THE BAYH-DOLE ACT

A guide to the law
and implementing regulations

COGR

COUNCIL ON GOVERNMENTAL RELATIONS

NOVEMBER 30, 1993

Council on Governmental Relations

This document, which deals with the Bayh-Dole Act, is intended to inform the public about technology transfer at U.S. research universities. This Guide has a compendium piece, entitled "University Technology Transfer—Questions and Answers". Although each document fulfills its own purpose, they complement each other. When taken together they present a primer on the subject.

The Council on Governmental Relations is an organization which includes among its members over 135 research intensive universities. This booklet does not claim to be a manual of university technology transfer and licensing activities. Rather, it illustrates the philosophy and processes currently practiced in the university community.

In preparing the material, the COGR Subcommittee on Technology Transfer drew on the assistance of many COGR universities. Their help is gratefully acknowledged. Reproduction for purposes of sale or profit is prohibited without the written consent of the Council on Governmental Relations. Otherwise, reproduction is encouraged.

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Abstract

Modern day technology transfer from universities to industry can be dated to the 1980 enactment of P.L. 96-517, the Bayh-Dole Act, and amendments included in P.L. 98-620, passed in 1984. This paper provides a summary of the legislation and the implementing regulations, and describes some of the results to date.

Introduction

Technology transfer—the transfer of research results from universities to the commercial sector—is closely linked to fundamental research activities in universities. The concept is said to have originated in a report, entitled "Science—The Endless Frontier" which Vannevar Bush wrote for the President of the U.S. 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, recognized the value of university research as a vehicle for enhancing the economy by increasing the flow of knowledge to be used by 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 is now considered a vital role of the federal government.

In the 1960s and 1970s, there was much study and debate surrounding federal patent policy, which eventually resulted in legislative activity. A major concern was the apparent inability of the federal government to transfer its technologies. There was no government-wide policy regarding ownership of inventions made under federal funding and the diversity in policies among the various funding agencies resulted in a mea-

- The term limitation on exclusive licenses was deleted.
- The Secretary of Commerce was substituted for the Comptroller General as the responsible party to determine "exceptional circumstances" when contractor rights might be overruled.

In summary, the Bayh-Dole statute and subsequent amendments created incentives for the government, universities, industry and the small business sector, and herein may lie the reason for its success. It was not until 1987, however, that all these provisions—the Bayh-Dole Act, its statutory amendment, the OMB policy guidance and the Presidential Memorandum—were finalized in rulemaking, published by the Department of Commerce.[6] These rules specify the rights and obligations of all parties involved and constitute the operating manual of the modern technology transfer officer.

Current Regulations

Procedures implementing legislative and executive 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 to maintain these rules.[7] As technology transfer takes place, the following regulations must be observed:

- The provisions apply to all inventions conceived or first actually reduced to practice in the performance of a project, whether fully or partially funded by a federal agency.
- The university has an obligation to disclose each new invention to the federal funding agency within two months after the inventor discloses it 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 is shortened, if, due to publication of results, the one year U.S. statutory patent bar has been set in motion. Under those circumstances, the university must make an election at least sixty days before the end of the statutory period.
- 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 applications. If the university does not intend to file, the agency may then file on its own behalf.
- If the university elects to retain title, the federal government is provided a non-exclusive, irrevocable, paid-up license to practice the invention (or have it practiced on behalf of the U.S.) throughout the world.
- Any company that holds an exclusive license for sales 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 in the U.S.
- As they proceed to license an invention, universities must give preference to a small business firm, provided the firm has the resources and capability for bringing the invention to practical application. However, if a large company has provided research support that led to the invention, that company may be awarded the license.
- Universities may not assign their rights to inventions to third parties, except to a patent management organization.
- Universities must share with the inventor any income collected on the invention. Any remaining income, after expenses, must be used to support scientific research or education.
- Agencies may decide, due to exceptional circumstances, that title is better vested in the federal agency. Such decision must be made up front and becomes part of the funding agreement with the university. The agency must file an "exceptional circumstances" determination with the Department of Commerce, which rules on its validity. These exceptional circumstances might pertain to national security or sensitive research projects.[8]
- In some circumstances, the government can require the university to grant a license to a third party. This might

occur if the invention was not brought to practical use within a reasonable time, if health or safety issues arose, if public use of the invention was in jeopardy, or if other legal requirements were not satisfied.[9]

Details of procedure and other rights and obligations not cited above, as well as further elucidation of those items discussed, can be found in 37 CFR 401 and 35 USC 200-212.

Results

Has Bayh-Dole been effective in promoting technology transfer by universities? What measures can verify its effectiveness; and how much data are available? Some compelling data exist:

- In 1980, there were approximately 25–30 universities engaged in technology transfer; by 1992, there were 200.[10]
- Between 1974–1984, 84 universities applied for 4,105 patents (2,944 subsequently issued); in 1992 alone, 139 universities received 1,557 patents.[11]
- During 1974–1984, 1,058 licenses were granted by universities; in the period of 1989–1990, 1,510 licenses were granted.[12]
- In 1986, 112 universities reported licensing income of $30 million; in the two year period of 1989 and 1990, 35 universities reported income of $113 million.[13]
- According to the General Accounting Office, industrial support of university research has risen from 4% in 1980 to 7% in 1990.[14]
- A 1993 survey including 98 universities further illustrates the growing activity and success in university technology transfer for fiscal years 1991 and 1992.[15]

Conclusions

These data lead clearly to the conclusion that the Bayh-Dole Act has promoted a substantial increase in technology transfer from universities to industry, and ultimately to the public, as products become generally available. The Act provided a secure base to which universities could link some of their key research projects. Certainty of title to inventions made under federal funding proved to be most significant. While allowing commercialization, title also protects a researcher's rights to use and continue to build on a specific line of inquiry. Implementation of uniform patent and licensing procedures became the second ingredient for success. This combination of factors led to a tremendous boost in university technology transfer activities.

As Vannevar Bush foresaw, striking economic benefits to U.S. business have been a critical spinoff from this effort. University research and technology transfer has spawned the biotechnology industry and led to advances in the medical, engineering, chemical, computing and software industries, among others. Transfer of technologies has led to the creation of new companies, thousands of jobs, cutting-edge educational opportunities and spinoff to service industries.

As one example of this spinoff, the licensing income in 1989 and 1990 of over $100 million for thirty-five universities can be extrapolated, on a 4% royalty basis, to over $2.5 billion in sales, supporting thousands of jobs. And, this is only part of the picture. One should also take into account the funds invested by industry in development and in supporting these sales. One must also recognize the investment in new start-up companies all across the U.S., from which products are forthcoming. Finally, one must remember that U.S. universities have invested tens of millions of dollars since 1980 in developing their productive technology transfer infrastructure.

Perhaps, most importantly, one must acknowledge how technology transfer, facilitated by the Bayh-Dole Act, has improved our lives. New drugs, medical treatments, building materials, consumer products and diagnostic devices are but a few of the products that started as an idea in a university research laboratory and now touch our lives daily. The Bayh-Dole Act permits universities to be effective in promoting technology transfer. We must all be mindful of the tenets from which the Act was derived, and must be vigilant in protecting the rights granted by the Act.

Footnotes

[1] The term university(ies) as used in the text applies to all grantees/contractors.

[2] P.L. 96-517, Patent and Trademark Amendments of 1980. This law amended Title 35 USC, by adding Chapter 18, Section 200-212.

[3] Office of Management and Budget (OMB) Circular A-124 was subsequently codified at 37 CFR Part 401.

[4] The Presidential Memorandum was incorporated into the text of Office of Management and Budget (OMB) Circular A-124 on March 24, 1984.

[5] P.L. 98-620 amended Chapter 18, of Title 35 USC.

[6] Final rules were published on March 18, 1987 (52 FR 8552) and subsequently codified at 37 CFR Part 401.1-401.16.

[7] The Secretary of Commerce delegated this authority under 35 USC 206 to the Assistant Secretary for Productivity, Technology and Innovation.

[8] 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.

[9] Such conditions, including appropriate procedures, are described at 37 CFR Part 401.6.

[10] Informal survey of the Association of University Technology Managers (AUTM)

[11] Data for the 1974-1984 period are taken from a General Accounting Office (GAO) report, entitled "Patent Policy: Universities Research Efforts Under Public Law 96-517", dated April 1986.

[12] Data for the 1989-1990 period is contained in a General Accounting Office (GAO) report entitled "University Research - Controlling Inappropriate Access to Federally Funded Research Results", dated May 1992.

[13] The source for the 1986 data is a General Accounting Office (GAO) report, entitled "R&D Funding: Foreign Sponsorship of U.S. University Research", dated March 1988, Appendix I.

[14] See reference [12].

[15] The AUTM Licensing Survey: Fiscal Years 1991 and 1992. Association of University Technology Managers, Inc., dated October 1993.

Invention Disclosures: 1991-4,848:1992-5,645;

Total Patent Filings: 1991-1,922:1992-2,329;

Licenses: 1991-2,096:1992-2,632;

Royalties Received: 1991-$130M:1992-$171M.