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**UNIVERSITY SCIENCE RESEARCH FUNDING:
PRIVATIZING POLICY AND PRACTICE**

by

Risa L. Lieberwitz*

Associate Professor of Labor Law, Cornell University School of Industrial and Labor Relations; associated faculty, Cornell Law School. This paper was prepared for the Cornell Higher Education Research Institute conference on “Science and the University,” May 20-21, 2003. I would like to thank Liana Fox for her able research assistance.

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I. INTRODUCTION

Contemporary discussions of the university often seek to balance its traditional public role with the increasing expansion of university-industry relationships. The growth of university commercial activities and “alliances” with corporations are defended as a necessity for financing costly research programs that will benefit the public, particularly in the life sciences. This perspective reflects two underlying beliefs: first, that decreases in public funding for costly scientific research programs require universities to engage in increased market activities and to seek more private funding, including funding through contractual arrangements with industry; and secondly, that close relationships with industry “partners” will not alter the essence of the university’s identity.

The endorsement of the university’s public role as an independent research institution, viewed side by side with the endorsement of university-industry partnerships, raises questions about the status of university independence in the context of its current policies and practices. These questions will be the focus of this paper, which will address issues of science research funding in relation to the university’s institutional identity and the professional identity of university faculty. At the broadest level, the paper explores the question of whether increasingly close ties between universities and industry have compromised or threaten to compromise the values that are fundamental to the university’s institutional identity and social role. This question will be addressed by focusing on university research in the life sciences. The choice of the life sciences is made for several reasons: life sciences research has emerged most recently as the university research program with large needs for financial support and with great

potential for attracting funding from industry; changes in political, legislative, and judicial forums have created social and economic conditions that encourage and facilitate closer relations between universities and industry in the life sciences; and universities have responded to these developments by broadening and deepening their relations with industry through university patenting and licensing practices and through expanded corporate financing of university science programs. The paper will explore the issue of whether these changes in policies and practices are in tension with the university's identity as an independent institution with a public mission. In addressing this issue, the paper will raise questions about the university's options for action; that is, whether potential or real conflicts of interest can be adequately addressed through specific legal reforms and narrow changes in university practices or whether the university faces fundamental threats to its institutional identity that call for fundamental systemic responses.

Part II of the paper describes the developments in university science research and in the political and judicial arenas that cumulatively created the foundation for the increased privatization and commercialization of the university. This discussion will focus on the life sciences, including the expansion and commercialization of the fields of molecular biology and biotechnology. The political and judicial developments that promoted and facilitated the market activity of the life sciences will be addressed, including the Bayh-Dole Act of 1980, the creation of the Federal Circuit Court of Appeals to decide appeals in patent cases, and judicial decisions concerning patents in the life sciences. Part III of the paper will describe the changes in university policies and practices that were made in response to these advances in life science research and to the new legislative and judicial

developments. This description will include the growth of university technology transfer activities and expanded university-industry relations.

Part IV will present an analysis and critique of these developments, comparing values of academic freedom and independence in the traditional culture of science with the values of the market, as represented in the new university practices to promote commercialization of university research through patents, licenses, and closer relations with industry partners. This section of the paper will also address the implications of these market activities for the identity of university science, including research agenda, collegial relations, socialization of graduate students, and the identity of university scientists in relation to the market and the broader public. Even more broadly, this critique will address the implications for the university's identity, including its independence from financial supporters, the university's relation to the public interest, and the university's ability to maintain a unique identity that can be distinguished from commercial business. Finally, Part V of the paper will make recommendations for reform, addressing the question of the adequacy of narrow reforms in law and policy to respond to major changes in university practices and identity. In making these recommendations, the paper will consider reforms in university science research within the broader context of increased trends of the corporatization of the university.

II. SCIENCE AND PUBLIC POLICY

A. The Culture of University Science

The culture of university science research has been the subject of close study by sociologists, including Robert Merton and Bernard Barber, who described the unusual

community created by academic scientists.¹ The practices of university scientists traditionally have reflected deeply held values that promote openness and sharing of research.² The university science culture emphasizes full disclosure of research methods and results through scholarly publications. These values of “communism” or “communalism” have been fundamental to the advancement of science, enabling scientists to engage in research building upon the foundations laid by their colleagues.³ A closely related value is “disinterestedness,” which equates scientists’ self-interest with the public interest, to ensure that research contributes the public good of expanding knowledge rather than to a narrower personal interest.⁴ The independence of scientists is required to enable them to choose their research agendas and to freely engage in debate and critique.⁵

Under traditional communal norms, the drive for individual recognition has been harmonized with communal values, based on a shared belief by academic scientists in the role of science in society. This shared view of the public interest has not required a suppression of competition among scientists, who are known for their fierce competitiveness to make discoveries ahead of their colleagues.⁶ The structure of the university science reward system reinforces the role of scientists in contributing to the

¹ See, BENJAMIN BARBER, *SCIENCE AND THE SOCIAL ORDER* (1953); ROBERT K. MERTON, *THE SOCIOLOGY OF SCIENCE* (1973). For excellent discussions of the traditional norms of science, including Barber’s and Merton’s work, see, Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L. J. 177, 181-84 (1987); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW U. L. REV. 77, 88-94 (1999).

² Eisenberg, *supra* note 1, at 182; Rai, *supra* note 1, at 89-90.

³ Eisenberg, *supra* note 1, at 183; Rai, *supra* note 1, at 90.

⁴ Eisenberg, *supra* note 1, at 183-84; Rai, *supra* note 1, at 91, n.67.

⁵ Rai, *supra* note 1, at 91.

⁶ Rai, *supra* note 1, at 92.

public interest while also gaining individual recognition.⁷ As the first to publish significant results from a course of research, an individual scientist achieves public recognition of his/her excellent research and gains public respect and status.⁸ This recognition and respect is enhanced through full disclosure of research methods and data, which permits other scientists to confirm the results through replication of the research. The full access to research data ensures that the science community can protect its standards of excellence and maintain the integrity of science research, which depends on scientists' independence in shaping and implementing their research agendas, allowing them to "go where the science leads" rather than searching for or shaping results that will serve any individual or third party interest.

These values of the academic scientific research community are consistent with the traditional values of academic freedom long accepted in the broader university community.⁹ With the founding of the American Association of University Professors (AAUP) in 1915, faculty in higher education demanded professional academic freedom to engage in teaching and research that was independent from influence or pressure by third parties, including governments, boards of trustees, or corporate financial donors.¹⁰ Such independence was identified as essential to fulfilling the goal of the university to serve the public good through teaching and research based on the search for truth and the expansion of knowledge, free from conflicts of interest. Academic freedom of individual faculty includes the right to choose a research agenda, to pursue research on controversial

⁷ Eisenberg, *supra* note 1, at 183-84.

⁸ *Id.* at 183.

⁹ Rai, *supra* note 1, at 92-93.

¹⁰ Risa L. Lieberwitz, *The Corporatization of the University: Distance Learning at the Cost of Academic Freedom?*, 12 BOSTON U. PUB. INT. L. J. 73, 80-85 (2002).

matters, to determine course content in teaching, and to express public opinions on extramural matters. Professional academic freedom is also a collective right, including the autonomy of the profession to engage in self-governance through the process of peer review, in which the standards of the professional discipline are applied to judge the merit of the academic work of one's colleagues.¹¹

In the decades following the creation of the AAUP, the values of academic freedom have been deeply embedded in higher education. The 1940 AAUP Statement of Principles on Academic Freedom and Tenure was endorsed by the Association of American Colleges and over subsequent decades by more than 150 academic professional organizations and universities.¹² Consistent with the original AAUP 1915 Declaration of Principles, the 1940 Statement of Principles on Academic Freedom and Tenure justifies the right of academic freedom on the basis of the contribution of higher education to the “common good,” rather than on the basis of individual or institutional interests.¹³ To make this contribution, faculty need academic freedom, which is essential to the “advancement of truth” in research and freedom in teaching and learning.¹⁴

¹¹ *Id.*

¹² ACADEMIC FREEDOM AND TENURE: A HANDBOOK OF THE AMERICAN ASSOCIATION OF UNIVERSITY PROFESSORS 157 (Louis Joughin, ed., 1967); AAUP POLICY DOCUMENTS & REPORTS 1 (1995); *see generally*, Walter P. Metzger, *The 1940 Statement of Principles on Academic Freedom and Tenure*, 53 LAW & CONTEMP. PROBS. 2 (1990). The AAUP has continued to issue policy statements, investigate alleged breaches of academic freedom in higher education, and more recently, represent university and college faculty in collective bargaining. *See*, AAUP POLICY DOCUMENTS & REPORTS 215 (1995).

¹³ *1940 Statement of Principles on Academic Freedom and Tenure*, AAUP POLICY DOCUMENTS & REPORTS 3 (1995).

¹⁴ *Id.*

B. Changes in University Science Research

Though communal values have been deeply internalized by university scientists, key developments in the life sciences and in politics, beginning in the 1970s, have converged to promote values and practices that are in tension with the traditional culture of academic science. University-industry ties, which had already been developed in such fields as chemistry, engineering, and geology, did not exist in the field of biology until the mid-1970s.¹⁵ Even in fields outside of biology, the relationships between universities and industry had waned in the post-World War II decades as federal funding expanded to constitute more than seventy percent of university research funding in the 1960s.¹⁶ The discovery, in 1973, of recombinant DNA (rDNA) technology, reinvigorated university-industry ties.¹⁷ Professor Sheldon Krimsky describes this event: “In that monumental discovery, the biological sciences had made the transition from an analytic to a synthetic science....The introduction of rDNA technology established the absolute fungibility of genes, opening up possibilities for synthesizing new organisms and establishing revolutionary methods for mass producing biological products. The commercial opportunities of this discovery were recognized immediately by scientists.”¹⁸ Professor Martin Kenney describes this invention as “the single pivotal event in the transformation of the ‘basic’ science of molecular biology into an industry.”¹⁹ With the subsequent growth in the study of genetics, basic research in molecular biology could be envisioned

¹⁵ Sheldon Krimsky, *The Profit of Scientific Discovery and Its Normative Implications*, 75 CHI.-KENT L. REV. 15, 16-17 (1999).

¹⁶ *Id.*; MARTIN KENNEY, BIOTECHNOLOGY: THE UNIVERSITY-INDUSTRIAL COMPLEX 13-15, 32-33 (1986).

¹⁷ Krimsky, *supra* note 15, at 17.

¹⁸ *Id.* at 17-18.

¹⁹ KENNEY, *supra* note 16, at 23.

as the foundation for applied research. For-profit corporations in agribusiness, chemicals and pharmaceuticals, seeing the commercial potential of university research in molecular biology, became interested in pursuing close ties with university scientists.²⁰

There are several aspects of biotechnology research that make it of particular significance in the discussion about privatization and commercialization of academic research. First, the timing of privatization trends in public policy in the 1980s coincided with the explosion of academic research in the life sciences, including genetics and biotechnology. Further, as the sole location of early biotechnology research, the university was of particular interest to businesses, which was eager to establish university-industry relationships that would enable them to benefit commercially from the academic research.²¹ The continued growth of university-industry relationships in the life sciences shows that academic biologic research has a sustained commercial appeal to industry.²²

As will be discussed *infra*, the privatization trends of the 1980s have encouraged universities to engage actively in patent and licensing practices with regard to both publicly and privately funded research. These trends have been especially important in biomedical research, where patents play a greater role than in other fields, both in the university and in industry.²³ Close to half of university patent income comes from

²⁰ *Id.* at 6,12-13, 27.

²¹ *Id.* at 4.

²² David Blumenthal, Nancyanne Causino, Eric Campbell, and Karen Seashore Louis, *Relationship Between Academic Institutions and Industry in the Life Sciences – an Industry Survey*, 334 NEW ENG. J. MED. 368, 371-72 (1996).

²³ Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 700 (1998); Rai, *supra* note 1, at n.182.

biomedical patents.²⁴ Contributing to the profusion of patents in biomedical research is the blurred distinction between basic and applied research in the biomedical field. While the line between basic and applied research is often unclear in any field, the distinction is made more difficult in the biomedical field as the potential commercial value of basic research becomes clearer at an earlier stage and as the time period between basic research and its application is shortened.²⁵ The cumulative result of the privatization trends and the narrowing of the basic/applied research distinction has been a proliferation of patents and licenses of biomedical research, including patents on basic research tools, and a trend of increased industry financial “investment” in university research programs.

C. Political and Legal Changes

1. Generally

The 1980s was also a crucial period for changes in public policy in the United States, with particular emphasis on privatization of governmental functions through measures such as contracting out of government services.²⁶ Three trends during this period demonstrate the effects of this privatization agenda on science research in the universities. First, though federal funds from agencies such as the National Institutes of Health (NIH) continued to comprise the greatest percentage of funding for university science research programs, Congressional appropriations for research funding began to

²⁴ Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 91 AMER. SCIENTIST 52, 54 (Jan.-Feb. 2003).

²⁵ KENNEY, *supra* note 16, at 106; Rai, *supra* note 1, at n.1; Eisenberg, *supra* note 1, at 196, n.1 (defining “basic research” as “‘pure’ research directed solely toward expanding human knowledge, as opposed to ‘applied’ research directed toward solving practical problems,” and noting that “whatever the validity this dichotomy may have in other contexts, it is difficult to maintain in the context of contemporary biotechnology research.”)

²⁶ KENNEY, *supra* note 16, at 28-29.

drop in the 1980s.²⁷ Second, public policy created by Congress and by the judiciary encouraged patenting and licensing activities by universities. With the enactment of the 1980 Patent & Trademark Act Amendments,²⁸ commonly known as the Bayh-Dole Act, Congress authorized and encouraged universities to apply for patents on results of federally funded research. Prior to 1980, the results of federally funded research projects could not be patented by the inventor, but instead remained part of the public domain. With Bayh-Dole, universities' attention was now shifted to marketing their patented products to industry licensees. Shortly after passing the Bayh-Dole Act, Congress created the Federal Circuit Court of Appeals, which exercises exclusive jurisdiction over appeals of patent cases.²⁹ The Federal Circuit's pro-patent interpretation of the patent laws, together with the Bayh-Dole Act, has supported the increased patent activity by universities of both publicly and privately funded inventions.³⁰ Third, the 1980s showed an upward trend in direct corporate financing of university research programs, increasing by 93 percent between 1980 and 1984.³¹ In addition to private consulting arrangements with faculty, corporate funding has financed individual faculty members' research through directed or undirected corporate contributions, contract research, privately funded university research centers, or even large long-term contracts for corporate support of entire university departments or research groups.³² Universities will generally retain patent rights to inventions developed with corporate funds, with either exclusive or non-exclusive licensing rights to the corporations to use the patents.

²⁷ *Id.*; Eisenberg, *supra* note 1, at n.2.

²⁸ 35 U.S.C. Secs. 200-212. *See*, Eisenberg, *supra* note 1, at 196.

²⁹ KENNETH J. BURCHFIEL, BIOTECHNOLOGY AND THE FEDERAL CIRCUIT 5-6.

³⁰ Rai, *supra* note 1, at 100-09.

³¹ Eisenberg, *supra* note 1, at n.2.

³² KENNEY, *supra* note 16, at 36-72.

Though these privatization trends are listed separately, they should be analyzed as interacting developments. As public funding is tightened, universities and faculty become anxious to locate private sources of research funding, including the “deep pockets” of industry. Legislation, such as the Bayh-Dole Act, which encourages the use of public funds to promote market activities, reinforces the relationship between universities and private commercial business activities. Increased university and faculty activity in the market enhances the possibility for closer university-industry relationships through exchanges of corporate financing for licensing rights to patents and for preferred access to faculty and their research. Pro-patent judicial doctrine in the Federal Circuit Court of Appeals provides further support for privatizing academic research results through patents and licensing activities.

The next two subsections of this paper will discuss in more detail the Bayh-Dole Act and judicial developments broadening the use of patents in the life sciences. This discussion will provide the context for Part III of the paper, analyzing the changes in university practices adopted in response to the privatization trends in federal public policy.

2. The Bayh-Dole Act

Though policies favoring privatization are often justified as a means of restricting “big government,” some privatization policies simply alter the distribution of government largesse by providing public subsidies to private businesses through government contracts and tax benefits. The Bayh-Dole Act created a public subsidy for businesses by privatizing federally funded research results and providing a competitive advantage to American businesses in their commercialization of university science research. Prior to

the Bayh-Dole Act, federal law granted the government title to inventions developed with federal funds, a policy that placed these inventions in the public domain. The government agency could choose to dedicate the invention to the public domain by publishing the results without obtaining a patent or by providing nonexclusive licenses to private parties seeking to use a government-owned patent.³³ The Bayh-Dole Act implemented a major change in this policy by authorizing and encouraging universities, other nonprofit organizations, and small businesses to apply for patents on research results that had been funded in whole or in part with federal funds. Where the federal fund recipient chooses to apply for a patent, the federal funding agency retains a nonexclusive license to use the publicly funded invention.³⁴ The Bayh-Dole Act was soon amended to expand patenting rights to all businesses receiving federal research funds, regardless of the size of the business.³⁵ The policy favoring privatization was also extended by the Stevenson-Wydler Technology Innovation Act of 1980³⁶ to technological research conducted by federal agencies. This legislation directs federal agencies to “strive where appropriate” to transfer such technology to state or local governments or to the private sector.³⁷ As amended by the Federal Technology Transfer Act of 1986,³⁸ the Stevenson-Wydler Act also authorizes government-operated laboratories to enter into

³³ Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1675-76 (1996); Rai, *supra* note 1, at n.113. In some agencies, a university or other government contractor could petition the federal agency to shift title from the government to the contractor. Eisenberg, *supra* note 33, at 1683-84, 1691-92.

³⁴ Eisenberg, *supra* note 1, at 196.

³⁵ The extension of the Act to large business was done first by a Presidential Memorandum in 1983 and then by Congress in a 1984 amendment to the Bayh-Dole Act. Eisenberg, *supra* note 33 at 1694-95, n.180.

³⁶ 15 U.S.C. sec. 3710(a)(b).

³⁷ *Id.* Eisenberg, *supra* note 33 at 1705-06.

³⁸ 15 U.S.C. sec. 3710a(a)(1), b(2)-(3), c.

cooperative research and development agreements with industry, including assignment of patents on all inventions to the industry collaborator, subject to a nonexclusive, royalty free license to the government.³⁹

The Bayh-Dole Act shifts the presumption of ownership of federally funded inventions from title in the government to title in the recipient of the federal funds. Under this statutory presumption, the federal agency can retain title to the invention only by demonstrating “exceptional circumstances” that support a determination that this will “better promote the policy and objectives” of the Act.⁴⁰ This change reflects a shift away from the priority of using public funding to expand the public domain and towards an emphasis on exclusive private control of federally funded research. Congress justified this shift as a means of promoting the commercialization of the inventions developed through publicly funded research programs, with particular emphasis on promoting the role of small business in the United States and the collaboration between universities and businesses.⁴¹ Though federally funded inventions had been accessible to commercial businesses prior to 1980 as part of the public domain, Congress concluded that privatization of federally funded inventions was needed to encourage greater commercial exploitation of the research discoveries. Congress reasoned that if a commercial businesses had exclusive rights to a federally funded invention, as either patent-owner or

³⁹ Eisenberg, *supra* note 33, at 1707-08.

⁴⁰ 35 U.S.C. sec. 202. *See*, Rai, *supra* note 1, at 147-48. The Bayh-Dole Act also gives federal agencies “march-in rights” to require the government contractor to issue licenses on a patent when needed to “achieve practical application” of the invention. 35 U.S.C. sec. 203(a). Federal agencies rarely, if ever, exercise these march-in rights. Peter Mikhail, *Hopkins v. CellPro: An Illustration that Patenting and Exclusive Licensing of Fundamental Science is Not Always in the Public Interest*, 13 HARV. J. LAW & TECH. 375, 382 (2000).

⁴¹ 35 U.S.C. sec. 200. *See*, Rai & Eisenberg, *supra* note 24, at 54.

as licensee of a university-owned patent, the business would be more willing to invest the large amounts of research and development (R&D) funds needed to develop a marketable product.⁴² Permitting the government contractor to patent the federally funded research would also avoid the bureaucratic complexities of navigating among twenty-six different federal agency regulations in the process of applying for licensing rights.⁴³

The Bayh-Dole Act, thus, promoted commercial exploitation of federally funded inventions by providing businesses with competitive advantages as either patent-owners or exclusive licensees of university-owned patents. By extending the Bayh-Dole Act to provide patenting rights to large businesses, Congress weakened the legislative rationale of promoting small business and reinforced the primary emphasis on the goal of commercializing publicly funded inventions. The Act also addressed Congress's fears that American businesses were losing their competitive position in international markets by providing United States businesses with advantages over non-U.S. businesses⁴⁴ in two ways. First, a funding agreement between a contractor and a federal agency may withhold the right to retain title to an invention from non-U.S. contractors.⁴⁵ Additionally, private patent-holders to federally funded inventions must give preference

⁴² Eisenberg, *supra* note 33, at 1698-99.

⁴³ *Id.* at 1663-64, 1676; Eisenberg, *supra* note 1, at 181-82; Mikhail, *supra* note 40, at 378;

⁴⁴ Joshua A. Newberg & Richard L. Dunn, *Keeping Secrets in the Campus Lab: Law, Values, and Rules of Engagement for Industry-University R&D Partnerships*, 39 AM. BUS. L. J. 187, 192-93 (2002).

⁴⁵ 35 U.S.C. sec. 202.

on exclusive licenses to businesses that will use the license in manufacturing done in the United States.⁴⁶

3. *Judicial Expansion of Patents*

Almost simultaneously with the enactment of the Bayh-Dole Act, the United States Supreme Court decided the case of *Diamond v. Chakrabarty*,⁴⁷ which greatly expanded the scope of patents that could be obtained in the emerging field of molecular biology. In *Chakrabarty*, the Court established that life forms can be patented, holding that a genetically engineered bacterium that degraded crude oil was patentable subject matter. The Court agreed that “products of nature, whether living or not” are not patentable, but concluded that “human-made inventions,” which could include living materials, may be patented.⁴⁸ Congress intended the scope of patenting to “include anything under the sun that is made by man.”⁴⁹ With this decision, the Court expanded the potential impact of the Bayh-Dole Act, by opening the door to patent applications for the many research results from university laboratories and business R&D departments conducting research in fields such as genetics.⁵⁰

Following the Supreme Court’s expansion of the scope of patents in the field of the life sciences, it was now left to the lower federal courts to interpret *Chakrabarty*. The structure of the federal courts considering patent issues changed significantly at this time with Congress’s creation, in 1982, of the Federal Circuit Court of Appeals, with exclusive

⁴⁶ 35 U.S.C. sec. 204. See, Kenneth Sutherland Dueker, *Biobusiness on Campus: Commercialization of University-Developed Biomedical Technologies*, 52 FOOD DRUG L. J. 453, 463 (1997).

⁴⁷ 447 U.S. 303 (1980).

⁴⁸ *Id.* at 313.

⁴⁹ *Id.* at 309, *quoting*, Congressional Committee Reports from the 1952 patent law recodification.

⁵⁰ Rai, *supra* note 1, at 102.

jurisdiction over federal patent appeals at the federal circuit court level. As the only federal circuit court of appeals to hear patent appeals from the federal district courts, the Federal Circuit provides a uniform interpretation of the patent law, replacing the diverse doctrine that had resulted from the former system of decision-making by the multiple Circuit Courts of Appeals, some of which were viewed as “pro-patent” and others as “anti-patent.”⁵¹

The consolidation of all federal patent appeals in a single tribunal gave the Federal Circuit broad power to set national policy through its interpretations of federal patent legislation. As demonstrated by Professor Arti Kaur Rai, “[t]he Federal Circuit has...strengthened patent rights quite significantly”⁵² through its interpretation of the patent law requirements, most notably, the requirements that a patent application covers patentable subject matter, demonstrates the utility of the invention, and establishes that the invention is “nonobvious.”⁵³

The Federal Circuit’s liberal interpretation of the requirement of patentable subject matter has been important in the field of genetics, where the court has upheld patents on “purified and isolated full gene sequences whose physiological function (i.e., the protein for which they code) has been identified.”⁵⁴ While Professor Rai recognizes that “granting patents on purified and isolated forms of products that occur in raw form in

⁵¹ *Id.* at 102-03.

⁵² *Id.* at 103.

⁵³ *Id.* at 103-08. *See also, Symposium: The Human Genome Project, DNA Science and the Law: The American Legal System’s Response to Breakthroughs in Genetic Science, Panel One: Intellectual Property and Genetic Science: The Legal Dilemmas*, 51 AM. U. L. REV. 371, 377-78 (2002) [hereafter cited as, *Symposium*]

⁵⁴ Rai, *supra* note 1, at 104.

nature has been around for a long time,”⁵⁵ she is concerned about the implications of the Federal Circuit’s decisions in the full gene sequence cases, which open the door to patent applications for basic research tools, including “smaller pieces of DNA that are significantly further away from practical commercial application.”⁵⁶ A Federal Circuit decision that such genetic material is patentable subject matter could result in hundreds of thousands of patents on basic research, given the magnitude of these materials that include expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs).⁵⁷ One biotechnology company, Incyte, has reportedly claimed that it has filed 50,000 patent applications on pieces of various genes.⁵⁸

The “utility” and “nonobviousness” patent requirements are essential to fulfilling the justification for the legal protection of private property rights in patents as a means to encourage invention and disclosure of inventions to the public. As an incentive to individuals to invent and then to recoup the costs of the process of invention, the patent laws provide a private monopoly for a period of years to an inventor in exchange for the inventor’s public disclosure of the invention. Patent law thus creates public policy to achieve the goal of encouraging invention and expanding public knowledge of an invention by guaranteeing that the inventor will be protected from competitors during the patent period. As of 1995, the U.S. patent term is twenty years from the date of filing the patent application; prior to 1995, the term had been for seventeen years from the date of

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Id.* at 104-05.

⁵⁸ *Symposium, supra* note 53, at 387.

issuance of the patent.⁵⁹ Granting the private monopoly over the rights to use the invention, though, depends on the fulfillment of the requirements that the inventor demonstrate the invention's "novelty" and "nonobviousness," to ensure that the invention adds to scientific knowledge in a significant way, rather than simply making a change to prior existing knowledge that would be "obvious" to any individual "of ordinary skill in the art."⁶⁰ The "utility" requirement is also intended to promote the public good by requiring the inventor to demonstrate a well developed conception of the application of the invention that goes beyond a general statement of its potential use.⁶¹ The utility requirement provides monopoly rights of a patent only for an invention that will be of immediate practical use, rather than providing a right to exclude others from use of information that could be more beneficially used in the public domain.⁶²

The statutory requirement of demonstrating the "specific and practical utility" of the invention is important to limiting patent protection to applied research.⁶³ Here, too, the Federal Circuit has made the statutory requirement less stringent in the life sciences by finding that the utility requirement is fulfilled by an "expectation of further research and development," rather than by a showing of a current practical use.⁶⁴ In January 2001, the United States Patent and Trademark Office (PTO) increased the standard for defining utility to require that a patent application show that the utility of an invention is not only

⁵⁹ ROBERT L. HARMON, *PATENTS AND THE FEDERAL CIRCUIT*, FIFTH EDITION 4-5 (2001); BURCHFIEL, *supra* note 29, at 237.

⁶⁰ 35 USC sec. 103; *see*, Rai, *supra* note 1, at 107.

⁶¹ *Id.* at 106.

⁶² *Id.* at 101-02.

⁶³ *Id.*

⁶⁴ *Id.* at 106-07.

specific and credible, but is also substantial.⁶⁵ This change was made in response to the concern about the proliferation of patents on ESTs.⁶⁶

In Professor Rai's view, the Federal Circuit's relaxation of the "nonobviousness" requirement is its most significant expansion of patent rights in the biotechnology field. For example, the court has held that "DNA sequences of genes that code for particular proteins" are not obvious, despite the fact that the amino acid sequence of the protein and the method for isolating the DNA sequence are already known.⁶⁷ Again, Professor Rai's primary concern is with the implications of future applications of the court's standard, which may permit wide scale patenting of basic research discoveries such as ESTs and SNPs, whose identification all depend on application of the same research technique.⁶⁸

The combined results of the Bayh-Dole Act and the Federal Circuit's interpretation of patent law requirements has been the subject of critique by scholars in the fields of patent law and biotechnology, most notably Professors Eisenberg, Heller and Rai.⁶⁹ These scholars have argued that the privatization policies have undermined the purpose of the patent laws to grant private monopolies only to enhance the broader progress of science, consistent with Congress's constitutional power to provide for patent and copyright protection "to promote the Progress of Science and the Useful Arts by securing for

⁶⁵ Utility Examination Guidelines, 66 *Fed Reg.* 1092 (Jan. 5, 2001), available at <http://www.uspto.gov/web/offices/pac/utility/utility.htm>; *Symposium, supra* note 53, at 379; Timothy J. Balts, *Note: Substantial Utility, Technology Transfer, and Research Utility: It's Time for a Change*, 52 SYRACUSE L. REV. 105, 124-36 (2002) (critiquing the new guidelines as too stringent).

⁶⁶ DALE H. HOSCHEIT & LISA M. HEMMENDINGER, *BIOTECHNOLOGY AND THE FEDERAL CIRCUIT*, 2000 CUMULATIVE SUPPLEMENT 17 (2000).

⁶⁷ Rai, *supra* note 1, at 107.

⁶⁸ *Id.* at 108.

⁶⁹ Eisenberg, *supra* note 1; Rai, *supra* note 1; Heller & Eisenberg, *supra* note 23; Rai & Eisenberg, *supra* note 24.

limited Times To Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”⁷⁰ Instead, the proliferation of patents, particularly in the biomedical field, has restricted the free use of research discoveries to make further research advances.⁷¹ Biomedical patents constitute close to fifty percent of university patent activity.⁷² Private biotechnology companies have sought patents on basic research tools, including DNA sequences, gene fragments, and cell receptors.⁷³ The increase in patents on publicly and privately funded research in the biomedical sciences and the lowered standards for meeting the statutory patent requirements have resulted in more patents being approved for “upstream” research; that is for scientific discoveries of basic research tools and techniques that are not of immediate practical applicability but will be of great use in a wide range of future scientific research and development.⁷⁴ If each research tool is patented, then future science research will be impeded by the need to obtain multiple licensing rights to use research tools. Further, the owner of a patented upstream research tool may seek to share in the profits of subsequent downstream patents through licensing agreements that provide for royalties on future sales of downstream products or for exclusive or nonexclusive licenses to use downstream discoveries. Such “reach through” patent rights may, thus, inhibit future investment in research that depends on using

⁷⁰ U.S. Constitution, Art. I, sec. 8, cl. 8.

⁷¹ Heller & Eisenberg, *supra* note 23, at 698-700; Rai & Eisenberg, *supra* note 24, at 52-55.

⁷² Eisenberg & Rai, *supra* note 24, at 54.

⁷³ Heller & Eisenberg, *supra* note 23, at 699; Rai & Eisenberg, *supra* note 24, at 55.

⁷⁴ Heller & Eisenberg, *supra* note 23, at 699-700; Rai & Eisenberg, *supra* note 24, at 55-56.

patenting tools. Even if the future research is carried out, reach through rights will increase litigation over distribution of profits from the later invention.⁷⁵

Professors Eisenberg and Rai describe an example of an impediment to innovation in the case of a basic genetic research discovery (for the cell-signaling pathway for nuclear factor kappa B), resulting from federally funded research by university scientists at Harvard, MIT and the Whitehead Institute for Biomedical Research.⁷⁶ Despite the importance of this basic research tool for further research on a wide range of diseases, the universities obtained “a broad patent claiming all drugs that work by inhibiting NF-Kb cell signaling,” and granted an exclusive license on the patent to Ariad Pharmaceuticals. Ariad Pharmaceuticals and the universities have sued Eli Lilly & Co. for patent infringement, claiming the right to royalties on sales of products developed with the use of the patented research tool.⁷⁷

The obstacles to the free flow of research knowledge might appear to be less relevant for research carried out by universities, which could claim an “experimental use” exemption for the use of patents for non-commercial purposes. The “experimental use” exemption is a judicially created exemption from patent law enforcement for research carried out for “idle curiosity” or as a “strictly philosophical inquiry.”⁷⁸ This exemption, though, provides less protection for university research than might be assumed by many academic scientists. There are several reasons for this. First, as a judicially created

⁷⁵ Heller & Eisenberg, *supra* note 23, at 699-700; Rai & Eisenberg, *supra* note 24, at 55-56.

⁷⁶ Eisenberg & Rai, *supra* note 24, at 57.

⁷⁷ *Id.*

⁷⁸ Roche Prods, Inc. v. Bolar Pharmaceuticals Co., 733 F.2d 858, 863 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984), *quoted in*, BURCHFIEL, *supra*, note 29, at 353. *See also*, Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989).

doctrine, the experimental use exemption is subject to expansion and contraction at the will of the judiciary. The courts have, in fact, defined the experimental use exemption narrowly.⁷⁹ The Federal Circuit has recently narrowed the exemption even more, holding that universities and nonprofit organizations, in general, do not enjoy any greater access to the experimental use exemption than do for-profit businesses. In *Madey v. Duke University*,⁸⁰ the court found that universities, in using patented inventions to carry out their “business” of scholarly research, are not acting within the narrow experimental use exemption.⁸¹ As the court additionally noted in *dicta*, despite Duke University’s claim to have used patented research tools in furtherance of a non-commercial research program, Duke also engaged in “an aggressive patent licensing program from which it derives a not insubstantial revenue stream.”⁸²

These legislative and judicial developments relating to patents create an important foundation for analyzing changes in the university science research programs and other university policies and practices. The Bayh-Dole Act and the Federal Circuit Court of Appeals’ interpretation of patent law requirements have expanded the ability of universities to apply for patents on research results, whether publicly or privately funded. At the same time, the expansion of the scope of patentable inventions, including basic research tools, may have the effect of restricting the free flow of information in the scientific research community. Further, the Federal Circuit’s recent narrowing of the

⁷⁹ BURCHFIEL, *supra*, note 29, at 351-53.

⁸⁰ 307 F.3d 1351 (Fed. Cir. 2002).

⁸¹ *Id.* at 1362. See, Rebecca S. Eisenberg, *Patent Swords and Shields*, 299 SCIENCE 1018 (Feb. 14, 2003).

⁸² 307 F.3d at n.7.

experimental use exemption has created added concerns for university science research programs.

As will be discussed in Section III of the paper, universities have responded to these legislative and judicial developments by increasing their market activity in patenting, licensing, and university-corporate “alliances.” Section IV of the paper will analyze and critique these legislative and judicial changes and the universities’ responses in the context of implications for the university’s identity and societal role.

III. CHANGES IN UNIVERSITY SCIENCE RESEARCH FUNDING AND PRACTICES

A. University Technology Transfer Offices: Patents and Licenses

Universities responded positively to the legislative changes enabling them to apply for patents on federally funded research results. The increase in university patents after the effective date of the Bayh-Dole Act demonstrates universities’ embrace of the opportunity to patent and license faculty research. In 1979, before the Bayh-Dole Act, U.S. universities obtained 264 patents, compared with 1997, when U.S. universities obtained ten times that number, at 2,436 patents.⁸³ In fiscal year 2000, U.S. universities filed for 8,534 patents, an increase of 12 percent over the prior year.⁸⁴ From 1980 to 1990, U.S. university-owned patents increased from one percent to 2.4 percent of all U.S. origin patents.⁸⁵ During the same period, patent applications on NIH-funded inventions

⁸³ Rai & Eisenberg, *supra* note 24, at 53.

⁸⁴ Goldie Blumenstyk, *Value of University Licenses on Patents Exceeded \$1-Billion in 2000, Survey Finds*, CHRON. HIGHER EDUC., Mar. 5, 2002.

⁸⁵ Krinsky, *supra* note 15, at 22.

increased by almost 300 percent.⁸⁶ This change in patent activity is also a reminder of the importance of federal funding for university research programs. Since the post-WWII period, federal funding has consistently been the most important source of university research financial support, ranging from approximately 60 percent to 70 percent of university research funding since 1960.⁸⁷ Under the Reagan administration in the 1980s, federal science research funding was cut significantly, though the cuts were ultimately less drastic than feared.⁸⁸ Public funding has maintained its importance for university life sciences research, estimated at 70 percent to 80 percent of total funding for university life sciences research.⁸⁹ Prior to the Bayh-Dole Act, though universities could apply for patents on research results developed with private research funds, patenting activity remained low, reflecting the relative lack of importance of private research funding and a culture that did not place a high value on universities' assertion of private ownership rights of research.

The legislative change of the Bayh-Dole Act initiated a change in the culture of university research programs. Instead of tax dollars supporting research that entered the public domain, public funds could now support university research resulting in inventions

⁸⁶ *Id.*

⁸⁷ KENNEY, *supra* note 16, at 35-36; Eyal Press & Jennifer Washburn, *The Kept University*, THE ATLANTIC MONTHLY, Mar., 2000, at 39; *See*, Sheila Slaughter & Gary Rhoades, *The Emergence of a Competitiveness Research and Development Policy Coalition and the Commercialization of Academic Science and Technology*, 21 SCI. TECH. & HUM. VALUES 303, 327 (1996)(discussing the decline in funding from 1973, when 69 percent of university R&D was federally funded, to 1993, when 56 percent of university R&D was supported by federal funds.)

⁸⁸ KENNEY, *supra* note 16, at 28; Krinsky, *supra* note 15, at 20; Eisenberg, *supra* note 1, at n.2.

⁸⁹ David Blumenthal, *Biotech in Northeast Ohio Conference: Conflict of Interest in Biomedical Research*, 12 HEALTH MATRIX 377, 380 (2002); Dueker, *supra* note 46, at 457.

patented by the university and licensed to commercial businesses in exchange for licensing fees and royalties on any products subsequently developed. Given the potential impact of the Bayh-Dole Act, universities created or expanded technology transfer offices to carry out the functions of screening research for patent potential, working with faculty on patent applications, taking action to protect against patent infringements, and negotiating with businesses to license the rights to use university-patented inventions. One commentator describes the technology transfer offices' references to "faculty/inventors as 'customers,'" and the offices' "outreach programs' and other marketing campaigns to advertise the benefits of technology commercialization while overcoming academia's aversion to such tactics."⁹⁰ The scope of patenting and licensing activities could now encompass the full range of faculty research programs, whether supported by private or public funds. Given the central role of federal funding to support academic research, the Bayh-Dole Act increased universities' contact with industry to negotiate for licensing agreements. As these relationships brought commercial businesses into more direct interaction with faculty and their research, the potential for more private corporate funding for university research also increased.

Despite the expansion of their technology transfer offices, universities have not yet reaped substantial profits from patenting and licensing the results of academic research, with most universities using such revenue to cover the costs of running the technology transfer activities.⁹¹ Further, only a small group of universities accounts for most of the

⁹⁰ Dueker, *supra* note 46, at 464.

⁹¹ Eisenberg, *supra* note 33, at 1713-14.

revenue from technology transfer activities.⁹² Even successful university technology transfer operations are identified as comprising only one or two percent of their universities' total research budget, with the most successful ones relying "on single 'blockbuster' patents for the majority of their revenue."⁹³ One commentator, though, views the royalty income to universities to be "a significant and valued source of revenue," in spite of the fact that it is small compared to the amount of federal funding of university research.⁹⁴

B. Individual Faculty Responses

As different academic disciplines have expanded from basic research to applied research programs with commercially marketable research products, faculty have been attracted by the potential for profits.⁹⁵ Prior to the mid-1970s, the biological sciences did not attract much industry attention, given the lack of commercial application of the basic research.⁹⁶ The growth of the biotechnology field in universities, beginning in the mid-1970s with the groundbreaking discovery of recombinant DNA technology, also signaled the important commercial potential of such research advances. The expansion of university-industry relationships in the life sciences followed, fueled by the fact that virtually all the biotechnology research was located in universities rather than in industry

⁹² *Id.* Professor Eisenberg cites to Association of University Technology Managers (AUTM) data "indicat[ing] that in FY 1994 the top ten institutions in terms of royalties received accounted for 65% of the gross royalties received by the 159 institutions responding to the AUTM survey." *Id.* at n.193.

⁹³ Dueker, *supra* note 46, at 466 (quoting the Director of MIT's Technology Transfer Licensing Office).

⁹⁴ *Id.* at 478-79. The \$300,000,000 in gross royalties to universities from licensed technologies in FY 1995 represented 2.6 percent of federal funding to universities. *Id.*

⁹⁵ Eisenberg, *supra* note 1, at n.6; (discussing the fields of chemistry and engineering).

⁹⁶ See notes 15-22 *supra*, and accompanying text.

labs.⁹⁷ Today, in the life sciences, faculty in fields such as plant and human genetics are engaged in basic and applied research of interest to industry, including agri-business and pharmaceutical companies. A research team led by Dr. David Blumenthal has documented the extent of faculty relationships with industry. Faculty often enter into consulting arrangements with businesses while continuing their university teaching and research, with an estimate that about half of life sciences faculty act as consultants for industry.⁹⁸ Since the mid-1980s, twenty-one to twenty-eight percent of life sciences faculty have consistently received research support from industry.⁹⁹ During that time period, about seven to eight percent of faculty reported that they hold equity in a company related to their research.¹⁰⁰ During the 1980s and 1990s, faculty participated in founding twenty-four Fortune 500 companies and over 600 non-Fortune 500 companies in the life sciences.¹⁰¹

Faculty may find the increased university-industry relationships to be individually beneficial in a number of ways. In the context of publicly funded research, the Bayh-Dole Act requires the university to share with a faculty member the profits from royalties related to a university-owned patent invention created by that faculty member.¹⁰² In the context of privately funded research, individual faculty may be supported in their research programs by corporate funds through contracts negotiated by the university that commonly exchange corporate financing for licensing rights to the corporation to use university patents resulting from the research. These licensing rights may be exclusive or

⁹⁷ *Id.*

⁹⁸ Blumenthal, *supra* note 89, at 379; Krinsky, *supra* note 15, at 19.

⁹⁹ Blumenthal, *supra* note 89, at 378.

¹⁰⁰ *Id.* at 379.

¹⁰¹ *Id.* at 385.

¹⁰² 35 U.S.C. sec. 202(c)(7)(C).

nonexclusive and may or may not require the corporation to pay royalties to the university.

Given the widespread nature of faculty involvement in such market activity, it is easy to forget the instances of faculty resistance to applying for patents on their research. Within the traditional culture of academic research that emphasizes public access to research results and a reward system that is based on professional recognition through academic publications, all faculty did not immediately embrace a system of private ownership of research results through patents and licenses.¹⁰³ There are some well-known examples of faculty resistance to applying for patents. When asked who owned his polio vaccine, Dr. Jonas E. Salk is quoted as replying, “Well, the people, I would say. There is no patent. Could you patent the sun?”¹⁰⁴ Dr. Salk, himself, was apparently influenced by the commercial biomedical explosion of the 1980s, when he applied for seven patents on his therapeutic AIDS vaccine, Remune, and helped found a biotechnology company to develop it.¹⁰⁵ Professor Martin Kenney describes Cesar Milstein and Georges Kohler’s decision, in 1975, not to patent their Nobel prize-winning invention of monoclonal antibody-producing hybridoma cells, and their request to recipients of the cell line that they also not patent it.¹⁰⁶ Professors Stanley Cohen and Herbert Boyer are reported to have initially resisted Stanford’s University pressure to

¹⁰³ KENNEY, *supra* note 16, at 32 (describing the “ideology...of scientists working for the public good...” as leading to the view that “industry’s motives – especially that of profitability – were suspect, and the applied science orientation of industry...to be scientifically uninspiring to scientists.”)

¹⁰⁴ Douglas M. Birch & Gary Cohn, *Standing Up to Industry: As Corporations Increasingly Hold Their Purse Strings, Many Researchers Feel Pressed to Deliver Favorable Results*, BALTIMORE SUN, Jun. 26, 2001, at 1A.

¹⁰⁵ *Id.* See also, *Symposium*, *supra* note 53, at 376-77.

¹⁰⁶ Rai, *supra* note 1, at 94; Eisenberg, *supra* note 1, at n. 6, n.8; KENNEY, *supra* note 16, at 129.

patent their 1973 groundbreaking invention of the Cohen-Boyer rDNA gene-splicing technique, based on their concern about patenting basic research that had been built upon the prior research of other scientists.¹⁰⁷ They agreed to apply for the patent, jointly owned by Stanford and University of California, but required that the university engage in non-exclusive licensing, with royalties going only to the university.¹⁰⁸ Boyer did subsequently pursue commercial interests in 1976, as co-founder of the biotechnology company, Genentech, leading to his multi-millionaire status as a stockholder in the company.¹⁰⁹ Most universities currently require faculty to sign agreements to disclose all their research inventions to the university and to assign all patent rights to the university.¹¹⁰

Individual faculty members have also followed their private market activities off campus as founders and officers of spin-off corporations. As noted above, during the 1980s and 1990s, faculty participated in founding twenty-four Fortune 500 companies and over 600 non-Fortune 500 companies in the life sciences.¹¹¹ To create spin-off corporations, faculty find venture capital to finance a corporation to develop and market the patented products that resulted from their research in the university.¹¹² Since the university normally owns the patents on the research, the spin-off corporation will license the rights to the patent from the university, often in exchange for university equity in the

¹⁰⁷ Rai, *supra* note 1, at 93-94; Dueker, *supra* note 46, at 493-94.

¹⁰⁸ Rai, *supra* note 1, at 93-94

¹⁰⁹ Krinsky, *supra* note 15, at 19.

¹¹⁰ Rai, *supra* note 1, at n.180.

¹¹¹ See *supra* note 100-101, and accompanying text.

¹¹² Krinsky, *supra* note 15, at 28.

corporation.¹¹³ The faculty members may or may not continue as faculty of the university while engaged in their work as officers of the spin-off corporation.¹¹⁴

C. Corporate Strategic Alliances

Survey research of life sciences companies, conducted by a research team led by Dr. David Blumenthal, demonstrates the extent and growth of industry relationships with universities. In 1994, ninety percent of life sciences companies had a relationship with an academic institution.¹¹⁵ Eight-eight percent of the companies used faculty as consultants.¹¹⁶ The study concludes that “life-sciences firms were significantly more likely to support academic research in 1994 than in 1984 (57 percent vs. 46 percent, $P=0.05$).”¹¹⁷ The study cites the National Science Foundation estimate that in 1993, industry supported seven percent of university research and development in all scientific fields.¹¹⁸ The study estimates that, in 1994, industry support of university life sciences research consisted of \$1.5 billion (11.7 percent) of the \$12.8 billion of all extramural support of life science academic research.¹¹⁹ Another source reports that industry support of university research grew from \$1.45 billion in 1994 to \$2.16 billion in 1999, an annual increase of nearly 10 percent.¹²⁰ Comparing the survey data from 1984 and 1994 leads to the Blumenthal study’s conclusion that “[e]vidence of the persistent and even growing support of university activities by industrial firms contradicts a view commonly held

¹¹³ Newberg & Dunn, *supra* note 44, at 204-05.

¹¹⁴ *Id.*

¹¹⁵ Blumenthal et al., *supra* note 22, at 368.

¹¹⁶ *Id.* at 369.

¹¹⁷ *Id.* at 371.

¹¹⁸ *Id.* at 369.

¹¹⁹ *Id.*

¹²⁰ Charles F. Larson, *The Boom in Industry Research*, 16 ISSUES IN SCI. & TECH. 27 (Summer 2000).

early in the biotechnology revolution – namely, that life-science companies would retreat from relationships with academia when they became more familiar with the new techniques of biologic research created in American universities during the late 1970s and early 1980s.”¹²¹ Two-thirds of the surveyed companies expected their funding of university life science research to increase “greatly or somewhat over the next five years.”¹²² The study reports that most (71 percent) of research projects are funded by industry at less than \$100,000 a year, with only six percent funded annually at \$500,000 or more.¹²³ Most university-research relationships are also relatively short in duration, at two years or less, with six percent lasting more than three years.”¹²⁴ As the study explains, though, “given that industrial firms support many projects, the small percentage of projects that are large or long-lasting represents a considerable number...[W]e estimate that in 1994 approximately 280 academic research projects funded at \$500,000 a year or more.”¹²⁵ The study concludes that such large, long-term funding “undoubtedly” supports basic research.¹²⁶

University-industry agreements provide for the terms of the exchange, including the corporation’s right to exclusive or non-exclusive licensing rights to any university-owned patents resulting from the research program supported by corporate funds. As the corporate funding becomes more significant, the likelihood increases that the corporation will negotiate for exclusive licensing rights.¹²⁷ While all contracts for corporate funding

¹²¹ Blumenthal et al., *supra* note 22, at 372.

¹²² *Id.* at 369.

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ Dueker, *supra* note 46, at 498.

raise issues concerning effects on academic freedom and the independence of academic researchers, the “considerable number” of research projects supported by large, long-term corporate funding raises these concerns on a much larger scale, particularly when a single corporation finances an entire department or research program. For example, in 1974, Harvard entered an agreement with Monsanto corporation for a 12-year, \$23 million grant from Monsanto to Harvard Medical School in exchange for Monsanto’s right to a worldwide exclusive license for inventions resulting from this research funding.¹²⁸ After entering into this agreement, Harvard eliminated its policy, dating from 1934 that had required approval from the president and fellows before obtaining university “patents primarily concerned with therapeutics or public health” and further required that such patents be taken only “for dedication to the public.”¹²⁹ In 1982, Monsanto entered a long-term agreement with Washington University for \$23.5 million over five years in exchange for exclusive licensing rights to patents resulting from the biomedical research.¹³⁰ After being renewed three times, Monsanto’s financing of the university came to about \$100 million.¹³¹ In 1980, MIT and Exxon entered an agreement for \$8 million of corporate funding over ten years for research on combustion engineering. The agreement provided for corporate control over research presentations and a ninety-day publication delay to allow for filing patent applications.¹³² In 1994, MIT and Amgen entered an agreement for \$30 million of corporate funding to the Departments of Biology and of Brain and Cognitive Sciences over a ten-year period in exchange for resulting

¹²⁸ KENNEY, *supra* note 16, at 58-60.

¹²⁹ Eisenberg, *supra* note 1, at n.9.

¹³⁰ Krimsky, *supra* note 15, at 28-29; KENNEY, *supra* note 16, at 67-69.

¹³¹ Krimsky, *supra* note 15, at 28.

¹³² KENNEY, *supra* note 16, at 60-61. For a list of large scale, long-term university-corporate agreements between 1974-1983, *see, id.* at 56.

patents to be jointly held by MIT and Amgen.¹³³ In 1997, the pharmaceutical corporation, Merck, agreed to give MIT \$15 million over five years in exchange for licensing rights to resulting patents.¹³⁴ A controversial and much publicized example is the 1998 agreement between University of California at Berkeley's Department of Plant and Microbial Biology and Novartis, a Swiss pharmaceutical corporation that also produced genetically engineered crops.¹³⁵ The UC Berkeley agreement is now with Syngenta, the world's largest agribusiness, which purchased the research institute created by a merger of Novartis's and multinational corporation Zeneca's agricultural-business units.¹³⁶ In exchange for corporate funding of \$25 million over five years, Syngenta gains exclusive licensing rights to about a third of the department's discoveries and holds two of five seats on the department's research committee that makes decisions on distribution of the funds.¹³⁷ Syngenta is given the right to review all proposed publications and presentations by participating faculty and their graduate students, including publicly funded research.¹³⁸ The agreement also authorizes Syngenta to ask for a ninety-day publication delay to provide time for patent applications.¹³⁹ Novartis has large-scale funding agreements with other universities, including \$24 million paid over a six year period to University of Maryland's Psychiatric Research Center in exchange for

¹³³ Andrew Lawler, *Last of the Big Time Spenders?*, 299 SCIENCE 330 (2003); *MIT's Alliances with Industry*, MIT News, available at <http://web.mit.edu/newsoffice/nr/2000/alliance.html>

¹³⁴ William H. Honan, *Corporations Still Give, but Also Get*, NY TIMES, July 15, 1998, at B9.

¹³⁵ Press & Washburn, *supra* note 87, at 41-42; Vicky Elliott, *Who Calls the tune? The Money Game; Novartis Strategic Alliance with the University of California at Berkeley*, UNESCO COURIER, Nov. 1, 2001, at 21.

¹³⁶ Goldie Blumenstyk, *A Vilified Corporate Partnership Produces Little Change (Except Better Facilities)*, CHRON. HIGHER EDUC., Jun. 22, 2001, at 24.

¹³⁷ *Id.*; Press & Washburn, *supra* note 87.

¹³⁸ Blumenstyk, *supra* note 87.

¹³⁹ *Id.*

half the seats on the eight-member panel that distributes the funds, exclusive commercial access to its bank of brain tissue, and exclusive licensing rights to its patents.¹⁴⁰ Novartis (and its predecessor Sandoz) pays \$20 million a year to the Scripps Research Institute in California, which provides exclusive licenses to Novartis for about one-half the Scripps Institute's research.¹⁴¹ Other universities have been attracted by the potential for large scale corporate funding, as is the case at Cornell University, which has launched an effort to seek "corporate strategic alliances" to finance its planned investment of \$500 million in an expanded life sciences program and facilities. The proposed Cornell University "Strategic Corporate Alliance Plan," which is still being developed, identifies five target industries: agricultural biotechnology; bioengineering; food production, distribution, and safety; information; and pharmaceuticals. The plan describes the benefits that Cornell will offer companies, including the possibility of royalty-bearing exclusive licenses to inventions resulting from the corporate financing and "shared management of the Alliance via [the] Joint Steering Committee."¹⁴²

In addition to the exchange of funding for exclusive licenses, these university-industry "partnerships" expand the role of corporations in determining university research agendas and increase the presence of corporations in university research laboratories. Universities attract corporate support at the level of tens of millions of dollars by offering exclusive licenses as well as access to the university facilities, faculty, and graduate

¹⁴⁰ Birch & Cohn, *supra* note 104.

¹⁴¹ *Id.* See also, Dueker, *supra* note 46, at 481-507 (describing in detail patenting, licensing, start-up corporations, and corporate funding activities at Harvard, Stanford, and MIT); Andrew Lawler, *supra* note 133.

¹⁴² "Cornell University New Life Sciences Strategic Corporate Alliance Plan," located at <http://web.cornell.edu/UniversityFaculty/> (Agenda for April 9, 2003 Faculty Senate meeting)

students.¹⁴³ The corporation will appoint its own representatives to research committees where, along with faculty and university administrators, they will select faculty proposals for funding grants.¹⁴⁴ Corporate research scientists are given access to university research facilities and the opportunity to consult with university faculty. With this close involvement in the university department, corporations have the opportunity to become acquainted with graduate students, who may then be hired after graduation into industry science R&D departments.¹⁴⁵

Additional “academic-industrial relationships resemble joint-ventures” between universities and biotechnology companies.¹⁴⁶ For example, under an agreement between Harvard University and Genica to work jointly on an eye test for Alzheimer’s disease, Genica will receive the exclusive license to market the test and Harvard will receive the royalties on future sales.¹⁴⁷ Johns Hopkins, together with Genetics Institute, Inc., has formed a separate company to research diseases of the nervous system. Genetics Institute has invested \$3.8 million for a 58 percent share in the company. Johns Hopkins has contributed nineteen genes in exchange for a 42 percent share, and will receive future royalties.¹⁴⁸

¹⁴³ KENNEY, *supra* note 16, at 55-72.

¹⁴⁴ *Id.* See text accompanying notes 135-138, *supra*.

¹⁴⁵ KENNEY, *supra* note 16, at 55-72.

¹⁴⁶ Rai, *supra* note 1, at 110.

¹⁴⁷ *Id.* at n.186.

¹⁴⁸ *Id.*

IV. ANALYSIS AND CRITIQUE

As discussed in Section II of this paper, there is a harmony between the traditional public mission of the university and the traditional communal values of science. The university exists to promote the public interest in teaching and research, independent from third party interference or self-interest; the sciences serve that institutional goal through teaching and research guided by communal values. The privatization of university research, through university patenting and licensing activity and expanded university-industry relationships, creates a tension between these public interest goals and the self-interested goals of the market. This section of the paper will provide a critique of the privatization trends in university research and the consequences of these trends. First, the discussion will present a critique of the Bayh-Dole Act as representing a seismic shift in the university's role from serving the public interest to serving the private interests of industry. This analysis of Bayh-Dole will provide the foundation for a subsequent critique of the expanded industry presence in the university through "corporate strategic alliances." Privatization and commercialization of university research will then be explored through the lens of the consequences for the identity of university science and of the university as a whole.

A. Bayh-Dole: Redefining the Public Interest

The Bayh-Dole Act initiated a major change in university practices by permitting universities and other nonprofit organizations to patent the results of publicly funded research. With this restriction of the public domain, Congress expressed the view that promoting commercialization of publicly funded research was in the public interest. Whether this perspective is justified, though, requires much closer scrutiny of the

meaning of the public interest in relation to the university and industry. This analysis raises a number of questions: Is the Bayh-Dole Act's goal of commercializing university science research in conflict with the university's public mission? Does the Act's authorization to universities to patent publicly funded research create an indirect public subsidy for industry and is such a subsidy a legitimate use of public funds? Is the patent system needed or justified to encourage research activity in the university? Do university patents on publicly funded research create a conflict of interests between public and private interests?

The question concerning the justification of university-owned patents provides a useful point of departure for addressing the broader policy issues raised by the Bayh-Dole Act. Application of the patent system to university research creates contradictions, illustrated by examining the underlying justification for the patent system and then asking whether this same justification applies to patents in the university structure. A patent provides the patent holder with a monopoly over the use of a patented invention, including the right to maintain complete control over the invention during the patent period. The monopoly control to the patent holder is justified as promoting the public good by providing an incentive to individuals to risk the investment of capital to invent and then to disclose their inventions to the public.¹⁴⁹ As Professor Eisenberg has stated, "patent rights on existing inventions result in a net social loss ex post, a loss that we endure only to preserve ex ante incentives to make future patentable inventions."¹⁵⁰

¹⁴⁹ Eisenberg, *supra* note 33, at 1668.

¹⁵⁰ *Id.* at 1666-67.

These incentives to invent and disclose created by the patent system are unnecessary for university researchers, who already have an incentive to invent and disclose. As discussed in Section II, both the communal values of science and the professional structure of the university encourage and require university scientists to invent and disclose their research to the public. These professional incentives have been highly successful, as evidenced by the intense competition among academic scientists to be the first to publish their research results and methodology. The patent system and the university system can, thus, be described as parallel systems to expand the public domain of knowledge. The patent system is based on private ownership and monopoly control of inventions during the patent period in exchange for public disclosure. From this perspective, the patent period is a justifiable cost of expanding the public domain; the patent holder will provide the information to the public through the patent application, but the invention will be freely available in the public domain only at the end of the patent period. The university, as an institution with a public mission, traditionally places inventions and other research developments directly into the public domain through scholarly publications. As patents are not needed to provide an incentive to invent and disclose, patents are not justified as a cost of expanding the public domain.¹⁵¹

How, then, does Congress justify the Bayh-Dole Act's expanded use of patents to permit a university monopoly over publicly funded research results? This question is particularly thorny when raised in the context of ensuring that public funds are used in the public interest. The "Policy and Objective" section of the Bayh-Dole Act¹⁵² advocates the use of the patent system "to promote the utilization of inventions arising

¹⁵¹ Rai, *supra* note 1, at 119-20.

¹⁵² 35 U.S.C. sec. 200.

from federally supported research or development;...to promote collaboration between commercial concerns and nonprofit organizations, including universities;...to promote the commercialization and public availability of inventions made in the United States by United States industry and labor....”¹⁵³ With these statements, Congress equates the public interest with the commercial interests of industry, following the logic that university patents on federally funded research will encourage collaboration between universities and industry, increasing the number of products marketed by industry, and ultimately promoting the public interest in having more commercially available goods. Advocates of the Bayh-Dole Act have justified this policy as a means of increasing the utilization of federally funded inventions through corporate licensing of university patents. They support the need for privately owned patents to encourage the use of federally funded inventions by citing evidence of the low licensing rate of government-owned patents, purportedly due to corporate disinterest in nonexclusive licensing rights and the difficulty of navigating the bureaucratic morass of twenty-six different federal agency licensing regulations. Evidence of the great increase in university-owned patents and corporate licenses is provided as proof that the Bayh-Dole Act was needed and is successful.¹⁵⁴

There are a number of problems with these arguments. Regarding the pre-1980 licensing of government-owned patents, Professor Eisenberg has argued that the statistical evidence presented by Bayh-Dole advocates understates the actual use of federally funded inventions, given the common practice of unlicensed use of government-

¹⁵³ *Id.*

¹⁵⁴ Eisenberg, *supra* note 33, at 1702.

owned patents and the availability of unpatented federally funded inventions.¹⁵⁵

Additionally, even prior to Bayh-Dole, the Department of Defense (DoD) generally permitted private contractors to retain title to patents on DoD sponsored research, leaving title in government only to those inventions that the defense industry had chosen not to patent.¹⁵⁶ In agencies such as Health, Education, and Welfare (HEW), which retained title to federally funded inventions, the licensing rate was higher.¹⁵⁷

Even more importantly, the Bayh-Dole Act's encouragement of privatization of publicly funded inventions makes two major changes of well-established definitions of the public interest: one in defining the goal of the patent system; and the other in defining the mission of the university. While the courts have widely recognized the public interest in issuing patents to promote innovation and public disclosure of an invention, the courts have not applied a public policy of using the patent system to encourage further development and commercialization of an already patented invention.¹⁵⁸ The public interest promoted by the patent system is the expansion of public access to inventions, with the patent period accepted as a cost that may be necessary to achieve that public interest.¹⁵⁹ The public mission of universities is similar in regard to the goal of enhancing the public domain of knowledge. Universities are institutions supported by the public through funding appropriations and tax exemptions, with the expectation that universities will serve the public interest in fulfilling its teaching and research functions independent

¹⁵⁵ *Id.* at 1702-03.

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ Eisenberg, *supra* note 33, 1669-70; Eisenberg, *supra* note 78, at 1043-45.

¹⁵⁹ Eisenberg, *supra* note 33, at 1667-68.

from self-interests or third party interests. University-owned patents on publicly funded research alter this understanding of the university's role in promoting the public interest.

Within this context, we must ask whose interests are being served by the Bayh-Dole Act policy of promoting university-industry collaboration through patents and licensing agreements. By permitting universities to patent their federally funded inventions, the Bayh-Dole Act creates a cost of removing the invention from the public domain for the duration of the patent period. Bayh-Dole, in fact, doubles the cost to the public, as the public pays for federally funded university research and pays another cost when the federally funded invention is removed from the public domain under a university-owned patent.¹⁶⁰ Given the fact that university researchers do not need patents as an incentive to invent and disclose their findings in the public domain, does the public benefit from these added costs?

Pursuing this question of who pays and who benefits supports a conclusion that the added costs of the Bayh-Dole Act are borne by the public, while the benefits are reaped primarily by industry. The costs of public funding for research and the costs of the patent's removal of the invention from the public domain describe only some of the costs to public. With the "success" of the Bayh-Dole Act, universities' patenting and licensing activities have grown enormously, bringing universities into the market to license their research findings to the highest corporate bidder. These university-industry relations add more costs to the public. The Bayh-Dole Act encourages universities to engage in research for commercial gains from patenting and licensing federally funded research results. As these commercial goals will include the universities' revenue from

¹⁶⁰ *Id.* at 1666.

licensing fees and royalties, the universities' interests will overlap with the corporate licensee's commercial success. This creates a conflict of interests for the universities between these private commercial interests and university's institutional mission to engage in independent research in the public interest. The public pays for this conflict of interests, as the university will promote corporate profits through arrangements that include exclusive corporate licenses to use university-owned patents, enabling the corporation to charge high monopoly prices. Perhaps even more costly to the public is the university's loss of its independence from outside interests, with a resulting loss of institutional legitimacy.

Examination of the "benefits" side of Bayh-Dole reveals that industry reaps the profits of commercializing federally funded research, while using public funds to reduce its costs and risks. Professor David Noble's critique of university-industry "corporate strategic alliances" applies to the context of the Bayh-Dole Act as well: "They [the corporations] have socialized the costs and the risks – because the taxpayer is paying – and privatized the benefits."¹⁶¹ Under the Bayh-Dole Act, businesses receive both direct and indirect public subsidies. Businesses receive a direct subsidy as government contractors who use public funds in their R&D departments and then obtain patents on any resulting inventions. That a business may also invest its own funds in the research does not change the fact that the public funding constitutes a subsidy that is fully appropriated by the business and that will lower the business's costs and risks in carrying out the R&D. If the publicly funded R&D results in an invention, the business may tax the public further through the business's monopoly rights under the patent, which enables

¹⁶¹ Professor Noble is quoted in, Blumenstyk, *supra* note 136.

the business to charge higher prices for the marketed product.¹⁶² In providing a direct subsidy to industry, it is questionable whether Bayh-Dole serves the public interest, as now the public pays twice for a product – once to a corporation's R&D department and a second time for the commercial product, with higher profits to the company made possible by the patent on the results of the federally funded research.¹⁶³

The Bayh-Dole Act also provides an indirect subsidy to businesses by allowing publicly funded university research to reduce industry costs and risks.¹⁶⁴ Prior to Bayh-Dole, federally funded university research results entered the public domain. In this way, commercial businesses, along with the rest of the public, gained the benefits of the publicly funded research and were free to invest their own capital to develop and market products that used the publicly funded research results. Under the Bayh-Dole Act, the use of university-owned patents will be determined through negotiations for private licensing contracts, including exclusive licenses that limit use of a patent to a single corporation. A corporation may be willing to pay the cost of fees and royalties for an exclusive licensing agreement in return for the competitive advantage gained by blocking access to the university patent by other businesses. The corporate licensee may now use the university-patented invention in its R&D, which may lead to further patented inventions to be sold in the commercial market. Thus, through exclusive licensing agreements, a business can reap the benefit of publicly funded research by, in effect, purchasing the university's patent. Again, though the industry licensee may also invest

¹⁶² Lawrence M. Sung, *Collegiality and Collaboration in the Age of Exclusivity*, 3 DEPAUL J. HEALTH CARE L. 411, n.3 (2000).

¹⁶³ Eisenberg, *supra* note 33, at 1666-69.

¹⁶⁴ See, Mikhail, *supra* note 40, at 382 (describing Rep. Jack Brooks's criticism of patents to universities under the Bayh-Dole Act).

more capital and take further risks in developing products that use the university-owned patent, the public funds that covered the cost and risks in developing the original patent still provide a significant indirect public subsidy to the business. And again, the public pays multiple times – for the federal grant to the university; for the removal of the patented invention from the public domain; and for the higher prices that a business may charge where it has a monopoly use over the university-owned patent.

The combined effect of the blurred distinction between basic and applied research in the life sciences and the relaxed patent standards of the Federal Circuit Court of Appeals exacerbates the impact of the Bayh-Dole Act, enabling universities to obtain patents on a broad scope of basic research tools that can then be licensed to industry. As a result, the traditional public function of universities to engage in basic research will be privatized and commercialized. Suggested reforms of the Bayh-Dole Act have included limiting the patenting by universities of “upstream” basic research tools, to return to a traditional concept of the public domain in academic basic research. This recommendation would be a significant reform aimed at promoting a goal of broad public access to university discoveries. Additionally, a reform of the Bayh-Dole Act to eliminate the use of exclusive, rather than nonexclusive, licenses to university-owned patents would also broaden access to university research.¹⁶⁵ As will be discussed further in the recommendations presented in Section V of this paper, while both of these reforms would be significant measures designed to return universities to their public mission, they do not fully address the underlying problems of the use of public funds to support

¹⁶⁵ See, Eisenberg, *supra* note 33, at 1700-1701 (During the Bayh-Dole hearings, some university officials testified that they preferred nonexclusive licensing because this promoted wider dissemination of discoveries and inventions.)

privately-owned patents nor the conflict of interests of universities acting for commercial rather than public interests.

B. *The “Corporate Strategic Alliance”: Serving Private Interests*

“Corporate Strategic Alliances” have taken university-industry “collaboration” to another level, with private corporate financing on the scale of tens of millions of dollars to support entire departmental research programs. The agreements between the university and the corporate funder will normally include the corporation’s right to exclusive licensing of any university patents resulting from the funded research program. These agreements go beyond the contracts that provide corporate funding for individual faculty research. While individual faculty research contracts raise serious problems of conflict of interests, they do not place an entire department in the service of corporate research agendas. Though an individual faculty member may opt out of research funding from a “corporate strategic alliance,” membership in a department funded at such a large scale of funding from a single corporation implicates the department in the funding arrangements and creates pressure on faculty to participate. As discussed in Section III of this paper, the corporate strategic alliance creates a university-industry partnership that exchanges corporate funding for exclusive licenses and for an active corporate presence at the university, including corporate representatives on research funding committees, preferred access by the corporation to faculty and graduate students, and use of university research facilities for scientists in the corporation’s R&D department.

While such corporate strategic alliances are not as widespread as individual faculty research contracts with industry, their presence is significant in demonstrating the extent to which universities have become closely aligned with corporate commercial

interests. Universities seeking this scale of industry funding will need to convince a potential corporate sponsor that the university will use the corporate funds for research that is likely to enhance the corporation's profits. In persuading the business corporation that their interests overlap, a university will focus on the commercial potential for the university research. Such university-industry partnerships undermine the university's public mission and independence by giving commercial businesses a powerful position in shaping the research agendas of entire departments. The focus on the instrumental value of the research to corporate needs creates a priority for research with commercial potential rather than defining the value of research based on its contribution to the public interest. The independence and legitimacy of the research findings is also called into question, given the conflict of interests created by the level of dependence on a particular corporate sponsor. As discussed *infra*, there is evidence that corporate sponsorship of faculty research does result in more favorable findings concerning the sponsor's products.

Despite these problems, universities continue to endorse such broad scale alliances as an acceptable means of funding academic research programs, as long as the agreements contain clauses that the university views as adequately protecting its interests. This focus on the content of the contract, though, misses the fundamental problem of the impact of the university-industry partnership on the university's mission and legitimacy. By serving the corporation's interest, the university shifts its mission from the public good to the private commercial interests of the corporation. The university loses its independence upon which its legitimacy is based.¹⁶⁶ Though universities may assert that faculty remain

¹⁶⁶ See, SLAUGHTER AND LESLIE, *ACADEMIC CAPITALISM: POLITICS, POLICIES, AND THE ENTREPRENEURIAL UNIVERSITY*; CAPITALIZING KNOWLEDGE: NEW INTERSECTIONS OF

free to set their own research agendas, the department's dependence on the corporate funds and the active role of the corporation's representatives on research funding committees sends a different message. The coercive effects on faculty research agendas occur through faculty researchers shaping their agendas to increase the likelihood of corporate funding, rather than from explicit threats or requirements that faculty research must comport with corporate demands. While it may be true that faculty commonly shape their research proposals to fit the interests of a funding source,¹⁶⁷ the degree of control over faculty research increases with private corporate funding as opposed to public funding or foundation grants. As a corollary, as a university department becomes more dependent on one corporation's large scale funding, the corporation will gain greater ability to influence the department's agenda to fit the corporation's commercial interests.

Though the Bayh-Dole Act applies to university patents on publicly funded research, its impact has extended to private corporate funding to universities. The Bayh-Dole Act creates government policy favoring a shift of the university mission from primary concern for research that contributes to the public domain of knowledge to research that contributes to the private commercial utilization of academic research. By extension, this policy also encourages direct corporate funding of individual faculty research and of entire academic research departments in exchange for commercially valuable research. In the broader context, then, of privatization of university research, corporate strategic

INDUSTRY AND ACADEMIA (Henry Etzkowitz, Andrew Webster, and Peter Healey, eds., 1998)

¹⁶⁷ See, KENNEY, *supra* note 16, at 12.

alliances can look like just another step in the process rather than a fundamental change in university identity.

Corporate strategic alliances result in some of the same public costs as the Bayh-Dole Act. Whether academic research is publicly or privately funded, universities exist for a public mission, which is served by expanding the public domain of knowledge. The values of academic freedom support this public mission by providing faculty with the right to engage in their research independently and autonomously. These values are compromised by university-industry agreements exchanging corporate funds for exclusive licenses to university-owned patents. As under the Bayh-Dole Act, such patenting and licensing arrangements constrict the public domain by reducing public access to university inventions. The university has become a business partner of the corporate funder, serving the corporation's commercial interests, including the corporation's ability to use its exclusive license to university-owned patents as a means for charging higher prices on subsequent products. As one scholar has described the relationship: "In a very real sense, the universities are now experiencing a shift from corporate *contribution* to corporate *investment* in academia."¹⁶⁸ Public perception of university research will also be negatively affected, as the public no longer can trust in the independence of academic research from corporate influence.

Faculty protest of the UC Berkeley-Novartis agreement raised some of these issues, when faculty and students voiced widespread protest of having an entire university department financed by a single corporation. The protests raised concerns about the secrecy surrounding the negotiations between the university and Novartis, the potential

¹⁶⁸ Charles C. Caldart, *Industry Investment in University Research*, 8 SCIENCE, TECHNOLOGY, AND HUMAN VALUES 24, 25 (Spring, 1983)(emphasis in original).

inroads on academic freedom, the effects on research agendas, and the conflict with the public mission of the university.¹⁶⁹ Results of a faculty survey showed that forty-one percent of UC Berkeley faculty supported the university-Novartis agreement; fifty percent expressed concerns that the agreement would have a “negative” or “strongly negative” effects on academic freedom; about half the faculty thought that the agreement would negatively affect the university’s commitment to “public good research”; and sixty percent were concerned that the agreement would undermine openness in science research at the university.¹⁷⁰

C. Consequences for the Identity of University Science: Changes in Professional Values and Practices

Thus far, this paper’s critique of the privatization and commercialization of university research has focused on the changes in public policy and university practices. These trends have also had a significant impact on the culture of the scientific community, including its values and practices.

1. Communal Values vs. Individualistic Values

Much of the commentary and critique of the privatization trends in university science has focused on the changes in the traditional norms of science research. University-industry relationships bring the traditional communal values of science in conflict with the individualistic values of the market. The conflicts of values can be seen in every form of the marketing of university research, whether through university patents on publicly or privately funded research, licensing of patents to industry, corporate funding of individual faculty research, or corporate strategic alliances to finance entire

¹⁶⁹ Press & Washburn, *supra* note 87.

¹⁷⁰ *Id.*

departments or programs. The individual faculty member's reward for research no longer rests solely in the public recognition inside and outside the science community. Instead, a conflict of interests is created between independent science in the public interest and research carried out for financial profit. The researcher's individual interest becomes intertwined with the commercial potential of the research. With the Bayh-Dole Act, the university's ability to license patents resulting from publicly supported research carries as great a potential for profit making as licenses on patents resulting from industry-financed research. The individual scientist's financial interests now comprise a significant concern in the research agenda, as the researcher will share in a portion of any revenue realized through licensing of patents. By extension, then, the academic scientist's interests become aligned with private businesses that will engage in the marketing of the university-owned patent. Additionally, academic scientists' dependence on corporate funding will create an alignment of interests between faculty and the private business funder.¹⁷¹

As academic scientists become more involved in the patenting practice, their view of research may change as well. Rather than contributing research results to the public domain, scientists are creating new commodities for the market. The scope of this phenomenon is broadened by the expanded scope of patents that cover basic research tools. The expansion of patents to such "upstream" research, which will be needed by many other scientists for their research projects, changes the nature of scientific

¹⁷¹ Cf. Daniel Lee Kleinman, *Untangling Context: Understanding a University Laboratory in the Commercial World*, 23 SCIENCE, TECH., & HUMAN VALUES 285 (Summer 1998) (discussing the indirect effects on academic science research practices from the need to "play by the rules" created when academic researchers seek funding from business corporations).

discoveries available in the public domain. As Professor Eisenberg has described the problem, the proliferation of patents on basic research tools creates an “anticommons” in science, with resulting complexities in obtaining licenses for using patented basic research tools and increased potential litigation concerning rights of “upstream” patent owners to share in profits from “downstream” inventions.¹⁷² As the Federal Circuit Court of Appeals narrows the judicially created experimental use exemption, the problems of obtaining licenses to use patents will likely affect university researchers just as they affect R&D departments in industry.

2. Increased Secrecy

With privatization of academic science, the individual competition among researchers has come to include competition in the market. While academic scientists will continue to compete for recognition in the public domain of academic publications, faculty competition in the market creates a conflict of interests between the scientists’ contribution to the public good and their contribution to private industry interests. As the critiques of science research privatization have identified, this conflict of interests has resulted in concrete changes in the norms and practices of academic scientists. A major alteration is the increased secrecy among scientists concerning their research.¹⁷³

University scientists report changes in their discussions with colleagues engaged in research financed by private corporations, who are unwilling to discuss their research methods or results, either because of corporate funding contracts that restrict the researcher from sharing the information or that give the corporation the right to see this

¹⁷² Heller & Eisenberg, *supra* note 23.

¹⁷³ Blumenthal, et al., *supra* note 22, at 368, 372-73; Rebecca S. Eisenberg, *Academic Freedom and Academic Values in Sponsored Research*, 66 TEX. L. REV. 1363, 1375 (1988); KENNEY, *supra* note 16, at 108-11, 121-31.

information first, or because of the researcher's interest in protecting information for future patents.¹⁷⁴ With the Bayh-Dole Act, the increased secrecy of information related to patents affects publicly funded research as well.

Another contrast between scholarship and patents concerns attribution. The traditional culture of communalism in academic science promotes the value of attribution of credit to other scientists whose work had created the foundation for new research discoveries. This strongly held value is expressed in the famous quotation of Sir Isaac Newton, that he was able to see farther by "standing on the shoulders of giants."¹⁷⁵ In contrast, the requirement of originality and "nonobviousness" for a successful patent application creates pressure on the applicant to overstate the originality of an invention and describe the invention in isolation from prior researchers' discoveries. Given the possibility that prior researchers' results have also been patented, a subsequent patent applicant may need to emphasize the differences of his invention from prior patents to ensure a credible claim of nonobviousness.¹⁷⁶

3. Limits on Researchers' Independence

The integrity of university research, including science, is based on its independence from interests other than the drive for the expansion of knowledge and the progress of the discipline. While the reality of academic research will always fall short of this ideal, the privatization of science research creates a conflict of interests that threatens the

¹⁷⁴ *Id.*; David Blumenthal, M. Gluck, K.S. Louis, M.A. Stoto, *University-Industry Research Relationships in Biotechnology: Implications for the University*, 232 SCIENCE 1361, 1361-66 (1986); Krinsky, *supra* note 15, at 29-31. Birch & Cohn, *supra* note 104.

¹⁷⁵ *Quoted in*, Sung, *supra* note 162, at n.17.

¹⁷⁶ Kathryn Packer & Andrew Webster, *Patenting Culture in Science: Reinventing the Scientific Wheel of Credibility*, 21 SCIENCE, TECH. & HUMAN VALUES 427 (Autumn, 1996).

legitimacy of the university as an institution dedicated to the independent pursuit of knowledge. The profit motive built into the patenting, whether of research that is publicly or privately funded, affects researchers' independence due to their own financial self-interest, the university's interests in revenues from royalties and licenses, or a corporation's interests in marketing university-owned patents.¹⁷⁷

As a quid pro quo for corporate funds, universities typically agree to delays of publication for periods ranging from three to six months, or even longer, to provide time for the corporation to review the research results and for a patent application to be filed prior to disclosure through scholarly publication.¹⁷⁸ As discussed above, this university-industry relationship has promoted secrecy in research. Additionally, such agreements insert the business corporation into substantive aspects of the research process.

Universities defend such practices as a reasonable process to protect from disclosure any corporate trade secrets provided by the corporation to the researcher. Regardless of such assertions, the practice of corporate review prior to publication places the corporation in a privileged and potentially influential position in relation to the research. There have been incidents related by academics of corporate pressure to change research reports to

¹⁷⁷ Press & Washburn, *supra* note 87, at 45-47; Krinsky, *supra* note 15, at 30-35; Patricia C. Kuszler, *Conflicts of Interest in Clinical Research: Legal and Ethical Issues: Curing Conflicts of Interest in Clinical Research: Impossible Dreams and Harsh Realities*, 8 WID. L. SYMP. J. 115 (2001); *Report Emphasizes Biotech's Need for Academic-Corporate Study*, SAN FRANCISCO CHRON., Jun. 11, 2001, at D1 (describing a 117 page report, "Working Together, Creating Knowledge: The University-Industry Research Collaboration Initiative," "written by leading academic, corporate and governmental research officials," that supports the benefits of university-industry research relationships, but recommends changes in conflict of interest policies and in provisions for publication limits and delays.)

¹⁷⁸ Eisenberg, *supra* note 1, at 216-26; Krinsky, *supra* note 15, at 30; Newberg & Dunn, *supra* note 44 at , 201-12.

eliminate negative results in relation to a corporate product.¹⁷⁹ Studies have reported that corporately financed researchers are significantly more likely than researchers who are not funded by the corporation to reach favorable results concerning a corporation's product, including pharmaceutical products.¹⁸⁰ Concerns about the potential negative influence of corporate funding on research integrity has led scholarly journals to strengthen their requirements of authors' disclosures of financial sources of research support. On October 1, 2001, the journals *Nature*, the *New England Journal of Medicine*, *The Lancet*, and the *Journal of the American Medical Association* addressed the problem of conflicts of interests of researchers with close ties to private funders by requiring that authors of articles accepted for publication submit sources of funding, records of employment, and histories of financial investments. Readers will also be informed of an author's refusal to disclose this information.¹⁸¹ Even these disclosures do not reveal, however, the practice of some pharmaceutical companies to commission university professors to write an article, which is then ghostwritten by an employee of the drug

¹⁷⁹ Press & Washburn, *supra* note 87, at 42 (describing a case in 1996 where four university science researchers resigned after their corporate sponsor, Sandoz [now Novartis], altered a manuscript to remove findings of potential negative effects of the corporation's drugs: "The researchers aired their concerns in a letter to the *Journal of the American Medical Association*: 'We believe that the sponsor...was attempting to wield undue influence on the nature of the final paper. This effort was so oppressive that we felt it inhibited academic freedom.'")

¹⁸⁰ *Id.* at 42; Mildred K. Cho & Lisa A. Bero, *The Quality of Drug Studies Published in Symposium Proceedings*, 124 *ANNALS OF INTERNAL MEDICINE* 485 (1996); Mark Clayton, *Corporate Cash and Campus Labs*, *CHRISTIAN SCIENCE MONITOR*, Jun. 19, 2001, at 11; Krimsky, *supra* note 15, at 34.

¹⁸¹ Kathleen Huvane, *Researchers Required to Show Money Trail*, *WORLD WATCH*, Jan. 1, 2002, Vol. 15, No. 1, at 7.

company or medical marketing company and submitted to the professors for their approval prior to submission to a medical journal.¹⁸²

The compromise of academic researchers' independence goes beyond the problem of conflict of interests of those faculty eager to engage in research with commercial potential. The emphasis on commercialization of research creates restrictions on all faculty members' academic freedom to shape their research agendas and carry out their research.¹⁸³ The reality existed long before the growth of biotechnology that faculty are influenced in making their research choices by the availability of funding sources. The convergence of privatization trends during the 1980s, however, has consolidated and strengthened pressures on faculty to shape their research agendas to appeal to commercial interests. Thus, public policy, university practices, and corporate interests have combined to set a high priority on research with commercial potential.

Conflicts of interests may also affect faculty willingness to exercise their right to engage in extramural speech, which has long been recognized as part of faculty academic freedom.¹⁸⁴ In fact, university retaliation against faculty for extramural speech critical of corporate benefactors was a triggering event for the formation of the AAUP and demands for academic freedom. If faculty limit their exercise of academic freedom due to their financial interests, such self-censorship will produce an added cost to the public, which will lose the benefit of public critique by faculty concerning their areas of expertise. For

¹⁸² Melody Petersen, *Madison Ave. Has Growing Role in the Business of Drug Research*, NY TIMES, Nov. 22, 2002, at A1 (describing “[a] 1998 survey of named authors writing for some of the nation’s top journals, including The Journal of the American Medical Association, which published the survey, [] that 11 percent of the articles had been ghostwritten.”)

¹⁸³ See, KENNEY, *supra* note 16, at 111-13; Eisenberg, *supra* note 172, at 1377.

¹⁸⁴ Lieberwitz, *supra* note 10, at 83-84.

example, faculty who share in royalties from university-owned patents may not express views that the Bayh-Dole Act should be amended or repealed. Faculty who depend on research funding from a particular corporation may be unwilling to criticize that corporation's policies. For example, an academic scientist who relies on research funding from Glaxo-Smith Kline may avoid making public statements critical of that corporation's refusal to deal with Canadian pharmacies that fill prescriptions for American customers at the lower cost of drugs under Canadian price controls.¹⁸⁵ This example illustrates the potential negative effects from a university-industry relationship where the corporation's funds directly support specific faculty research, as contrasted with a corporation's undirected financial contribution to the university. The fear of losing a specific corporate funding grant will create much more serious constraints on a faculty member's willingness to contribute to the public domain through extramural speech.

4. Impact on Graduate Student Socialization

Graduate students represent the future of university science. Their work in faculty research labs is important, in part, for socializing them in the research science culture. The changes in the communal values in science resulting from the privatization and commercialization trends will be part of the training that graduate students receive in working with faculty. As changes in values become firmly incorporated into the culture, students will be socialized in an environment that includes commercial values and practices as part of the status quo. Currently, the traditional communal values and the more recent individualistic commercial values co-exist in a contradictory way. Graduate

¹⁸⁵ Alice Dembner, *Rallies Aim to Save Canadian Drug Sales*, BOSTON GLOBE (Feb. 20, 2003).

students may learn that both values are acceptable, depending on the nature of the science research. One can speculate, though, on the future of graduate student training. If trends continue toward university science as a commercial enterprise, graduate students may be socialized in a culture that has moved significantly far from the values of communalism.¹⁸⁶ Such changes may also affect the quality of the science research as researchers internalize individualistic values that result in greater secrecy among colleagues and if research agendas become too narrowly focused on commercial potential.

The closer relationship between universities and industry may also affect graduate student training in other ways. As science is defined by its instrumental value in serving corporate needs, the individuals working in the research programs may also be viewed more instrumentally. This may result in graduate students being used as “cheap labor” for their work in the labs.¹⁸⁷ Perhaps more importantly, the instrumental value of graduate students may be greater in future terms to the corporate funders who are given preferred access to faculty and graduate students. In this way, the corporation may seek to attract the best graduate students to work in their R&D departments after graduation.¹⁸⁸ While this may seem to be a benefit to graduate students, it is a much greater benefit to the corporations, which through their research financing can use the university as an employment agency in addition to the research carried out for the corporation’s benefit.

Further, as the research performed in the university is viewed in terms of its commercial value, the career choice of an academic or an industry research job may lose

¹⁸⁶ KENNEY, *supra* note 16, at 116-21; Press & Washburn, *supra* note 87.

¹⁸⁷ KENNEY, *supra* note 16, at 88, 117-18.

¹⁸⁸ *Id.* at 5-6.

its distinction. As the public mission of the university becomes blurred into the private interest of market actors, faculty and graduate students may cease to place a priority on pursuing research for the public good, independent from the desires or needs of their financial benefactors. If graduate students are trained in university labs engaged in extensive patenting and licensing activities, the students may see very little distinction between the science profession in a university or in a corporate R&D department.

D. Changes in the Identity of Academic Science: Part of the Corporatization of the University

The privatization trends in science do not stand alone in the university, but are part of the broader issue of the “corporatization” of the university, which imports the values, policies, and practices of business corporations into the university.¹⁸⁹ The corporatization of the university is in conflict with the fundamental values and practices of academic freedom, which are essential to retaining the public mission of the university. These corporatization trends are seen in both the teaching and research functions of the university. One major area of concern is the weakening of the tenure system. University administrations have attempted to restrict the tenure process by introducing post-tenure reviews or eliminating tenure altogether. Universities have drastically reduced tenure-track faculty positions, accompanied by an enormous increased hiring of nontenure-track faculty, including part-time and adjunct faculty. Related to this problem is the increase in graduate student teaching loads as universities use graduate students to fill the gaps created by the reduction in tenure-track faculty positions.¹⁹⁰

¹⁸⁹ Lieberwitz, *supra* note 10.

¹⁹⁰ *Id.* at 98.

The attacks on the tenure system are at the heart of the corporatization trend, reflecting shifts from the unique structure of the university to the model of the business corporation.¹⁹¹ The demands for academic freedom and tenure formed the basis of the AAUP's 1915 Declaration of Principles, reflecting the essential link between the university's public mission and faculty autonomy in choosing and carrying out their teaching and research programs.¹⁹² Academic freedom to protect faculty engaged in controversial work – including research and public speech critical of corporate benefactors of the university – makes the university a unique workplace. Faculty self-governance, through which faculty engage in peer review of their colleagues' teaching and research, is crucial to maintaining faculty independence from third parties, including administrators, trustees, government officials, and corporate donors. These faculty rights stand in stark contrast to the employment conditions of most other employees in the United States, who are subject to the "employment at will" doctrine. Under this common law doctrine, employer have the unilateral power to hire and fire employees for any reason at all, limited only by restrictions in statutes such as Title VII of the Civil Rights Act or by collective bargaining agreements or individual employment contracts. A weakened tenure system and the growth of nontenure-track faculty will increase the power of the university administration and trustees over faculty, similar to the power of business corporations, and will, conversely, decrease faculty academic freedom and independence.

Another part of the corporatization trend is the growth of for-profit education ventures by public or nonprofit universities, through which universities are engaged in

¹⁹¹ *Id.* at 96-99.

¹⁹² *See* notes 9-14 *supra* and accompanying text.

credit or noncredit education programs in a for-profit corporate structure.¹⁹³ These programs take a number of forms, including university-industry partnerships and for-profit spin-off corporations in which the university holds full or partial equity. While most of these ventures have been financial failures, the universities' enthusiastic embrace of the for-profit structure reflects the incursion of industry models into the basic educational function of the university. These for-profit educational ventures raise concerns about the university's fulfillment of its public mission. Where universities engage in education with the goal of profit-making, they have entered a conflict of interests between their public mission and their private financial interests. Universities also lose their independence from third party business interests where these businesses have been made joint partners or own equity in the for-profit spin-off corporation.

As part of the broader context of university corporatization, university patenting and licensing practices, university-industry partnerships, and corporate strategic alliances play a central role in moving the university closer to a corporate business model. The same deep concerns exist, as with other corporatization trends, about undermining faculty academic freedom and university independence from third parties. The university and its faculty are engaged in activities creating a conflict of interests between the university's public mission and their own private financial interests. These corporatization trends, particularly when viewed as a whole, raise concerns about the loss of the unique identity of the university as an institution with a public mission. Losing this identity means losing the benefits of university independence, which include: the ability to serve the public good, without the pressure to serve private interests; academic freedom, including

¹⁹³ Lieberwitz, *supra* note 10, at 104-122.

teaching and research that are in conflict with the interests of corporate financial supporters; the freedom to work with a broad imagination in choosing research agendas; and faculty rights to self-governance. If the university loses its unique identity, perhaps the greatest loss will be the loss of the university's institutional legitimacy, which depends on the public trust in the integrity of academic teaching and research that are carried out in the public interest. As the university acts for its own financial ends and for the commercial interests of corporate "partners" or "allies," the university's identity changes from a public institution to a private market actor.

The recent decision of the Federal Circuit Court of Appeals in *Madey v. Duke University* provides concrete evidence of the reality of these concerns.¹⁹⁴ In rejecting Duke University's experimental use defense to the patent infringement claim, the court stated that it found no basis for treating nonprofit institutions differently from for-profit entities in applying the patent laws. The court concluded that, as the university was using the patented invention in its regular "business" of engaging in research, it would not fall within the narrow scope of the experimental use exemption, which was intended to cover research carried out for "idle curiosity" or as a "strictly philosophical inquiry." The court did not directly base its equation of nonprofit and for-profit institutions under patent law on the similarities of universities' patent and licensing activities and for-profit commercial business. Further, the court's interpretation of the experimental use exemption denies the exemption even to non-commercial research of the university, including basic research without any potential for patenting or licensing.¹⁹⁵ Given the breadth of the its reasoning and holding, the court's decision could be critiqued simply as

¹⁹⁴ See notes 78-82 *supra* and accompanying text.

¹⁹⁵ *Madey v. Duke University*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

an overly narrow view of the experimental use exemption in the context of the university's general research function. The court's opinion did, though, include *dicta* noting that Duke's large technology transfer office engages in extensive commercial patenting and licensing activities. It is reasonable to speculate that the court's attitude toward Duke's experimental use defense was influenced by Duke's desire to have it both ways; that is, to claim freedom from patent claims for research without commercial potential while gaining the benefits of the patent laws through its own technology transfer activities, which would include collecting royalties and filing patent infringement claims.¹⁹⁶ The *Duke* decision, therefore, could be viewed as a warning of the consequences of universities' contradictory identities as institutions with a public mission and as commercial market actors. The immediate consequences may be financial and administrative, in terms of the expense and inconvenience of obtaining licensing rights to use patented research tools. The potential long-term consequences, though, are most important. As universities take on the identity of a commercial corporation, they may lose their unique position in society as institutions that are trusted to engage in independent research for the public good.

V. RECOMMENDATIONS

Proposals for reforms of public policy and private practices have aimed at reducing the problem of the restricted public domain of biomedical research discoveries, including the expansion of patents of basic research tools and the related problem of the multiplicity of licensing agreements needed to engage in biomedical research. These proposals fall into several categories: legal reforms; changes in federal agency policies

¹⁹⁶ See, Eisenberg, *supra* note 81, at 1019.

and practices; and voluntary patenting and licensing practices by universities and industry. Some of the reforms include proposals have been partially adopted, while some would require new measures.

Proposals for legal reforms call for changes in judicial doctrine interpreting current law and for legislative amendments of patent law. Stricter interpretation by the Federal Circuit of the patent law requirements of utility and non-obviousness would limit private monopoly rights on basic research by reducing the proliferation of patents in the life sciences, including in genetics research.¹⁹⁷ The PTO's adoption, in January 2001, of stricter guidelines for application of the utility requirement is a positive step in that direction.¹⁹⁸ Broader interpretation of the experimental use exemption would also be important to encourage non-commercial use of patented inventions, particularly in universities.¹⁹⁹ These changes could also be accomplished through legislative amendments of the patent laws.

Even without judicial or legislative reform, federal agencies may play a role in broadening the scope of research that enters the public domain. For example, the NIH has decided not to file for patents on most research tools developed in its intramural research program.²⁰⁰ The NIH and other funding agencies may also issue grants with the condition that grantees place research results in the public domain, though the Bayh-Dole Act limits federal agencies' ability to enforce this restriction on patenting.²⁰¹ In 1996, the National Human Genome Research Institute and the NIH announced this condition for

¹⁹⁷ Rai, *supra*, note 1, at 137-140.

¹⁹⁸ See notes 65-66 *supra* and accompanying text.

¹⁹⁹ Eisenberg, *supra* note 78; Rai, *supra* note 1, at 139.

²⁰⁰ Rai, *supra* note 1, at 148; *Symposium*, *supra* note 53, at 390.

²⁰¹ Rai, *supra* note 1, at 148.

large-scale human sequencing grants and, more recently, for grants for research on SNPs.²⁰²

Proposals for legislative reform have also focused on strengthening the power of federal agencies to require public dissemination of federally funded basic research. Congress could amend the Bayh-Dole Act to expand a federal agency's ability to withhold title from government contractors or to require government contractors to issue nonexclusive licenses for use of their federally funded patents.²⁰³ Congress could also amend the Bayh-Dole Act to give federal agencies the power to require government contractors to share basic research tools with each other.²⁰⁴

In the category of voluntary practices, some universities have adopted policies against patenting and exclusive licensing of certain types of basic research in biotechnology, due to their concern with broad dissemination and use of basic research discoveries. For example, MIT policy supports patents and exclusive licenses to patents on basic research where needed to encourage commercialization, but avoids patents on basic research that is far from the point of practical commercial development, such as ESTs. MIT licenses cell receptor patents on a nonexclusive basis. Harvard and Stanford do not patent ESTs and have a general policy not to patent SNPs.²⁰⁵ In industry, voluntary practices include patent pools, in which firms agree to provide licensing rights to patents through various

²⁰² *Id.* at 147-48; Mikhail, *supra* note 40 at 384, n.38, 392, *citing*, NATIONAL INSTITUTES OF HEALTH, REPORT OF THE NATIONAL INSTITUTES OF HEALTH WORKING GROUP ON RESEARCH TOOLS 3 (1998), *available at* <http://www.nih.gov/news/researchtools/index.htm>) *See also*, http://ott.od.nih.gov/NewPages/RTguide_final.html

²⁰³ Rai, *supra* note 1, at 151.

²⁰⁴ *Id.* at 113, 150-51.

²⁰⁵ *Id.* at 112.

systems, such as royalty-free licensing rights given to members for use of each other's patents or through licensing fees paid by nonmember firms.²⁰⁶

These proposed reforms of public and private policies and practices represent positive measures toward a goal of increasing public dissemination and use of inventions, particularly with regard to basic research tools. Reinvigorated judicial interpretation of patent law requirements would restrict the number of patents issued on basic research inventions and thereby increase the scope of the public domain, as would federal agency policies that condition receipt of public funding on the public release of research results. University or federal agency policies that discourage patents on basic research tools or that encourage nonexclusive licenses for use of patents will expand the public distribution of research discoveries. They may also create some pressure on commercial firms to place basic research in the public domain, as was the case with the policy by the federally funded consortium to publicly release data on human gene sequencing. Given the public consortium's success in publicly releasing much of this data, Celera decided that it, too, would make "raw" gene sequence data publicly available.²⁰⁷

Even with their salutary effects, though, such reform measures do not address two fundamental questions relating to the public interest: first, whether publicly funded research, either basic or applied, should be subject to privately-owned patents; and secondly, whether the university practice of patenting publicly or privately funded research is inconsistent with the university's public mission. Policies that exclude some basic research from patenting and exclusive licensing may succeed in reserving certain discoveries to the public domain. Such policies, though, do not challenge the premise

²⁰⁶ *Id.* at 129-130; *Symposium*, *supra* note 53, at 381.

²⁰⁷ Rai, *supra* note 1, at 114-15.

that private entities should own and profit from publicly funded research through patents and licenses.²⁰⁸ Nor do such policies challenge the premise that universities should be involved in market activities for the commercial interests of the university and industry. Thus, such reforms would not fully address the problems of restrictions on the public domain or the conflict between the university's commercial interests and the public interest.

The optimal means for reinvigorating the public domain and the university's public mission would be a full repeal of the Bayh-Dole Act, reinstating the pre-1980 policy of a presumption of government title to publicly funded research. The repeal of the Bayh-Dole Act would return public funding to its role of supporting research that is placed in the public domain. Given the central role of public funding in university research, this reform would also go a long way toward returning the university to its public mission to engage in research in the public interest. With the expanded public domain of federally funded inventions, legislators and federal agencies could turn their attention to adopting further reforms that would encourage broad use of these inventions by the public, including businesses. Such reforms could include measures to address the problem of the diverse and complex federal licensing regulations that had existed prior to the Bayh-Dole Act. Proponents of the Bayh-Dole Act had cited this problem to support the need for legislative reform that emphasized privatization. A different sort of reform, which avoids the problems of privatization, could directly address the problem of complicated agency regulations by adopting new procedures that meet the goal of encouraging broad access to publicly funded inventions. Federal agencies could follow consistent practices to

²⁰⁸ See, Krimsky, *supra* note 15, at 38.

broadly publicize the results of federally funded research. Further, uniform licensing procedures would encourage the broad use of publicly funded inventions. There may be cases where a federal agency decides that it is in the public interest to apply for a government-owned patent on federally funded inventions. A government-owned patent may be the best way to ensure that a private party does not apply for a patent on the same invention and to avoid litigation over the issue of prior publication of the invention.²⁰⁹ In the case of such government-owned patents on federally funded inventions, uniform policies could provide for uncomplicated procedures to apply for nonexclusive licenses. Such regulations would not be needed at all where the federal agency does not apply for a patent on a publicly funded invention, as the public may use the invention without the need for licensing.

Objections to the repeal of the Bayh-Dole Act will likely raise the point that businesses will not be interested in nonexclusive licenses to federally funded inventions, nor will businesses be interested in acting as federal contractors if their federally funded inventions will remain in the public domain. These objections, though, do not respond to the concern for using public funds in the public interest, rather than as a public subsidy for private business. The repeal of the Bayh-Dole Act would place a business back in the position of maintaining ownership, including through patents, over research results in which it invests its own capital. The business is then free to exclude all others from use of the patent or to license the patent on an exclusive or nonexclusive basis. If, on the other hand, the business receives public research funds, the business gains the benefit of

²⁰⁹ Eisenberg, *supra* note 33, at 1675-76.

carrying out experiments with the use of tax dollars.²¹⁰ Where such an experiment fails to yield commercially use results, the business has benefited from gaining this knowledge at the public's expense. If the experiment yields commercially useful results, the business could continue to use the invention under a license from the government.

Repeal of the Bayh-Dole Act would also address the problem of universities' conflict of interests, restoring a greater harmony between the traditional communal culture of science and the universities' public mission. Publicly funded university research would be placed in the public domain through scholarly publications and through government title to resulting inventions. Repealing the Bayh-Dole Act would take care of much of the problem of university patents, given the continued central role of federal funding for university research. In addition, the same rationale supports reform of university policies in relation to privately funded research. Whether academic research is publicly or privately funded, universities should not patent resulting inventions. Placing academic research results into the public domain is most consistent with the university's public mission, without the conflict of interests due to commercial activities for its own gain or for the profitability of business corporations. Adopting a presumption against patents and exclusive licenses would revive the policy followed by universities prior to the mid-1970's, including Harvard's policy that had required approval from the president and fellows before obtaining university "patents primarily concerned with therapeutics or public health" and requiring that such patents be taken only "for dedication to the public."²¹¹ Businesses would still be free to make donations to the university in the belief that academic research would provide information that will be of use to industry. If

²¹⁰ *Id.* at 1668-69.

²¹¹ Eisenberg, *supra* note 1, at n.9.

universities continue to accept corporate funding to support specific research programs and if patent rights will still be involved, universities should insist on retaining the patent, subject to nonexclusive licenses only, to encourage broad distribution of research results.

By returning its priorities to fulfilling its public mission, the university will also restore its legitimacy as an institution that exists for the public interest. The consequences of restricting university market activities may include both intangible benefits, such as boosting public confidence in university integrity, and tangible benefits, such as helping to lower the cost of medical procedures or drugs by providing publicly accessible research tools. Professor Krimsky cites several examples, including the contrast between the cost of a screening test for Tay-Sachs disease (\$100) and the screening test for two breast cancer genes (\$2400). The patent for the Tay-Sachs disease is held by the Department of Health and Human Services. A private company, Myriad Genetics, owns the patent for the breast cancer genes.²¹² Without the licensing fees, the cost for the genetic test for breast cancer is estimated at about \$50.²¹³ The tangible impact may be felt in the courts as well, in relation to the experimental use exemption. If universities return to their traditional mission of serving the public, the courts may be more inclined to treat universities as unique research institutions that require special treatment such as a broad experimental use exemption from the patent law.

These recommendations for restoring the university to its public mission in research are also important for addressing the broader problem of the corporatization of the university. The only way to protect the university's identity as an institution working in

²¹² Krimsky, *supra* note 15, at 37.

²¹³ Charles Leroux, *Biotech's Traffic Cop: Chicago Attorney Lori Andrews Stands Where Science and the Law Intersect*, CHI. TRIB., Oct. 7, 2001, at C12.

the public interest is to restrict the university's policies and practices that promote a commercial corporate identity. Reforms, therefore, are needed on all fronts: to contribute research to the public domain; to provide critical education in the public interest; and to contribute to public debate. Such reforms, in short, should enhance the full exercise of academic freedom. In the research domain, academic freedom will be strengthened through greater independence of the faculty and the university from commercial interests, whether self-interest or corporate interests. With this goal in mind, public policy and university practice can be shaped to benefit the public good.