



*Office of Inspector General*

July 19, 2010

**MEMORANDUM**

**TO:** M/OAA/OD Director, Maureen Shauket

**FROM:** IG/A/PA Acting Director, Michael W. Clinebell /s/

**SUBJECT:** Review of USAID's Effectiveness in Obtaining the Benefits of Its Research and Development Efforts (Report No. 9-000-10-001-S)

This memorandum transmits our final report on the subject review. We considered your comments on the draft in finalizing the report and have included your response in its entirety in the appendix.

The report contains three recommendations. Based on an evaluation of management comments, management decisions have been reached for all three recommendations. Determination of final action for these recommendations will be made by the Audit, Performance and Compliance Division upon completion of the planned corrective actions.

I appreciate the cooperation and courtesy extended to my staff during this review.

# SUMMARY

At the annual meeting of the National Academy of Sciences in 2009, President Obama set a goal to “devote more than 3 percent of our GDP [gross domestic product] to research and development.” Research and development allows USAID to develop, test, and refine new and improved tools, approaches, and interventions for addressing concerns in developing countries and countries in transition.

In 1980 the Bayh-Dole Act<sup>1</sup> established a uniform Federal patent policy that is designed to encourage research and development award recipients<sup>2</sup> to collaborate with industry. Collaboration is expected to promote the use, development, and commercialization of technology invented with Federal funding. In accordance with the Bayh-Dole Act, USAID added a chapter to its Automated Directives System (ADS) on patent rights (chapter 318), which has since been expanded to intellectual property rights.

The version of ADS 318 that was in effect during the start of our review aimed to promote the use of inventions arising from U.S. Government-supported research or development; to ensure that the inventor's and U.S. Government's rights regarding inventions conceived or first applied under a USAID funding agreement (contract, grant, or cooperative agreement) are protected; and to protect taxpayers' rights.

As noted in the revised ADS 318, “Intellectual Property Rights,”<sup>3</sup> USAID often finances the development of intellectual property such as software, manuals, textbooks, and Web sites for the benefit of host governments, the U.S. Government, and other institutions and beneficiaries. Additionally, intellectual property may be implicated in Agency-funded activities even if not specifically created with such funding. USAID must ensure that the intellectual property meets its development goals and that beneficiaries continue to use the intellectual property as appropriate after the USAID project concludes.

According to ADS 318, the Office of General Counsel (General Counsel) serves as the primary USAID office for intellectual property issues including patents. It reviews and provides guidance on intellectual property rights reports, and tracks patents on behalf of USAID using the National Institutes of Health (NIH) Edison patent-tracking system.<sup>4</sup> General Counsel also coordinates with USAID contracting officers and their technical representatives and with agreement officers and their technical representatives to

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<sup>1</sup> Bayh-Dole University and Small Business Patent Procedures Act, Public Law 96-517, section 6(a), codified in 35 U.S.C. 200 to 211.

<sup>2</sup> For the purposes of this review, a recipient is an organization whose research work is funded either in whole or in part through research grants, contracts, or cooperative agreements.

<sup>3</sup> During the course of the review, ADS 318, “Patent Rights,” was revised to include trademarks and copyrights, and to update the patent section. Effective March 16, 2010, the new title of ADS 318 is “Intellectual Property Rights.”

<sup>4</sup> The NIH Edison system provides recipients of Federal funding agreements with the means to learn more about the Bayh-Dole Act and its regulations, as well as to comply with regulations by submitting invention, patent, and invention utilization reports to any of a number of Federal agencies through a single user interface.

ensure that contractors and recipients report USAID-funded inventions through the NIH Edison patent-tracking system in accordance with U.S. regulations and statutes.

ADS 318 states that contracting officers and agreement officers are responsible for:

- Ensuring that the appropriate intellectual property rights provisions and clauses are included in solicitation documents and funding agreements.
- Closely examining and confirming claims by offerers, applicants, or current implementers of exclusive or proprietary rights to intellectual property that has specific and frequent application in USAID activities.
- Analyzing valuations of intellectual property that are offered as a cost-sharing contribution or as leveraging in a public-private partnership and ensuring that the U.S. Government does not already have rights to the intellectual property.

This review was conducted to determine whether USAID has ensured that U.S. Government-financed patented terms and processes reflect U.S. Government rights. The review team found that USAID's right to use patented products for which funding was provided is protected, except under 2 of the 15 assistance awards selected for review.

Contracting officers and agreement officers did not include property rights provisions and clauses in two funding agreements reviewed from the Bureau for Global Health. To address these concerns, this review recommends that:

- The Office of Acquisition and Assistance update the Contraceptive Research and Development (CONRAD) Proprietary Products Research and Development Program award during the next modification to include the Bayh-Dole Act requirements and standard provisions and clauses.
- The Office of Acquisition and Assistance issue an Agency Notice to remind contracting officers and agreement officers of their responsibilities to verify that appropriate Bayh-Dole Act property rights provisions and clauses are included in contracts and agreements.
- The Office of Acquisition and Assistance include the Bayh-Dole Act requirements and standard provisions and clauses in training materials for technical representatives of contracting officers and agreement officers.

In response to this report, the Office of Acquisition and Assistance agreed with all three recommendations and presented plans to implement the recommendations by December 30, 2010. Based on an evaluation of management's response to the draft information report, management decisions have been reached on these recommendations.

Management comments are presented in their entirety in the appendix.

# REVIEW RESULTS

USAID's right to use patented products for which funding was provided is protected, except under 2 of the 15 assistance awards selected for review. The review team obtained a listing of 24 active research and development awards from the Office of Acquisition and Assistance with total obligations of \$736 million as of February 2010. From this listing, the team sampled seven awards from the Bureau for Global Health, and eight awards from the Bureau for Economic Growth, Agriculture, and Trade. The sampled awards had total obligations of \$499 million, covering 68 percent of the two bureaus' active awards as of February 2010.

This review found that USAID needs to ensure that provisions for intellectual property rights are included in all its research and development awards to allow U.S. Government access to patented products. Although standard provisions and clauses were included in all eight research and development awards sampled from the Bureau for Economic Growth, Agriculture, and Trade, standard provisions and clauses were not included in two of seven awards selected for review from the Bureau for Global Health (see below).

## **USAID Needs To Ensure Standard Provisions Are Included in Awards**

According to Automated Directives System (ADS) 318.2b as revised,<sup>5</sup> contracting officers and agreement officers have the following responsibilities:

- Ensuring that the appropriate intellectual property rights provisions and clauses from the Federal Acquisition Regulation and USAID Acquisition Regulation are included in solicitation documents and contracts.
- Ensuring that the appropriate intellectual property rights provisions and clauses from title 22 of the Code of Federal Regulations, part 226, are included in grants and cooperative agreements with U.S. nongovernmental organizations.
- Ensuring that the appropriate intellectual property provisions are included in grants and cooperative agreements with non-U.S. nongovernmental organizations, public international organizations, or any other entities with which USAID has agreements, when necessary or applicable.
- Closely examining and confirming claims by offerers, applicants, or current implementers of exclusive or proprietary rights to intellectual property that has specific and frequent application in USAID activities.
- Analyzing valuations of intellectual property that is offered as a cost-sharing contribution or as leveraging in a public-private partnership, and ensuring that the USG does not already have rights to the intellectual property.

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<sup>5</sup> During the course of the review, ADS 318, "Patent Rights," was revised to include trademarks and copyrights and to update the patent section. Effective March 16, 2010, the new title of ADS 318 is "Intellectual Property Rights."

The Office of Acquisition and Assistance has implemented procedures to ensure USAID obtains the benefits of its research and development awards. These procedures include (1) inserting award clauses into draft agreements and contracts that provide USAID access to processes and products resulting from research and development awards, and (2) checking completed agreements and contracts against a listing of contract requirements, including required award clauses, prior to approval.

Despite these procedures, exceptions were noted during this review. The review found that agreement officers did not include the intellectual property rights provisions and clauses in two of seven (29 percent) agreements awarded by the Bureau for Global Health. These two research and development awards were expected to develop the following:

- In 1998, USAID awarded a cooperative agreement<sup>6</sup> to the Eastern Virginia Medical School for the Contraceptive Research and Development (CONRAD) III Program with total obligations of \$109 million as of February 2010. Although the original focus was on contraception, the AIDS epidemic rapidly expanded the mandate to include research on the mechanisms and prevention of heterosexual transmission of HIV. The program sought to develop new chemical and physical barriers that would be more efficacious in preventing pregnancy and sexually transmitted diseases. At the conclusion of the CONRAD III Program, two products—SILCS diaphragm and a novel female condom (the Woman's Condom)—were in clinical trials.
- USAID awarded another cooperative agreement to the Eastern Virginia Medical School for the CONRAD Proprietary Products Research and Development (PPRD) Program, with total obligations of \$35 million as of February 2010. The program was to improve reproductive health in developing countries by reducing HIV/AIDS transmission through the development of new, safe, and effective microbicides.<sup>7</sup> Microbicide candidates will be delivered by a gel and a controlled-release device that offer protection from HIV, other sexually transmitted infections, and unplanned pregnancy. In addition, the CONRAD PPRD Program will continue trials and potential development and deployment of the SILCS diaphragm and the Woman's Condom.

The agreement officer for the CONRAD III award is no longer employed with the Agency and was not available for comment. The agreement officer's technical representative for the CONRAD PPRD award noted that efforts were made to collaborate with agreement officers during the design phase of the activity to ensure the standard patent clauses were inserted in the CONRAD PPRD award. However, the agreement officer did not ensure the clauses were included in the CONRAD PPRD cooperative agreement before award.

Failure to include intellectual property rights in contracts and agreements can potentially result in the U.S. Government not obtaining the right to use products invented using USAID's research and development funds.

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<sup>6</sup> The cooperative agreement for the CONRAD III Program ended on December 31, 2009.

<sup>7</sup> A microbicide is any compound or substance whose purpose is to reduce the infectious ability of microbes such as viruses and bacteria.

To address this problem, this review makes the following recommendations.

**Recommendation 1.** *We recommend that the Office of Acquisition and Assistance update the Contraceptive Research and Development Proprietary Products Research and Development Program award during the next modification to include the Bayh-Dole Act requirements and standard provisions and clauses.*

**Recommendation 2.** *We recommend that the Office of Acquisition and Assistance issue an Agency Notice reminding contracting officers and agreement officers of their responsibilities to verify that appropriate Bayh-Dole Act property rights provisions and clauses are included in contracts and agreements.*

**Recommendation 3.** *We recommend that the Office of Acquisition and Assistance include the Bayh-Dole Act requirements and standard provisions and clauses in training materials for technical representatives of contracting officers and agreement officers.*

# EVALUATION OF MANAGEMENT COMMENTS

USAID's Office of Acquisition and Assistance agreed with the three recommendations. Based on an evaluation of management comments, a management decision has been reached on each recommendation. Determination of final action for these recommendations will be made by the Audit, Performance and Compliance Division upon completion of the planned corrective actions.

**Recommendation 1.** Management agreed with the recommendation by beginning a modification to the Contraceptive Research and Development Proprietary Products Research and Development Program award to include the Bayh-Dole Act requirements and standard provisions and clauses. The target date for completion is September 30, 2010.

**Recommendation 2.** Management agreed with the recommendation and will issue an Agency Notice reminding contracting officers and agreement officers of their responsibilities to verify that appropriate Bayh-Dole Act property rights provisions and clauses are included in contracts and agreements. The target date for completion is July 30, 2010.

**Recommendation 3.** Management agreed with the recommendation and will initiate corrective action by including the Bayh-Dole Act requirements and standard provisions and clauses in training materials for technical representatives of contracting officers and agreement officers. The target date for completion is December 30, 2010.

Management comments are presented in their entirety in the appendix.

# MANAGEMENT COMMENTS



## MEMORANDUM

**TO:** Director, Performance Audit Division, Steven H. Bernstein

**FROM:** Director, Office of Acquisition and Assistance, Maureen A. Shauket /s/

**SUBJECT:** Office of Inspector General Draft Audit Report of May 21, 2010 on USAID's Effectiveness in Obtaining the Benefits of Its Research and Development Efforts.

This memorandum provides written comments to the 3 recommendations in the draft audit report to strengthen USAID's Effectiveness in Obtaining the Benefits of Its Research and Development Efforts.

## **AUDIT RECOMMENDATIONS:**

**Audit Recommendation 1.** We recommend that the Office of Acquisition and Assistance update the Contraceptive Research and Development Proprietary Products Research and Development Program award during the next modification to include the Bayh-Dole Act requirements and standard provisions and clauses.

**COMMENT:** We concur with the recommendation. OAA will initiate corrective action by commencing with a modification to the Contraceptive Research and Development Proprietary Products Research and Development Program to include the Bayh-Dole Act requirements and standard provisions and clauses. The target date for completion is September 30, 2010.

**Audit Recommendation 2.** We recommend that the Office of Acquisition and Assistance issue an Agency Notice reminding contracting officers and agreement officers of their responsibilities to verify that appropriate Bayh-Dole Act property rights provisions and clauses are included in contracts and agreements.

**COMMENT:** We concur with the recommendation. OAA will initiate corrective action by issuing an Agency Notice reminding contracting officers and agreement officers of their responsibilities to verify that appropriate Bayh-Dole Act property rights provisions and clauses are included in contracts and agreements. The target date for completion is July 30, 2010.



**Audit Recommendation 3.** We recommend that the Office of Acquisition and Assistance include the Bayh-Dole Act requirements and standard provisions and clauses in training for technical representatives of contracting officers and agreement officers.

**COMMENT:** We concur with the recommendation. OAA will initiate corrective action by including the Bayh-Dole Act requirements and standard provisions and clauses in training materials for technical representatives of contracting officers and agreement officers. The target date for completion is December 30, 2010.