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The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology

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Summary

Congressional interest in facilitating U.S. technological innovation led to the passage of P.L. 96-517, Amendments to the Patent and Trademark Act (commonly referred to as the Bayh-Dole Act after its two main sponsors). The act grants patent rights to inventions arising out of government- sponsored research and development (R&D) to certain types of entities with the expressed purpose of encouraging the commercialization of new technologies through cooperative ventures between and among the research community, small business, and industry.

Patents provide an economic incentive for companies to pursue further development and commercialization. Studies have shown that research funding accounts for approximately one-quarter of the costs associated with bringing a new product to market. Patent ownership is seen as a way to encourage the additional, and often substantial investment necessary for generating new goods and services. In an academic setting, the possession of title to inventions is expected to provide motivation for the university to license the technology to the private sector for commercialization in expectation of royalty payments.

The Bayh-Dole Act has been seen as particularly successful in meeting its objectives. However, while the legislation provides a general framework to promote expanded utilization of the results of federally funded research and development, questions are being raised as to the adequacy of current arrangements. Most agree that closer cooperation among industry, government, and academia can augment funding sources (both in the private and public sectors), increase technology transfer, stimulate more innovation (beyond invention), lead to new products and processes, and expand markets. However, others point out that collaboration may provide an increased opportunity for conflict of interest, redirection of research, less openness in sharing of scientific discovery, and a greater emphasis on applied rather than basic research. Additional concerns have been expressed, particularly in relation to the pharmaceutical and biotechnology industries, that the government and the public are not receiving benefits commensurate with the federal contribution to the initial research and development.

Actual experience and cited studies point to the conclusion that companies which do not control the results of their investments – either through ownership of patent title, exclusive license, or pricing decisions – tend to be less likely to engage in related R&D. The importance of control over intellectual property is reinforced by the positive effect P.L. 96-517 has had on the emergence of new technologies and techniques generated by U.S. companies.

This report will be updated as events warrant.

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Introduction

Congressional interest in facilitating U.S. technological innovation led to the passage of P.L. 96-517, Amendments to the Patent and Trademark Act, commonly referred to as the "Bayh-Dole Act" after its two main sponsors former Senators Robert Dole and Birch Bayh. Under this 1980 law, as amened, title to inventions made with government support is provided to the contractor if that contractor is a small business, a university, or other non-profit institution. The legislation is intended to use patent ownership as an incentive for private sector development and commercialization of federally funded research and development (R&D). As a response to congressional efforts to create a unified government patent policy pertaining to inventions made with federal support, the Bayh-Dole Act promotes cooperative activities among academia, small business, and industry leading to new products and processes for the marketplace.

This paper discusses the rationale behind the passage of P.L. 96-517, its provisions, and implementation of the law. Observers generally agree that the Bayh-Dole Act has successfully met its objectives. However, some experts argue that the issues associated with the law's patent policies should be revisited given the current R&D environment. Much of the renewed interest is a result of the legislation's effect on the biotechnology and pharmaceutical industries where critics assert that the private sector is receiving benefits to the detriment of the public interest. Other analysts, particularly in the defense arena, maintain that the existing rights maintained by the government are too restrictive and prevent industry from meeting national needs. Many of these issues and concerns are similar, if not identical to those addressed during the 15 to 20 years of deliberation prior to enactment of the law. These too will be explored to provide a context for current discussions.

An Historical Perspective

The Rationale

In the late 1970s, the United States Congress was involved in a series of legislative debates over ways to promote private sector development and utilization of federally funded research and development. This was soon followed by expanded congressional interest in additional means to foster technological advancement and commercialization in industry. During the 1980s and 1990s, various initiatives

resulted in laws designed to encourage increased innovation-related activities in the business community and to remove barriers to technology development, thereby permitting market forces to operate.[1] Laws promoting cooperative R&D and/or joint ventures involving the federal government, industry, and academia have been a cornerstone of the majority of these efforts and include legislation that created a system to transfer technology from federal laboratories to the private sector; implemented tax incentives for collaborative work; instituted direct and indirect government support for increased R&D; and changed government patent policy to provide an economic inducement for commercialization of federally funded technology, the subject of this report.

P.L. 96-517, the Bayh-Dole Act, was one of the first of these initiatives. Prior to 1980, only 5% of government owned patents were ever used in the private sector although a portion of the intellectual property portfolio had potential for further development, application, and marketing. The Bayh-Dole Act was developed, in part, to address the low utilization rate of these federal patents. The House report to accompany H.R. 6933 (the House counterpart to the Senate bill that eventually became the Bayh-Dole Act) noted that, at the time the bill was considered, 26 different agency policies existed regarding the use of the results of federally funded R&D. Generally the government retained title to inventions made with government support whether the research was performed in federal laboratories, in universities, or by individual companies. Licenses to use the government patents were then negotiated with firms either on a non-exclusive basis (meaning additional companies could use the technology) or, more rarely, for the exclusive use by one manufacturer. However, it was widely argued that without title (or at least an exclusive license) to an invention and the protection it conveys, a company would not invest the additional, and substantial time and money necessary to commercialize a product or process for the marketplace.

In 1980, the federal expenditures for research and development totaled $55.5 billion (in constant 2000 dollars).[2] The money typically was used to support research and development to meet the mission requirements of the federal departments and agencies (e.g., defense, public health, environmental quality) or to finance work in areas where there was an identified need for research, primarily basic research, not being performed in the private sector. While the government's investment led to many new inventions that have profoundly influenced our society, many in Congress were of the opinion that additional applications could be pursued by the private sector if provided the proper incentives.

The intent of the new law was to replace this situation with a "single, uniform national policy designed to cut down on bureaucracy and encourage private industry to utilize government financed inventions through the commitment of the risk capital

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[1] For additional discussion see CRS Report RL33528, *Industrial Competitiveness and Technological Advancement: Debate Over Government Policy*, by Wendy H. Schacht.

[2] National Science Board, *Science and Engineering Indicators – 2006*, Washington, National Science Foundation, A4-5.

necessary to develop such inventions to the point of commercial application."[3] Expanded technology commercialization was to be accomplished by employing the patent system to augment collaboration between universities (as well as other nonprofit institutions) and the business community to ensure that inventions are brought to market. The Bayh-Dole Act also provides for the increased participation of small firms in the national R&D enterprise under the assumption that these companies tend to be more innovative than larger companies.

The Patent System: A Brief Overview

The patent system was created to promote invention and innovation. Article I, Section 8, Clause 8 of the U.S. Constitution states: "The Congress Shall Have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . ." Patents are widely believed to encourage innovation by simultaneously protecting the inventor and fostering competition. They provide the inventor with a right to exclude others, temporarily, from use of the invention without compensation. Patents give the owner an exclusive right for 20 years (from date of filing) to further develop the idea, commercialize a product or process, and potentially realize a return on the initial investment. Concurrently, the process of obtaining a patent places the concept in the public arena. As a disclosure system, the patent can, and often does, stimulate other firms or individuals to invent "around" existing patents to provide for parallel technical developments or meet similar market needs.[4]

Not everyone agrees that the patent system facilitates innovation. Critics argue that patents provide a monopoly which induces additional social costs and that cross licensing between companies can result in exploitation of markets. Some analysts claim that the patent system was designed to assist the individual inventor and the shift toward more R&D being performed in large companies has diminished the patent's value to society since these firms can utilize other methods to protect their investments including lead time and trade secrets.

The importance of patents varies among industrial sectors. Patents are perceived as critical in the drug and chemical industries in part because of the ease of replicating the finished product. While it is expensive, complicated, and time consuming to duplicate an airplane, it is relatively simple to chemically analyze a pill and reproduce it.[5] The degree to which industry perceives patents as effective has been characterized as "positively correlated with the increase in duplication costs and

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[3] House Committee on the Judiciary, *Report to Accompany H.R. 6933*, 96th Cong., 2d Sess., H.Rept. 96-1307, Part 1, 3.

[4] For more information see CRS Report 97-599, *Patents and Innovation: Issues in Patent Reform*, by Wendy H. Schacht,

[5] Federic M. Scherer, "The Economics of Human Gene Patents", 77 *Academic Medicine*, December 2002, 1350.

time associated with patents."[6] In certain industries, patents significantly raise the costs incurred by nonpatent holders wishing to use the idea or invent around the patent — an estimated 40% in the pharmaceutical sector, 30% for major new chemical products, and 25% for typical chemical goods — and are thus viewed as significant. However, in other industries, patents have much smaller impact on the costs associated with imitation (e.g. in the 7%-15% range for electronics), and may be considered less successful in protecting resource investments.[7]

Patents provide an economic incentive for companies to pursue further development and commercialization. Studies have shown that research funding accounts for approximately one-quarter of the costs associated with bringing a new product to market. According to *The Economist*, "A dollar's worth of academic invention or discover requires upwards of $10,000 of private capital to bring [it] to market."[8] Patent ownership is seen as a way to encourage the additional, and often substantial investment necessary for new goods and services, particularly in the case of small business. In an academic setting, the possession of title to inventions is expected to provide motivation for the university to license the technology to the private sector for commercialization in anticipation of royalty payments.

University-Industry Cooperation

Changes to the patent laws embodied in the Bayh-Dole Act had as an objective the facilitation of collaborative ventures between and among academia, industry, and government. In 1980, universities performed 14% of the R&D undertaken in the United States (similar to today); much of this fundamental research basic to technological advance.[9] The work is accomplished as part of the education process and provides training for scientists, engineers, and managers subsequently employed by the private sector.

Universities, however, generally do not have the means of production necessary to take the results of research and generate marketable products. Such activities are carried out by industry. Thus, the emphasis in the Bayh-Dole Act on the promotion of cooperative efforts between academia and the business community. By providing universities with intellectual property ownership with which to pursue and structure collaborative ventures, the legislation encourages the two sectors to work together to generate new goods, processes, and services for the marketplace. Such joint work allows for shared costs, shared risks, shared facilities, and shared expertise.

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[6] Richard C. Levin, Alvin K. Klevorick, Richard R. Nelson, and Sidney G. Winter. "Appropriating the Returns for Industrial Research and Development," *Brookings Papers on Economic Activity*, 1987, in *The Economics of Technical Change*, eds. Edwin Mansfield and Elizabeth Mansfield (Vermont, Edward Elgar Publishing Co., 1993), 269.

[7] Edwin Mansfield, Mark Schwartz, and Samuel Wagner. "Imitation Costs and Patents: An Empirical Study," *The Economic Journal*, December 1981, in *The Economics of Technical Change*, 270.

[8] "Innovation's Golden Goose," *The Economist (US)*, Dec. 14, 2002.

[9] National Science Board, *Science and Engineering Indicators – 2002*, Washington, Natinal Science Foundation, A4-9.

Prior to World War II, industry was the primary source of funding for basic research in universities. This financial support helped shape priorities and build relationships. However, after the war, the federal government supplanted the private sector as the major financial contributor and became the principal determinant of the type and direction of the research performed in academic institutions. This situation oftentimes resulted in a disconnect between the university and industrial communities. Because the private sector and not the government typically is involved in commercialization, the difficulties in moving an idea from the research stage to a marketable product or process appeared to have been compounded. Thus, efforts to encourage increased collaboration between and among the sectors through the Bayh-Dole Act were expected to augment the contribution of both parties to technological advancement.

Small Business

Special consideration concerning patent title is given to small businesses in part because of the role these companies were seen as playing in the generation of new jobs and in technological advancement. Research supported by several federal agencies concluded that small, high technology companies are the source of significant innovation. An often cited 1982 study financed by the Small Business Administration determined that small firms were 2.4 times as innovative per employees as large companies.[10] Similar work performed at the time the legislation was being considered found that firms of less than 1,000 employees were responsible for more major innovations than large firms in the years 1953-1966 and for an equal number from 1967-1973.[11] A study of national and regional data by the Federal Reserve Bank of Chicago concluded that "small firms - - those with 20 or fewer employees - - create a larger proportion of new jobs than their share of employment in the economy and continue to create jobs even during recession."[12]

However, certain caveats need to be stated particularly within the context of small business, innovation, and technology development. Over the years, experts have argued that the contribution of small firms to the economy is overstated. Marc Levinson, writing in Dun's Business Month, maintained that small companies tended to produce fewer goods than larger ones because they are less capital intensive and, on the whole, add less to the gross national product because they offer lower salaries and often do not provide health insurance or pension plans.[13] Professors Zoltan Acs (University of Baltimore) and David Audretsch (University of Indiana) argued that

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[10] National Science Board, *Science and Engineering Indicators – 1993*, Washington, National Science Foundation, 185.

[11] National Science Board, *Science Indicators – 1976*, Washington, National Science Foundation, 116.

[12] Eleanor H. Erdevig, "Small Business, Big Job Growth," *Chicago Economic Perspectives*, Nov.-Dec. 1986, 22.

[13] Marc Levinson, "Small Business: Myth and Reality," *Dun's Business Month*, Sept. 1985, 32-33.

the relationship between company size and innovation capacity varies by industry.[14] Others maintain that there is no conclusive evidence that firm size affects the "success" of R&D.[15]

An important factor affecting the ability of small companies to effect technological advance is the relationship between these firms and large corporations, a concept that is reflected in the provisions of the Bayh-Dole Act. It appears evident that "small high-tech companies play a critical and diverse role in creating new products and services, in developing new industries, and in driving technological change and growth in the U.S. economy," as a National Academy of Engineering study concluded.[16] The reasons for this include the ability of these firms to rapidly develop markets, generate new goods and services and offer product diversity. Small businesses tend to be willing to take those technological risks that are not taken by large firms and may be in a position to quickly exploit market opportunities.[17] Yet, while small businesses can serve as the source of new products and processes, they often "cannot take advantage of their initial technological lead to establish a secure foothold in the key markets."[18]

Bayh-Dole and Related Law

Provisions

In enacting P.L. 96-517, the Congress accepted the proposition that vesting title to the contractor will encourage commercialization and that this should be used to support innovation in certain identified sectors. The law states:

> 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

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[14] Zoltan J. Acs and David B. Audretsch, *Innovation and Small Firms* (Cambridge: The MIT Press, 1990), 50-51.

[15] Charles Brown, James Hamilton, and James Medoff, *Employers Large and Small*, (Cambridge: Harvard University Press, 1990), 10.

[16] National Academy of Engineering, *Risk & Innovation, The Role and Importance of Small High-Tech Companies in the U.S. Economy* (Washington: National Academy Press, 1995), 37.

[17] For more information see CRS Report RL30216, *Small, High Tech Companies and Their Role in the Economy: Issues in the Reauthorization of the Small Business Innovation Research Program*, by Wendy H. Schacht.

[18] Clyde V. Prestowitz, Jr., "Big Versus Little," *Business Month*, April 1989, 60.

> Government and protect the public against nonuse or unreasonable use of inventions. . .[19]

Each nonprofit organization (including universities) or small business is permitted to elect (within a reasonable time) to retain title to any "subject invention" made under federally funded R&D; except under "exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter."[20] The institution must commit to commercialization within a predetermined, agreed upon, time frame. As stated in the House report to accompany the bill, "the legislation establishes a **presumption** [emphasis added] that ownership of all patent rights in government funded research will vest in any contractor who is a nonprofit research institution or a small business."[21]

Certain rights are reserved for the government to protect the public's interests. The government retains "a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world. . . ." The government also retains "march-in rights" which enable the federal agency to require the contractor (whether he owns the title or has an exclusive license) to "grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants. . ." (with due compensation) or to grant a license itself under certain circumstances. The special situation necessary to trigger march-in rights involves a determination that the contractor has not made efforts to commercialize within an agreed upon time frame or that the "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor. . . ."[22]

The government is "authorized" to withhold public disclosure of information for a "reasonable time" until a patent application can be made. Licensing by any contractor retaining title under this act is restricted to companies which will manufacture substantially within the United States. Initially, universities were limited in the time they could grant exclusive licenses for patents derived from government sponsored R&D to large companies (5 of the *then* 17 years of the patent). This restriction, however, was voided by P.L. 98-620, the Trademark Clarification Act of 1984. According to S.Rept. 98-662, extending the time frame for licensing to large firms "is particularly important with technologies such as pharmaceuticals, where long development times and major investments are usually required prior to commercialization."[23]

Most experts continue to argue that patent exclusivity is important for both large and small firms. In a February 1983 memorandum concerning the vesting of title to

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[19] P.L. 96-517, sec. 200.

[20] Ibid.

[21] *Report to Accompany H.R. 6933*, 5.

[22] P.L. 96-517, sec. 203.

[23] Senate Committee on the Judiciary, *Report to Accompany S. 2171*, 98th Cong., 2d Sess. S.Rept. 98-662, 1984, 3.

inventions made under federal funding, then President Ronald Reagan ordered all agencies to treat, as allowable by law, all contractors regardless of size the same as prescribed in P.L. 96-517. This, however, does not have a legislative basis. P.L. 98-620, noted above, further amended Bayh-Dole by loosening the time limitations for both disclosure of an invention to the government agency and for the amount of time provided within which to elect to take title. Nonprofit institutions were subsequently permitted to assign title rights to another organization (e.g., one which markets technology) and government-owned, contractor-operated laboratories (primarily those of the Department of Energy) run by nonprofits were permitted to retain title to inventions made in the facility with the exception of those dedicated to naval nuclear propulsion or weapons development. In addition, the Federal Technology Transfer Act (P.L. 99-502) allows firms regardless of size to be awarded patents generated under a cooperative research and development agreement (CRADA) with a federal laboratory.[24]

Implementation and Results

The Bayh-Dole Act appears to have met its expressed goals of using "the patent system to promote the utilization of inventions arising from federally-supported research or development;. . .and to promote collaboration between commercial concerns and nonprofit organizations, including universities. . ."[25] In one of the earliest studies of the legislation, the General Accounting Office (GAO) found agreement among university administrators and small business representatives that P.L. 96-517 had "a significant impact on their research and innovation efforts."[26] While noting it was not correct to generalize about academia from the 25 universities studied, GAO did find that by 1987 all university administrators questioned indicated that the Bayh-Dole Act had "been significant in stimulating business sponsorship of university research, which has grown 74 percent . . ." from FY1980 to FY1985.[27] According to the National Science Foundation (NSF), industry support for academic research grew faster than any other funding source until FY2002. Industry financing expanded from 3.9% of university R&D in 1980 to 7.2% in 2000, although by FY2004 industry support had dropped to 4.9% of academic R&D due to market conditions. In 1980, federal financing comprised 67.5% of the total academic undertaking; by 2000 federal support declined to 58.2% of university funding, yet

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[24] For additional discussion see *Industrial Competitiveness and Technological Advancement: Debate Over Government Policy*.

[25] P.L. 96-517, sec. 200.

[26] U.S. General Accounting Office, *Patent Policy: Recent Changes in Federal Law Considered Beneficial*, RCED-87-44, Apr. 1987, 3.

[27] Ibid., 3.

increasing to 63.8% in FY2004.[28] It should be noted, however, that the federal government still remains the major source of academic research funding.

The majority of the university personnel involved in the GAO study indicated that the increase in industry support for research at universities was "directly" attributed to the patent changes in P.L. 96-517 and P.L. 98-620. Academic faculty interviews conducted by GAO found that "since businesses knew that universities could take title to federally funded inventions, they no longer were concerned that their research efforts could be 'contaminated' by federal funding with the possibility that a federal agency could assert title rights to resulting inventions."[29] All respondents agreed that the removal of licensing restrictions on nonprofit institutions (including universities) by P.L. 98-620 was of vital importance in promoting industry-university interaction.[30] This was reinforced by the finding that 9 out of 10 business executives questioned identified the Bayh-Dole Act as an "important factor" in their decisions to fund R&D in academia.[31]

Another GAO study published in May of 1998 reported that agency and university representatives believed the Bayh-Dole Act was meeting its goals as articulated by the Congress and the law had a positive impact on all involved. Academia was "receiving greater benefits from their inventions and were transferring technology better than the government did when it retained title to inventions."[32] In addition, the report states that the increased commercialization of federally funded research that resulted from the implementation of the act, positively affected both the federal government and the American people.[33]

Other experts agree. Yale President Richard Levin argues that the purpose of the Bayh-Dole Act is to transition the results of government funded research "into practice for the benefit of humanity. . ." and that results indicate a "pretty emphatic positive answer that the Bayh-Dole Act has created public benefits" with minimal costs.[34] As stated in a recent article in *The Economist*, the Bayh-Dole Act is

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[28] National Science Foundation, "Changes in Federal and Non-Federal Support for Academic R&D Over the Past Three Decades," *InfoBrief*, June 2002 available at [http://www.nsf.gov], National Science Foundation, "National Patterns of R&D Resources: 2003, Special Report," available at [http://www.nsf.gov/statistics/nsf05308/pdfstart.htm], and National Science Foundation, "Industrial Funding of Academic R&D Continues to Decline in FY2004, *InfoBrief*, April 2006 available at http:www.nsf.gov.

[29] *Patent Policy: Recent Changes in Federal Law Considered Beneficial*, 20-21.

[30] *Ibid*., 16.

[31] *Ibid*., 23.

[32] U.S. General Accounting Office, *Technology Transfer: Administration of the Bayh-Dole Act by Research Universities*, RCED-98-126, May 1998, 2.

[33] *Ibid.*, 15.

[34] National Academy of Sciences, Board on Science, Technology, and Economic Policy, *Workshop on Academic IP: Effects of University Patenting and Licensing on Commercialization and Research*, April 17, 2001 [transcript], 261-262 available at [http://www.nas.edu].

"[p]robably the most inspired piece of legislation to be enacted in America over the past half-century. . . ."[35]

One of the major factors in the reported success of the Bayh-Dole Act is the certainty it conveys concerning ownership of intellectual property. The Director of Stanford University's Office of Technology Licensing, Katherine Ku, notes that exclusivity is what motivates firms to invest financial and human resources in technology development.[36] It provides an incentive for universities to take the time and effort to pursue a patent and to license those patents in its portfolio. This has led to a significant increase in academic patenting. In 1980, 390 patents were awarded to universities;[37] by 2003, this number increased to 3,259.[38]

Academia has become a major source of innovation for local and regional economic development. In the latest published survey (FY2004) performed by the Association of University Technology Managers (AUTM), universities identified 567 new products that were marketed that year based on academic R&D. In addition, the survey indicated that during FY2004 more than 462 new companies had been created to commercialize university research, small businesses are primarily responsible for the commercialization, and 74.5% of the new firms were located in the same state as the university. Since 1980, more than 4,500 new companies have been created to develop and market academic R&D. Of these, 2,671 were still in operation by the close of FY2004.[39]

The number of start-up companies created during FY2004 was 23.5% more than the 374 created in FY2003. Many of the start-up businesses were associated with just seven schools including the Massachusetts Institute of Technology (MIT), the University of California, California Tech, the University of Minnesota, the Johns Hopkins University, the University of Utah, and the University of Virginia.[40] Studies of technology transfer activities at MIT and the University of Pennsylvania indicate that each active exclusive license generates $1 million of additional R&D investment each year.[41] The Association of University Technology Managers also found that $1 billion in royalties were generated in FY2000 from 3,606 licenses, an increase of almost 9% over the previous year.

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[35] *Innovation's Golden Goose*

[36] *Workshop on Academic IP: Effects of University Patenting and Licensing on Commercialization and Research*, 9.

[37] *Science and Engineering Indicators – 1993*, 430.

[38] *Science and Engineering Indicators – 2006*, A5-148.

[39] Association of University Technology Managers, AUTM Licensing Survey: FY2004, and 3, available at [http://www.autm.net/events/File/04AUTMSurveySum-USpublic.pdf].

[40] Goldie Blumenstyk, "Income From University Licenses on Patents Exceeded $1-Billion," *The Chronicle of Higher Education*, March 22, 2002.

[41] Peter B. Kramer, Sandy L. Scheibe, Donyale Y. Reavis, and Louis P. Berneman, *Induced Investments and Jobs Produced by Exclusive Patent Licenses - a Confirmatory Study*, 1997 available at [http://www.autm.net].

However, several analysts argue that "Bayh-Dole was only one of a number of important factors behind the rise of university patenting and licensing activity."[42] In a study of the technology transfer and patenting activities of the University of California, Stanford University, and Columbia University, Professor David Mowery (University of California, Berkeley) and his colleagues concluded that increased federal funding for basic biomedical research, expanded research in biotechnology, specific court rulings, and government policies augmenting what can be patented all contributed to the rise in academic intellectual property activities. According to their assessment, the Bayh-Dole Act had "little impact on the content of academic research." The pursuit of patenting and licensing at universities has expanded because of changes in biomedical and biotechnology R&D, not because of the act.[43]

Yet, others criticize this assessment and point out that the act had the most significant impact on universities that were not actively engaged in patenting prior to its passage.[44] As a result of the Bayh-Dole Act, in part, "University patenting increased particularly rapidly during the second half of the 1980s and early 1990s."[45] This growth in patenting has been concentrated in "middle-tier" schools, not just the top research universities.[46] The Mowery et.al. study focused solely on universities that were previously involved in patenting and licensing and may not have fully considered patent problems that existed before the legislation was implemented. According to critics of the study, the analysts also failed to take into account changes in the venture capital industry that promoted the development of start-up companies to commercialize the results of university R&D.[47]

While the effects on the small business sector have not been as extensively studied, the results appear similar. All eight small business owners interviewed by the General Accounting Office for its 1987 study indicated that the patent changes had a significant beneficial effect on research, development, and innovation in their firms.[48] Perhaps most illustrative of the influence of the Bayh-Dole Act on small business is the biotechnology industry. According to Dr. Bernadine Healy, the former Director of the National Institutes of Health (NIH), P.L. 96-517 is responsible for the development and growth of the biotechnology sector.[49] The biotechnology

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[42] David C. Mowery, Richard R. Nelson, Bhaven N. Sampat, and Arvids A. Ziedonis, "The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980," *Research Policy* 30, 2001, 99.

[43] *Ibid*., 100.

[44] *Workshop on Academic IP: Effects of University Patenting and Licensing on Commercialization and Research*, 17.

[45] *Science and Engineering Indicators – 1993*, 152.

[46] Ibid., 152 and *Workshop on Academic IP: Effects of University Patenting and Licensing on Commercialization and Research*, 57-58.

[47] Ashley J. Stevens, "Is Bayh-Dole Under Siege Again?" *Technology Access Report*, July 2001.

[48] *Patent Policy: Recent Changes in Federal Law Considered Beneficial*, 4.

[49] House Committee on the Judiciary, *Biotechnology Development and Patent Law*, 102d

(continued...)

industry primarily is composed of small firms that are developing technologies and techniques derived from R&D funded by NIH. Many of these companies are established by NIH alumni or university professors previously supported by NIH grants. In Senate testimony delivered on August 1, 2001, Dr. Marie Freire, then Director of the Office of Technology Transfer at NIH, stated that "[i]t is widely recognized that the Bayh-Dole Act and the Federal Technology Transfer Act continue to contribute to the global leadership of the U.S. biomedical enterprise. . . ." An industry that was in its infancy when the Bayh-Dole Act was passed, biotechnology firms now generate annual sales of $33.3 billion (2004), and employ 187,500 people.[50]

The value of the Bayh-Dole Act might be reflected in state efforts to promote industry-university cooperation based on the contributions of these activities to local economic growth. As Mark Myers, retired Senior Vice-President of Xerox, told a meeting of the National Academy of Sciences (NAS), "[t]he role of the research university is growing ever important as an economic force in our economy. . . ."[51] By 2000, the National Governors Association reports 13 states had created programs to fund university-industry partnerships.[52] In a report for the Biotechnology Industry Organization (BIO), analysts found that there are biotechnology related initiatives in 40 states, including many that involve cooperative efforts between academia and the private sector. Between 2000 and 2004, 19 states have developed specific bioscience strategic plans. Twenty-six states have at least one seed or venture capital program to invest in small firms undertaking work in bioscience. State laws also have been changed to allow universities to become equity partners in start up firms designed to commercialize academic R&D.[53]

Current Issues and Concerns

While the Bayh-Dole Act provides a general framework to promote expanded utilization of the results of federally funded research and development, questions have been raised as to the adequacy of current arrangements. Most experts agree that closer cooperation among government, industry, and academia can augment funding sources (both in the private and public sectors), increase technology transfer, stimulate more innovation (beyond invention), lead to new products and processes, and expand markets. However, others point out that cooperation may provide an

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[49] (...continued)
Cong., 1st Sess., Nov. 20, 1991, 48.

[50] Biotechnology Industry Organization, *Biotechnology Industry Facts*, available at [http://www.bio.org/speeches/pubs/er/statistics.asp].

[51] *Workshop on Academic IP: Effects of University Patenting and Licensing on Commercialization and Research*, 255.

[52] Peter Schmidt, "States Push Public Universities to Commercialize Research," *Chronicle of Higher Education*, March 29,2002.

[53] Battelle Technology Partnership Practice and SSTI, *Laboratories of Innovation: State Bioscience Initiatives 2004*, June 2004, 27-29, available at [http://www.bio.org/local.battelle2003/battelle.2004.pdf].

increased opportunity for conflict of interest, redirection of research, less openness in sharing of scientific discovery, and a greater emphasis on applied rather than basic research.

The successes of the Bayh-Dole Act and the visibility of the results of its implementation have generated certain concerns, many of which are associated with the role of the university in research, as well as biomedical and biotechnology R&D, particularly as related to the availability and cost of pharmaceuticals. Several of these issues are discussed below. However, it is important to place the Bayh-Dole Act in context. The law is one significant factor in expanded industry, university, small business collaboration, but not the only one. Therefore, it may be difficult to assess what concerns are the direct result of the Bayh-Dole Act and which arise from the overall research environment. The rising costs associated with the performance of research and development, the availability of venture capital, increased R&D outsourcing by large firms, and expanded federal funding for biomedical research all contribute to increased interaction among the parties. Additional legislative initiatives including the research and experimentation tax credit, the National Cooperative Research Act, the small business technology transfer program, the advanced technology program, and cooperative R&D agreements established by the Stevenson-Wydler Technology Innovation Act all facilitate joint R&D activities leading to the commercialization of new technologies for the marketplace.[54]

Recoupment

Over the years, several legislators have suggested that the government "recoup" its investments from firms using federally supported research and development after profits are generated. This is particularly true in the area of pharmaceuticals. Such arguments are similar to those that were identified and considered as part of the original legislative debate over patent policy and cooperative R&D. Congress, over 20 or more years, weighed these issues and decided that, in the case of patent and technology policies, the benefits to the Nation brought about by increased innovation were paramount. The passage of the Bayh-Dole Act represented a determination that, with respect to certain types of organizations, the economic incentive to realize a return on investment provided by a patent is necessary to stimulate companies to provide the often substantial financial commitment to turn federally-funded R&D into marketable technologies and techniques. This decision was based on several determinations deriving from the rationale for federal support of basic research, the importance of technological progress to the Nation, and the critical role of private sector commercialization in technological advancement.

Federal support for basic research is founded, in large part, on the understanding that the rate of return to society as a whole generated by investments in research is significantly larger than the benefits that can be captured by any one firm performing

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[54] For additional information see CRS Report RL33526, *Cooperative R&D: Federal Efforts to Promote Industrial Competitiveness*, by Wendy H. Schacht, and CRS Report 95-50, *The Federal Role in Technology Development*, by Wendy H. Schacht.

it.[55] It has been estimated that the returns to society generated by investments in basic research are approximately twice those to the company performing the work. Government support reflects a consensus that basic research is the foundation for many innovations, but that incentives for private sector financial commitments are dampened by the fact that spending for R&D runs a high risk of failure. Even results of fruitful R&D often are exploited by other domestic and foreign companies, thus resulting in underinvestment in research by the private sector. The returns from basic research are generally long term, sometimes not marketable, and not always evident.

It is now widely accepted that "from one-third to one-half of all [U.S.] growth has come from technical progress, and that it is the principal driving force for long-term economic growth and the increased standards of living of modern industrial societies."[56] Technological advancement can clearly contribute to the resolution of those national problems which are amenable to technological solutions. Such progress is achieved through innovation, the process by which industry provides new and improved products, processes, and services. An invention becomes an innovation when it has been integrated into the economy such that the knowledge created results in a new or improved good or service that can be sold in the marketplace or is applied to production to increase productivity and quality. It is only through commercialization, a function of the business sector, that a significant stimulus to economic growth occurs. Thus, there is congressional interest in accelerating development and commercialization activities in the private sector through the Bayh-Dole Act as well as other legislation.

Actual experience and cited studies point to the conclusion that companies which do not control the results of their investments – either through ownership of patent title, exclusive license, or pricing decisions – tend to be less likely to engage in related R&D. This fact is reflected in the provisions of the Bayh-Dole Act (as well as other laws). Providing universities, nonprofit institutions, and small businesses with title to patents arising from federally-funded R&D offers an incentive for cooperative work and commercial application. Royalties derived from intellectual property rights provide the academic community an alternative way to support further research and the business sector a means to obtain a return on their financial contribution to the endeavor. While the idea of recoupment was considered by the Congress in hearings on the legislation, it was rejected as an unnecessary obstacle, one which would be perceived as an additional burden to working with the government. It was thought to be particularly difficult to administer. Instead, Congress accepted as satisfactory the anticipated payback to the country through increased revenues from taxes on profits, new jobs created, improved productivity, and economic growth. For example, according to the MIT Technology Licensing Office, 15% of the sales of licensed products derived from federally funded

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[55] Edwin Mansfield, "Social Returns From R&D: Findings, Methods, and Limitations," *Research/Technology Management*, Nov.-Dec. 1991, 24.

[56] Gregory Tassey, *The Economics of R&D Policy* (Connecticut: Quorum Books, 1997), 54. See also: Edwin Mansfield, "Intellectual Property Rights, Technological Change, and Economic Growth," in: *Intellectual Property Rights and Capital Formation in the Next Decade*, eds. Charls E. Walker and Mark A. Bloomfield (New York: University Press of America, 1988), 5.

university research is returned to the government in the form of income taxes, payroll taxes, capital gains taxes, and corporate income taxes. This is estimated to be 6 times the royalties paid by companies to the universities.[57] The emergence of the biotechnology industry and the development of new therapeutics to improve health care are other prominent indications of such benefits. These benefits have been considered more important than the initial cost of the technology to the government or any potential unfair advantage.

Government Rights: Royalty Free Licenses and Reporting Requirements

As discussed above, the government retains certain rights under the Bayh-Dole Act to protect the public interest. The act states that the government is provided a "nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world. . . ." This license, commonly known as a "royalty free license," has been the subject of some discussion including whether or not this permits government purchasers to obtain discounts on products developed from federally funded R&D, particularly pharmaceuticals. A July 2003 GAO report addressed this issue and concluded that the license entitles the government to practice or have practiced the invention on the government's behalf, but "does not give the federal government the far broader right to purchase, 'off the shelf' and royalty free (i.e. at a discounted price), products that happen to incorporate a federally funded invention when they are not produced under the government's license."[58] The study goes on to say that rights in one patent do not "automatically" permit rights in subsequent, related patents.[59] Because the government apparently holds few licenses on the biomedical products it purchases (generally through the Veteran's Administration and the Department of Defense),[60] federal officials indicated that procurement costs were best reduced by use of the Federal Supply Schedule and national contracts.[61] Government licenses are used primarily in the performance of research in the biomedical area.[62]

A related issue is that of tracking the government's interest in patents resulting from federally funded research and development. In an August 1999 study, GAO noted that federal contractors and grantees were not meeting the reporting requirements associated with the Bayh-Dole Act, making it difficult to identify and assess what licenses the government retained, among other things.[63] Two years later,

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[57] Kenneth D. Campbell, "TLO Says Government Research Pays Off Through $3 billion in Taxes, *MIT Tech Talk*, April 15, 1998 available at [http://web.mit.edu].

[58] General Accounting Office, *Technology Transfer: Agencies' Rights to Federally Sponsored Biomedical Inventions*, GAO-03-536, July 2003, 7.

[59] *Ibid*., 8.

[60] *Ibid*., 8.

[61] *Ibid*., 12.

[62] *Ibid*., 10.

[63] General Accounting Office, *Technology Transfer: Reporting Requirements for Federally* (continued...)

in a follow-up report, GAO stated that four of the five agencies had taken steps to insure improved compliance with the law including several new monitoring systems, although more needed to be done.[64] Of particular interest is iEdison, created by the NIH, which electronically tracks federal inventions and is used by other agencies in addition to NIH.[65]

University Research

A question often posed is whether or not patent ownership rights provided by P.L. 96-517 have interfered with the traditional operating procedures of academia. A fear is that private sector funding of university R&D has led to conflicts of interest by scientists performing the research, particularly when academics have equity positions in the relevant companies. There are concerns that industry agendas will distort or supplant the basic research and educational responsibilities of academia. Complaints have also been expressed that the free exchange of ideas and scientific discovery are constrained as a result of both the university and the business community's interest in protecting their competitive positions.

The issue of conflict of interest is a complex one particularly when trying to determine what direct role the Bayh-Dole Act has in generating such concerns and what are the results of other factors that have lead to increased industrial funding of university research. As noted above, laws that provide tax incentives for private sector financing of university basic research and facilitate technology transfer and cooperative R&D among government, industry, and academia, as well as changes in the way companies obtain the basic research necessary for product development shape the environment within which academic research is pursued. Thus, as argued by Stanford University's Katherine Ku, it is necessary to evaluate criticisms of the Bayh-Dole Act and to understand that the success of the law has made many in government uncomfortable despite the clear guidelines for technology transfer it established.[66]

Senior Research Scholar Mildred Cho (Stanford University Center for Biomedical Ethics) and her coauthors assert that the Bayh-Dole Act:

> has created opportunities for conflict of interest for university faculty members because academic-industry partnerships can offer direct financial rewards to individual faculty members in the form of consulting fees, royalties, and equity in companies while simultaneously funding these faculty members' research.[67]

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[63] (...continued)
Sponsored Inventions Need Revision, August 1999, GAO/RCED-99-242, 2.

[64] General Accounting Office, *Intellectual Property: Federal Agency Efforts in Transferring and Reporting New Technology,* October 2002, GAO-03-47, 29.

[65] *Ibid*., 33.

[66] *Workshop on Academic IP: Effects of University Patenting and Licensing on Commercialization and Research,* 98, 100-101.

[67] Mildred K. Cho, Ryo Shohara, Anna Schissel, and Drummond Rennie, "Policies on (continued...)

This, it is argued, has resulted in situations where the researcher's ties to private sector interests may not be evident and may adversely affect "the quality, outcome, and dissemination of research."[68] Other studies indicate that obligations to industry "pose a threat to scientific integrity."[69] Private sector funded research tends to generate conclusions favorable to industry; however, the factor that is primarily associated with the withholding or delay of information is the involvement of the scientist in bringing his research to market in a product, not the industrial financing itself.[70]

Data collected by Harvard Medical School Professor David Blumenthal and his colleagues also support the assessment that involvement in commercialization activities is related to delays in publication.[71] This study indicated that approximately 20% of life science researchers delayed publication of their studies more than six months at least once for reasons associated with patents and commercialization considerations. Almost 9% of faculty refused to share research or materials with other university scientists in the past three years. However, the authors conclude that "Withholding of research results is not a widespread phenomenon among life-science researchers."[72] A survey of industry-university research centers by Wesley Cohen (now at Duke University), et. al. found that over half of the centers permitted firms to request publication delays and 35% of the institutions allowed researchers to delete information prior to publication. At those centers with a mission to improve industrial products and processes, 63% allowed publication delays and 54% permitted the deletion of information.[73]

Delays in publication and the free flow of information from academia, according to Carnegie Mellon University Professor Richard Florida, "may well discourage or even impede the advancement of knowledge, which retards the efficient pursuit of scientific progress, in turn slowing innovation in industry."[74] Professor Florida also

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[67] (...continued)
Faculty Conflicts of Interest at U.S. Universities," *Journal of the American Medical Association*, Nov. 1, 2000.

[68] *Ibid.*

[69] Justin E. Bekelman, Yan Li, and Cary P. Gross, "Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review," *Journal of the American Medical Association*, Jan.22/Jan.29, 2003.

[70] *Ibid*.

[71] David Blumenthal, Eric G. Campbell, Melissa S. Anderson, Nancyanne Causino, and Karen Seashore Louis, "Withholding Research Results in Academic Life," *Journal of the American Medical Association*, April 16, 1997, 1224.

[72] *Ibid*., 1224

[73] Wesley M. Cohen, Richard Florida, Lucien Randazzese, and John Walsh, "Industry and the Academy: Uneasy Partners in the Cause of Technological Advance," in: Challenges to Research Universities, eds. Linda R. Cohen, Wesley Cohen, Roger Noll, William Rogerson, and Albert Teich (Washington: The Brookings Press, 1998), 188-189.

[74] Richard Florida, "The Role of the University: Leveraging Talent, Not Technology," *Issues* (continued...)

points to concerns over the increasing number of academic institutions taking equity positions in and/or incubating spin-off companies. These actions "simply tend to distract the university from its core missions of conducting research and generating talent." Professor Florida concludes that publication delays and greater secrecy in the research process resulting from implementation of the Bayh-Dole Act have shifted the university away from the pursuit of its traditional goals.

Other experts, including Robert Barchi, Provost of the University of Pennsylvania, maintain that the Bayh-Dole Act has not generated a significant set of issues concerning conflicts of interest and publication delays primarily because of the importance of academic freedom to the faculty.[75] Publications are the basis for promotion and tenure and methods to respect reasonable intellectual property protection have been established. Similarly, as noted by Professor Pam Samuelson (University of California, Berkeley), conflicts of interest would jeopardize tenure thus regulations are in place to instruct faculty what is required of them.[76]

In response to these issues, many universities have hired professional technology managers to work with faculty and to address patents. Universities with extensive research capabilities and resources were the first to create offices of technology transfer; after passage of the Bayh-Dole Act these offices were established with much greater frequency.[77] These university technology transfer offices have established guidelines to cover industry-university relationships, with education and publication remaining academic priorities.[78] The financial rewards derived from patenting are only a small portion of the total amount of R&D funding for academic institutions (3% in FY2000)[79] and what substantial money does flow into individual institutions tends to be the result of one "blockbuster" patent. University technology managers report that the major reason for patent licensing is commercialization, not profit, particularly since the cost of a patent, which can run approximately $10,000, is so high.[80] While the Bayh-Dole Act focused universities on ". . .commercially relevant technologies and closer ties between research and technological development,"[81] the

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[74] (...continued)
in Science and Technology, Summer 1999.

[75] *Workshop on Academic IP: Effects of University Patenting and Licensing on Commercialization and Research*,19-20.

[76] *Workshop on Academic IP: Effects of University Patenting and Licensing on Commercialization and Research*, 193.

[77] Rogers, Everett, Jing Yin, and Joern Hoffmann, "Assessing the Effectiveness of Technology Transfer Offices at U.S. Research Universities," *Journal of the Association of University Technology Managers*, v. XII, 2000, available at [http://www.autm.net].

[78] *Technology Transfer: Administration of the Bayh-Dole Act by Research Universities*.

[79] National Science Foundation, *Academic Research and Development Expenditures: Fiscal Year 2001*, 44 available at [http://www.nsf.gov/sbe/srs].

[80] Ann M. Thayer, "University Technology Moves to Market via Patenting, Licensing,: *Chemical and Engineering News*, Aug. 24, 1992, 17-18.

[81] National Science Board, *Science and Engineering Indicators - - 2002*, Washington, 5-54.

costs of patenting are such that "most university licensing offices barely break even."[82]

University limitations on outside research, expeditious publication obligations mandated for certain federally-funded R&D, and conflict of interest provisions also help to preserve a balance between federal policies like the Bayh-Dole Act that promote industry-university cooperation and concerns over excessive control of the research environment by the business community. For example, NIH requires grant recipients to publish the results of their government funded R&D. This is augmented by tax code regulations necessitating prompt dissemination of actual research results in order for a university or research institution to retain its tax exempt status. NIH also has policies and guidelines promoting the availability of patents arising from federal funding for use by other scientists for research purposes without acquisition of a license.[83]

Critics argue that the Bayh-Dole Act is distorting the traditional role of the university to the detriment of future technological development. Professor Florida maintains that because universities are seen as "engines" of growth, they focus on applied rather than fundamental research. This has lead to unrealistic national and local policies and practices that encourage the commercialization of academic research while ignoring the real value of universities as the "nation's primary source of knowledge creation and talent."[84] Mildred Cho also asserts that university research is "skewed" toward marketable products and not basic research.[85] Studies by Washington University researchers Dianne Rahm and Robert P. Morgan et. al. indicate the greater the faculty interaction with industry the more the applied research.[86]

Other experts disagree. A study of 3,400 faculty at six major research institutions by Professors Jerry Thursby (Emory University) and Marie Thursby (Georgia Institute of Technology) found that "the basic/applied split in research did not change over the period 1983-1999 even though licensing had increased by a factor greater than 10."[87] Data collected by NSF appear to support this assessment. According to NSF, in 1980, basic research comprised 66.6% of academic R&D endeavors while applied research and development were 33.4% of the total. In 2004,

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[82] Lita Nelson, "Increase of Intellectual Property Licensing at Universities Stems from Changes in Funding and Legislation," MIT Tech Talk, Aug. 26, 1998 available at [http://web.mit.edu].

[83] Available at [http://www.nih.gov].

[84] *The Role of the University: Leveraging Talent, Not Technology.*

[85] Eric Niller, "Biotech & Health: Report Fails to Address the Downside of Academic-Industry Collaborations," *Wall Street Journal (Europe)*, Aug. 6, 2001, 17.

[86] *Industry and the Academy: Uneasy Partners in the Cause of Technological Advance*, 186.

[87] Jerry G. Thursby and Marie C. Thursby, *University Licensing Under Bayh-Dole: What are the Issues and Evidence?*, May 2003.

the percent of academic R&D expenditures devoted to basic research increased to 75.2% while applied research and development declined to 24.8% of the total.[88]

Commentators claim that the Bayh-Dole Act encourages the type of research that is attractive to faculty. James Severson, President of the Cornell Research Foundation, testified before the House Committee on the Judiciary that

> Today, the protection and commercialization of academic research is one way for universities to attract, retain, and reward talented faculty who wish to see the results of their research programs benefit society. A commitment to the protection of research results is important for universities to develop closer ties to companies, and to attract additional funds to support research programs.[89]

As noted by Terry Young, Assistant Vice Chancellor for Technology Transfer atTexas A&M University, the act requires funds generated by licensing to be used for future education and research necessary to "deliver 'real world' products to the public."[90] Assessing the legislation, the Biotechnology Industries Association, contends that "Without the Bayh-Dole Act, few licensing agreements would be executed between private companies and federally supported research institutions, and the enormous investment our government makes in medical research would be wasted."[91]

Biotechnology and Pharmaceuticals

Many of the current concerns about the Bayh-Dole Act primarily arise out of its application to the biotechnology and pharmaceutical industries. Congressional interest in providing lower cost drugs, particularly to seniors, has focused attention on the role the act has had on the development of new pharmaceuticals for the marketplace. Certain critics maintain that the price of many therapeutics derived from federally funded R&D are excessive considering the government's financial contribution.[92] Others argue that the Bayh-Dole Act does not significantly affect pharmaceutical prices and point to a July 2001 study by NIH that found only four of the 47 FDA approved drugs generating $500 million a year were developed in part

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[88] National Science Foundation, *Academic Research and Development Expenditures: Fiscal Year 2004*, Table 2 available at [http://www.nsf.gov/statistics/nsf06323/pdf/tab2.pdf].

[89] House Committee on the Judiciary, Subcommittee on Courts and Intellectual Property, *Hearings on Gene Patents and Other Genomic Inventions*, July 13, 2000, available at [http://www.house.gov/judiciary/seve0713.htm].

[90] U.S. Department of Commerce, Technology Administration, *Innovation in America: University R&D*, June 11, 2002, available at [http://www.ta.doc.gov/reports].

[91] Biotechnology Industry Organization, *Testimony on Bayh-Dole and Technology Transfer Before the President's Council on Science and Technology, Office of Science and Technology Policy*, April 11, 2002, available at [http://www.bio.org].

[92] See CRS Report RL32324, *Federal R&D, Drug Discovery, and Pricing: Insights from the NIH-University-Industry Relationship*, by Wendy H. Schacht,.

with NIH funded technologies.[93] Although the government generally does not directly support pharmaceutical research aimed at product development,[94] legislative attempts have been made to require cost controls or recoupment on drugs generated, in part, with federal funds. This is in sharp contrast to congressional and executive branch efforts, particularly in the defense arena, to make it easier for firms to acquire and utilize intellectual property associated with federally financed R&D.[95]

Funding for university R&D in the life sciences, particularly medical and biological sciences, comprises by far the largest portion of academic research support. In 2004, 51% of total R&D expenditures at academic institutions went to finance the medical and biological sciences.[96] When the Bayh-Dole Act was passed in 1980, 40% of the research spending at universities was in these areas.[97] Industry's share of biomedical R&D grew from approximately 32% in 1980 to 62% in 2000 while at the same time, the federal share declined.[98] According to the National Science Foundation, the federal portion of academic research funding in biological sciences declined from approximately 74% in 1980 to 70% in 2004 although government support for medical research increased from approximately 64% to 67% during the same time period.[99] The federal government continues to be the primary source of funding for university R&D in these areas.

Overall support for biological and medical sciences has grown significantly since the passage of the Bayh-Dole Act. As measured in constant 2000 dollars, total (federal and non-federal) spending for academic R&D in these areas has increased from $4,618 million in 1980 to $19013 million in 2003.[100] This expanded support is important in light of findings by the late University of Pennsylvania Wharton School of Business Professor Edwin Mansfield showing that academic research was

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[93] Department of Health and Human Services, National Institutes of Health , *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected*, July 2001, available on the web at [http://www.nih.gov/news/070101wyden.htm].

[94] See CRS Report RL30913, *Pharmaceutical Research and Development: A Description and Analysis of the Process*, by Richard E. Rowberg.

[95] See House Committee on Government Reform, Subcommittee on Technology and Procurement Policy, *Toward Greater Public-Private Collaboration in Research and Development: How the Treatment of Intellectual Property Rights is Minimizing Innovation in the Federal Government*, hearings, July 17, 2001, available at [http://www.house.gov/reform].

[96] *Academic Research and Development Expenditures: Fiscal Year 2004*, Table 4 available at [http://www.nsf.gov/statistics/nsf06323/pdf/tab4.pdf].

[97] *Changes in Federal and Non-Federal Support for Academic R&D Over the Past Three Decades.*

[98] *Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review* and *Academic Research and Development Expenditures: Fiscal Year 2004*, Table 5 available at [http://www.nsf.gov/statistics/nsf06323/pdf/tab5.pdf].

[99] *Changes in Federal and Non-Federal Support for Academic R&D Over the Past Three Decades.*

[100] *Science and Engineering Indicators* – 2006, A5-7.

particularly significant in the development of new products and processes in the pharmaceutical and medical device industries.[101] His research indicated that between 1986 and 1994, 31% of new innovations would not have been developed without substantial delay in the "absence of academic research."

Interest and activity in the biomedical and biotechnology sectors has sparked some concern over the effects of the Bayh-Dole Act on research in these areas. According to information provided by the Boston Consulting Group, in the years between 1990 and 1999, new gene patents granted increased from about 400 to 2,800 while the number granted to universities expanded from 55% to 73% during that time period.[102] Similarly, the number of U.S. biotechnology patents granted each year grew from 1,765 in 1990 to 7,763 in 2002.[103] The focus on intellectual property has led critics to charge that the Bayh-Dole Act encourages the patenting of fundamental research which, in turn, prevents further biomedical innovation. Law professors Rebecca Eisenberg (University of Michigan) and Arti Rai (University of Pennsylvania) argue that due to the legislation, "[p]roprietary claims have increasingly moved upstream from the end products themselves to the ground-breaking discoveries that made them possible in the first place."[104] While patents are designed to spur innovation, Rai and Eisenberg maintain that certain patents hinder the process. From their perspective, by permitting universities to patent discoveries made under federal funding, the Bayh-Dole Act "draws no distinction between inventions that lead directly to commercial products and fundamental advances that enable further scientific studies."[105] These basic innovations are generally known as "research tools."

Eisenberg and Richard Nelson of Columbia University argue that ownership of research tools may "impose significant transaction costs" that result in delayed innovation and possible future litigation.[106] It also can stand in the way of research by others:

> Broad claims on early discoveries that are fundamental to emerging fields of knowledge are particularly worrisome in light of the great value, demonstrated time and again in history of science and technology, of having many independent minds at work trying to advance a field. Public science has flourished by permitting scientists to challenge and build upon the work of rivals.[107]

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[101] Edwin Mansfield, "Academic Research and Industrial Innovation: An Update of Empirical Findings," *Research Policy*, 1998, 773-776.

[102] Hamilton Moses, III and Joseph B. Martin, "Academic Relationships with Industry," *Journal of the American Medical Association*, Feb. 21, 2001, 933.

[103] *Biotechnology Industry Facts*.

[104] Arti K. Rai and Rebecca S. Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine," *American Scientist*, Jan.- Feb. 2003, 52.

[105] *Ibid*.

[106] Rebecca S. Eisenberg and Richard R. Nelson, "Public vs. Proprietary Science: A Fruitful Tension?," *Daedalus*, Spring 2002.

[107] *Ibid*.

Similar concerns were expressed by Harold Varmus, President of Memorial Sloan-Kettering and former Director of NIH. In July 2000 prepared testimony, he spoke to being "troubled by widespread tendencies to seek protection of intellectual property increasingly early in the process that ultimately leads to products of obvious commercial value, because such practices can have detrimental effects on science and its delivery of health benefits."[108] While the Bayh-Dole Act and scientific advances have helped generate a dynamic biotechnology industry, there have been changes that ". . .are not always consistent with the best interests of science."[109]

However, as Varmus and others acknowledge, the remedies to this situation are not necessarily associated with the Bayh-Dole Act. Yale President Richard Levin notes that while some research should be kept in the public domain, including research tools, the fact that it is privatized is not the result of the Bayh-Dole Act, but rather the result of patent law made by the courts and the Congress. Therefore, he believes that changes to the act are not the appropriate means to address the issues.[110]

Current law, as reaffirmed by court decisions, permits the patenting of research tools. However, there have been efforts to encourage the widespread availability of these tools. Marie Freire testified that the value to society is greatest if the research tools are easily available for use in research. She asserted that there is a need to balance commercial interests with public interests.[111] To achieve this balance, the NIH has developed guidelines for universities and companies receiving federal funding that make clear research tools are to be made available to other scientists under reasonable terms.[112] In addition, the U.S. Patent and Trademark Office recently made changes in the guidelines used to determine the patentability of biotechnology discoveries.

A study by Professors John Walsh (University of Illinois, Chicago), Ashish Arora (Carnegie Mellon University), and Wesley Cohen (Duke University) found that although there are now more patents associated with biomedical research, and on more fundamental work, there is little evidence that work has been curtailed due to intellectual property issues associated with research tools.[113] Scientists are able to continue their research by "licensing, inventing around patents, going offshore, the development and use of public databases and research tools, court challenges, and simply using the technology without a license (i.e., infringement)." According to the authors of the report, private sector owners of patents permitted such infringement

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[108] *Hearings on Gene Patents and Other Genomic Inventions*.

[109] *Ibid*.

[110] *Workshop on Academic IP: Effects of University Patenting and Licensing on Commercialization and Research*, 262.

[111] Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education and Related Agencies, *Hearings*, Aug. 1, 2001.

[112] Available on the NIH website at [http://www.nih.gov].

[113] John P. Walsh, Ashish Arora, Wesley M. Cohen, "Working Through the Patent Problem," *Science*, Feb. 14, 2003, 1021.

in academia (with the exception of those associated with diagnostic tests in clinical trials) "partly because it can increase the value of the patented technology."

Concluding Observations

The discussion surrounding changes to the patent laws in 1980 and 1986, and the debate over technology transfer since the late 1970s, acknowledged many of the issues currently being explored. As a result of expressed concerns, certain safeguards were built into the activities authorized by the Bayh-Dole Act. As discussed previously, march-in rights, the government's retention of an irrevocable license to patents generated under federally funded R&D, publication requirements, and commercialization schedules, among other things, all are incorporated into the process to protect the public interest. While there is a potential for creating an "unfair" advantage for one company over another, this is balanced against the need for new technologies and techniques and their contribution to the well-being of the Nation.

Despite arguments that title should remain in the public sector where it is accessible to all interested parties, the earlier lack of exclusivity interfered with the further development and commercialization of federally funded R&D. During the 1980s, Congress determined that the dispensation of patent rights to universities, small businesses, and nonprofit institutions and cooperative efforts took precedence, projecting the greater good generated by new products and processes that improve the country's health and welfare. Lawmakers anticipated the economic benefits through increased revenues from profits, wages, and salaries. The government receives a significant payback through taxes on profits and society benefits from new jobs created and expanded productivity. The importance of patent ownership has been reinforced by the positive effects studies have demonstrated P.L. 96-517 is reported to have had on the emergence of new technologies and new techniques generated by American companies.

There remain areas of concern, as discussed above, that Congress may decide to pursue. Some argue, particularly with respect to pharmaceuticals and biotechnology, that under the Bayh-Dole Act companies are receiving too many benefits at the expense of the public. Others, particularly in the defense arena, assert that the existing rights retained by the government under the act are too restrictive and are an impediment to meeting federal needs. But the impact of the legislation is still seen as significant. As summed up by Howard Bremer, who was patent counsel to the Wisconsin Alumni Research Foundation from 1960 through 1988:

> One important factor, which is often overlooked, is that the success was achieved without cost to the taxpayer. In other words, no separate appropriation of government funds was needed to establish or manage the effort. In fact, it has been estimated that the economic benefits flowing from the universities' licensing activities adds about $41 billion to the United States economy.
>
> Significant as that dollar amount is, it should not be overlooked that university inventions, arising, as most of them do, from basic research, have led to many

products which have or exhibit the capability of saving lives or of improving the lives, safety and health of the citizens of the United States and around the world. In that context their contribution to society is immeasurable.[114]

[114] Howard Bremer, "The First Two Decades of the Bayh-Dole Act as Public Policy," *National Association of State Universities and Land-Grant Colleges*, November 11, 2001, available at [http://www.nasulgc.org].