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Report to the Chairman, Human Resources and Intergovernmental Relations Subcommittee, Committee on Government Operations, House of Representatives

May 1992

UNIVERSITY RESEARCH

Controlling Inappropriate Access to Federally Funded Research Results

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Resources, Community, and
Economic Development Division

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May 4, 1992

The Honorable Ted Weiss
Chairman, Human Resources and Intergovernmental
Relations Subcommittee
Committee on Government Operations
House of Representatives

Dear Mr. Chairman:

The importance of university research to technological innovation increased dramatically during the 1980s, creating new linkages among the academic community, industry, and the federal government. Universities expanded programs to collaborate with businesses and transfer technologies that can benefit the U.S. economy. In fiscal year 1990, businesses spent $1.1 billion, while the federal government spent $9.6 billion, in sponsoring research at universities. However, closer ties between universities and businesses raise concern about possible conflicts of interest or other relationships that might give a business inappropriate access to, and therefore an unfair advantage in commercializing, the results of federally funded research.

You requested that we examine these linkages by surveying the principal universities receiving funding from the National Institutes of Health (NIH) and the National Science Foundation (NSF). Specifically, we obtained information about (1) the extent of licensing activities for technologies developed in whole or in part with NIH or NSF funding; (2) foreign participation in industrial liaison programs that, in return for membership fees, provide companies with access to research programs; and (3) policies and procedures to control potential conflicts of interest by faculty or administrators that could give companies inappropriate access to research results. The information in this report primarily is based on responses of 35 universities to our questionnaire. As agreed with your office, we assessed the overall relationship between universities and businesses without seeking to identify specific instances of inappropriate access.

Background

One of the primary changes strengthening links between universities and businesses was enactment of the Patent and Trademark Amendments of 1980. The act encourages universities, as well as other nonprofit organizations and small businesses, to commercialize inventions they

make in whole or in part with federal funding by allowing them, with few exceptions, to elect to retain title rights to such inventions. Universities then can transfer these rights to businesses by granting exclusive (sole) or nonexclusive (generally available) licenses. In accordance with the act, several federal agencies require funding recipients to periodically report on their commercialization efforts.

Many universities also offer businesses access to research programs through industrial liaison programs. In return for a membership fee, industrial members are given a "window" to the research through seminars, symposia, or other formal meetings; various publications such as research reports, abstracts, and newsletters; and, in some cases, opportunities for advance access to research before the results are publicly released through, for example, interactions or consultations with university faculty.

Appropriate access to federally funded research can include (1) granting an exclusive license to commercialize resulting technology to a business that co-sponsored a research project, (2) granting an exclusive license to a business that did not fund the research but is considered best able to commercialize the technology, or (3) encouraging the scientist who developed a technology to further develop and commercialize it by working with the licensee. In contrast, inappropriate access can occur if a business that has not sponsored a research project obtains inside information about it or gets favored treatment in obtaining license rights to the resulting technology. Such inappropriate access could result from a financial or personal relationship between the business and a member of the university or a financial relationship between the business and the university itself—such as through an industrial liaison program.

Results in Brief

During fiscal years 1989 and 1990, the 35 universities we surveyed granted 536 licenses and received $82 million in income for technologies developed in whole or in part with NIH or NSF funding. Typical licensees given exclusive rights to commercialize the results of NIH- or NSF-funded research were small U.S. businesses; most exclusive licensees were pharmaceutical, biotechnology, or other medical companies.

Twenty-four universities had industrial liaison programs with at least one foreign company member. Fourteen of these universities reported that industrial liaison program members can get advance access to the results of federally funded research before the results are made generally

available. NIH and NSF guidelines do not address the extent to which program members can be given such advance access.

NIH and NSF, which spent $5.8 billion for university research in fiscal year 1990, have general guidelines that rely on funding recipients to establish policies and procedures to manage any potential conflicts of interest. Despite growing interactions with businesses, however, many universities we surveyed continue to require only voluntary disclosures by faculty and administrators. NIH and NSF are considering alternatives to strengthen funding recipients' controls to better ensure that potential conflicts of interest are disclosed and appropriately resolved.

Universities License a Substantial Amount of Federally Funded Technology

Technologies developed in whole or in part with NIH or NSF funding accounted for about 35 percent of all licenses granted and 70 percent of all license income received by the 35 universities during fiscal years 1989 and 1990. For NIH- or NSF-funded technologies, the universities (1) granted 197 exclusive licenses and 339 nonexclusive licenses and (2) earned $29.3 million from exclusive licenses and $52.7 million from nonexclusive licenses.

Most of the surveyed universities substantially expanded their programs to transfer technology to businesses during the 1980s. Twelve universities formed an office to license technology, while many others expanded and/or reorganized their technology licensing activities. For example, Harvard University, which granted its first license in December 1980, granted 39 licenses in fiscal year 1990.

Relationships between licensees and universities are becoming increasingly complex. The 35 universities reported that (1) scientists who developed the technologies for 61 exclusive licenses consulted for, owned a substantial amount of stock in, or had other relationships with the licensees and (2) members of industrial liaison programs were granted exclusive licenses in four cases. In 12 additional cases, companies that had long-term agreements with universities to fund general research received exclusive licenses for technology they did not directly co-sponsor. None of these relationships are necessarily inappropriate and, in fact, in many cases, they are necessary for commercializing the technology. However, the potential exists that exclusive rights to federally funded technology could be inappropriately granted because of undisclosed conflicts of interest or other relationships. (See app. I.)

Foreign Participation in Industrial Liaison Programs

Twenty-four of the 30 universities with industrial liaison programs reported that they had at least 1 foreign company member. Three universities—the Massachusetts Institute of Technology, Stanford University, and the University of California at Berkeley—accounted for 290, or 58 percent, of a total of 499 foreign members reported. While these universities provide industrial liaison program members general access to research programs, they reported that they do not give advance access to federally funded research results. In contrast, 18 universities—including 14 universities with foreign members—reported that industrial liaison program members can get advance access to the results of federally funded research before those results are made publicly available to others, including to U.S. companies that are not program members. NIH and NSF guidelines for universities and other funding recipients do not address the extent to which industrial liaison program members can be given advance access to the results of research NIH or NSF has funded. (See app. II.)

NIH and NSF Lack Strong Controls Over Inappropriate Access to Research Results

NIH and NSF rely on funding recipients to establish policies and procedures to resolve and report any potential conflicts of interest or other relationships. Neither agency requires funding recipients to submit their policies and procedures for review to ensure that they adequately address conflict-of-interest issues.

The 35 universities surveyed have established various policies and procedures to prevent inappropriate access to research results by businesses. Fourteen universities generally rely upon faculty and other members of their university community to voluntarily disclose a potential conflict of interest.

In contrast, 21 universities require that faculty and/or technology licensing personnel disclose outside interests or certify whether potential conflicts of interest exist at specified points. In particular, of the 21 universities (1) 16 require faculty who are principal investigators to certify in writing whether any potential conflicts of interest exist as part of the approval process for sponsored research projects, (2) 9 require that some or all of their faculty annually disclose outside interests, and (3) 14 require that technology licensing office personnel annually disclose outside interests or certify whether a potential conflict of interest exists. These procedures increase the likelihood that potential conflicts of interest will be disclosed, allowing the universities then to decide how best to resolve and/or monitor any such relationships.

In response to the growing involvement of businesses in university research, both NIH and NSF are considering alternatives to strengthen their guidelines for universities and other funding recipients to better, and more uniformly, control potential conflicts of interest in the conduct of research. In December 1989 NIH withdrew proposed guidelines that would have restricted interactions between grant investigators and businesses in response to many commenters' strong concerns about their effect on university-industry relationships. NIH currently plans to promulgate a regulation by publishing a Notice of Proposed Rulemaking in the Federal Register for public comment. NIH's Associate Director for Extramural Affairs indicated that the proposed rule is likely to retain the requirement that all investigators and other key personnel involved in NIH-funded research disclose certain types of outside interests before an award is made and annually thereafter. In addition, NIH is considering whether to prohibit investigators and other key personnel for clinical drug trials from having any financial relationship with a business whose product is being tested.

NSF is considering ways to strengthen its current guidelines, primarily by requiring that investigators involved in NSF-funded research disclose certain types of outside interests before an award is made. (See app. III.)

Conclusions

Growing interactions between universities and businesses increase the potential for conflicts of interest or other relationships that might give a business inappropriate access to, and therefore an unfair advantage in commercializing, the results of federally funded research. Requiring that investigators and other key personnel disclose certain types of outside interests as part of the grant award process, which both NIH and NSF are considering, is an essential first step for improving university management controls over potential conflicts of interest. However, we believe additional steps are warranted to strengthen these controls and to address the ability of industrial liaison program members to get advance access to the results of federally funded research.

Recommendations

We recommend that the Secretary of Health and Human Services and the Director of NSF require that their grantees have procedures in place to effectively manage potential conflicts of interest. Such procedures should, at a minimum, require disclosure of specified types of outside interests to appropriate university representatives by (1) investigators and other key personnel as part of the grant award process and annually thereafter for

This report was prepared under the direction of Victor S. Rezendes, Director, Energy Issues, who may be contacted at (202) 275-1441. Major contributors to this report are listed in appendix VI.

Sincerely yours,

J. Dexter Peach
Assistant Comptroller General

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Abbreviations

GAO	General Accounting Office
MIT	Massachusetts Institute of Technology
NIH	National Institutes of Health
NSF	National Science Foundation
R&D	research and development

exclusive or nonexclusive license, a university usually considers such factors as the potential size of the market, the number of companies interested in obtaining a license, and the resources the companies will invest to develop a commercial product. For industrial-sponsored research projects, universities typically retain intellectual property rights to any resulting technology, while offering the sponsor either an exclusive license or the right of first refusal to negotiate an exclusive license to the technology, provided that the sponsor has an acceptable plan for commercialization.

Many Universities Have Expanded Their Technology Licensing Activities

Most of the 35 surveyed universities have substantially expanded their patent and licensing programs since 1980. For example, while 22 of the 35 universities had an internal office or an associated foundation to license technologies before 1980, 34 universities now have a technology licensing office. Only five universities—Illinois, Colorado, Indiana, Rochester, and the University of Washington—used external organizations to manage the licensing of more than 10 percent of their inventions.

In addition, many universities expanded and/or reorganized their technology licensing activities during the 1980s. Harvard, which granted its first license in December 1980, granted 39 licenses in fiscal year 1990. The Massachusetts Institute of Technology (MIT) reorganized its office in the mid-1980s by shifting responsibility from its patent counsel to technology licensing specialists who have specific subject-matter expertise from working in industry. The University of California supplemented its central licensing office by establishing licensing offices on its Berkeley and Los Angeles campuses.

Table I.1 shows that during fiscal years 1989 and 1990, the 35 surveyed universities granted 1,510 licenses for patents, computer software, and such tangible research properties as cell lines. (See table IV.1 in app. IV for patenting and licensing data for each university.) Of the 1,510 licenses, 483 were exclusive, with each university granting at least 1 exclusive license, while 1,027 were nonexclusive. According to technology licensing officials at the four universities we visited, many universities license a relatively high percentage of their patent portfolio because they typically seek to identify a licensee before filing a patent application. A company that either licenses or takes an option to license the patent often will pay associated expenses and fees for patenting the invention.

Of the 197 exclusive licenses granted in fiscal years 1989 and 1990, 175 were for technologies developed with NIH funding, 19 were for technologies developed with NSF funding, and 3 were developed with both NIH and NSF funding.

Table I.2: Patenting and Licensing of Technology Resulting From NIH- or NSF-Funded Research (Fiscal Years 1989 and 1990)

Dollars in millions

Universities	Patent applications filed	Licenses granted: Patents	Licenses granted: Other[a]	License income
All surveyed	690	329	207	$82.0
Top five[a]	274	203	156	67.1

[a]Includes licenses granted for computer software and such tangible research properties as cell lines, unless technology was provided at nominal or no cost.

[b]Top five universities for each specific category.

Income From NIH- and NSF-Funded Technology Is Mainly From Nonexclusive Licenses

As shown in table I.3, exclusive licenses accounted for $29.3 million, or 36 percent, of the income the 35 universities earned during fiscal years 1989 and 1990 for technologies developed in whole or in part with NIH or NSF funding. (See table IV.3 in app. IV for data for each university.) In comparison, exclusive licenses accounted for $24 million, or 77 percent, of the universities' $31 million in income for technologies not developed with either NIH or NSF funding.

Table I.3: Income From Exclusive and Nonexclusive Licenses for NIH- or NSF-Funded Technologies (Fiscal Years 1989 and 1990)

Dollars in millions

Universities	Licenses granted: Exclusive	Licenses granted: Nonexclusive	License income: Exclusive	License income: Nonexclusive
All surveyed	197	339	$29.3	$52.7
Top five[a]	99	263	20.6	50.8

[a]Top five universities for each specific category.

Seven universities received more than $1 million in income from exclusive licenses for technologies developed with NIH or NSF funding during fiscal years 1989 and 1990. In particular, Michigan State University received $11.5 million in royalties in fiscal years 1989 and 1990 for an exclusive license granted in 1976 for a pharmaceutical invention that the Food and Drug Administration subsequently approved as a cancer drug. Although the research was jointly funded by NIH and two companies in the metals industry, Michigan State decided to grant an exclusive license to Bristol

Table I.4: University Scientist's Association With Exclusive Licensee for NIH- or NSF-Funded Technology

Universities	Owner	Significant stockholder[a]	Officer	Consultant	Other[b]	No affiliation	No basis to know[c]
All surveyed	2	21	5	45	6	85	51
Top five[d]	2	7	2	32	4	36	24

Note: In several cases, the university scientist had more than one association with the licensee.

[a]Defined as owning more than 3 percent of the company's stock.

[b]Includes serving on the licensee's scientific advisory board.

[c]A university may not know of an affiliation if the scientist was not involved in the licensing decision process.

[d]Those universities that granted the most exclusive licenses for technology developed in whole or in part with NIH or NSF funding.

University respondents generally appeared to be aware of a business relationship between the principal investigator and exclusive licensee. Only Colorado, Cornell, Northwestern, North Carolina, and Wisconsin reported no basis to know about such a relationship for all of the 25 exclusive licenses they granted. MIT reported that a relationship existed between its scientist and the licensee for 9 of 23 exclusive licenses. According to MIT technology licensing officials, the scientist who develops the technology often is involved in selecting the licensee because (1) a continuing relationship between the scientist and the licensee increases the probability for commercializing the technology and (2) venture capitalists and the faculty scientist in some cases are interested in creating a startup company based around the technology. Because startup companies typically lack capital, many offer stock in lieu of royalty payments. To avoid potential conflicts of interest, MIT's policy is that a licensee cannot sponsor research related to the licensed technology if either the scientist or MIT owns equity in the company.

Stanford, which has granted few licenses to startup companies involving a university scientist, adopted guidelines in early 1991 for licensing technology to and investing in startup companies in which faculty are involved. These guidelines are anticipated to facilitate future licensing to startup companies.

Table I.5 shows that at the time of licensing, the licensee had a relationship with the university for 57 of the 197 exclusive licenses granted for technology developed with NIH or NSF funding. While the licensee

Foreign Participation in Universities' Industrial Liaison Programs

Of the 30 universities that have established industrial liaison programs, 24 universities reported having at least 1 foreign member. At 14 of the universities with foreign members, industrial liaison program members can get advance access to the results of federally funded research before those results are made generally available to others. Program members are not given advance access at the other 10 universities with foreign members.

Extent of Foreign Participation

Thirty of the 35 university respondents have at least 1 industrial liaison program that charges one-time and/or annual membership fees and, in return, provides companies general access to research results, university scientists, and/or laboratories in specified areas.[1] The other five universities—the University of Alabama at Birmingham, the University of California at San Francisco, the Johns Hopkins University, the University of North Carolina at Chapel Hill, and Yeshiva University—do not have an industrial liaison program that charges membership fees.

Twenty-four universities reported that 499 foreign companies participate in at least 1 industrial liaison program. (Because a foreign company might participate in more than one university's program, the number of distinct foreign companies is likely to be less than the aggregate total of 499 companies reported.)

Nine of the 24 universities with foreign members in their industrial liaison programs reported that, as of January 1991, they held more than $10,000 in stock through their endowments in at least one of the foreign members. MIT reported stockholdings in foreign members of $9.2 million, the most reported. MIT officials noted that these holdings represented less than 1 percent of MIT's total endowment.

Foreign Members' Rights

As shown in table II.1, 18 universities reported that they provide industrial liaison program members, which would include any foreign members, with advance access to the results of federally funded R&D before those results are made generally available. In contrast, 12 universities reported that, excluding information such as preprints of scientific journal articles, program members are not given advance access to the results of federally funded research before these results are made generally available. In particular, MIT, Stanford, and the University of California at Berkeley, which accounted for 290, or 58 percent, of the foreign members, reported

[1]Carnegie Mellon University accounted for 59 of 278 industrial liaison programs identified.

and approving requests to join, (2) allowing members to participate in program activities, or (3) assessing membership fees. The University of Michigan and the University of Washington each had one program limited only to U.S. members, while some of the University of Wisconsin's programs require the consent of U.S. members for any foreign applicant to join.

Regarding the rights of U.S. and foreign members to participate in the activities of one or more programs, Columbia University stated that any rights that members receive through its Columbia Forum in Japan, which is designed to coordinate its contacts with Japanese companies in biomedicine, are (1) limited to technologies already in the open literature and not claimed by U.S. companies and (2) restricted to the Japanese market. The University of Michigan reported that one program limits foreign participation to basic research only. The University of Wisconsin said that at least one program limits access by Japanese companies to any technology unless technology of equal value is exchanged.

A few universities distinguish between U.S. and foreign companies in assessing membership fees. For example, since 1988 the engineering industrial liaison program at the University of California at Berkeley generally has charged foreign companies twice the membership fee amount applicable to domestic U.S. companies. The Center for Supercomputing Research and Development at the University of Illinois offers a special affiliate membership to foreign companies for an annual $25,000 fee that entitles the company to (1) attend the annual affiliate meeting; (2) receive the center's papers, theses, and reports; (3) receive free copies of the center's videotape series; and (4) attend, free of charge, symposia, including gatherings by invitation only of leading researchers. Alternatively, the center offers affiliate membership to companies with less than $100 million annual sales that entitles a company access only to the first two programs for an annual $15,000 fee, while full members receive additional benefits for an annual fee that begins at $50,000 per year.

- "On Preventing Conflicts of Interest in Government-Sponsored Research at Universities," a joint statement by the Council of the American Association of University Professors and the American Council on Education issued in December 1964 and
- "Principles to Govern College and University Compensation Policies for Faculty Engaged in Sponsored Research," which was prepared in April 1978 by a task force sponsored jointly by the Association of American Universities, the American Council on Education, and the National Association of State Universities and Land Grant Colleges.

In particular, the 1964 document identified several situations in or from which conflicts of interest might arise and suggested that universities (1) implement procedures that enable them to be aware of relevant outside professional work of staff members participating in government-sponsored research and (2) formulate standards to guide staff members in governing their conduct in relation to outside interests that might raise questions of conflicts of interest. The 1978 document provided additional guidance for formulating policies and practices regarding the compensation of faculty engaged in sponsored research.

In addition, NSF in April 1989 promulgated an "Important Notice to Presidents of Colleges and Universities and Heads of Other NSF Grantee Organizations," which states in part:

> NSF advocates and encourages open scientific communication. NSF expects significant findings from research it supports to be submitted promptly for publication, with authorship that reflects accurately the contributions of those involved. It expects investigators to share with other researchers, at no more than incremental cost and within a reasonable time, the primary data, samples, physical collections, and other supporting materials created or gathered in the course of the research. It also encourages awardees to share software and inventions or otherwise act to make such items or products derived from them widely useful and usable.

Universities Have Varying Conflict-Of-Interest Policies

Fourteen of the 35 universities rely on members of their university community to voluntarily disclose a potential conflict of interest once the situation becomes evident. Four of these universities do not provide specific examples in their policies of what constitutes a conflict of interest, leaving the decision about what should be disclosed to the affected university community member.

Table III.1: Universities That Require Disclosures or Certifications by Faculty or Technology Licensing Personnel

Surveyed university	Faculty: Project approval	Faculty: Annual disclosure	Licensing personnel annual disclosure
California			
Berkeley	Yes	No	Yes
Los Angeles	Yes	No	Yes
San Diego	Yes	No	Yes
San Francisco	Yes	No	Yes
Santa Barbara	Yes	No	Yes
Columbia	No	No	Yes
Duke	Yes	Yes	Yes
Harvard	No	Yes[a]	Yes
Illinois	Yes	Yes	Yes
Johns Hopkins	Yes[b]	No	No
MIT	Yes	Yes	Yes
Michigan	Yes	No	No
Minnesota	Yes	No	No
Pittsburgh	Yes	Yes	Yes
Purdue	Yes	Yes	Yes
Rochester	Yes	No	No
Southern California	No	No	Yes
Stanford	Yes	Yes[c]	No
University of Washington	Yes	No	No
Wisconsin	No	Yes	Yes
Yale	No	Yes	No

[a]Faculties of Medicine and Public Health only.

[b]Faculties of Medicine, Nursing, and Public Health only.

[c]Faculty of Medicine only.

Sponsored Research Agreements

As part of the approval process for each proposed sponsored research project, 16 of the 35 universities require the principal investigator to submit a signed form disclosing any relationships with the research sponsor(s). The following are examples of the information that principal investigators are required to provide:

- As part of its approval process for a sponsored research project, the University of California requires that if a nongovernmental entity provides

confidence in the judgment of researchers and clinicians and in the dedication of academic research institutions to the integrity of the scientific enterprise. According to the Faculty of Medicine, with clear guidelines and principles in conjunction with appropriate mechanisms for supervision and monitoring, cooperation between industry and academic medicine is consistent with the highest traditions of the medical profession and can energize scientific creativity.

Technology Licensing

Fourteen of the 35 universities require that technology licensing office personnel annually (1) disclose outside interests or (2) certify whether a potential conflict of interest exists. In addition to this requirement, the five University of California campuses and MIT require their licensing officer(s) responsible for negotiating a license and a principal investigator who participates in the licensing decision to state in writing at the time of licensing whether a relationship with the licensee exists. Pittsburgh requires a written statement only from the principal investigator, while Stanford requires such a statement from the principal investigator only if the licensee was a startup company.

Officials at several of the 21 universities that do not require technology licensing personnel to submit an annual disclosure noted that the university has an unwritten operating policy that licensing personnel may not have an equity or other interest in any company with which they are negotiating a license. At some of these universities, the technology licensing office consists of a single person who self-polices the policy, while other offices consist of several individuals who informally monitor any such relationships through discussions. None of the 35 universities requires the concerned technology licensing officers to certify both the integrity of the licensing decision and the lack of any improper influence on them.

Requests to Restrict the Publication of Research Results

In approving a research project funded by industry, the 35 universities generally reserve the right to publish research results in the scientific literature, while giving the sponsor a limited period of time to review the manuscript for inadvertent disclosure of proprietary information and/or to identify any patentable inventions.[1] None of the universities were aware of any instances in fiscal years 1989 or 1990 in which any of their researchers,

[1]To protect the right to file patent applications in foreign countries, a business would have to file a patent application at the U.S. Patent and Trademark Office before information about the invention is publicly disclosed.

NIH and NSF Plan to Strengthen Conflict-Of-Interest Controls

Both NIH and NSF are considering ways to strengthen their policies for controlling potential conflicts of interest. In September 1989, NIH requested comments on a proposed revision to its conflict-of-interest guidelines that required investigators and other key personnel to disclose financial interests, outside professional activities, and other sources of funding to appropriate representatives of the university as part of the award process and annually thereafter. These disclosures would be treated as confidential unless confidentiality would interfere with the interests of the university or the federal government. In addition, the proposed guidelines would have prohibited investigators and other key personnel from (1) having personal equity holdings or options in any company that would be affected by the outcome of the research or that produces a product or equipment being evaluated in the research project and (2) sharing of information and/or research products derived from NIH-funded projects with any company with which a conflict of interest exists unless and until the information or research products are made publicly available. In December 1989 NIH withdrew its proposed guidelines in response to many commenters' strong concerns about their impact on university-industry relationships and the transfer and commercialization of NIH-supported technology.

Because of the importance of the conflict-of-interest issue, NIH plans to promulgate a regulation, which will involve publishing a Notice of Proposed Rulemaking in the Federal Register for public comment. NIH's proposed rule is likely to require that all investigators and other key personnel involved in NIH-funded research disclose certain types of outside interests before an award is made and annually thereafter and may prohibit investigators and other key personnel for clinical drug trials from having any financial relationship with a business whose product is being tested.

NSF is considering ways to strengthen its current guidelines, primarily by requiring that investigators involved in NSF-funded research disclose certain types of outside interests before an award is made. NSF's General Counsel noted that requiring annual disclosure of outside interests by faculty and professional employees involved in NSF-funded research would be administratively burdensome for universities to implement.

Dollars in thousands

Surveyed university	Invention disclosures	Patent applications filed	Patents received	Licenses granted		License income[b]
				Patents	Other[a]	
Yale	108	50	21	17	14	1,170
Yeshiva	30	10	0	7	7	754
Total	**4,380**	**2,043**	**1,036**	**731**	**779**	**$113,055**

[a]Includes licenses granted for computer software and such tangible research properties as cell lines, unless technology was provided at nominal or no cost. During the 2-year period, the 35 universities granted 644 licenses for computer software and 135 licenses for tangible research properties.

[b]License income may include an initial fee payable with the execution of the license, an annual minimum fee, and royalties, which typically represent a percentage of the resulting product's sales.

[c]Includes 20 licenses for 1 patent granted to the member companies of Semiconductor Research Corporation.

Table IV.2: Patents and Licenses Resulting From Research Funded in Whole or in Part by NIH or NSF (Fiscal Years 1989 and 1990)

Dollars in thousands

Surveyed university	Invention disclosures	Patent applications filed	Patents received	Licenses granted[a]		License income[c]
				Patents	Other[b]	
Alabama	0	0	0	3	6	$ 357
California						
Berkeley	42	40	10	3	0	338
Los Angeles	28	13	5	3	1	30
San Diego	8	7	5	2	0	819
San Francisco	48	41	5	7	0	7,405
Santa Barbara	8	2	3	0	0	0
California Institute of Technology	9	16	12	0	1	145
Carnegie Mellon	4	5	0	1	0	24
Chicago	18	7	2	4	1	41
Colorado	51	33	8	56	0	3,599
Columbia	59	41	27	10	25	10,454
Cornell	34	38	16	2	0	63
Duke	32	22	8	2	0	39
Harvard	64	37	27	32	12	2,030
Illinois	34	9	7	7	13	245
Indiana	13	3	3	4	0	6
Johns Hopkins	56	36	7	6	3	918

(continued)

Table IV.3: Exclusive and Nonexclusive Licensing and Income for Technology Developed in Whole or in Part With NIH or NSF Funding (Fiscal Years 1989 and 1990)

Dollars in thousands

	Licenses granted		License income[a]	
Surveyed university	**Exclusive**	**Nonexclusive**	**Exclusive**	**Nonexclusive**
Alabama	8	1	$ 344	$ 13
California				
Berkeley	1	2	33	306
Los Angeles	4	0	30	0
San Diego	1	1	742	77
San Francisco	7	0	3,191	4,215
Santa Barbara	0	0	0	0
California Institute of Technology	0	1	125	20
Carnegie Mellon	1	0	24	0
Chicago	4	1	41	0
Colorado	2	54	2,608	991
Columbia	4	31	1,757	8,698
Cornell	2	0	63	0
Duke	2	0	39	0
Harvard	19	25	1,586	444
Illinois	4	16	217	28
Indiana	4	0	6	0
Johns Hopkins	6	3	898	20
Maryland	0	1	0	8
MIT	23	7	1,366	282
Michigan	1	1	6	2
Michigan State	0	0	11,502	0
Minnesota	7	2	1,334	221
North Carolina	6	6	562	6
Northwestern	2	2	131	0
Pittsburgh	3	0	20	0
Princeton	2	0	0	87
Purdue	1	42	108	21
Rochester	1	0	59	0
Southern California	1	1	7	0
Stanford	23	111	840	15,983
Washington University	1	0	0	0
University of Washington	20	10	445	37
Wisconsin	13	6	53	20,905

(continued)

Objectives, Scope, and Methodology

The Chairman, Human Resources and Intergovernmental Relations Subcommittee, House Committee on Government Operations, has expressed concern that closer links between universities and businesses have increased the potential for conflicts of interest that would give businesses inappropriate access to, and therefore an unfair advantage in commercializing, the results of federally funded research. To assess the extent of these linkages, the Chairman requested that we survey the universities receiving the most funding from NIH and NSF in fiscal year 1989 about (1) the extent of licensing activities for technologies developed in whole or in part with NIH or NSF funding; (2) foreign participation in industrial liaison programs that, in return for membership fees, provide companies with access to research programs; and (3) policies and procedures to control potential conflicts of interest by faculty or administrators that could give companies inappropriate access to research results. As agreed with the Subcommittee, we assessed the overall relationship between universities and businesses without seeking to identify specific instances of inappropriate access.

To obtain information about the extent of linkages between universities and businesses, we sent a questionnaire to 37 universities that were among the 25 leading university recipients of funding from NIH and/or the 25 leading university recipients of funding from NSF in fiscal year 1989.[1] All of the universities, except the Baylor College of Medicine and the University of Pennsylvania, responded to the questionnaire. We also obtained additional data through telephone interviews with administrators at the 35 universities that responded. We did not independently verify the accuracy of data that the universities reported.

In addition, we visited the University of California system office, Harvard, MIT, and Stanford to interview administrators and faculty members about policies, procedures, and controls for reducing the potential for companies' obtaining inappropriate access to the results of research funded by NIH or NSF. These universities, which are among the leaders in patenting and licensing activities, represent both private and public universities.

For purposes of this report,

[1]NIH and NSF accounted for about $2.8 billion, or 42 percent, of the $6.6 billion that these universities spent on R&D in 1989.

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the duration of the grant and (2) technology licensing personnel and others involved in making licensing decisions for technologies developed in whole or in part with NIH or NSF funding. We also recommend that NIH and NSF review their funding recipients' policies and procedures to ensure that they adequately address conflicts-of-interest issues. Furthermore, we recommend that NIH and NSF develop policies that address the extent to which U.S. and foreign industrial liaison program members can be given advance access to research the agencies have funded.

Agency Comments and Our Evaluation

We discussed the report's contents with officials in NIH's Office of Extramural Research and NSF's Office of General Counsel and Division of Grants and Contracts, who are responsible for funding research at universities. NIH officials agree with the thrust of the report's recommendations. NSF officials agree with the need to strengthen NSF's policy toward potential conflicts of interest by investigators, which currently is under review, but have not considered whether to require disclosures by technology licensing personnel and others involved in making licensing decisions for technologies developed in whole or in part with NSF funding. NSF officials also agree with the need to address the extent to which industrial liaison program members can be given advance access to NSF-funded research. We believe disclosures are important controls that provide periodic checks by universities during the conduct of research and transfer of any resulting technology whether investigators or other key personnel have any conflicts of interest. As requested, we did not obtain written agency comments on a draft of this report.

We conducted our review between February 1990 and March 1992 in accordance with generally accepted government auditing standards. See appendix V for details of our objectives, scope, and methodology.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after the date of this letter. At that time, we will send copies to the Secretary of Health and Human Services; the Director, National Science Foundation; and the Director, Office of Management and Budget. We will also make copies available to others upon request.

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Universities License a Substantial Amount of Federally Funded Technology

Since the enactment of the Patent and Trademark Amendments of 1980, the 35 surveyed universities have expanded their efforts to transfer technology to businesses. Most of their license income in fiscal years 1989 and 1990 was derived from technologies developed in whole or in part with funding from the National Institutes of Health (NIH), within the Department of Health and Human Services, and the National Science Foundation (NSF). Exclusive licensees for NIH- or NSF-funded technologies often had an association with the scientist who developed the technology or the university.

Rights to Federally Funded Technology

The Patent and Trademark Amendments of 1980 (35 U.S.C. 200 et seq.) gave universities, other nonprofit organizations, and small businesses the option, with few exceptions, to retain title rights to their federally funded inventions.[1] Key objectives of the act are to promote collaborations between businesses and universities and facilitate the commercialization of federally funded inventions by U.S. businesses. While providing more autonomy in commercializing technologies, the act, as amended, requires that universities (1) may grant exclusive rights to use or sell the invention in the United States only if the licensee agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States and (2) give preference to small businesses in licensing federally funded inventions, unless it proves infeasible after reasonable inquiry. In addition, federal agencies can require funding recipients to periodically report on their invention commercialization efforts. According to administrators at 25 universities we surveyed in 1986, the act had been significant in stimulating business sponsorship of university research.[2]

Universities normally seek to commercialize technologies developed in the course of research by licensing them to businesses, which typically seek exclusive rights to a technology to prevent competitors from making or using it. Exclusivity is particularly important for new drugs because businesses often spend more than $150 million to further develop a drug and test its safety and effectiveness to obtain Food and Drug Administration approval for its use. Alternatively, nonexclusive licenses are appropriate for other technologies. In determining whether to grant an

[1]While not required to report software developed in the course of R&D, funding recipients generally are required by federal civilian agencies to obtain a waiver of the agency's rights before establishing a copyright claim subsisting in such software.

[2]See Patent Policy: Recent Changes in Federal Law Considered Beneficial (GAO/RCED-87-44, Apr. 16, 1987).

Table I.1: Patenting and Licensing of Technology Resulting From All Sources of Funding (Fiscal Years 1989 and 1990)

Dollars in millions

Universities	Patent applications filed	Licenses granted		License income
		Patents	Other[a]	
All surveyed	2,043	731	779	$113.1
Top five[b]	893	393	481	81.8

[a]Includes licenses granted for computer software and such tangible research properties as cell lines, unless technology was provided at nominal or no cost.

[b]Top five universities for each specific category.

During the 2-year period, 15 of the 35 universities received more than $1 million each in license income. The $113.1 million in license income that the 35 universities received in fiscal years 1989 and 1990 is substantially greater than license income of about $30 million that 112 leading research universities—including almost all of the 35 universities—reported to us for fiscal year 1986.[3]

Technology licensing officials told us that most of a university's license income typically is generated by licenses for only a few technologies. Perhaps the best known university license is for a patented invention for cloning DNA within cells developed by Stanford and University of California scientists. Because this process is fundamental for performing genetic engineering R&D, Stanford and California decided to license the patent nonexclusively. In 1990, 107 licensees paid the universities royalties of $6.9 million for using this process. One of the licensees of this technology is Genentech, which was founded in 1976 by a venture capitalist and one of the scientists who developed the technique.

NIH- and NSF-Funded Technologies Accounted for Most of the Universities' License Income

As shown in table I.2, technology developed in whole or in part with NIH and NSF funding accounted for $82 million, or 73 percent, of $113.1 million that the 35 universities received in license income in fiscal years 1989 and 1990. Nine universities received more than $1 million in license income for technologies developed with NIH or NSF funding during the 2-year period. In contrast, NIH- or NSF-funded inventions accounted for only 34 percent of the universities' patent applications, 45 percent of the patent licenses granted, and 27 percent of the licenses granted for software and tangible research properties. (See table IV.2 in app. IV for each university's patent and licensing activities for technology developed with NIH or NSF funding.)

[3]See R&D Funding: Foreign Sponsorship of U.S. University Research (GAO/RCED-88-89BR, Mar. 4, 1988).

Myers, a pharmaceutical company that had not supported the research. A university administrator told us that Michigan State did not grant license rights to the two metals companies because (1) the university believed that a pharmaceutical company was needed to develop the invention into an approved drug and (2) none of the pharmaceutical companies contacted was interested in jointly licensing the invention with the metals companies. The two metals companies receive a share of the royalties earned.

Typical Exclusive Licensees Were Small U.S. Businesses

Overall, the 35 universities reported that during fiscal years 1989 and 1990, small U.S. businesses were granted 146 of the 197 exclusive licenses for technologies developed in whole or in part with NIH or NSF funding. In particular, 148 of the exclusive licensees were small businesses, 45 were large businesses, and 4 were nonprofit organizations or individuals. In addition, 168 of the exclusive licensees were organizations headquartered in the United States or foreign subsidiaries of U.S. corporations, 11 were U.S. subsidiaries of foreign corporations, and 18 were foreign companies.

The 18 foreign businesses granted exclusive licenses included 4 French companies, 3 British companies, 2 Swiss companies, 1 Canadian company, 1 Finnish company, 1 Israeli company, and 1 Japanese company. Two of the foreign licensees were small businesses, while 16 were large businesses. State universities granted 12 of the 18 licenses giving exclusive U.S. rights to a foreign company.

Exclusive Licensees Often Had Association With Scientist or University

Overall, licensees were associated with either the scientist who developed the technology and/or the university at the time of licensing for 93 of 197 exclusive licenses granted for technology developed in whole or in part with NIH or NSF funding. As shown in table I.4, the university scientist who developed the technology being licensed was associated with the licensee in 61 cases, primarily as a consultant. Cases in which the scientist was an owner, significant stockholder, and/or officer of the licensee typically involved a "startup" company established specifically to commercialize the university's technology.[4]

[4]Stanford University notes that a company normally would be considered a "startup" if it was not publicly traded, was less than 5 years old, had fewer than 100 employees, and had annual sales of less than $5 million.

co-sponsored the research that led to the technology in 24 cases, in 33 other cases the licensee (1) sponsored research through long-term agreements but did not sponsor the research resulting in the licensed technology, (2) was a member of an industrial liaison program, or (3) was a startup company in which the university accepted stock.

Table I.5: University's Association With Exclusive Licensee for NIH- or NSF-Funded Technology

	Licensee funded R&D		Stock ownership			
Universities	Resulting in invention	Through long-term agreement	Startup firm[a]	Existing firm[b]	Industrial liaison member	No affiliation
All surveyed	24	12	17	0	4	141
Top five[c]	9	8	6	0	4	73

Note: In one case, the university had two associations with the licensee.

[a]The licensee was a startup company owned in whole or in part, either directly or indirectly by the university.

[b]The licensee was an established company owned in whole or in part, either directly or indirectly by the university as part of a university incubator, industrial park, or similar type of program.

[c]Those universities that granted the most exclusive licenses for technology developed in whole or in part with NIH or NSF funding.

that industrial liaison program members are not given such advance access. A May 1991 report by an MIT Faculty Study Group describes how MIT's program works in practice:

> Through its activities the industrial liaison program facilitates access to MIT on the part of member companies. It does not provide privileged access; all the information available through the industrial liaison program is equally available to nonmembers on their own initiative. Clearly, however, there is an advantage for a company that uses the industrial liaison program to learn about research of interest and to obtain information and contact with the faculty more efficiently. It is that efficiency of access to information that is intended to be the primary motive for companies to join the program.

NIH and NSF guidelines for universities and other funding recipients do not address the extent to which industrial liaison program members can be given advance access to the results of research NIH or NSF has funded before these results are made generally available.

Table II.1: Universities Providing Industrial Liaison Program Members With Advance Access to the Results of Federally Funded Research

University	Number of foreign members in industrial liaison programs
California at San Diego	2
Chicago	0
Colorado	0
Columbia	18
Cornell	12
Duke	0
Illinois	4
Maryland	1
Michigan	15
Michigan State	0
Minnesota	3
Northwestern	3
Pittsburgh	70
Rochester	3
Southern California	9
University of Washington	1
Washington University	3
Wisconsin	7

Only a few of the 30 universities reported that their industrial liaison programs distinguish between U.S. and foreign companies in (1) reviewing

NIH and NSF Lack Strong Controls Over Inappropriate Access to Research Results

Both NIH and NSF rely on universities and other funding recipients to establish policies and procedures for controlling conflicts of interest that could give businesses inappropriate access to research results. NIH and NSF currently are considering alternatives for strengthening controls over inappropriate access to research results, such as by requiring disclosure of outside interests by investigators and other key personnel as part of the grant award process.

NIH's and NSF's Approach for Controlling Potential Conflicts of Interest

NIH and NSF provided $5.8 billion, or 66 percent, of the $8.8 billion that federal agencies obligated for research and development (R&D) at universities and colleges in fiscal year 1990, primarily through grants. Both agencies have addressed potential conflicts of interest associated with such R&D by establishing general guidelines and relying on funding recipients to establish appropriate policies and procedures for managing and reporting instances of potential or actual conflicts of interest. Neither NIH nor NSF requires funding recipients to submit their policies and procedures for approval.

NIH grantees are covered by the Public Health Service's Grants Policy Statement, which requires that funding recipients establish safeguards to prevent employees, consultants, and members of governing bodies from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain. In particular, funding recipients are required to have written policy guidelines on conflicts of interest that (1) cover financial interests, gifts, gratuities and favors, nepotism, and other areas; (2) indicate the conditions under which outside activities, relationships, or financial interests are proper or improper; (3) provide for notification of these kinds of activities, relationships, or financial interests to a responsible and objective institution official; and (4) require prompt notification of violations to a responsible and objective grantee official and specify the type of administrative action that may be taken against an individual for violations. NIH also requires that funding recipients give these rules of conduct to each officer, employee, board member, and consultant of the recipient organization who is working on the grant-supported project or activity.

NSF's guidance to grantees on consulting and other activities of principal investigators urges—but does not require—all grantee institutions and principal investigators to adhere to, and take effective actions to implement, the principles enunciated in the following documents:

In contrast, 21 universities require that faculty and/or technology licensing office personnel disclose outside interests or certify whether potential conflicts of interest as part of either (1) the approval process for a sponsored research project and/or (2) an annual disclosure requirement. (See table III.1) For example, MIT requires that principal investigators certify whether a conflict of interest exists as part of the approval process for a sponsored research project, and all members of its community annually submit a form disclosing their outside interests. This disclosure, which is considered confidential, is reviewed by departmental chairmen for faculty members. Potential conflicts of interest that cannot be resolved easily or that are particularly sensitive may be referred to senior MIT officers for resolution.

$250 or more in funding through a contract, grant, or gift, the principal investigator must submit a statement of economic interests disclosing business or financial affiliations with the sponsor.

- Stanford requires each principal investigator to submit a project summary that asks whether any of the involved researchers have consulting arrangements, line management responsibilities, or substantial equity holdings in the proposed sponsor, vendor(s), or subcontractor(s).

If a potential conflict of interest is disclosed, the 17 universities require submission of additional information about the relationship for review and resolution before the sponsored project is approved.

Annual Disclosure of Outside Interests

Overall, 9 of the 35 university respondents require some or all of their faculty members to disclose outside interests annually, while 13 additional universities require senior officers and/or Board of Regents to make annual disclosures, as follows:

- Duke, Illinois, MIT, and Wisconsin require all three groups to disclose outside interests annually;
- Pittsburgh and Purdue require both faculty and senior officers to file an annual disclosure;
- Yale requires all faculty to disclose outside interests annually; Harvard and Stanford require only the medical and/or public health faculties to disclose outside interests annually;
- Alabama, all five University of California campuses we surveyed, Chicago, Cornell, Maryland, North Carolina, Rochester, and the University of Washington require both senior officers and Board of Regents members—but not faculty—to submit annual disclosures; and
- Minnesota requires only Board of Regents members to file an annual disclosure.

Some states, such as California, require senior state officials—including senior officers and members of the Board of Regents for state universities—to submit an annual disclosure. A primary concern is potential conflicts of interest associated with purchasing or selling university real estate. In contrast, 10 private universities and 4 state universities do not require any of the 3 groups to annually disclose outside interests.

Harvard's Faculty of Medicine, in instituting an annual disclosure requirement in 1990, cited the need to ensure the continued public

at a company's request, agreed to either limit public disclosure or delay publication of the results of research funded by NIH or NSF.

Senior administrators at the University of California, Harvard, MIT, and Stanford told us that their universities have rejected funding for projects when a sponsor insisted upon the right to approve a manuscript before publication. For example, Harvard does not accept classified research or research involving proprietary information to which other researchers cannot get access because it will not conduct research that cannot be published and verified by others. University of California administrators told us that their universities have standard requirements that the sponsor has a limited right, typically 30 to 90 days, to review manuscripts (1) for inadvertent disclosure of proprietary information or compounds and (2) to identify patentable inventions. The administrators noted that some research sponsors request broader rights than these to review manuscripts, citing as an example the following proposed contract provision by the National Institute on Drug Abuse in the Department of Health and Human Services:

> Notwithstanding any language in any prior contract, clause, or prior agreement with any party, the contractor (the University of California) will hold in total confidence and will not publish, release, or disclose any data, procedures, methods or product designs or manufacturing specifications or other information developed under this contract except to the National Institute on Drug Abuse unless prior permission is obtained in writing from the institute.

According to a University of California administrator, the National Institute on Drug Abuse's clause does not conform with the university's policy because (1) the Institute would have a right of prior approval before publication and (2) no time limit is specified for the Institute's review.

Several administrators and faculty we interviewed stated that a request to delay the publication of research results is rare because the referee process for scientific publications normally requires several months to complete, giving the sponsor ample time available to review the manuscript for either proprietary information or potentially patentable inventions. They noted that a more common problem is the need to file a patent application to protect foreign patent rights before the principal investigator addresses a conference about the research.

Individual Universities' Patent and Licensing Activities

Table IV.1: Total Patent and Licensing Activities (Fiscal Years 1989 and 1990)

Dollars in thousands

Surveyed university	Invention disclosures	Patent applications filed	Patents received	Licenses granted		License income[b]
				Patents	Other[a]	
Alabama	95	11	7	9	6	$ 457
California						
Berkeley	96	62	22	9	11	808
Los Angeles	83	47	17	6	1	421
San Diego	72	49	14	7	0	1,009
San Francisco	101	98	37	12	0	11,394
Santa Barbara	30	16	13	1	68	83
California Institute of Technology	61	44	29	9	2	803
Carnegie Mellon	65	15	12	4	5	166
Chicago	86	45	24	10	4	98
Colorado	135	71	17	79	1	3,762
Columbia	109	51	37	12	29	11,540
Cornell	181	141	54	36	30	1,186
Duke	105	49	23	8	14	605
Harvard	165	61	37	37	36	2,568
Illinois	104	25	23	12	58	672
Indiana	47	9	8	10	2	251
Johns Hopkins	141	57	18	8	3	1,059
Maryland	79	16	3	13	5	208
MIT	609	411	200	64	43	5,213
Michigan	162	75	44	2	19	716
Michigan State	64	30	8	10	1	12,053
Minnesota	309	118	83	84	0	2,286
North Carolina	138	39	10	10	4	685
Northwestern	57	20	15	5	3	232
Pittsburgh	51	21	19	4	4	483
Princeton	45	20	19	3	0	157
Purdue	102	40	31	15	56	1,084
Rochester	67	18	30	5	6	442
Southern California	99	30	15	6	40	283
Stanford	311	79	62	120[c]	256	24,786
Washington University	100	52	22	16	27	598
University of Washington	148	38	14	46	24	3,024
Wisconsin	225	125	48	35	0	21,999

(continued)

Dollars in thousands

Surveyed university	Invention disclosures	Patent applications filed	Patents received	Licenses granted[a]		License income[c]
				Patents	Other[b]	
Maryland	3	0	0	1	0	8
MIT	84	96	51	26	4	1,648
Michigan	38	19	13	1	1	7
Michigan State	11	5	0	0	0	11,502
Minnesota	41	26	22	9	0	1,554
North Carolina	60	33	5	7	5	568
Northwestern	15	1	5	4	0	131
Pittsburgh	10	5	7	3	0	20
Princeton	10	3	3	2	0	87
Purdue	17	13	5	1	42	128
Rochester	17	2	2	1	0	59
Southern California	11	11	3	2	0	7
Stanford	81	17	10	70	64	16,824
Washington University	3	3	0	1	0	0
University of Washington	51	22	3	18	12	482
Wisconsin	43	56	38	19	0	20,958
Yale	58	23	15	15	10	770
Yeshiva	11	5	0	7	7	753
Total	**1,072**	**690**	**327**	**329**	**207**	**$82,019**

[a]Licenses that include the right to make or use the technology in the United States. In addition, 8 universities granted 13 licenses giving foreign companies exclusive rights to NIH- or NSF-funded technology in at least one foreign country.

[b]Includes licenses granted for computer software and such tangible research properties as cell lines, unless technology was provided at nominal or no cost. During the 2-year period, the 35 universities granted 142 licenses for computer software and 65 licenses for tangible research properties developed with NIH or NSF funding.

[c]License income may include an initial fee payable with the execution of the license, an annual minimum fee, and royalties, which typically represent a percentage of the resulting product's sales.

Dollars in thousands

	Licenses granted		License income[a]	
Surveyed university	**Exclusive**	**Nonexclusive**	**Exclusive**	**Nonexclusive**
Yale	14	11	414	356
Yeshiva	10	4	739	14
Total	**197**	**339**	**$29,290**	**$52,734**

[a]License income may include an initial fee payable with the execution of the license, an annual minimum fee, and royalties, which typically represent a percentage of the resulting product's sales.

- foreign organizations include companies and nonprofit organizations headquartered in a foreign country, foreign governments, and foreign individuals;
- foreign-controlled companies located in the United States include U.S. subsidiaries of foreign corporations and joint venture companies located in the United States in which a foreign partner has controlling interest; and
- U.S. and U.S.-controlled organizations include organizations headquartered in the United States and foreign subsidiaries of U.S. corporations.

We used separate categories for foreign-controlled companies located in the United States and foreign organizations to response to the domestic manufacture requirement in 35 U.S.C. 204 for granting an exclusive license. We asked the universities to use their best judgments in identifying the nationality of a company in which the controlling interest was not readily apparent.