creating new industries, improving the productivity and competitiveness of companies, and creating new companies and jobs.\textsuperscript{78}

Post-Bayh-Dole, commercial biotechnology firms have carved out an area of specialized research and development somewhere between the basic scientific research traditionally within the purview of academic research and the targeted drug and medical-device development at the level of the large pharmaceutical companies.\textsuperscript{79} Biotechnology firms, for the most part, are for-profit, but they tend to have much closer contractual ties to nonprofit research institutions. Academic scientists have had a significant role in the founding of these companies, either moving out of academic employment or participating actively in both worlds.\textsuperscript{80} Between 25 and 40 percent of large pharmaceutical companies' sales are now reported as coming from drugs originated in the biotech sector.\textsuperscript{81}

Some "product" biotechnology companies have entered the industry as direct horizontal competitors to established firms, intending to realize profits by using their command of new techniques and insights from molecular biology to developing products that will be sold to end users. Other "tool" companies have inserted themselves into the industry value chain at the interface between academic research and the downstream for-profit pharmaceutical firms, with a business model based on licensing or selling leading edge knowledge, research tools, or intellectual property to companies focused on less science-intensive clinical development, manufacturing, and marketing. By taking over a certain amount of research activity from both upstream and downstream entities, these new entrants have forced some important adjustments in university-industry relations and ushered in a new "partnering" mode of research.\textsuperscript{82}

There has also been a trend toward privatization of research, in which research is primarily conducted in private research institutes, supported by private funding, or privately acquired through

\textsuperscript{78} Council on Governmental Relations, \textit{supra} note 60, at 9 (citing Press Release, The Ass'n of Univ. Tech. Managers (Dec. 17, 1998)).

\textsuperscript{79} Heller & Eisenberg, \textit{supra} note 1, at 698.


\textsuperscript{81} Cockburn, \textit{supra} note 52, at 7 (citing CMR Int'l, THE PHARMACEUTICAL INDUSTRY IN FIGURES (2000)).

\textsuperscript{82} Id.
intellectual property rights or licenses. This has removed many subsequent upstream inventions from the public domain. At the national level, industry support for research and development at universities represents less than 7 percent of the total funding of university-based research. While small compared to the 60 percent that federal agencies provide, this private investment in the creativity of universities, including professors, students, and staff, drives a form of technology transfer that is increasingly important to industry. Industrial investment is secure because it is based on the principles and provisions of the Bayh-Dole Act. The Bayh-Dole Act has created incentives for government, universities, and industry to work together in the commercialization of new technologies for the public benefit and has promoted a substantial increase in technology transfer from universities to industry and, ultimately, to the public.

Certainty of intellectual property rights to inventions made under federal funding also protects the right of scientists to pursue highly specialized research programs. Fundamental research is no longer passed directly into the public domain, where numerous researchers in diverse fields can use it as a building block. Instead, the Bayh-Dole Act requires disclosure of patentable inventions and provides incentive to universities and nonprofit research institutions to patent early and often. This has led to increased patenting of fundamental research, or "upstream" inventions, particularly in the area of biotechnology. These upstream inventions include drug development targets such as genes and proteins, molecular biology reagents, and experimental animal systems, which are frequently used as tools or building blocks for future discoveries. Increased patenting of these research tools serves to remove them from the public domain, where they were freely available to the scientific community. This trend has led scholars to question the potentially inhibiting effects of upstream patenting of research tools on downstream scientific research, such as targeted drug development and clinical research.

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83 Heller & Eisenberg, supra note 1, at 698–99 (noting that upstream research is increasingly private).
84 COUNCIL ON GOVERNMENTAL RELATIONS, supra note 60, at 3.
85 Id.
86 See id. at 9.
87 Id.
III. UPSTREAM PATENTING: DOES IT AFFECT NONPROFIT INSTITUTES AND INDUSTRY ALIKE?

A. "Working Solutions" for Surmounting the Barriers that Upstream Patenting Poses

Both the Walsh et al. and Straus studies report that researchers in the biomedical sciences have developed "working solutions" in response to restrictions that upstream patenting of research tools pose. These "working solutions" include traditional practices such as licensing, inventing around third-party patent claims, creating and using public databases, and challenging third-party patents in court. However, despite these practices that respect third-party patent rights, researchers also admit to ignoring patents, willfully infringing patents, and going offshore so as to avoid licensing patented research tools.  

Although nonobservance of intellectual property rights may be effective in some circumstances, downstream infringers face several types of risks, including detection, prosecution, and liability. Patent infringement may be very difficult to detect, especially in early research efforts that are never publicized or commercialized. Researchers may ignore patent rights at an early stage of their research and only seek to obtain a license once a discovery appears to be worth pursuing. Many researchers feel that research-tool patent claims are of debatable validity and willfully infringe, under the assumption that the claims will not hold up in court. In addition, university researchers routinely ignore patent rights under the assumption that they are covered by a "research exemption," although a legal-research exemption is quite narrow and likely applies to few, if any, of these researchers. Furthermore, even if infringement is detected, firms are typically reluctant to enforce their patent rights against nonprofit researcher-infringers because of low damage awards and bad publicity. Most university researchers want to maintain collaborations and good relationships with each other, and universities are not likely to enforce their rights. Moreover, the

88 Walsh et al., supra note 4, at 327–28.
90 Walsh et al., supra note 4, at 324.
91 See Moorcroft, supra note 89, at 75–79.
92 Madey v. Duke Univ., 413 F. Supp. 2d 601 (M.D.N.C. 2006) (holding that the exemptions are limited only to government directed use); see also Walsh et al., supra note 4, at 324, 335.
93 Walsh et al., supra note 4, at 326–27.
six-year statute of limitations may expire before infringement is detected.\textsuperscript{94} Lastly, patent holders are aware that, even if they bring a suit against an infringer, the infringer may not be found liable if the patent claims are held to be invalid or the research exemption is held to apply.\textsuperscript{95}

In addition to ignoring patents or willfully infringing, another "working solution" is to conduct the research outside of the United States, in order to use patented technologies without securing legal rights to them, thus avoiding licensing costs.\textsuperscript{96} This is similar to the practice of ignoring the patent altogether, except offshore use of the research tools is not illegal unless a product is developed, and the firm tries to import the product into the United States.

\textbf{B. Viable "Working Solutions" Vary Between Nonprofits Institutes and For-Profit Firms}

The tragedy of the anticommons is viewed as raising the greatest potential impediments to researchers at nonprofit institutes and small biotechnology firms.\textsuperscript{97} This is because of the low level of funding and lack of sophistication and support of legal counsel, as compared with that available to researchers in large for-profit firms. According to the previously mentioned empirical studies, upstream patenting of research tools does not create insurmountable barriers to downstream research. However, if these barriers actually do exist and are overcome only through the aforementioned "working solutions," it is likely that the availability and effectiveness of these solutions will vary between researchers at nonprofit institutes and small biotechnology firms, compared with large for-profit firms.

Walsh et al. reported that third-party patent concerns do not preempt research projects in industry. In regard to licensing, Walsh et al. reported that the total royalty payments for input technologies associated with drug development range from 1 to 5 percent of sales, and are higher for exclusive licenses, occasionally reaching 10 percent or higher.\textsuperscript{98} Firms may license research tools, such as a gene for screening or microarray analysis for a set fee ranging from ten thousand to twenty thousand dollars.\textsuperscript{99} Fees for access to genomic databases may be in the range of tens of millions of dollars, and

\textsuperscript{94} Id. at 328.
\textsuperscript{95} See Moorcroft, supra note 89, at 78.
\textsuperscript{96} Walsh et al., supra note 4, at 328.
\textsuperscript{97} Heller & Eisenberg, supra note 1, at 698–99.
\textsuperscript{98} Walsh et al., supra note 4, at 300.
\textsuperscript{99} Id.
occasionally are over one hundred million dollars. Although manageable by large pharmaceutical firms, and even established biotechnology firms, licensing fees of this magnitude are prohibitive to researchers at small start-up companies and nonprofit research institutions. Some firms offer discounted licensing fees to university researchers, but this does not appear to be a common practice across the industry. Additional, non-monetary costs for academic researchers are publication restrictions that may be attached to licensing agreements or collaborations with for-profit firms.

While large firms do not usually pursue projects that are commercially less viable, they state that a plethora of drug targets and diseases insure that lucrative avenues for commercial research are not lacking. Again, these are not options available to nonprofit researchers confronting patent thickets and royalty stacking or to those searching for a cure for an orphan disease. Likewise, conducting research in overseas labs is a solution most likely to be employed by for-profit firms, rather than nonprofit institutes. However, individual researchers may choose to conduct their research outside of the United States in order to avoid patented or illegal research tools, as in the case of stem cell research.

This does not mean that nonprofit researchers do not pursue their own solutions. The practice of simply ignoring third-party patent rights, or willfully infringing and claiming the shield of a research exemption, are common practices in academic and nonprofit research. Researchers view the risks associated with detection, prosecution, and liability as minimal. According to Walsh et al., downstream research infringers at universities are largely left alone so long as they are engaged in noncommercial or precommercial research, with the exception of clinical research using patented diagnostic tests. So long as the researchers are not viewed as competitors, large for-profit firms feel that the negative publicity and minimal damages, or lack of damages available, outweighs any advantage in asserting their rights against university researchers. Some firms will send cease-and-desist letters to nonprofit infringers, but the action usually ends there.

100 Id. at 302.
101 Id. at 302 n.25.
102 Id. at 304-05.
103 Id. at 328.
104 See Moorcroft, supra note 89, at 77-78.
105 Walsh et al., supra note 4, at 317-18.
107 Id.
IV. POST-BAYH-DOLE NONPROFIT COMMERCIALIZATION

A. Nonprofit Institutions Emerging as Industrial Competitors

Post-Bayh-Dole

Jennifer Henderson and John Smith at the Center for Integration of Medicine and Innovative Technology argue that commercialization of nonprofit research is an implied mandate of the Bayh-Dole Act. According to Henderson and Smith:

[t]he combination of Bayh-Dole's, (1) stated goal of increased public access to federally-funded research, (2) provision for the transfer of intellectual property to grantees/contractors, and (3) identification of the crucial role of industry in transforming ideas into available products and services, create an implied duty on the part of grant recipients and government contractors to partner with industry to commercialize promising federally-funded research. By its nature, this implied duty transforms the academia-industry relationship from the traditional view of disparate entities into a Congressionally-mandated partnership, intended to advance technology and benefit the public.108

Since the enactment of Bayh-Dole, universities have become major players in patenting biotechnology and generating start-up companies.109 By acquiring property rights in inventions resulting from federally-funded research, universities and nonprofit institutes acquire bargaining power and are able to negotiate with for-profit firms for the commercialization of these inventions, resulting in revenue and increased research funding for the nonprofits. Although the number of patents applied for by universities remains small, compared with large firms, the numbers have risen sharply since Bayh-Dole was enacted in 1980. Moreover, university-held patents tend to concentrate in a few utility classes, especially those related to life sciences and biotechnology.110 Post-Bayh-Dole, there has been an eight-fold increase in the number of universities transferring patent rights to the private sector.111 In recent years, universities have demonstrated that their technology-transfer programs are effective in licensing inventions from federally-funded research to commercial

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108 Henderson & Smith, supra note 3.
109 Walsh et al., supra note 4, at 295.
110 Id.
111 Henderson & Smith, supra note 3, at 6; see also AUTM SURVEYS, supra note 74.
partners.112 In 1999, approximately four thousand new licensing agreements were executed, and an 11 percent increase was recorded in 2000.113 As a result, over one thousand products have been patented and successfully introduced into public use.114

In addition, patent rights form the foundation of many biotechnology firms and are responsible for a surge in biotechnology start-up activity over last two decades.115 Approximately 450 new companies and start-ups were founded in 2000, with approximately 2,200 new companies formed since 1980.116 Post-Bayh-Dole, more than 1,100 companies have been founded based on NIH and university research.117 These technology partnerships and the patents on which they are based are particularly important to small biotechnology companies, which focus their research on breakthrough technologies that arise from basic biomedical research. Such companies must have strong patent protection to justify the risk of investing in early-stage, unproven ideas. With no revenue from product sales to fund research, most of these firms depend on venture capital and public market investors. Altogether, technology transfer under Bayh-Dole activities has generated substantial economic activity, and has added an estimated forty billion dollars into the U.S. economy.118

B. Implications of Non-Profit Commercialization for Downstream “Working Solutions”

Although it remains unclear whether upstream patenting impedes downstream research in the biomedical sciences, it is possible to speculate on how increasing commercialization of federally-funded research under Bayh-Dole may affect the “working solutions” available to nonprofit and academic researchers. Currently, nonprofit researchers who ignore or willfully infringe third-party patents rely on their status as non-competitors with for-profit firms. However, the traditional view of nonprofits being engaged in noncommercial or precommercial research no longer applies post-Bayh-Dole. Nonprofit and academic researchers whose research is commercialized or who

112 See Council on Governmental Relations, supra note 60.
113 See AUTM Surveys, supra note 74.
114 Council on Governmental Relations, supra note 60 (citing AUTM Surveys, supra note 74).
115 Walsh et al., supra note 4, at 287.
116 See AUTM Surveys, supra note 74.
118 See Henderson & Smith, supra note 3, at 7.
enter into partnerships with for-profit firms may find that their for-profit counterparts now regard them as indirect, or even direct, competitors. This has led to a growing "push back" from industry in the form of challenges to patents that universities hold.\(^{119}\)

What effect will this have on the "working solutions" nonprofit and academic researches employ to surmount upstream patenting barriers? If for-profit firms and other nonprofits or universities bent on commercialization choose to defend their patent rights against nonprofit competitors, the risks of infringement associated with detection, prosecution, and liability increase. These researchers may not be able to rely on ignorance of upstream patents or the research exemption to protect themselves from infringement liabilities. According to Walsh et al., infringement is the most common "working solution" in the nonprofit sector.\(^{120}\) If this solution is no longer viable, nonprofit researchers will have to find alternative working solutions or face the impediments that upstream research-tool patenting raises.

The alternative "working solutions" that for-profit firms routinely use are also unlikely to be available to nonprofit researchers. Although nonprofit researchers may benefit from increased funds and support of legal counsel through privatization and partnerships with industry, it is unlikely that commercialization will provide the level of funding required for nonprofit researchers to pay the exorbitant licensing fees that large firms charge their competitors. Thus, if discounted licensing fees are no longer available to nonprofit researchers, the cost of obtaining essential licenses may be prohibitive. Likewise, while partnerships with for-profit firms may make conducting research in overseas labs a feasible solution for some, it is not likely to become common practice for academics who have teaching and administrative responsibilities at their home institutions.

\[C. \text{Responding to Upstream Patenting in the Non-Profit Commercial Setting}\]

The commercialization of nonprofit research may force universities and nonprofit research institutes to address the tragedy of the anticommons through policy initiatives or by developing new "working solutions" that do not depend upon their traditional


\(^{120}\) Walsh et al., supra note 4, at 324.
non-competitive, nonprofit status. Unless these institutions can provide their researchers monetary and legal support at a level equivalent to what is available to industrial researchers, they will have adopt entirely new strategies for surmounting the barriers that upstream patenting has raised. The greatest resource available to nonprofits and universities is the large number of similarly placed institutions and their relationship with government funding agencies. These institutions could band together as a whole to support non-commercialized research and the establishment and enforcement of policy and rules governing industry relationships and intellectual property rights.  

By banding together to create policy and set appropriate limits on industry relations that are vigorously enforced, nonprofit and academic researchers may be able to establish a position of power from which to bargain for licensing rights and access to patented research tools. Universities could agree not to grant exclusive licenses or other restrictions on upstream discoveries with other researchers. Universities and nonprofits could review all industry contracts and reject those that would require excessive secrecy, inhibit discussion, or permit the corporate sponsor undue influence over the research at issue. Likewise, Congress could modify existing legislation to deny universities the right to grant exclusive licenses on patented technology developed with the support of federal funds. Increased government funding could prevent excessive reliance on industry support, and an adequate and stable level of support could serve to protect academic values and limit commercialization. Finally, universities and nonprofits could step back from the brink of commercialism and retain their non-competitive status.

Patent pools and public domain access offer two possible mechanisms for dealing with upstream patenting across the biotechnology industry as a whole. A patent pool is an agreement between patent owners to cross-license their patent rights to each other or third parties. Members of the patent pool may receive a license without paying a royalty or may pay a set fee per patent claim. Third parties who are not members may pay a licensing fee

122 Id. at 143.
123 Id. at 142.
124 Id. at 196.
125 UNITED STATES PATENT AND TRADEMARK OFFICE, PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS (2000).
to secure the right to use patented technology. Currently, public domain databases are growing, and the registration of genetic sequences with public databases has become commonplace. In the field of bioinformatics, academic researchers have embraced the aggressive use of public domain and open source licensing.\textsuperscript{127} In part, this trend toward open domain access may result from the large cost to all researchers in bioinformatics from fragmentation of data sources and restrictions on access, such that availability of the whole outweighs any partial property rights.\textsuperscript{128} It is possible that researchers in biotechnology will also support patent pools or public domain access to research tools if the potential barriers to research that the tragedy of the anticommons describes become a reality and begin to impact downstream research. However, if these barriers disproportionately affect nonprofit and academic researchers, industry may not willingly embrace patent pools or the public domain. In this case, it will be critical for nonprofit and academic researchers to act in concert to create new “working solutions.”

Lastly, if the benefits of commercialization outweigh the disadvantages for nonprofit and university researchers competing in the biotechnology field, these institutes may decide to enter fully into their new role as competitors in the biotechnology marketplace. Nonprofits and university technology-transfer departments choosing to strengthen their position as competitors need to seek additional legal support and education for their researchers. This includes due diligence in the form of patent searches and mandatory licensing, as opposed to intentional patent infringement or infringement resulting from willful blindness on the part of researchers. Likewise, nonprofits choosing this path must be prepared to rigorously defend their own intellectual property rights. If nonprofits and universities choose to become competitors in the biotechnology marketplace, they must be willing to accept the legal consequences in the form of more frequent litigation and challenges to the validity of their patents. The increased legal and administrative costs associated with this path will not be insignificant. However, if nonprofits and universities want to benefit economically from patenting under Bayh-Dole, they must be prepared to reinvest a portion of their profits to support this goal. With sufficient legal support and education, nonprofits and universities may be able to meet and overcome the same barriers that upstream patenting poses to their competitors.

\textsuperscript{127} Cockburn, supra note 52, at 16.
\textsuperscript{128} Id.
CONCLUSION

It is unclear whether upstream research-tool patenting impedes downstream research in the biomedical sciences or whether the "working solutions" that researchers have developed surmount these impediments. If the working solutions are all that hold the tragedy of the anticommons at bay, increasing commercialization of nonprofit research post-Bayh-Dole may affect the "working solutions" available to nonprofit and academic researchers. When nonprofit researchers become viewed as commercial competitors in the field of biotechnology, they may not be able to take advantage of their "protected" status as non-competitors. If infringement, the common "working solution" in the nonprofit sector, becomes unviable, the costs and barriers potentially associated with upstream research-tool patenting may begin to impede downstream nonprofit research, making Bayh-Dole a "catch-22" scenario and giving truth to the tragedy of the anticommons. This may force universities and nonprofit research institutes to band together to address the tragedy of the anticommons through policy initiatives or by developing new "working solutions" that do not depend upon their traditional non-competitive, nonprofit status.

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