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The Bayh-Dole Act: A Guide to the Law and Implementing Regulations

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A Guide to the Law and Implementing Regulations

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This brochure is intended to inform the public about the Patent and Trademark Law Amendment Act of l980, more commonly known as the Bayh-Dole Act, which is the legal framework for transfer of university generated, federally funded inventions to the commercial market place. The brochure provides information about the Act, as well as about its implementing regulations and compliance requirements.

The Council on Governmental Relations is an organization which includes in its membership 145 research intensive universities. This brochure does not claim to be a manual of university technology transfer and licensing activities. Rather, it illustrates the basis for university-industry collaboration and developments since the passage of the Act.

In preparing this brochure, the COGR Committee on Technology Transfer and Research Ethics drew on the assistance of many universities. Their help is gratefully acknowledged. Special appreciation is due to Terence A. Feuerborn, Office of the President, University of California. Reproduction for purposes of sale or profit is prohibited without written consent of the Council on Governmental relations. Otherwise, reproduction is encouraged.

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INTRODUCTION

The transfer of new technology from university laboratories to the private sector has a long history and has taken many different forms. The current national emphasis on this activity, however, can be dated to the 1980 enactment of P.L. 96-517, the Patent and Trademark Law Amendments Act, more commonly known as the Bayh-Dole Act, and amendments included in P.L. 98-620, enacted into law in 1984.

This brochure reviews the Bayh-Dole legislation, the implementing regulations that have evolved, and the major issues associated with complying with the law and related regulations. It also highlights the significant benefits of the Bayh-Dole Act that have occurred to date.

BACKGROUND

Technology transfer--the transfer of research results from universities to the commercial marketplace for the public benefit--is closely linked to fundamental research activities in universities. Although a handful of U.S. universities were moving science from the laboratory to industrial commercialization as early as the 1920s, academic technology transfer as a formal concept, is said to have originated in a report entitled "Science - The Endless Frontier" that Vannevar Bush wrote for the President in 1945. At that time, the success of the Manhattan Project had demonstrated the importance of university research to the national defense. Vannevar Bush, however, also recognized the value of university research as a vehicle for enhancing the economy by increasing the flow of knowledge to industry through support of basic science. His report became instrumental in providing a substantial and continuing increase in funding of research by the federal government. It stimulated the formation of the National Institutes of Health (NIH), the National Science Foundation (NSF), and the Office of Naval Research (ONR). Due to the success of these and other agencies, the funding of basic research by the federal government is now considered to vital to the national interest.

In the 1960s and 1970s, there was much study and debate surrounding federal patent policies. A major concern was the lack of success by the federal government in

promoting the adoption of new technologies by industry. There was no government-wide policy regarding ownership of inventions made by government contractors and grantees under federal funding. Inconsistencies in policies and practices among the various funding agencies resulted in a very limited flow of government-funded inventions to the private sector. In 1980, the federal government held title to approximately 28,000 patents. Fewer than 5% of these were licensed to industry for development of commercial products.[1]

This problem was due, in part, to restrictions imposed on the licensing of new technologies and reluctance on the part of the agencies to permit ownership of inventions to vest in universities and other grantees.[2] The government would not relinquish ownership of federally funded inventions to the inventing organization except in rare cases after petitions had moved through a lengthy and difficult waiver process. Instead, the government retained title and made these inventions available through non-exclusive licenses to anyone who wanted to practice them.

As a result, companies did not have exclusive rights under government patents to manufacture and sell resulting products. Understandably, companies were reluctant to invest in and develop new products if competitors could also acquire licenses and then manufacture and sell the same products. Accordingly, the government remained unsuccessful in attracting private industry to license government-owned patents. Although taxpayers were supporting the federal research enterprise, they were not benefiting from useful products or the economic development that would have occurred with the manufacture and sale of those products.

In 1980, however, legislators and the administration concluded that the public would benefit from a policy that permitted universities and small businesses to elect ownership of inventions made under federal funding and to become directly involved in the commercialization process. This new policy would also permit exclusive licensing when combined with diligent development and transfer of an invention to the marketplace for the public good. It was understood that stimulation of the U.S. economy would occur through the licensing of new inventions from universities to businesses that would, in turn, manufacture the resulting products in the U.S.

EVOLUTION

With the passage of the Bayh-Dole Act, colleges and universities immediately began to develop and strengthen the internal expertise needed to effectively engage in the patenting and licensing of inventions. In many cases,

institutions that had not been active in this area began to establish entirely new technology transfer offices, building teams with legal, business, and scientific backgrounds. These activities continue to accelerate nationally as the importance of the Bayh-Dole Act becomes fully appreciated. Evidence of this is reflected in the fact that the membership of the Association of University Technology Managers (AUTM) increased from 691 in 1989 to 2,178 in 1999. In 1979, the year before passage of the Bayh-Dole Act, the Association counted only 113 members.[3]

University technology transfer offices perform a wide variety of highly specialized functions related to the patenting and licensing of inventions. In addition, these offices also perform a vital function related to the formation of research partnerships with industry, and in negotiating the exchange of research materials and research tools.

In recent years, the wisdom of the new federal policy has become increasingly apparent. Growing numbers of universities have demonstrated that their newly formed technology transfer programs are effective in licensing inventions made with federal support to commercial partners. As a result, many new technologies have been diligently and successfully introduced into public use.

Another significant result of the Bayh-Dole Act is that it provides a strong incentive for university-industry research collaborations. At the national level, industry support for research and development at universities represents less than 7% of the total funding of university-based research. While small compared to the 60% provided by federal agencies, this private investment in the creativity of universities, including professors, students and staff, drives a form of technology transfer that is increasingly important to industry. The investment by industry rests on a secure footing because it is based on the principles and provisions of the Bayh-Dole Act.[4]

SOME PERSPECTIVE

The principles of the Bayh-Dole Act were the result of years of intense and emotional debate, dealing with fundamental concerns. The record shows that the debate included such issues as whether exclusive licenses would lead to monopolies and higher prices; whether taxpayers would get their fair share; whether foreign industry would benefit unduly; and whether ownership of inventions by a contractor is anti-competitive. Safeguards were hammered out in numerous legislative drafts. It is certain that the Act became much stronger because of the thorough debate that took place prior to its passage.

From the beginning, it was obvious that economic interests rather than academic science interests were the

driving forces for the change in government policy. As early as October l963, President Kennedy had issued a Presidential Memorandum and Statement of Government Policy. This memorandum marked the beginning of an intense discussion about the effect that government patent policy had on commercial utilization of federally sponsored inventions, on industry participation in federally sponsored R & D programs, and on business competition in the marketplace.[5] It was not until industry, academe and the government recognized that their individual interests could be reconciled in the pursuit of commercialization that passage of the Bayh-Dole Act became possible and ended years of debate.

Until the Bayh-Dole Act became effective on July 1, 1981, the federal agencies kept tight control over intellectual property rights resulting from funded research, premised largely on traditional expectations rooted in the procurement process. After the passage of the Bayh-Dole Act, codifying and implementing it at the agency level was not an easy process. As the success of the Act became quickly apparent, subsequent legislative initiatives broadened its reach even further. These initiatives and the technical amendments involved are described in the Appendix.

CURRENT REGULATIONS

Regulations implementing federal patent and licensing policy regarding "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms" are codified at 37 CFR Part 401. The Department of Commerce is designated as the federal agency to promote commercialization and to assume responsibility for maintaining these rules.[6] The following summarizes the significant aspects of these regulations:

- The provisions apply to all inventions conceived or first actually reduced to practice in the performance of a federal grant, contract, or cooperative agreement. This is true even if the federal government is not the sole source of funding for either the conception or the reduction to practice. The provisions do not, however, apply to federal grants that are primarily for the training of students and postdoctoral scientists.
- The university is obligated to have written agreements with its faculty and technical staff requiring disclosure and assignment of inventions.
- The university has an obligation to disclose each new invention to the federal funding agency within two months after the inventor discloses it in writing to the university.
- The decision whether or not to retain title to the invention must be made within two years after disclosing

the invention to the agency. This time may be shortened, if, due to publication of research results or public use, the one-year U.S. statutory patent bar has been set in motion. Under such circumstances, the university must make an election at least sixty days before the end of the statutory period. If the university does not elect to retain title, the agency may take title to the invention.

- Upon election of title, the university must file a patent application within one year, or prior to the end of any statutory period in which valid patent protection can be obtained in the United States. The university must, within ten months of the U.S. filing, notify the agency whether it will file foreign patent applications. If the university does not intend to file foreign applications, the agency may then file on its own behalf in the name of the United States.
- Universities must include within the specification of the patent a notification of government support of the invention and government rights in the invention.
- If the university elects to retain title, the university must provide the government, through a confirmatory license, a non-exclusive, non-transferable, irrevocable, paid-up right to practice or have practiced the invention on behalf of the U.S. throughout the world.
- The university must submit periodic reports regarding the utilization of the invention as requested by the funding agency, but no more often than annually.
- Any company holding an exclusive license to a patent that involves sales of a product in the United States must substantially manufacture the product in the U.S. Waivers of this rule may be granted by the federal agency upon a showing that reasonable but unsuccessful efforts had been made to find a company that would manufacture the product in the U.S., or that manufacture in the U.S. would not be economically feasible.
- In their marketing of an invention, universities must give preference to small business firms (fewer than 500 employees), provided such firms have the resources and capability for bringing the invention to practical application. However, if a large company has also provided research support that led to the invention, that company may be awarded the license.
- Universities may not assign their ownership of inventions to third parties, except to patent management organizations.
- Universities must share with the inventor(s) a portion of any revenue received from licensing the invention. Any remaining revenue, after expenses, must be used to support scientific research or education.

- Agencies may decide, for compelling reasons, that title should be vested in the federal government. Such decisions must be consistent with provisions within the Bayh-Dole Act and made in writing before entering into a funding agreement with a university. The agency must also file a Determination of Exceptional Circumstances (DEC) with the Department of Commerce. The NIH, for instance, has issued several DECs for programs where NIH determined it was necessary to protect rights in intellectual property obtained from third parties.[7]
- Under certain circumstances, the government can require the university to grant a license to a third party, or the government may take title and grant licenses itself (these are called "march-in rights"). This might occur if the invention was not brought to practical use within a reasonable time, if health or safety issues arise, if public use of the invention was in jeopardy, or if other legal requirements were not satisfied.[8]

Procedural details, other rights and obligations not cited above, and further information regarding these matters, can be found in 37 CFR Part 401 and 35 USC 200-212.

RELATED NIH POLICIES

On November 8, 1994 the NIH published a notice in the Federal Register (59 FR 55673) entitled: "Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts." This document is intended to ensure compliance with the requirements of the Bayh-Dole Act by providing NIH awardees with guidance in developing sponsored research agreements with commercial entities when that research may be partially funded by NIH or other federal agencies.

The NIH also issued two policy statements in the NIH Guide (Volume 25, Number 16, May 17, 1996; and Volume 25, Number 29, August 30, 1996) that establish procedures for managing certain patentable inventions. These rules apply to situations in which a university wishes to elect title to biological materials, which may be patentable, but does not want to file a patent application because the cost is not justified or because the patentability of the materials appears to be weak.

In May l999, the NIH published a proposed set of guidelines for grantees on the subject of obtaining and disseminating biomedical research resources.[9] This guidance is intended to help avoid or minimize problems that sometimes result from the dissemination and use of proprietary research tools that involve the competing inter-

ests of intellectual property owners and research users. NIH issued this guidance because, as a public sponsor of biomedical research, it has a dual interest in accelerating scientific discovery through the use of research tools and facilitating product development.

COMPLIANCE WITH BAYH-DOLE ACT REGULATIONS

When a university elects title to an invention, it assumes responsibility for taking certain actions to properly manage the invention and provide certain reports to the government regarding the invention as outlined in the section on Current Regulations above. Compliance with these obligations is critical to the success of, and ongoing federal support for, the Bayh-Dole Act. As public and Congressional interest in technology transfer increases, and as the volume of activity continues to grow, government reviews of the practices of institutions involved in the process of commercialization of inventions will be conducted more frequently. Accordingly, there will be an increasingly greater need for attention to the details involved in meeting federal reporting obligations and other requirements imposed by 37 CFR Part 401.

Each federal agency is responsible for maintaining and monitoring its own repository of information on inventions developed under its funding. In October 1995, the NIH established the "Interagency Edison" system, an electronic reporting system whereby universities can enter data directly into a national database to satisfy their reporting obligations to those federal agencies participating in the system.

Federal agencies have the authority to periodically audit grantees and contractors for compliance with the Bayh-Dole Act. The General Accounting Office (GAO) in turn may also conduct studies to assess how effectively federal agencies are overseeing grantees and contractors in the management of government-funded inventions. 35 U.S.C. Section 202(b)(3) requires the Comptroller General to review the implementation of the Bayh-Dole Act at least once every five years and report its findings to the Judiciary Committees of the House and Senate. In 1991, the GAO focused its review on the licensing of federally owned inventions (GAO/RCED-91-80 issued April 3, 1991). In 1992, the GAO reviewed federal agency mechanisms for controlling inappropriate access to federally funded research results (GAO/RCED-92-104 issued May, 1992). More recently, the GAO reviewed the implementation of the Bayh-Dole Act by research universities (GAO/RCED-98-

126 issued May 7, 1998). In 1999, GAO issued a report on the number and characteristics of inventions licensed by six federal agencies (GAO/RCED-99-173, issued June 1999) and a report on compliance with reporting requirements for federally sponsored inventions (GAO/RCED-99-242, issued August 12, 1999). The GAO reports can be obtained from the Government Printing Office. See Web Resources below.

In order to assist grantees in their efforts to maintain compliance with the Act, some federal agencies have periodically issued guidance to the grantee community. An example is a question and answer document regarding invention reporting, printed in the NIH Guide to Grants and Contracts in l995. (NIH Guide, Vol.24, No.33, September 22, l995).

RESULTS OF THE BAYH-DOLE ACT

University patenting and licensing efforts under the Bayh-Dole Act have fostered the commercialization of many new technological advances that impact the lives of millions of people across the nation. A recent national survey conducted by AUTM[10] reports that 70% of the active licenses of responding institutions are in the life sciences--yielding products and processes that diagnose disease, reduce pain and suffering, and save lives. Most of the inventions involved were the result of federal funding. While it would be impossible to list all such inventions, a few examples of technologies and products originating from federally funded university discoveries include:

- Artificial lung surfactant for use with newborn infants, University of California
- Cisplatin and carboplatin cancer therapeutics, Michigan State University
- Citracal® calcium supplement, University of Texas Southwestern Medical Center
- Haemophilus B conjugate vaccine, University of Rochester
- Metal Alkoxide Process for taxol production, Florida State University
- Neupogen® used in conjunction with chemotherapy, Memorial Sloan Kettering Cancer Institute
- Process for inserting DNA into eucaryotic cells and for producing proteinaceous materials, Columbia University
- Recombinant DNA technology, central to the biotechnology industry, Stanford University and University of California
- TRUSOPT® (dorzolamide) ophthalmic drop used for glaucoma, University of Florida

These examples of successful new technologies demon-

strate that a strong national infrastructure to support technology transfer has been established at academic institutions across the nation since passage of the Bayh-Dole Act. In 1980 there were approximately 25-30 universities actively engaged in the patenting and licensing of inventions. It is estimated that there has been close to a ten-fold increase in institutional involvement since then. The AUTM survey reflects the impact of this growth in activity:

- Academic institutions were granted more than 8,000 U.S. patents between 1993 and 1997 for technologies discovered by their researchers.
- Over 2,200 new companies have been formed since 1980 that were based on the licensing of an invention from an academic institution, including over 330 companies formed in FY 1997 alone.
- Approximately $30 billion of economic activity each year, supporting 250,000 jobs can be attributed to the commercialization of new technologies from academic institutions.
- There are more than 1000 products currently on the market that are based on university licensed discoveries.
- Technologies licensed from academia have been instrumental in spawning entirely new industries, improving the productivity and competitiveness of companies, and creating new companies and jobs.[11]

In summary, the Bayh-Dole Act and its subsequent amendments created incentives for the government, universities, and industry to work together in the commercialization of new technologies for the public benefit. The success of this three-way partnership cannot be understated.

CONCLUSIONS

On a nation-wide basis, the results support the conclusion that the Bayh-Dole Act has promoted a substantial increase in technology transfer from universities to industry, and ultimately to the public. Certainty of title to inventions made under federal funding is perhaps the most important incentive for commercialization. Implementation of uniform patenting and licensing procedures, however, combined with the ability of universities to grant exclusive licenses, are also significant ingredients for success. This combination of factors led to a tremendous acceleration in the introduction of new products through university technology transfer activities.

Certainty of title to inventions made under Federal funding has one other significant benefit—it protects the right of scientists to continue to use and to build on a specific line of inquiry. This is fundamentally important to research-intensive institutions because of the complex way in which research is typically funded, with multiple fund-

ing sources. The retention of title to inventions by the institution is the only way of ensuring that the institution will be able to accept funding from interested research partners in the future. This is a critically important benefit of the Bayh-Dole Act that is not widely understood.

As Vannevar Bush foresaw, enormous benefits to the U.S. economy have occurred because of federal funding of research. These benefits have been significantly enhanced by the adoption of federal policies encouraging technology transfer. Such policies have led to breathtaking advances in the medical, engineering, chemical, computing and software industries, among others. The licensing of new technologies has led to the creation of new companies, thousands of jobs, cutting-edge educational opportunities and the development of entirely new industries. Accordingly, the Bayh-Dole Act continues to be a national success story, representing the foundation of a successful union among government, universities, and industry.

WEB RESOURCES

- http://www.nih.gov/grants/guide/index.htm (search for NIH Bayh-Dole-related policies)
- http://www.access.gpo.gov (GAO and other federal reports)
- http://137.187.120.232/ (Interagency Edison project)
- http://www.autm.net (AUTM home page)
- http://www.cogr.edu (COGR home page)

APPENDIX

Bayh-Dole Act and Related Legislation

The Bayh-Dole Act and subsequent amendments provide the basis for current university technology transfer practices. The federal patent and licensing policy was shaped by four events that occurred between 1980 and 1985.

1. On December 12, 1980, P.L. 96-517, the Bayh-Dole Act was enacted into law. After lengthy and contentious congressional debate, legislation was crafted that created a balance between incentives and controls. Universities applauded the legislation because a uniform federal patent policy was established that clearly stated that universities may elect to retain title to inventions developed under government funding. Industry, particularly the small business community, appreciated an ownership policy that was applied uniformly on a government-wide basis. In addition, industry expected to benefit from the message that universities were encouraged to collaborate with companies to promote

the utilization of inventions arising from federal funding, that preference in licensing be given to small business, and that, to the extent possible, licensed products were to be manufactured in the U.S. The federal government, in turn, was assured that universities would file, at university expense, patent applications on inventions they elected to own. In addition, the government retains rights to enforce diligent commercial development of inventions. It also enjoys royalty-free, non-exclusive licenses to practice federally funded inventions throughout the world for government purposes.

2. On February 10, 1982, the Office of Management and Budget issued OMB Circular A-124 to provide guidance to federal agencies regarding implementation of the Bayh-Dole Act. This Circular established standard patent rights clauses for use in federal funding agreements. It also set up standard reporting requirements for universities electing title to inventions.
3. On February 18, 1983, a Presidential Memorandum on "Government Patent Policy" was issued. This Memorandum was issued to satisfy those that recognized the benefits of the legislation and wanted broader coverage. The Presidential Memorandum directed federal agencies to extend the terms and provisions of the Bayh-Dole Act to all government contractors, with a follow-on amendment to the Federal Acquisition Regulations to assure that all federal R&D agencies would implement the Act and the Memorandum.
4. On November 8, 1984, the original Bayh-Dole statute was amended by P.L. 98-620. New language was added to remove term limitations placed on exclusive licenses under the original Act. In addition, the Department of Commerce was designated as the federal agency responsible for overseeing the implementation of the Bayh-Dole Act and for monitoring the granting of exceptions to the rules.
5. On March 18, 1987 (52 FR 8552), all of the relevant provisions--the Bayh-Dole Act, the amendment, OMB Circular A-124, and the Presidential Memorandum--were finalized and consolidated in a rulemaking published by the Department of Commerce—appearing at 37 CRF Part 401. These regulations, augmented by the NIH guidelines discussed in this brochure, specify the rights and obligations of all parties involved and constitute the operating manual for technology transfer on a national basis.

FOOTNOTES

1. U.S. Government Accounting Office (GAO) Report to Congressional Committees entitled "Technology Transfer, Administration of the Bayh-Dole Act by Research Universities" dated May 7, 1998.
2. The term "university" or "universities" as used in the text applies to all non-profit grantees/contractors.
3. We gratefully acknowledge the courtesy and and cooperation of AUTM in providing these statistics. See also AUTM Licensing Survey FY 1991-1995 and subsequent years.
4. In 1997, federal agencies provided an estimated $14.3 billion or about 60% of total support for research performed at universities. Academic institutions provided $4.5 billion of their funds. State and local governments and non profit organizations each contributed $18.1 billion and industry $1.7 billion. Although the proportion of academic R&D expenditures supplied by industry has been rising fairly steadily, it still only represents a fraction (7%) of total academic R&D support. Science and Engineering Indicators 1998. National Science Board: 4-8 and 4-9.
5. Presidential Memorandum and Statement of Government Patent Policy, issued October 10, 1963. Published in the Federal Register, Vol. 28, No. 200.
6. The Secretary of Commerce delegated this authority under 35 USC 206 to the Assistant Secretary for Productivity, Technology and Innovation.
7. Other circumstances, not clearly elucidated in the regulations, may be invoked by the government. Further detail can be found in 37 CFR Part 401.3; general appeal mechanisms are found in Part 401.4.
8. March-in rights, including appropriate procedures, are described at 37 CFR Part 401.6.
9. Notice for Public Comment, 64 FR 100,28205-28209.
10. AUTM Licensing Survey, Fiscal Year 1997.
11. AUTM press release December 17, 1998.

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