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UNIVERSITY-INDUSTRY COLLABORATION: THE UNITED STATES EXPERIENCE

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The importance of university research in the United States system of technological innovation has been much admired, and it is often cited as a model that other countries should emulate, particularly developing countries. The success of this model is often identified with the Bayh-Dole Act of 1980, which allowed universities to patent the results of federally funded—government funded—research. However, recent studies claim that the role of Bayh-Dole—of intellectual property law—has been exaggerated, and the general context in which it operates has been somewhat misunderstood.[1]

I personally believe that the American experience with regard to collaboration between universities and industry is worthy of emulation by developing countries, but only if we clarify the context that made Bayh-Dole work in the U.S. and if we take pains to identify the conditions in developing countries that are needed to transplant such a model to those countries. Even in the United States, moreover, we must improve upon the Bayh-Dole formula to resolve the new pressures it has put on the conduct of research generally. In particular, action is needed to promote the dissemination of research results as inputs into future research, and also to ensure

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[1] DAVID C. MOWERY, RICHARD R. NELSON, BHAREN N. SAMPAT, AND ARVID A. ZIEDONIS, IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT IN THE UNITED STATES (Stanford Business Books, 2004). *See also* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 12 VA. L. REV. 1663 (1996). For the Bayh-Dole Act, see Act of December 12, 1980, Pub. L. No. 96-517, §6(a), 94 Stat. 3015, 3019-28 (1980), codified as amended at 35 U.S.C. §§200-212 (1994).

that the products of federally funded research are made available to the public at reasonable and affordable prices.

I. Background to the Bayh Dole Act of 1980

From their origins, American universities were highly focused on agriculture, the mechanical arts, and regional economic industries, i.e., on utilitarian pursuits and not just basic research. This was particularly true of the land-grant universities that are the backbone of the fifty state's higher education system. These state universities succeeded by responding to the needs of their local communities; and dependence on local support was also true, to a lesser extent, of the great private universities in the nineteenth and twentieth centuries.[2] So, unlike their European counterparts, U.S. universities undertook teaching and research in very practical fields from the beginning, and they were not primarily training graduates for governmental service. Moreover, in the United States, there is a "unified national market for faculty at… research universities." This makes for a very competitive situation, in which a professor's status depends on contributions to research in his or her field, there is strong interinstitutional mobility, and "strong competition among… universities for prestige, resources, and students."[3] These structural characteristics created strong industry-university ties early on, with emphasis on commercial applications regardless of formal intellectual property protection. There was also rapid dissemination of results as graduates moved into industry.[4]

The Second World War and then the Cold War led to massive federal funding of university research, especially in areas related to defense and public health. In the postwar period, moreover, it became clear that "basic research was the ultimate source of economic growth."[5] From about $150 million a year in 1935-36, federal support for university research grew to about $2.1 billion in 1960 and to about $14 billion in 1995 (at least 60% of all academic research support since 1960).[6]

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[2] *See* MOWERY et al, above n. 1, 9-14.
[3] *Id*. at 10-13.
[4] *Id*.
[5] *Id*. at 22. (citing Vannevar Bush).
[6] *Id*. at 23-24.

Let me stress that the bulk of federally funded research is neither primarily practical nor primarily theoretical, but rather a little of both. Most of it was designed as basic research in the sense of aiming for "fundamental understanding of the object of study," but "it was also motivated by the desire to solve practical problems." This type of research is located in what a famous book by Stokes called "Pasteur's Quadrant,"[7] and it is supplemented by growing industrial support for university research (7.4% in 1998) as well.

This context enabled American universities to explore "fundamentally uncertain technologies," especially information technologies, biomedical science, and materials science in the postwar period. Very important in achieving successful outcomes was the emphasis on peer reviewed grants and inter-institutional competition in virtually all federal programs supporting academic research and development. Interaction between universities and new industrial enterprises then became even more intense as Silicon Valleys and analogous research parks built around universities were set up in California, Massachusetts, North Carolina, and elsewhere.[8]

While university research was thus relevant to many key industries in the knowledge economy, it was generally received as basic inputs from published papers, conferences, consulting, and the hiring of graduate students, not primarily from patents or intellectual property. Studies show that only certain industries, relatively few industries, relied on university research as a main source of inventions, especially biotech and pharmaceuticals, engineering and scientific instruments, semiconductors, and certain other, especially new areas of engineering. In other words, university research affects different industries differently,[9] and in most fields, universities receive important inputs from industry as well. Collaboration between universities and industry in the United States has thus usually been a two-way street.

II. Patenting by Universities Before and After the Bayh-Dole Act of 1980

According to Mowery and co authors, it was not until the 1970s that U.S. universities began to take a keen interest in patenting and the management of their own patent portfolios. Biomedical patents were the wedge, but university patents were still controversial: many feared

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[7] *Id*. at 26. *See generally* D.E. STOKES, PASTEUR'S QUADRANT: BASIC SCIENCE AND TECHNOLOGICAL INNOVATION (Brookings Inst. 1997).
[8] MOWERY et al, above n. 1, at 27.
[9] *Id*. at 34.

that patenting would conflict with open access and the sharing norms of science and with the public good mission of universities. Nevertheless, federal funding of research in biomedical research in the 1970s led to big payoffs in both research and product potential. Competing universities sought to patent inventions for the benefit of state taxpayers; federal agencies each had different patent policies; and stronger links between industry and universities were forged in a constant search for resources.[10]

By the 1980s, the universities most active in patenting wanted more control over their federally funded research results, and they also wanted a uniform federal policy, rather than agency-by-agency decisions, as matters stood. So these universities lobbied for the Bayh-Dole Act. Another impetus were concerns that U.S. competitiveness in global markets depended on more and better basic research and on more and better applications of basic research. It was argued that these goals would require investors to obtain reliable property rights in order to take embryonic discoveries out of the labs and convert them to working inventions at considerable cost and risk.[11]

The Bayh-Dole Act of 1980 allowed universities, especially Harvard, Stanford, University of California and M.I.T., to obtain exclusive patent rights on federally funded research results. The federal government retains an exclusive royalty-free license (i.e., for government use). The government also retains “march in” rights to compel licensing in the public interest, including public health and safety (with rules for disclosure). This public interest license has never been used. The government also retains the power to impose a public interest compulsory license to remedy cases of abuse, which could occur if [the] products of research results were not made available to the public on reasonable terms.[12]

Some commentators view this last provision as a *de facto* basis for price controls of pharmaceuticals resulting from federally funded research.[13] My own analysis of the statute suggests that this provision was closely analogous to, and perhaps modeled on, the Canadian statute governing abuse of patents, in force at the time; but that it was never intended as a price

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[10] *Id*. at 34.
[11] *Id*. at 57.
[12] *See, e.g.,* J. H. Reichman, Testimony Before NIH Public Hearing on March-In Rights under the Bayh-Dole Act, Washington D.C., May 25, 2004.
[13] *See* Peter S. Arno & Michael H. Davis, *Why Don’t We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TUL. L. REV. 631 (2001).

control regime as such, like that which Canada adopted after 1992.[14] In any event, triggering a Bayh-Dole compulsory license for public health depends initially on the discretion of the Director of the National Institutes of Health (NIH), and "the overall administrative obstacles are sufficiently cumbersome" that the provision has never successfully been invoked.[15]

The primary effect of the Bayh-Dole Act was mainly to codify a single uniform federal policy and to legitimate what some major universities had already been doing. What really changed after 1980 was thus not so much university patent policies or federal grant-making policies. What changed was first, the *Diamond v. Chakrabarty* case in the Supreme Court, 1980, which opened the door to "patenting the organisms, molecules and research techniques emerging from biotechnology;"[16] and second, the creation of the United States Court of Appeals for the Federal Circuit in 1982, which enormously expanded both patentable subject matter and the scope of protection. This broader shift toward stronger intellectual property rights from the 1980s on meant that universities would inevitably have patented more federally funded research results with or without Bayh-Dole, but in a more uncertain and less efficient legal climate. Hence, Mowery and coauthors conclude that Bayh-Dole was an effect, not a cause, of a surge in university patenting and licensing.

The real or deeper causes of this trend were those we have already identified:

- Long-standing relationships between U.S. industries and universities;
- Broad shift to stronger intellectual property rights from the 1980s on;
- Transformation of biomedical science from 1970s on.[17]

Moreover, while university patents increasingly do support some important technology transfers, they remain only a part of the United States innovation system. The role of non-IP interaction between universities and industry is much greater overall, and experts warn that there are growing risks for U.S. universities from too much intellectual property protection.[18]

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[14] *See* Reichman, Testimony, above n. 12; *see also* Jerome H. Reichman with Catherine Hasenzahl, *Non-Voluntary Licensing of Patented Inventions, Pt. I, Historical Perspective, Legal Framework Under TRIPS and an Overview of the Practice in Canada and the United* States (UNCTAD) ICTSD, September 2002) and *Pt. II, The Canadian Experience* (UNCTAD/ICTSD, October 2002).
[15] *See* Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine,* 66 LAW & CONTEMP. PROBS. 289, 294 (2003).
[16] MOWERY *et al*, above n. 1, at 26; Diamond v. Chakrabarty, 447 U.S. 303 (1980).
[17] MOWERY *et al*, above n. 1, at 19-20.
[18] *See, e.g.*, MOWERY *et al*, above n. 1, Ch. 9; Rai & Eisenberg, above n. 15.

III. Evaluation of University Patenting of Government Funded Research Results under Bayh-Dole

The American experience shows that university-industry collaboration can play a major role in present-day economic development strategies. However, intellectual property as a component of that role is more complex and nuanced than much of the literature extolling Bayh-Dole would have us believe. Today, indeed, there are growing concerns that the intellectual property component requires much more careful balancing and management than was previously considered, if it is not to impede upstream research and retard future development.[19]

While the Bayh-Dole Act mainly codified existing trends in university patenting (e.g., the case of Columbia University), it did increase patenting at some major universities, e.g., Stanford and the University of California. Gradually, many more universities became active in the patenting of federally funded research results, but their returns were mostly marginal until recently. There is evidence that the quality of university patents and their economic potential has improved lately, as technology transfer offices become more proficient.[20] Nevertheless, university patenting in the United States remains concentrated in a narrow range of fields, primarily biomedical, where patents are strong and of great value, in part because they support the costs of clinical trials and perfecting embryonic discoveries and thus help to attract venture capital.

Mowery and coauthors doubt that the universities' contribution to economic growth and innovation was qualitatively greater after 1980 than before passage of the Bayh-Dole Act. Rather, they stress the continuing importance of general interaction between the two communities—universities and industry—through research and training, publications, and responsiveness to local community needs.[21] While patents sometimes facilitate technology transfer, often it does not depend on intellectual property at all.[22] However, reliance on

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[19] *See, e.g.,* Rai & Eisenberg, above n. 15; *see also* Keith E. Maskus & Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods, in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME (K. E. Maskus & J. H. Reichman eds. Cambridge Univ. Press 2005).

[20] *See, e.g.,* MOWERY et al, above n. 1, at 93. On the whole, however, university technology transfer offices have produced mixed results. They lack qualified personnel and they over-concentrate on revenues rather than other aspects of the university mission.

[21] *Id.,* at 183.

[22] *Id.,* at 184.

intellectual property at universities may be growing, a phenomenon which data in existing studies may not adequately capture.[23]

The good news is that Bayh-Dole seems not so far to have affected the direction of research, mainly because U.S. research was always focused on the relations between basic and applied goals, nor has it adversely affected the research climate in most university departments.[24] In some fields, especially biomedicine, patents, help to attract venture capital and to bring embryonic discoveries out of the laboratory and into commerce. Patent disclosures can also function as publications in the public domain.

However, Mowery and coauthors warn that the biotech model could prove harmful to other fields, and that patents can actually "discourage university-industry collaboration in other fields" where it is more fluid and inherently interactive.[25] Moreover, as patentable subject matter expands, we encounter more and more patents on what were formerly scientific activities—ideas, materials, and techniques, especially, research tools—that represent key inputs into scientific research. [26] There has also been a shift at university technology transfer offices to increasingly strong exclusive licenses, which can create blocking effects and patent thickets, problems that are made worse by the issuance of over-broad patents on research results, which inherently hinder follow-on research. [27]

Other growing problems include:

- Delays of publication to favor obtaining patents (despite a novelty grace period in the U.S.) (20% of respondents).[28]
- Increasing denials of access to data, materials, or research outcomes (50% in biotech, 73% genetics) (conflict with open access and sharing norms of science).[29]
- Evidence of growing transaction costs—patent thickets—when too many intellectual property rights clog the research path.[30]

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[23] *See generally*, J. H. Reichman & Paul F. Uhlir, *A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment*, 66 LAW & CONTEMP. PROBS. 315 (2003)
[24] MOWERY et al, above n. 1, at 183-84.
[25] *Id.* at 183-84.
[26] *See, e.g.,* Rai & Eisenberg, above n. 15 (citing authorities).
[27] *See id*.
[28] *See* MOWERY et al, above n. 1, at 185.
[29] *See id.*at 186; *see generally*, Reichman & Uhlir, above n. 22.

- More and more complex licensing agreements and Material Transfer Agreements (with intricate reach through and grant back clauses).[31]

On the whole, the evidence reveals a growing need to balance the economic incentives of researchers with the research needs of the scientific and technical communities. This concern elicits interest in new types of intellectual property, such as open-source licensing strategies and especially, potential uses of liability rules instead of exclusive property rights in regard to government-funded research results, which we are working on at Duke.[32] Note in this connection that federal funders may be able to impose sharing rules, non-exclusive licenses, and even *ex ante* automatic licenses (liability rules), if they want to, without federal legislation.[33]

Looking to the future, there is a need to organize the inter-university sharing of data and research tools on a separate track from industrial applications, so as to ensure that universities have access for research purposes without impeding their ability to commercialize research results for other purposes.[34] Otherwise, universities may view themselves too much as commercial competitors rather than research collaborators. There is also a pressing need for an appropriate research exemption to patents after *Duke v. Madey*,[35] and ways must be found to strengthen the federal agencies' ability to limit patenting or restrictive licensing of critically important scientific discoveries.[36]

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[30] *See, e.g.,* Rai & Eisenberg, above n. 15. *But see* John Walsh *et al, The Patenting and Licensing of Research Tools and Biomedical Innovation,* May 5, 2002.
[31]*See,* Rai & Eisenberg, above n. 15 (citing authorities).
[32] *See, e.g.,* Arti K. Rai, *Open Source Biotech* (lecture a Duke University School of Law); *cf.* J. H. Reichman, *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation,* 53 Vanderbilt L. Rev. 1743 (2000); Tracy Lewis & J. H. Reichman, *Using Liability Rules to Stimulate Innovation in Developing Countries: Application to Traditional Knowledge, in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY, above n. 19.
[33] *See, e.g.,* Reichman & Uhlir, above n. 22, Pt. IV.
[34] *See* generally *id.*
[35] Duke University v. John M.S. Madey, 539 U.S. 958 (2003).
[36] *See, e.g.,* Rai & Eisenberg, above n. 15.