94-501 SPR

CRS Report for Congress

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

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June 14, 1994



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THE BAYH-DOLE ACT: PATENT POLICY AND THE COMMERCIALIZATION OF TECHNOLOGY

SUMMARY

In 1980, the Congress passed P.L. 96-517, Amendments to the Patent and Trademark Act (commonly referred to as "Bayh-Dole" after its two main sponsors) which was designed to utilize the ownership of inventions arising out of Government-sponsored research and development (R&D) to facilitate the commercialization of new technologies through cooperation between 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 only accounts for approximately 25 percent 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 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.

This legislation has been seen as particularly successful in meeting its objectives. However, while Bayh-Dole 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 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 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 is not receiving benefits commensurate with its 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.

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THE BAYH-DOLE ACT: PATENT POLICY AND THE COMMERCIALIZATION OF TECHNOLOGY

INTRODUCTION

In 1980, the Congress passed P.L. 96-517, Amendments to the Patent and Trademark Act (commonly referred to as "Bayh-Dole" after its two main sponsors), which was designed to utilize the ownership of inventions arising out of Government-sponsored research and development (R&D) to facilitate the commercialization of new technologies through cooperation between the research community, small business, and industry. This legislation generally has been seen as successful in meeting its objectives. However, there are several Members of Congress and others who have chosen to revisit the issues associated with the patent policies established under Bayh-Dole given the R&D environment 15 years later. Much of the renewed congressional interest is the result of the legislation's effect on the biotechnology and pharmaceutical industries.

This paper discusses the rationale behind the passage of P.L. 96-517, its provisions, and its implementation. Many of the issues and concerns that are being expressed today are similar, if not identical to those addressed during the 15 to 20 years of deliberation on the topic prior to enactment of Bayh-Dole. These too will be explored to provide a context for the current debate.

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 continuing to this day), 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

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[1] For additional discussion see: U.S. Congress. Congressional Research Service. Industrial Competitiveness and Technological Advancement: Debate Over Government Policy, by Wendy H. Schacht. CRS Issue Brief IB91132. [updated regularly]

majority of these efforts and include legislation which (1) created a system to transfer technology from Federal laboratories to the private sector; (2) implemented tax incentives for collaborative work; (3) instituted direct and indirect Government support for increased R&D; and (4) changed Government patent policy to provide an economic inducement for commercialization of federally-funded technology, the subject of this report.

P.L. 96-517, Amendments to the Patent and Trademark Laws (Bayh-Dole), was one of the first of these initiatives. Prior to its passage in 1980, the Government generally retained title to inventions made under Federal funding and issued to companies either an exclusive license in rare cases, or, more commonly, a nonexclusive license. However, it was argued that without title (or at least an exclusive license) to an invention and the protection it conveys, a company would not invest the time and money necessary for commercialization. This contention was supported by the fact that, although a portion of ideas patented by the Federal Government had potential for further development, application, and marketing, by 1980 only five percent of these were ever used in the private sector.

The year Bayh-Dole was enacted, the Federal Government's total R&D expenditure (both defense and civilian) was $41,393,000 (constant 1987 dollars). Of these funds, approximately $19,566,000 went to industry, $8,994,000 to universities, and $2,023,000 to nonprofit research institutions.[2] This 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. This Government investment has led to many new inventions which have profoundly influenced our society including, but by no means limited to: antibiotics, plastics, jet aircraft, computers, and electronics. However, many in Congress were of the opinion that there were additional applications which could be pursued by the private sector if provided the right incentives.

P.L. 96-517 was passed by the Congress, in part, to address the low utilization rate of patents resulting from Government-sponsored research. The House report to accompany H.R. 6933 notes that, at the time the bill was considered, there were 26 different agency policies regarding the use of the results of Government-funded R&D. The intent was to replace this with a "single, uniform national policy designed to cut down on bureaucracy and encourage private industry to utilize government funded inventions through the commitment of the risk capital necessary to develop such inventions to the point

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[2] U.S. National Science Board. Science and Engineering Indicators-1993. Washington, U.S. Govt. Print. Off., 1993. p. 332. Note that the figures quoted here include expenditures for Federally Funded Research and Development Centers (FFRDCs) operated by industry, universities, and nonprofit institutions.

of commercial application."[3] This was to be accomplished by employing the patent system to (1) augment collaboration between universities (as well as other nonprofit institutions) and the business community to ensure that inventions are brought to market and (2) provide for increased participation of small firms in the Federal R&D enterprise under the assumption that these companies tend to be more innovative than larger companies.

The Patent System

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 encourage innovation by simultaneously protecting the inventor and fostering competition. They provide the inventor with an exclusive right for 17 years to further develop his idea, commercialize, and thereby realize a return on his initial investment. Concurrently, the process of obtaining a patent places the concept in the public domain. 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.

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. It has also been claimed that the patent system was designed to assist the individual inventor and that 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 (e.g., trade secrets). For example, in the pharmaceutical arena, a firm can strengthen its competitive position over other companies because of the long lead-time necessary to bring a product to market and by utilizing the FDA approval process, clinical trials, and the data generated, among other things, to capture "monopoly profits" prior to similar goods reaching the marketplace.[4]

However, these arguments may not hold up well when considering those industries where similar products can be made by different processes or identical processes used to make different products. This is particularly relevant in the biotechnology and drug industries, which are the areas most affected by Bayh-

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[3] U.S. Congress. House. Committee on the Judiciary. Report to Accompany H.R. 6933. House Report No. 96-1307, Part 1. 96th Cong., 2d Sess. Washington, U.S. Govt. Print. Off., 1980. p. 3.

[4] Mansfield, Edwin and Anthony Romeo, Mark Schwartz, David Teece, Samuel Wagner, and Peter Brach. Technology Transfer, Productivity, and Economic Policy. New York, W.W. Norton and Co., 1982. p. 134-135.

Dole as discussed later. Process patents,[5] which are of vital importance for most biotechnology and pharmaceutical companies, are often harder to enforce and thus protect the companies' investment.

> Not only is it difficult to detect and prove infringement of such a patent [one that claims products or processes that are used only during product development], but often the only effective remedy even for proven infringement will be damages, because an injunction against future use of the invention will not thwart the efforts of a competitor who has already finished using the invention.[6]

Patents provide an economic incentive for companies to pursue further development and commercialization. Studies have shown that research funding only accounts for approximately 25 percent 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 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 anticipation of royalty payments.

Objective: University-Industry Cooperation

Efforts to foster joint ventures between academia, industry, and Government through changes to the patent laws as embodied in Bayh-Dole are an attempt to utilize and integrate what these sectors do best and to direct these activities toward the goal of generating new products and processes for the marketplace. Proponents maintain that collaborative projects allow for shared costs, shared risks, shared facilities, shared expertise, and possibly shared profits. Opponents argue that joint ventures stifle competition; proponents assert that they are designed to accommodate the strengths and responsibilities of each participant in the innovation process.

The lexicon of current cooperative activity covers various different institutional and legal arrangements. Collaborative ventures can be structured either "horizontally" or "vertically." The former involves efforts in which companies work together to perform research and then use the results of this research within their individual organizations. The latter involves activities where researchers, producers, and users work together. Both approaches are seen as ways to address some of the perceived obstacles to the competitiveness of American firms in the marketplace. Issues of patent ownership, disclosure of

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[5] A process patent is a patent on the methodology used in creating or producing a product.

[6] Eisenberg, Rebecca S. Genes, Patents, and Product Development. Science, v. 257, Aug. 14, 1992. p. 906.

information, licensing, and antitrust are resolved within the guidelines established by law governing joint ventures.[7]

Of particular interest to the Federal Government was industry-university cooperation, as evidenced by the provisions of P.L. 96-517. Traditionally, universities perform much of the basic research integral to certain technological advancements. They are generally able to undertake fundamental research because it is part of the educational process and because they do not have to produce for the marketplace. The risks attached to basic research in this setting are fewer than those in industry where companies must earn profits. Universities also educate and train the scientists, engineers, and managers employed by companies.

Academic institutions do not have the commercialization capacity or responsibility available in industry to translate the results of research into products and processes that can be sold in the marketplace. Thus, if the work performed in the academic environment is to be integrated into goods and services, a mechanism to link the two sectors must be available. 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 industry as the major financial contributor and became the principal determinant of the type and direction of the research performed in academic institutions. This situation resulted in some disconnection between the university and industrial communities. Because industry and not the Government is responsible for commercialization, the difficulties in moving an idea from the research stage to a marketable product or process appear to have been compounded. Thus, efforts to encourage increased collaboration between the academic and industrial sectors might be expected to augment the contribution of both parties to technological advancement. For the Government, which funded academic research at $16,700,000 (current dollars) in FY 1993 ($13,577,000 in constant 1987 dollars for comparison to figures above),[8] it is of benefit to see that the results of this Federal investment are commercialized.

Objective: Increased Small Business Participation

In P.L. 96-517, special consideration was given to small businesses in part because of the role these companies were seen as playing in job generation and because small, high tech firms tend to be particularly innovative. According to David Birch and others, small companies have been responsible for the creation

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[7] For additional information see: U.S. Library of Congress. Congressional Research Service. Cooperative R&D: Federal Efforts to Promote Industrial Competitiveness. CRS Issue Brief IB89056, by Wendy H. Schacht. [updated regularly]

[8] Science and Engineering Indicators 1993, op. cit., p. 331-332.

of a major portion of new jobs over the past several decades.[9] Similarly, in a study of national and regional data, Eleanor Erdevig of 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."[10]

However, certain caveats need to be stated particularly within the context of small business, innovation, and technology development. Some experts argue that the contribution of small firms to the economy is overstated. Marc Levinson, writing in Dun's Business Month, maintains that small companies tend to produce less than larger ones because they are less capital intensive, and on the whole add less to GNP because they offer lower salaries and often do not provide health insurance or pension plans.[11] He adds that corporations with over 500 workers employ almost one half the workforce and may operate at critical mass in an environment where all aspects of technology development can be accomplished within a firm. Small companies are perhaps best at creating jobs in declining economies;[12] yet this is often in response to cutbacks in employment by larger firms or as a result of demands by large companies for goods and services no longer produced in-house.

It is also important to refrain from looking at the small business sector as a monolith; the small business community is made up of many different types of companies from "Mom and Pop" shops to leading edge, high technology firms; from service providers to manufacturing firms. The implications for policy decisions tend to be different for each type of business. Small companies are well represented in the service arena. Ninety-seven percent of service firms employ less than 100 people and employment in the service sector has grown twice as fast as overall employment.[13] Yet, technology based and other high growth companies are only 10-15 percent of all new small businesses.[14] And those small firms which are innovative tend to grow to the point where they can no longer be considered small; other innovative firms often are bought by larger

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[9] Birch, David. Job Creation in America. The Free Press, N.Y., 1987. p. 7.

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

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

[12] Campbell, Candace and David N. Allen. The Small Business Incubator Industry: Micro-Level Economic Development. Economic Development Quarterly, May, 1987. p. 188.

[13] Ibid., p. 31.

[14] The Small Business Incubator Industry: Micro-Level Economic Development, op. cit., p. 187.

companies who can provide the capital and commercial, financial, and/or business expertise needed to bring a product to market.

However, there are reasons for decision makers to choose to focus on particular types of small firms in the areas of technology development. Many believe that small, high technology companies tend to be very innovative. Studies have shown that firms of less than 1000 employees were responsible for more major innovations than large firms in the years 1953-1966 and for an equal number from 1967-1973.[15] Additional research indicates that small companies of less than 500 employees are about 2.5 times as innovative per employee as large firms.[16] According to Roland Tibbetts then at the National Science Foundation, small firms produce six times more net new products for every $1 million spent on R&D than do larger companies.[17]

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 Government and protect the public against nonuse or unreasonable use of inventions. . .[18]

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[15] U.S. National Science Board. Science Indicators--1976. Washington, U.S. Govt. Print. Off., 1977. p. 116.

[16] Statement by James Sanders, Administrator, Small Business Administration in: U.S. Congress. Senate. Committee on Small Business. Small Business Innovation Development Act, P.L. 97-219. Hearings, 98th Cong., 2d Sess. Mar. 1, 1984. Washington, U.S. Govt. Print. Off., 1984. p. 8.

[17] Anderson, Anne. Small Businesses Make it Big in the SBIR Program. New Technology Week, June 6, 1988. p. 2.

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

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."[19] 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."[20]

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. . ."[21]

The Government is "authorized" to withhold public disclosure of information for a "reasonable time" until a patent application can be made. This supplements additional law (35 U.S.C. 205) which prohibits the Patent and Trademark Office from releasing information associated with a patent until it is issued. 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 17 years of the patent). This restriction, however, was voided by P.L. 98-620, The Trademark Clarification Act of 1984. According to Senate Report 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."[22]

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[19] Ibid.

[20] Report to Accompany H.R. 6933, op. cit., p. 5.

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

[22] U.S. Congress. Senate. Committee on the Judiciary. Report to Accompany S. 2171. Senate Report No. 98-662, 98th Cong., 2d Sess. Washington, U.S. Govt. Print. Off., 1984. p. 3.

It continues to be argued that patent exclusivity is important for both large and small firms. In a February 1983 memorandum concerning the vesting of title to inventions made under Federal funding, President Reagan ordered all agencies to treat, as allowable by law, all contractors regardless of size 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.[23]

Implementation and Results

From most indications, Bayh-Dole has been successful in meeting 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. . . ."[24] The General Accounting Office (GAO) found agreement among the university administrators and small business representatives they interviewed that P.L. 96-517 had ". . . a significant impact on their research and innovation efforts."[25] While noting it was not correct to generalize about all of academia from the 25 universities studied, GAO did find that by 1987 all the university administrators questioned indicated that Bayh-Dole had ". . . been significant in stimulating business sponsorship of university research, which has grown 74 percent . . ." from FY 1980 to FY 1985.[26] This trend continues. According to the National Science Foundation, at the time the legislation was enacted in 1980, the Federal Government funded 67.5 percent of university R&D while industry funded 3.9 percent. By 1993,

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[23] For additional discussion of the legal aspects of this legislation see: U.S. Library of Congress. Congressional Research Service. Patent Rights in Inventions Made with Federal Assistance: The Bayh-Dole Act. CRS Report No. 94-452 A, by Michael V. Seitzinger. Washington, 1994.

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

[25] U.S. General Accounting Office. Patent Policy: Recent Changes in Federal Law Considered Beneficial; Report to the Congress by the Comptroller General of the United States. RCED-87-44, Apr. 1987. Washington, 1987. p. 3.

[26] Ibid., p. 3.

Federal support dropped to 55.5 percent while industry funding rose to 7.3 percent of the total.[27]

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 by the vast majority of the university personnel involved in the GAO study. Most indicated ". . . since businesses knew that universities could take title to federally funded invention, 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."[28] All 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.[29] This was reinforced by the finding that 9 out of 10 business executives questioned identified Bayh-Dole as an "important factor" in their decisions to fund R&D in academia.[30]

In 1980, 390 patents were awarded to universities; in 1991, this number increased to 1,324.[31] While it is difficult to provide direct correlations because of time lags between research and a patentable product or process as well as time lags between filing and issuance of a patent, the trend is still clear. The rate of increase also appears to be rising: ". . . 24 percent of all patents issued to U.S. academic institutions since 1969 were awarded in 1990-91."[32] In addition, in 1993, the number of patents received by universities expanded five percent over the previous year.[33] It should also be noted that this growth in patenting is concentrated in the "middle-tier" schools, not just the top research universities.[34] The increase in academic patenting is a good indication of potential commercialization because, according to the Association of University Technology Managers, if universities pursue patents and the expense this entails, they usually have a licensee ready to exploit the patent.[35]

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[27] Science and Engineering Indicators-1993, op. cit., p. 135-136.

[28] Patent Policy: Recent Changes in Federal Law Considered Beneficial, op. cit., p. 20-21.

[29] Ibid., p. 16.

[30] Ibid., p. 23.

[31] Science and Engineering Indicators-1993, p. 430.

[32] Ibid., p. 152.

[33] Intellectual Property Happenings, Mar. 1994, p. 3.

[34] Ibid., p. 152.

[35] Thayer, Ann M. University Technology Moves to Market via Patenting, Licensing. Chemical and Engineering News, Aug. 24, 1992. p. 17.

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 in 1987 indicated that the patent changes had a significant beneficial effect on research, development, and innovation in their firms.[36] Perhaps most illustrative of the influence of Bayh-Dole 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.[37] This industry is made up primarily of small firms which are developing technologies and techniques derived from NIH supported R&D. These companies often are started by National Institutes of Health alumni or university professors previously funded by NIH grants. An industry which did not exist 15 years ago, biotechnology firms now generate annual sales of $7 billion,[38] a figure which is projected to increase to $50 billion by the year 2000.[39] This was achieved to a great extent by both the expansion of cooperative efforts among Government, industry, and academia and by the intellectual property protection Bayh-Dole provided.

CURRENT ISSUES AND CONCERNS

While Bayh-Dole provides a general framework to promote expanded utilization of the results of federally funded research and development, it is evident that questions are being raised as to the adequacy of current arrangements. The Department of Commerce, under the auspices of Dr. Mary Good, Under Secretary for Technology, is currently reviewing the effects of the law to determine if any legislative changes are advisable. Most agree that closer cooperation 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 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.

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[36] Patent Policy: Recent Changes in Federal Law Considered Beneficial, op. cit., p. 4.

[37] U.S. Congress. House. Committee on the Judiciary. Biotechnology Development and Patent Law. Hearings, 102d Cong., 1st Sess., Nov. 20, 1991. Washington, U.S. Govt. Print. Off., 1993. p. 48.

[38] Burrill, G. Steven and Kenneth B. Lee, Jr. Biotech 94, Long-Term Value Short-Term Hurdles. San Francisco, Ernst and Young, 1993. [Unnumbered page]

[39] U.S. National Academy of Sciences. Putting Biotechnology to Work: Bioprocess Engineering. Washington, 1992.

Biotechnology and Pharmaceuticals

The current congressional challenges to Bayh-Dole primarily arise out of interest in its application to the biotechnology and pharmaceutical industries.[40] Several Members of Congress maintain that the price of many therapeutics developed from federally funded R&D are excessive considering the Government's financial contribution. Representative Ron Wyden, Chairman of the Subcommittee on Regulation, Business Opportunities, and Energy of the House Committee on Small Business, stated that he ". . . is troubled by the reality that drug manufacturers have used NIH technologies to develop products and . . . have gouged consumers on the pricing of pharmaceuticals developed in whole or in part from Federal research."[41] The final cost to the consumer should, it has been asserted, reflect the relative contribution of both the Government and the company. In response, the Representative has introduced H.R. 1334 to mandate that all NIH cooperative research and development agreements include a set formula for pricing any future commercial products. The legislation also requires the National Institutes of Health to co-license to multiple companies as a means of encouraging future price competition in the marketplace.[42] Other bills (including H.R. 916 and H.R. 1434) would create some form of pharmaceutical price review board which would have the authority to revoke a patent on a drug if the cost to the consumer is found to be "excessive." If that particular therapeutic is not patented, title to another product manufactured by that firm would be canceled in its place. H.R. 4151 necessitates compulsory licensing of a drug patent if a company does not take "all reasonable steps toward the commercial marketing or use of that product" and its availability is of "vital importance to the public health or welfare."

Additional issues were raised at the beginning of last year in response to a proposed commercial agreement contract between Scripps Research Institute

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[40] For example see: U.S. Congress. Senate. Special Committee on Aging. The Federal Government's Investment in New Drug Research and Development: Are We Getting Our Money's Worth? Hearing, 103d Cong., 1st Sess. Feb. 24, 1993; and U.S. Congress. House. Committee on Small Business. Subcommittee on Regulation, Business Opportunities, and Technology. Conflict of Interest, Protection of Public Ownership in Drug Development Deals Between Tax-Exempt, Federally Supported Labs and the Pharmaceutical Industry. Hearing, 103d Cong., 1st Sess. Mar. 11, 1993.

[41] U.S. Congress. House. Committee on Small Business. Subcommittee on Regulation, Business Opportunities, and Energy. The National Institutes of Health and Its Role in Creating U.S. High-Technology Industry Growth and Jobs. Hearings, 100th Cong., 1st Sess. Dec. 9, 1991. p. 2.

[42] For a discussion detailing the arguments in the biotechnology arena see: U.S. Library of Congress. Congressional Research Service. Biotechnology, Breakthrough Drugs, and Health Care Reform: Lessons From the NIH-University-Industry Relationship. CRS Report 94-375 SPR, by Wendy H. Schacht. Washington, 1994.

and Sandoz, a Swiss pharmaceutical company. Several concerns were expressed. Among these are: Should the significant amount of support the National Institutes of Health gives Scripps, a nonprofit research institution, entitle the Government to any input into the terms of a contract between the organization and a private company? To what extent, if any, can the Government exert influence over the practices of the institutions to which it provides some, but not all, funding? Will the work of federally-financed Scripps personnel be influenced by Sandoz's priorities? Will federally-funded technology go to a foreign company under this contract despite the provisions of Bayh-Dole? Although the agreement was not finalized in its original form, the debate focused attention on the impact of P.L. 96-517 in areas of enormous commercial potential.

Legislators have also suggested that the Government should "recoup" its investments from firms using federally-supported research and development after profits are generated. Along these lines, bills by The Honorable Constance Morella and The Honorable Jay Rockefeller (H.R. 3590 and S. 1537) would require that all patents generated under a cooperative research and development agreement be assigned to the collaborating party in exchange for "reasonable compensation to the laboratory."

Such arguments and questions are similar to those which 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 are paramount. A determination was made 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 it.[43] 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

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

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."[44] 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. Yet, while the United States has a strong basic research enterprise, foreign firms have at times appeared more adept at taking the results of these scientific efforts and making commercially viable products. Often U.S. companies are competing in the global marketplace against goods and services developed by foreign industries from research performed in the United States. Thus, there is congressional interest in accelerating development and commercialization activities in the private sector through Bayh-Dole 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 Bayh-Dole (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 provides 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, 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. The emergence of the biotechnology industry and the development of new therapeutics to improve health care are prominent examples of such benefits. These benefits have been considered more

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[44] Landau, Ralph. Technology, Economics, and Public Policy. In: Landau, Ralph and Dale W. Jorgenson, eds. Technology and Economic Policy. Cambridge, Ballinger Publishing Co., 1986. p. 2.

important than the initial cost of the technology to the Government or any potential unfair advantage.

University Research

A question often posed is whether or not the patent ownership provided by P.L. 96-517 has interfered with the traditional operating procedures of academia. A fear is 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 the business community's interest in protecting its competitive position. A study (published in 1986) of over 120 faculty involved in biotechnology research at 40 U.S. universities found that while professors with industrial support tend to be particularly productive in their university roles, there were some "risks" involved with such collaboration.[45] Faculty with industry funding were four times as likely than other colleagues to acknowledge that trade secrets ("information kept secret to protect its proprietary value") resulted from their work (12 percent versus 3 percent). Twenty-four percent of this group allowed that publication of research was dependent on agreement by the sponsor in contrast to five percent of professors with other funding sources. In addition, faculty members with industrial support were four times as likely to identify the influence of commercial applications in research decisions as their peers who received no such funds (30 percent versus 7 percent).[46]

In response to these issues, many universities have hired professional technology managers to work with faculty and to address patents. According to several of these professionals, guidelines have been established to cover industry-university relationships, with education and publication remaining academic priorities.[47] Royalties on licenses are estimated to account for less than one percent of the total research budgets of U.S. universities[48] and what substantial money does flow into individual institutions tends to be the result of one "blockbuster" patent.[49] These university technology managers report that the major reason for patent licensing is commercialization, not profit,[50]

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[45] Blumenthal, David, Michael Gluck, Karen Seashore Louis, Michael A. Stoto, and David Wise. University-Industry Research Relationships in Biotechnology: Implications for the University. Science, June 13, 1986. p. 1365.

[46] Ibid., p. 1364.

[47] Thayer, Ann M. University Technology Moves to Market via Patenting, Licensing. Chemical and Engineering News, Aug. 24, 1992. p. 17.

[48] Ibid., p. 17.

[49] Ibid., p. 18.

[50] Ibid., p. 18.

particularly since the cost of a patent, which can run approximately $10,000 per filing, is too high.[51]

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 Bayh-Dole which 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. The National Institutes of Health also demands that the patented work be available for use by other scientists for research purposes without acquisition of a license.

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 these issues. As a result of expressed concerns, safeguards have been built into the activities authorized by law. As discussed previously, march-in rights, the Government's retention of an irrevocable license to these patents, 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 lack of exclusivity interfered substantially 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 takes precedence because of the greater good generated by new products and processes which improve the country's health and welfare. This is augmented by the understanding that the economy gets a significant payback through taxes on profits, through new jobs created, and expanded productivity. The Government benefits through increased revenues from profits, wages, and salaries. The importance of patent ownership has been reinforced by the positive effects P.L. 96-517 has had on the emergence of new technologies and new techniques generated by American companies.

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[51] Ibid., p. 17.