Technology transfer : administration of the Bayh-Dole Act by research universities : report to Congressional committees / United States General Accounting Office.

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TECHNOLOGY TRANSFER

Administration of the Bayh-Dole Act by Research Universities

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The Honorable Orrin G. Hatch
Chairman, Committee on the Judiciary
United States Senate

The Honorable Henry Hyde
Chairman, Committee on the Judiciary
House of Representatives

As you know, the Patent and Trademark Laws Amendments of 1980, as amended (commonly known as the Bayh-Dole Act), requires us to review periodically chapter 18 of title 35 of the U.S. Code, which promotes the use of federally funded inventions by small businesses and nonprofit organizations. The act purposes to do this by allowing (1) nonprofit organizations such as universities to retain title to and market the inventions they created using federal research funds and (2) federal agencies to grant exclusive licenses for federally owned inventions to provide more incentive to businesses.

In our last report on this subject in 1991,[1] we focused largely on the granting, selling, and licensing of government-owned inventions. Our current report addresses the manner in which the Bayh-Dole Act is being administered in research universities, as agreed with staff from the Senate Committee on the Judiciary and from the Courts and Intellectual Property Subcommittee of the House Committee on the Judiciary. We provide information on (1) the administration of the Bayh-Dole Act by the eight largest federal agencies that fund research and development (R&D), (2) the administration of the Bayh-Dole Act by 10 of the largest U.S. research universities, and (3) the impact of the Bayh-Dole Act, largely on the basis of annual surveys of research universities conducted by the Association of University Technology Managers (AUTM).[2] (Additional details on our objectives, scope, and methodology are included in app. I.)

Results in Brief

Federal agencies' administration of the Bayh-Dole Act as it applies to research universities is decentralized. While the Department of Commerce has issued implementing regulations and provides coordination under limited circumstances, the act actually is administered by the agencies

[1]Technology Transfer: Federal Agencies' Patent Licensing Activities (GAO/RCED-91-80; Apr. 3, 1991).

[2]AUTM is a nonprofit organization formed to assist university technology administrators in the effective transfer of technology to the public.

providing the funds. The agencies' activities consist largely of ensuring that the universities meet the reporting requirements and deadlines set out in the act and regulations. According to Commerce officials, no agency has yet taken back the title to any inventions because they were not being commercialized.

We visited 10 major research universities and found that they had established formal programs and procedures to implement the act. The universities had special units to handle the reporting and licensing of inventions, had established procedures to ensure adherence to the act's reporting requirements, had set up computerized databases to monitor activities involving inventions, and were actively pursuing licensing for their inventions. They also appeared to be pursuing licensing opportunities wherever possible and sharing royalties with the inventors.

Officials within the agencies and universities we visited said the act was having a positive impact and was working as the Congress intended. They believed that the universities and researchers were receiving greater benefits from their inventions and were transferring technology better than the government did when it retained title to inventions. Although there is no database or study showing the impact specifically attributable to the act, a fiscal year 1996 report from a survey conducted by the Association of University Technology Managers indicates that inventions from all funding sources, including federal agencies, are increasing in their importance to universities. In fiscal year 1996, the number of inventions disclosed by universities increased by 9.3 percent for the year, and licensing income—which totaled $365.2 million—increased by 22.1 percent.

Background

Since World War II, the U.S. government has made significant contributions to the world's science and technology base, both by supporting basic scientific research and by pursuing science and technology missions within federal agencies. Two major beneficiaries of this federal spending have been universities and U.S.-based corporations. The universities benefited because the government was willing to underwrite basic research that may not lead to the creation of new and profitable products or services in the near term. The corporations benefited from the products and services they were able to develop for the government itself as well as from the "spin-off" process, whereby the results of government-sponsored research could be used to develop products and services for the private sector.

Despite the perceived success of federal efforts to support R&D, by the late 1970s there was a growing dissatisfaction with federal policies related to the patenting of the scientific knowledge resulting from the research. Many officials, for example, believed that federal laboratories harbored information that was not being disseminated to those who could make use of it. Similarly, there was a concern that the advances attributable to university-based research were not being pursued because there was little incentive to seek practical uses for inventions to which the federal government retained title. Those seeking to use government-owned technology found a maze of rules and regulations set out by the agencies in question because there was no uniform federal policy on patents for government-sponsored inventions or on the transfer of technology from the government to the private sector.

In 1980, the Congress addressed these concerns by enacting legislation to bolster the economic impact of federal R&D investments. One such law was the Bayh-Dole Act (P.L. 96-517, Dec. 12, 1980). The purpose of this act was to reform U.S. patent policy related to government-sponsored research. At the time, fewer than 5 percent of the 28,000 patents being held by federal agencies had been licensed, compared with 25 percent to 30 percent of the small number of federal patents for which the government had allowed companies to retain title to the invention. In this connection, the Bayh-Dole Act had two purposes: (1) to allow universities, not-for-profit corporations, and small businesses to patent and commercialize their federally funded inventions and (2) to allow federal agencies to grant exclusive licenses for their technology to provide more incentive to businesses.

In 1987, the Department of Commerce issued regulations, which are codified in 37 C.F.R. 401, to implement Bayh-Dole. Some of the key provisions of the law and regulations are as follows:

- Unless the agency informs the university at the time funding is provided that the agency will retain title to inventions derived from the projects funded because of specifically identified "exceptional circumstances" or other specified conditions, the university is entitled to retain ownership of any inventions created as a result of the funding.
- The university must disclose to the appropriate federal agency any invention created with the use of federal funds within 2 months of the date the inventor discloses the invention in writing to the university.
- To retain ownership, the university generally must notify the agency of its election to retain title within 2 years of the date of disclosure. When

publication, sale, or public use has initiated the 1-year statutory period in which valid patent protection can be obtained in the United States, the agency may shorten the period of election to not more than 60 days prior to the end of the statutory period.

- The university must provide the U.S. government a nontransferable, irrevocable, paid-up, nonexclusive license ("confirmatory license") to use the invention.
- The university must attempt to develop the invention. Otherwise, the government retains the right to take control of the invention. The government also may take control of the invention for other reasons, such as a need to alleviate health or safety concerns. This provision is referred to in the law as the government's "march-in" rights.
- In granting licenses to use the invention, the university generally must give priority to small businesses.
- When granting an exclusive license, the university must ensure that the invention will be "manufactured substantially" in the United States.
- The university must share a portion of the royalties with the inventor(s).

While a discussion of the impact of the Bayh-Dole Act in connection with large businesses is beyond the scope of this report, the basic provisions of the act—which apply only to universities, other nonprofit organizations, and small businesses—were extended to large businesses by Executive Order 12591, dated April 10, 1987.

Federal Oversight and Administration of Bayh-Dole Is Decentralized

In fiscal year 1995, U.S. universities received about $12.1 billion in direct federal funds for science and engineering R&D and controlled billions more through their affiliations with other nonprofit research institutions and their management of federally funded research and development centers. All of these funds were subject to the provisions of the Bayh-Dole Act, as administered by the funding agencies and the recipient universities.

By design, federal oversight of Bayh-Dole is decentralized—that is, each funding agency administers the law as it applies to grants and contracts. For university projects, the bulk of the administration is left to the universities, which must meet specific requirements related to disclosing, reporting, and licensing inventions. For the most part, the agencies' activities are limited to collecting and managing the information submitted by the universities.

Universities' Funding Subject to Bayh-Dole May Be Direct or Indirect

The best aggregate information on federal funding subject to Bayh-Dole is that accumulated and reported by the National Science Foundation (NSF), which annually surveys federal agencies to obtain information on funds awarded for research by type and recipient. According to NSF, direct federal funding to universities for science and engineering R&D totaled $12.1 billion in fiscal year 1995. As shown in table 1, 98.1 percent of this funding was provided by eight agencies. (App. II shows fiscal year 1995 funding to the top 100 universities receiving funds.)

Table 1: Funding to Universities for Science and Engineering R&D, by Eight Federal Agencies, in Fiscal Year 1995

Dollars in thousands

Agency	Award amounts	Percent of total
Health and Human Services	$6,511,543	54.0
National Science Foundation	1,731,968	14.4
Department of Defense	1,609,588	13.3
National Aeronautics and Space Administration	696,201	5.8
Department of Energy	601,019	5.0
Department of Agriculture	440,617	3.7
Environmental Protection Agency	148,657	1.2
Department of Commerce	94,960	0.7
Other	233,889	1.9
Total	**$12,068,442**	**100.0**

Source: NSF.

Within these departments and agencies, the level of funding attributable to individual agencies, functions, or services varies widely. In the Department of Health and Human Services (HHS), for example, about 98 percent of the funding comes from one agency—the National Institutes of Health (NIH). In the Department of Defense (DOD), however, funding is split among the Army (14.2 percent), Navy (27.4 percent), Air Force (13.5 percent), and the remaining Defense agencies (45.0 percent). (App. III shows direct funding for science and engineering R&D from all federal departments and agencies in fiscal year 1995.)

The statistics in table 1 do not include R&D funds the departments and agencies provide to other organizations affiliated with universities. There are two primary types of such organizations: (1) other nonprofit institutions and (2) federal laboratories designated as Federally Funded Research and Development Centers (FFRDC).

Federal agencies provide R&D funding to certain nonprofit institutions other than universities. Institutions of this type include such organizations as research hospitals, independent laboratories, and other research-specific institutes. In fiscal year 1995, federal funding for science and engineering R&D at nonprofit institutions other than universities totaled $3.3 billion, according to NSF. Some of these nonprofit institutions are managed or staffed by universities, although NSF does not separate or identify these in its statistical reports. For example, the Harvard Medical School provides staff for five independent hospitals, which in total received $191.5 million in direct science and engineering R&D funds in fiscal year 1995.

Similarly, the reach of the Bayh-Dole Act through universities is greater because of funding provided to FFRDCs that are administered by universities. According to NSF, federal agencies provided $3.6 billion in science and engineering R&D funding to 18 such organizations in fiscal year 1995. (App. IV shows each of these FFRDCs, the administering university, and the funding for fiscal year 1995.) One example of a university-managed FFRDC is Lincoln Laboratories, which is managed by the Massachusetts Institute of Technology (MIT) and received $314.2 million in federal R&D funds in fiscal year 1995.

The Administration of the Bayh-Dole Act Is Decentralized and Relies Heavily on Voluntary Compliance by the Universities

The administration of the act is decentralized. Each federal agency awarding R&D funds is required to ensure that the universities receiving such funds abide by the act's requirements. The agency that comes closest to coordinating the Bayh-Dole Act is the Department of Commerce. The act, as amended, provided that Commerce could issue regulations for the program and establish standards for provisions in the funding agreement entered into by federal agencies and universities, other nonprofit institutions, and small businesses. Commerce did so in 1987. Commerce is looked upon by the other agencies as a type of coordinator and may be consulted when questions arise. However, Commerce does not maintain any overall Bayh-Dole database.

Commerce officials told us that they see their overall role in administering the Bayh-Dole Act as one of facilitating its operation. They support the objectives of Bayh-Dole and believe the law has achieved its objective of getting more government-funded inventions to those who can make use of them. They had few details on how individual agencies administered Bayh-Dole, however. They said that, to their knowledge, the march-in rights provision had never been asserted by any agency. As discussed in

appendix V, NIH refused to initiate march-in procedures in the one case in which a petition was filed. Commerce officials noted that, as provided by law, the act is largely self-regulating in that the primary responsibility is placed upon the universities to comply voluntarily with the act.

To learn more about how the funding agencies were administering the act, we contacted officials at the eight agencies listed in table 1 that grant the most funds subject to the act's requirements. We discussed the procedures followed by the agencies, the databases that had been established to record and monitor the information provided to the agencies by the universities, and the program's results and achievements. (App. V provides a brief description of each agency's activities.) Generally, we found the following:

- The funding agencies generally had not established separate operating procedures for Bayh-Dole but did include a provision showing the act's applicability in individual funding agreements. In most cases, the universities were allowed to use their own forms for the various notifications required by the act.
- The agencies we visited relied on the universities to ensure that all federally funded inventions were meeting the requirements of the law and regulations. Some agency officials said they use their post-grant or contract reviews to see if any of the results reported in the documentation indicated an invention that was not reported under the provisions of the act. If so, they said that they would query the university to determine if there was in fact an invention that should have been reported. However, they did not document these activities in such a way that the frequency or results of these reviews could be determined.
- The agencies' monitoring activities consisted largely of collecting and recording the information the universities provided. The agencies generally did not have data for some areas, such as whether the universities were giving priority to small businesses in licensing or how they ensured substantial domestic manufacture under exclusive licenses. The one area of compliance that most agencies did stress was that the universities provide the confirmatory licenses to the government.
- Those agencies most involved in administering Bayh-Dole—NIH, NSF, and DOD—were also those agencies with the most funding subject to the act.
- The confirmatory licenses are provided to Commerce's Patent and Trademark Office (PTO), which maintains the information in the Government Register and makes it available to those who need it. We did not attempt to review how the federal agencies actually make use of confirmatory licenses.

- Generally, the agencies did not appear to be pursuing the licensing of university-created inventions on their own when the universities elected not to retain title. Some officials said that if commercialization did not appeal to the university or the inventor, it usually had no appeal to the government either.
- None of the agencies had made analyzed the impact of the act, although all were pleased with the way the act was working and said that it should be resulting in more federally supported inventions reaching the marketplace.

Probably the most aggressive system for monitoring the Bayh-Dole Act was that established by NIH. In October 1995, NIH deployed its "Edison" system for monitoring the act's reporting requirements. NIH designed Edison at least in part to respond to criticism from the HHS Inspector General that it was not properly documenting reporting under the act.

Edison is a real-time, computer-based system that uses the Internet and allows (1) the university to enter data into the system as needed and (2) the agency to review and analyze the activity on any particular invention at any time. In addition to showing all of the significant reporting elements of the act, Edison provides the agency with the ability to know when a particular report or activity is due. For example, the system alerts the agency when a university is nearing the end of the period during which it has to make an election on retaining title to an invention. Edison also allows the agency to produce reports that detail activity for a particular university, invention, time period, and so on. At present, Edison is optional, and universities can use paper documents rather than entering data electronically if they so choose. NIH officials said that the goal is eventually to make Edison a completely paperless system, but at present even those who enter data electronically must provide a paper backup for documents that require a signature.

In designing Edison, NIH wanted to develop a system that could be used governmentwide. However, some agencies did not elect to use it for various reasons: (1) They believed at the time that NIH would require the agency to pay a fee, (2) the agency did not have enough inventions activity to warrant such an elaborate database, (3) the agency already had a database that was meeting its needs, or (4) the agency did not believe that the Edison format was adaptable to its own inventions-oversight programs or those of its recipient universities. At the time of our review, NIH had signed memorandums of understanding with six agencies to use Edison. These agencies were NSF, Agriculture, the National Oceanic and Atmospheric Administration within Commerce, the Centers for Disease

Control and Prevention and the Food and Drug Administration within HHS, and the Agency for International Development within the Department of State. According to NIH officials, none of the agencies are required to pay a fee for using Edison.

Universities Visited by GAO Had Established Invention Programs to Implement Bayh-Dole

On the basis of our visits to 10 universities that were among the largest in terms of federal R&D funding and licensing income, we found that the universities had established programs to meet the requirements of the Bayh-Dole Act, designating units and personnel to oversee the activities involving inventions. They also had set out policies and procedures to ensure that their programs were complying with the act's reporting requirements, that they were pursuing licensing opportunities to the extent possible, and that royalties were being shared with those responsible for the inventions.

Universities Were Among the Leaders in R&D Funds and Licensing Income

We visited 10 universities that had extensive Bayh-Dole activities because of their high volume of federal funding, their high level of licensing income, or both. Table 2 shows these 10 institutions, their direct federal science and engineering R&D funding for fiscal year 1995, their licensing income for fiscal year 1996, and their ranking according to other universities nationwide in both areas.

Table 2: Federal Science and Engineering R&D Funding for Fiscal Year 1995 and Licensing Income for Fiscal Year 1996 for Universities GAO Visited

Dollars in thousands

	Federal research funding, fiscal year 1995[a]		Licensing income, fiscal year 1996	
University	Amount	Rank	Amount	Rank
Johns Hopkins University	$569,329	1	$3,091	23
University of Washington	299,631	2	8,651	10
MIT	282,120	3	10,083	8
Stanford University	266,744	4	43,752	2
University of Michigan	243,126	5	1,075	48
University of Wisconsin-Madison	207,504	8	13,092	5
Harvard University	191,499	13	7,642	11
Columbia University	186,179	14	40,632	3
Michigan State University	69,175	55	17,232	4
University of California	1,071,280	[b]	63,200	1
Total	$3,386,587		$208,450	

[a]Does not include federal funds provided to affiliated organizations, such as research hospitals using university staff or FFRDCs administered by universities.

[b]The University of California has a centralized technology transfer office providing oversight for nine campuses. Since we visited the central office, the total shown is for all nine campuses. The highest-ranking single campus receiving funds was San Diego, which ranked number 6 overall, although 7 of the 9 campuses were among the top 61.

Source: NSF and AUTM.

The universities we visited accounted for over 28 percent of the direct science and engineering research funding awarded to universities in fiscal year 1995 and received 57.1 percent of all licensing income going to universities in fiscal year 1996. (Apps. VI through XV describe the Bayh-Dole activities at each of the 10 universities.)

Universities Had Established Programs to Administer Inventions Resulting From Research

Each of the universities we visited had established specialized units to handle the reporting and licensing of inventions under the Bayh-Dole Act. On the basis of our visits and discussions with personnel in the federal funding agencies and AUTM, we determined that four different types of programs are in place nationwide. These are as follows:

- Centralized licensing office. In this type of office, all activities are concentrated in one centralized unit. An example of such an office is the Technology Licensing Office at MIT, which coordinates activities MIT-wide, including any inventions coming out of Lincoln Laboratory, an FFRDC.
- Decentralized licensing offices. In this type of office, reporting and licensing activities are carried out by separate offices in the various schools, departments, and other units of the university. Johns Hopkins, for example, has three licensing offices—one for the medical school, one for its Applied Physics Laboratory, and one for the remainder of the university.
- Foundation. In this type of program, the licensing activities are carried out by an independent foundation specifically set up for this purpose, although the university may retain an office to handle reporting on Bayh-Dole activities. This scenario appears to be more common among state universities. Wisconsin's licensing unit—the Wisconsin Alumni Research Foundation (WARF)—is an example of an independent foundation.
- Contractor. Some universities contract out some or all of their licensing activities. One of the largest such contractors is Research Corporation Technologies, Inc. (RCT), of Tucson, Arizona. Michigan State, one of the universities we visited, used RCT previously but now has a centralized office handling these activities.

Some universities have programs that combine these various types of reporting and licensing units. For example, Harvard has a centralized unit for administration and reporting purposes but has a separate unit that handles licensing for the medical school.

Universities Developed Policies and Procedures for Bayh-Dole

Officials at each of the universities visited said that (1) the only procedures for Bayh-Dole were the law itself and the regulations issued by Commerce, (2) the agencies generally do not make site visits to monitor compliance with the act, (3) a primary interest of the agencies is ensuring that they receive the confirmatory licenses, and (4) the agencies do not become involved in the licensing activities.

We looked at the procedures that each of the universities implemented to monitor compliance with Bayh-Dole. We found that the institutions had their own publications, forms, requirements, and so on for identifying inventions, recording data, reporting to the funding agencies, licensing inventions, and sharing royalties.

Identifying Inventions

Officials at the universities visited said that they used various methods to identify inventions created through the use of federal funds. Most, for example, have developed information to inform researchers of the Bayh-Dole Act's and the university's requirements for inventions as well as the benefits that are available from such inventions. Also, the universities have handbooks and other brochures that set out the requirements and the university's conflict-of-interest policy. Some encourage the researchers to discuss their work while it is ongoing to get feedback on what inventions might come out of the research and when they should be reported. Some universities also review post-grant and contract documentation and faculty publications to see if any results were discussed that might indicate an invention.

The policies varied among the universities in connection with how they determined whether the invention was created with government funds. University officials said that the best resource for determining the source of funds is the researcher, who usually works on a specific grant or contract from which the invention came. The universities held that if funding came from more than one source, the invention was considered subject to Bayh-Dole if any federal money at all was involved in the work. Officials at one university said that they presume an invention is subject to Bayh-Dole if anyone working in the same laboratory was getting any federal funds on any project.

Recording Data

The 10 institutions we visited had their own computerized invention databases for monitoring Bayh-Dole activities. While these varied somewhat in form and format, they all included certain background data, such as the inventor, grant, and type of invention, as well as key reporting dates and events concerning Bayh-Dole, patent prosecution, and licensing activities. Some of the more extensive databases provided information on costs, fees, and royalties. Some of the universities reporting to NIH were using Edison as a parallel system.

Reporting to Funding Agencies

Each of the universities visited had systems that allowed them to track dates and meet reporting deadlines for all Bayh-Dole requirements. However, some university officials noted that determining compliance

with certain requirements can be difficult. For example, as noted above, it may be difficult to tell when an invention actually was conceived or when the university first learned of it. University officials told us that, as a practical matter, it may not be possible to know whether an invention exists until there is at least a preliminary patent search. Thus, how to meet the requirement in the regulations to report an invention within 2 months is unclear.

Licensing

The universities we visited were attempting to license their inventions. Often, these activities begin prior to the university's electing to retain title to the invention, since there may be little benefit to retaining title to an invention and incurring the costs of obtaining a patent if it cannot be licensed. The universities varied in how they determined whether to retain title. Officials from Johns Hopkins, for example, said that they usually will not retain title to an invention unless they believe that it is useful to the public and they can license it and at least recoup the costs. Officials at Harvard said that they generally elect to retain title on everything but would pursue a patent only if the invention would make money. They also said that even if they do obtain a patent on an invention, they may abandon the patent if it is not making money, rather than elect to pay the maintenance fees for the patent.

The universities required the licensee to pay the costs of prosecuting and maintaining the patent on the invention, which would include patent fees. While most universities had in-house legal staff, most used outside counsel for obtaining and enforcing the patents.

Officials at some of the universities visited told us that they would assist with raising capital, help form start-up companies, or take an equity interest in lieu of royalties. However, this practice is not always a preferred choice for licensing. Such companies have the potential for creating ethical dilemmas and conflicts of interest because the university's primary goal in research is to pursue knowledge rather than make money.

None of the universities visited had a specific policy in place to give priority to small businesses in licensing. However, the majority of the inventions they licensed were licensed to small businesses. Some university officials said that companies rarely compete for the right to license. In addition, licensing priority often is given to a company that was a co-sponsor of the project from which the invention came, regardless of the company's size.

In the licensing agreements, the universities were requiring their exclusive licensees to substantially manufacture the products in the United States. However, the universities have no practical method for ensuring that this is done, other than requiring it in the licensing agreement.

Sharing Royalties

Each of the universities visited had procedures for sharing royalties with inventors and others, such as the department or laboratory in which the inventor worked. In some cases, the formula could be complicated, depending on the royalties received, the persons involved, the type of invention, and so on. Typically, the universities would have different royalty-sharing provisions for different levels of revenue. For example:

- Johns Hopkins' medical school uses a sliding scale for royalties. For the first $100,000 in annual revenues, the distribution is 35 percent to the inventor, 30 percent to the inventor's laboratory, 10 percent to the inventor's department, 23 percent to the medical school, and 2 percent to the university. At $1 million to $3 million in annual revenues, the distribution is 15 percent to the inventor, 10 percent to the inventor's laboratory, 15 percent to the inventor's department, 50 percent to the medical school, and 10 percent to the university.
- Harvard also uses a sliding scale in distributing royalties, shifting a portion of the inventor's share to the inventor's department as royalties increase. The first $50,000 generated by an invention is distributed 35 percent to the inventor, 30 percent to the inventor's department, 20 percent to the inventor's school, and 15 percent to the university. Income greater than $50,000 is distributed 25 percent to the inventor, 40 percent to the inventor's department, 20 percent to the inventor's school, and 15 percent to the university.
- WARF, the University of Wisconsin-Madison's licensing foundation, gives the inventor $1,500 up front when a new invention's patent application is assigned to the foundation. In addition, WARF distributes royalty income to the inventors and the university according to a formula set by the university. The current formula provides that the first $100,000 in gross income is divided 70 percent to the inventor's laboratory, 20 percent to the inventor, and 10 percent to WARF. Gross income greater than $100,000 is divided 65 percent to WARF, 20 percent to the inventor, and 15 percent to the inventor's department.

The Bayh-Dole Act requires that royalties be shared with the inventor but is silent as to what the percentage should be. As discussed above, the inventor's portion can vary substantially, depending on the university and the amount of royalties derived from the invention. If there was more than

one inventor, the institutions we visited divided the inventor's royalty share among the co-inventors.

University-Based Inventions Appear to Have a Growing Impact

The officials at the universities and agencies we visited believed the Bayh-Dole Act was accomplishing its objectives. They said that the universities and their researchers were benefiting because they could receive royalties on their inventions. The government and the public were benefiting because more government-funded technology was being brought to those who could make use of it.

Despite the perception that Bayh-Dole is working well, none of the federal agencies or universities we contacted evaluated the effects of Bayh-Dole. The only available nationwide data on the effects are those published by AUTM. While limited in application because they apply to all inventions regardless of funding source and are based on a survey of participants, AUTM's statistics nevertheless indicate that universities are increasing their licensing activities and that revenues from licenses are growing. AUTM also believes that the activities involving inventions have added to the economy in general.

Success with inventions and licensing varied widely among the universities we visited. However, we noted that most of them had at least one notable invention. We also noted that, to date, most of the revenues generated by the universities came from a small number of inventions.

AUTM's Survey Indicates a Continuing Increase in Activities Involving Inventions

The only nationwide evaluations of universities' activities involving inventions are those carried out by AUTM, a nonprofit organization formed to assist university intellectual property administrators in the effective transfer of technology to the public. Each year, AUTM surveys universities, other research institutions, and patent management firms to obtain information on licensing activities. The most recent survey report, which became available in January 1998, includes new data for fiscal year 1996 as well as data reported in earlier surveys dating to fiscal year 1991.

The AUTM survey is limited in its application to Bayh-Dole R&D because the survey covers the activities involving inventions by the universities from all funding sources—not just federal. Also, the AUTM survey is limited as an evaluation device in that (1) the data are based on a survey sent to the organizations, (2) not all organizations respond, (3) respondents report data according to their own fiscal year, and (4) no independent

verification or validation of the data is provided. The AUTM report states that "[T]he information contained in the Survey reports is best used as a starting place or as a point of departure for more extensive analysis."

AUTM sent the fiscal year 1996 survey to 212 research universities and received 131 responses, a response rate of 58 percent. However, the response rate among the top 100 universities—as measured by direct federal R&D funding based on NSF statistics—was 89 percent. These institutions accounted for 95 percent of all revenues reported.

As noted above, in interpreting the data, it is not possible to isolate the impact of inventions related to Bayh-Dole. Rather, the universities report their activities for all inventions. Also, it is difficult to measure the increase in activity from year to year because the number of respondents differs by year. For this reason, AUTM presents data for all respondents as well as for those respondents that have participated continuously in the survey in fiscal years 1991 through 1996. Some of the survey's major reported results are as follows:

- The 131 universities responding reported total sponsored research expenditures of about $18.7 billion in fiscal year 1996. Of this amount, $12.3 billion, or 65.9 percent, was from federal government sources.
- In total, the respondent universities reported invention disclosures of 8,119, up 9.3 percent from the 7,427 disclosures of fiscal year 1995. For the recurring respondents, the percent of increase in disclosures was 9.4 percent.
- Total U.S. patent applications were down. Respondents reported 5,100 applications for fiscal year 1995 compared with 3,872 for fiscal year 1996, a decrease of 24.1 percent. Total patent applications for recurring respondents were down 26.5 percent. New patent applications for all respondents increased, from 2,373 to 2,734, or 15.2 percent. New applications for recurring respondents increased 13.1 percent.
- The number of U.S. patents issued to the respondents increased 14.6 percent, from 1,550 in fiscal year 1995 to 1,776 in fiscal year 1996. Among recurring respondents, the increase was 12.4 percent.
- New licenses or options executed by all respondents increased slightly in fiscal year 1996, from 2,142 to 2,209, or 3.1 percent. Recurring respondents reported a larger increase of 8.4 percent. About 10.9 percent of the licenses or options granted in fiscal year 1996 for all respondents were to start-up companies, 54.7 percent were to small businesses (500 or fewer employees), and 34.4 percent were to large businesses. Slightly more than half, or 51.3 percent, of the new licenses or options were exclusive.

- At the end of fiscal year 1996, the universities were reporting 10,487 active licenses or options, up 12.9 percent from the 9,287 reported in fiscal year 1995. Licenses or options actually producing income increased by 16.1 percent, from 4,272 in fiscal year 1995 to 4,958 in fiscal year 1996.
- Gross license income received increased dramatically in the latest survey. Respondents reported income of $365.2 million, an increase of 22.1 percent over the $299.1 million reported for fiscal year 1995. Recurrent respondents reported an increase of 20.6 percent in licensing income in fiscal year 1996.
- New research funding generated by or related to licenses and options during fiscal year 1996 totaled $155.7 million, an increase of 38.4 percent over the $112.5 million for fiscal year 1995.

The AUTM survey report concluded that the economic impact of licensing activities undertaken by academic institutions, nonprofit organizations, and patent management firms is extensive. Using a model that (1) measures pre-production investment (investment made prior to the sales of licensed products) and (2) uses estimates of post-production sales of products by licensees to convert sales to jobs, the AUTM survey report estimated that the licensing activities of those academic institutions, nonprofit organizations, and patent management firms participating in its survey add more than $24.8 billion and 212,500 jobs to the U.S. economy each year. While the survey did not show how much of these amounts is contributed by universities alone, it did show that 61.7 percent of all licensing income reported was reported by universities.

For the reasons discussed earlier, we did not verify the accuracy of the model or the projections made by AUTM for economic impact, nor did we attempt to determine what portion of this impact was attributable to Bayh-Dole. The underlying data are based on unverified information reported on a survey. Furthermore, the projections are based on one approach for measuring economic impact; other approaches might yield substantially different results. Also, the projections cover the impact of all licensing activities, not just those attributable to federal funding and not just those attributable to universities. (App. XVI provides a summary of universities' invention activities for fiscal years 1995 and 1996, for all respondents as well as for those who have responded each year of the survey.)

Universities Were Among the More Successful in Activities Involving Inventions

The universities we visited were among the leaders in activities involving inventions. According to the AUTM survey report, for example, the 10 institutions we visited ranked among the top 29 respondent universities in disclosures of inventions, the top 16 in U.S. patents applied for, and the top 26 in patents issued during fiscal year 1996.

Similarly, the institutions visited were among the leaders in licensing activities: The 10 universities collectively hold 3,721 active licenses or options, or 35.5 percent of active licenses held by all respondent universities. These institutions accounted for 30.7 percent of new licenses or options and 57.1 percent of all licensing revenues received by the respondent universities during fiscal year 1996.

Like other institutions responding to the AUTM survey, the 10 institutions visited had less than half—1,768—of their active licenses producing income. However, there appears to be a disparity in earnings even among those inventions producing income. During our visits to the universities (as discussed in apps. VI through XV), we found that the bulk of the revenues was generated by a relatively small number of inventions. An AUTM official said that this gap is somewhat misleading because products may take several years to begin producing revenues.

The institutions visited pointed to a number of successful inventions they believed showed that university research subject to the Bayh-Dole Act was having a positive impact. For example:

- In 1989, University of Wisconsin researchers developed a solution that extends the time that human organs can be held outside the body prior to transplant. This invention has generated an estimated $8 million to $10 million in licensing income.
- In fiscal year 1996, 72 percent of Stanford's licensing income came from one invention. This invention, recombinant DNA, actually dates to the 1970s and was funded in part by NIH and NSF. More recently, Stanford and the University of California developed phycobiliproteins, which, among other things, are used to detect cancerous tumors. This invention earns about $3 million a year.
- The University of Washington has two inventions—known as the Hall technologies—that generate the bulk of the university's royalties. One of these involved the creation of a Hepatitis B vaccine and the other involved a method for using yeast to produce interferon, a cancer treatment drug.
- One of Columbia University's higher-profile inventions is the co-transformation process, a gene transfer process that can produce a

specific protein for commercial production. Patented in 1983, this invention has been used by 28 companies in making new pharmaceuticals and was critical in the development of a protein used to dissolve blood clots.

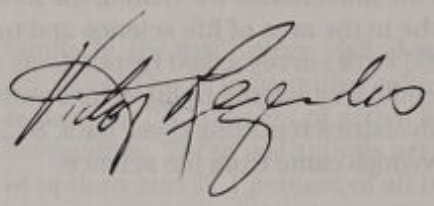
At the universities we visited, the more marketable technologies appeared to be in the area of life science and to come largely from NIH funding. The 1996 AUTM survey asked respondents to show what portion of overall income was related to life science and to physical science. Among those universities reporting these data, 80.2 percent of all fiscal year 1996 revenues came from life science.

Agency Comments and Our Evaluation

We transmitted a draft of this report to the Department of Commerce for its review and comment. The Department suggested some technical clarifications. We agreed with each of these clarifications and incorporated them into our report as appropriate. The Department also suggested that we cite all previous GAO reports that concerned Bayh-Dole. We did not believe this was necessary because most of these reports were more than 10 years old. We did list our most recent report, which was issued in 1991. The full text of Commerce's comments is included in appendix XVII.

Unless you publicly announce its contents earlier, we plan no further distribution of this report until 3 days after the date of this letter. At that time, we will send copies to the appropriate House and Senate committees; interested Members of Congress; the Secretary of Commerce; the Director, Office of Management and Budget; and other interested parties. We will make copies available to others upon request.

This report was prepared under the direction of Susan Kladiva, Associate Director of Energy, Resources, and Science Issues, who may be reached at (202) 512-7106 if you or your staff have questions. Major contributors to this report are listed in appendix XVIII.



Victor S. Rezendes
Director, Energy, Resources,
and Science Issues

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Abbreviations

APL	Applied Physics Laboratory
AUTM	Association of University Technology Managers
CIE	Columbia Innovation Enterprise
CSREES	Cooperative State Research, Education and Extension Service
CU	Columbia University
DOD	Department of Defense
DOE	Department of Energy
FFRDC	Federally Funded Research and Development Centers
GAO	General Accounting Office
HHS	Department of Health and Human Services
JHU	Johns Hopkins University
MIT	Massachusetts Institute of Technology
MSU	Michigan State University
MSUF	Michigan State University Foundation
NASA	National Aeronautics and Space Administration
NIH	National Institutes of Health
NSF	National Science Foundation
OIP	Office of Intellectual Property
ONR	Office of Naval Research
OTL	Office of Technology Licensing
OTT	Office of Technology Transfer
OTTL	Office for Technology and Trademark Licensing
PTO	Patent and Trademark Office
R&D	Research and Development
RCT	Research Technology Corporation
TLO	Technology Licensing Office
TMO	Technology Management Office
UC	University of California
UIR	University-Industry Relation
UM	University of Michigan
USDA	United States Department of Agriculture
UW	University of Washington
UWM	University of Wisconsin-Madison
WARF	Wisconsin Alumni Research Foundation
WRF	Washington Research Foundation

Objectives, Scope, and Methodology

Public Law 102-204 (35 U.S.C. section 202(b)(3)) requires the Comptroller General to review, at least once every 5 years, the implementation of the Bayh-Dole Act, which promotes the use of federally funded inventions by small businesses and nonprofit organizations, and to issue a report to the House and Senate Committees on the Judiciary. Our last report in direct reference to Bayh-Dole implementation was Technology Transfer: Federal Agencies' Patent Licensing Activities (GAO/RCED-91-80), issued April 3, 1991. In that report, we focused largely on the granting, selling, and licensing of government-owned inventions. Since that report, we have issued a number of reports concerning patent issues.[1]

For our current review, we met with staff from the Senate Committee on the Judiciary and from the Courts and Intellectual Property Subcommittee of the House Committee on the Judiciary to discuss those issues that should be addressed in our current report. We agreed to focus on the manner in which Bayh-Dole is being implemented by research universities. To do this, we would provide information on (1) the administration of the Bayh-Dole Act by the eight largest federal agencies that fund research and development (R&D), (2) the administration of the Bayh-Dole Act by 10 of the largest U.S. research universities, and (3) the impact of the Bayh-Dole Act, largely based on annual surveys of research universities conducted by the Association of University Technology Managers (AUTM).

To learn more about how the federal agencies were administering the act, we first contacted officials from the Department of Commerce, which issued regulations on Bayh-Dole. We then contacted officials at each of the eight agencies granting the most funds subject to the act's requirements,[2] as determined by the statistics on funding for science and engineering research developed by the National Science Foundation (NSF). In addition to Commerce and NSF, these agencies included the Department of Health and Human Services (HHS), the Department of Defense (DOD), the Department of Energy (DOE), the National Aeronautics and Space Administration (NASA), the Department of Agriculture (USDA), and the

[1]Patent Examination Statistics (GAO/RCED-96-152R, May 22, 1996); Intellectual Property: Enhancements Needed in Computing and Reporting Patent Examination Statistics (GAO/RCED-96-190, July 15, 1996); Intellectual Property: Patent Examination and Copyright Office Issues (GAO/T-RCED/GGD-96-230, Sept. 18, 1996); Intellectual Property: Comparison of Patent Examination Statistics for Fiscal Years 1994 and 1995 (GAO/RCED-97-58, Mar. 13, 1997); and Intellectual Property: Fees Are Not Always Commensurate With the Costs of Services (GAO/RCED-97-113, May 9, 1997).

[2]We also contacted the Department of Education but did not make a site visit. Agency officials told us that there were virtually no inventions resulting from Education funding to universities and that the agency had no formal program for administering Bayh-Dole. The officials said that if a federally funded invention was identified, the grants manager would contact Education's Office of General Counsel and work out the reporting details for the Bayh-Dole Act.

Environmental Protection Agency (EPA). The agencies we contacted accounted for 97.8 percent of all direct federal funding to universities for science and engineering research in fiscal year 1995.

At each of the funding agencies visited, we discussed with agency officials the procedures that had been implemented, the databases that had been established to record and monitor the information provided by the universities, and the program's results and achievements. In some of the agencies, more than one unit granted funds. In these cases, we contacted those units that were responsible for the majority of the funding. In this connection, we worked with the National Institutes of Health (NIH) in HHS and with the Army, Navy, and Air Force within DOD.

To learn more about how universities were administering the act, we visited 10 universities that had extensive Bayh-Dole activities. We selected universities that had a high volume of federal funding, according to NSF, or high levels of licensing income, according to AUTM. From these, we chose Johns Hopkins University, ranked number 1 by NSF and number 23 by AUTM; the University of Washington, ranked number 2 by NSF and number 10 by AUTM; the Massachusetts Institute of Technology, ranked number 3 by NSF and number 8 by AUTM; Stanford University, ranked number 4 by NSF and number 2 by AUTM; the University of Michigan, ranked number 5 by NSF and number 48 by AUTM; the University of Wisconsin-Madison, ranked number 8 by NSF and number 5 by AUTM; Columbia University, ranked number 14 by NSF and number 3 by AUTM; Michigan State University, ranked number 55 by NSF and number 4 by AUTM; Harvard University, ranked number 13 by NSF and number 11 by AUTM; and the University of California, which would have been ranked number 1 by NSF if all campuses had been included in the calculations and was ranked number 1 by AUTM.

For each of the universities selected, we visited the technology transfer office and in some cases the office overseeing grants administration. We met with officials and discussed the funding that is subject to the Bayh-Dole Act at the university and any affiliated organizations, procedures that had been implemented to administer the act, databases that had been established to record and monitor the information gathered on inventions by the university, the methods by which the university was ensuring that it met the reporting and other requirements of the act, the university's relationships with Commerce and the funding agencies, and the program's results and achievements. The universities we contacted accounted for 28.1 percent of all direct federal funding to universities for

science and engineering research in fiscal year 1995 and for 57.1 percent of licensing income reported by all universities to AUTM in fiscal year 1996.

To determine how the AUTM data could be used to measure the impact of the act, we discussed with AUTM officials the procedures and methodologies involved in the annual surveys of universities and other organizations and obtained the survey reports for fiscal years 1995 and 1996. We used the fiscal year 1995 report to select universities for our case studies; however, we have updated the information in our report to show the results of the fiscal year 1996 survey report.

To assess the quality of the data obtained through the AUTM survey, we reviewed copies of the survey instruments that AUTM used in collecting data for fiscal years 1991 through 1996. We looked at the clarity of questions and the layout of the questionnaire, concentrating on features of the survey that could affect the collection of data across several years. In this connection, we explored the consistency of questions asked in multiple years and the effects of changes in wording. We also examined the use of definitions and how changes in definitions might affect data across the years of the survey's administration. In addition to discussing the AUTM data with each of the 10 universities we visited, we interviewed officials from Emory University to understand how questions might be interpreted by respondents.

While we believe the AUTM data are the best available showing universities' licensing activities, important limitations restrict the use of the data in reaching any conclusions in our report. These are as follows:

- The AUTM data are based on a survey; therefore, the data available come from those who were willing to respond. There is no information on those who were not surveyed or those who did not respond.
- The AUTM data are not verified or validated, although AUTM does follow-up work in an attempt to improve the uniformity of the responses.
- The AUTM data include all research activities, not just those associated with federally funded inventions; thus, the inventions subject to the Bayh-Dole Act cannot be segregated.
- The universities report data according to their own fiscal years, which may differ from the fiscal year of other universities and the federal government.
- For some elements of the data, the definitions included in the survey were improved or changed over the years in which the survey has been administered in ways that might increase or decrease the reporting of the data.

Despite these limitations, we have included the data from the AUTM survey reports in our own report with the appropriate caveats because (1) they are the only data available on technology transfer by universities nationwide; (2) the schools reporting showed an aggregate of 65.9 percent of their research expenditures coming from federal sources and, thus, applicable to the Bayh-Dole Act; and (3) university officials recommended the AUTM survey results as the best data available.

We did not independently verify the data we obtained from the agencies, the universities, or AUTM.

We conducted our review from August 1997 to March 1998 in accordance with generally accepted government auditing standards.

Federal Funding to Universities for Science and Engineering Research and Development, Fiscal Year 1995

Dollars in thousands

Rank	University	Agency	
		USDA	DOC
1	Johns Hopkins	$251	$42
2	Washington, Seattle	4,844	4,406
3	Massachusetts Institute of Technology	80	2,146
4	Stanford	578	251
5	Michigan	361	1,151
6	California, San Diego	490	10,838
7	California, Los Angeles	290	404
8	Wisconsin, Madison	10,112	982
9	Minnesota	9,887	1,463
10	Cornell	14,365	81
11	California, San Francisco	46	0
12	Pennsylvania	1,163	85
13	Harvard	99	0
14	Columbia, New York City	0	1,758
15	Yale	850	0
16	Pittsburgh	0	0
17	Colorado	327	4,560
18	Washington	335	139
19	North Carolina, Chapel Hill	245	225
20	Duke University	676	35
21	Pennsylvania State	8,746	369
22	Southern California	110	405
23	California, Berkeley	11,476	610
24	Arizona	5,275	929
25	Case Western Reserve	30	101
26	Alabama, Birmingham	316	0
27	Texas, Austin	451	355
28	Illinois, Urbana-Champaign	10,749	97
29	California Institute of Technology	0	94
30	Rochester	101	0
31	Chicago	0	238
32	Northwestern	60	49
33	California, Davis	5,787	0
34	Ohio State	8,830	700

Agency								
DOD	ED	DOE	EPA	HHS	NASA	NSF	Other	Total
$288,918	$104	$7,977	$341	$241,726	$19,031	$10,879	$60	$569,329
31,912	798	15,085	723	193,058	11,117	34,514	3,174	299,631
68,205	0	68,184	1,867	51,514	44,125	42,736	3,263	282,120
39,688	0	6,285	5,757	128,905	56,656	26,058	2,566	266,744
21,560	578	6,139	12,547	156,771	12,075	29,630	2,314	243,126
32,680	0	14,069	786	125,573	13,381	40,421	840	239,078
17,534	3,500	16,051	1,256	146,307	9,255	21,525	301	216,423
11,443	0	16,282	1,695	119,080	12,608	33,657	1,645	207,504
13,748	1,265	5,436	1,973	131,528	2,962	32,921	1,171	202,354
20,457	0	4,616	1,304	87,509	4,913	68,163	669	202,077
1,972	530	2,878	0	192,001	1,549	2,444	350	201,770
8,522	0	6,613	840	161,915	521	17,395	175	197,229
6,894	0	6,140	5,104	141,742	7,046	23,838	636	191,499
8,797	127	7,711	91	128,638	6,568	31,980	509	186,179
6,570	0	9,015	0	151,431	1,529	10,147	0	179,542
11,240	7,473	1,664	150	139,758	1,442	9,576	0	171,303
11,802	819	5,265	1,175	96,853	16,100	27,886	586	165,373
5,091	0	2,948	238	145,377	3,809	7,436	0	165,373
6,097	125	2,173	3,442	129,096	1,152	10,814	3,240	156,609
4,727	0	5,709	1,786	127,514	706	13,695	150	154,998
57,165	1,412	4,066	1,629	46,865	9,264	19,655	3,211	152,382
43,934	0	1,217	129	83,739	2,721	17,977	1,947	152,179
14,589	1,100	4,718	1,221	54,043	23,395	29,977	1,209	142,338
11,475	631	4,236	1,518	58,402	35,110	17,244	2,194	137,014
7,107	498	483	202	108,433	4,477	4,787	1,632	127,750
1,052	1,379	1,108	182	101,077	8,144	6,933	0	120,191
53,791	0	13,584	625	17,291	7,636	21,423	726	115,882
22,046	175	2,447	875	25,379	4,105	48,051	1,793	115,717
23,234	0	9,204	130	21,815	30,066	25,488	3,653	113,684
5,051	0	24,874	629	67,221	1,235	8,493	0	107,604
2,643	0	3,934	0	77,295	5,732	16,866	15	106,723
12,626	1,228	4,142	121	59,427	1,430	20,180	3,298	102,561
5,150	650	13,200	2,520	50,415	2,553	15,342	3,315	98,932
8,112	2,500	4,562	1,220	42,761	6,937	14,659	6,148	96,429

(continued)

Dollars in thousands

Rank	University	Agency	
		USDA	DOC
35	Vanderbilt	433	0
36	Iowa	9	226
37	Utah	205	221
38	Maryland, College Park	5,644	3,341
39	Indiana	205	0
40	Georgetown	10	167
41	Boston	120	59
42	New York	0	196
43	Baylor College of Medicine	125	0
44	Florida	10,462	1,478
45	Miami	160	939
46	Carnegie Mellon	0	563
47	Virginia	98	1,077
48	Emory	0	0
49	Texas, SW Medical Center Dallas	0	0
50	Georgia Institute of Technology	0	228
51	Princeton	0	1,126
52	Rutgers	6,100	2,555
53	Purdue	10,541	644
54	State University New York, Stony Brook	0	1,187
55	Michigan State	13,421	22
56	Woods Hole Oceanographic	0	1,185
57	California, Irvine	0	227
58	Maryland, Baltimore	44	0
59	Yeshiva, New York	0	0
60	Oregon State	15,692	2,031
61	California, Santa Barbara	275	47
62	North Carolina State, Raleigh	11,586	1,280
63	Texas A&M	12,871	1,612
64	Virginia Polytech Institute and State University	7,405	139
65	City University of New York, Mt. Sinai School of Medicine	0	0
66	Colorado State	8,351	896
67	Louisiana State	5,767	1,320
68	Illinois, Chicago	205	0

Agency								
DOD	ED	DOE	EPA	HHS	NASA	NSF	Other	Total
8,839	460	949	139	77,735	1,519	4,347	0	94,421
3,207	150	816	784	76,789	4,576	6,918	392	93,867
9,368	0	4,939	0	62,963	1,205	14,336	546	93,783
22,432	0	7,581	1,140	7,436	21,876	19,852	3,399	92,701
5,552	122	3,247	40	63,849	1,257	14,689	69	89,030
20,719	0	0	0	50,327	267	1,214	15,765	88,469
6,870	897	2,990	140	62,176	2,048	10,790	0	86,090
2,784	150	3,496	768	69,123	318	8,708	0	85,543
641	985	1,100	73	79,909	1,243	0	0	84,076
9,373	0	2,248	627	41,016	5,669	11,518	1,311	83,702
7,383	0	1,403	256	57,183	3,303	10,076	0	80,703
35,467	0	5,792	792	9,325	3,021	24,100	1,167	80,227
5,725	274	3,093	466	51,666	5,687	9,792	1,433	79,311
771	125	411	0	71,523	23	2,509	401	75,763
60	250	0	0	72,825	1,769	703	0	75,607
44,052	0	2,933	3,614	1,932	7,925	13,767	1,105	75,556
15,266	0	8,366	452	17,313	4,802	24,100	479	71,904
9,477	1,575	4,862	802	24,004	1,267	15,576	5,251	71,469
11,031	0	7,948	294	18,779	2,335	19,070	679	71,321
6,953	0	4,569	7	38,166	2,518	16,413	234	70,047
2,702	1,750	4,088	535	22,614	295	22,886	862	69,175
24,202	0	1,287	259	107	1,528	37,921	635	67,124
6,264	0	4,528	364	40,429	2,826	12,421	20	67,079
816	0	237	295	63,910	0	604	0	65,906
540	0	0	0	63,534	0	618	0	64,692
8,062	0	568	5,041	7,463	4,542	14,847	2,749	60,995
17,067	0	4,410	407	5,396	4,327	26,186	1,622	59,737
11,180	944	2,743	3,479	6,815	1,684	16,346	3,288	59,345
5,544	0	2,659	590	15,027	3,203	13,112	1,111	55,729
7,575	0	22,961	154	2,077	3,584	9,332	1,380	54,607
0	1,028	110	0	52,559	609	97	0	54,403
6,689	0	2,863	758	18,180	2,566	11,068	2,523	53,894
5,518	0	2,422	4,814	23,880	2,355	3,091	2,509	51,676
2,627	1,450	770	230	37,794	378	7,974	0	51,428

(continued)

Dollars in thousands

		Agency	
Rank	University	USDA	DOC
69	Cincinnati	0	0
70	Texas Health Center, San Antonio	0	0
71	New Mexico	36	0
72	Wake Forest	222	0
73	Texas Health Center, Houston	286	0
74	Oregon Health Sciences	0	0
75	Kentucky	6,070	70
76	Thomas Jefferson	0	0
77	Hawaii, Manoa	4,011	0
78	Wayne State	0	39
79	Connecticut	1,896	3,064
80	Medicine and Dentistry, New Jersey	536	0
81	Texas, MD Anderson Cancer	0	0
82	Virginia Commonwealth	205	0
83	Rockefeller	0	0
84	Brown	0	51
85	Iowa State	13,566	1,211
86	Georgia	10,713	696
87	Massachusetts, Amherst	3,147	135
88	Dartmouth College	218	410
89	Kansas	0	0
90	Florida State	0	1,466
91	Tulane	50	4
92	Utah State	5,374	54
93	Massachusetts, Worcester	0	0
94	Texas, Medical Branch Galveston	0	0
95	New Mexico State	3,277	0
96	State University of New York, Buffalo	350	0
97	Vermont	4,388	0
98	Arizona State, Main	478	25
99	Tufts	231	0
100	Missouri, Columbia	9,729	0
	Total	**$271,442**	**$62,504**

Agency								
DOD	ED	DOE	EPA	HHS	NASA	NSF	Other	Total
2,745	151	508	3,976	39,406	1,103	3,297	0	51,186
341	0	0	0	49,049	424	533	0	50,347
18,061	0	737	220	21,909	3,082	5,603	384	50,032
49	0	0	107	47,914	80	1,113	0	49,485
120	0	0	550	46,882	352	135	0	48,325
0	0	4,893	120	42,476	250	351	0	48,090
699	307	5,209	159	26,872	233	7,757	609	47,985
238	373	120	110	46,626	0	376	0	47,843
6,238	0	256	0	15,614	6,458	14,035	1,097	47,709
1,484	481	716	278	40,575	426	3,238	0	47,237
2,525	0	815	0	31,901	180	6,109	424	46,914
40	150	0	559	43,018	562	777	425	46,067
50	0	0	0	45,238	0	169	0	45,457
596	1,812	235	101	40,646	80	1,260	40	44,975
465	0	1,029	0	39,904	40	1,264	0	42,702
8,637	0	2,441	0	16,777	1,815	12,157	187	42,065
1,473	0	6,258	2,274	6,638	1,018	6,286	3,112	41,836
1,149	400	3,243	1,288	13,263	67	6,176	4,239	41,234
13,124	0	1,483	651	5,573	2,381	14,281	341	41,116
2,123	252	658	130	31,772	1,140	3,981	0	40,684
1,097	1,477	384	428	28,125	459	6,493	314	38,777
1,457	0	6,422	54	4,395	1,709	20,102	2,025	37,630
655	0	12,520	267	22,740	251	953	0	37,440
21,563	121	158	492	2,976	3,128	2,723	449	37,038
807	0	0	0	34,515	371	851	0	36,544
1,495	0	465	115	33,709	190	371	0	36,345
4,188	0	4,084	375	1,303	19,692	2,127	634	35,680
1,865	0	35	0	24,119	677	4,195	3,002	34,243
699	700	534	0	24,323	44	3,153	49	33,890
9,086	0	1,383	2,681	6,734	2,876	9,649	0	32,912
1,435	0	995	357	27,738	119	2,020	0	32,895
1,092	745	1,186	174	14,247	739	3,516	545	31,973
$1,316,184	**$42,021**	**$475,171**	**$94,862**	**$5,801,260**	**$519,821**	**$1,312,822**	**$117,596**	**$10,013,683**

Source: NSF.

Estimated Federal Funding to Universities for Research and Development, by Department and Agency, Fiscal Year 1995

Dollars in millions

Department/agency	Amount	Percent of total federal funding
Department of Agriculture		
Agriculture Research Service	$29.5	0.2
Animal and Plant Health Inspection Service	1.2	[a]
Cooperative State Research Service	378.2	3.1
Economic Research Service	2.1	[a]
Forest Service	19.5	0.2
Foreign Agriculture Service	0.4	[a]
National Agricultural Statistics Service	0.2	[a]
Rural Business and Cooperative Development Service	1.1	[a]
Total Department of Agriculture	**$432.2**	**3.6**
Department of Commerce		
Economic Development Administration	$0.1	[a]
National Institute of Standards and Technology	15.6	0.1
National Oceanic and Atmospheric Administration	78.9	0.7
Total Department of Commerce	**$94.6**	**0.8**
Department of Defense		
Army	$237.6	2.0
Navy	459.1	3.8
Air Force	226.9	1.9
Advanced Research Projects Agency	298.8	2.5
Ballistic Missile Defense Organization	59.4	0.5
Defense Information Systems Agency	1.0	[a]
Defense Logistics Agency	6.5	[a]
Defense Mapping Agency	1.0	[a]
Defense Nuclear Agency	1.3	[a]
Washington Headquarters Services	385.1	3.2
Total Department of Defense	**$1,676.7**	**13.9**
Total Department of Education	**$112.4**	**0.9**
Total Department of Energy	**$617.4**	**5.1**
Department of Health and Human Services		
Administration on Aging	$4.1	[a]
Administration for Children and Families	10.3	[a]
Agency or Health Care Policy and Research	59.3	0.5

(continued)

Dollars in millions

Department/agency	Amount	Percent of total federal funding
Centers for Disease Control and Prevention	31.4	0.3
Food and Drug Administration	12.0	[a]
Health Care Financing Administration	10.3	[a]
Health Resources and Services Administration	12.1	[a]
National Institutes of Health	6,342.3	52.4
Office of the Assistant Secretary for Health	0.3	[a]
Office of the Secretary	3.2	[a]
Social Security Administration	.7	[a]
Total Department of Health and Human Services	**$6,486.0**	**53.6**
Total Department of Housing and Urban Development	**$0.9**	[a]
Department of the Interior		
Bureau of Mines	$6.7	[a]
Bureau of Reclamation	0.1	[a]
Geological Survey	17.3	0.1
Minerals Management Service	8.7	[a]
National Biological Survey	13.9	0.1
National Park Service	10.5	[a]
Total Department of the Interior	**$57.2**	**0.5**
Total Department of Justice, Office of Justice Programs	**$5.1**	[a]
Department of Labor		
Bureau of Labor Statistics	$9.3	[a]
Employment and Training Administration	0.7	[a]
Office of the Secretary	0.1	[a]
Total Department of Labor	**$10.1**	[a]
Department of Transportation		
Coast Guard	$0.5	[a]
Federal Aviation Administration	20.4	0.2
Federal Highway Administration	36.8	0.3
Federal Railroad Administration	0.2	[a]
Federal Transit Administration	3.4	[a]
Maritime Administration	0.2	[a]
National Highway Traffic Safety Administration	6.0	[a]

(continued)

Dollars in millions

Department/agency	Amount	Percent of total federal funding
Total Department of Transportation	**$67.5**	**0.6**
Total Department of the Treasury, Bureau of Engraving and Printing	**$1.7**	[a]
Total Department of Veterans Affairs	**$2.8**	[a]
Other agencies		
Agency for International Development	$20.8	0.2
Appalachian Regional Commission	0.5	[a]
Environmental Protection Agency	97.4	0.8
National Aeronautics and Space Administration	652.0	5.4
National Science Foundation	1,762.7	14.6
Nuclear Regulatory Commission	4.7	[a]
Total other agencies	**$2,538.1**	**21.0**
Total all departments and agencies	**$12,102.7**	**100.0**

[a]Less than 0.1 percent

Source: NSF.

Federal Funding to FFRDCs Administered by Universities for Science and Engineering Research and Development in Fiscal Year 1995

FFRDC	Administering university	Award amounts (dollars in thousands)
National Optical Astronomy Observations	Association of Universities for Research in Astronomy, Inc.	$29,099
Lawrence Berkeley National Laboratory	University of California	174,707
Jet Propulsion Laboratory	California Institute of Technology	1,031,706
Lawrence Livermore National Laboratory	University of California	482,027
Stanford Linear Accelerator Center	Stanford University	117,713
National Center for Atmospheric Research	University Corporation for Atmospheric Research	65,689
Argonne National Laboratory	University of Chicago	252,074
Fermi National Accelerator Laboratory	Universities Research Association, Inc.	170,917
Ames Laboratory	Iowa State University	21,845
Lincoln Laboratory	Massachusetts Institute of Technology	314,239
Princeton Plasma Physics Laboratory	Princeton University	115,284
Los Alamos National Laboratory	University of California	523,196
Brookhaven National Laboratory	Associated Universities, Inc.	203,535
Software Engineering Institute	Carnegie Mellon University	31,582
Oak Ridge Institute for Science and Education	Oak Ridge Associated Universities, Inc.	17,176
Thomas Jefferson National Accelerator Facility	Southeastern Universities Research Association, Inc.	59,031
National Radio Astronomy Observatory	Associated Universities, Inc.	29,597
National Astronomy and Ionosphere Center	Cornell University	7,669
Total		**$3,647,086**

Source: NSF.

Federal Agencies' Programs for Administering Bayh-Dole Funding

Department of Health and Human Services

Within HHS, we reviewed only the extramural inventions programs of NIH. NIH is the largest federal provider of direct funding for research and development, accounting for 97.8 percent of HHS' estimated obligations for research and development for fiscal year 1995.

The Division of Extramural Invention Reports within NIH is responsible for overseeing the federal regulations promulgated by the Department of Commerce concerning Bayh-Dole reporting for extramural programs. In order to carry out its oversight responsibilities, NIH has required that grantees and contractors submit various documentation, including copies of the invention disclosure and election of title. NIH has also required grantees and contractors to submit copies of the patent application, issued patent, and nonexclusive government license, although these documents are not specifically required by the regulations. As of October 23, 1992, NIH also began requesting that grantees and contractors submit annual utilization reports.

According to an NIH official, NIH deployed Edison, an on-line system for invention reporting, in October 1995. While some of the information that NIH receives from grantees and contractors can now be transmitted electronically, NIH still requires three pieces of documentation in hard-copy form. These include the invention disclosure form, the confirmatory license, and the portion of the patent application containing the government support clause.

NIH does not require that grantees and contractors certify that they have complied with royalty distribution requirements or made efforts to give licensing preference to U.S. industry and small businesses. The regulations do not specify how these royalty distributions should be documented. However, NIH officials said they had not received any serious complaints about royalty payments. NIH has also not received any complaints that small businesses were not being given preference in manufacturing inventions resulting from federally funded research or that such inventions were not being manufactured substantially within the United States.

NIH has received one request that it invoke the march-in procedures under the Bayh-Dole Act. In March 1996, a company called Cellpro, Inc., asserted that march-in was necessary to alleviate health needs. A Federal District Court found that the stem cell separation device developed by Cellpro infringed on patents owned by Johns Hopkins University and licensed to another company. The court had issued an order in the case allowing Cellpro to keep its product on the market until an alternative was

approved by the Food and Drug Administration and made available for sale. The case currently is under appeal. In August 1997, NIH concluded that the initiation of march-in procedures was not warranted but that it would continue to monitor the situation until a comparable alternative product became available for sale in the United States. NIH has declared exceptional circumstances and retained the rights to a patent in about six or fewer cases.

Department of Defense

DOD does not have a centralized office monitoring Bayh-Dole. Rather, each of the military services, as well as some of the other defense agencies, has separate offices, and even these may be decentralized. We identified at least seven DOD organizations that are responsible for implementing the act. While the Navy has at least two organizations that are responsible for Bayh-Dole, the bulk of Navy research funding subject to Bayh-Dole is from the Office of Naval Research (ONR). The Army has at least three organizations that are responsible for inventions resulting from Bayh-Dole R&D, and the Air Force has at least two.

ONR is taking steps to participate in Edison, working on the software programming necessary to interface with Edison's Internet web site. NIH is developing a screen format to display DOD-specific data. Once ONR is on Edison, the Army and Air Force can easily join Edison. Participation in Edison would give DOD a central Bayh-Dole monitoring and reporting capability.

National Science Foundation

Bayh-Dole is administered within NSF by the Office of General Counsel. NSF officials said that Bayh-Dole is self-regulating in that it is left to the universities to determine whether they wish to retain title to and commercialize their federally funded inventions.

NSF does very little monitoring of Bayh-Dole, recording information received from the universities on a computerized spreadsheet. NSF is in the process of developing a new grants-tracking system called FastLane. One component of this system is the Project Reporting System, which would allow—among other things—universities to provide information on activities involving inventions on-line via the Internet.

Department of Energy

DOE field offices located in Chicago, Illinois, and Oakland, California, administer research contracts and grants with universities and thus handle

all Bayh-Dole reporting. Of these two offices, Chicago handles the vast majority—about 90 percent—of the activity.

DOE's computer system tracks activities involving inventions and ensures that the universities are exercising their right to elect title to inventions. In this connection, the computer will generate a letter that goes out 60 days prior to the end of the 2-year election period to ensure that DOE is preserving its own rights in case the university does not elect to retain title. DOE also verifies that the universities issue the confirmatory licenses and files them with the Patent and Trademark Office (PTO), although DOE officials said they may be as far as 2 years behind in filing licenses.

DOE does not use NIH's Edison system, viewing it as not very comprehensive and lacking in security because it uses the Internet. DOE uses its own computer system to track a broad array of data on its 7,000 to 8,000 contractors, only a portion of which are subject to the provisions of the Bayh-Dole Act.

National Aeronautics and Space Administration

NASA has 10 field centers that manage contracts and grants. Each center has a patent attorney assigned to it as well as a commercialization office that can become involved in the Bayh-Dole reporting process. Universities report their inventions to the appropriate centers, which then handle all subsequent contacts with the universities.

NASA has a computer system to track activities involving inventions because the agency generates inventions not only through universities but also through contractors, grants with other nonprofit research institutions, and in its own facilities. This system, known as TechTracS, automatically generates letters to grantees and contractors setting out requirements for Bayh-Dole reporting. In addition, the system provides sample format letters for use in the reporting process and will notify the universities when the 2-year reporting date is nearing.

According to NASA officials, the universities send the confirmatory licenses to the NASA centers, which then send them to NASA headquarters. Subsequently, NASA files the confirmatory licenses with the PTO within several months of receipt.

Department of Agriculture

The Cooperative State Research, Education and Extension Service (CSREES) has the responsibility for administering the Bayh-Dole Act within

USDA. CSREES does no monitoring and, until recently, has had no computerized database following Bayh-Dole activities. Thus, while CSREES keeps records of the information the universities submit, USDA officials said they have little idea of the level of activity or whether the universities are complying with the act's requirements, such as making disclosures, electing title, or submitting confirmatory licenses. USDA officials believe that the number of federally funded inventions created by universities receiving USDA research funds is small, probably no more than 100 a year.

USDA will begin using NIH's Edison system in mid-1998, and USDA officials believe this action will allow them to improve their tracking capabilities in the future.

Environmental Protection Agency

According to officials from EPA, few inventions—probably no more that 10 or so a year—are coming out of universities and thus subject to the Bayh-Dole Act. For this reason, no separate office or unit monitors the agency's R&D activities among universities; rather, any Bayh-Dole reporting is handled by Patent Counsel in EPA's Office of General Counsel. EPA does no monitoring of universities' Bayh-Dole activities and maintains no special inventions database. EPA is considering using NIH's Edison system.

Department of Commerce

The Department of Commerce is involved in Bayh-Dole on two levels. The agency is responsible for overall coordination of certain activities governmentwide and is also the eighth largest agency in providing federal funding for science and engineering research and development. According to Commerce officials, Commerce largely limits its coordination role to one of encouragement and providing assistance if requested. It does not maintain an overall database nor does it monitor the activities of the funding agencies. Commerce carries out its coordination role through the Office of Technology Policy.

According to Commerce officials, Commerce does not have a centralized office for monitoring Bayh-Dole activities for the research programs it sponsors, except that most inventions are reported to and docketed by Patent Counsel for the Department of Commerce. Rather, such monitoring is carried out by the organization actually receiving the research funds. In this connection, organizations such as the National Oceanic and Atmospheric Administration and the National Institute of Standards and Technology monitor their own funds. We did not review the activities of any of these organizations.

Implementing Bayh-Dole at Johns Hopkins University

Federal Research

According to NSF, Johns Hopkins University (JHU) received $569.3 million in federal funds for science and engineering research in fiscal year 1995, ranking it first nationwide. The bulk of this funding came from DOD, with $288.9 million in awards, and HHS, with $241.7 million. According to information provided by JHU, federal funding accounted for 86.5 percent of the university's overall research budget for its fiscal year 1996, which ended June 30, 1996.

The Applied Physics Laboratory (APL) is a division of JHU and, in the university's fiscal year 1996, received about 50 percent of JHU's federal research funds and about 45 percent of all JHU research funds. About 99 percent of APL's research funding is from the federal government.

Technology Transfer Unit

JHU has a decentralized technology transfer program with three units responsible for Bayh-Dole implementation. The JHU School of Medicine's Office of Technology Licensing (OTL) is responsible for inventions from the School of Medicine. APL's Office of Patent Counsel handles the disclosure and marketing of inventions arising from APL's research. The Homewood Campus Office of Technology Transfer (OTT) is responsible for inventions from the remainder of JHU. Each office has its own staff, policies, procedures, and forms.

Reporting Inventions

Each of the three JHU technology transfer offices publishes its own intellectual property policy, and these policies include a requirement for researchers to report inventions to JHU. Technology transfer personnel are aware of Bayh-Dole requirements; however, the technology transfer offices have no written internal procedures to accomplish Bayh-Dole reporting and other requirements.

All three of JHU's technology transfer offices have separate, automated intellectual property databases. APL has customized software to track patent and licensing activities and is on a local area network connecting the Office of Patent Counsel staff. OTL's automated database contains basic information on the invention to include licensing income and expenses. OTT's automated database tracks disclosure and patent activity. OTT is working to include modules for tracking financial, licensing, and marketing activity.

Licensing Inventions

All of JHU's technology transfer offices consider inventors to be the best resources for identifying potential licensees. Researchers have industry contacts developed from working with industry on research and from raising research grant funds. In some cases, the disclosure forms require the inventor to provide the names of companies that may be interested in the technology. At APL, the inventor is included in a committee that provides licensing negotiations oversight.

JHU has no formal mechanism for ensuring that small businesses receive priority in licensing. However, JHU personnel were aware of the Bayh-Dole requirement to give priority to small businesses. JHU personnel stated that there is little competition for most inventions and that most licenses go to small businesses. In the university's fiscal year 1996, 73.9 percent of JHU licenses or license options were issued to small businesses.

Each of JHU's technology transfer offices has its own distribution formula for royalty income. As seen in table VI.1, OTT and OTL use a sliding scale to distribute the income.

Table VI.1: Royalty Distribution Formula for OTL and OTT

	Percent royalty distribution									
	Inventors		Inventors' laboratory		Inventors' department		School		University	
Annual net income	OTL	OTT	OTL	OTT	OTL	OTT	OTL	OTT	OTL	OTT
First $100 thousand	35	35	30	30	10	10	23	23	2	2
To $300 thousand	30	30	30	30	10	10	25	25	5	5
To $1 million	20	30	15	25	10	10	45	25	10	10
Over $1 million		15		25		10		40		10
$1 million to $3 million	15		10		15		50		10	
Over $3 million	5		5		5		75		10	

Source: JHU.

For APL, a sole inventor receives one-third of the net income up to $20,000. After the $20,000 level is reached, the inventor receives 10 percent of the net income. If there are co-inventors, they share equally one-third of the net income up to $20,000. After this point, the inventors share equally 10 percent of the net income. The JHU President's Discretion Fund receives

10 percent of the net income, and the APL Development Fund receives the remainder of net income after the other distributions.

Bayh-Dole's Impact

According to data provided to AUTM, JHU received 194 invention disclosures, executed 46 new licenses or options, applied for 74 new U.S. patents, and was issued 24 U.S. patents during the university's fiscal year 1996. At the end of fiscal year 1996, JHU had 233 active licensing agreements, 100 (42.9 percent) of which were producing licensing income. Licensing income in the university's fiscal year 1996 totaled $3.1 million. For the university's fiscal years 1995 and 1996, JHU's School of Medicine received 60.9 percent of its royalty revenue from inventions supported by federal research funds. For the period 1991 through 1996, JHU's APL received 25.7 percent of its royalty revenue from inventions supported by federal research funds.

According to JHU personnel, JHU does not have the royalty income comparable to many universities of its size and influence. Most universities get a least three-fourths of their royalty income from one or two inventions, but JHU officials said they have not had a "big hit" yet.

Implementing Bayh-Dole at the University of Washington

Federal Research

The University of Washington (UW) received $299.6 million in federal funds for engineering and science research in fiscal year 1995, according to NSF, ranking it second among universities nationwide. Of this amount, $193.1 million, or about 64 percent, came from HHS. Most of the remainder came from NSF ($35 million), DOD ($32 million), and DOE ($15 million).

UW officials said UW is not responsible for any research activities at affiliate organizations that receive separate funding. UW's Applied Physics Laboratory receives funding from the Navy, but since the laboratory is part of the university, the funds are channeled through the university. Likewise, funding for the two hospitals owned by UW is channeled through the university.

Technology Transfer Unit

Established in 1983, UW's Office of Technology Transfer (OTT) is responsible for administering UW's intellectual property policies and for coordinating technology transfer. Located within UW's Office of Research, OTT is responsible for ensuring that innovations developed at UW achieve their full potential to benefit the public and the academic community. OTT is organized into (1) the Health Science Sector, (2) the Science-Engineering-Arts Technologies Sector, and (3) the Software Sector. The chief functions of OTT are

- protecting inventions and other intellectual property developed by faculty, staff, employees, and students through patents, copyrights, and trademarks;
- assessing the commercial potential of these innovations and licensing suitable technologies to companies that can successfully commercialize them;
- providing a responsive resource to campus inventors; and
- using technology transfer as a means to advance mutually beneficial relationships between UW and private industry.

Reporting Inventions

As a condition of employment, all UW employees agree to assign inventions made in the normal course of their work to the university. Inventors are required to disclose promptly all potential inventions to OTT, which reports all disclosures for federally funded inventions to the respective funding agencies. Researchers complete a disclosure form supplied by OTT describing the innovation and its funding sources.

When OTT receives the disclosure forms, a technology manger reviews them with the researcher to learn the developmental history of the invention, to identify any publications describing the invention, and to clarify the inventive contributions of those involved. OTT may decide to file a patent application, obtain financial support for further development, negotiate licenses, or waive its rights to the invention. If OTT does not elect title to an invention or chooses not to file or to continue a patent application, it promptly offers title or rights back to the sponsoring federal agency. According to the OTT Director, UW will elect to retain title to an invention if it will either be "revenue producing" or "revenue neutral." Generally, OTT files a patent application whenever it believes patent costs can be recovered.

The entire invention reporting process is tracked through both a document system and a custom-designed computer database containing standard letters and forms used in the reporting process. According to UW officials, OTT does not currently use the National Institutes of Health's Edison system because it is not compatible with UW's computer system and does not meet OTT's criteria for replacing the system.

Licensing Inventions

At present, OTT performs all licensing activities for inventions made by UW researchers. Prior to 1995, the Washington Research Foundation (WRF) also negotiated and managed licensing agreements for inventions developed by UW researchers. WRF is a private, nonprofit organization serving research institutions in the state. While WRF continues to manage all of the active license agreements for UW inventions, it does not negotiate any new ones. Instead, its current role is to evaluate whether UW inventions have the potential for forming a start-up company. UW made the decision to stop using WRF to license its inventions because it believed a more comprehensive service approach was needed.

In seeking licensing arrangements, OTT technology managers work with inventors to determine who may be interested in the invention. OTT has no specific procedures for ensuring that small businesses receive preference in the licensing process and does not keep statistics on the number of license agreements with small businesses. According to the Director, there is seldom any competition in the licensing process, and the majority of the licenses are with small businesses. Licensing agreements for inventions that were federally funded contain a clause which specifies that the agreement is subject to all of the requirements contained in the Bayh-Dole Act and implementing regulations.

UW shares royalty income on inventions with the inventors, the schools and departments sponsoring the research, and other research programs. The direct costs of obtaining the patent(s) must be recovered in addition to a 15-percent service fee before the distribution of royalty income begins. The remainder of the income will be distributed as shown in table VII.1.

Table VII.1: Royalty Income Distribution Schedule for the University of Washington

	Percent of distribution share		
Cumulative net income	Inventor	Inventor's department/ college	University research funds
First $10,000	100		
$10,000 - $40,000	50	25	25
Above $40,000	30	20	50

Source: The University of Washington.

Bayh-Dole's Impact

During UW's fiscal year 1996, it received 233 invention disclosures, 97 of which were federally funded. UW elected to retain title to 12 federally funded inventions and signed 44 license agreements during the year. Excluding recovery of legal costs, UW received $784,000 in royalties for federally funded inventions and $1.4 million for other inventions. WRF provided UW with royalty income of $223,000 for federally funded inventions and $3.5 million for other inventions.

Two inventions, known as the Hall technologies, are largely responsible for the amount of royalties received from the commercialization of inventions at UW. One of these technologies was a Hepatitis B vaccine, and the other was a method of using yeast to produce interferon, a cancer treatment drug. According to the OTT Director, these two inventions would have accounted for 80 percent of UW's licensing revenue 3 years ago. This is no longer true because many successful start-up companies have been formed. The Director estimated that 25 to 40 of UW's estimated 200 active license agreements are with start-up companies.

Implementing Bayh-Dole at the Massachusetts Institute of Technology

Federal Research

According to NSF, the Massachusetts Institute of Technology (MIT) ranks third overall in the nation in the receipt of federal science and engineering R&D funding, with $282.1 million in fiscal year 1995. DOD and DOE were the largest contributors of federal research funding, with each providing $68.2 million. HHS was also a significant source of funding, awarding the university $51.5 million. MIT also manages Lincoln Laboratory, an FFRDC, which received a total of $314.2 million in federal research funds from DOD and the Department of the Interior in fiscal year 1995.

Technology Transfer Unit

Established in 1940, the Technology Licensing Office (TLO) is the only office at MIT that reports, patents, and licenses inventions developed by faculty and staff at MIT and Lincoln Laboratory. TLO also conducts licensing activities for inventions arising from work administered by the Whitehead Institute, a biomedical research institute that is affiliated with MIT. TLO does not review Whitehead's invention disclosures or decide whether or not to apply for patents on these inventions.

TLO's goals are to facilitate the transfer to public use and benefit of MIT-developed technology and to provide an additional source of unrestricted income to support research and education at MIT. However, research has priority over technology development, and TLO will work with the MIT developers of technology and industry only if such work does not interfere with the normal flow of technical and academic information through publications, conferences, and consulting.

Reporting Inventions

MIT employees are obligated to disclose to TLO any intellectual property developed or discovered at MIT, which is made under a grant or contract to MIT or which make significant use of MIT's facilities or funds. TLO assigns each invention disclosure a case number and, for inventions that were federally funded, informs the appropriate federal agency that an invention disclosure has been received. If TLO decides to apply for a patent, TLO references the patent application in its electronic database to the case number and informs the appropriate federal agency that it has either filed or will soon file a patent application. When the application is actually filed, TLO provides a copy of the application, together with a confirmatory license, to the appropriate federal agency. If TLO decides not to file a patent application, it informs the appropriate federal agency and the inventor that it has not elected title to the invention. The inventor may then petition the federal agency for a release of patent rights to himself.

TLO has a custom-designed intellectual property database and has elected not to use the Edison system to report inventions to NIH. According to the TLO's Intellectual Property Counsel, Edison is not compatible with TLO's database, does not track the data TLO needs, and does not allow full compliance with federal reporting requirements.

Licensing Inventions

Once a disclosure form is submitted to TLO, the inventor typically meets with the assigned licensing officer as a first step in evaluating the invention. Researchers are often the best source of leads to identify companies interested in the new technology. According to TLO's Director, researchers decide they want to form start-up companies about 10 percent of the time. This decision results in 8 to 10 start-up companies being formed each year. MIT sometimes accepts equity in these companies in lieu of royalty payments. The Director said that TLO licenses inventions to the companies best suited to commercialize them. Most inventions are licensed to small companies because they tend to be more willing to invest in new technology. As of December 1997, 275 of 491 active patent and copyright licenses were with small entities, while the remaining 216 were with large entities. License agreements for inventions that were federally funded are to contain a clause requiring that licensed products leased or sold in the United States be substantially manufactured in the United States.

The royalty income received for a technology license is distributed on an annual basis. Fifteen percent is deducted from gross royalty income to cover the expenses of TLO. Out-of pocket costs, such as patent filing, are then deducted to arrive at adjusted royalty income. Inventors receive one-third of the adjusted royalty income. The difference between 15 percent and the actual pro-rata cost of operating the TLO is deducted or added to the remaining adjusted royalty income. Out-of pocket expenses for unmarketable patents are then deducted to arrive at the net royalty income, which is shared equally by MIT's general fund and the inventor's laboratory or department.

Bayh-Dole's Impact

During MIT's fiscal year 1996, which ended on June 30, 1996, MIT received 323 invention disclosures, of which 166 were for federally funded inventions. MIT elected to retain title to 77 federally funded inventions. MIT signed 68 license and option agreements during fiscal year 1996.[1] According to AUTM, MIT ranked eighth among universities nationwide in

[1]This figure includes inventions made at the Whitehead Institute.

license income received from inventions during fiscal year 1996—a total of $10.1 million. MIT could not determine what percent of this income was derived from federally funded inventions. According to TLO's Director, about 90 percent of the money MIT receives in licensing royalties each year comes from about 10 percent of its licenses. In fiscal year 1996, the commercialization of the public key encryption method, which was developed under grants from the Navy and NSF, resulted in $271,875 in royalties to MIT. MIT received an additional $91,679 in royalties from the commercialization of the arrhythmia prediction diagnostic technology, which was developed with funding from various federal agencies.

Implementing Bayh-Dole at Stanford University

Federal Research

According to NSF, Stanford University received $266.7 million in federal funds for science and engineering research in fiscal year 1995, ranking fourth nationwide. The bulk of this funding came from HHS, with $128.9 million in awards, and NASA, with $56.7 million. According to information provided by Stanford, federal funding accounted for 85.2 percent of the university's overall research budget for its fiscal year 1996, which ended August 31, 1996.

Stanford operates the Stanford Linear Accelerator Center under contract with DOE. This facility investigates the structure of matter at the atomic level with X-rays and at much smaller scale with electron and positron beams.

Technology Transfer Unit

Since 1970, Stanford University's Office of Technology Licensing (OTL) has been the universitywide office designated to promote technology transfer. OTL is responsible for all patenting and licensing activities. OTL's mission is to promote the transfer of technology for public benefit while generating income to support research and education.

Reporting Inventions

Stanford researchers are required to disclose to OTL all inventions made in the course of their university responsibilities or with more than incidental use of the university's resources. OTL personnel are then to review the invention and forward copies of the disclosures to all the relevant federal funding agencies as required. Stanford sends the funding agencies copies of (1) the election letter, (2) the patent application, (3) the confirmatory license, (4) assignments, and (5) the patent when issued.

About 2 years ago, OTL automated its operations using a customized system that contains information on all aspects of technology transfer actions, including licensing and patent activity; data prior to this time are not available in automated form. The current automated system does not provide a suspense function to automatically track Bayh-Dole reporting dates and other deadlines. However, OTL has given its highest priority to efforts to modify the automated system software to provide suspense or tickler capability.

Licensing Inventions

OTL licensing associates are to review each invention disclosure and evaluate the invention for commercial value. As part of this process, the associates discuss the invention and its possible application with the

inventor and obtain an opinion from a patent attorney on the patentability of the invention. Although it is often difficult to predict which inventions will become commercially viable, generally OTL would like to focus on inventions that have a potential of generating at least $100,000 per year in royalty income.

Inventors often are aware of companies that might successfully commercialize their inventions, and the associates are to work closely with the inventors to identify potential licensees. Associates market inventions by (1) sending mailings to selected companies, (2) calling contacts in industry, (3) listing available technologies on the Internet, (4) attending professional meetings, and (5) sending updates of new disclosures to industrial affiliate groups.

OTL has no formal mechanism for ensuring that small businesses get first opportunity at a license. However, OTL personnel were aware of the Bayh-Dole requirement to give priority to small businesses, and OTL expects its licensing associates to know the licensees' small-entity status. Of the 136 licenses for the university's fiscal year 1996, 109, or 80.1 percent, of these were with small entities.

After deductions of 15 percent for OTL's expenses and other direct expenses, royalty income is split evenly between the inventors, the inventor's department, and the inventor's school. The 15 percent deducted from the gross royalty income is used by OTL to pay operating expenses, and any funds remaining go to the OTL Research Incentive Fund, managed by the Dean of Research.

Bayh-Dole's Impact

For calendar years 1991 through 1996, university staff reported 993 inventions to OTL. Federal funds were involved in 518 invention disclosures, or 52.2 percent. In this same period, federal funding was involved in 260, or 56.0 percent, of the 464 patent filings and 113, or 56.2 percent, of the 201 patents issued to Stanford. In Stanford's fiscal year 1996, OTL executed 136 licenses and had a total of 903 active licenses in its portfolio.

According to AUTM, Stanford ranked second among universities nationwide in license income received from inventions in the university's fiscal year 1996—a total of $43.8 million. Of this amount, the inventions subject to Bayh-Dole accounted for at least $40.6 million, or 92.7 percent.

A few successful inventions generate the bulk of Stanford's royalty revenue. In the university's fiscal year 1996, one invention accounted for 72 percent of license royalties. This invention, dating back to the 1970s, was for recombinant DNA, and the research was funded, in part, by NIH and NSF. Another invention developed by Stanford and the University of California with NIH funding is phycobiliproteins, which are used to detect cancerous tumors and for other screening tests. This invention earns about $3 million a year in royalties.

Implementing Bayh-Dole at the University of Michigan

Federal Research

According to NSF, the University of Michigan (UM) ranks fifth overall in the nation and second among public institutions in the receipt of federal science and engineering support. Federal obligations for science and engineering research and development at UM totaled $243.1 million in fiscal year 1995. Of this amount, $156.8 million, or about 64 percent, was provided by HHS. NSF awarded the university $29.6 million, while DOD awarded the University $21.6 million.

According to UM officials, UM is not responsible for any research activities at affiliate organizations that receive separate funding. UM owns a hospital that is staffed by faculty and students from its medical school.

Technology Transfer Unit

Established in 1982, the Technology Management Office (TMO) is the only office at UM that reports, patents, and licenses inventions developed by its faculty and staff. The medical school has its own technology office but does not have the authority to sign license agreements. The medical school works with TMO in commercializing inventions developed at the medical school.

TMO's objectives and intellectual property development activities are to facilitate the efficient transfer of knowledge and technology from the university to the private sector in service of the public interest, to support the discovery of new knowledge and technology and to attract resources for the support of the university's programs, to provide services to the university faculty and staff to facilitate their efforts to carry out the university's mission, and to promote local and national economic development.

Reporting Inventions

UM employees are obligated to disclose to TMO (and to the medical school administration if the inventor is an employee of the medical school) any intellectual property developed or discovered at UM. Invention disclosure forms are available from either the TMO or by downloading from UM's Internet website. Following the invention disclosure, TMO personnel hold a conference with the inventor to discuss the inventor's expectations, the invention's applications, and the types of companies that may be interested in licensing the invention. According to TMO officials, TMO reports inventions that received support from the federal government to the respective funding agency within 60 days. Also, TMO evaluates each invention as quickly as possible for potential patenting and licensing. Assessment criteria include patentability, commercial viability, stage of

development, and market receptivity. If there are assessment questions about commercial attractiveness, the technology may be evaluated by an internal science committee or reviewers external to UM. According to the Business Manager of TMO, the decision whether to elect title to an invention will depend upon the likelihood of obtaining a patent and the commercial viability of the invention. TMO's goal is to commercialize inventions and assist the faculty in achieving the technology transfer goals of the university.

UM has a custom-designed inventions database. While the system is adequate for entering and tracking data, according to TMO officials, it is not capable of analyzing data. For this reason, TMO has hired a consultant to make a major revision of the database. TMO uses the Edison system to report inventions to NIH. Information is transmitted over the Internet because it cannot currently be downloaded directly from TMO's computer system. TMO officials said that the biggest problem with using the Edison system is that the transmission process is very slow and the user is sometimes locked out of the system for large increments of time. However, TMO personnel stated that they would not object to using Edison if it totally replaced the current paper reporting system and all federal agencies used the system.

Licensing Inventions

The Business Manager of TMO stated that licensing specialists contact companies that might be interested in the new technology. New technologies available for licensing are also reported on UM's Internet website. In addition, researchers often produce leads for marketing their own inventions. If the research project had a corporate sponsor, the sponsor usually has the option to license the technology. In cases in which TMO has been unsuccessful in marketing its inventions, it has offered to allow a contractor, Research Corporation Technologies (RCT), to do so. However, RCT has not agreed to market any of these inventions.

According to TMO's Business Manager, UM tries to attract small businesses in its licensing efforts through targeted mailings and phone calls. These efforts are successful because small businesses tend to be more entrepreneurial than large companies and are more interested in marketing new technologies. As of November 1997, 75 of UM's 148 license agreements were with small entities, while the remaining 73 were with large entities. License agreements for inventions that were federally funded contain a clause requiring that the product be substantially manufactured in the United States.

UM may enter into license agreements with business entities in which the inventor holds an ownership interest. The emphasis on structuring license agreements with start-up companies will be on helping the company remain viable. The terms may include royalty payment, equity interest, or a combination thereof. License agreements between UM and an employee or UM and a company in which a UM employee has either a financial or management interest are subject to the state of Michigan's Conflict of Interest Statute. The statute permits such agreements provided that certain disclosure, approval, and reporting requirements are met.

After recovery of UM's out-of-pocket expenses, such as those necessary for patent protection, marketing, and licensing, aggregate revenues resulting from royalties and sale of equity interest will be shared as shown in table X.1.

Table X.1: Royalty Income Distribution Schedule for the University of Michigan

	Percent of distribution share		
Cumulative net income	Inventor	Originating unit(s)	Originating school, college, division or other responsibility center(s)
Up to $200,000	50	25	25
Over $200,000 (and up to $2,000,000)	33-1/3	33-1/3	33-1/3
Over $2,000,000	33-1/3		66-2/3

Source: University of Michigan.

Bayh-Dole's Impact

During UM's fiscal year 1996, it received 122 invention disclosures, of which 46 were federally funded. UM elected to retain title to 20 federally funded inventions and signed 30 license agreements during the fiscal year. UM received $231,000 in royalties for federally funded inventions and $844,000 for other inventions.

According to TMO's Business Manager, UM has not yet had any individual inventions that have resulted in a large amount of royalties. However, he said many inventions are currently on the verge of entering the marketplace and appear to be very promising. One of these is an intranasal influenza vaccine, which was funded jointly by a private sponsor and NIH.

Implementing Bayh-Dole at the University of Wisconsin-Madison

Federal Research

According to NSF, the University of Wisconsin-Madison (UWM) received $207.5 million in federal funds for science and engineering research in fiscal year 1995, ranking it eighth nationwide. The bulk of this funding came from HHS, with $119.1 million in awards, and NSF, with $33.7 million. According to information provided by UWM, federal funding accounted for 56.5 percent of the university's overall research budget for its fiscal year 1996, which ended June 30, 1996.

Technology Transfer Unit

The Graduate School's Office of University-Industry Relation (UIR) has overall responsibility for Bayh-Dole implementation at UWM. However, UWM assigns inventions to the Wisconsin Alumni Research Foundation (WARF), a nonprofit foundation, for invention licensing or commercialization purposes. Since WARF was established in 1925, its primary goals have been providing UWM's scientific discoveries to the public and providing support for the university's research efforts. Through the use of patents and licensing, the foundation (1) generates funds for further research, (2) provides financial benefits to inventors, and (3) controls the use of the university's inventions.

Reporting Inventions

UWM researchers are required to disclose all inventions resulting from federally funded research and development to UIR. UIR personnel then evaluate the disclosure to determine the funding sources behind the invention and forward copies to all of the relevant federal agencies and to WARF, which assumes the responsibility for reporting and transmitting the subsequent documentation to the federal funding agencies. The foundation is to send the funding agencies copies of (1) the election letter, (2) the patent application, (3) the confirmatory license, (4) assignments, (5) notices of foreign filings, and (6) the patent when issued.

UIR uses UWM's extramural support databases and commercially available spreadsheet software to track invention disclosure information, such as the (1) funding agency, (2) funding agency contact, (3) grant number, and (4) date of invention disclosure. This database goes back only to February 1995, when the Dean of the Graduate School delegated the responsibility to process disclosures to UIR. WARF uses a sophisticated, custom-designed database to track and report activities involving inventions.

Licensing Inventions

Licensing efforts begin as soon as WARF decides to retain the invention. In those few instances in which both corporate and federal funding are involved in an invention, the corporate party usually is given first right to negotiate a license. Otherwise, WARF licensing associates start looking for other potential licensees. In some cases, the principal investigator may have some industry sources or contacts. The licensing associates also have their own contacts with companies. Articles on the invention in scientific publications may generate inquiries to WARF from private industry.

WARF negotiates the licensing details, and neither UWM nor the principal investigator is generally involved in these negotiations. WARF prefers license terms that are based on a percentage of the value of net retail sales; however, other royalty arrangements, such as a paid-up license or fixed annual fee, may be considered for selected situations.

UWM and WARF have no formal mechanism for ensuring that small businesses receive first opportunity at a license. However, WARF personnel were aware of the Bayh-Dole requirement to give priority to small businesses, and WARF personnel said that most of their licensing negotiations are with small businesses. At the time of our review, WARF had 215 active licenses; 131, or 60.9 percent, of these were with small entities.

WARF gives the inventor(s) $1,500 up front when a new invention patent application is assigned to the foundation. In addition, WARF distributes royalty income to the inventor(s) and to UWM on the basis of a formula set by the university. In October 1997, UWM revised its royalty-sharing formula. UWM's current formula provides that the first $100,000 in gross income is divided (1) 70 percent to the inventor's laboratory, (2) 20 percent to the inventor(s), and (3) 10 percent to WARF. Gross income greater than $100,000 is divided (1) 65 percent to WARF, (2) 20 percent to the inventor(s), and (3) 15 percent to the inventor's department.

WARF annually distributes a grant to UWM. The disbursement is equal to 85 percent or more of a 5-year average of its net income. Net income includes income from invention royalties, investments, and other sources. WARF has a multimillion-dollar endowment and receives 72 percent of its income from investments. Income from invention royalties accounts for 23 percent of WARF's income, and the remaining 5 percent of income is from gifts, donations, and bequests.

Bayh-Dole's Impact

During the university's fiscal year 1996, UWM applied for 76 patents of which 72, or 94.7 percent, involved federal funds. During this same period, UWM was issued 47 patents of which 36, or 76.6 percent, involved federal funds. As of October 1997, UWM had 215 active licenses involving 291 inventions. Of the 215 licenses, 194, or 90.2 percent, involved inventions developed with federal funding.

According to AUTM, UWM ranked fifth among universities nationwide in license income—a total of $13.1 million—received from inventions during UWM's fiscal year 1996. Of this amount, inventions subject to Bayh-Dole accounted for $12.9 million, or 98.9 percent. In UWM's fiscal year 1996, WARF disbursed $16.4 million to UWM for research-related purposes. As explained above, this disbursement differs from the earnings for Bayh-Dole inventions for UWM's fiscal year 1996.

A few successful inventions generate most of the revenue. The most impressive example is a 1971 vitamin D discovery that has generated about $100 million in revenue. This discovery led to new derivatives of vitamin D used for the treatment or prevention of osteoporosis, renal osteodystrophy, and other calcium-related disorders. More recently, UWM researchers developed a solution that extends the time that organs can be held outside a living body prior to an organ transplant. This 1989 invention has earned about $8 million to $10 million in licensing income.

Implementing Bayh-Dole at Harvard University

Federal Research

According to NSF, Harvard University received $191.5 million in federal funds for science and engineering research and development in fiscal year 1995, ranking it number 13 among all U.S. universities. By far the largest source of funds is HHS, which accounted for 70 percent of all federal funds received in fiscal year 1995. Some Harvard Medical School faculty have dual appointments at five independent hospitals—Brigham and Womens, Massachusetts General, Children's Hospital, Beth Israel-Deaconess, and Dana Farber Cancer Institute. These hospitals receive separate funding from NIH, and each operates its own licensing office.

Technology Transfer Unit

Harvard has a centralized program for monitoring and licensing activities involving inventions. All activities are coordinated through the Office for Technology and Trademark Licensing (OTTL), which is responsible for recordkeeping and Bayh-Dole reporting. The Harvard Medical School has a separate unit that handles licensing activities for medical school inventions, but this unit reports its activities to the OTTL.

The reach of Bayh-Dole is greater at Harvard because of its affiliation with the aforementioned five hospitals. Each of these hospitals ranked among the top 25 recipients of federal funds to other nonprofit research institutions in fiscal year 1995, according to NSF. When Harvard Medical School staff are involved in the creation of an invention at one of these hospitals, the two organizations coordinate their activities for such factors as who reports to the federal agencies, who actually owns the invention, how royalties will be distributed, and so on.

Harvard has its own computerized database, known as JAKE, for tracking and monitoring inventions. This database tracks patent prosecution and technology information, government compliance, license agreements, company data, contract management, legal expenses, and biomaterial transfers. On a financial level, the database assists in analyzing, paying, and invoicing legal expenses; recording and distributing income; and producing various reports. Harvard provides the information needed by NIH for Edison but has not adopted Edison as its own inventions database. OTTL officials said they need the additional data their own system provides and do not want to run two parallel systems. Thus, they are taking a wait-and-see approach to Edison.

Reporting Inventions

According to university officials, Harvard researchers must sign a participation agreement that controls the reporting and licensing of

inventions created while working at Harvard. Periodically, the case managers contact the university's various departments and deans to ensure that everyone is familiar with the process. Forms are available in every department for reporting inventions to the university. Harvard encourages inventions, with an objective of bringing new products and processes into public use as rapidly as possible while protecting academic freedoms and generating a return to the university, the inventors, and their departments.

Generally, OTTL finds out about an invention when it is contacted by the inventor. If the inventor has not already done so, OTTL helps him or her complete an invention disclosure form. An OTTL patent coordinator researches the invention to determine whether federal funds were involved and thus whether Bayh-Dole applies. Bayh-Dole is considered to apply if any federal funds at all were used in developing the invention. After the patent coordinator has established that a federally funded invention appears to exist and has all the relevant information, OTTL is to report the invention to the appropriate federal agencies.

Once the disclosure of the invention is made, Harvard determines whether it will retain title. Harvard's philosophy essentially is to retain title on everything. However, Harvard officials said they usually will not pursue a patent unless the university believes it can make money on the invention. Similarly, if Harvard obtains a patent and believes it cannot make money from the invention, Harvard may well abandon the patent rather than pay one or more of the maintenance fees assessed by PTO.

Licensing Inventions

In deciding whether to elect title, Harvard must determine whether there is a market for the invention. If the invention was created under industry-sponsored research, the sponsor is given an option to license. Otherwise, the case manager looks for a licensee that can pay an appropriate royalty and will pursue the development of the invention. If there are two or more candidates—not a typical situation according to university officials—Harvard will focus more on which one has the ability to bring the product to market. Most Harvard licensees are small businesses; however, Harvard has no formal mechanism for ensuring that small businesses get first opportunity at a license. OTTL puts the requirement for substantial domestic manufacture in its licensing agreements.

Harvard may work with inventors to begin start-up companies by helping them raise the necessary capital. However, this practice is not the first choice for licensing, and Harvard's rules may sometimes work against it. A professor is allowed to work only 1 day a week on outside interests. Also, researchers are subject to a conflict-of-interest policy that would make it difficult for them to work privately on a project that was in direct competition with the work they are involved in at Harvard. The university states its policy on staff and industry research relationships thusly: "Harvard encourages scientifically-productive research collaborations between its scientists and for-profit companies. But the maintenance of academic freedoms—scientific integrity, pursuit of knowledge and the open exchange of information—remain the first priority."

Harvard uses a sliding scale in distributing royalties, shifting a portion of the inventor's share to the inventor's department as royalties increase. The first $50,000 generated by an invention is distributed 35 percent to the inventor, 30 percent to the inventor's department, 20 percent to the inventor's school, and 15 percent to the university. Income greater than $50,000 is distributed 25 percent to the inventor, 40 percent to the inventor's department, 20 percent to the inventor's school, and 15 percent to the university.

Bayh-Dole's Impact

According to data provided to AUTM, Harvard had 112 inventions disclosed by its researchers, executed 57 new licenses or options, applied for 53 new patents, and was issued 28 patents during fiscal year 1996. At the end of fiscal year 1996, Harvard had 306 active licensing agreements, 144 (47.1 percent) of which were producing licensing income. Licensing income in fiscal year 1996 totaled $7.6 million. While Harvard does not separately report income from those inventions subject to Bayh-Dole, it reported that 70 percent of its sponsored research expenditures were derived from federal sources.

Like other institutions, the bulk of Harvard's licensing royalties come from a small number of very successful inventions. In fiscal year 1996, for example, $3.9 million, or 52 percent of all royalties, came from the license for Cardiolite, a heart-imaging contrast agent developed through funding provided by NIH and DOE. Another $1.3 million, or 17 percent, came from the license for Sequenase, which consists of research agents used to determine DNA sequences and which was developed under an NIH grant.

Implementing Bayh-Dole at Columbia University

Federal Research

Columbia University (CU) received $186.2 million in federal funds for engineering and science research in fiscal year 1995, according to NSF, ranking it 14th overall in the nation. The majority of this funding came from HHS, which provided $128.6 million in awards. NSF was also a significant source of funding, providing about $32 million.

Technology Transfer Unit

Technology transfer activities at CU are administered by the Columbia Innovation Enterprise (CIE). Although CIE has a second office located on the Health Science Campus, the Executive Director is the only individual with the authority to sign license agreements for commercializing inventions. CIE's mission is to evaluate, protect, and license CU's intellectual property, increase private-sector funding for research and development, encourage technology transfer, distribute income from those activities among CU entities and faculty, and start up new companies based on CU technology. According to its Finance/Administration Director, CIE also provides some reporting and licensing services for inventions at a nonprofit hospital with which CU staff are affiliated.

Reporting Inventions

As a condition of employment, all CU faculty members and students engaged in federally funded research must sign an agreement to promptly report and assign to CU all inventions and discoveries that may be patentable, as well as the technology associated with them. Faculty and staff send invention report forms to CIE, where they are to be date stamped, checked for signatures and sponsorship, and reviewed for accuracy and completeness. Inventor review meetings are held about 12 times a year and are attended by both CIE staff and outside patent counsel. Inventors are allotted 45-minute time slots to discuss their inventions. The decision on whether to retain title to inventions is typically made immediately following these meetings. According to CIE's Executive Director, CU will generally elect title to an invention if it is "good science," has commercial applications, and makes good business sense. A financial analyst is to send a copy of the invention report and CU's decision whether to elect or waive title to the appropriate funding agency.

The process of reporting inventions is tracked through a custom-designed computer database. Although CIE staff have not used NIH's Edison system to electronically submit reports on inventions to funding agencies, they have used the system to prepare an annual utilization report for NIH. According to the CIE's Finance/Administration Director, a programmer has

been working to correct problems that have been identified in CU's use of Edison.

Licensing Inventions

According to CIE officials, CIE markets new technologies through its Internet website and personal contact with companies that may be interested in particular technologies. Corporate sponsors have the first option on any technologies that arise out of the research they have sponsored. Although CIE has no formal mechanism for ensuring that small businesses receive preference in the licensing process, the majority of its license agreements are with small businesses because they are typically more interested in new technology. As of October 1997, 245 of CU's 463 license agreements were with small entities, while the remaining 218 were with large entities. License agreements for inventions that were federally funded contain the provision that the licensee will comply with all governmental regulations.

After the recovery of the university's expenses, calculated as 20 percent of the gross income, net proceeds from an invention are first distributed among the inventor, the inventor's research activities, and the university. The inventor receives 50 percent of net income up to $100,000 and 25 percent of the excess. The inventor also receives 25 percent of net income to spend on research activities or any other proper and specific purposes of the university designated by the inventor. This income is subject to certain restrictions. The university receives 25 percent of net income up to $100,000 and 33 percent of the excess. After royalties have been allocated among the inventor, the inventor's research activities, and the university, any remaining funds are divided equally between the inventor's department and faculty but are subject to certain restrictions.

Bayh-Dole's Impact

During CU's fiscal year 1996, it received 145 invention reports, of which 62 were federally funded. The university elected to retain title to 55 federally funded inventions. The university signed 62 license agreements during the year. The university received $38.8 million in royalties for federally funded inventions and $1.8 million for other inventions. According to CU's estimates, licensing fees at Columbia represent product sales of approximately $4 billion.

One of CU's highest profile inventions is the co-transformation process, a gene transfer process that can produce a specific protein for commercial production. The process was patented in 1983, has been used by 28

companies to make new pharmaceuticals, and was critical in the development of a blood-clot-dissolving protein. Other such inventions include Xalatan, a new drug for treating glaucoma, and Avonex, a new drug for treating multiple sclerosis. Also, CU joined with a group of electronic manufacturers to pool patents relating to the MPEG2 video compression standard. The MPEG2 Standard is involved in the transmission, broadcast, and reproduction of all digital video signals.

Implementing Bayh-Dole at Michigan State University

Federal Research

Michigan State University (MSU) received about $69.2 million in federal funds for engineering and science research and development in fiscal year 1995, according to NSF, ranking it 55th overall in the nation. The majority of this funding came from NSF, with $22.9 million in awards, and HHS, with $22.6 million. USDA was also a significant source of funding, awarding MSU about $13.4 million. According to a university official, MSU is not responsible for any research activities at affiliate organizations that receive separate funding.

Technology Transfer Unit

Technology transfer activities at MSU are administered by the Office of Intellectual Property (OIP). MSU provides OIP with office space and services, such as phones and facsimile machines, and pays the salary of one professional employee. The Michigan State University Foundation (MSUF) funds the salaries of the OIP Director and other employees with licensing royalty income. MSUF also pays for other expenses, such as office supplies and legal fees. According to the OIP Director, MSUF is a separate, nonprofit organization that was established to manage licensing royalty income from MSU's inventions.

Reporting Inventions

OIP requests that MSU researchers report their inventions as early as possible. As a result, invention disclosure forms may arrive in OIP before the inventions are fully developed. OIP personnel enter the information from these forms into an electronic database, and a licensing associate meets with the inventor to discuss the invention. An inventions review committee then evaluates each invention to determine whether it should be patented. The committee, which meets periodically throughout the year, is comprised of representatives from both MSU and MSUF. During these meetings, committee members are updated on the status of inventions, patent applications, and license agreements. The Director of OIP stated that he and his staff are successful in reporting federally funded inventions to the respective funding agencies within the required 60-day time frame about 95 percent of the time.

According to the OIP Director, OIP purchased the rights to use the Daily Evaluation and Licensing Support database system from the Washington Research Foundation. OIP has chosen not to use NIH's Edison system because it does not see any advantages in doing so. However, the Director stated that he would use Edison if it became a requirement.

Licensing Inventions

MSU previously used a contractor, RCT, to market some of its technologies. While RCT was not MSU's exclusive marketing agent, MSU had signed a contract that specified various terms of its relationship with RCT, such as royalty income distribution. In March 1995, MSU notified RCT that it wanted to terminate the existing contract. RCT and MSU are currently working through the details of this termination (such as how future royalties from existing licenses for MSU inventions will be distributed) in an ongoing arbitration case.

OIP and MSUF currently market all new MSU inventions. According to the OIP Director, these inventions are marketed in various ways, such as at technology transfer conferences, through phone calls to potential licensees, and on the Internet. The OIP Director said that MSU does not have a need to ensure that small businesses are given preference in licensing federally funded inventions because the vast majority of its licensees are small businesses. As of November 1997, 47 of MSU's 55 active license agreements were with small entities, while the remaining 8 were with large entities.

The first $1,000 of royalty income is distributed to the inventor when it is received. No further distributions are made until all patenting and licensing costs are recovered. Distributions are made from the net income remaining, according to the schedule shown in table XIV.1.

Table XIV.1: Royalty Income Distribution Schedule for Michigan State University

	Percent of distribution share		
Net royalty income	Inventor	Academic units	University
First $1,000	100		
Next $100,000	33-1/3	33-1/3	33-1/3
Next $400,000	30	30	40
Next $500,000	20	20	60
All additional net royalties over $1,001,000	15	15	70

Source: Michigan State University.

Impact of Federal Research Funding

During MSU's fiscal year 1996, which ended on June 30, 1996, university staff received 90 invention disclosures. MSU signed 16 license agreements during the year and received about $17.2 million in licensing royalty income. About $16.8 million of this amount was from federally funded inventions.

Two of MSU's most successful inventions provide the vast majority of its royalty income. These inventions involve the use of platinum complexes as anti-tumor agents. The research that led to the inventions was funded by NIH and two companies. According to the OIP Director, these inventions account for approximately 98 percent of MSU's total royalty income.

Implementing Bayh-Dole at the University of California

Federal Research

According to NSF, the University of California (UC) received $1.1 billion in federal funds for science and engineering research and development in fiscal year 1995. The bulk of this funding came from HHS, with $626.4 million in awards, and NSF, with $162.7 million in awards. According to information provided by UC, federal agencies provided 57.2 percent of the direct research funds expended in its fiscal year 1996, which ended June 30, 1996.

UC manages three laboratories for DOE. Since 1988, each of these laboratories has had its own independent technology transfer office. UC reports on activity and financial information for the DOE laboratories separately.

Technology Transfer Unit

UC considers technology transfer an important part of its public service mission. UC states that the major objectives of its patent program are ". . . to promote the progress of science and technology, to assure that inventions are made available to the public, and to provide appropriate royalty revenues to the University and to inventors." UC designated the Office of Technology Transfer (OTT) as the responsible unit for the operation and management of UC's technology transfer program. OTT also manages a small portfolio of DOE laboratory inventions disclosed prior to 1988. In addition, UC manages some more recent DOE inventions having UC co-inventors. UC is implementing a "distributed" or decentralized approach to technology transfer. Since January 1990, UC has created independent technology transfer offices at the Berkeley, Los Angeles, San Diego, and San Francisco campuses.

OTT receives invention disclosures from UC campuses without independent technology transfer offices and manages a large portfolio of older inventions from all nine campuses. For the inventions it manages, OTT carries out reporting, patenting, and licensing activities. In addition, OTT performs certain systemwide functions, such as (1) intellectual property policy guidance, (2) legislative analysis, (3) legal review of all proposed UC license agreements, and (4) coordination of annual reporting.

The four independent campus technology transfer offices receive invention disclosures from their respective campuses. The campus technology transfer offices manage the patenting, marketing, and licensing of most new inventions, while inventions existing at the time the offices were created or that relate to older inventions are managed by OTT. For the

Irvine campus, OTT manages the patenting activities, while the campus is responsible for marketing and licensing selected inventions.

Reporting Inventions

UC's policy requires university employees to promptly disclose inventions resulting from their research activities at UC. OTT has one group that receives and handles disclosures and subsequently reports them to the appropriate federal agencies. Each invention has a reporting requirements check list that is initialed by OTT personnel as the reports are accomplished. OTT sends the funding agencies copies of (1) the election letter, (2) the patent application, (3) the confirmatory license, (4) notices of foreign filings, and (5) the patent when issued.

OTT has developed a customized automated database that provides a calendar function which alerts OTT on reporting dates and provides status reports. This system provides data for inventions case management, reporting data for the federal government, licensing activity, license income, license income disbursement, and post-license diligence monitoring.

Licensing Inventions

OTT assigns inventions to licensing associates who are responsible for commercializing the invention. As part of this process, the licensing associates will

- review the invention for patentability and commercial potential;
- discuss the invention with the inventor to determine if the invention has been reduced to practice and to obtain commercial leads;
- send the invention to a patent attorney for a search of the art;
- make the decision to patent on the basis of patentability, commercial potential, and other factors; and
- review the obligation to sponsors before attempting to market the invention.

If OTT decides to patent, the licensing associate puts together a technical package for the invention. In an effort to find a licensee, the associate will put the invention on OTT's Internet web site, develop a list of companies that may be interested, and mail technical packages to and call potential licensees.

OTT has no formal mechanism for ensuring that small businesses get first opportunity at a license. However, OTT personnel were aware of the

Bayh-Dole requirement to give priority to small businesses. For OTT-managed inventions, 164, or 52 percent, of the 315 licenses for utility patents were with small businesses. Nearly all of the 371 licenses for plant patents are with small businesses.

Effective October 1, 1997, UC revised its formula for sharing inventions' royalty income universitywide. The formula provides that the inventor(s) receive 35 percent of the net income. Of the remaining net income, 15 percent goes to research at the inventor's campus or laboratory, and 50 percent is allocated to a general pool at the inventor's campus or laboratory.

Bayh-Dole's Impact

For UC's fiscal years 1992 through 1996, university staff reported 2,795 inventions to all UC technology transfer offices, including OTT. In UC's fiscal year 1996, 661 inventions were reported to UC. UC did not provide a breakout of the inventions involving federal funding universitywide. For OTT alone, in UC's fiscal years 1991 through 1996, university staff reported 2,238 inventions. Federal funds were involved in 1,264, or 56.5 percent, of the total disclosures.

In UC's fiscal years 1991 through 1996, UC applied for 1,662 patents based on inventions disclosed to OTT. Of these applications, 883, or 53.1 percent, involved federal funding. In UC's fiscal year 1996, UC (all campuses) applied for 325 U.S. patents and 150 foreign patents. In UC's fiscal year 1996, 159 U.S. patents and 250 foreign patents were issued to UC (all campuses). At the end of UC's fiscal year 1996, UC had 1,132 U.S. patents and 1,183 foreign patents in its portfolio.

In UC's fiscal year 1996, UC issued 108 license agreements for all campuses, and as of June 30, 1996, UC had a total of 755 active licenses. Of the 686 of these licenses that were in OTT's portfolio, 34.1 percent were from inventions developed with federal research and development funds.

According to AUTM, the UC system ranked first among universities nationwide in license income received from inventions during UC's fiscal year 1996— a total of $63.2 million. From UC's fiscal year 1991 to 1996, license royalty income for OTT-managed inventions only was $261.0 million, and royalty income from government-funded inventions amounted to $135.2 million, or 51.8 percent.

A few successful inventions generated the bulk of the licensing revenue. As of June 30, 1996, UC had 437 inventions that generated income. The top 5 income-earning inventions earned $46.2 million, while the top 25 earned $56.0 million in the university's fiscal year 1996. One percent of the income-generating inventions earned 73 percent of the total income. One example of a success story is an artificial lung surfactant discovered at UC San Francisco in 1980 with the assistance of NIH funding. UC credits this surfactant with saving the lives of 20,000 infants a year while earning $0.7 million in UC's fiscal year 1996. Another example is a nicotine patch developed by UC Los Angeles in 1984 with VA funding. This device assists smokers to stop smoking and in UC's fiscal year 1996, earned $1.6 million.

Inventions Activities Reported by U.S. Universities to AUTM's Fiscal Year 1996 Survey

Table XVI.1: AUTM Survey Responses—All Respondents

	Fiscal year 1996[a]	Fiscal year 1995[b]	Change from 1995 to 1996	Percent change
Research expenditures: industrial sources	$1,530,203,487	$1,362,478,058	$167,725,429	12.31
Research expenditures: federal government sources	$12,317,829,551	$11,380,770,352	$937,059,199	8.23
Total sponsored research expenditures	$18,688,253,796	$17,211,913,185	$1,476,340,611	8.58
Licenses/options executed	2,209	2,142	67	3.13
Gross license income received	$365,218,642	$299,148,128	$66,070,514	22.09
License income paid to other institutions	$28,591,054	$25,621,678	$2,969,376	11.59
Licenses/options yielding license income	4,958	4,272	686	16.06
Legal fees expended	$75,096,654	$60,233,235	$14,863,419	24.68
Legal fees reimbursed	$28,567,190	$25,870,778	$2,696,412	10.42
Invention disclosures received	8,119	7,427	692	9.32
Total U.S. patent applications filed	3,872	5,100	-1,228	-24.08
New U.S. patent applications filed	2,734	2,373	361	15.21
U.S. patents issued	1,776	1,550	226	14.58

[a]A total of 131 universities responded.

[b]A total of 127 universities responded.

Source: AUTM.

Table: XVI.2: AUTM Survey Responses—Recurring Respondents, Fiscal Years 1991 Through 1996

	Fiscal year 1996[a]	Fiscal year 1995[b]	Change from 1995 to 1996	Percent change
Research expenditures: industrial sources	$1,052,715,974	$913,644,931	139,071,043	15.22
Research expenditures: federal government sources	$9,302,549,690	$8,767,424,553	535,125,137	6.10
Total sponsored research expenditures	$13,534,156,386	$12,650,055,744	884,100,642	6.99
Licenses/options executed	1,632	1,506	126	8.37
Gross license income received	$328,741,253	$272,637,217	56,104,036	20.58
Licenses/options yielding license income	3,887	3,373	514	15.24
Legal fees expended	$58,629,666	$44,233,131	14,396,535	32.55
Legal fees reimbursed	$22,104,222	$18,945,793	3,158,429	16.67
Invention disclosures received	6,101	5,576	525	9.42
Total U.S. patent applications filed	2,799	3,807	-1,008	-26.48
New U.S. patent applications filed	2,013	1,780	233	13.09
U.S. patents issued	1,519	1,351	168	12.44

[a]A total of 73 respondents.

[b]A total of 78 respondents.

Source: AUTM.

Comments From the Department of Commerce

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

THE SECRETARY OF COMMERCE
Washington, D.C. 20230

APR 15 1998

Mr. Victor S. Rezendes
Director, Energy, Resources &
Science Issues
General Accounting Office
Washington, DC 20548

Dear Mr. Rezendes:

Thank you for the opportunity to comment on the draft report entitled Technology Transfer: Administration of the Bayh-Dole Act by Research Universities (GAO/RCED-98-126). We appreciate the effort which your staff put into this review of university-related activities under the Bayh-Dole Act. In the enclosed document, we offer several comments, largely of an editorial nature, concerning the draft text.

Once again, thank you for sharing the draft report with us. Please let me know if we can be of further assistance.

Sincerely,

William M. Daley

Enclosure

"COMMENTS ON GAO DRAFT REPORT (GAO/RCED 98-126)"

See comment 1.

1. Page 1, first paragraph, last line: change "make them more attractive" to "provide more incentive."

2. Page 2, first full paragraph, line 7: The sentence should be revised to read: "According to Commerce officials, no agency has yet taken back the title to any inventions because they were not being commercialized."

3. Page 4, last line, change "make it more attractive" to "provide more incentive."

4. Page 10, second full paragraph, line 1: The sentence should be revised to read: "Commerce officials told us they see their overall role in administering the Bayh-Dole Act as one of facilitating its operation.

The use of the word "cheerleader" is inappropriate. As the report notes, agency operations under the Act are decentralized. However, Commerce does act as a continuing liaison between the agencies, the university community and industry.

5. Page 10, second full paragraph, line 6: change "applied " to "asserted."

6. Page 12, third indented paragraph, second line, add "in the Government Register" after "information."

7. Page 19, second paragraph, change "created" in line 5 to "conceived" and "is somewhat nebulous" in the last line to "may be uncertain." Many university contractors and grantees report their inventions within two months of when they were reported to them without questioning whether, in fact, an invention was made.

Enclosure

See comment 2.

8. Page 23, first full paragraph. We suggest that GAO may wish to reference its earlier reports on Bayh-Dole: 82-32(B-206676), 84-26(B-207939) and especially 87-44(B-207939).

See comment 1.

9. Page 56, second paragraph, add at the end of the first sentence in line 2: "except that most inventions are reported to and docketed by Patent Counsel for the Department of Commerce."

The following are GAO's comments on the Department of Commerce's letter dated April 15, 1998.

GAO's Comments

1. We agreed with the technical clarifications suggested by the Department of Commerce and incorporated them into our report as appropriate.

2. In connection with the Department's suggestion that we cite all previous GAO reports that concerned Bayh-Dole, we did not believe this was necessary because most of these reports were more than 10 years old. We did list our most recent report, which was issued in 1991.

Appendix XVIII

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