DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

JUL 8 1994

Memorandum

Date

From June Gibbs Brown
Inspector General

Subject Follow-up Review of Public Health Service Controls Over Technology Transfers and Royalty Income (A-01-94-01502)

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

The attached final report presents the results of the subject review. The objective of our review was to determine if corrective actions were taken by the Public Health Service (PHS) through its National Institutes of Health (NIH) with regard to the recommendations contained in our March 1992 report. The NIH Office of Technology Transfer has implemented five of the six recommendations from our prior report. The remaining recommendation, dealing with the Department of Commerce's National Technical Information Service's (NTIS) licensing and marketing functions, is no longer applicable. The NIH now performs all licensing and marketing functions for PHS and no longer needs to monitor NTIS. As a result, the Office of Inspector General (OIG), Office of Audit Services has no additional recommendations related to the subject review.

On March 4, 1992, OIG issued a report (prior report) to the Assistant Secretary for Health entitled, "Review of Public Health Service Controls Over Technology Transfers and Royalty Income" (A-01-90-01502). The objective of that review was to evaluate the adequacy of PHS' controls over technology transfer activities. The Stevenson-Wydler Technology Innovation Act of 1980 (Act) made technology transfer a mission of all Federal agencies conducting research. The intent of the Act was to assure that the results of Government conducted research are made available to the commercial sector through patenting and licensing of inventions and, thereby, contribute to the United States' competitiveness in the world marketplace.

Our prior report recommended that PHS: (1) centralize the technology transfer function for all PHS agencies; (2) establish priorities and milestones to complete a reconciliation of patents; (3) establish procedures and systems to monitor NTIS' compliance with the memorandum of understanding; (4) establish adequate procedures to ensure that valuable foreign patent rights are obtained and filed in a timely manner; (5) disclose in the Fiscal Year (FY) 1992 Federal Managers' Financial Integrity Act (FMFIA) Report that there were internal control weaknesses in the technology transfer and royalty income areas which constitute material weaknesses and include corrective actions that have been taken, are underway, or planned; and (6) conduct a detailed internal control review of technology transfer activities.

Our follow-up review disclosed that PHS has implemented five of the recommendations in our prior report. Specifically, PHS has: (1) centralized the technology transfer function by designating the NIH as lead agency for the Federal Technology Transfer Act of 1986 in the PHS, effective June 7, 1994; (2) established procedures to ensure that valuable foreign patent rights are obtained and filed in a timely manner; (3) completed a reconciliation of patent applications; (4) declared a material weakness in the FY 1993 FMFIA Report; and (5) conducted a detailed internal control review of technology transfer activities.

As stated above, the remaining recommendation is no longer needed because the NIH now performs all licensing and marketing functions for PHS and no longer needs to monitor the NTIS. Since our review determined that PHS took appropriate corrective actions and that we have no additional recommendations to make, we decided to issue this report directly as a final report.

If you or your staff wish to discuss the issues raised by our report, please call me or have your staff contact Michael R. Hill, Assistant Inspector General for Public Health Service Audits, at (301) 443-3582.

To facilitate identification, please refer to Common Identification Number A-01-94-01502 in all correspondence relating to this report.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

FOLLOW-UP REVIEW OF PUBLIC HEALTH SERVICE CONTROLS OVER TECHNOLOGY TRANSFERS AND ROYALTY INCOME

JUNE GIBBS BROWN
Inspector General

JULY 1994
A-01-94-01502

Memorandum

Date JUL 8 1994

From June Gibbs Brown
Inspector General

Subject Follow-up Review of Public Health Service Controls Over Technology Transfers and Royalty Income (A-01-94-01502)

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

This report presents the results of our follow-up review of the March 1992 Office of Inspector General (OIG) report entitled, "Review of Public Health Service Controls Over Technology Transfers and Royalty Income" (A-01-90-01502). The objective of our review was to determine if corrective actions were taken by the Public Health Service (PHS) through its National Institutes of Health (NIH) with regard to the six recommendations contained in our March 1992 report. The NIH Office of Technology Transfer (OTT) has implemented five of the six recommendations from our prior report. The remaining recommendation, dealing with the Department of Commerce's National Technical Information Service's (NTIS) licensing and marketing functions, is no longer applicable. The NIH now performs all licensing and marketing functions for PHS and no longer needs to monitor NTIS. As a result, the OIG, Office of Audit Services (OAS) has no additional recommendations related to the subject review.

Background

To help contribute to the competitiveness of the United States (U.S.) in the world marketplace, Congress passed the Stevenson-Wydler Technology Innovation Act (Act) of 1980. The Act made technology transfer a mission of all Federal agencies that conduct research. The intent of the Act was to ensure that the results of Government-conducted research are made available to the commercial sector through patenting of Government inventions and licensing of patent rights to U.S. industry. At NIH, OTT is responsible for administering technology transfer.

On March 4, 1992, OIG issued a report (A-01-90-01502) to the Assistant Secretary for Health on the results of our review of PHS controls over technology transfers and royalty income. The objective of the review was to evaluate the adequacy of PHS controls over the transfer of technology and the maximization of royalty income. The review focused primarily on one PHS agency, NIH, which accounted for about

85 percent of PHS' technology that was transferred to NTIS for licensing and commercialization. For the purpose of that audit, we reviewed the significant internal controls relating to: (1) the NIH management systems for accounting for inventions and tracking the transfer of technologies; (2) the monitoring of NTIS performance; and (3) the timely filing and preservation of foreign patent rights.

Scope

We conducted this review in accordance with generally accepted government auditing standards. The objective of our review was to determine if corrective actions were taken by NIH with regard to the recommendations contained in our March 1992 report.

To accomplish our objective, we: (1) held meetings with OTT, NIH's Office of Management Assessment (formerly the Division of Management Policy), PHS' Internal Control Office, and the PHS Audit Liaison Office; (2) reviewed PHS' draft Material Weaknesses Corrective Action Plan, dated November 1, 1993; (3) obtained and reviewed OTT policies and procedures pertaining to foreign filing; (4) obtained and reviewed the Fiscal Year (FY) 1993 Federal Managers' Financial Integrity Act (FMFIA) Report; and (5) obtained and reviewed the May 1993 NIH Division of Management Policy Internal Control Report on OTT.

We conducted our field work during December 1993 and January 1994 at PHS offices in Rockville, Maryland and at OIG Regional Office in Boston, Massachusetts. We also held a preliminary exit conference with PHS officials on May 6, 1994, to discuss our finding and recommendation. After that exit conference, PHS officials also provided us with a copy of the June 7, 1994 memorandum from the Assistant Secretary for Health which officially designated the NIH as lead agency for implementing the Federal Technology Transfer Act of 1986 in the PHS.

Results of Prior Review

The prior review disclosed that PHS and its NIH:

(1) did not have controls in place to provide an adequate accounting of the status of its patents;

(2) did not have adequate procedures to ensure that technology, once transferred to the private sector, was developed, commercialized, and NIH received its proper share of royalty income. As part of its memorandum of understanding (MOU) with PHS, NTIS was to monitor licensees' product development, provide NIH and other applicable PHS agencies with copies of licensee progress reports and conduct verification of licensees'

product sales. We found that NTIS was not performing these tasks; and

(3) did not have adequate procedures to ensure timely decisions and proper coordination for filing foreign patent rights. Specifically, we found 49 inventions where the Government's options to file for the foreign patent rights expired or were lost due to early public disclosure.

The report recommended that PHS:

(1) centralize, within OTT, the technology transfer function for all PHS agencies;

(2) establish priorities and milestones with all parties to complete the reconciliation of 1,732 patents to ensure that valuable patents are accounted for and made available for marketing and that abandoned patents, if valuable, are revived in an expedient manner. (FOLLOW-UP NOTE: Subsequent to the original audit, we were provided with documentation showing that not all the 1,732 items in the data base were patents. The items included employee invention reports, grants, inventions which came from outside of NIH, and patent applications which were deliberately not pursued because succeeding applications superseded older applications);

(3) establish procedures and systems to monitor NTIS compliance with the MOU to ensure against nonperforming licensees and understatement of royalty sales;

(4) establish adequate procedures to ensure that valuable foreign patent rights are obtained and filed in a timely manner;

(5) disclose in the FY 1992 FMFIA Report that there were internal control weaknesses in the technology transfer and royalty income areas which constitute material weaknesses and include corrective actions that have been taken, are underway, or planned; and

(6) conduct a detailed internal control review during FY 1992, to assure that the weaknesses disclosed in the report have been corrected.

The OIG recommended that PHS take the above corrective actions to ensure that technology is transferred to the private sector in an efficient and effective manner as

intended by Congress and that royalty opportunities are not needlessly lost. The PHS generally concurred with our recommendations and indicated that corrective actions will be completed by June 30, 1994.

Results of Audit

We found that PHS has taken appropriate corrective actions on five of the six recommendations from our prior report. The remaining recommendation, pertaining to procedures for monitoring NTIS compliance with the MOU, is no longer applicable. The NIH now performs all licensing and marketing functions for PHS and no longer needs to monitor the NTIS. Specifically, PHS has: (1) centralized the technology transfer function by designating NIH as lead agency for the Federal Technology Transfer Act of 1986 in PHS, effective June 7, 1994; (2) established procedures to ensure that valuable foreign patent rights are obtained and filed in a timely manner; (3) completed a reconciliation of patent applications; (4) declared a material weakness in the FY 1993 FMFIA Report; and (5) conducted a detailed internal control review of technology transfer activities. As a result, OIG/OAS has no additional recommendations related to the subject review.

The remaining recommendation, dealing with NTIS licensing and marketing functions, is no longer applicable. We had recommended that PHS develop procedures to monitor NTIS' compliance with the MOU to ensure against nonperforming licensees and understatement of royalty sales. On December 17, 1993, OTT formally advised NTIS that, effective February 1, 1994, OTT will perform all marketing and licensing functions for PHS cases and will not need NTIS marketing and licensing services beyond that date. As of June 30, 1994, NIH will complete the transition of all patent, licensing, and license administration functions, including foreign filings. As a result, we believe that procedures for monitoring NTIS are no longer necessary.

See the APPENDIX for details regarding each recommendation in the prior report as well as auditee comments along with actions taken and current status.

If you or your staff wish to discuss the issues raised by our report, please call me or have your staff contact Michael R. Hill, Assistant Inspector General for Public Health Service Audits, at (301) 443-3582.

To facilitate identification, please refer to Common Identification Number A-01-94-01502 in all correspondence relating to this report.

APPENDIX

PRIOR RECOMMENDATION **Centralize, within OTT, the technology transfer function for all PHS agencies.**

Our March 1992 report disclosed that NIH maintained a decentralized and informal record keeping system and did not assign responsibility for complete accountability of patents.

Auditee Position

The PHS officials concurred with our recommendation that the technology transfer function should be centralized.

Action Taken and Current Status

During our current review, PHS centralized the technology transfer function by designating the NIH as lead agency for the Federal Technology Transfer Act of 1986 in the PHS, effective June 7, 1994.

PRIOR RECOMMENDATION **Establish priorities and milestones with all parties to complete the reconciliation of 1,732 patents to ensure that valuable patents are accounted for and made available for marketing and that abandoned patents, if valuable, are revived in an expedient manner.**

Our March 1992 report disclosed that NIH did not have controls in place to provide an adequate accounting of the status of its patents.

FOLLOW-UP NOTE: Subsequent to the original audit, we were provided with documentation showing that the 1,732 items in the data base provided to OIG included employee invention reports, grants, inventions which came from outside of NIH, and patent applications which were deliberately not pursued due to newer patent applications.

Auditee Position

The PHS officials concurred with our recommendation that they perform a reconciliation of all patents.

Action Taken and Current Status

The OTT performed a patent reconciliation in the summer of 1993 which identified eight patents that were not transferred to NTIS for Federal Register publication. The OTT completed another reconciliation by manually comparing every record in

OTT's data base with every record in DOC's data base. This reconciliation showed that all patent applications were advertised in the Federal Register.

PRIOR RECOMMENDATION **Establish procedures and systems to monitor NTIS compliance with the MOU to ensure against nonperforming licensees and understatement of royalty sales.**

As part of its MOU with PHS, NTIS was required to monitor licensee product development, provide NIH and other applicable PHS agencies with copies of licensee progress reports and conduct verification of licensees' product sales. Our March 1992 report disclosed that NTIS was not performing these tasks. Further, neither PHS nor NIH had procedures to monitor NTIS performance. As a result, PHS and NIH did not know whether the licensees were developing and commercializing technology as planned, or reporting accurate sales and appropriate royalties.

Auditee Position

The PHS originally did not concur with this recommendation. Because the DOC has legal custody of the patents licensed by its subagency, NTIS, PHS believed that DOC should be responsible for the administration of its own licensing program. Despite their original nonconcurrence, the Material Weaknesses Corrective Action Plan includes steps to address the monitoring of NTIS.

Action Taken and Current Status

On December 17, 1993, OTT issued a memorandum formally advising NTIS that as of February 1, 1994, OTT will perform all marketing and licensing functions for PHS cases and will not need NTIS marketing and licensing services beyond that date. We were also advised that OTT will assume foreign filing responsibilities by June 30, 1994.

Additional OIG Comments:

Procedures for monitoring NTIS compliance with the MOU are no longer applicable.

PRIOR RECOMMENDATION **Establish adequate procedures to ensure that valuable foreign patent rights are obtained and filed in a timely manner.**

Our March 1992 report disclosed that NIH did not have adequate procedures to ensure that valuable foreign patent rights were obtained prior to established deadlines or publication and other disclosures. We found 49 inventions where the Government's options to file for the foreign patent rights expired or were lost due to early public disclosure.

Auditee Position

The PHS concurred with this recommendation and stated that procedures for accomplishing this goal had already been implemented.

Action Taken and Current Status

The OTT has developed procedures to take foreign rights at the time of filing patents in the United States. These policies were adopted by NIH/CDC Patent Policy Board on September 24, 1990. The OTT has also developed procedures to ensure that foreign filing status data is given to OTT by NTIS. Further, procedures were developed to remind responsible PHS scientists and officials of approaching decisions. The OTT is also in the process of implementing the Invention Tracking System foreign filing module.

PRIOR RECOMMENDATION **Disclose in the FY 1992 FMFIA Report that there were internal control weaknesses in the technology transfer and royalty income areas which constitute material weaknesses and include corrective actions that have been taken, are underway, or planned.**

Our March 1992 report states that the internal control weaknesses, at the time of our field work, met the Office of Management and Budget criteria for material weaknesses under FMFIA. In this regard, these weaknesses could have: (1) adversely impacted the agency's mission of promoting the transfer of technology needed to maintain this country's world competitiveness; (2) resulted in significant royalty losses; and (3) merited the attention of senior departmental and congressional officials.

Auditee Position

The PHS agreed to declare a material weakness in the technology transfer area after the Division of Management Policy's internal review of OTT concluded that all OIG recommendations should be implemented.

Action Taken And Current Status

The PHS declared a material weakness in the Department of Health and Human Services 1993 FMFIA Report.

PRIOR RECOMMENDATION **Conduct a detailed internal control review of the Office of Technology Transfer**

Auditee Position

The PHS agreed to perform an internal control review of technology transfer activities.

Action Taken and Current Status

The NIH Division of Management Policy completed a review of internal controls between September 1992 and March 1993 and issued a report in May 1993. The internal control report stated that PHS should completely implement all recommendations in OIG's audit report.