Memorandum

Date JUN 15 1994

From June Gibbs Brown
Inspector General

Subject Underreporting Federal Involvement in New Technologies Developed at the Scripps Research Institute (CIN: A-15-93-00029)

To Philip R. Lee, M.D.
Assistant Secretary for Health

The attached report alerts you to weaknesses in procedures at the National Institutes of Health (NIH) for monitoring compliance with provisions of the Patent and Trademark Amendments Act (Act) of 1980 at the Scripps Research Institute (SRI) of La Jolla, California. The objectives of the Act are, in part, to promote utilization of inventions and technology arising from federally supported research and development, require manufacture of patented products in the United States, protect the public against nonuse or unreasonable use of new technologies, and ensure that the United States obtain sufficient rights in inventions.

We found that NIH did not have effective procedures to detect that SRI underreported, in its patent applications, NIH's involvement in inventions resulting from NIH sponsored research. Because NIH was not aware of inventions being developed at SRI with NIH grant funds, it could not provide assurance that the objectives of the Act were being met. Information we obtained from NIH showed that only 51 (41 percent) of the 125 patents awarded to SRI were developed with help from Federal grant funds. However, after we raised questions about the accuracy of SRI's reporting, SRI, on June 30, 1993, revealed to NIH that 94 of the 125 patents were developed with the help of Federal funds.

We recommended that the Public Health Service (PHS) have NIH determine if SRI properly reported all patented inventions and that NIH establish procedures to better monitor SRI's compliance with the Act. The PHS generally concurred with our recommendations, however we continue to have concerns regarding the adequacy of NIH planned procedures for assuring that other grantees complied with the Act's reporting requirements.

We would appreciate being advised within 60 days of the status of corrective actions taken or planned on each recommendation. If you have any questions, please call me or have your staff contact Michael R. Hill, Assistant Inspector General for Public Health Service Audits, at (301)443-3582.

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

UNDERREPORTING FEDERAL INVOLVEMENT IN NEW TECHNOLOGIES DEVELOPED AT THE SCRIPPS RESEARCH INSTITUTE

JUNE GIBBS BROWN
Inspector General

JUNE 1994
A-15-93-00029

Memorandum

Date JUN 15 1994

From June Gibbs Brown
Inspector General

Subject Underreporting Federal Involvement in New Technologies Developed at the Scripps Research Institute (CIN: A-15-93-00029)

To Philip R. Lee, M.D.
Assistant Secretary for Health

This final report alerts you to weaknesses in procedures at the National Institutes of Health (NIH) for monitoring compliance with provisions of the Patent and Trademark Amendments Act (Act)[1] at the Scripps Research Institute (SRI) in La Jolla, California. Our audit was requested by the Chairman, Subcommittee on Regulation, Business Opportunities and Technology, House Committee on Small Business.

We found that NIH did not have effective procedures to detect that SRI underreported, in its patent applications, NIH's interest in inventions resulting from NIH sponsored research. Because NIH was not aware of the patenting of new inventions which had been developed at SRI with NIH grant funds, it could not provide assurance that the objectives of the Act were being met. Such objectives include that patented products are manufactured in the United States, and that the public is protected against nonuse or unreasonable use of new technologies.

Specifically, information we obtained from the United States Patent and Trademark Office (USPTO) and a commercial data base showed that only 51 (41 percent) of the 125 patents awarded to SRI were developed with help from Federal grant funds. However, after we raised questions about the accuracy of SRI's reporting to NIH, on June 30, 1993, NIH was provided data indicating 94 of the 125 patented inventions were developed with the help of Federal funds--SRI also provided information on additional patents.

Although our review focused on SRI's reporting of Federal involvement in patent applications to the USPTO, we also found that NIH was not always aware of new inventions developed by SRI. For example, we found that NIH did not have disclosure records for 22 inventions that had already been patented by SRI. We believe additional audit work is warranted to determine the full extent of this problem.

---

[1] Public Law (P.L.) 96-517, and amended by P.L. 98-620 in 1984--also known as the Bayh-Dole Act.

In this audit report, we are recommending to the Public Health Service (PHS) that NIH determine if SRI properly reported all patented inventions, and that NIH establish procedures to better monitor SRI's compliance with the Act. The PHS partially concurred with our recommendations. We continue to have concerns with the adequacy of NIH's procedures for determining if similar problems exist at other grantees and detecting on-going noncompliance with reporting requirements.

Background

In Fiscal Year (FY) 1992, NIH, an agency of the Department of Health and Human Services (HHS), awarded about $6.2 billion (26,467 research grants) to universities and nonprofit institutions and private sector organizations (grantees). In FY 1992, SRI received $70 million in grants from NIH. In the 10-year period ending in FY 1992, SRI received almost $471 million (2,138 grants) from NIH. According to SRI's audited financial statements, about 96 percent of SRI's Federal grants were awarded by HHS.

Under the Act, grantees normally have an option to claim title, and patent inventions and technologies developed in whole, or in part, with Federal grant funds. The funding Federal agency maintains the right to restrict title, in exceptional circumstances, to better promote the policy and objectives of the Act. Also, the Federal agency may assert certain rights over the invention. The objectives of the Act are to:

- promote utilization of inventions arising from federally supported research and development;
- facilitate the commercialization of federally funded inventions by United States businesses and labor, and encourage the maximum participation of small businesses in federally funded research;
- ensure grantee inventions are used to promote free competition and enterprise;
- promote commercialization and public availability of inventions made in the United States by United States industry and labor; and
- ensure the United States obtains sufficient rights in inventions to meet the needs of the Government, and to protect the public against nonuse or unreasonable use of new technologies.

The Act is codified in 35 United States Code, section 200 (35 U.S.C. § 200), and implementing regulations are found at Title 37 Code of Federal Regulations (C.F.R.) Part 401 (37 C.F.R. § 401). The NIH's instructions to grantees are found in the NIH Guide for Grants and Contracts (Guidelines).

When a grantee develops a new technology supported with NIH grant funds, the Act and regulations require grantees to disclose the invention to NIH within 60 days--see 35 U.S.C. § 202(c)(1), and 37 C.F.R. § 401.14. This regulation requires the disclosure be in the form of a written report and be sufficiently complete in technical detail to convey a clear understanding of the invention. The regulations further require the grantee to elect to retain title to the invention within 2 years of disclosing the invention to the granting agency. A patent application with the USPTO must be filed within 1 year after retaining title. If a patent application is filed, a grantee is also obligated to include a statement in the application that the invention was made with Government support--see 35 U.S.C. § 202(c)(6).

The grantee must also provide the Government with a nonexclusive, nontransferable, irrevocable, paid up license to use the invention. According to NIH, the nonexclusive license also allows the Government to obtain the technology or product without paying a royalty, which is normally included in the purchase price of drugs, devices, and other products produced using the new technology.

The Government may assert its rights under 35 U.S.C. § 203 and "march in" and provide a license (the authority to manufacture and sell the product) to an entity other than the grantee that developed the invention. The Government can provide a license to others when the original grantee has not taken (or is not expected to take) effective steps within a reasonable time to achieve practical application[2] of an invention, or when it is necessary to alleviate health or safety needs.

At NIH, monitoring grantee compliance with the Act is the responsibility of the Director, Division of Extramural Invention Reports (Division), in the Office of the Deputy Director of Extramural Research. At the time of our review, the Division consisted of only two people: the Director and an assistant. The Division maintains computerized information on grantees' invention disclosures, elections to take title, and patent applications.

---

[2] According to 37 C.F.R. § 401.2, practical application means the manufacture of an invention so that its benefits are available to the public on reasonable terms.

Objective, Scope and Methodology

Our audit was requested by the Chairman, Subcommittee on Regulation, Business Opportunities and Technology (Subcommittee), House Committee on Small Business. The Chairman asked the Office of Inspector General (OIG) to review 130 patents issued to SRI[3] and provide the Subcommittee with an assessment as to whether the Federal involvement in underlying technologies has been properly reported in SRI's patent applications.

To determine if the Federal involvement in underlying technologies has been properly reported in SRI's patent applications, we reviewed pertinent laws, regulations, and NIH policies and procedures which cover this area. We also obtained, from USPTO, a detailed list of patents issued to SRI from January 1979 to March 1993--a period of more than 14 years. We also used Dialog, a sequentially numbered commercial data base that contains data on SRI's patents and is used by patent attorneys and NIH. The Dialog data base showed 125 patents were issued to SRI from January 1979 to March 4, 1993. Both lists contained the names of the scientists/inventors, relevant dates, a description of the patented invention, and whether the patented invention development included Federal funds.

To determine if any of the patents not crediting NIH could have been developed with Federal grant funds, we compared information on the patents to information on a listing of NIH grants awarded to SRI since 1970. We matched the names of inventors and titles on the patents to names of principal investigators and titles on the grants. We reviewed revised invention and patent data that SRI sent to NIH on June 30, 1993. We also performed tests to determine whether NIH had copies of disclosures for inventions related to 43 patents that SRI added the Government rights notice to in June 1993.

Our audit was conducted at the Division, NIH, Bethesda, Maryland, and at the Department of Commerce (DOC) in Washington, D.C. We did not conduct any audit work at SRI. Our audit was conducted in accordance with generally accepted government auditing standards.

---

[3] This number was used by NIH officials in testimony given to the Subcommittee and was based on a March 1993 NIH estimate of patents issued to SRI since February 1979.

Results of Our Review

SRI's Patents Did Not Always Disclose Inventions Were Supported with Government Funds

The Act (35 U.S.C. § 202(c)(1) and (6)) requires grantees to disclose the invention to the Government and include in the patent application filed with the USPTO and in the patent that the invention or technology was supported with Federal funds and that the Government has certain rights in the invention. According to 37 C.F.R. § 401.14(f)(4) and NIH Guidelines, grantees are required to include in the patent application and in the patent the following statement:

> "This invention was made with Government support under (grant/contract number) awarded by the (Federal agency). The Government has certain rights in the invention."

We found that SRI was not always including the required statement in its patent applications acknowledging that the invention was developed with Government support and that the Government had certain rights in the invention. Our review of the Dialog data base's 125 patents and those on the USPTO list disclosed that only 51 contained a statement crediting Government funding as required by the Act, 37 C.F.R. § 401.14(f)(4) and NIH Guidelines. Our initial comparison of inventor names and titles on the remaining 74 SRI patents to specific grants awarded to SRI disclosed that many of these patents could also have been supported with NIH grants. For example, we noted in some cases that the inventor shown on the patent was also the principal investigator on NIH grants awarded to SRI, which could have supported research that led to the invention. We requested that NIH review this matter and obtain additional data on inventions from SRI.

According to NIH, an SRI official told the Director of the Division that the reason SRI had credited the Government on so few patents was because it believed that credit should only be given if Government funding could be directly tied to one of the claims on the patent.[4] The NIH informed SRI that this was an erroneous interpretation, and that it must credit the Government if any Federal funds were used in the development of the invention.

The SRI, in a June 14, 1993 letter to NIH, stated that it was reviewing all patents and patent applications and was in

[4] A claim on the patent application is an assertion regarding the suitability and effectiveness of the invention for a particular purpose.

"...the process of adding the Government rights notice to all patents and patent applications that should have contained the notice." In July 1993, NIH informed us it received new data from SRI related to its review of patents. We examined the new data in August 1993, and found SRI has now determined that the Government should be credited with supporting an additional 43, or 94 of the 125 patents shown on Dialog and USPTO lists. The SRI's new data also included seven additional patents that were not shown on Dialog or the USPTO lists and four patents that were issued after March 4, 1993, the cut-off date for the Dialog data base.

We also found that NIH did not always have records of disclosures related to SRI's inventions, as required by the Act and regulations. The Act and regulations require that when a grantee develops a new technology that was supported with NIH grant funds, it must disclose the invention to NIH within 60 days. We reviewed NIH's files to determine if it had disclosures for the 43 patents to which SRI added the Government's rights notice. We found that NIH did not have records of disclosure for 22 of the subject inventions.[5]

With respect to those SRI patents that SRI determined were developed without Government support, NIH told us it had not yet begun the process of validating SRI's assessment of the Government's involvement.

The NIH Lacks Information to Ensure Compliance with the Law and Regulations

The NIH does not periodically obtain from the USPTO data on patents awarded to SRI. We also found that NIH does not have effective procedures to collect data on SRI's invention disclosures and patents. When grantees develop inventions produced with Federal funds, the law requires them to disclose the invention to the Government, elect whether to take title to the invention, and provide the Government with a nonexclusive license. The Act and 37 C.F.R. § 401.14(f)(4) require grantees to include the Government rights clause in the patent application and the patent.

Information we obtained from Dialog and USPTO showed that SRI had 125 patents and only 51 contained the statement giving the Government credit for supporting the patents. When we first

[5] The NIH may claim title to any invention for which a timely disclosure has not been made--35 U.S.C. § 202(c)(1); 37 C.F.R. § 401.14. By regulation, NIH must exercise this remedy within 60 days of discovery that an agency has failed to make a disclosure. The remedy is a form of intermediate sanction for failure to disclose. It is to be distinguished from the government "march-in rights," through which the government can gain control of useful inventions which the patent-holder is not putting to use--35 U.S.C. § 203, and 37 C.F.R. § 401.6.

contacted NIH in March 1993, it could not locate all the records regarding patents awarded to Scripps that should have credited the Government with supporting the invention.

When we attempted to reconcile this data with files maintained at NIH, the Director of the Division told us that because of the way SRI coded invention disclosures, he was having difficulty matching the data to Dialog's and USPTO's patent lists. We were unable to perform our reconciliation until additional information related to inventions and patents was obtained from Scripps several months later.

Conclusion and Recommendations

When the Government is not aware of a grantee's invention, it is not able to exercise its rights and to protect the taxpayers' interests. For instance, the Government retains rights through a nonexclusive license to use the invention, and the right to restrict title, in exceptional circumstances, to better promote the policy and objectives of the Act. Also, according to NIH and DOC officials, the Government has the right to obtain the technology without paying a royalty, which is normally included in the purchase price of the product. If the Government is unaware of situations where it might obtain nonexclusive licenses, it may be missing opportunities for savings on purchases of medical supplies or devices.

The SRI did not always comply with reporting requirements found in 37 C.F.R. § 401, and NIH instructions found in the NIH Guidelines. Also, NIH has not compared grants awarded to SRI and patents issued to SRI to determine the validity of SRI's claim that a number of its patents were developed without the support of Federal funds. The NIH also has not taken the necessary steps to establish procedures and systems that ensure that SRI discloses inventions to NIH, and includes the statement of Government support on patent applications. We believe that NIH's management of this area could be improved if it obtained patent data from the USPTO and Dialog and maintained systems that compared and reconciled this data with information provided by SRI and other research organizations. Without such information, NIH is not in a position to determine whether the objectives of the Act are being met with regard to sponsored activities.

We also conclude that additional review is warranted concerning the adequacy of SRI's disclosure of inventions to NIH, and the effectiveness of NIH's remedy where necessary disclosures are not made.

With regard to SRI and other grantees, we recommend that you have NIH:

1. examine the remaining patents SRI claims were not developed with the help of Federal funds and determine if SRI's assessment of the Government's involvement is correct;

2. determine the extent of noncompliance by other grantees with reporting requirements found in 37 C.F.R. § 401, and NIH Guidelines; and

3. develop procedures to obtain from USPTO information on patents issued to NIH grantees. The Division of Extramural Invention Reports should determine whether such patented inventions were supported by NIH funds.

Other Matters

The OIG, in May 1994, issued a final report (OEI-03-91-00930) on NIH's oversight of grantees' compliance with the requirements of the Bayh-Dole Act. The inspection was unrelated to the Subcommittee's March 15, 1993 request for an audit of SRI's activities. The inspection found, in part, that NIH lacks a systematic process for ensuring that grantees submit required invention information, and that NIH has limited its oversight of grantees by not requiring that grantees document compliance with Federal regulations. The inspection also found that NIH does not fully utilize its invention data base to monitor grantees. The report recommended NIH re-examine its oversight role, add more detailed information to its data base, and use it to track grantee compliance.

Agency Response and OIG Comments

On May 24, 1994, the PHS responded to the recommendations in our draft report. The PHS partially concurred with our recommendations. We continue to have problems with NIH's procedures for assuring that its grantees are in compliance with reporting requirements. The recommendations, a summary of PHS' response to each recommendation and, where applicable, our comment on PHS' response are presented below. The PHS response is included in its entirety as an Appendix to this report.

With regard to our first recommendation that PHS have NIH examine the remaining patents SRI claims were not developed with the help of Federal funds and determine if SRI's assessment of the Government's involvement is correct, PHS

concurred. It said that it is reviewing 35 patents that SRI stated were not funded with Government support. According to NIH, preliminary results show that 11 of the 35 were developed with Government support. The NIH expects to complete its review of these patents and issue an opinion regarding Government involvement by December 31, 1994.

With regard to our second recommendation that PHS have NIH determine the extent of noncompliance by other grantees with reporting requirements found in 37 C.F.R. § 401, and NIH Guidelines, PHS said it concurred with the intent of our recommendation and stated it has taken steps to enhance its oversight capabilities to ensure grantees comply with reporting requirements. The PHS stated NIH is developing a new system to track inventions reported to it by grantees and stated it intends to coordinate information on technology transfer now maintained by the Association of University Technology Managers (AUTM).

We do not believe that NIH's actions will allow it to determine compliance with reporting requirements. The PHS did not state how NIH will use the AUTM data to determine the extent of grantee noncompliance with current reporting requirements. Our understanding is that AUTM's data on inventions, patents and licenses is obtained on a voluntary basis from universities and others. If a grantee does not disclose an invention or patent to PHS or to AUTM, NIH will have no way of determining grantee compliance with reporting requirements of the Act.

We believe NIH should maintain information on patents awarded by the USPTO. The NIH could investigate those grantees which, based on a review of the data from the USPTO, appear to be underreporting inventions to NIH. For example, NIH might review the USPTO patents of selected grantees and investigate those that show an unreasonably low percentage of their patents were developed with Government funds.

Finally with regard to our third recommendation that PHS have NIH develop procedures to obtain, from the USPTO, information on patents issued to NIH grantees and that the Division of Extramural Invention Reports should determine whether such patented inventions were supported by NIH funds, the PHS stated that it concurred with our recommendation if the intent of the recommendation was for NIH to validate USPTO data to NIH files when the Government rights clause is included on the patent. The PHS stated it does not agree with our recommendation if the intent of the recommendation requires NIH to validate USPTO data against NIH data for all grantee patents not indicating Government support. The PHS claims that the latter would require too much work.

We disagree with PHS. If NIH only validates USPTO data when the Government clause is included in the patent, it will not detect underreporting similar to that which existed at SRI. Our recommendation is intended to suggest an approach that would allow NIH to identify those cases where inventions should have been reported and the rights clause included in the patent; but were not. With respect to NIH's position that our recommendation would require too much work, we suggest that NIH might use as risk-based approach that would ensure that those grantees most likely to have inventions and file for patents are reviewed.

We would appreciate being advised within 60 days of the status of corrective actions taken or planned on each recommendation. If you have any questions, please call me or have your staff contact Michael R. Hill, Assistant Inspector General for Public Health Service Audits, at (301)443-3582.

APPENDIX

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date MAY 24 1994

From Assistant Secretary for Health

Subject Office of Inspector General (OIG) Draft Report "Underreporting Federal Involvement in New Technologies Developed at the Scripps Research Institute," A-15-93-00029

To Inspector General, OS

Attached are the Public Health Service comments on the subject draft report. We concur with the report's recommendations. The actions taken or planned to implement these recommendations are described in the comments.

Philip R. Lee, M.D.

Attachment

IG	
SAIG	✓
PDIG	
DIG-AS	✓
DIG-EI	
DIG-OI	
AIG-MP	
OGC/IG	
EXSEC	✓
DATE SENT	5-25

PUBLIC HEALTH SERVICE (PHS) COMMENTS ON THE OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT "UNDERREPORTING FEDERAL INVOLVEMENT IN NEW TECHNOLOGIES DEVELOPED AT THE SCRIPPS RESEARCH INSTITUTE," A-15-93-00029

General Comments

The National Institutes of Health (NIH) awards over 28,000 research grants and about 1,400 contracts to approximately 1,700 non-profit organizations, universities, hospitals, and businesses each year. In comparison with the number of awards made, the total number of inventions developed is relatively small (approximately 10,000 total invention disclosures in the past 15 years).

The Bayh-Dole Act (Act) facilitates the utilization of inventions arising from Federally-supported research; transfer of technology to promote free competition and enterprise; and rights of the Government in protecting the interests of the public. NIH will take steps to increase the effectiveness of compliance with the Act through education efforts directed to recipients of NIH funding, improved reporting procedures, and oversight that is consistent with a purpose of the Act (35 United States Code § 200) to minimize the costs of administering policies in this area.

OIG Recommendation

We recommend that NIH:

1. Examine the remaining patents SRI [Scripps Research Institute] claims were not developed with the help of Federal funds and determine if SRI's assessment of the Government's involvement is correct.

PHS Comment

We concur. NIH is in the process of reconciling 35 SRI patents to determine if the Government supported their development. Preliminary information indicates that 11 were developed with Federal support and 24 were developed without Federal funds. Of the 11, one was a fellowship grant which is exempt from reporting under the Act's implementing regulations [37 C.F.R. § 401.1(b)]; eight were funded by NIH grants issued before the passage of the Act when it was not a requirement that a Government support clause be added to a patent application; and the remaining two are still under review.

The NIH expects to complete its review of these patents and issue an opinion on SRI's assessment of the Government's involvement by the end of calendar year 1994.

OIG Recommendation

2. Determine the extent of noncompliance by other grantees with reporting requirements found in 37 C.F.R. § 401, and NIH guidelines.

PHS Comment

We concur with the objective of this recommendation and have taken steps to enhance the oversight capabilities of the NIH's Division of Extramural Invention Reports (DEIR) to ensure grantees' compliance with the reporting requirements of 37 C.F.R. § 401. DEIR is developing a new computer system that will augment its ability to determine compliance with reporting requirements.

This system will allow grantees to transmit reports electronically, thereby increasing the timeliness and accuracy of the reports while reducing paper transactions. Electronic transmittal will also improve the accessibility of the data in a form readily available for analysis and reports. The improved database will facilitate follow-up actions on invention disclosures to determine if subsequent patents contain appropriate clauses to protect Government rights, as well as information on waivers, licensing and utilization. Finally, electronic reporting will be much more cost effective for both the recipient and the Government, a goal of the Act. It is expected that this electronic transfer mechanism will become operational in Fiscal Year 1995.

The DEIR also intends to coordinate, with the Association of University Technology Managers (AUTM), the exchange of information of mutual interest on technology transfer. For example, the AUTM Licensing Survey, which is updated each year, provides the most recent statistics on licensing activities from universities, hospitals, research institutes, government agencies, and third-party patent management firms. It reports on discoveries or inventions that have been licensed within the past 10 years and are currently on the market generating sales. It covers such topics as sponsored funding amounts, licensing activity, gross royalties received, and statistics on invention disclosures and patent filings.

The AUTM is conducting a follow-up survey entitled "AUTM Public Benefits Survey." A summary report, developed from survey data, will identify concrete examples demonstrating that U.S. institutions are carrying out the mandate, and achieving the goals of the Act.

OIG Recommendation

3. **Develop procedures to obtain from the USPTO [United States Patent and Trademark Office] information on patents issued to NIH grantees. The DEIR should determine whether such patented inventions were supported by NIH funds.**

PHS Comment

We concur with this recommendation if OIG envisions NIH developing the capacity to obtain USPTO information on patents to NIH grantees and, in cases where Government support is acknowledged, cross-check DEIR records with USPTO information on disclosure and subsequent reporting on waivers, licensing and utilization. Such a process may assist in identifying patents that had not been properly disclosed in the first place. In the long-term, NIH can develop such a capacity.

However, we do not concur with this recommendation if it suggests an identification of patents to organizations in cases where there has been no acknowledgement of Government support. This implies that NIH would identify patents issued to organizations that happen to be recipients of NIH funds and confirm whether NIH may have supported the development of the activity. This is a far more complex undertaking than matching database records between the USPTO and NIH. To begin with, it would require a cross-walk between data elements in the patent and in NIH databases. In the event of matches, there would need to be a determination by NIH program staff that a close enough fit exists to suggest that the patent may have been developed under NIH support. There would then need to be an inquiry to the organization, various analyses, and a final determination.

Implementation of a process like that just described would result in an enormous burden that we believe would show little gain in compliance, and not be consistent with the Act.