
AUDIT OF PATENT REPORTING, DISCLOSURE AND PROCUREMENT

Report No. 9-000-96-001
December 5, 1995





U.S. AGENCY FOR
INTERNATIONAL
DEVELOPMENT

December 5, 1995

MEMORANDUM FOR EXECUTIVE DIRECTOR, AGENCY RESEARCH COUNCIL,
FRANCES CARR

FROM: IG/A/PA, Toby L. Jarman *Toby L. Jarman*

SUBJECT: Audit of Patent Reporting, Disclosure and Procurement
(Audit Report No. 9-000-96-001)

This report presents the results of our audit of patent reporting and disclosure associated with USAID research agreements and USAID's procurement of items invented with U.S. Government funds. We understand that the Agency Research Council was established to provide a more comprehensive approach to policy formulation which will assure that USAID research facilitates sustainable development and supports Science and Technology Initiatives set forth by the President of the United States. The report makes six recommendations to assist the Council in carrying out these responsibilities.

We considered your comments on the draft report and have included them as an appendix to this report. Based on the comments, Recommendations number 1, 2.1, 5, and 6 are resolved. Recommendations number 2.2, 3, and 4 are unresolved.

I appreciate the cooperation and courtesies you extended during the audit. Please provide us information within 30 days documenting the actions taken or planned to implement the recommendations.

EXECUTIVE SUMMARY

Background

USAID provides funds to research recipients to finance research and development activities in many areas. Frequently, inventions and patents result from this Government-funded research. In these cases, the Bayh-Dole Act (the Act) was enacted into law in 1980 to clarify the inventor's and Government's rights regarding inventions and to protect taxpayers' rights to the technology. The Act and implementing regulations require recipients to:

- (1) inform USAID in writing of the subject invention (i.e. subject to the Act--see definitions at Appendix III) within two months after recipient personnel responsible for patent matters become aware of it; and
- (2) disclose the U.S. Government's rights to the subject invention in the patent filings by using the standardized "Government's Rights Disclosure".

The Act is important because it allows USAID to receive credit for funding important technology advancements and also gives the Government the right to purchase the patented item at a lower price--free of royalties. Furthermore, the Federal Acquisition Regulation states that royalty costs are not allowable in cases where the U.S. Government has rights to the patented item being purchased.

Although accurate data was not available, the Agency Research Council estimated that USAID budgeted \$342 million for research and development activities in fiscal year 1993.

AUDIT RESULTS

The audit found that USAID did not have management controls to ensure that its recipients informed USAID of their subject inventions and disclosed the Government's rights in their patent filings. Instead, USAID relied on its

recipients to comply. Nine of the 17 research agreements selected for review produced a total of 35 inventions (29 subject inventions and six inventions which may be subject to the Act) and 29 patent filings. The other eight agreements did not produce any inventions.

Of the nine research agreements with inventions, seven had inventions which were all subject inventions, one had both subject inventions and inventions which may be subject to the Act and the ninth only had inventions which may be subject to the Act (see Appendix IV). Audit tests showed that:

- Recipients for five agreements did not submit invention disclosure reports.
- Six recipients did not disclose the U.S. Government's rights in their patent filings of subject inventions.
- Only 11 invention disclosure reports (38 percent) for the 29 subject inventions were provided to USAID.
- Furthermore, only five (22 per cent) of the 23 patent filings of subject inventions included the required Government's rights disclosure paragraph. (See page 3.)

However, during the course of our audit, some recipients became aware of the Act's requirements and took immediate action to comply. In addition, USAID management showed a keen interest in learning more about the Act's requirements. Also, during government-wide meetings concerning the Act it was apparent that other Government agencies had problems concerning what they should do to comply with the Act. Recent audits of the National Institutes of Health also found problems relating to compliance with the Act.

The audit also found that USAID's Office of Procurement has not been requesting or obtaining the royalty information specified in the FAR and has not been determining the Government's rights to items being acquired, in order to purchase patented items at a lower price. Our audit identified ten USAID direct purchase contracts for various types of contraceptives valued at approximately \$163 million. We reviewed three of these contract solicitations totaling \$17.7 million and found that none requested the royalty information specified in the FAR--even though USAID is spending millions to develop new contraceptive methods. (See page 9.)

Although USAID invests a substantial amount in research, it has not established controls to ensure that taxpayer and U.S. Government interests in technologies have been recorded and important public rights have been safeguarded. In addition, USAID has not followed the FAR to ensure that royalty costs are

excluded from its direct commodity purchases. The savings by excluding the cost of royalties from future direct purchases could be significant, based on the dollar value of current direct purchases of approximately \$163 million. On a broader scale, indirect purchases by grantees and contractors represent the bulk of USAID purchases. The potential savings by excluding the cost of royalties from these indirect purchases may be substantial, if it is determined that the U.S. Government's rights also extend to grantees and contractors. (See page 13.)

RECOMMENDATIONS

The report recommends that the Agency:

- develop controls to comply with the Act;
- follow-up to ensure that invention disclosure reports are submitted and the Government's rights disclosure have been included in the patent filings;
- for two recipients in which it is not clear whether USAID funded the inventions, obtain proof that USAID funds were or were not spent to invent the patented items;
- report the control weaknesses associated with the Act to the Management Control Review Committee to be considered for inclusion as a weakness in USAID's Federal Managers' Financial Integrity Act Report;
- determine if the U.S. Government has rights to Norplant and, if so, obtain a refund of the royalty costs;
- develop controls to ensure that USAID identifies royalty costs and Government rights associated with its direct purchases and, in appropriate cases, excludes royalty costs from its purchases; and
- determine if the U.S. Government's patent rights extend to purchases made on USAID's behalf by its recipients and contractors (see pages 8, 9, and 13).

MANAGEMENT COMMENTS AND OUR EVALUATION

Management expressed a desire to develop appropriate preventive and corrective actions and stated they were willing to address all issues cited in the report's recommendations. Based on their comments, Recommendations number 1, 2.1, 5, and 6 are resolved. While not expressing disagreement with Recommendations

number 2.2, 3, and 4, management's response was insufficient for us to resolve the recommendations at this time.

Management did have concerns about several aspects of the report. The major concerns and our response are discussed on page 14. Appendix II contains management's complete comments.

Office of the Inspector General

Office of the Inspector General

December 5, 1995

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INTRODUCTION

Background

USAID provides funds to research recipients to finance research and development activities in areas such as agriculture, energy, health and population. Frequently, inventions and patents result from this Government-funded research. In cases where U.S. Government funds were used to develop the invention, the Bayh-Dole Act (the Act) was enacted into law in 1980 to clarify the inventor's and Government's rights regarding inventions and to protect taxpayers' rights to the technology. The Act and regulations issued by the Department of Commerce are the foundation for the standard provisions relating to patents which USAID incorporates into its agreements (contracts, grants and cooperative agreements). These standard provisions and regulations require, in part, that recipients:

- (1) inform USAID in writing (referred to as the Invention Disclosure Report) of the subject invention within two months after recipient personnel responsible for patent matters become aware of it; and
- (2) disclose the U.S. Government's rights to the subject invention in the patent filings by using the standardized "Government's Rights Disclosure".

The Act is important because it allows USAID to receive credit for funding important technology advancements and also gives the Government the opportunity to purchase patented items at a lower price--free of the costs of royalties. Furthermore, the Federal Acquisition Regulation states that royalty costs are not allowable in cases where the U.S. Government has rights to the patented item being purchased.

Although accurate data was not available, the Agency Research Council estimates that USAID budgeted \$342 million for research and development activities in fiscal year 1993. We reviewed 17 research agreements with total estimated

budgets of \$196 million. However, four agreements with estimated budgets of \$134 million did not identify how much of their budgets were for research and development and how much were for other USAID activities. The remaining 13 agreements reflected budgeted research and development expenditures of approximately \$26 million.

See Appendix III for a list of definitions of the technical terms used in this report.

Audit Objectives

The Inspector General's Office of Performance Audits performed an audit of patent reporting and disclosure and USAID's procurement of items invented with U.S. Government funds. The audit was performed to answer the following questions:

1. Did USAID have management controls to ensure that its recipients informed USAID of their subject inventions and disclosed the Government's rights in their patent filings?
2. Did USAID follow procedures specified in the Federal Acquisition Regulation to determine the Government's rights to the items being acquired, in order to purchase patented items at a lower price?

Appendix I discusses the audit's scope and methodology.

REPORT OF AUDIT FINDINGS

Did USAID have management controls to ensure that its recipients informed USAID of their subject inventions and disclosed the Government's rights in their patent filings?

USAID did not have management controls in place to ensure that its recipients informed USAID of their subject inventions and disclosed the Government's rights in their patent filings. Instead, USAID relied on its recipients to comply.

The scope of our audit was limited because of USAID's lack of controls in this area. USAID could not provide, nor could we develop, a universe of research agreements which were resulting in subject inventions and patents. Thus, 17 agreements were selected for review based upon USAID's and the audit team's perception that these agreements may have resulted in a subject invention. Eight of the 17 agreements reviewed did not result in any inventions. The nine that produced inventions resulted in a total of 35 inventions (29 subject inventions and six inventions which may be subject to the Act) and 29 patent filings.

Invention Disclosure Reports and Government's Rights Disclosure

Of the nine research agreements with inventions, seven had inventions which were all subject inventions, one had both subject inventions and inventions which may be subject inventions and the ninth had inventions which may be subject inventions. Recipients for five agreements did not submit invention disclosure reports and six did not disclose the U.S. Government's rights in their patent filings. Only one recipient complied with both the reporting and disclosure requirements. However, during the course of our audit some recipients became aware of the reporting and disclosure requirements and then took immediate action to comply. In addition, USAID management showed a keen interest in learning more about the Act's requirements and the controls needed to ensure

Agency compliance.

During recent government-wide meetings concerning compliance with the Act (attended by representatives from the audit team and the Agency) it was apparent that many other Government agencies had problems and questions regarding what they should do in order to comply with the Act's requirements. Also, recent audits of the National Institutes of Health performed by the Department of Health and Human Services Office of Inspector General found problems concerning compliance with the Act.

We noted that these nine agreements resulted in the development of 35 inventions (29 subject inventions and six inventions which may be subject to the Act). Invention reporting and the Government's rights disclosure were as follows:

- Only 11 invention disclosure reports (38 percent) of the 29 subject inventions were provided to USAID.
- Research recipients elected to apply for patents on 23 of the 29 subject inventions. Only five (22 per cent) of these 23 patent filings included the required Government's rights disclosure paragraph.

As part of our audit methodology we conducted field work at the U.S. Patent and Trademark Office (USPTO) to identify patents associated with USAID's research recipients. We noted that the USPTO had a user-friendly computer system, the Automated Patent System, that quickly and easily matched the names of USAID's research recipients with their patents. We believe the system could be an important part of USAID's management controls to help ensure compliance with the Act.

See Appendix IV for an analysis of the agreements reviewed and Appendix I for a detailed discussion of our methodology.

Reporting and Disclosure Requirements

The Bayh-Dole Act and regulations issued by the Department of Commerce are the foundation for USAID's standard provisions relating to patents. These standard provisions, which were included in all of the agreements we reviewed, require, in part, that the recipient:

- **"Disclose each subject invention to USAID within two months after the inventor discloses it in writing to recipient personnel responsible for patent matters. [Emphasis added.]** The disclosure to USAID shall be in the form of a written report and shall identify the agreement under which the invention was made and the inventors. It shall be sufficiently complete

in technical detail to convey a clear understanding . . . of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention."

- " agrees to include within the specification of any United States patent application and any patent issuing thereon covering a subject invention the following statement: **'This invention was made with Government support under (Identify the agreement awarded by USAID). The Government has certain rights in this invention.** [Emphasis added.]"

There are more standard provisions relating to patents, but we did not include them in the scope of our audit.

Why Reporting and Disclosure Were Not Made

For the agreements reviewed, invention disclosure reports and the patent disclosure of the Government's rights were not made in eight of these agreements for several reasons:

- In three agreements (Jerusalem College, University of Arizona and Family Health International), USAID management did not have a proactive system in place to ensure compliance.
- In two agreements (Affymax Technologies N.V. and DNAX Research Institute), USAID management was aware of the standard provision requirements, but the recipients overlooked them.
- In one agreement (Michigan State University), the recipient was initially not certain whether USAID funded the subject inventions, but subsequently determined that it did. The recipient then reported the subject inventions to USAID and took action to have the patent filings corrected.
- In two agreements (Program For Appropriate Technology in Health and Population Council), the recipients contended that the inventions in question were not developed with U.S. Government funds, even though the agreements called for the development of such new technologies. Due to this discrepancy these two situations are discussed in more detail below.

In most cases, Program for Appropriate Technology in Health (PATH) complied with the invention disclosure and Government's rights disclosure requirements. However, for one possible subject invention--the "SyringeLOCK" single use syringe--PATH did not comply, because it contended that the item was not developed with U.S. Government funds. USAID could not provide definitive proof

as to whether U.S. Government funds were used in this case, but there were indications that U.S. Government funds may have been used. The agreement said:

"The project will support the USAID child survival program through the identification, development and introduction of new low cost primary health care technologies in less developed countries. . . . The project will develop and introduce a single use non-reusable vaccine injection system . . . and other immunization and child survival technologies."

In addition, the USAID Evaluation Summary for the project with PATH said:

"HealthTech (the name of this USAID project) has achieved a private sector cooperation in the development of two major injection technologies: SyringeLOCK and SafeTject."

Furthermore, an outside manufacturer who wants to produce the "SyringeLOCK" syringe contends that it has been prevented from doing so because PATH gave exclusive rights for this syringe to another company. Allegedly this other company, to protect its currently marketed disposable syringe from competition, is not producing this "SyringeLOCK" single use syringe. The outside manufacturer has requested that USAID exercise its "March-in Rights" to enable this new technology to be marketed to the public.

In the second situation, Population Council and USAID management contended that Population Council's various family planning inventions ¹ which may be subject to the Act were not developed with U.S. Government funds, even though the current and prior agreements called for the development of new technologies. The current Population Council agreement said, in part:

- "A.I.D. will support activities conducted by the Population Council that are directed toward fostering the development and introduction of methods of fertility control A.I.D. will (a) continue to emphasize the contraceptive development research area and introduction of new products as they become available, (b) . . ."
- "All stages of contraceptive development, including the widespread assessment, introduction and adaptation of family planning technology through clinical field trials in a variety of countries and clinical settings will

¹ Population Council's family planning inventions included: luteinizing hormone releasing hormone conjugate of tetanus vaccine and its uses (Patent No. 5,324,512); leydig cell stimulator (Patent No. 5,304,603); apparatus for effecting occlusion of target vessels or tissue (Patent No. 5,067,958); method for androgen supplementation (Patent No. 5,342,834); and medicated intracervical and intrauterine devices (Patent No. 4,578,076).

be an integral part of the research program."

Additionally, related Project Implementation Order/Technical Services (PIO/T) No. 8361476 defined contraceptive development as follows:

- "The contraceptive development process typically begins with the identification of a new lead with the potential for fertility regulation and is followed by a series of laboratory and chemical studies All stages of contraceptive development, including the widespread assessment, introduction and adaptation of family planning technology through clinical field trials in a variety of countries and clinical settings will be an integral part of the research program."

Thus, there appears to be a significant discrepancy -- which we did not attempt to resolve -- between the terms of the agreements and the assertions made by PATH and Population Council.

Taxpayer And Government Interests Not Recorded and Public Rights Not Safeguarded

The eight agreements which did not reflect compliance with the standard provisions have total estimated budgets of approximately \$122 million. Seven of these reflected research and development budgets of approximately \$19 million, and one with a total budget of over \$66 million did not identify how much was for research and development and how much was for other activities. Although this one budget did not identify how much was for research and development it is likely that a substantial amount funded this activity. We believe this represents a substantial investment for which taxpayer and U.S. Government interests in technologies have not been recorded and important public rights have not been safeguarded.

For example, USAID is funding Family Health International's (FHI) development of a plastic condom. As of April 1994, FHI had applied for 9 patents relating to this new product, but had not informed USAID of these subject inventions or included the Government's rights in its patent filings. In May 1994, as a result of our audit inquiries, FHI became aware of the patent standard provisions and took immediate action to comply with both the invention reporting and Government's rights disclosure requirements. According to an employee of FHI, this innovative condom could possibly revolutionize the condom industry because it is more durable and reliable. In addition, by withstanding adverse and lengthy storage conditions better than the currently used latex condoms, the plastic condom would be particularly beneficial to USAID, given the prolonged and often unsatisfactory storage conditions found in third world countries. USAID currently has three contracts for condom purchases with a total value of approximately \$90

million. Thus, because of the immense potential of this subject invention, and its ramifications for future USAID contraceptive purchases, it is critical that the Government's rights to this product be properly recorded and protected.

Furthermore, because of omissions such as these, USAID and other U.S. Government agencies may needlessly pay for the costs of royalties included in the purchase prices of products invented with USAID funds. We presume that USAID will eventually purchase products that were invented with its funds for use in its development activities. Similarly, other U.S. Government agencies could reduce their future procurement costs since the Act gives royalty-free rights to the U.S. Government--not just USAID--for items invented with USAID funds. See Audit Objective No. 2 for a further discussion of this issue.

RECOMMENDATIONS

Recommendation No. 1: We recommend that the Agency Research Council develop management controls that will help ensure compliance with the patent standard provisions. Such controls should include the following guidelines or other similarly appropriate controls to be implemented by USAID management:

- 1.1** An annual certification which states whether the research recipient has developed any subject inventions with U.S. Government funds. This certification should be required and obtained from all research recipients subject to the Bayh-Dole Act.
- 1.2** A proactive control procedure whereby USAID, at least annually, compares a representative sample of its research recipients with the electronic files of the U.S. Patent and Trademark Office.

Recommendation No. 2: We recommend that the Agency Research Council, in conjunction with the Bureau for Global Programs, Field Support and Research:

- 2.1** Take appropriate action to communicate with its staff and research recipients on the requirements of the Bayh-Dole Act and patent standard provisions.
- 2.2** For the five recipients (Jerusalem College, University of Arizona, Family Health International, Affymax Technologies N.V., and DNAX Research Institute) that were clearly not in compliance, follow-up to ensure that invention disclosure reports have been submitted and that the Government's rights disclosure have been included in the patent filings.

Recommendation No. 3: We recommend, for the other two recipients (Program for Appropriate Technology in Health and Population Council) in which it is not clear whether USAID funded the inventions, that the Agency Research Council, in conjunction with the Office of General Counsel, obtain from the recipient or other sources, detailed and verifiable proof that USAID funds were or were not spent to invent the patented items. If it is determined that USAID funds were used, USAID should follow-up to ensure compliance.

Recommendation No. 4: We recommend, unless the problems are corrected, that the Agency Research Council report the internal control weaknesses associated with subject inventions and patents to the Management Review Control Committee for consideration for inclusion in the Agency's annual Federal Managers' Financial Integrity Act Report.

Did USAID follow procedures specified in the Federal Acquisition Regulation to determine the Government's rights to the items being acquired, in order to purchase patented items at a lower price?

USAID has not been requesting or obtaining royalty information as specified in the Federal Acquisition Regulation (FAR); and thus, USAID has not been determining the Government's rights to items being acquired, in order to purchase patented items at a lower price.

**Government Rights Not
Determined in USAID Purchases**

The FAR specifies procurement procedures and requirements relating to the purchase of patented items containing royalty costs (see page 10-11). However, USAID's Office of Procurement has not been requesting or obtaining the royalty information specified in the FAR. Thus, USAID has not, in order to purchase patented items at a lower price, been determining the Government's rights to items being acquired.

According to USAID officials in the Office of Procurement, most project purchases are made by USAID's grant recipients and contractors, but USAID does directly purchase large amounts of contraceptives for its family planning activities. Our audit identified ten USAID direct purchase contracts for various types of contraceptives valued at approximately \$163 million. We reviewed three of these

audit identified ten USAID direct purchase contracts for various types of contraceptives valued at approximately \$163 million. We reviewed three of these contract solicitations totaling \$17.7 million and found that none requested the royalty information specified in the FAR--even though USAID is spending millions to develop new contraceptive methods.

Our audit did not find any clear-cut instances where USAID purchased contraceptives which included unallowable royalty costs. Identifying unallowable royalty costs was difficult because USAID did not request and obtain royalty cost information before making the purchases. However, there was one possible instance.

This instance involved the purchase of 190,000 units of Norplant, a long-acting implantable progestin contraceptive. According to records in the Office of Procurement, the estimated total contract value (including Norplant, trocars (surgical instruments), labeling and packaging) was \$4,392,800. This procurement included a five percent royalty on the Norplant units, which increased the Norplant purchase cost by \$100,700--a cost which was avoidable if the U.S. Government had rights to the product.

Nevertheless, we were unable to conclusively determine if the U.S. Government had rights to this item. Officials in the Office of Population believed USAID had no royalty rights because Norplant was invented before the effective date of USAID's funding for Norplant, before the effective date of the Bayh-Dole Act and because it was developed by someone other than Population Council. However, there were indications (described below) that USAID may have funded the invention of Norplant, and consequently may have certain rights to it.

- A January 1991 publication, "Norplant Worldwide", issued by the Population Council claimed that it developed this product. In addition, a USAID memorandum from a senior level official also stated that Norplant was developed with federal support.
- A Project Paper (dated May 24, 1988) for the "Population Council Program" said: (1) "The Office of Population has supported the Council since 1969 through a series of contracts and cooperative agreements." (2) "Areas supported . . . have included: contraceptive research, service delivery research, training" (3) "During the last several years the preponderance of USAID S&T/POP support to the Population Council Programmatic Cooperative Agreement has been to the contraceptive development area where the five major areas of research are subdermal contraceptive implants including primarily Norplant implants; levonorgestrel releasing IUDs, contraceptive vaginal rings"

- A representative from USAID's Office of General Counsel said that before the Bayh-Dole Act became effective, the U.S. Government had more rights, not less, to products that were invented with U.S. Government funds.

Thus, based on the above indications and management opinions, USAID and the U.S. Government may or may not have rights to Norplant.

The above discussion relates to USAID direct purchases. However, many project purchases are not made directly by USAID, but are made by grantees and contractors using USAID funds. According to a representative from the USAID Office of General Counsel, it is uncertain--from a legal perspective--whether the U.S. Government's rights extend to its recipients and contractors.

Government Rights and Unallowable Royalty Costs

The U.S. Government's rights to subject inventions, developed with Government funds, are specified in the Bayh-Dole Act and regulations issued by the Department of Commerce. These rights have been incorporated into the standard provisions of USAID's agreements with its research recipients and state, in part, that:

- "With respect to any subject invention in which the recipient retains title, the Federal Government shall have a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world."
- "The recipient agrees to include, within the specification of any United States patent application and any patent issuing thereon covering a subject invention, the following statement: "This invention was made with Government support under (identify the agreement awarded by AID). The Government has certain rights in this invention."

The Federal Acquisition Regulation, as shown below, requires prospective suppliers to disclose royalty costs in contract pricing proposals, defines when these costs are not allowable and provides provisions for the refund of royalties:

- "27.204-1 General
 - (a)(1) To determine whether royalties anticipated or actually paid under Government contracts are excessive, improper, or inconsistent with any Government rights in particular inventions, patents or patent applications, contracting officers shall require prospective contractors to furnish certain royalty information and shall require contractors to furnish certain royalty reports. Contracting officers shall take appropriate action

to reduce or eliminate excessive or improper royalties."

- "27.204-2 Solicitation provision for royalty information. The contracting officer shall insert a solicitation provision substantially as shown in 52.227-6, Royalty Information, in any solicitation that may result in a negotiated contract for which royalty information is desired or for which cost or pricing data is obtained under 15.804."
- "31.205-37 Royalties and other costs for use of patents.
(a) **Royalties on a patent** or amortization of the cost of purchasing a patent or patent rights necessary for the proper performance of the contract and applicable to contract products or processes **are allowable unless --**
(1) **The Government has a license or the right to a free use of the patent; . . . [Emphasis added.]**"
- "27.206-2 Clause for refund of royalties. The contracting officer shall insert the clause at 52.227-9, Refund of Royalties, in negotiated fixed-price contracts and solicitations contemplating such contracts if the contracting officer determines that circumstances make it questionable whether or not substantial amounts of royalties will have to be paid by the contractor or a subcontractor at any tier."
- 52.227-9 says, in part, "To the extent that any royalties that are included in the contract price . . . are determined by the Contracting Officer not to be properly chargeable to the Government and allocable to the contract, the contract price shall be reduced."

The Office of Procurement Did Not Have Controls or Guidelines

The USAID Office of Procurement has not been determining whether the U.S. Government has rights to items being acquired (in order to purchase patented items at a lower price) for two reasons:

1. The Office of Procurement did not have management controls to ensure that, in appropriate situations, royalty information was specifically requested in its solicitations.
2. The Office of Procurement had no guidelines for the contracting officer to determine in which situations royalty information should be requested. As a result, the contracting officer believed that requesting this information was optional and thus chose not to request it.

Therefore, USAID purchased patented items without knowing if avoidable royalty costs were included in its purchase prices.

Royalty Costs May Increase USAID's Costs

Royalty costs can be substantial and can increase the cost of USAID's purchases. For example, in the case of Norplant, USAID may have paid \$100,700 more than necessary because royalty costs were included in its purchase price. Additionally, the savings to USAID by excluding the cost of royalties from future direct purchases could be substantial, based on the dollar value of its current direct purchases of approximately \$163 million of contraceptives.

On a broader scale, indirect purchases by grantees and contractors represent the bulk of USAID-funded purchases. The potential savings by excluding the cost of royalties from these indirect purchases may be substantial, if it is determined that the U.S. Government's rights also apply to its grantees and contractors.

RECOMMENDATIONS

Recommendation No. 5: We recommend that the Agency Research Council:

- 5.1 In conjunction with the Office of General Counsel and the Office of Procurement, determine if the U.S. Government has rights to Norplant and, if so, obtain a refund of the royalty costs.**
- 5.2 In conjunction with the Office of Procurement, develop management controls to ensure that, as specified in the FAR, USAID identifies royalty costs and U.S. Government rights associated with its direct purchases and, in appropriate cases, excludes royalty costs from the price of its purchases.**

Recommendation No. 6: We recommend that the Agency Research Council, in conjunction with the Office of General Counsel and the Office of Procurement, determine if the U.S. Government's patent rights apply to USAID's recipients and contractors, thereby enabling them to exclude royalty costs from the price of their USAID-funded purchases.

MANAGEMENT COMMENTS AND OUR EVALUATION

Management expressed a desire to develop appropriate preventative and corrective actions and stated they were willing to address all issues cited in the report's recommendations. Based on their comments, we consider Recommendations number 1, 2.1, 5, and 6 to be resolved as discussed below. While not expressing disagreement with Recommendations number 2.2, 3, and 4, management's response was insufficient for us to resolve the matter at this time.

Management was concerned about several aspects of the report. For example, they cited the need for the report to define and differentiate between the terms "development" and "subject invention". We have modified the final report accordingly. Management believed that a lack of clarity on these terms was a glaring problem which reflected the essence and tenor of the report. We do not believe that a lack of clarity on these terms would have any effect on the essence of the report. We found that the Agency had no management controls to help ensure compliance with the Act and our tests confirmed that the vast majority of research recipients did not provide invention disclosure reports to USAID nor did they include the Government right's disclosure paragraph in their patent filings.

Another concern was that the report falls short in addressing weaknesses in ways that are not overly bureaucratic and onerous to USAID or its customers. We fully agree with this concept. To ensure this happens, the report recommends that management develop the controls to help ensure compliance with patent standard provisions. We have not specified any controls which are bureaucratic, onerous or unnecessary.

Management also believed that several report conclusions were prematurely drawn. To avoid this, the report clearly identified unresolved issues and asked management to obtain information needed to decide the issue. Any unsettled issue occurred because it was either beyond the scope of the audit to pursue resolution or it was outside the OIG's area of responsibility to decide the issue. The report clearly identifies unresolved areas and no conclusions are drawn. Furthermore, when the matter is outside the OIG's area of responsibility we recommended that the cognizant Agency official resolve the matter.

Management believed that since the Bayh-Dole was a "fairly new mandate" the audit should use best practice analysis by drawing on the experience of other agencies. It was considerably beyond the scope of the audit to analyze the controls and experiences other agencies have had in the 15 years since passage of the Act. We did attend Government-wide meetings concerned with the Act and invited USAID personnel to attend these meetings. Pertinent information obtained at these meetings was given to Agency officials.

A final concern of management was that the report recommendations be addressed to the appropriate operating unit within USAID. We believe this concern had already been met. The recommendations involving other USAID operating units all state for the Agency Research Council, in conjunction with the appropriate unit (Office of Procurement, General Counsel) to take the necessary measures. We believe that coordination between the Agency Research Council and these other units is the best way to ensure that a coordinated and cost effective system of management controls is developed.

Recommendation Nos. 1.1, 1.2 and 2.1 are resolved based on management's statement that it is developing policy and implementation guidance on intellectual property rights, including the Bayh-Dole Act. Training for USAID staff and research recipients is also planned. These recommendations will be considered for closure after we receive and review the adequacy of the guidelines being developed as well as details on the training to be conducted.

Recommendation No. 2.2 is unresolved because management did not comment on the status of the subject inventions of Jerusalem College and University of Arizona. Also, management said there were no outstanding inventions by DNAX Research Institute (DNAX), whereas we identified one subject invention by DNAX. This recommendation can be resolved when there is agreement on the status of compliance of the five recipients mentioned in this recommendation. It can be closed when these recipients submit invention disclosure reports and the Government's rights disclosure has been included in patent filings.

Recommendation No. 3 is unresolved. Management stated that documents showing that the subject inventions were made without USG funds were provided throughout this audit. The documents were also reviewed by the General Counsel who opined that the subject invention occurred prior to USAID funding. We believe that management is confusing the inventions (one by PATH and five by the Population Council) which may be subject to the Act in this recommendation with the possible subject invention (Norplant) covered in Recommendation No. 5. They are different. Recommendation No. 3 can be resolved when the Research Council and the Office of General Counsel agree to furnish the OIG with evidence that USAID funds were or were not spent to invent the patented items. It can be closed after our review of the documentation supporting this decision.

Recommendation No. 4 is unresolved. Management stated that no action was required for the upcoming Federal Manager's Financial Integrity Act (FMFIA) because corrective actions are either identified or are in process. Much of these corrective actions have not been implemented and the pertinent recommendations are still open. Therefore, we believe that serious control weaknesses still exist. We have modified this recommendation to request that the Agency Research Council report these weaknesses to the Management Control Review Committee for their consideration for inclusion in the FMFIA report. This recommendation can be resolved when the OIG and management agree that either the problems are corrected or the weaknesses should be considered for inclusion in the next FMFIA report.

Recommendation No. 5.1 is resolved based on management's efforts to determine if the U.S. Government has rights to "Norplant". It can be closed when management provides us with appropriate documentation which justifies their conclusion. We are uncertain about the role the Office of Procurement played in reaching this determination. Management comments do not reflect clearance by the Office of Procurement, but only show a copy of the comments being sent to them.

Management believed that the report should not cite a possible overexpenditure for royalty payments unless there is a clear determination of a legitimate government claim. The report does not make any claim that there has been an overexpenditure of royalty payments. We included this example in the report because the Government spends enormous amounts on procurements and this case is an excellent example of the amount of savings which might be obtained by developing controls to comply with the Act.

Recommendation No. 5.2 is also resolved based on management's statement that it is developing policy and implementation guidance on intellectual property rights, including the Bayh-Dole Act. We note that based on the determination made by management to our Recommendation No. 6 (see below and page 12 of the audit report), these controls become even more important because of the increased magnitude of potential savings associated with USAID funded purchases by its grantees, recipients and contractors.

Recommendation No. 6 is resolved based on management's action to determine if U.S. Government patent rights apply to USAID's recipients and contractors. During the course of the audit we asked the GC for this determination. We

commend the GC for investigating this issue and arriving at a determination so quickly. This recommendation can be closed when we receive documentation supporting the GC determination.

See Appendix II for management's complete comments.

SCOPE AND METHODOLOGY

Scope

We audited patent reporting and disclosure associated with USAID's research agreements, and its procurement of items invented with U.S. Government funds. This audit was conducted in accordance with generally accepted government auditing standards. Our fieldwork was conducted from October 12, 1994 to March 17, 1995. Fieldwork in Washington, D.C. included USAID's Agency Research Council, as well as its Offices of Agriculture and Food Security, Health and Nutrition, Policy and Programs, Population, and Procurement. Our fieldwork also included visits to the U.S. Patent and Trademark Office (USPTO), the Commerce Department and the National Institutes of Health, discussions with appropriate USAID and recipient officials associated with the agreements we reviewed, and discussions with officials in the Office of Inspector General of the Department of Health and Human Services.

Although there are many requirements associated with the Bayh-Dole Act and USAID's patent standard provisions, our audit only reviewed two requirements: (1) invention reporting and (2) the disclosure of the Government's rights in patent filings. We did not review compliance with other aspects of the Bayh-Dole Act and USAID's standard provisions.

Furthermore, for the two agreements in which the recipients contended USAID funds were not used, we did not visit the recipients' offices to definitively determine whether USAID funds were, in fact, used in developing the inventions. In addition, the scope of our audit was limited because of USAID's weak controls. As a result of these weak controls, USAID could not provide us with, and we could not develop a universe of research agreements which had resulted in inventions.

Methodology

Audit Objective No. 1

Due to the internal control weakness and resultant scope limitation mentioned above, we were not able to select agreements for our review from a universe of all USAID research agreements. Instead, agreements were selected for review where USAID and the audit team thought that the agreement may have resulted in an invention.

We selected 17 agreements with total estimated budgets of approximately \$196 million. We reviewed these agreements and held discussions with USAID and recipient personnel to determine the following:

- Did the agreements contain the patent standard provisions?
- Did they produce any inventions?
- Were patents filed on the subject inventions?
- Were the subject inventions correctly reported to USAID?
- Were the Government's rights disclosed in the patent application filings?
- Why were the subject inventions not reported to USAID and why were the Government's rights not disclosed in the patent filings?

We also performed fieldwork in the USPTO. Using the USPTO's "Automated Patent System", an easy-to-use computer system, we matched recipients' names to their patents and confirmed whether these patents contained the required Government's rights disclosure.

Our discussions with officials in the Office of Inspector General of the Department of Health and Human Services included background information based on their recent patent audits at the National Institutes of Health.

Audit Objective No. 2

To determine if the USAID Office of Procurement was requesting or obtaining royalty information in order to purchase patented items at a lower price, we held discussions with various officials in the Office of Procurement. We also examined the files for 3 purchase contracts totaling \$17.7 million, which were judgmentally selected from a universe of ten. More specifically, our analysis of the contract files included a review of the solicitations to determine if they contained the

required requests for royalty information, and an examination of the entire file to see if any royalties were associated with the items being purchased.

Our discussions with USAID procurement officials focused on the reasons why USAID had not obtained royalty information as specified in the FAR, and the systems needed to ensure that USAID does not unnecessarily incur royalty costs in the future.



U.S. AGENCY FOR
INTERNATIONAL
DEVELOPMENT

OCT 25 1995

MEMORANDUM

TO: IG/A/PSA, Toby L. Jarman

FROM: AA/PPC, Frances Carr *FC*

SUBJECT: Response to the Final Report on the Audit of Patent Reporting, Disclosure and Procurement compiled by IG/A/PSA

Thank you for extending to us the opportunity to review the final report of the subject audit. Again, let me emphasize that through the audit process, you and your staff have helped raise everyone's awareness of an important issue. Your willingness to have a second discussion on the draft report reflects your commitment to conducting audits collaboratively so as to enhance the outcome. At the onset, I wish to recognize the changes that were in fact made subsequent to our further discussion. I commend you for such an approach and, as my review indicates, hope that we can acknowledge the benefits of such a process and take appropriate measures to expand in those areas that were still problematic through this process.

Before addressing the specific recommendations of this audit, I wish to make three fundamental points in this review.

First, the opportunity to review a draft audit and further discuss the central issues of the findings with both the IG office and USAID staff reflected a significant change in the quality of the final report.

Second, while the conduct of this audit reflected the full consultative nature that we had hoped for, the final report does not. It falls short on the substantive changes needed both in findings and in recommendations. It failed to incorporate the facts and interpretations that USAID staff has provided IG throughout the process. The most glaring problem reflects the essence and the tenor of the Audit report. Repeatedly throughout the entire process, the terms subject invention and development were used interchangeably. Since only subject invention is subject to Bayh-Dole Act, it is imperative to have clarity on these definitions. It should be noted that USAID involvement in the development of a product might occur well after the subject was invented. USAID pointed out where there was inappropriate use of the terms and requested repeatedly that these terms be defined in the Glossary. As the accurate and appropriate use of the words is critical to the Audit process and findings, it is inappropriate to find the terms still used interchangeably and

not defined.

Third, while we had all been hopeful that we would be able to move to a new willingness of your office to work with us to address weaknesses in ways that are not overly bureaucratic and onerous to our customers or our staff, the end result falls short of that expectation.

Let me elaborate on these points.

REFLECTING USAID'S ISSUES

USAID staff spent a tremendous effort attempting to provide the documentation requested for each area of concern. Nevertheless, the process appeared to be unclear. While USAID staff provided documentation to answer the requests, there was no indication of closure on issues raised. In fact, there appeared to be no clarity on the required proof that USAID did not support the subject invention. The findings and recommendations did not take into full account the comments that the Agency staff have provided in written or oral form throughout the conduct and review of the audit. The result is that the report cites unresolved issues as indications of misconduct. Where there was disagreement over facts, we had hoped that you would take steps to determine which facts are correct and use them in the report. Where there was disagreement in interpretation, the disagreement should be acknowledged and no assumptive conclusion of misconduct should be drawn using one or the other interpretations. The result is that several of the conclusions are at best prematurely drawn.

ADDRESSING WEAKNESSES

The report does little to acknowledge the reality of the world in which we are operating: it identifies weaknesses in a relatively new regulatory area -- an area which we all agree is both important but fairly unexplored. Similarly, compliance with the law needs to be made so as to improve the Agency's responsiveness, not further hamper it, as we deal with our collaborating partners and customers. This last issue is no small point; both our accountability and our responsiveness are at the heart of the current debate over the Agency's future. We look to IG to cooperate with us in dealing with these realities.

What does this context mean vis a vis the audit?

First, in recognition of the fairly new mandate proscribed by Bayh-Dole, it means that the audit should fully use best practice analysis. USAID is not the only Agency affected by Bayh-Dole. How have others in the 15 years since passage effectively met the requirements? The draft report does not draw on the experience of others. Beyond best practices, I view the audit report as an opportunity to make the case for needing appropriate USAID-relevant definitions and clarifications of Bayh-Dole that we need

in order to effectively apply the law within the Agency's unique portfolio of international programs.

Second, the only way to maintain balance between accountability and streamlining is to first, clarify the meaning of the law in terms that make sense to USAID staff, then develop guidance that is as free of bureaucratic hurdles as absolutely possible, and finally raise staff's awareness of that guidance. The report's recommendations in this area focus on raising awareness largely through issuing reporting requirements and periodic tracking. This approach will provide accountability. And as the audit indicates, USAID staff are quite willing to behave responsibly when informed (a point that could be emphasized more strongly in the audit). But merely adding requirements to an already long list of contractual boilerplates will not suffice. We invite IG to think with us creatively (again, drawing on best practices) on how to best address streamlining issues that reinvention and, indeed, continued existence requires.

Finally, we remain concerned that an overexpenditure for royalty payments is cited in reference to what your office recognized as an unresolved issue. The report should not cite the figure unless there is a clear determination that it is a legitimate government claim. As cited, USAID Office of the General Counsel has accepted provided documentation and determined there is no legitimate USG claim to patent rights.

Specific actions taken in response to the recommendations in the final report are attached. As mentioned in previous correspondence, the Agency recognizes the critical issues raised in the report and has taken immediate corrective actions where appropriate. As previously discussed, I certainly question whether the Agency Research Council is the appropriate recipient for all of the recommendations and have so indicated at the relevant recommendations.

Rest assured that I and my staff, along with others in the Agency, are quite concerned and willing to address all issues cited in the recommendations (See attached.). We look forward to collaboratively working with you to develop steps that will enable us to ensure appropriate preventative and corrective actions.

Attachment: As cited

Clearance:

GC/LE, Jerome Patterson
SDAA/PFC, Janet Ballantyne

Cleared
JB

Date:
Date:

10/24/97
10/21/97

cc:
DA, Carol Lancaster
SDAA/G, Ann Van Dusen
M/OP, Marcus Stevenson
G/PDSP, Timothy Mahoney

RESPONSE TO THE RECOMMENDATIONS

It is crucial to carefully examine the issues raised in the Specific Recommendations of the Report to devise an appropriate management structure to ensure future compliance with the Bayh-Dole Act while not over-burdening contractors and USAID staff. It should be noted that the Agency Research Council is not a management unit at USAID, nor does it oversee procurement. Recommendations should be directed to the appropriate Operating Unit within USAID. Nevertheless, the following actions have been undertaken.

RECOMMENDATION No. 1: Agency Research Council develop management controls that will help ensure compliance with the patent standard provisions. Such controls should include the following guidelines or other similarly appropriate controls to be implemented by USAID management:

1.1 An annual certification which states whether the research recipient has developed any inventions with the U.S. Government funds. This certification should be required and obtained from all research recipients subject to the Bayh-Dole Act.

1.2 A proactive control procedure whereby USAID, at least annually, compares a representative sample of its research recipients with the electronic files of the U.S. Patent and Trademark Office.

RESPONSE:

1. A comprehensive USAID Program on Intellectual Property Rights (IPR Program) is being developed with the purpose of helping developing country public and private sectors to help USAID-assisted countries to fully realize the economic benefits of proper IPR enforcement. Training of USAID personnel, contractors, partners in all aspects of IPR including Bayh-Dole Act will be part of the implementation of this program.

2. A USAID Policy and Implementation Guidance on IPR (including Bayh-Dole Act) is being developed.

3. A review of standard provisions and requirement for invention disclosures in USAID supported cooperative agreements, grants and contracts is ongoing. We will ensure that Bayh-Dole issues are included in the review.

4. The Agency Research Council is not the responsible authority for the management of procurement issues.

RECOMMENDATION No. 2: Recommend that the Agency Research Council, in conjunction with the Bureau for Global Programs, Field Support and Research:

2.1 Take appropriate action to communicate with its staff and research recipients on the requirements of the Bayh-Dole Act and patent standard provisions.

2.2 For the five recipients (Jerusalem College, University of Arizona, Family Health International, Affymax Technologies N.V., and DNAX Research Institute) that were clearly not in compliance, follow-up to ensure that invention disclosure reports have been submitted and that the Government's rights disclosure have been included in the patent filings.

RESPONSE:

1. In addition to the new IPR program which includes training; communication with USAID staff and research recipients will be a priority. Several mechanisms will be used to raise awareness of the requirements including development of guidance to be issued through USAID automated directives.

2. The following have been addressed to ensure compliance. The Family Health International and Affymax Technologies N.V. patents have been revised to reflect USG rights under Bayh-Dole Act. There are no outstanding inventions with DNAX Research Institute.

RECOMMENDATION No. 3: Recommend that the other two recipients (Program for Appropriate Technology in Health and Population Council) in which it is not clear whether USAID funded the inventions, that the Agency Research Council, in conjunction with the Office of General Counsel obtain, from the recipient or other sources, detailed and verifiable proof that USAID funds were or were not spent to invent the patented items. If it is determined that USAID funds were used, USAID should follow-up to ensure compliance.

RESPONSE:

1. Documents that indicate that the subject inventions were made without USG funds have been provided throughout this Audit. Specifically in the case of the Population Council, support documents have been reviewed by the Office of the General Counsel. In the opinion of the Office of the General Counsel, the subject invention occurred prior to USAID funding.

2. The support documents in the case of Program for Appropriate Technology in Health have been provided. To date, there is no indication that USAID funds were used in the subject invention under review. This product has in fact not been brought to production. Further verifying documentation has been requested to be reviewed by the Office of the General Counsel.

RECOMMENDATION No 4.: Unless the problems are corrected, that the Agency Research Council, in conjunction with the Management Control Review Committee, disclose the internal control weaknesses associated with inventions and patents in its upcoming

Federal Managers' Financial Integrity Act Report.

RESPONSE:

1. Corrective actions have been identified; measure are being taken to address concerns raised through this audit. No action required for the upcoming Federal Managers' Financial Integrity Act Report.

RECOMMENDATION No. 5: Recommend that the Agency Research Council, in conjunction with the USAID Office of Procurement:

5.1 Determine if the U.S. Government has rights to Norplant and, if so, obtain a refund of the royalty costs.

5.2 Develop management controls to ensure that as specified in the FAR, USAID identifies royalty costs and U.S. Government Rights associated with its direct purchases and, in appropriate cases, excludes royalty costs from the price of its purchases.

RESPONSE:

1. As cited in Response to Recommendation No.3; in conjunction with the Office of the General Counsel, a review of the support documents indicates that the U.S. Government does not have rights to Norplant. Therefore no refund of royalty costs is applicable.

2. As cited in Response to Recommendation No. 1 and 2.

RECOMMENDATION No. 6: Recommend that the Agency Research Council, in conjunction with the Office of General Counsel and the Office of Procurement, determine if the U.S. Government's patent rights apply to USAID's recipients and contractors, thereby enabling them to exclude royalty costs from the price of their USAID-funded purchases.

RESPONSE:

The determination has been made. The standard patent rights language of US research contracts and grants is: "(T)he Federal government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world." The Office of the General Counsel has determined that the application is to permit USAID to acquire a government-financed "subject invention" product or process using our license royalty free, or to sublicense the "subject invention" to a USAID recipient or contractor provided that the recipient or contractor is utilizing the invention on our behalf, or for an authorized purpose, or in an authorized program of USAID.

in order to effectively apply the law within the Agency's unique portfolio of international programs.

Second, the only way to maintain balance between accountability and streamlining is to first, clarify the meaning of the law in terms that make sense to USAID staff, then develop guidance that is as free of bureaucratic hurdles as absolutely possible, and finally raise staff's awareness of that guidance. The report's recommendations in this area focus on raising awareness largely through issuing reporting requirements and periodic tracking. This approach will provide accountability. And as the audit indicates, USAID staff are quite willing to behave responsibly when informed (a point that could be emphasized more strongly in the audit). But merely adding requirements to an already long list of contractual boilerplates will not suffice. We invite IG to think with us creatively (again, drawing on best practices) on how to best address streamlining issues that reinvention and, indeed, continued existence requires.

Finally, we remain concerned that an overexpenditure for royalty payments is cited in reference to what your office recognized as an unresolved issue. The report should not cite the figure unless there is a clear determination that it is a legitimate government claim. As cited, USAID Office of the General Counsel has accepted provided documentation and determined there is no legitimate USG claim to patent rights.

Specific actions taken in response to the recommendations in the final report are attached. As mentioned in previous correspondence, the Agency recognizes the critical issues raised in the report and has taken immediate corrective actions where appropriate. As previously discussed, I certainly question whether the Agency Research Council is the appropriate recipient for all of the recommendations and have so indicated at the relevant recommendations.

Rest assured that I and my staff, along with others in the Agency, are quite concerned and willing to address all issues cited in the recommendations (See attached.). We look forward to collaboratively working with you to develop steps that will enable us to ensure appropriate preventative and corrective actions.

Attachment: As cited

Clearance:

GC/LE, Jerome Patterson
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JAP

Date:

10-24-95

Date:

10/24/95

cc:

DA, Carol Lancaster
SDAA/G, Ann Van Dusen
M/OP, Marcus Stevenson
G/PDSP, Timothy Mahoney

DEFINITIONS

Research recipient: A nonprofit or small business recipient of USAID funds under a grant, contract or cooperative agreement, in which some or all of the funds under the agreement are to be used for research and development purposes. (Source: IG/A/PA.)

Development: The systematic application of knowledge toward the production of useful materials, devices, systems or methods, including design, development and improvement of prototypes and new processes to meet specific requirements. (Source: FY 1996 Mission Budget Guidance Attachment B.)

Contraceptive development: A process that typically begins with the identification of a new lead with the potential for fertility regulation and is followed by a series of laboratory and chemical studies, toxicology, dose finding studies in animals and humans, and finally large-scale clinical efficacy studies. This is a long and very expensive process, taking an estimated 15 to 17 years and \$50 to \$100 million to bring a product to market. All stages of contraceptive development, including the widespread assessment, introduction and adaptation of family planning technology through clinical field trials in a variety of countries and clinical settings will be an integral part of the research program. (Source: PIOT No. 83G1476 dated July 11, 1988, and Project Paper dated May 24, 1988.)

Government's rights: Under the Bayh-Dole Act, organizations that elect to retain title to a federally funded invention must give the federal government a non-exclusive, nontransferable, irrevocable, royalty-free, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world. (Source: Association of University Technology Managers, Part I, Chapter 1; and Department of Commerce Regulations (37 CFR Part 401.14b).)

Government's rights disclosure: The disclosure required in patents, which reflects the Government's rights to an invention that was conceived or first

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actually reduced to practice under a Government funded agreement. This disclosure is required by Commerce Department regulations and USAID standard provisions. (Source: IG/A/PA)

Invention disclosure report: The written report, required under the standard provisions and Department of Commerce regulations, that the research recipient must submit to USAID. (Source: IG/A/PA.)

Patent: A primary form of intellectual property rights. A grant of a property issued by a national government for an invention, which typically gives an inventor the right to exclude others from commercially making, using or selling the invention during the patent term. (Source: GAO Testimony on Intellectual Property Rights.)

Invention: Any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act. (Source: Department of Commerce Regulations, 37 CFR Part 401.2.)

Subject invention: Any invention of a contractor (a person, small business firm or nonprofit organization which is a party to a funding agreement) conceived or first actually reduced to practice in the performance of work under a funding agreement; provided that in the case of a variety of plant, the date of determination must also occur during the period of contract performance. (Source: Department of Commerce Regulations, 37 CFR Part 401.2.) Only "subject inventions" are subject to the Bayh-Dole Act.

ANALYSIS OF AGREEMENTS REVIEWED

USAID Office	Agreement Number	Grantee	Period	Estimated Budget	Research Objective	Number of Inventions	No. of Invention Disclosure Reports submitted to USAID	No. of Patent Filings	No. of patents with Government's Rights Disclosure
(1)									
HN	HRN-6001-A-00-2043-00	Affymax Res. Inst.	9/4/92-9/3/94	\$332,258	Produce and test malaria vaccines.	1	0	1	0
HN	DPE-5979-A-00-1050-00	DNAX Res. Inst.	9/28/91-9/27/94	\$491,230	Produce and test malaria vaccines.	1	1	1	0
HN	DPE-5979-A-00-1030-00	Emory Univ.	8/30/91-8/29/94	\$454,131	Develop malaria vaccines.	0			
HN	DPE-5979-A-00-0006-00	NYU Med. Ctr.	4/1/90-3/31/93	\$3,345,374	Develop the experimental basis for a malaria vaccine.	0			
HN	HRN-6001-A-00-3008-00	NYU Med. Ctr.	7/1/93-6/30/96	\$1,373,803	Develop malaria vaccine.	0			
HN	HRN-6001-A-00-3013-00	NYU Med. Ctr.	8/18/93-8/17/94	\$594,987	Develop malaria vaccine.	0			
HN	HRN-6001-A-00-3014-00	NYU Med. Ctr.	8/18/93-8/17/96	\$618,070	Develop malaria vaccines.	0			
HN	DPE-5979-A-00-0042-01	Univ. of Maryland	8/30/90-8/29/93	\$479,484	Assess the malaria vaccine potential of PF83.	0			
HN	DPE-5968-A-00-0025-00	PATH	7/25/90-7/24/95	\$13,381,000	Develop diagnostic and drug delivery technologies. (5)	9	9	4	4
POP	CCP-3044 / DPE-3044	E. VA Med. School	6/1/92-5/31/97	\$40,000,000	Develop methods of fertility regulation. (5)	1	1	1	1
POP	DPE-3041-A-00-0043-00	Family Health Int'l	8/31/90-8/30/95	\$66,465,627	Develop new contraceptive methods. (3), (5)	9	0	9	0
POP	DPE-3061-A-00-1029-00	Georgetown Univ.	8/31/91-8/30/96	\$17,500,000	Develop ovulation prediction kit.	0			
AFS	DAN-4197-A-00-1126-00	Mich. St. Univ.	9/30/91-9/29/95	\$3,706,000	Develop genetically engineered pest resistant crops.	5	0	4	0
AFS	LAG-4198-A-00-2017-00	U. of Ga. Res. Fnd.	8/25/92-7/31/97	\$10,000,000	Develop new production technologies.	0			
PP	DPE-5544-G-SS-7042-00	Jerusalem College	8/14/87-12/31/90	\$148,874	Convert hides/scrap leather to thermoplastic	2	0	2	0
PP	DPE-5542-G-SS-6043-00	Univ. of Arizona	8/29/86-12/31/90	\$146,490	Gene probes for detecting viruses in water/sewage	1	0	1	0
TOTAL SUBJECT INVENTIONS						29	11	23	5
POP	DPE-3050-A-00-8059-00	The Pop. Council	8/26/88-8/25/93	\$37,000,000	Develop contraceptives including probing studies. (2) (4) (5)	5	0	5	0
HN	DPE-5968-A-00-0025-00	PATH	7/25/90-7/24/95	see total above	Develop diagnostic and drug delivery technologies. (2), (5)	1	0	1	0
TOTAL INVENTIONS WHICH MAY BE SUBJECT INVENTIONS						6	0	6	0
GRAND TOTALS						35	11	29	5

- (1) USAID Office Symbols: HN= Health and Nutrition; POP= Population; AFS= Agriculture and Food Security; PP= Policy and Programs.
- (2) USAID needs to determine if the inventions were funded by USAID.
- (3) Family Health International is in the process of amending their patent application to include the Government's Rights Disclosure.
- (4) Per The Population Council and USAID, verbal agreement to only do clinical trials, not invent/develop items. During the course of the audit, we identified ten patent filings by The Population Council. We have only included five of these in this schedule as we did not think the other five bore a clear relationship to the research and development called for in the grant agreements.
- (5) This agreement continues the research activities and objectives of a prior agreement. The inventions and patents noted in our audit may have been funded by either the current and/or prior agreement.

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