Functional Series 300: Acquisition and Assistance ADS Chapter - 318 Patent Rights

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318.1 Authority

- 1 The Bayh-Dole Act of 1980
- 2. Title 35 of the U.S. Code
- Technology Transfer Act of 1986

318.2 Objective

The objective is to promote the use of inventions arising from U.S. Government (USG)-supported research or development, to ensure that the inventor's and USG's rights regarding inventions that are conceived or first actually reduced to practice under a funding agreement (contract, grant, or cooperative agreement) with USAID are protected, and that taxpayer's rights to the technology are protected.

318.3 Responsibility

1. The Bureau for Global Programs, Field Support and Research (Global) serves as the cognizant USAID office for patent and other Intellectual Property Rights (IPR) issues arising directly from USAID-funded research, technology development, and technology transfer for commercialization or other means of diffusion. Global is responsible for formulating current USAID practices, procedures, and policies related to patent rights of the U.S. Government, as legislated in the Bayh-Dole Act, including administering a system to report and track patent or other IPR on behalf of USAID.

Currently, the National Institutes of Health (NIH) under a "Memorandum of Understanding" (MOU) with USAID has provided the Agency with the right to use the NIH EDISON invention reporting and tracking database system.

Global's Office of Program Development and Strategic Planning (G/PDSP), under the terms and conditions established in the MOU as amended, is responsible for coordinating with NIH the receipt, acknowledgement, and tracking of invention reports under USAID-funded agreements. G/PDSP is the point of contact for the Agency with the NIH on the administration of the EDISON invention reporting system, including implementation of specific USAID policy related to patent title, licensing, and waivers. G/PDSP will also be responsible for coordinating with USAID's operating units to ensure that USAID-funded contractors and grantees report research inventions through the EDISON system, in accordance with the Bayh-Dole Act requirements. In addition, G/PDSP

will be responsible for issuing annual summary reports, specific to each Cognizant Technical Office (CTO) of activities tracked in the database.

G/PDSP is the point of contact for USAID officers for patent and IPR issues. G/PDSP maintains a current list of activities that are involved in these issues, with most activities being funded through the Global Bureau. USAID officers associated with such activities that ought to be added to the list may contact G/PDSP. G/PDSP maintains contact with involved Cognizant Technical Officers (CTOs) annually and provides appropriate training for the proper reporting through NIH's EDISON invention reporting and tracking database system.

- 2. The Bureau for Management, Office of Procurement (M/OP) and Mission Contracting Officers are responsible for ensuring that the appropriate patent provisions and clauses from the Federal Acquisition Regulation are included in solicitation documents and contracts, that USAID Regulation 26 is incorporated in grants and cooperative agreements with U.S. non-governmental organizations, and that the patents provision is included in grants and cooperative agreements with non-U.S. organizations when applicable.
- 3. The Cognizant Technical Officer (CTO) is responsible for taking necessary actions under the provisions of FAR Subparts 27.2 and 27.3 and 37 CFR Part 401 with regard to USAID's rights to subject inventions. This includes being responsible for granting the funding recipient extensions in time for disclosure, election to retain title, and filing at the CTO's discretion and determining whether to shorten the time for election of title. (See 318.5.3 and 318.5.4)
- 4. The funding recipient is responsible for complying with the terms of the provisions of its contract, grant or cooperative agreement and any applicable regulations including requirements for disclosure and election of title. Such disclosure and elections must be provided to the CTO via the NIH EDISON system.

318.4 Definitions (See <u>ADS Glossary</u>)

funding recipient invention subject invention

318.5 POLICY

The statements contained within the .5 section of this ADS chapter are the official Agency policies and corresponding essential procedures.

318.5.1 APPLICABLE REGULATIONS

USAID's contractors and recipients are subject to applicable regulations governing patents and inventions, including the government-wide regulations issued by the Department of Commerce at 37 CFR Part 401, "Rights to Inventions Made by Nonprofit and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements," Federal Acquisition Regulation (FAR) Subpart 27.2, "Patents," and Subpart 27.3, "Patent Rights Under Government Contracts," and any clauses or provisions on patents or inventions included in the specific contract, grant, or cooperative agreement with USAID.

USAID's rights and responsibilities with regard to subject inventions are also set forth in 37 CFR Part 401 and FAR Subparts 27.2 and 27.3. (See Mandatory References 37 CFR Part 401, FAR Subpart 27.2 and FAR Subpart 27.3)

E318.5.1 Applicable Regulations - N/A

318.5.2 ALLOCATION OF PRINCIPAL RIGHTS

The funding recipient may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions and exceptions of applicable regulations, this Chapter and 35 USC Sec. 203. (See Mandatory Reference 35 USC Sec. 203) When the funding recipient retains the title to any subject invention, 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 U.S., the subject invention throughout the world.

E318.5.2 Allocation of Principal Rights - N/A

318.5.3 INVENTION DISCLOSURE, ELECTION OF TITLE, AND FILING OF PATENT APPLICATIONS BY FUNDING RECIPIENT

a) The funding recipient must disclose each subject invention to USAID, through the NIH EDISON system and the Cognizant Technical Office, as prescribed in the applicable regulations. The funding recipient must also provide to NIH detailed invention disclosures for entry into the EDISON patent tracking system. In addition, after disclosure to USAID, the funding recipient must promptly notify USAID of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the funding recipient. A contract clause or assistance provision entitled, Patent Reporting Procedures, provides contractors/recipients information on using the EDISON tracking system.

- b) The funding recipient must elect in writing whether or not to retain title to any such invention by notifying, via EDISON, the USAID Cognizant Technical Office in accordance with the applicable regulations. In any case where publication, on sale, or public use has initiated the one-year statutory period wherein valid patent protection can still be obtained in the United States, the period of election of title may be shortened by the Cognizant Technical Office to a date that is no more than 60 days prior to the end of the one-year statutory period.
- c) The funding recipient must file an initial patent application on a subject invention when it elects to retain title in accordance with the requirements, including timing, of the applicable regulations.
- d) Requests for extension of the time for disclosure to USAID, election, and filing may, at the discretion of USAID, be granted by the Cognizant Technical Office.

E318.5.3 Invention Disclosure, Election of Title, and Filing of Patent Applications by Funding Recipient

The Cognizant Technical Office must refer any reports of inventions to the Global Bureau's Office of Program Development and Strategic Planning (G/PDSP). G/PDSP must reconcile this information with the data entered into the EDISON reporting and tracking database system operated by the National Institutes of Health.

318.5.4 RIGHTS AND RESPONSIBILITIES

The funding recipient has rights and responsibilities with regard to subject inventions. These are set forth in the applicable regulations. Where the regulations require or allow USAID to take action or authorize action by the funding recipient, unless the regulations, contract clause, or assistance agreement provide otherwise, the responsible office for taking such actions and granting approvals shall be the Cognizant Technical Office, in consultation with G/PDSP and the Office of General Counsel.

E318.5.4 Rights and Responsibilities - N/A

318.5.5 APPLICABILITY OF GOVERNMENT'S RIGHTS TO CONTRACTORS AND RECIPIENTS

Whatever rights the Federal Government has in any patent apply also to contractors and recipients under their agreements with USAID. When the Government is entitled to royalty free use, the right does not end by virtue of its being exercised under a USAID contract or assistance instrument.

E318.5.5 Applicability of Government's Rights to Contractors and Recipients - N/A

318.5.6 ROYALTIES

The Contracting/Agreement Officer must ensure that the appropriate patent and royalty clauses are included in contracts, grants, and cooperative agreements. Contracting Officers must request royalty information in accordance with the requirements of FAR Subpart 27.2. (See Mandatory Reference FAR Subpart 27.2)

E318.5.6 Royalties - N/A

318.5.6a ADJUSTMENT OF ROYALTIES

- 1) If at any time the Contracting/Agreement Officer has reason to believe that royalties paid, or to be paid, under an existing or prospective contract, grant, cooperative agreement, subcontract, or subaward are inconsistent with Government rights, excessive, or otherwise improper, the Contracting/Agreement Officer (or someone else with knowledge of the case) must promptly report the facts in writing to USAID's Office of General Counsel (GC) with a copy to G/PDSP. GC must review the royalties thus reported and such royalties as may be reported in accordance with other regulatory requirements and recommend appropriate action to the Contracting/Agreement Officer.
- 2) In coordination with GC, the Contracting/ Agreement Officer must promptly act to protect the Government against payment of royalties on supplies or services:
 - a) When the Government has a royalty-free license;
 - b) At a rate in excess of the rate at which the Government is licensed; or
 - c) When the royalties in whole or in part otherwise constitute an improper charge.

E318.5.6a Adjustment of Royalties - N/A

318.6 Supplementary Reference - N/A

318.7 Mandatory Reference

37 CFR Part 401 "Rights to Inventions Made by Nonprofit and Small Business Firms under Government Grants, Contracts, and Corporate Agreements"

FAR Subpart 27.2 "Patents"

FAR Subpart 27.3 "Patent Rights under Government Contracts"

35 USC Sec. 203 "Patent Rights in Inventions Made With Federal Assistance - March-in Rights"

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