DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Memorandum

Date MAR 4 1992

From Richard P. Kusserow
Inspector General

Subject Review of Public Health Service Controls Over Technology Transfers and Royalty Income (A-01-90-01502)

To James 0. Mason, M.D., Dr. P.H.
Assistant Secretary
for Health

Attached is our final report entitled, "Review of Public Health Service Controls Over Technology Transfers and Royalty Income." Our review disclosed that the Public Health Service (PHS) and its National Institutes of Health (NIH) did not have adequate: (1) accounting of the status of its patents; (2) procedures to ensure that technology, once transferred to the private sector, was developed, commercialized and receiving its proper share of royalty income; and (3) procedures to ensure timely decisions and proper coordination for filing of foreign patent rights. We believe that these were internal control weaknesses which met the criteria specified by the Office of Management and Budget for material weaknesses under the Federal Managers' Financial Integrity Act (FMFIA), Public Law 97-255. The PHS had not reported these material weaknesses under the FMFIA.

We recommended that PHS take the necessary 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. We also recommended that PHS disclose in its Fiscal Year (FY) 1991 FMFIA report that there were internal control weaknesses and include corrective actions that have been taken, are underway or planned. The PHS in response to our draft report, stated that improvements and innovations have been made which have significantly changed the management and oversight of the technology transfer program and corrected the material internal control weaknesses. According to PHS, it did not include this matter in its FY 1991 FMFIA report. Because the FMFIA legislation requires that material weaknesses be disclosed in these reports, we believe that PHS should report this matter in its FY 1992 FMFIA report. Also, the Department of Health and Human Services requires that a review must be conducted within 1 year after material weaknesses are reported as being corrected. The PHS stated that they will perform a previously scheduled internal control review of this programmatic area in FY 1992.

We would appreciate being advised within 60 days of any actions taken or planned on each recommendation. If you have any questions, please contact me or your staff may call Daniel W. Blades, Assistant Inspector General for Public Health Services Audits, at (FTS)443-3583.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

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

The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed, as well as other conclusions and recommendations in this report, represent the findings and opinions of the HHS/OIG Office of Audit Services. Final determination on these matters will be made by authorized officials of the HHS operating divisions.

Richard P. Kusserow
INSPECTOR GENERAL

A-01-90-01502

SUMMARY

Our review disclosed that the Public Health Service (PHS) and its National Institutes of Health (NIH) did not have adequate: (1) accounting of the status of its patents: (2) procedures to ensure that technology, once transferred to the private sector, was developed, commercialized and receiving its proper share of royalty income: and (3) procedures to ensure timely decisions and proper coordination for filing of foreign patent rights.

We believe that these were internal control weaknesses which met the criteria specified by the Office of Management and Budget (OMB) for material weaknesses under the Federal Managers' Financial Integrity Act (FMFIA), Public Law 97-255. The PHS had not reported these material weaknesses under the FMFIA. These weaknesses, at the time, could have: (1) adversely impacted the agency's mission of promoting the transfer of technology needed to maintain this country's competitiveness; (2) resulted in significant royalty losses: and (3) merited the attention of senior departmental and congressional officials.

The intent of the Stevenson-Wydler Technology Innovation Act of 1980 was to assure that the results of Government conducted research become available to the commercial sector and, thereby, contribute to United States (U.S.) competitiveness in the world marketplace. The Federal Technology Transfer Act of 1986 (FTTA) amended the Stevenson-Wydler Technology Innovation Act of 1980 by providing for collaborative research by Federal laboratories and incentives for Federal employees to promote the transfer of technology through the sharing of royalty income.

The objective of our review was to evaluate the adequacy of PHS controls over the transfer of technology and the maximization of royalty income. Our review focused primarily on NIH since it accounts for about 85 percent of the PHS technology transferred to the Department of Commerce's (DOC) National Technical Information Service (NTIS) for licensing and commercialization.

Our review disclosed that:

-- The NIH was not aware that over 1,000 or 60 percent of its patents had not been transferred to NTIS for commercialization and in effect had been abandoned. This was the result of NIH maintaining a decentralized and informal record keeping system and not assigning responsibility for complete accountability of patents. In September 1990, NIH began to account for all patents. Until NIH completes this process, technologies on which significant Government funds were expended for research and patent application remain lost and unavailable to the general public. Further,

inventors are not provided with an opportunity to earn royalty income as an incentive to further their scientific research efforts.

-- Neither the PHS nor its NIH had procedures to monitor NTIS performance and to enforce compliance with PHS' Memorandum of Understanding (MOU) with NTIS. We found that NTIS did not: (1) monitor licensee product development: (2) provide NIH with copies of licensee progress reports; and (3) conduct verification of licensee product sales. As a result, PHS and NIH did not know whether licensees were developing and commercializing technology as planned or reporting accurate sales and appropriate royalties. The royalty income was intended under the FTTA as an incentive to scientists to increase the number of inventions, thus promoting the transfer of technology to help maintain this country's world competitiveness.

-- The existing NIH system did not ensure that valuable foreign patent rights were protected prior to established deadlines. The value of patentable inventions may be materially diminished as a result of lost foreign rights. This weakness contributes to making U.S. firms less competitive in the world marketplace.

-- The PHS has not conducted internal control reviews under FMFIA for technology transfers and royalty income.

During our review, the NIH started corrective actions on the above internal control weaknesses. These corrective actions include: the acquisition of a patent docketing system to account for patents: the input of Patent Branch files into the new docketing system; the proposed transfer of the Patent Branch from the Office of General Counsel (OGC) to NIH's Office of Technology Transfer: the implementation of new procedures for foreign patent rights; efforts to establish an electronic bulletin board containing PHS inventions: and the services of a consultant to review and establish Patent Branch procedures.

The Office of Inspector General (OIG) recommended that PHS take the necessary 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. We also recommended that PHS disclose in the Fiscal Year (FY) 1991 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. The PHS should also conduct a detailed internal control review during

FY 1992, to assure that these material weaknesses have been corrected. The PHS generally concurred with the OIG recommendations and indicated they have taken or are taking actions to implement them. The PHS comments, dated October 25, 1991, have been incorporated in the Agency Comments and OIG Response section of this report and are included in the Appendix.

The PHS did not agree that there are material internal control weaknesses in this program. According to PHS, improvements and innovations have been made which have significantly changed the management and oversight of the technology transfer program and corrected the material internal control weaknesses. Because the FMFIA legislation requires that material weaknesses be disclosed in these reports, we believe that PHS should report this matter in its FY 1992 FMFIA report. The PHS stated that it will perform a previously scheduled internal control review of this programmatic area in FY 1992.

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INTRODUCTION

Our review concentrated on NIH, the largest of PHS' eight agencies. We devoted our audit efforts to NIH's process of transferring the results of Government conducted research to the commercial sector for development and commercialization. The objective of our review was to evaluate the adequacy of controls over the transfer of technology and the maximization of royalty income. We covered existing patents during the period from December 1989 through December 1990.

BACKGROUND

The Stevenson-Wydler Technology Innovation Act of 1980 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 U.S. competitiveness in the world marketplace. The FTTA amended the Stevenson-Wydler Technology Innovation Act of 1980 by delegating authority to laboratory directors to enter into cooperative research agreements with private firms. The FTTA also provided an incentive for Federal laboratories and employees to promote the transfer of technology through the sharing of royalties arising from licensed inventions.

The transfer of technology from Government laboratories to the private sector is an involved process requiring patent protection, a license with a private firm for commercial development, and the cooperation and coordination of several Government entities. The patent is a property right awarded by the Government, whereby, in exchange for the inventor's complete disclosure of the invention, the Government grants the right to exclude others from making, using or selling the invention for a period of 17 years. Under international treaty, foreign patent rights provide protection against foreign infringement and must be filed within one year from the date of U.S. patent filing. The license is a legal agreement used to transfer the right to make, use or sell a product or process to the licensee in exchange for royalties.

The cooperation and coordination of the Government entities starts with the Government researcher/inventor who is responsible for preparing an invention report. The PHS agency forwards the invention report to the Department of Health and Human Services (HHS), OGC, Patent Branch, for patent application. The patent application process includes a determination of patentability, drafting technical documents, and filing the U.S. patent application with the DOC's Patent and Trademark Office. Once the U.S. patent application is filed, HHS' OGC Patent Branch transfers a copy of the patent filing to DOC's NTIS for licensing and commercialization.

In 1988, the NIH established the Office of Technology Transfer (OTT) within the Office of Intramural Affairs and the Institute Technology Development Coordinator (TDC) position to facilitate and coordinate the technology transfer process. The PHS has a MOU with NTIS. Under the MOU, NTIS is responsible for: (1) marketing and licensing of PHS intramural inventions: (2) licensee compliance with product development and commercialization plans; (3) the verification of product sales: and (4) filing for foreign patent rights. In return, PHS provides payment to NTIS for work performed.

Within PHS, intramural research is performed primarily at the NIH, the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA), the Food and Drug Administration (FDA) and the Centers for Disease Control (CDC). The NIH has an agreement to manage the technology transfer process for ADAMHA and CDC. The FY 1989 PHS budget for intramural research was $967 million, with NIH totaling $777 million. The NIH is the Federal focal point for health research and conducts intramural research in over 200 laboratories within 12 institutes.

As of December 31, 1989, PHS had accounted for 540 patents and patent filings with 184 active license agreements which generated royalty income of $4.8 million in FY 1989. Two examples of technologies developed in NIH laboratories, which have been patented and licensed, are a test kit to detect Acquired Immunodeficiency Syndrome (AIDS) infected blood and a method for the development of an AIDS vaccine.

SCOPE OF REVIEW

Our review was made in accordance with generally accepted Government auditing standards. The objective of our review was to evaluate the adequacy of PHS controls over the transfer of technology and the maximization of related royalty income. Our review focused primarily on NIH since it is the PHS agency which accounts for about 85 percent of the technology transferred to NTIS for licensing and commercialization. Our review primarily covered existing patents during the period from December 1989 to December 1990. However, selected audit procedures covered some patents prior to this period.

As part of our examination, we made a study and evaluation of NIH's internal control structure to the extent we considered necessary to evaluate the structure as required by standards for governmental audits. For the purpose of this audit, we reviewed the significant internal controls related to the technology transfer process. These include: NIH management systems for accounting for inventions and tracking the transfer of technologies; monitoring of NTIS performance: and the timely filing and preservation of foreign patent rights.

To accomplish our audit objective we reviewed:

- -- applicable statutes and regulations:
- -- applicable policies, procedures and guidelines at NIH, ADAMHA, CDC and FDA;
- -- information systems used to account for the status of transferred technology at OTT and the institutes; and
- -- selected records at eight NIH institutes,[1] the OTT, the Patent Branch and the NTIS.

In addition, we interviewed officials from the NIH, ADAMHA, FDA, CDC, Patent Branch and the NTIS.

We were unable to obtain a reliable universe of patentable technology available for commercialization due to the absence of a management system at PHS or the NIH. Accordingly, we performed sufficient audit tests under the circumstances to evaluate the effectiveness of the internal controls mentioned above without being able to fully quantify the potential effect of disclosed weaknesses. With respect to foreign patent rights, we performed a limited review and did not perform independent verification of publication dates or institute decisions to seek foreign patent protection. We relied on available summary schedules and corroborating verbal evidence from responsible NIH institute, OTT, Patent Branch and NTIS officials.

Our review was conducted at the NIH campus in Bethesda, Maryland; the OTT in Rockville, Maryland: the NTIS in Springfield, Virginia and the OIG's Boston Regional Office between January and December 1990. We discussed the preliminary results of our review in April 1990 with NIH officials and provided an early alert memorandum in October 1990. Subsequently, we reviewed corrective actions taken in response to our early alert and conducted an exit conference with NIH on April 1, 1991. On August 2, 1991, we provided PHS officials with a draft report for their comment. Their written response, dated October 25, 1991, has been appended to this report (See Appendix). The PHS' relevant comments are also summarized in the Agency Comments and OIG Response section of this report.

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[1] The eight NIH institutes are: (1) National Cancer Institute; (2) National Institute of Allergy and Infectious Diseases; (3) National Institute of Dental Research; (4) National Institute of Diabetes and Digestive and Kidney Diseases: (5) National Institute of Environmental Health Sciences; (6) National Eye Institute: (7) National Heart, Lung and Blood Institute; and (8) National Institute of Neurological Disorders and Stroke.

FINDINGS AND RECOMMENDATIONS

Since the enactment of the FTTA, the NIH has established the OTT and the institute TDCs to manage the anticipated increase in inventions from intramural research. However, our review disclosed that material internal control weaknesses existed at the time of our review in the technology transfer process. We found that PHS and its NIH did not have an adequate management information system to track or monitor inventions from development through patent application to licensing, commercialization and collection of royalties. Specifically, we found that NIH did not have adequate: (1) accounting of the status of its patents: (2) procedures to ensure that technology, once transferred, was developed, commercialized and receiving its proper share of royalty income; and (3) procedures to ensure timely decisions and proper coordination for filing of foreign patent rights.

During our review, the NIH started corrective actions on the above. These corrective actions included the acquisition of a patent docketing system to account for its patents: the input of Patent Branch files into the new docketing system; the proposed transfer of the Patent Branch from the OGC to NIH's OTT: the implementation of new procedures for foreign patent rights; efforts to establish an electronic bulletin board containing PHS inventions; and, the services of a consultant to review and establish Patent Branch procedures. However, we determined that additional corrective actions are still necessary.

ACCOUNTING FOR INVENTIONS

We found that NIH did not have controls in place to provide an adequate accounting of the status of all patents. Specifically, at the start of our review, NIH maintained a decentralized and informal record keeping system and did not assign overall responsibility for complete accountability of patents. As a result, NIH was not aware that approximately 1,000 or 60 percent of its patents had not been transferred to NTIS for commercialization. During September 1990, the OTT started a process to account for the status of all patents. However, until OTT completes the process of full accountability, technologies on which significant Government funds were expended for research and patent application remain lost and unavailable to the general public. Accordingly, the NIH has not fully complied with the intent of the Stevenson-Wydler Technology Innovation Act of 1980 and the FTTA which is to transfer technology to the private sector for development and commercialization and provide technology transfer incentives to researchers through royalty opportunities.

At the start of our review, NIH's OTT was aware of only 540 inventions which had been transferred to NTIS for

commercialization. The OTT was not aware of approximately 1,000 additional inventions for which the NIH had applied for U.S. patents. Since there was no accountability, these additional 1,000 inventions had not been transferred to NTIS.

Prior to the establishment of OTT and the institute TDCs in 1988, invention information, if any, was kept with the researchers at the numerous laboratories and institutes. At that time, individual researchers dealt directly with the Patent Branch, its contract law firms and NTIS. We were informed that many researchers preferred to conduct research and did not always have the time or inclination to follow the progress on patenting of their inventions. The Patent Branch was responsible for arranging for the patent applications, filing of U.S. patent applications by contract law firms and for submitting through its contract law firms a notice of patent filing to NTIS. However, there was no assurance that a notice of a patent filing was submitted in all cases by the contracted law firm to NTIS to initiate marketing activity. Nor was there adequate monitoring at NIH to ensure that NTIS received notice of all patent filings.

In 1988, the NIH established the OTT (formerly the Office of Invention Development) and the institute TDCs. The OTT centrally coordinates invention development and facilitates technology transfer activities for NIH and other PHS agencies under agreement (ADAMHA and CDC). The OTT's major responsibilities include the development of patent procedures and management of the Patent Branch. The OTT is also responsible for coordinating a comprehensive data management system which is utilized as a central repository for all PHS invention reports, with status information on U.S. patent applications, foreign filings, research agreements, licenses and royalties. The TDCs serve as coordinators for technology transfer within each institute. The TDCs maintain the institutes' technology transfer records and files, assure compliance with transfer policies and procedures and work with OTT, NTIS and the inventor regarding patenting and licensing matters.

Since the establishment of the OTT and the TDCs in 1988, accounting for patents was done individually by the TDCs and the OTT. The information was maintained by each group without the necessary checks and balances or controls to track and monitor numerous inventions through the technology transfer process. Further, this information, was only maintained on a prospective basis from the time the TDC position and OTT was established in 1988. Information on inventions or patent properties that existed prior to and during part of 1988 was incorporated into the current records only if that invention came up for discussion.

In 1989, one institute TDC performed a reconciliation in an attempt to account for the status of inventions for 1 of its 67

laboratories. This institute's technology coordinator compared its records with records maintained by inventors, Patent Branch, OTT and NTIS. The reconciliation showed that 15 of the 76 inventions for this laboratory during the period 1984-1988 had not been transferred to NTIS as intended. Another three were noted as abandoned without any explanation. The technology coordinator also performed reconciliations for two of its researchers who requested a status and inventory of their inventions. These two reconciliations showed that 9 out of a total of 28 patent filings had not been received by NTIS. Two of the nine not received by NTIS occurred during 1989 after the establishment of the OTT and the technology coordinator. Another five were noted as abandoned without any explanation.

These reconciliations were a time consuming exercise due to poor record keeping by the Patent Branch. We found that important papers and documents were randomly dumped into case files, not in any logical order and not referenced to other related patents. Although the OTT and the institutes began to account for the status of current inventions *on* a prospective basis in 1988, the reconciliations show that current systems allowed some inventions with patent filings (at least two 1989 inventions) not to be transferred to NTIS.

In April 1990, we informed NIH officials of our tentative findings relative to the absence of accountability for patents including a potentially large number of cases that have not been transferred for commercialization. The NIH transmitted its procurement request for a docketing system in August 1989. Due to procurement delays, NIH did not acquire a new docketing system for entering all Patent Branch case file information until September 1990. The result was a data base containing 1,732 patents which was substantially greater than the number of patents reflected in either of the inventories maintained by OTT or NTIS. Using the August 1990 NTIS inventory listing of 717 patents, there is a substantial unreconciled difference of 1,015 patents. The OTT officials stated that the large number of unreconciled cases and patents not transferred for commercialization was greater than expected. As of December 1990, the OTT was still in the process of determining the status and potential for licensing and commercialization for these patents. According to PHS comments (See Appendix), this task has been completed.

The OTT officials have distributed the 1,732 cases to the various institutes and NTIS for their review and analysis. Discussions with NTIS officials indicate that patent applications less than 5 years old may have potential value. However, through December 1990, OTT had not established milestones or due dates for the various parties to complete the review and reconciliation of these cases.

Although our review focused primarily on NIH patents, NIH also has technology transfer responsibilities for ADAMHA and CDC. In addition, the FDA also conducts intramural research and utilizes the Patent Branch and NTIS to transfer technology to the private sector. The most efficient and effective means in accounting for the transfer of technology within PHS would be to centralize this function for all PHS agencies, including FDA, within the OTT.

DEVELOPMENT, COMMERCIALIZATION AND ROYALTY INCOME OF TRANSFERRED TECHNOLOGY

Our review of technology transferred to NTIS disclosed that PHS and NIH did not have adequate controls to monitor NTIS performance for ensuring that technology was properly developed, commercialized and receiving its proper share of royalties. As part of its MOU with PHS, NTIS is 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. Based on our limited review, we found 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. These weaknesses could result in potentially valuable technology not being commercialized and potential losses in royalty income. Thus, these weaknesses result in less incentives to Government researchers and have a possible negative impact on U.S. world competitiveness.

The PHS entered into a MOU with the NTIS to make the results of federally sponsored research available for the widest possible utilization in the shortest possible time. According to PHS, this could increase U.S. economic competitiveness and advance the objectives of the FTTA, including incentives to Government researchers. Under the MOU, NTIS is responsible for receipt and management of issued patents and patent applications for licensing, marketing inventions, negotiation of license agreements, reporting to PHS agencies, management and administration of licenses, and funds management and transfer to PHS agencies. In return, PHS is to provide payment to NTIS for work performed under the MOU, including direct salaries, support staff, other direct costs, overhead and the cost of foreign filings.

As part of the license agreement, the licensee is required to submit annual progress reports during the development phase to the NTIS. These reports contain progress information on the development of the licensed technology into a marketable product. The NTIS has the authority to terminate a license agreement if the licensee is not complying or does not develop the product within the agreed to market plan time frame. During the product development phase, a licensee is required to pay a negotiated

annual maintenance fee. Once a product is in production, the licensee is required to pay royalties based on a percentage of the product sales.

To determine if the NTIS was performing as required under its MOU with PHS and whether licensees were complying with the terms of their license agreements, we judgmentally selected 17 license agreements dated prior to 1987 for review at NTIS during April 1990. These examples were selected to evaluate whether licensees were developing and commercializing the technology in accordance with market plans which provide for product development periods between 2 and 5 years. Eight of the 17 license agreements related to licensees who either developed and commercialized the technology in accordance with market plans, or were identified to terminated or expired license agreements. However, we found that the remaining nine licensees were without a product after the development period stipulated in the license agreement and had not requested or received an extension. There was no evidence in the files for these nine licensees to indicate that NTIS tried to conduct discussions on the necessity to extend the product development period and related annual maintenance payments. In addition, these nine licensees did not submit all progress reports as required.

Two examples of the type of conditions we found are as follows:

-- One license dated July 3, 1986, stated that the licensee was to bring the invention to market within 2 years. We found no progress reports. The NTIS official stated that this licensee should have been cited for default in 1988 and the license agreement terminated so other licensees could be solicited. We found no evidence that the licensee had requested an extension or amended the license agreement to develop this product.

-- Another licensee agreement signed May 8, 1981, submitted no progress reports or annual maintenance payments since 1987. An NTIS official stated that the licensee was in default with its agreement which specified a 5-year development period. The NTIS should have terminated the license. There was no evidence of follow-up by NTIS to extend the development period and related annual maintenance payments.

The OTT was unaware of which progress reports had been received. The results of our testing show that neither PHS nor the NIH monitored the development or commercialization of its technologies once they had been transferred to NTIS.

Regarding verification of product sales, it should be noted that there were 34 license agreements with product sales from NIH inventions which generated $4.8 million in royalty income in FY 1989. All license agreements contain a provision for the audit and verification of product sales. In April 1990, NTIS officials informed us that they had never audited or verified sales to determine the appropriateness of reported royalties. Subsequently, NTIS requested DOC's OIG to perform an audit of royalty income on one licensee and its sublicensees. The DOC's OIG staff informed us that its audit disclosed approximately $692,000 of under reported royalties by the licensee and two of its sublicensees.

As of December 1990, OTT had not established procedures for monitoring NTIS performance under its MOU. The OTT planned to implement review procedures in FY 1991. In a December 13, 1990 memorandum, OTT stated that an additional staff person will be hired and assigned responsibility for tracking and reviewing progress reports. However, PHS in its comments to the draft report, stated that DOC has legal custody of the patent property licensed by NTIS. The PHS believes that DOC should be responsible for administration of its own licensing program and PHS expects to substantially discontinue the use of NTIS licensing services during FY 1992.

FOREIGN PATENT RIGHTS

Our review disclosed that NIH procedures were not adequate 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 option to file for the foreign patent rights had expired or the Government lost the foreign patent rights due to early public disclosure. As a result, the value of patentable inventions to licensees was materially diminished. Further, NIH was not maximizing potential royalty income in order to provide the incentives for Federal laboratories and employees as intended under the FTTA. This deficiency contributes to making U.S. firms less competitive in the world marketplace.

Foreign patent rights are necessary to provide protection against foreign infringement. Under international treaty, foreign patent rights are lost if foreign filings are not completed within 1 year from the date of U.S. patent filing. Foreign patent rights can also be lost if publication or other disclosure of an invention occurs before the U.S. patent application is filed. Further, Federal regulations require that the Government's intent to file for foreign patent rights must be communicated to the inventor within 6 months from the U.S. filing date. Otherwise, the Government's option to file for the foreign patent rights expires and the inventor obtains the right to file. The

Government's option to file for foreign patent rights after this 6-month period can be regained only if the employee/inventor agrees to waive the foreign patent rights.

As shown below, we determined that there were at least 49 instances involving eight institutes, during the period January 1985-May 1990, where NIH either let the option to file for foreign rights expire, or lost the foreign patent rights due to early public disclosure.

Failure to Obtain Foreign Patent Rights

Reason	No. of Instances
Option to file expired	39
Foreign rights lost due to public disclosure	10
Total	49

We limited our review primarily to the activity at three of the largest research institutes for the most recent 6 to 18 month period. These three institutes processed technology transfers for 67 inventions during this period and either lost the foreign patent rights or allowed them to expire for 14 inventions. In addition, we utilized a reconciliation performed by one of the three largest institutes which disclosed another 22 instances from 1985 to 1989. For the other institutes, discussions with the TDCs disclosed five instances of lost or expired foreign patent rights while our review of the log of foreign filings maintained by OTT disclosed another eight instances. However, without adequate procedures or processes, NIH has no assurance that additional instances did not exist at these eight institutes or other institutes during this same period.

Option to File Foreign Patent Rights Expired

We found 39 instances, involving five institutes, where the option to file foreign patent rights expired because the Government did not communicate its intent within 6 months from the U.S. patent filing date. The NIH subsequently recovered the foreign rights in 12 instances because inventors agreed to provide waivers and reassign foreign rights to the Government. However, these cases show that NIH did not maintain a management system designed to adequately control this process. While we do not know the value of the foreign rights NIH allowed to expire, the effect is not just monetary. The effects of smaller market shares on U.S. firms' willingness to develop and commercialize products must be considered. For example, we noted one instance where an American pharmaceutical firm with world-wide sales declined to complete negotiation for a license because the license did not include the foreign patent rights which were

owned by the inventors. This firm stated that it was economically not feasible for a U.S. firm to develop this drug unless it could be marketed on a world-wide basis. However, the inventors were planning to license the foreign rights exclusively to a Swiss firm. Accordingly, NIH not only lost potential royalty income but also the opportunity to contribute to this country's world competitiveness.

The OTT is responsible for coordinating decisions and the flow of information between the Patent Branch, the institutes and the NTIS regarding foreign patent filings. The institutes are responsible for the decision on whether to file for foreign patent rights. The OTT program analyst maintains a log of foreign filings. This log lists the inventor, the institute, subject, inventions number, date of U.S. filing and OTT reference number for all inventions within 6 months of U.S. filing. The log is used as the control point for notifying the institutes that a decision on foreign filing is needed. However, data essential to control the foreign filing process is not recorded in the OTT log. This essential data includes the date of: (1) receipt or notice of U.S. filing date: (2) certification for foreign filing sent to institutes; (3) scheduled response from institutes or date of OTT follow-up; (4) actual response from institutes; (5) notification to NTIS for authorization of foreign filing: and (6) notice by NTIS to inventor of intent to file for foreign patent rights.

Utilizing OTT and institute records, we were unable to determine whether OTT received notification of the U.S. filing date from OGC in a timely manner. We found instances where OTT sent certifications for foreign filings to the institutes within 1 week of the option expiration date, after the option expiration date, or certification inquiries were communicated by telephone with no formal records. One TDC stated that it was a common occurrence to receive notices of foreign certification within 1 week of the option expiration date. Further, we noted instances where the institute failed to respond in a timely manner when OTT provided adequate notice. In these instances, the OTT had no follow-up procedures to assure a timely response.

In September 1990, NIH adopted new foreign filing policies. Under these new procedures, the Patent Branch's contracted law firms are responsible for obtaining an assignment of foreign rights from the inventor at the time of the U.S. filing. This effectively does away with the 6-month option period and allows NIH a l-year period from the U.S. filing date to decide whether to file for foreign patent rights. The institute's Scientific Director must still make a decision by the 10th month whether to go forward with the filing of foreign rights. Once a decision is made to file for foreign rights, the OTT sends an authorization to NTIS to proceed with the foreign filing.

This system applies to all foreign filings as of October 1, 1990. We were unable to determine if any foreign rights have been lost under the new system since the l-year period to file for foreign rights was not up until September 30, 1991. However, our review of the new procedures disclosed that they could be improved. In this respect, the new procedures changed the timing but NIH did not have procedures to remind responsible individuals of approaching dates and to determine whether appropriate actions have taken place. This could be accomplished with the new docketing system by the inclusion of the following data fields: (1) date which the foreign patent rights assignment was obtained from inventors: (2) date that the certification for a foreign filing decision was forwarded to the Scientific Director: (3) date OTT receives the Scientific Director's foreign filing decision: and (4) date of actual foreign filing by NTIS. With these data fields, the docketing clerk could print reminder notices and verify whether appropriate actions have taken place.

Foreign Patent Rights Lost Due to Public Disclosure

The OTT and the institutes did not have adequate procedures to prevent publication or other disclosure prior to filing for U.S. patent rights. We found 10 instances involving six institutes where the foreign patent rights were lost due to publication or disclosures made prior to the U.S. filing date. While we do not know the value of the lost foreign rights, an institute official informed us that, in 1 of the 10 instances, NIH lost a $30 million foreign market or about $1.5 million in related royalty income (based on a 5-percent royalty rate). Further, the technology becomes available to foreign companies, thereby lessening this country's world competitiveness.

The NIH guidelines state that foreign patent rights are lost if inventions are published or otherwise disclosed prior to U.S. filing. Further, these guidelines, to allow sufficient time for the U.S filing, recommend that inventors provide 90-days notification prior to publication.

In 4 of the 10 instances where the foreign patent rights were lost due to early publication, the institutes knew that an invention report had been forwarded to the Patent Branch. However, institute officials did not confirm that the U.S. filing had actually taken place. In four other instances, the inventor received supervisory approval to publish prior to filing an invention report.

The institutes required approval prior to publishing or other public disclosures. However, the supervisors did not determine whether a patent was contemplated or confirm whether the U.S. filing had actually taken place. Accordingly, supervisors were not fully aware of the status of the foreign filing process at the time they provided approval for publication. As evidenced

above, institute procedures were not effective in preventing or justifying early publication or other disclosures.

Within the research environment there is great emphasis to publish the latest findings to maintain and/or achieve scientific stature. This type of environment creates a need for strong controls to assure that publication or other public disclosure related to patentable research does not take place prior to the U.S. filing date.

The NIH officials are examining cases to determine whether the foreign patent rights can be regained. We believe that NIH should continue these efforts. However, we do not believe that attempts to salvage foreign patent rights after early disclosures have been made should be the *only* control. This is not a prudent or efficient method to protect the Government's interest. Without an effective management control system, the opportunities for foreign patent protection are lost, accountability is lost and expedient corrective action becomes difficult. Foreign patent protection not only provides for increased royalty income but provides the protection and incentives to promote the transfer of technology needed to maintain this country's world competitiveness.

FEDERAL MANAGERS' FINANCIAL INTEGRITY ACT

We found that the material weaknesses we disclosed in our draft report, along with corrective actions that have been taken, are underway or planned were not reported under the FMFIA and PHS has not conducted internal control reviews under FMFIA for technology transfers and royalty income. However, in its FY 1990-1994 Management Control Plan (MCP), PHS has scheduled a review of patents, copyrights and royalty income in FY 1992. We noted that a risk rating, based on a risk assessment, has not been assigned to this planned FY 1992 review.

The FMFIA requires that Federal agencies periodically review their systems of internal control and to report annually on the status of these systems. This law requires that the reports disclose material internal control weaknesses and corrective actions taken or planned. The FMFIA reviews are to be made in accordance with the policies and procedures contained in OMB Circular A-123, Revised. In addition, each agency is required to develop a 5-year MCP to plan and direct the process for reviewing risk, and identifying and correcting material weaknesses in internal control systems. The HHS requires that a detailed internal control review must be conducted within 1 year after a material internal control weakness is reported as corrected.

CONCLUSIONS

The Stevenson-Wydler Technology Innovation Act of 1980 and the FTTA were enacted in response to increasing international competition to promote the transfer of technology from Federal laboratories to the private and public sectors for commercialization. According to the 1989 President's Economic Report, the Federal Government funds about $63 billion of this country's research. The anticipated return on investment will be in jobs, products and processes and the improvement in this nation's economic position. An efficient and effective transfer of this technology will enhance the rate of return.

The NIH has responded to the FTTA through: the establishment of the OTT and the TDCs; the purchase of a patent docketing system; the establishment of databases for its patents: transfer of the Patent Branch: the implementation of new transfer policies and procedures: and, increases in the number of inventions and research agreements with the private sector. However, PHS and NIH need to fully address the issues of accountability and internal controls.

In this respect, NIH needs to: (1) fully determine the status of all its patents and take appropriate actions to market those with potential commercial value: (2) develop an effective system to monitor the development and commercialization of transferred technology and product sales; and (3) develop an effective system to ensure that valuable foreign patent rights are protected prior to established deadlines.

Without accountability and adequate controls: technologies on which significant Government funds were expended for research and patent application remain lost and unavailable to the general public: licensees' have no incentive to comply with license terms and conditions or report a fair share of royalty income; and NIH is not maximizing royalty income through available foreign patent protection.

Accordingly, NIH has not fully complied with the intent of the Stevenson-Wydler Technology Innovation Act of 1980 and the FTTA which is to transfer technology to the private sector and provide technology transfer incentives to researchers through royalty opportunities. This income was intended under the FTTA as an incentive to NIH scientists to increase the number of inventions, thus, promoting the transfer of technology to help maintain this country's world competitiveness.

We believe that the internal control weaknesses, at the time of our field work, met the OMB criteria for material weaknesses under the 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. The PHS should disclose these material weaknesses in the FY 1991 FMFIA report and include corrective actions that have been taken, are underway or planned.

However, PHS in its response to our draft report (See Agency Comments and OIG Response section below) indicated that improvements and innovations have been made by the NIH which have significantly changed the management and oversight of the technology transfer program. According to PHS, it did not include this matter in its FY 1991 FMFIA report. Because the FMFIA legislation requires that material weaknesses be disclosed in these reports, we believe that PHS should report this matter in its FY 1992 FMFIA report. The PHS stated that it will perform a previously scheduled internal control review of this programmatic area in FY 1992. While we have not reviewed all the improvements, we believe that, if effectively implemented, these improvements should correct the material weaknesses which existed at the time of our field work.

RECOMMENDATIONS

We recommend that PHS:

- -- Centralize, within OTT, the technology transfer function for all PHS agencies.
- -- 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.
- -- Establish procedures and systems to monitor NTIS compliance with the MOU to ensure against nonperforming licensees and understatement of royalty sales.
- -- Establish adequate procedures to ensure that valuable foreign patent rights are obtained and filed in a timely manner.
- -- 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.

-- Conduct a detailed internal control review during FY 1992, to assure that the weaknesses disclosed in this report have been corrected.

AGENCY COMMENTS AND OIG RESPONSE

The PHS, in its October 25, 1991 letter commenting on our draft report, generally concurred with our recommendations and indicated it has implemented a continuing series of program innovations and improvements. These were: (1) OTT was given operational control of the Patent Branch and Secretary Sullivan officially reorganized the Patent Branch to become part of OTT on May 21, 1991; (2) PHS established new contracts for outside patent services, effective November 15, 1991, which will dramatically enhance the quality and timeliness of substantive case work: (3) OTT has completed its reconciliation of all patents and is testing a customized technology management system to provide improved docketing and status controls for patenting and licensing activities; (4) PHS implemented procedures to exercise its option to take foreign patent rights at the time that the U.S. patent is filed: and (5) in August 1991, the NIH Director approved an increased FY 1992 budget for OTT that will permit a major expansion of professional staff in the Patent and Technology Licensing Branches, and permit OTT to begin to conduct licensing and patenting either in-house or under more extensive case-by-case oversight.

The PHS' response is included as an Appendix to this report and certain responses are paraphrased in this section.

The PHS agreed that the technology transfer function for all PHS agencies within OTT should be centralized. For patenting, this was done as of November 1990 when the Patent Branch was moved off-campus together with OTT. On May 21, 1991, Secretary Sullivan officially recognized this reorganization of the Patent Branch. The PHS said that OTT will be negotiating updated inter-agency agreements with ADAMHA, CDC and FDA.

The PHS concurred with our recommendation to 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. The PHS said that in essence this task had already been completed.

The PHS did not agree with the OIG recommendation to establish procedures to monitor the performance of NTIS under its MOU to ensure against non-performing licensees and understatement of royalty sales.

The PHS agreed that adequate procedures must be established to ensure that valuable foreign patent rights are obtained and filed

in a timely manner. The PHS said that procedures for accomplishing this goal have already been implemented.

The PHS did not agree that material internal control weaknesses exist in the technology transfer program because improvements and innovations made by NIH have significantly changed the management and oversight of the technology transfer program. According to PHS, the improvements and innovations made by NIH are significant process changes that should correct previous deficiencies and weaknesses. The PHS has not however, conducted an FMFIA review or reported its material internal control weaknesses and any corrective actions taken or planned. Because the FMFIA legislation requires that material weaknesses be disclosed in these reports, we believe that PHS should report this matter in its FY 1992 FMFIA report. Also, the Department requires that a review must be conducted within 1 year after material weaknesses are reported as being corrected. The PHS stated that to ensure that improvements and innovations made resulted in the desired outcomes, its previously scheduled internal controls review of this programmatic area will be conducted in FY 1992.

Those PHS detailed comments requiring OIG response are discussed below.

Monitoring NTIS Performance

The PHS states that DOC has legal custody of PHS patent properties through its subagency NTIS and therefore DOC should be responsible for administration of its own licensing program. Further, PHS expects to substantially discontinue use of NTIS in FY 1992.

We believe that the issue of legal custody of a patent property is not a valid reason for PHS not to monitor NTIS performance on patent properties in NTIS custody. When information which PHS routinely receives clearly shows that PHS technology is not being properly developed, commercialized, or receiving its proper share of royalty income, the PHS has a responsibility to the general public and its own researchers to take action. The current MOU, effective January 9, 1990, contains provisions which require NTIS to furnish copies of all required progress reports and other documents to OTT on a timely basis. We believe that OTT's customized technology management system which will provide improved docketing and status controls for patenting and licensing activities could be used to track the documents received from NTIS and disclose nonperformance.

Although PHS stated that it will use NTIS substantially less beginning in FY 1992, we do not believe that this lessens to any degree its monitoring responsibilities for existing patent properties now maintained by NTIS. As of August 1990, an NTIS listing showed a total of 717 PHS patent properties.

Foreign Patent Rights

The PHS concurs with our recommendation to establish adequate procedures to ensure that foreign patent rights are obtained and filed in a timely manner. A new policy effective in September 1990 provided for PHS to take assignment of foreign rights for inventions at the time of the U.S. filing. The OTT is also testing a customized technology data management system which should provide improved docketing and status controls for patenting and licensing activities. However, PHS disagrees that strong controls are needed to assure that publications or other disclosures related to patentable research do not take place prior to the U.S. filing date. While PHS agrees that it would be desirable for NIH never to lose foreign rights, in some cases it is conceivable that the public's need for knowledge will take precedence over patent concerns.

We agree that in some cases it is conceivable that the public's need for knowledge will take precedence over patent concerns. However, we believe that there should be accountability for this decision. Currently, OTT and NIH procedures do not document whether a responsible decision was made that the public's need for knowledge took precedence over patent concerns. We believe that uniform guidelines will serve to protect against unnecessary loss of valuable foreign patent protection needed to maintain this country's competitiveness.

APPENDIX

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date OCT 25 1991

From Assistant Secretary for Health

Subject OXG Draft Report "Review of PHS Controls Over Technology Transfers and Royalty Income," A-01-90-01502

TO Inspector General, OS

Attached are the PHS comments on the subject OIG draft report. Included are general comments on the report, as well as comments specific to the report's recommendations. Although the OIG report describes circumstancea that existed in the pant, we believe that the Improvement8 and innovations made by the National Institutes of Health have significantly changed the management and overeight of the technology tranefer program. Therefore, we do not agree that there are material internal control weaknesses in this program. However, to ensure that the changes we have made result in the desired outcomes, we will perform a previously scheduled internal controls review of this programmatic area in Fiscal Year 1992. Also, we invite you co schedule a followup review of this program in the near future.

James O. Mason

James O. Mason, M.D., Dr.P.H.

Attachment

COMMENTS OF THE PUBLIC HEALTH SERVICE (PHS) ON THE OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT "REVIEW OF PHS CONTROLS OVER TECHNOLOGY TRANSFER AND ROYALTY INCOME," A-01-99-91502. AUGUST 1991

General Comments

PHS, for reasons described more fully in the following paragrapha, does not believe that its technology transfer program represents a material internal control weakness. In fact, the PHS technology transfer program is recognized as a leader among government agencies. We disagree with OIG's interpretation of some of its findings and conclusions. In particular, we disagree with OIG's conclusion *concerning* the existence of material internal control weaknesses that should be reported to the President and Congress under the Federal Managers' Financial Integrity Act (FMFJA).

We believe that the OIG conclusions are incorrect for two principal reasons: (1) few of the identified problems were the organizational responsibility of PHS, and most of these problems have been corrected; and (2) the report does not rely upon the most timely and relevant evidence *when* making judgments about management controls.

NIH, after identifying problems and devising solutions, has implemented a continuing series of program innovations and improvements. NIH's Office of Technology Transfer (OTT) has taken the lead, under the guidance of the NIH/ADAMHA/CDC Patent Policy Board, in developing technology transfer policies and programs for the PHS agencies. OTT was given operational control of the Patent Branch in November 1990, during a time period in which all Patent Branch cases were physically reorganized and logged into a computerized docketing-system under OTT direction.

New contracts for outside patent services scheduled to go into effect on November 15, 1991, will dramatically enhance the quality and timeliness of aubatantive case work. OTT currently is testing a customized technology data management system, designed in coordination with the PHS agencies' institutes, centers and diviaiona (ICDs) that will provide improved docketing and status controls for patenting and licensing activities. Lastly, in Auguet 1991, the NIH Director approved an increased Fiscal Year (FY) 1992 budget for OTT that will permit a major expansion of professional staff in ths Patent and Technology Licensing Branches, and permit OTT to begin to conduct licensing and patenting either in-house or under more extensive case-by-case oversight.

PKS does not believe that its technology tranafer and royalty income program has material internal control weaknesaes. Through the procedural change8 and management improvements described above, NIH has made significant process changes that should correct previous deficiencies and weaknesses. To ensure that these changes produce the desired outcomes, we invite OIG to re-review this program at a future date.

PHS is willing to share available technology transfer and royalty income program information and indicators with OIG. For example, NIH will soon release a report to Congress of PHS technology transfer efforts for FY 1991 and intended programs for FY 1992. When this report becomes available, PHS will provide a copy to OIG *for* its information. We believe that this report will obviate the need for OTT to provide the. special semiannual report that OIG requested.

OIG Recommendation

We recommend that PHS:

1. Centralize the technology transfer function for all PHS agencies within OTT.

PHS Comment

We concur. Por patenting, this was done as of November 1990 when the Patent Branch (Office of the General Counsel) was moved off-campus together with OTT (NIH). Secretary Sullivan officially reorganized the Patent Branch to become part of OTT on May 21, 1991. The PH8 has advised the National Technical Information Service (NTIS), currently the licensing agent for most PH8 patent applications, that OTT intends to bring its licensing work in-house during FY 1992-93. OTT will be negotiating updatod inter-agency agreements with ADAM-IA, CDC and FDA to encompass OTT's technology management services.

OIG Recommendation

2. Establish priorities and milestones with all parties to complete the reconciliation of 1,732 patent8 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.

PHS Comment

We concur. In essence this task has boon completed already. OIG should be aware that tho total count it refers to includes

pending and abandoned (i.e., inactive) patent applications as well as issued patents. The number of active cases is only about one half of that total. All have been or will aoon be available for marketing to the private sector. Decisions to revive inadvertently abandoned cases have been made on a case-by-case basis if reasonable commercial. value exists.

OIG Recommendation

3. Establish procedure8 and systems to monitor the performance of NTIS under its MOU to ensure against non-performing licensees and understatement of royalty sales.

PHS Comment

We do not concur. Because the Department of Commerce (DOC) has legal custody of the patent properties licensed by its subagency, NTIS, PHS believes that DOC should be responsible for administration of its own licensing program. PHS has been encouraging NTIS and DOC to implement an auditing program. OTT has discussed potential management controls with the OIC to ensure proper monitoring of the licensee6 of NIH-negotiated patent license agreementa. These include the possibility of spot check audits performed by the OIG or special audit provisions in the license agreements themselves.

PHS expects to substantially discontinue the use of NTIS licensing services during FY 1992.

OIG Recommendation

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

PHS Comment

We concur. Procedures for accomplishing this goal already have been implemented.

In September 1990 the NIH/ADAMHA/CDC Patent Policy Board adopted the policy that PHS will exercise its option to take foreign patent rights at the time that the corresponding U.S. patent application is filed. NIH also is the first Government agency to have adopted this innovative approach to solve a time-critical management problem that affects all agencies.

The draft report indicates that some investigators in some ICDs have published articles without the previous filing of a U.S. patent application, thereby eliminating the possibility of foreign patent rights. Thie concern has been raised by OTT with

the Patent Policy Board, NIH/ADAMHA ScientificDirectors, and with the PHS ICD Technology Development Coordinators. The draft report suggests "a need for strong controls to assure that publication or other public disclosure related to patentable research doee not take place prior to the U.S. filing date." PHS disagrees.

The primary statutory mioolon of PHS researchagenciesis to disseminate knowledge, and the Federal Technology Transfer Act of 1986 requires implementation of a technology transfer program that is consistent with that mission. Whfle PHS agrees that it would be desirable for NIH never to lose foreign rights, in aome cases it is concoivable that the public's need for knowledge will take precedence over patent concerns.

Office of Audit Services note -- Comments have been deleted at this point because they pertain to material not included in this report.

QIG Recommendation

6. Disclose in this year's FMFIA report that there are 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.

PHS Comment

We do not concur. Past and largely corrected problems do not constitute a present violation of the FMFIA. A detailed description of why PHS does not believe that there are internal control weaknesses in the technology tranafer and royalty income areas is included in the general comments section above.

Office of Audit Services note -- Comments have been deleted at this point because they pertain to material not included in this report.