



United
States
Department
of
Agriculture



Cooperative State
Research, Education,
and Extension
Service

Washington, D.C.
20250

March 1, 2006

To: All Recipients of CSREES Research Funds

From: Colien Hefferan *Colien Hefferan*
Administrator
Cooperative State Research, Education, and Extension Service

Subject: Reminder and Clarification of Bayh-Dole Act Responsibilities for All CSREES Grants Including Formula Funds and Cooperative Agreements

The Bayh-Dole Act of 1980 ("the Bayh-Dole Act"), 35 U.S.C. 200-212, created a government-wide policy that transformed the scientific community by allowing awardees to retain title to inventions arising from Federally-funded research agreements (including grants, formula funds, and cooperative agreements). This privilege sparked a revolution in technology transfer and helped fuel the explosion of technologies such as biotechnology.

This memorandum is to inform you of the significance of the Bayh-Dole Act, to highlight some of the procedures in the Act and its implementing regulation, 37 C.F.R. Part 401, that need to be followed in order to maintain compliance, and to clarify the applicability of the Act to certain situations.

You are encouraged to read the Bayh-Dole Act and the implementing regulation for full understanding of its benefits and requirements.

Overview of the Bayh-Dole Act

The Bayh-Dole Act was enacted in response to lack of clear and consistent Federal policy regarding the ownership of inventions arising from Federal funding. Prior to the Bayh-Dole legislation, hundreds of inventions from Federally-funded research had been shelved, due to lack of industry involvement and an incentive for further investment to bring the inventions to commercial application. The purpose of the Bayh-Dole Act is to facilitate and accelerate the transfer of technologies and other such products resulting from Federally-funded research into public use, taking advantage of the market-based incentives of the patent and plant variety protection processes.

The Bayh-Dole Act allows any person, small business firm, or non-profit organization that receives a Federally-funded research contract, grant, or cooperative agreement to retain the rights to any resulting inventions so long as the recipient of these Federal funds complies with certain conditions and procedures. *You are reminded that formula funds are legally a type of grant and all laws and regulations that apply to grants in general, including the Bayh-Dole Act, apply equally to formula funds.* The Bayh-Dole Act does *not* apply to funding agreements made primarily for educational purposes, such as scholarships, fellowships or training grants (35 U.S.C. 212). Note that, after initial definition, the Bayh-Dole Act refers to contracts, grants, and cooperative agreements simply as contracts and the recipients simply as contractors.

You should be aware that failure to follow the various conditions and procedures of the Bayh-Dole Act may result in a contractor's *loss of rights to the invention* (35 U.S.C. 202(c)(1), (2) and (3)).

The Bayh-Dole Act defines an invention in 35 U.S.C. 201(e) as "any invention of a contractor 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 (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance." Generally, this means an invention is anything derived during the conduct of Federally-funded research that could receive patent and/or plant variety protection even if this protection is not pursued.

Ownership Under the Bayh-Dole Act

As discussed above, the Bayh-Dole Act allows the contractor to retain the entire right, title, and interest throughout the world to inventions covered by the Act, subject to the conditions of the Act. The Bayh-Dole Act contractor also grants to the Federal government a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the invention throughout the world (35 U.S.C. 202(c)(4)).

If the recipient of Federal research funding does not take advantage of its rights to an invention in a timely way by following the procedures of the Bayh-Dole Act *or* if it waives its rights to an invention, the ownership of the invention may go to the Federal government. Therefore, a contractor may not simply transfer its rights to a third party (such as the inventor or a corporation); however, it may ask the Federal government for permission to transfer its rights over to a named third party. Such transfers are subject to certain Government rights. See 37 C.F.R. 401.9. Note that 35 U.S.C. 202(c)(7) prohibits a non-profit organization from assigning its rights except to a patent management organization unless approval of the funding Federal agency is obtained.

Bayh-Dole Reporting Procedures

As a condition of retaining rights to inventions, and in the interest of ensuring that inventions arising from Federal funds are rapidly made available for public use, the Bayh-Dole Act requires a contractor to report to the granting agency the discovery of an invention and various activities regarding the contractor's management of the intellectual property rights for the invention. *These requirements apply regardless of whether a patent is actually sought for the invention.* The

requirements, as set forth in the standard patent rights clause in 37 C.F.R. 401.14, are summarized as follows:

1. Within two months of the time that the inventor discloses in writing to contractor personnel responsible for patent matters that an invention has been created, the contractor must submit an invention disclosure to the funding agency that identifies the grant or cooperative agreement, the inventors, and a description of the invention that shall be sufficiently complete in technical detail to convey a clear understanding to the extent known of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the invention.
2. Within two years after the disclosure of an invention (as described in step 1), the contractor must notify the agency as to whether it is electing to retain title to the invention. This period is shortened if a public use or sale of the invention has occurred.
3. Within one year after the election of title (as described in step 2), the contractor must file its initial patent application and must notify the agency of its decision. Any foreign or international application must be filed within 10 months of the initial patent application. This period is shortened if a public use or sale of the invention has occurred.
4. The contractor must include within the specification of any United States patent application and any resulting patent the following statement:

This invention was made with government support under (identify the grant number) awarded by the Cooperative State Research, Education, and Extension Service, USDA. The government has certain rights in the invention.
5. The institution must notify the agency of the patent grant and provide a copy of the patent. The contractor must notify the agency prior to thirty days before the expiration of a response period if it is not going to continue the prosecution of a patent application or pay a maintenance fee. 37 C.F.R. 401.14 (f)(3).
6. The contractor must report on request (no more frequently than annually) the utilization or efforts to obtain utilization of the invention.

Requests for extensions of time in steps 1 – 3 may be made to the agency.

Invention disclosure statements shall be made by creating an invention record using Interagency Edison. Interagency Edison is a web-based system specifically designed to support Bayh-Dole Act reporting and compliance and is operated by the National Institutes of Health at www.iedison.gov. If possible, all supporting documentation shall also be submitted electronically using Interagency Edison. However, if electronic submission of supporting documentation is not feasible, paper copies should be submitted via facsimile or U.S. Mail to:

Extramural Inventions and Technology Resources Branch
National Institutes of Health
6705 Rockledge Drive, MSC 7980
Bethesda, Maryland 20892-7980

Telephone: (301) 435-1986
Facsimile: (301) 480-0272
E-mail: edison@od.nih.gov

Do not send paper copies to CSREES, except requests for permission to assign rights or requests for extensions of time. These should be sent to:

Information Technology Policy Leader
Information Systems and Technology Management
Cooperative State Research, Education, and Extension Service, USDA
STOP 2216
1400 Independence Avenue, SW
Washington, DC 20250-2216
Telephone: (202) 720-2678
Facsimile: (202) 720-0857

Clarifications of the Applicability of the Bayh-Dole Act

As stated above, the Bayh-Dole Act applies to inventions arising from Federally-funded research, including inventions from formula funds. The nature and implementation of CSREES formula funds by land-grant universities complicates the applicability of the Bayh-Dole Act to various activities of the State Agricultural Experiment Stations. The following is to clarify these situations.

Non-Federally Funded Research Conducted in a Facility Constructed with Federal Funds

The Bayh-Dole Regulation specifically states that it “is not intended to apply to arrangements under which nonprofit organizations, small business firms, or others are allowed to use government-owned research facilities and normal technical assistance provided to users of those facilities, whether on a reimbursable or non-reimbursable basis.” Further, the Bayh-Dole Regulation specifically states that an invention which is made outside the research activities of a government-funded project is not viewed as a “subject invention” since it cannot be shown to have been “conceived or first actually reduced to practice” in performance of the project. Since grants for the construction of a facility are not research grants, nor is research conducted as part of a construction grant, research done in facilities built with Federal funds are *not* automatically subject to Bayh-Dole. This is more complicated for formula funds, which may support both research and facilities-projects. However, the primary determinant is whether the invention arose from a Federally-funded research project, not where the research occurred (see 37 C.F.R. 401.1(g)).

Non-Federally Funded Research Conducted Using Equipment Purchased with Federal Funds

The Bayh-Dole Regulation specifically addresses this situation in 37 C.F.R. 401.1(a)(2), as follows:

An invention which is made outside of the research activities of a government-funded project is not viewed as a “subject invention” since it cannot be shown to have been “conceived or first actually reduced to practice” in performance of the project. An obvious example of this is a situation where an instrument purchased with government

funds is later used, without interference with or cost to the government-funded project, in making an invention all expenses of which involve only non-government funds.

Non-Federal Use of Faculty Time

Faculty salaries are often funded from a variety of Federal, State, and private sources. When faculty who are only partially paid from Federal funds are working on a non-Federally funded project, Federal regulation requires that their salaries be paid from a non-Federal source for that period of time. At that point, Federal research dollars are not being applied to the project and thus the Bayh-Dole Act does not apply.

Inventions Arising from a Non-Federally Funded Project That Has a CRIS Number

A number of contractors enter projects into the CRIS system for their own management and reporting purposes that have no CSREES funding. CRIS is simply a database system; entering a project into CRIS does not automatically link a project to Federal funding. The Bayh-Dole Act specifically applies only to inventions arising from Federal research funding, regardless of whether they are recorded in a Federal database system. Therefore, the Bayh-Dole Act does not apply to projects entered into CRIS that have no Federal funding.

For Further Information

Further information on the Bayh-Dole Act can be found on the Intellectual Property page of the CSREES web site (www.csrees.usda.gov, located under Doing Business with CSREES). The Interagency Edison web site (www.iedison.gov) also provides information about Bayh-Dole compliance. Specific information about CSREES procedures can be found in CSREES' grant terms and conditions, available on CSREES' web site.