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Biotechnical Transfer: The Weaknesses and Strengths of Bayh-Dole

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In 1980, Congress enacted the Patent and Trademark Law Amendments Act, which is generally referred to as the Bayh-Dole Act.¹ Even though Bayh-Dole was enacted almost three decades ago, its ramifications still persist today.² This statute instructed universities to patent and commercialize publicly-funded scientific research.³ The rationale behind Bayh-Dole was to allow “universities and small businesses...to become directly involved in the commercialization process.”⁴ In short, Bayh-Dole facilitates the transfer of research results from universities to the commercial marketplace for the public benefit; a practice known as technology transfer.⁵ Since its passage in 1980, Bayh-Dole has turned universities into centers for breakthroughs in technology and medicine.⁶

Congress enacted this legislation after a series of congressional debates

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¹ The Patent and Trademark Law Amendments Act (Bayh-Dole) of 1980, Pub. L. No. 96-517, 94 Stat. 3015 (1980); COUNCIL ON GOVERNMENTAL RELATIONS, THE BAYH-DOLE ACT: A GUIDE TO THE LAW AND IMPLEMENTING REGULATIONS 1 (1999), available at http://www.cogr.edu/docs/Bayh_Dole.pdf [hereinafter COGR].

² Brett T. Roseman, *Advice from the Top: University Research Helps USA Compete*, USA TODAY, June 5, 2008, available at http://www.usatoday.com/money/companies/management/2008-05-18-texas-instruments-rich-templeton_N.htm.

³ THE INT’L EXPERT GROUP ON BIOTECHNOLOGY, INNOVATION, AND INTELL. PROPERTY, TOWARD A NEW ERA OF INTELLECTUAL PROPERTY: FROM CONFRONTATION TO NEGOTIATION (EXECUTIVE SUMMARY) 5 (2008), available at http://www.theinnovationpartnership.org/ieg/documents/report/TIP_Executive_Summary_E.pdf [hereinafter NEW ERA].

⁴ COGR, *supra* note 1, at 2.

⁵ *Id.* at 1.

⁶ Roseman, *supra* note 2.

and deliberations throughout the 1960s and 1970s.⁷ Prior to 1980, the private sector utilized less than five percent of government-owned patents, despite the fact that there was potential for further commercialization.⁸ At the time, government-owned patents offered little protection because they were made available through non-exclusive licenses and were offered to anyone who wanted to utilize them.⁹ Industry investment in technology development was curtailed because exclusive licenses were not widely available for government-funded inventions.¹⁰ Congress thought the economy would be stimulated if the inventions of publicly funded universities could be easily licensed to businesses that would manufacture resulting products.¹¹ The legislation reflects this belief, stating:

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising 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; [and] to ensure that the Government obtains sufficient rights in federally-supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions....¹²

To accomplish its objective, Bayh-Dole provides that universities may retain title to any invention made with federal funds, except in limited circumstances where the government determines that restriction or elimination of the right to retain title is necessary.¹³ If the university chooses to retain title, the

⁷ WENDY H. SCHACHT, CONG. RES. SERV., THE BAYH-DOLE ACT: SELECTED ISSUES IN PATENT POLICY AND THE COMMERCIALIZATION OF TECHNOLOGY 1 (2008) *available at* <http://italy.usembassy.gov/pdf/other/RL32076.pdf>.

⁸ COGR, *supra* note 1, at 2.

⁹ *Id.*

¹⁰ SCHACHT, *supra* note 7, at 2.

¹¹ COGR, *supra* note 1, at 2.

¹² The Patent and Trademark Law Amendments (Bayh-Dole) Act of 1980, Pub. L. No. 96-517, § 200, 94 Stat. 3015 (1980).

¹³ SCHACHT, *supra* note 7, at 7.

government retains a non-exclusive, non-transferable, irrevocable right to practice or have practiced the invention on behalf of the United States.¹⁴ The university “must commit to commercialization within a predetermined, agreed upon, time frame.”¹⁵ If the university does not meet this requirement, the government may exercise “march-in rights,” which enable the government to require a contractor to “grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants.”¹⁶ The university is also obligated to obtain written agreements with its technical staff and faculty requiring assignment and disclosure of inventions.¹⁷ Moreover, the university must disclose each new invention to the federal agency that provided federal funding within two months of the inventor disclosing the discovery to the university.¹⁸

Many Bayh-Dole supporters contend that it is a catalyst for economic growth and is vital for the transfer of technology from university to industry.¹⁹ That assertion, however, is countered by the argument that a fixation on patents and privately-controlled research often impedes innovation.²⁰ For example, one study examined stem cell researchers and suggested that the least collaborative researchers are those who patent the most.²¹ Still, the United States granted 8,000 patents to institutions between 1993 and 1997, with more than 1,000 products based on university-licensed inventions currently on the market.²² A Government Accountability Office study found that nine out of ten business executives identified Bayh-Dole as an “important factor” in their decisions to fund research

¹⁴ COGR, *supra* note 1, at 5.

¹⁵ SCHACHT, *supra* note 7, at 7.

¹⁶ *Id.* at 7-8.

¹⁷ COGR, *supra* note 1, at 4.

¹⁸ *Id.*

¹⁹ Sara Boettiger & Alan B. Bennett, *Bayh-Dole: If We Knew Then What We Know Now*, 24 NATURE BIOTECHNOLOGY 320, 320 (2006), available at http://www.bios.net/daisy/cambia/2012/version/default/part/AttachmentData/data/Bayh-Dole-if_we_knew_then_what_we_know_now.pdf.

²⁰ NEW ERA, *supra* note 3, at 5.

²¹ Maureen Martino, *Landmark Study Reports Breakdown in Biotech Patent System*, FIERCEBIOTECH, Sept. 10, 2008, <http://www.fiercebiotech.com/press-releases/landmark-study-reports-breakdown-biotech-patent-system>.

²² COGR, *supra* note 1, at 9.

and development in academia.²³

A growing area of concern with regard to Bayh-Dole is the increasing number of patents being issued for research tools. A research tool is technology that is used by researchers to refine, design, or identify new innovations.²⁴ A study of U.S. academic scientists has shown that research tool patents have posed such a hurdle to innovation that scientists routinely ignore patent rights in conducting their research.²⁵ In response, research institutions funded by the National Institutes of Health voluntarily adopted a guideline that research tools be nonexclusively licensed.²⁶ The International Expert Group on Biotechnology, Innovation and Intellectual Property suggested that universities implement clear values relating to the use and spread of intellectual property to promote broad licensing and greater access to research tools.²⁷ Some have suggested that research tools should be protected by implementing a federal research tool policy which would encompass Bayh-Dole.²⁸ In contrast, a Yale scholar posited that although research tools ought to be kept in the public domain, Bayh-Dole is not responsible for their privatization.²⁹ Instead, research tool privatization lies with patent law enacted by Congress and developed by the courts.³⁰

For a long time, researchers operated under Bayh-Dole thinking that they were exempted from patents, so long as they were only using the technology for further research.³¹ However, in the wake of *Madey v. Duke University*, it appears that any university research may be considered to advance the business interests of the institution, making such pursuits commercial, not philosophical (or exempt

²³ SCHACHT, *supra* note 7, at 9.

²⁴ ANN MILLS & PATTI TERESKERZ, BIOTECHNOLOGY INDUSTRY ORGANIZATION, PROPOSED PATENT REFORM LEGISLATION: LIMITATIONS OF EMPIRICAL DATA USED TO INFORM THE PUBLIC POLICY DEBATE 7 (2008), available at http://bio.org/ip/domestic/UVA_Limitations_of_Empirical_Data.pdf.

²⁵ NEW ERA, *supra* note 3, at 5.

²⁶ Boettiger & Bennett, *supra* note 19, at 321.

²⁷ Martino, *supra* note 21.

²⁸ Boettiger & Bennett, *supra* note 19, at 321.

²⁹ SCHACHT, *supra* note 7, at 25.

³⁰ *Id.*

³¹ Boettiger & Bennett, *supra* note 19, at 321.

from IP restrictions).³² If an invention is exclusively licensed, it may be unavailable for future research, even by the very scientist who created it.³³ The University of California has been progressive in its licensing and patenting practices, so that other institutions may use University of California technology to further research.³⁴ However, this practice has not been widely adopted.³⁵

Despite its difficulties, the current patenting procedure does not appear to be impeding research. A 2006 study identified the top five reasons for project abandonment, in order of frequency: “‘lack of funding’ (62%), ‘conflict with other priorities’ (60%), ‘a judgment that the project was not feasible’ (46%), ‘not scientifically important (40%),’ and ‘not that interesting’ (35%).”³⁶ Only three percent of survey respondents named “too many patents covering needed research inputs” as a reason for project abandonment.³⁷ However, no comment was made as to how much funding is needed to finance licenses on research inputs covered by patents. If this number is high, patents may be a greater impediment to research than these numbers suggest.

Despite concerns, Bayh-Dole is widely considered a success, causing one commentator to note that Bayh-Dole is “probably the most inspired piece of legislation to be enacted in America over the past half-century.”³⁸ Bayh-Dole has elicited innovations such as artificial lung surfactant for use with newborn infants from the University of California; Citracal[®], a calcium supplement from the University of Texas Southwestern Medical Center; and recombinant DNA technology from Stanford University and the University of California.³⁹

Bayh-Dole and its subsequent amendments performed just as intended: the law provided incentives for industry, universities, and the government to

³² 307 F.3d 1351 (Fed. Cir. 2002); Boettiger & Bennett, *supra* note 19, at 321.

³³ Boettiger & Bennett, *supra* note 19, at 321.

³⁴ *Id.*

³⁵ *Id.*

³⁶ MILLS & TERESKERZ, *supra* note 24, at 17.

³⁷ *Id.* at 17-18.

³⁸ SCHACHT, *supra* note 7, at 10.

³⁹ COGR, *supra* note 1, at 8.

cooperate in the development of new technologies for the public benefit.⁴⁰ Bayh-Dole has allowed universities to generate funds for additional research. For example, in 2004, university licensees generated \$1.4 billion in royalties.⁴¹ Certainty of title and implementation of uniform patenting and licensing procedures for inventions made under federal funding are identified as the most important incentives for commercialization.⁴² By actualizing these factors, at little cost to taxpayers, Bayh-Dole has proven to be a leader in the promotion of innovation.

⁴⁰ *Id.* at 9.

⁴¹ SCHACHT, *supra* note 7, at 11.

⁴² COGR, *supra* note 1, at 9.